

LILLY ELI & CO  
Form 10-Q  
May 06, 2008

**SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**  
**Form 10-Q**  
**Quarterly Report Under Section 13 or 15(d) of the**  
**Securities Exchange Act of 1934**  
**FOR THE QUARTER ENDED MARCH 31, 2008**  
**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 ☒

The number of shares of common stock outstanding as of April 20, 2008:

Class	Number of Shares Outstanding
Common	1,136,974,738

**PART I. FINANCIAL INFORMATION***Item 1. Financial Statements***CONSOLIDATED CONDENSED STATEMENTS OF INCOME**

(Unaudited)

Eli Lilly and Company and Subsidiaries

	Three Months Ended March 31,	
	2008	2007
	(Dollars in millions except per-share data)	
Net sales	\$ 4,807.6	\$ 4,226.1
Cost of sales	1,111.3	922.5
Research and development	877.1	834.2
Marketing, selling, and administrative	1,550.5	1,336.8
Acquired in-process research and development (Note 3)	87.0	328.5
Asset impairments, restructuring, and other special charges (Note 4)	145.7	123.0
Other income net (Note 12)	(20.3)	(38.3)
	3,751.3	3,506.7
Income before income taxes	1,056.3	719.4
Income taxes (Note 9)	(8.0)	210.7
Net income	\$ 1,064.3	\$ 508.7
Earnings per share basic (Note 8)	\$ .97	\$ .47
Earnings per share diluted (Note 8)	\$ .97	\$ .47
Dividends paid per share	\$ .47	\$ .425

See Notes to Consolidated Condensed Financial Statements.

CONSOLIDATED CONDENSED BALANCE SHEETS  
Eli Lilly and Company and Subsidiaries

	March 31, 2008	December 31, 2007
	(Dollars in millions)	
	(Unaudited)	
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 3,145.4	\$ 3,220.5
Short-term investments (Note 5)	2,289.1	1,610.7
Accounts receivable, net of allowances of \$109.7 (2008) and \$103.1 (2007)	2,661.1	2,673.9
Other receivables	709.0	1,030.9
Inventories	2,594.4	2,523.7
Deferred income taxes	565.4	583.6
Prepaid expenses	529.8	613.6
<b>TOTAL CURRENT ASSETS</b>	<b>12,494.2</b>	<b>12,256.9</b>
<b>OTHER ASSETS</b>		
Prepaid pension (Note 10)	1,842.5	1,670.5
Investments (Note 5)	596.1	577.1
Goodwill and other intangibles net (Note 3)	2,378.5	2,455.4
Sundry	1,246.8	1,252.8
	<b>6,063.9</b>	<b>5,955.8</b>
<b>PROPERTY AND EQUIPMENT</b>		
Land, buildings, equipment, and construction-in-progress	15,164.5	14,841.3
Less allowances for depreciation	(6,502.4)	(6,266.2)
	<b>8,662.1</b>	<b>8,575.1</b>
	<b>\$27,220.2</b>	<b>\$ 26,787.8</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Short-term borrowings	\$ 73.0	\$ 413.7
Accounts payable (Note 1)	789.8	924.4
Employee compensation	468.2	823.8
Sales rebates and discounts	728.1	706.8
Dividends payable		513.6
Income taxes payable (Note 9)	280.5	238.4
Other current liabilities (Note 1)	1,824.7	1,647.6
<b>TOTAL CURRENT LIABILITIES</b>	<b>4,164.3</b>	<b>5,268.3</b>
Long-term debt	4,648.3	4,593.5

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

Accrued retirement benefit (Note 10)	1,169.6	1,145.1
Long-term income taxes payable (Note 9)	951.0	1,196.7
Deferred income taxes	339.3	287.5
Other noncurrent liabilities	1,037.5	632.3
	8,145.7	7,855.1
SHAREHOLDERS' EQUITY (Notes 6 and 7)		
Common stock	711.2	709.5
Additional paid-in capital	3,787.7	3,805.2
Retained earnings	13,033.8	11,967.2
Employee benefit trust	(2,635.0)	(2,635.0)
Deferred costs-ESOP	(95.3)	(95.2)
Accumulated other comprehensive income	207.0	13.2
	15,009.4	13,764.9
Less cost of common stock in treasury	99.2	100.5
	14,910.2	13,664.4
	\$27,220.2	\$ 26,787.8

See Notes to Consolidated Condensed Financial Statements.

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

	Three Months Ended March 31,	
	2008	2007
	(Dollars in millions)	
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net income	\$ 1,064.3	\$ 508.7
Adjustments to reconcile net income to cash flows from operating activities:		
Changes in operating assets and liabilities, net of acquisition of ICOS Corporation	(33.6)	(35.6)
Depreciation and amortization	277.5	245.1
Stock-based compensation expense	58.5	72.7
Change in deferred taxes	162.8	(289.6)
Acquired in-process research and development, net of tax	56.6	319.6
Asset impairments, restructuring, and other special charges, net of tax	94.9	84.9
Other, net	21.6	(14.0)
<b>NET CASH PROVIDED BY OPERATING ACTIVITIES</b>	<b>1,702.6</b>	<b>891.8</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Net purchases of property and equipment	(184.2)	(239.4)
Net change in short-term investments	(715.7)	(15.4)
Purchase of noncurrent investments	(41.5)	(210.2)
Proceeds from sales and maturities of noncurrent investments	36.0	267.1
Cash paid for ICOS Corporation, net of cash acquired		(2,225.6)
Purchase of in-process research and development	(87.0)	(25.0)
Other, net	(41.6)	(6.8)
<b>NET CASH USED IN INVESTING ACTIVITIES</b>	<b>(1,034.0)</b>	<b>(2,455.3)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Dividends paid	(513.6)	(462.9)
Proceeds from issuance of long-term debt	0.1	2,500.0
Repayment of long-term debt	(0.8)	(1,097.2)
Issuances of common stock under stock plans		7.6
Net change in short-term borrowings	(342.5)	(3.9)
Other, net	(5.1)	
<b>NET CASH (USED IN) PROVIDED BY FINANCING ACTIVITIES</b>	<b>(861.9)</b>	<b>943.6</b>
Effect of exchange rate changes on cash and cash equivalents	118.2	2.0

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

NET DECREASE IN CASH AND CASH EQUIVALENTS	(75.1)	(617.9)
Cash and cash equivalents at January 1	3,220.5	3,109.3
CASH AND CASH EQUIVALENTS AT MARCH 31	\$ 3,145.4	\$ 2,491.4

See Notes to Consolidated Condensed Financial Statements.

4

---

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

	Three Months Ended March 31,	
	2008	2007
	(Dollars in millions)	
Net income	\$1,064.3	\$508.7
Other comprehensive income <sup>1</sup>	193.8	31.7
Comprehensive income	\$1,258.1	\$540.4

<sup>1</sup> The significant component of other comprehensive income was a gain of \$259.9 million from foreign currency translation adjustments for the three months ended March 31, 2008, compared with a gain of \$73.5 million from foreign currency translation adjustments for the three months ended March 31, 2007.

See Notes to Consolidated Condensed Financial Statements.



## SEGMENT INFORMATION

We operate in one significant business segment pharmaceutical products. Operations of our animal health business segment are not material and share many of the same economic and operating characteristics as our pharmaceutical products. Therefore, they are included with pharmaceutical products for purposes of segment reporting. Our business segments are distinguished by the ultimate end user of the product: humans or animals. Performance is evaluated based on profit or loss from operations before income taxes. Income before income taxes for the animal health business for the first quarters of 2008 and 2007 was \$26.9 million and \$38.2 million, respectively.

## SALES BY PRODUCT CATEGORY

Worldwide sales by product category were as follows:

	Three Months Ended March 31,	
	2008	2007
	(Dollars in millions)	
Net sales to unaffiliated customers:		
Neurosciences	\$1,971.4	\$1,797.5
Endocrinology	1,410.8	1,265.7
Oncology	673.3	564.7
Cardiovascular	462.0	321.3
Animal health	235.3	215.1
Other pharmaceuticals	54.8	61.8
Net sales	\$4,807.6	\$4,226.1

## 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, 2007. We reclassified an immaterial amount within current liabilities in the December 31, 2007 balance sheet, shifting \$94.1 million from accounts payable to other current liabilities.

### Note 2: Implementation of New Financial Accounting Pronouncements

We adopted the provisions of Emerging Issues Task Force (EITF) Issue No. 07-3 (EITF 07-3), Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities, on January 1, 2008. Pursuant to EITF 07-3, nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense when the related goods are delivered or services are performed, or when the goods or services are no longer expected to be received. This Issue is to be applied prospectively for contracts entered into on or after the effective date.

We adopted the provisions of Financial Accounting Standards Board (FASB) Statement No. 157 (SFAS 157), Fair Value Measurements, on January 1, 2008. SFAS 157 defines fair value, establishes a framework for measuring fair value in GAAP, and expands disclosures about fair value measurements. The implementation of this Statement was not material to our consolidated financial position or results of operations.

In March 2008, the FASB issued Statement No. 161, Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133 (SFAS 161). SFAS 161 applies to all derivative instruments and related hedged items accounted for under FASB Statement No. 133, Accounting for Derivative Instruments and Hedging Activities. This Statement requires entities to provide enhanced disclosures about how and why an entity uses derivative instruments, how derivative instruments and related hedged items are accounted for under Statement 133 and its related interpretations, and how derivative instruments and related hedged items affect an entity's financial position, results of operations, and cash flows. This Statement is effective for us January 1, 2009, and we do not anticipate the implementation will be material to our consolidated financial position or results of operations.

In December 2007, the FASB revised and issued Statement No. 141, Business Combinations (SFAS 141(R)). SFAS 141(R) changes how the acquisition method is applied in accordance with SFAS 141. The primary revisions to this Statement require an acquirer in a business combination to measure assets acquired, liabilities assumed, and any noncontrolling interest in the acquiree at the acquisition date, at their fair values as of that date, with limited exceptions specified in the Statement. This Statement also requires the acquirer in a business combination achieved in stages to recognize the identifiable assets and liabilities, as well as the noncontrolling interest in

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

In December 2007, in conjunction with SFAS 141(R), the FASB issued Statement No. 160, Accounting for Noncontrolling Interests. This Statement amends Accounting Research Bulletin No. 51, Consolidated Financial Statements (ARB 51), by requiring companies to report a noncontrolling interest in a subsidiary as equity in its consolidated financial statements. Disclosure of the amounts of consolidated net income attributable to the parent and the noncontrolling interest will be required. This Statement also clarifies that transactions that result in a change in a parent's ownership interest in a subsidiary that do not result in deconsolidation will be treated as equity transactions, while a gain or loss will be recognized by the parent when a subsidiary is deconsolidated. This Statement is effective for us January 1, 2009, and we do not anticipate the implementation will be material to our consolidated financial position or results of operations.

In December 2007, the FASB ratified the consensus reached by the EITF on Issue No. 07-1 (EITF 07-1), Accounting for Collaborative Arrangements. EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. This Issue is effective for us beginning January 1, 2009 and will be applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date. While we have not yet completed our analysis, we do not anticipate the implementation of this Issue will be material to our consolidated financial position or results of operations.

#### Note 3: Acquisitions

##### ICOS Corporation Acquisition

On January 29, 2007, we acquired all of the outstanding common stock of ICOS Corporation (ICOS), our partner in the Lilly ICOS LLC joint venture for the manufacture and sale of Cialis® for the treatment of erectile dysfunction. The acquisition brings the full value of Cialis to us and enables us to realize operational efficiencies in the further development, marketing, and selling of this product. Under the terms of the agreement, each outstanding share of ICOS common stock was redeemed for \$34 in cash for an aggregate purchase price of approximately \$2.3 billion, which was financed through borrowings.

The acquisition has been accounted for as a business combination under the purchase method of accounting. Under the purchase method of accounting, the assets acquired and liabilities assumed from ICOS are recorded at their respective fair values as of the acquisition date in our consolidated financial statements. The excess of the purchase price over the fair value of the acquired net assets has been recorded as goodwill in the amount of \$646.7 million. No portion of this goodwill is expected to be deductible for tax purposes. ICOS's results of operations are included in our consolidated financial statements from the date of acquisition.

We have determined the following estimated fair values for the assets purchased and liabilities assumed as of the date of acquisition. The determination of estimated fair value required management to make significant estimates and assumptions.

	Estimated Fair Value at January 29, 2007
Cash and short-term investments	\$ 197.7
Developed product technology (Cialis) <sup>1</sup>	1,659.9
Acquired in-process research and development	303.5
Tax benefit of net operating losses	404.1
Goodwill	646.7
Other assets and liabilities net	(32.1)
Deferred taxes	(583.5)
Long-term debt assumed	(275.6)
Total purchase price	\$ 2,320.7

<sup>1</sup> The intangible asset will be amortized over the remaining expected patent lives of Cialis in each country; patent expiry dates range from 2015 to 2017.

The acquired in-process research and development (IPR&D) represents compounds currently under development that have not yet achieved regulatory approval for marketing. New indications for and formulations of the Cialis compound in clinical testing at the time of the acquisition represented approximately 48 percent of the estimated fair value of the IPR&D. The remaining value of IPR&D represents several other products in development, with no one asset comprising a significant portion of this value. In accordance with FIN 4, Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method, these IPR&D intangible assets totaling \$303.5 million have been written off by a charge to income immediately subsequent to the acquisition because the compounds do not have any alternative future use. This charge is not deductible for tax purposes. The ongoing activity with respect to each of these compounds under development is not material to our research and development expenses.

There are several methods that can be used to determine the estimated fair value of the acquired IPR&D. 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. The discount rate we used in valuing the acquired IPR&D projects was 20 percent.

Product Acquisitions

In December 2007, we entered into an agreement with BioMS Medical Corp. to acquire the rights to its compound for the treatment of multiple sclerosis. This agreement was contingent upon clearance under the Hart-Scott-Rodino Anti-Trust Improvements Act and became effective after clearance was received in January 2008. 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. Our charge for acquired IPR&D related to this arrangement was \$87.0 million, was included as expense in the first quarter of 2008, and is deductible for tax purposes.

In January 2007, we entered into an agreement with OSI Pharmaceuticals, Inc. to acquire the rights to its compound for the treatment of type 2 diabetes. At the inception of this agreement, this compound was in the development stage (Phase I 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. Our charge for acquired IPR&D related to this arrangement was \$25.0 million, was included as expense in the first quarter of 2007, and is 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: Asset Impairments, Restructuring, and Other Special Charges

In April 2008, we announced a streamlining of a portion of our manufacturing operations in Indianapolis and are offering a voluntary exit program to employees in selected areas. In total, this voluntary program is expected to reduce our Indianapolis employment by up to 500 people, predominantly in manufacturing but with a small portion in selected areas of research and development. As a result of these actions, we will be recording a restructuring charge in the second quarter of 2008. The amount of the charge has not yet been determined, as it will depend upon the number of employees that choose to take the exit package.

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 are transitioning the AIR Insulin patients in these studies to other appropriate therapies. We are implementing 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 (exit costs), and other special charges of \$145.7 million in the first quarter of 2008. These charges are primarily related to the decision to terminate development of AIR Insulin. Components of these charges include 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 are contractually obligated. The wind-down activities and patient programs should be substantially complete by the end of 2008. The remaining component of these charges, \$13.1 million, is related to exit costs incurred in the first quarter of 2008 in connection with previously announced strategic decisions made in prior periods.

In connection with previously announced strategic decisions, we recorded asset impairment, restructuring, and other special charges of \$123.0 million in the first quarter of 2007. These charges primarily related to a voluntary severance program at one of our U.S. plants and other costs related to this action as well as management actions taken in the fourth quarter of 2006. The component of these charges related to the non-cash asset impairment was \$67.6 million, and was necessary to adjust the carrying value of the assets to fair value. These restructuring activities were substantially complete at December 31, 2007.

## Note 5: Fair Value Measurements

The following table summarizes certain fair value information at March 31, 2008 for assets and liabilities measured at fair value on a recurring basis, as well as the carrying amount of certain other investments:

Description	Carrying Amount	Fair Value	Fair Value Measurements Using		
			Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Short-term investments					
Debt securities	\$ 2,289.1	\$ 2,289.1	\$ 883.2	\$ 1,405.9	\$
Noncurrent investments					
Marketable equity	\$ 73.7	\$ 73.7	\$ 73.7	\$	\$
Debt securities	418.9	418.9	80.3	338.6	
Equity method and other investments	103.5	N/A <sup>1</sup>			
	\$ 596.1				
Risk-management instruments assets	\$ 76.4	\$ 76.4	\$	\$ 76.4	\$

<sup>1</sup>The fair value of equity method and other investments is not readily available and disclosure is not required.

Total pretax unrealized gains and losses of our available-for-sale securities in other comprehensive income at March 31, 2008 were \$29.1 million and \$66.9 million, respectively, and the fair value of securities in an unrealized loss position was \$993.2 million. Substantially all of the securities in a loss position are investment-grade debt securities and have no indications of deterioration in credit quality. The majority of these securities first moved into an unrealized loss position during the first quarter of 2008. We have the intent and ability to hold these securities until the market values recover or the underlying cash flows have been received and we have concluded that no other-than-temporary loss exists at March 31, 2008. We did not hold auction rate securities, collateralized debt obligations, or securities issued by structured investment vehicles at March 31, 2008.

## Note 6: Stock-Based Compensation

In 2008 and 2007, our stock-based compensation expense consists primarily of performance awards (PAs), shareholder value awards (SVAs), and stock options. We recognized pretax stock-based compensation cost in the amount of \$58.5 million and \$72.7 million in the first quarter of 2008 and 2007, 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 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 fiscal year of the grant. As of March 31, 2008, the total remaining unrecognized compensation cost related to non vested PAs amounted to \$124.3 million, which will be amortized over the weighted-average remaining requisite service period of nine months.

SVAs are granted to officers and management and are payable in shares of common stock at the end of a three-year period. The number of shares actually issued varies depending on our stock price at the end of the three-year vesting period compared to pre-established target prices. We measure the fair value of the SVA unit on the grant date using a Monte Carlo simulation model. The Monte Carlo simulation model utilizes multiple input variables that determine the probability of satisfying the market condition stipulated in the award grant and calculates the fair value of the award. As of March 31, 2008, the total remaining unrecognized compensation cost related to nonvested SVAs amounted to \$76.0 million, which will be amortized over the weighted-average remaining requisite service period of 30 months. We discontinued issuing stock options subsequent to 2006. As of March 31, 2008, the total remaining unrecognized compensation cost related to nonvested stock options amounted to \$16.3 million, which will be amortized over the weighted-average remaining requisite service period of 10 months.

Note 7: Shareholders' Equity

As of March 31, 2008, we have purchased \$2.58 billion of our previously announced \$3.0 billion share repurchase program. During the first quarter of 2008, we did not acquire any shares pursuant to this program, nor do we expect any share repurchases under this program for the remainder of 2008.

Note 8: 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 unexercised stock options).

Note 9: Income Taxes

We file income tax returns in the United States (U.S.) federal jurisdiction and various state, local, and non-U.S. jurisdictions. We are no longer subject to U.S. federal, state and local, or non-U.S. income tax examinations in major taxing jurisdictions for years before 2002. During the first quarter of 2008, we completed and effectively settled our Internal Revenue Service (IRS) audit of tax years 2001-2004 except for one matter for which we will seek resolution through the IRS administrative appeals process. As a result of the IRS audit conclusion, gross unrecognized tax benefits were reduced by approximately \$618 million, and the consolidated results of operations were benefited by \$210.3 million through a reduction in income tax expense. The majority of the reduction in gross unrecognized tax benefits related to intercompany pricing positions that were agreed with the IRS in a prior audit cycle for which a prepayment of tax was made in 2005. Application of the prepayment and utilization of tax carryovers resulted in a refund of approximately \$50 million.



## Note 10: Retirement Benefits

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

	Defined Benefit Pension Plans Three Months Ended March 31,		Retiree Health Benefit Plans Three Months Ended March 31,	
	2008	2007	2008	2007
	(Dollars in millions)			
Components of net periodic benefit cost				
Service cost	\$ 64.3	\$ 65.5	\$ 14.4	\$ 19.1
Interest cost	102.9	86.0	26.5	25.3
Expected return on plan assets	(151.5)	(134.2)	(29.4)	(26.3)
Amortization of prior service cost	1.8	1.3	(9.0)	(3.9)
Recognized actuarial loss	19.2	31.3	16.5	23.4
Net periodic benefit cost	\$ 36.7	\$ 49.9	\$ 19.0	\$ 37.6

In 2008, we expect to contribute approximately \$85 million to our defined benefit pension plans to satisfy minimum funding requirements for the year. In addition, we expect to contribute approximately \$100 million of additional discretionary funding in 2008 to our defined benefit plans. As of March 31, 2008, approximately \$175 million of the total \$185 million expected 2008 contributions has been contributed.

## Note 11: 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):

Evista®: Barr Laboratories, Inc. (Barr), submitted an Abbreviated New Drug Application (ANDA) in 2002 seeking permission to market a generic version of Evista prior to the expiration of our relevant U.S. patents (expiring in 2012-2017) and alleging that these patents are invalid, not enforceable, or not infringed. In November 2002, we filed a lawsuit against Barr in the U.S. District Court for the Southern District of Indiana, seeking a ruling that these patents are valid, enforceable, and being infringed by Barr. Teva Pharmaceuticals USA, Inc. (Teva) has also submitted an ANDA seeking permission to market a generic version of Evista. In June 2006, we filed a similar lawsuit against Teva in the U.S. District Court for the Southern District of Indiana. The lawsuit against Teva is currently scheduled for trial beginning March 9, 2009, while no trial date has been set in the lawsuit against Barr. In April 2008, the FDA granted Teva tentative approval of its ANDA, but Teva's ability to market a generic product before a decision at trial is subject to expiration of a current statutory stay and our right to seek an extension of that stay on final FDA approval of Teva's ANDA or a preliminary injunction barring marketing by Teva of any approved generic product. We believe that Barr's and Teva's claims are without merit and we expect to prevail. However, it is not possible to determine the outcome of this litigation, and accordingly, we can provide no assurance that we will prevail. An unfavorable outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

Gemzar®: Sicor Pharmaceuticals, Inc. (Sicor), Mayne Pharma (USA) Inc. (Mayne), and Sun Pharmaceutical Industries Inc. (Sun) each submitted ANDAs seeking permission to market generic versions of Gemzar prior to the expiration of our relevant U.S. patents (compound patent expiring in 2010 and method of use patent expiring in 2013), and alleging that these patents are invalid. We filed lawsuits in the U.S. District Court for the Southern District of Indiana against Sicor (February 2006) and Mayne (October 2006, now closed, and January 2008), seeking rulings that these patents are valid and are being infringed. 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. We expect to prevail in this litigation and believe that these claims are without merit. However, it is not possible to determine the outcome of this litigation, and accordingly, we can provide no assurance that we will prevail. An unfavorable outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

Strattera®: Actavis Elizabeth LLC (Actavis), Glenmark Pharmaceuticals Inc., USA (Glenmark), Sun Pharmaceutical Industries Limited (Sun), Sandoz Inc. (Sandoz), Mylan Pharmaceuticals Inc. (Mylan), Teva Pharmaceuticals USA, Inc. (Teva), Apotex Inc. (Apotex), Aurobindo Pharma Ltd. (Aurobindo), Synthon Laboratories, Inc. (Synthon), and Zydus Pharmaceuticals, USA, Inc. (Zydus) 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. We filed a lawsuit against Actavis in the United States District Court for the District of New Jersey in August 2007, and added Glenmark, Sun, Sandoz, Mylan, Teva, Apotex, Aurobindo, Synthon, and Zydus as defendants in September 2007. In December 2007, Zydus agreed to entry of a consent judgment in which Zydus conceded the validity and enforceability of the patent and agreed to a permanent injunction. We expect to prevail in this litigation and believe that these claims are without merit. However, it is not possible to determine the outcome of this litigation, and accordingly, we can provide no assurance that we will prevail. An unfavorable outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

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

In Canada, several generic pharmaceutical manufacturers have challenged the validity of our Zyprexa compound and method-of-use patent (expiring in 2011). In April 2007, the Canadian Federal Court ruled against the first challenger, Apotex Inc. (Apotex), and that ruling was affirmed on appeal in February 2008. In June 2007, the Canadian Federal Court held that the invalidity allegations of a second challenger, Novopharm Ltd. (Novopharm), were justified and denied our request that Novopharm be prohibited from receiving marketing approval for generic olanzapine in Canada. Novopharm began selling generic olanzapine in Canada in the third quarter of 2007. We have sued Novopharm for patent infringement, and the trial is scheduled for November 2008. In November 2007, Apotex filed an action seeking a declaration of the invalidity of our Zyprexa compound and method-of-use patents, and no trial date has been set.

In Germany, generic pharmaceutical manufacturers Egis-Gyogyszergyar and Neolabs Ltd. challenged the validity of our Zyprexa compound and method-of-use patents (expiring in 2011). In June 2007, the German Federal Patent Court held that our patent is invalid. We are appealing the decision. Generic olanzapine was launched by competitors in Germany in the fourth quarter of 2007.

We have received challenges in a number of other countries, including Spain, the United Kingdom (U.K.), and several smaller European countries. In Spain, we have been successful at both the trial and appellate court levels in defeating the generic manufacturers' challenge, but we anticipate further legal challenges from generic manufacturers. In the U.K., a trial date has tentatively been set for July 2008.

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., 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. On May 4, 2006, a jury in Boston issued an initial decision in the case that Xigris and Evista sales infringe the patent. The jury awarded the plaintiffs approximately \$65 million in damages, calculated by applying a 2.3 percent royalty to all U.S. sales of Xigris and Evista from the date of issuance of the patent through the date of trial. In addition, a separate bench trial with the U.S. District Court of Massachusetts was held in August 2006, on our contention that the patent is unenforceable and impermissibly covers natural processes. In June 2005, the United States Patent and Trademark Office (USPTO) commenced a reexamination of the patent, and in August 2007 took the position that the Ariad claims at issue are unpatentable, a position that Ariad continues to contest. In September 2007, the Court entered a final judgment indicating that Ariad's claims are patentable, valid, 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 have been exhausted. We have appealed this judgment. We believe that these allegations are without legal merit, that we will ultimately prevail on these issues, and therefore that the likelihood of any monetary damages is remote.

#### Government Investigations and Related Litigation

In March 2004, the Office of the U.S. Attorney for the Eastern District of Pennsylvania (EDPA) advised us that it had commenced an investigation related to our U.S. marketing and promotional practices, including our communications with physicians and remuneration of physician consultants and advisors, with respect to Zyprexa, Prozac, and Prozac Weekly. In November 2007, we received a grand jury subpoena from the EDPA for a broad range of documents related to Zyprexa. A number of State Medicaid Fraud Control Units are coordinating with the EDPA in its investigation of any Medicaid-related claims relating to our marketing and promotion of Zyprexa. In October 2005, the EDPA advised that it is also conducting an inquiry regarding certain rebate agreements we entered into with a pharmacy benefit manager covering Axid®, Evista, Humalog®, Humulin®, Prozac, and Zyprexa. The inquiry includes a review of our Medicaid best price reporting related to the product sales covered by the rebate agreements.

In June 2005, we received a subpoena from the Office of the Attorney General, Medicaid Fraud Control Unit, of the State of Florida, seeking production of documents relating to sales of Zyprexa and our marketing and promotional practices with respect to Zyprexa.

In September 2006, we received a subpoena from the California Attorney General's Office seeking production of documents related to our efforts to obtain and maintain Zyprexa's status on California's formulary, marketing and promotional practices with respect to Zyprexa, and remuneration of health care providers.

In February 2007, we received a subpoena from the Office of the Attorney General of the State of Illinois, seeking production of documents and information relating to sales of Zyprexa and our marketing and promotional practices, including our communications with physicians and remuneration of physician consultants and advisors, with respect to Zyprexa.

Beginning in August 2006, we have received civil investigative demands or subpoenas from the attorneys general of a number of states under various state consumer protection laws. Most of these requests are now part of a multistate investigative effort being coordinated by an executive committee of attorneys general. We are aware that more than 30 states are participating in this joint effort, and it is possible that additional states will join the investigation. These attorneys general are seeking a broad range of Zyprexa documents, including documents relating to sales, marketing and promotional practices, and remuneration of health care providers.

We are cooperating in each of these investigations, including providing a broad range of documents and information relating to the investigations. It is possible that other Lilly products could become subject to investigation and that the outcome of these matters could include criminal charges and fines, penalties, or other monetary or nonmonetary remedies. We cannot determine the outcome of these matters or reasonably estimate the amount or range of amounts of any fines or penalties that might result from an adverse outcome. It is possible, however, that an adverse outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position. We have implemented and continue to review and enhance a broadly based compliance program that includes comprehensive compliance-related activities designed to ensure that our marketing and promotional practices, physician communications, remuneration of health care professionals, managed care arrangements, and Medicaid best price reporting comply with applicable laws and regulations.

#### Product Liability and Related Litigation

We have been named as a defendant in a large number of Zyprexa product liability lawsuits in the United States 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). The majority of non-federal cases are pending in the state court of Indiana. 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 31,300 claimants, including a large number of previously filed lawsuits and other asserted claims. The two primary settlements were as follows:

In June 2005, we reached an agreement in principle (and in September 2005 a final agreement) to settle more than 8,000 claims for \$690.0 million plus \$10.0 million to cover administration of the settlement.

In January 2007, we reached agreements with a number of plaintiffs' attorneys to settle more than 18,000 claims for approximately \$500 million.

The 2005 settlement totaling \$700.0 million was paid during 2005. The January 2007 settlements were paid during 2007.

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 250 lawsuits in the U.S. covering approximately 1,270 plaintiffs, of which about 160 cases covering about 310 plaintiffs are part of the MDL. Trial dates have been set for June 23, 2008, in the

Eastern District of New York, for two of the U.S. plaintiffs, and for as early as July 7, 2008 in Maine State Court for one other plaintiff.

In early 2005, we were served with four lawsuits seeking class action status in Canada on behalf of patients who took Zyprexa. One of these four lawsuits has been certified for residents of Quebec, and a second has been certified in Ontario and includes all Canadian residents, except for residents of Quebec and British Columbia. The allegations in the Canadian actions are similar to those in the litigation pending in the U.S.

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

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

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

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

In 2005, two lawsuits were filed in the Eastern District of New York 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 Eastern District of New York in 2006 on similar grounds. 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.

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

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

Because of the nature of pharmaceutical products, it is possible that we could become subject to large numbers of product liability and related claims for other products in the future. In the

past few years, we have experienced difficulties in obtaining product liability insurance due to a very restrictive insurance market. Therefore, for substantially all of our currently marketed products, we have been and expect that we will continue to be largely 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 on past claims.

#### 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 12: Other Income Net

Other income net, comprised the following:

	Three Months Ended March 31,	
	2008	2007
	(Dollars in millions)	
Interest expense	\$ 59.8	\$ 53.0
Interest income	(56.3)	(57.0)
Joint venture income		(11.0)
Other	(23.8)	(23.3)
	\$(20.3)	\$(38.3)

The joint venture income represents our share of the Lilly ICOS LLC joint venture results of operations, net of income taxes, prior to the acquisition of ICOS Corporation on January 29, 2007.

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

##### OPERATING RESULTS

##### Executive Overview

On April 1, 2008, John C. Lechleiter, Ph.D., assumed the role of chief executive officer, replacing Sidney Taurel. Taurel will remain chairman of our board of directors until December 31, 2008, at which time he will retire from the board and from the company.

##### I. Financial Results

Our worldwide sales for the quarter increased 14 percent, to \$4.81 billion, driven primarily by the collective growth of Cymbalta®, Cialis, Humalog, Alimta®, and Gemzar. Sales growth also benefited from the inclusion of Cialis sales for a full quarter in 2008 as compared with the first quarter of 2007, which included Cialis sales from the joint-venture countries subsequent to the ICOS acquisition on January 29, 2007. Net income and earnings per share increased to \$1.06 billion and \$.97, respectively, compared

with \$508.7 million and \$.47, respectively, for the first quarter of 2007. Net income for the first quarter of 2008 and the first quarter of 2007 were affected by the following significant items:

2008

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

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

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

2007

We incurred IPR&D charges associated with the acquisition of ICOS of \$303.5 million (no tax benefit) and the licensing arrangement with OSI Pharmaceuticals of \$25.0 million (pretax), which decreased earnings per share by \$.29.

We recognized asset impairments, restructuring, and other special charges associated with previously announced strategic decisions affecting manufacturing and research facilities of \$123.0 million (pretax), which decreased earnings per share by \$.08.

## II. Business Development and Recent Product and Late-Stage Pipeline Developments

We, along with our partner Amylin Pharmaceuticals, Inc., submitted Byetta® as a monotherapy treatment for type 2 diabetes to the FDA.

In April, the European health authorities approved Alimta in combination with cisplatin as a first-line treatment for non-small-cell lung cancer patients with other than predominantly squamous cell histology.

In April, the European Commission approved a new indication for Forsteo® for the treatment of osteoporosis associated with sustained, systemic glucocorticoid therapy in women and men at increased risk for fracture. We have also received an approvable letter from the FDA for Forteo® for the same indication.

In March, we entered into a licensing and collaboration agreement with Transition Therapeutics Inc. in which we were granted exclusive worldwide rights to develop and commercialize Transition's gastrin-based therapies, including the lead compound TT-223, which is currently in early Phase II testing as a potential treatment for type 2 diabetes.

In March, we terminated development of our AIR 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. We noted that this decision is 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.

In February, we received a not approvable letter from the U.S. Food and Drug Administration (FDA) for Zyprexa long-acting injection for the treatment and maintenance treatment of schizophrenia in adults. In its letter, the FDA said it needs more information to better understand the risk and underlying cause of excessive sedation events that have been observed in about 1 percent of patients in clinical trials.

Discussions with the FDA are ongoing, and our European application remains under review.

In February, the FDA accepted and gave priority review status to the New Drug Application for prasugrel. We, along with our partner Daiichi Sankyo Company, Limited, are seeking FDA approval for prasugrel as a treatment for patients with acute coronary syndrome being managed with percutaneous coronary intervention. We also submitted prasugrel to the European Medicines Agency (EMA) for the same indication.



### III. Legal, Regulatory, and Other Matters

We have reached agreements with claimants' attorneys involved in U.S. Zyprexa product liability litigation to settle a total of approximately 31,300 claims against us relating to the medication. Approximately 1,270 claims remain. As a result of our product liability exposures, since the beginning of 2005, we have recorded aggregate net pretax charges of \$1.61 billion for Zyprexa product liability matters.

In March 2004, we were notified by the U.S. Attorney's office for the Eastern District of Pennsylvania (EDPA) that it had commenced an investigation relating to our U.S. marketing and promotional practices for Zyprexa, Prozac®, and Prozac Weekly™. In November 2007, we received a grand jury subpoena from the EDPA requesting documents related to Zyprexa. Beginning in August 2006, we have received civil investigative demands or subpoenas from the attorneys general of more than 30 states under various state consumer protection laws seeking Zyprexa documents. In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), continues to effectively provide a prescription drug benefit under the Medicare program (known as Medicare Part D). Various measures have been discussed and/or passed in both the U.S. House of Representatives and U.S. Senate that would impose additional pricing pressures on our products, including proposals to legalize the importation of prescription drugs and either allow, or require, the Secretary of Health and Human Services to negotiate drug prices within Medicare Part D directly with pharmaceutical manufacturers. Additionally, various proposals have been introduced that would increase the rebates we pay on sales to Medicaid patients. We expect pricing pressures at the federal and state levels to continue.

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 or reduce the value of our intellectual property protection.

#### Sales

Sales increased 14 percent, to \$4.81 billion, driven primarily by the collective growth of Cymbalta, Cialis, Humalog, Alimta, and Gemzar. Sales in the U.S. increased by \$235.6 million, or 10 percent, for the first quarter of 2008 compared with the first quarter of 2007. Sales outside the U.S. increased \$345.9 million, or 18 percent, for the first quarter of 2008. Worldwide sales volume increased 8 percent, while exchange rates and selling prices contributed 5 percent and 1 percent of sales growth, respectively.

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

The following table summarizes our net sales activity for the three-month periods ended March 31, 2008 and 2007:

Product	Three Months Ended March 31, 2008			Three Months Ended March 31, 2007	Percent Change from 2007
	U.S. <sup>1</sup>	Outside U.S.	Total (Dollars in millions)	Total	
Zyprexa	\$ 499.3	\$ 620.9	\$ 1,120.2	\$1,108.0	1%
Cymbalta	511.1	94.0	605.1	441.8	37%
Gemzar	175.7	250.5	426.2	376.9	13%
Humalog	238.6	168.8	407.4	339.5	20%
Cialis <sup>2</sup>	123.0	213.9	336.9	193.1	74%
Evista	171.3	89.8	261.1	263.8	(1)%
Humulin	93.1	164.6	257.7	225.8	14%
Alimta	121.9	125.3	247.2	187.8	32%
Animal health products	107.6	127.7	235.3	215.1	9%
Forteo	118.3	66.7	185.0	153.4	21%
Strattera	115.5	32.5	148.0	139.9	6%
Humatrope	54.4	59.9	114.3	107.9	6%
Other pharmaceutical products	216.8	246.4	463.2	473.1	(2)%
Total net sales	\$2,546.6	\$2,261.0	\$ 4,807.6	\$4,226.1	14%

<sup>1</sup> U.S. sales include sales in Puerto Rico.

<sup>2</sup> Prior to the acquisition of ICOS, the Cialis sales shown in the table above represent results only in the territories in which we marketed Cialis exclusively. The remaining sales relate to the joint-venture territories of Lilly ICOS LLC (North America,

excluding  
Puerto Rico, and  
Europe). Our  
share of the  
joint-venture  
territory sales,  
net of expenses  
and taxes, is  
reported in other  
income net in  
our consolidated  
condensed  
income  
statement.

Subsequent to  
the acquisition,  
all Cialis  
product sales  
are included in  
our net sales.

Total worldwide  
Cialis sales for  
the first quarter  
of 2008 of  
\$336.9 million  
represent  
27 percent  
growth over the  
first quarter of  
2007.

#### Product Highlights

Zyprexa, our top-selling product, is a treatment for schizophrenia, acute mixed or maniac episodes associated with bipolar I disorder and bipolar maintenance. In the first quarter of 2008, Zyprexa sales in the U.S. decreased 5 percent compared with the first quarter of 2007, due to decreased demand and wholesaler buying patterns. Sales outside the U.S. increased 6 percent, driven by the favorable impact of foreign exchange rates. Demand outside the U.S. decreased slightly, as the impact of generic competition in Canada and Germany offset growth in Japan and several European markets.

U.S. sales of Cymbalta, a product for the treatment of major depressive disorder, diabetic peripheral neuropathic pain, and generalized anxiety disorder, increased 32 percent during the first quarter of 2008, as compared with the same period last year, driven primarily by strong demand. Sales outside the U.S. increased 69 percent, driven primarily by higher demand, as well as the favorable impact of foreign exchange rates.

U.S. sales of Gemzar, a product approved to fight various cancers, increased 8 percent during the first quarter of 2008 due to higher prices and increased demand. Sales outside the U.S. increased 17 percent as a result of the favorable impact of foreign exchange rates and increased demand.

U.S. sales of Humalog, our injectable human insulin analog for the treatment of diabetes, increased 13 percent during the first quarter of 2008 driven by higher demand and increased

prices. Sales outside the U.S. increased 31 percent during the first quarter driven by strong demand and the favorable impact of foreign exchange rates.

Total worldwide sales of Cialis, a treatment for erectile dysfunction, increased 27 percent to \$336.9 million during the first quarter of 2008, compared with \$265.8 million during the first quarter of 2007, which included \$72.7 million of sales in the Lilly ICOS joint-venture territories for the period prior to the acquisition of ICOS. Prior to the ICOS acquisition, Cialis sales in our territories were reported in net sales, while our 50 percent share of the joint-venture net income was reported in other income net. Total U.S. sales of Cialis increased 25 percent during the first quarter of 2008, driven by higher prices and increased demand. Total Cialis sales outside the U.S. increased 28 percent, driven primarily by higher demand and the favorable 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, were essentially flat during the first quarter of 2008, as a result of higher prices, offset by lower demand. Sales outside the U.S. decreased 2 percent driven by lower demand and lower prices, offset partially by the favorable impact of foreign exchange rates.

U.S. sales of Humulin, an injectable human insulin for the treatment of diabetes, increased 9 percent during the first quarter of 2008, due to higher prices, partially offset by lower demand. Sales outside the U.S. increased 17 percent during the first quarter of 2008 driven by the favorable impact of foreign exchange rates and increased demand, partially offset by lower prices.

U.S. sales of Alimta, a second-line treatment for non-small cell lung cancer and, in combination with another agent, for the treatment of malignant pleural mesothelioma, increased 17 percent during the first quarter of 2008, due primarily to increased demand. Sales outside the U.S. increased 50 percent, due primarily to increased demand and the favorable impact of foreign exchange rates, partially offset by lower prices.

U.S. sales of Forteo, an injectable treatment for osteoporosis in postmenopausal women and men at high risk for fracture, increased 10 percent during the first quarter of 2008, driven primarily by increased volume caused by variations in wholesaler buying patterns, as well as by higher prices. Sales outside the U.S. grew 45 percent, due to higher demand and the favorable impact of foreign exchange rates.

U.S. sales of Strattera, a treatment of attention-deficit hyperactivity disorder in children, adolescents, and adults, decreased 2 percent during the first quarter of 2008, compared with the same period in 2007, due to a decline in demand, partially offset by higher prices. Sales outside the U.S. increased 47 percent, due primarily to higher demand and the favorable impact of foreign exchange rates.

U.S. revenues of Actos®, an oral agent for the treatment of type 2 diabetes, were \$28.5 million, a decrease of 30 percent during the first quarter of 2008. Actos is manufactured by Takeda Chemical Industries, Ltd. Our U.S. marketing rights with respect to Actos expired in September 2006; however, we will continue receiving royalties from Takeda Pharmaceuticals North America at a declining rate through September 2009. We continue to sell the product and record sales in our territories outside the U.S. Sales outside the U.S. increased 22 percent, to \$55.6 million, due to the favorable impact of foreign exchange rates and increased demand.

Worldwide sales of Byetta, an injectable product for the treatment of type 2 diabetes, which we market with Amylin Pharmaceuticals (Amylin), increased 15 percent to \$169.0 million during the first quarter of 2008 as compared with the first quarter of 2007. We report as revenue our 50 percent share of Byetta's gross margin in the U.S., 100 percent of sales outside the U.S., and our sales of Byetta pen delivery devices to Amylin. Our revenues increased 16 percent to \$82.7 million during the first quarter of 2008.

Animal health product sales in the U.S. increased 16 percent, driven by the acquisition of Ivy Animal Health, Inc. and the launch of

Comfortis<sup>®</sup>, a new companion animal product. Sales outside the U.S. increased 4 percent, driven primarily by the favorable impact of foreign exchange rates.

#### Gross Margin, Costs, and Expenses

For the first quarter of 2008, gross margins as a percent of net sales declined 1.3 percentage points, to 76.9 percent. This decrease was primarily due to the impact of foreign exchange rates, offset in part by manufacturing expenses growing at a slower rate than sales.

Operating expenses (the aggregate of research and development and marketing, selling, and administrative expenses) increased 12 percent for the first quarter of 2008 compared with the first quarter of 2007. Marketing, selling, and administrative expenses rose 16 percent to \$1.55 billion, due to the impact of the ICOS acquisition, increased marketing expenses in support of key products (primarily Cymbalta, Cialis, and Humalog), the impact of foreign exchange rates, and increased legal costs, including a \$15.0 million settlement related to Zyprexa litigation with the state of Alaska. Research and development expenses were \$877.1 million, or 18 percent of sales. Compared with the first quarter of 2007, research and development expenses increased 5 percent. This increase was primarily due to increased discovery research and late-stage clinical trial costs, offset by lower prasugrel clinical trial costs and the first-quarter 2007 costs associated with the consequences of the FDA's rejection of our appeal of the approvable letter for Arxxant<sup>®</sup> and the withdrawal of the Arxxant application in Europe.

Acquired IPR&D charges were \$87.0 million in the first quarter of 2008 compared with \$328.5 million for the same period in 2007. We incurred asset impairments, restructuring (exit costs), and other special charges of \$145.7 million in the first quarter of 2008 compared with \$123.0 million for the same period in 2007. See Notes 3 and 4 to the consolidated condensed financial statements for additional information.

Other income<sup>1</sup> net decreased \$18.0 million, to \$20.3 million, and consists of interest expense, interest income, the after-tax operating results of the Lilly ICOS joint venture prior to the ICOS acquisition, and all other miscellaneous income and expense items.

Interest expense for first-quarter 2008 increased \$6.8 million, to \$59.8 million, due to less interest being capitalized and higher interest rates on debt, offset by lower average debt balances.

Interest income for first-quarter 2008 decreased \$0.7 million, to \$56.3 million, due to lower short-term interest rates, offset partially by larger average investment balances.

The Lilly ICOS joint-venture income prior to the acquisition was \$11.0 million. Subsequent to the acquisition, all activity related to ICOS is included in our consolidated financial results.

Net other miscellaneous income items increased \$0.5 million to \$23.8 million.

In the first quarter of 2008, we recognized an income tax benefit of \$8.0 million compared with income tax expense of \$210.7 million in the first quarter of 2007. This income tax benefit includes a discrete benefit of \$210.3 million, which was a result of the resolution of a substantial portion of the IRS audit of our federal income tax returns for the years 2001 through 2004. The reported effective tax rate for the first quarter of 2007 was 29.3 percent, because the in-process research and development charge associated with the acquisition of ICOS was not deductible.

#### **FINANCIAL CONDITION**

As of March 31, 2008, cash, cash equivalents, and short-term investments totaled \$5.43 billion compared with \$4.83 billion at December 31, 2007. Cash flows from operations of \$1.70 billion were partially offset by dividends paid of \$513.6 million and a net reduction in short-term borrowings of \$342.5 million. Total debt at March 31, 2008, was \$4.72 billion, a decrease of

\$285.9 million from December 31, 2007. Our current debt ratings from Standard & Poor's and Moody's remain at AA and Aa3, respectively.

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 product liability litigation, dividends, and taxes in 2008. We believe that amounts accessible through our existing commercial paper program should be adequate to fund maturities of short-term borrowings, if necessary. We currently have \$1.24 billion of unused committed bank credit facilities, \$1.20 billion of which backs our commercial paper program. Our access to credit markets has not been adversely affected by the recent illiquidity in the market. Various risks and uncertainties, including those discussed in the Financial Expectations for 2008 section, may affect our operating results and cash generated from operations.

#### LEGAL AND REGULATORY MATTERS

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

##### Patent Litigation

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

**Evista:** Barr Laboratories, Inc. (Barr), submitted an Abbreviated New Drug Application (ANDA) in 2002 seeking permission to market a generic version of Evista prior to the expiration of our relevant U.S. patents (expiring in 2012-2017) and alleging that these patents are invalid, not enforceable, or not infringed. In November 2002, we filed a lawsuit against Barr in the U.S. District Court for the Southern District of Indiana, seeking a ruling that these patents are valid, enforceable, and being infringed by Barr. Teva Pharmaceuticals USA, Inc. (Teva) has also submitted an ANDA seeking permission to market a generic version of Evista. In June 2006, we filed a similar lawsuit against Teva in the U.S. District Court for the Southern District of Indiana. The lawsuit against Teva is currently scheduled for trial beginning March 9, 2009, while no trial date has been set in the lawsuit against Barr. In April 2008, the FDA granted Teva tentative approval of its ANDA, but Teva's ability to market a generic product before a decision at trial is subject to expiration of a current statutory stay and our right to seek an extension of that stay on final FDA approval of Teva's ANDA or a preliminary injunction barring marketing by Teva of any approved generic product. We believe that Barr's and Teva's claims are without merit and we expect to prevail. However, it is not possible to determine the outcome of this litigation, and accordingly, we can provide no assurance that we will prevail. An unfavorable outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

**Gemzar:** Sicor Pharmaceuticals, Inc. (Sicor), Mayne Pharma (USA) Inc. (Mayne), and Sun Pharmaceutical Industries Inc. (Sun) each submitted ANDAs seeking permission to market generic versions of Gemzar prior to the expiration of our relevant U.S. patents (compound patent expiring in 2010 and method of use patent expiring in 2013), and alleging that these patents are invalid. We filed lawsuits in the U.S. District Court for the Southern District of Indiana against Sicor (February 2006) and Mayne (October 2006, now closed, and January 2008), seeking rulings that these patents are valid and are being infringed. 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.

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

Strattera: Actavis Elizabeth LLC (Actavis), Glenmark Pharmaceuticals Inc., USA (Glenmark), Sun Pharmaceutical Industries Limited (Sun), Sandoz Inc. (Sandoz), Mylan Pharmaceuticals Inc. (Mylan), Teva Pharmaceuticals USA, Inc. (Teva), Apotex Inc. (Apotex), Aurobindo Pharma Ltd. (Aurobindo), Synthon Laboratories, Inc. (Synthon), and Zydus Pharmaceuticals, USA, Inc. (Zydus) 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. We filed a lawsuit against Actavis in the United States District Court for the District of New Jersey in August 2007, and added Glenmark, Sun, Sandoz, Mylan, Teva, Apotex, Aurobindo, Synthon, and Zydus as defendants in September 2007. In December 2007, Zydus agreed to entry of a consent judgment in which Zydus conceded the validity and enforceability of the patent and agreed to a permanent injunction. We expect to prevail in this litigation and believe that these claims are without merit. However, it is not possible to determine the outcome of this litigation, and accordingly, we can provide no assurance that we will prevail. An unfavorable outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

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

In Canada, several generic pharmaceutical manufacturers have challenged the validity of our Zyprexa compound and method-of-use patent (expiring in 2011). In April 2007, the Canadian Federal Court ruled against the first challenger, Apotex Inc. (Apotex), and that ruling was affirmed on appeal in February 2008. In June 2007, the Canadian Federal Court held that the invalidity allegations of a second challenger, Novopharm Ltd. (Novopharm), were justified and denied our request that Novopharm be prohibited from receiving marketing approval for generic olanzapine in Canada. Novopharm began selling generic olanzapine in Canada in the third quarter of 2007. We have sued Novopharm for patent infringement, and the trial is scheduled for November 2008. In November 2007, Apotex filed an action seeking a declaration of the invalidity of our Zyprexa compound and method-of-use patents, and no trial date has been set.

In Germany, generic pharmaceutical manufacturers Egis-Gyogyszergyar and Neolabs Ltd. challenged the validity of our Zyprexa compound and method-of-use patents (expiring in 2011). In June 2007, the German Federal Patent Court held that our patent is invalid. We are appealing the decision. Generic olanzapine was launched by competitors in Germany in the fourth quarter of 2007.

We have received challenges in a number of other countries, including Spain, the United Kingdom (U.K.), and several smaller European countries. In Spain, we have been successful at both the trial and appellate court levels in defeating the generic manufacturers' challenge, but we anticipate further legal challenges from generic manufacturers. In the U.K., a trial date has tentatively been set for July 2008.

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., 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. On May 4, 2006, a jury in Boston issued an initial decision in the case that Xigris and Evista sales infringe the patent. The jury awarded the plaintiffs approximately \$65 million in damages, calculated by applying a 2.3 percent royalty to all U.S. sales of Xigris and Evista from the date of issuance of the patent through the date of trial. In addition, a separate bench trial with the U.S. District Court of Massachusetts was held in August 2006, on our contention that the patent is unenforceable and impermissibly covers natural processes. In June 2005, the United States Patent and Trademark Office (USPTO) commenced a reexamination of the patent, and in August 2007 took the position that the Ariad claims at issue are unpatentable, a position that Ariad continues to contest. In September 2007, the Court entered a final judgment indicating that Ariad's claims are patentable, valid, 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 have been exhausted. We have appealed this judgment. We believe that these allegations are without legal merit, that we will ultimately prevail on these issues, and therefore that the likelihood of any monetary damages is remote.

#### Government Investigations and Related Litigation

In March 2004, the Office of the U.S. Attorney for the Eastern District of Pennsylvania (EDPA) advised us that it had commenced an investigation related to our U.S. marketing and promotional practices, including our communications with physicians and remuneration of physician consultants and advisors, with respect to Zyprexa, Prozac, and Prozac Weekly. In November 2007, we received a grand jury subpoena from the EDPA for a broad range of documents related to Zyprexa. A number of State Medicaid Fraud Control Units are coordinating with the EDPA in its investigation of any Medicaid-related claims relating to our marketing and promotion of Zyprexa. In October 2005, the EDPA advised that it is also conducting an inquiry regarding certain rebate agreements we entered into with a pharmacy benefit manager covering Axid, Evista, Humalog, Humulin, Prozac, and Zyprexa. The inquiry includes a review of our Medicaid best price reporting related to the product sales covered by the rebate agreements.

In June 2005, we received a subpoena from the Office of the Attorney General, Medicaid Fraud Control Unit, of the State of Florida, seeking production of documents relating to sales of Zyprexa and our marketing and promotional practices with respect to Zyprexa.

In September 2006, we received a subpoena from the California Attorney General's Office seeking production of documents related to our efforts to obtain and maintain Zyprexa's status on California's formulary, marketing and promotional practices with respect to Zyprexa, and remuneration of health care providers.

In February 2007, we received a subpoena from the Office of the Attorney General of the State of Illinois, seeking production of documents and information relating to sales of Zyprexa and our marketing and promotional practices, including our communications with physicians and remuneration of physician consultants and advisors, with respect to Zyprexa.

Beginning in August 2006, we have received civil investigative demands or subpoenas from the attorneys general of a number of states under various state consumer protection laws. Most of these requests are now part of a multistate investigative effort being coordinated by an executive committee of attorneys general. We are aware that more than 30 states are participating in this joint effort, and it is possible that additional states will join the investigation. These attorneys general are seeking a broad range of Zyprexa documents, including documents relating to sales, marketing and promotional practices, and remuneration of health care providers.

We are cooperating in each of these investigations, including providing a broad range of documents and information relating to the investigations. It is possible that other Lilly products



could become subject to investigation and that the outcome of these matters could include criminal charges and fines, penalties, or other monetary or nonmonetary remedies. We cannot determine the outcome of these matters or reasonably estimate the amount or range of amounts of any fines or penalties that might result from an adverse outcome. It is possible, however, that an adverse outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position. We have implemented and continue to review and enhance a broadly based compliance program that includes comprehensive compliance-related activities designed to ensure that our marketing and promotional practices, physician communications, remuneration of health care professionals, managed care arrangements, and Medicaid best price reporting comply with applicable laws and regulations.

#### Product Liability and Related Litigation

We have been named as a defendant in a large number of Zyprexa product liability lawsuits in the United States 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). The majority of non-federal cases are pending in the state court of Indiana. 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 31,300 claimants, including a large number of previously filed lawsuits and other asserted claims. The two primary settlements were as follows:

In June 2005, we reached an agreement in principle (and in September 2005 a final agreement) to settle more than 8,000 claims for \$690.0 million plus \$10.0 million to cover administration of the settlement.

In January 2007, we reached agreements with a number of plaintiffs' attorneys to settle more than 18,000 claims for approximately \$500 million.

The 2005 settlement totaling \$700.0 million was paid during 2005. The January 2007 settlements were paid during 2007.

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 250 lawsuits in the U.S. covering approximately 1,270 plaintiffs, of which about 160 cases covering about 310 plaintiffs are part of the MDL. Trial dates have been set for June 23, 2008, in the Eastern District of New York, for two of the U.S. plaintiffs, and for as early as July 7, 2008 in Maine State Court for one other plaintiff.

In early 2005, we were served with four lawsuits seeking class action status in Canada on behalf of patients who took Zyprexa. One of these four lawsuits has been certified for residents of Quebec, and a second has been certified in Ontario and includes all Canadian residents, except for residents of Quebec and British Columbia. The allegations in the Canadian actions are similar to those in the litigation pending in the U.S.

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

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

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

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

In 2005, two lawsuits were filed in the Eastern District of New York 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 Eastern District of New York in 2006 on similar grounds. 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.

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

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

Because of the nature of pharmaceutical products, it is possible that we could become subject to large numbers of product liability and related claims for other products in the future. In the past few years, we have experienced difficulties in obtaining product liability insurance due to a very restrictive insurance market. Therefore, for substantially all of our currently marketed products, we have been and expect that we will continue to be largely 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 on past claims.

#### FINANCIAL EXPECTATIONS FOR 2008

We now expect earnings per share for the full year of 2008 to be in the range from \$3.90 to \$4.05. This guidance includes the income tax benefit of \$.19 per share resulting from the resolution of the IRS income tax audit, a \$.09 per share charge related to asset impairments and restructuring (exit costs) primarily related to the termination of the AIR Insulin program, and a \$.05 per share charge related to the licensing transaction with BioMS. This guidance does not reflect potential charges related to the voluntary exit program announced in April 2008. (See Note 4 to the

consolidated condensed financial statements for additional information.) Excluding the effect of the resolution of the IRS income tax audit, the estimated effective tax rate has been revised to approximately 22 percent from the previously stated 23 percent. This reduction is the result of a more favorable forecast of the mix of income between our domestic and international operations and the alignment of our practices with the conclusions of the most recent IRS audit. No other elements of our previously issued line item guidance have been changed.

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 and restructuring charges; acquisitions and business development transactions; foreign exchange rates; wholesaler inventory changes; other regulatory developments, litigation, and government investigations; and the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals or the protection of intellectual property rights. Other factors that may affect our operations and prospects are discussed in Item 1A of our 2007 Form 10-K, Risk Factors. We undertake no duty to update these forward-looking statements.

#### AVAILABLE INFORMATION ON OUR WEBSITE

We make available through our company website, free of charge, our company filings with the Securities and Exchange Commission (SEC) as soon as reasonably practicable after we electronically file them with, or furnish them to, the SEC. The reports we make available include annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements, registration statements, and any amendments to those documents. The website link to our SEC filings is <http://investor.lilly.com/edgar.cfm>.

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

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

Our management, with the participation of John C. Lechleiter, president and chief executive officer, and Derica W. Rice, senior vice president and chief financial officer, evaluated our disclosure controls and procedures as of March 31, 2008, and concluded that they are effective.

- (b) *Changes in Internal Controls.* During the first quarter of 2008, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### **PART II. OTHER INFORMATION**

##### *Item 1. Legal Proceedings*

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

The U.S. patent litigation involving Evista, Gemzar, Stratterra, 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 2007 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 60 suits involving approximately 115 claimants. In the thimerosal litigation, we have been named as a defendant in approximately 220 suits with approximately 310 claimants.

*Other Investigations*

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

Along with over 100 other pharmaceutical companies operating in Europe, we have received a questionnaire from the European Commission as part of its ongoing inquiry into whether pharmaceutical companies have improperly blocked or created artificial barriers to pharmaceutical innovation or market entry of medicines through the misuse of patent rights, settlement of patent claims, litigation, or other means. We are cooperating with this request.

*Shareholder Litigation*

Two lawsuits that seek class action status have been filed in the United States District Court for the Eastern District of New York against us and various current and former directors, officers and employees under the federal securities laws (Smith et al. v. Eli Lilly and Company et al., filed March 28, 2007, and Valentine v. Eli Lilly and Company et al., filed April 5, 2007). The suits have been consolidated under the caption In re Eli Lilly and Company Securities Litigation. In August 2007, the lead plaintiffs filed a consolidated amended complaint, seeking certification of a putative class of purchasers of our stock from August 1, 2002, through December 22, 2006. The complaint alleges that the defendants made false and misleading statements regarding Zyprexa in violation of the Securities Exchange Act of 1934, and seeks unspecified compensatory damages and the costs of suit, including attorneys' fees. In April 2008, the court granted summary judgment in favor of all defendants, dismissing the action. We anticipate that plaintiffs will appeal the decision. We believe these claims are without merit and intend to defend against them vigorously.

In 2007, the company received two demands from shareholders that the board of directors cause the company to take legal action against current and former directors and others for allegedly causing damage to the company through improper marketing of Evista, Prozac, and Zyprexa. In accordance with procedures established under the Indiana Business Corporation Law (Ind. Code § 23-1-32), the board has appointed a committee of independent persons to consider the demands and determine what action, if any, the company should take in response. Since January 2008, we have been served with six shareholder derivative lawsuits: Lambrecht, et al. v. Taurel, et al., filed January 17, 2008, in the United States District Court for the Southern District of Indiana; Staehr et al. v. Eli Lilly and Company et al., filed March 27, 2008, in Marion County Superior Court in Indianapolis, Indiana; Waldman et al., v. Eli Lilly and Company et al.,

filed February 11, 2008, in the United States District Court for the Eastern District of New York; Solomon v. Eli Lilly and Company et al., filed March 27, 2008, in Marion County Superior Court in Indianapolis, Indiana; Robbins v. Taurel, et al., filed April 9, 2008, in the United States District Court for the Eastern District of New York; and City of Taylor General Employees Retirement System v. Taurel, et al., filed April 15, 2008, in the United States District Court for the Eastern District of New York. Two of these lawsuits were filed by the shareholders who served the demands described above. All six lawsuits are nominally filed on behalf of the company, against various current and former directors and officers and allege that the named officers and directors harmed the company through the improper marketing of Zyprexa and, in certain suits, Evista and Prozac. We believe these shareholder derivative lawsuits are without merit and are prepared to defend against them vigorously.

*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. In November 2007, the plaintiffs amended their original complaint to add 50 new plaintiffs, as well as the national and local chapters of the National Association for the Advancement of Colored People. Under the current schedule, the plaintiffs are to file their class certification motion in April 2009. The company believes this lawsuit is without merit and is prepared to defend against it vigorously.

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., 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. We believe this lawsuit is without merit and are prepared to defend against it vigorously.

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

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

The following table summarizes the activity related to repurchases of our equity securities during the three-month period ended March 31, 2008:

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)
January 2008	45	\$ 52.99		\$ 419.2
February 2008	111	51.52		419.2
March 2008	2	49.84		419.2
Total	158			

The amounts presented in columns (a) and (b) above represent purchases of common stock related to our stock-based compensation programs. The amounts presented in columns (c) and (d) in the above table represent activity related to our \$3.0 billion share repurchase program announced in March 2000. As of March 31, 2008, we have purchased \$2.58 billion related to this program. During the first quarter of 2008, no shares were repurchased pursuant to this program and we do not expect to purchase any shares under this program during the remainder of 2008.

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

We held our annual meeting of shareholders on April 21, 2008. The following is a summary of the matters voted on at the meeting:

(a) The four nominees for director were elected to serve three-year terms ending in 2011, as follows:

Nominee	For	Withhold Vote
Michael L. Eskew	1,005,775,442	31,129,531
Alfred G. Gilman, M.D., Ph.D.	917,803,298	119,101,675
Karen N. Horn, Ph.D.	901,770,291	135,134,682
John C. Lechleiter, Ph.D.	949,562,590	87,342,383

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

For:	1,013,905,762
Against:	14,289,040
Abstain:	8,710,171

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

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

approximately 1.1 billion shares outstanding as of the record date:

			(77.3 percent of outstanding shares)
For:		879,244,915	
Against:		147,007,385	
Abstain:		10,652,673	
	32		

---

(d) By the following vote, the shareholders approved amendments to the company's articles of incorporation to provide for election of directors by majority vote:

For:	1,011,395,218
Against:	14,884,920
Abstain:	10,624,835

(e) By the following vote, the shareholders approved amendments to the 2002 Lilly Stock Plan:

For:	858,648,704
Against:	75,642,106
Abstain:	12,418,350
Broker Nonvote:	90,195,813

(f) By the following vote, the shareholders did not approve a shareholder proposal regarding international outsourcing of animal research:

For:	29,564,685
Against:	766,236,460
Abstain:	150,908,015
Broker Nonvote:	90,195,813

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

For:	461,381,376
Against:	473,781,460
Abstain:	11,546,324
Broker Nonvote:	90,195,813

(h) By the following vote, the shareholders approved a shareholder proposal regarding adopting a simple majority vote standard:

For:	598,094,703
Against:	336,931,693
Abstain:	11,682,764
Broker Nonvote:	90,195,813

(i) By the following vote, the shareholders did not approve a shareholder proposal regarding reporting on the company's political contributions:

For:	56,458,227
Against:	744,347,309
Abstain:	145,903,624
Broker Nonvote:	90,195,813



Item 6. Exhibits

The following documents are filed as exhibits to this Report:

EXHIBIT 3.1 Amended and Restated Articles of Incorporation as of April 21, 2008

EXHIBIT 3.2 Amended and Restated Bylaws as of April 21, 2008

EXHIBIT 10. Amended 2002 Lilly Stock Plan

EXHIBIT 11. Statement re: Computation of Earnings per Share

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

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

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

EXHIBIT 32. Section 1350 Certification

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: May 5,  
2008

/s/ James B. Lootens

James B. Lootens  
Secretary and Deputy General Counsel

Date: May 5,  
2008

/s/ Arnold C. Hanish

Arnold C. Hanish  
Executive Director, Finance, and  
Chief Accounting Officer

## INDEX TO EXHIBITS

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

### Exhibit

- EXHIBIT 3.1 Amended and Restated Articles of Incorporation as of April 21, 2008 (incorporated by reference from Exhibit 99.3 of the company's Form 8-K filed April 25, 2008)
- EXHIBIT 3.2 Amended and Restated Bylaws as of April 21, 2008 (incorporated by reference from Exhibit 99.2 of the company's Form 8-K filed April 25, 2008)
- EXHIBIT 10. Amended 2002 Lilly Stock Plan (incorporated by reference from Exhibit 99.1 of the company's Form 8-K filed April 25, 2008)
- 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, 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