LILLY ELI & CO
Form 10-Q
November 03, 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 SEPTEMBER 30, 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 incorporation or organization)	(I.R.S. Employer Identification No.)

LILLY CORPORATE CENTER, INDIANAPOLIS, INDIANA 46285
(Address of principal executive offices)
Registrant s telephone number, including area code (317) 276-2000

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months and (2) has been subject to such filing requirements for the past 90 days.
Yes þ No o

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes o No þ

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

Class	Number of Shares Outstanding
Common	1,136,953,333

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
	(Dollars in millions except per-share data)			
Net sales	$5,209.5	$4,586.8	$15,167.5	$13,443.9
Cost of sales	1,155.2	1,054.6	3,467.4	2,976.0
Research and development	953.0	844.5	2,781.6	2,533.1
Marketing, selling, and administrative	1,649.2	1,477.8	4,899.8	4,339.3
Acquired in-process research and development (Note 3)	28.0		150.0	656.6
Asset impairments, restructuring, and other special charges (Note 4)	1,659.4	81.3	1,894.0	204.3
Other income net (Note 12)	(2.5)	(49.8)	(55.1)	(89.9)
	5,442.3	3,408.4	13,137.7	10,619.4
Income (loss) before income taxes	(232.8)	1,178.4	2,029.8	2,824.5
Income taxes (Note 9)	232.8	252.1	472.3	725.9
Net income (loss)	$ (465.6)	$ 926.3	$ 1,557.5	$ 2,098.6
Earnings (loss) per share basic (Note 8)	$ (.43)	$ .85	$ 1.42	$ 1.93
Earnings (loss) per share diluted (Note 8)	$ (.43)	$ .85	$ 1.42	$ 1.93
Dividends paid per share	$ .47	$ .425	$ 1.41	$ 1.275

See Notes to Consolidated Condensed Financial Statements.

CONSOLIDATED CONDENSED BALANCE SHEETS
Eli Lilly and Company and Subsidiaries

	September 30, 2008 (Unaudited)	December 31, 2007
	(Dollars in millions)	
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 4,353.6	$ 3,220.5
Short-term investments (Note 5)	1,765.2	1,610.7
Accounts receivable, net of allowances of $99.2 (2008) and $103.1 (2007)	2,702.0	2,673.9
Other receivables	557.0	1,030.9
Inventories	2,111.6	2,523.7
Deferred income taxes	631.4	642.8
Prepaid expenses	825.0	613.6
TOTAL CURRENT ASSETS	12,945.8	12,316.1
OTHER ASSETS		
Prepaid pension (Note 10)	1,843.8	1,670.5
Investments (Note 5)	1,186.6	577.1
Goodwill and other intangibles net (Note 3)	2,298.8	2,455.4
Sundry	1,170.0	1,280.6
	6,499.2	5,983.6
PROPERTY AND EQUIPMENT		
Land, buildings, equipment, and construction-in-progress	14,895.6	14,841.3
Less allowances for depreciation	(6,633.5)	(6,266.2)
	8,262.1	8,575.1
	$27,707.1	$26,874.8
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES		
Short-term borrowings	$ 426.5	$ 413.7
Accounts payable	854.4	924.4
Employee compensation	662.5	823.8
Sales rebates and discounts	799.8	706.8
Dividends payable		513.6
Income taxes payable (Note 9)	403.7	238.4
Accrued marketing investigation charges (Note 11)	1,477.0	
Other current liabilities	1,885.9	1,816.1
TOTAL CURRENT LIABILITIES	6,509.8	5,436.8

Long-term debt	4,185.6	4,593.5
Accrued retirement benefit (Note 10)	1,105.8	1,145.1
Long-term income taxes payable (Note 9)	930.8	1,196.7
Deferred income taxes	284.2	287.5
Other noncurrent liabilities	949.3	711.3
	7,455.7	7,934.1
SHAREHOLDERS EQUITY (Notes 6 and 7)		
Common stock	711.1	709.5
Additional paid-in capital	3,913.1	3,805.2
Retained earnings	12,336.3	11,806.7
Employee benefit trust	(2,635.0)	(2,635.0)
Deferred costs-ESOP	(88.8)	(95.2)
Accumulated other comprehensive income (loss)	(395.9)	13.2
	13,840.8	13,604.4
Less cost of common stock in treasury	99.2	100.5
	13,741.6	13,503.9
	$27,707.1	$26,874.8

See Notes to Consolidated Condensed Financial Statements.

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

	Nine Months Ended September 30,	
	2008	2007
	(Dollars in millions)	
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income	$ 1,557.5	$ 2,098.6
Adjustments to reconcile net income to cash flows from operating activities:		
Changes in operating assets and liabilities, net of acquisitions	144.0	(621.5)
Depreciation and amortization	842.3	773.1
Stock-based compensation expense	192.7	214.5
Change in deferred taxes	288.7	(283.1)
Acquired in-process research and development, net of tax	107.3	634.7
Accrued marketing investigation charges, net of tax	1,456.3	
Other, net	326.3	108.5
NET CASH PROVIDED BY OPERATING ACTIVITIES	4,915.1	2,924.8
CASH FLOWS FROM INVESTING ACTIVITIES		
Net purchases of property and equipment	(671.5)	(715.7)
Net change in short-term investments	(237.3)	(225.2)
Purchases of noncurrent investments	(1,295.4)	(471.3)
Proceeds from sales and maturities of noncurrent investments	653.5	924.7
Cash paid for acquisitions, net of cash acquired	(44.4)	(2,667.5)
Purchase of in-process research and development	(122.0)	(25.0)
Other, net	(85.4)	(84.0)
NET CASH USED IN INVESTING ACTIVITIES	(1,802.5)	(3,264.0)
CASH FLOWS FROM FINANCING ACTIVITIES		
Dividends paid	(1,541.5)	(1,389.8)
Proceeds from issuance of long-term debt	0.1	2,500.0
Repayment of long-term debt	(10.8)	(1,057.7)
Issuances of common stock under stock plans		21.6
Net change in short-term borrowings	(392.2)	(432.1)
Other, net	(6.8)	3.8
NET CASH USED IN FINANCING ACTIVITIES	(1,951.2)	(354.2)
Effect of exchange rate changes on cash and cash equivalents	(28.3)	79.6

NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	1,133.1	(613.8)
Cash and cash equivalents at January 1	3,220.5	3,109.3
CASH AND CASH EQUIVALENTS AT SEPTEMBER 30	$ 4,353.6	$ 2,495.5

See Notes to Consolidated Condensed Financial Statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
	(Dollars in millions)			
Net income (loss)	$ (465.6)	$ 926.3	$1,557.5	$2,098.6
Other comprehensive income (loss)[1]	(610.0)	374.4	(409.1)	621.1
Comprehensive income (loss)	$(1,075.6)	$1,300.7	$1,148.4	$2,719.7

[1] The significant components of other comprehensive loss were losses from foreign currency translation adjustments of $640.4 million and $376.7 million for the three months and nine months ended September 30, 2008, respectively. In addition, the other comprehensive loss for the nine months ended September 30, 2008 reflected unrealized losses on investment securities of $103.4 million and reclassification adjustments of

$58.1 million of other comprehensive income as a result of the amortization of unrecognized losses from our defined benefit plans into the income statement. The significant components of other comprehensive income were gains from foreign currency translation adjustments of $304.3 million and $495.9 million for the three months and nine months ended September 30, 2007, respectively.

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 was $47.6 million and $32.0 million for the quarters ended September 30, 2008 and 2007, respectively, and $102.9 million and $99.5 million for the nine months ended September 30, 2008 and 2007, respectively.

SALES BY PRODUCT CATEGORY

Worldwide sales by product category were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
	(Dollars in millions)			
Net sales to unaffiliated customers				
Neurosciences	$2,160.4	$1,903.6	$ 6,258.5	$ 5,682.1
Endocrinology	1,483.2	1,363.7	4,412.3	3,990.1
Oncology	754.0	609.4	2,142.5	1,776.9
Cardiovascular	477.4	419.0	1,416.1	1,154.9
Animal health	277.1	236.6	766.9	666.4
Other pharmaceuticals	57.4	54.5	171.2	173.5
Net sales	$5,209.5	$4,586.8	$15,167.5	$13,443.9

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/A for the year ended December 31, 2007.

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.

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 and Collaborations

SGX Pharmaceuticals, Inc. Acquisition

On August 20, 2008, we acquired all of the outstanding common stock of SGX Pharmaceuticals, Inc. (SGX). The acquisition allows us to integrate SGX s structure-guided drug discovery platform into our drug discovery efforts. It also gives us access to FAST™, SGX s fragment-based, protein structure guided drug discovery technology, and to a portfolio of preclinical oncology compounds focused on a number of kinase targets. Under the terms of the agreement, the outstanding shares of SGX common stock were redeemed for an aggregate purchase price, including transaction costs, of approximately $66.5 million.

The acquisition has been accounted for as a business combination under the purchase method of accounting. We allocated $28.7 million of the purchase price to deferred tax assets and $28.0 million to acquired in-process research and development (IPR&D). The IPR&D represents products in development and technology that were not yet approved for marketing or were not yet proven technology and had no alternative future use. Accordingly, the $28.0 million allocated to acquired IPR&D was expensed immediately subsequent to the acquisition. SGX s results of operations are included in our consolidated condensed financial statements from the date of acquisition. The amount allocated to each of the intangible assets acquired is not deductible for tax purposes.

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 brought the full value of Cialis to us and enabled 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)[1]	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

[1] 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 IPR&D represented compounds under development that had 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 were written off by a charge to income

immediately subsequent to the acquisition because the compounds had no alternative future use. This charge was 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.

Other Acquisitions

During the second quarter of 2007, we acquired all of the outstanding stock of both Hypnion, Inc. (Hypnion), a privately held neuroscience drug discovery company focused on sleep disorders, and Ivy Animal Health, Inc. (Ivy), a privately held applied research and pharmaceutical product development company focused on the animal health industry, for $445.0 million in cash. The ongoing activities with respect to these companies products in development are not material to our research and development expenses. The results of operations are included in our consolidated condensed financial statements from the respective dates of acquisition.

The acquisition of Hypnion provided us with a broader and more substantive presence in the area of sleep disorder research and ownership of HY10275, a novel Phase II compound with a dual mechanism of action aimed at promoting better sleep onset and sleep maintenance. This was Hypnion s only significant asset. For this acquisition, we recorded a charge of $291.1 million, representing the estimated fair value of the acquired compound, to acquired IPR&D in the second quarter of 2007 because the development-stage compound acquired had no alternative future use. This charge was not deductible for tax purposes. Because Hypnion was a development-stage company, the transaction was accounted for as an acquisition of assets rather than as a business combination and, therefore, goodwill was not recorded.

The acquisition of Ivy provides us with products that complement those of our animal health product line. This acquisition has been accounted for as a business combination under the purchase method of accounting. We have allocated $88.7 million of the purchase price to other identifiable intangible assets, primarily related to marketed products, $37.0 million to acquired IPR&D, and $25.0 million to goodwill. The IPR&D represents products in development that were not yet approved for marketing and had no alternative future use. Accordingly, the $37.0 million allocated to acquired IPR&D was expensed immediately subsequent to the acquisition. The other identifiable intangible assets are being amortized over their estimated remaining useful lives of 10 to 20 years. Goodwill resulting from this acquisition was fully allocated to the animal health business segment. The amount allocated to each of the intangible assets acquired, including goodwill, was expected to be deductible for tax purposes.

Product Acquisitions

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

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 became effective upon clearance under the Hart-Scott-Rodino Anti-Trust Improvements Act 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. The charge of $87.0 million for acquired IPR&D related to this arrangement was included as expense in the first quarter of 2008 and is deductible for tax purposes.

In October 2007, we entered into an agreement with Glenmark Pharmaceuticals Limited India whereby we acquired the rights to a portfolio of transient receptor potential vanilloid sub-family 1 (TRPV1) antagonist molecules, including a clinical-phase compound. The compound was in early clinical phase development as a potential next-generation treatment for various pain conditions,

including osteoarthritic pain, and had no alternative future use. As with many development-phase compounds, launch of the product, if approved, was not expected in the near term. The charge of $45.0 million for acquired IPR&D was deductible for tax purposes and was included as expense in the fourth quarter of 2007. Development of this compound has been suspended.

In October 2007, we entered into a global strategic alliance with MacroGenics, Inc. (MacroGenics) to develop and commercialize teplizumab, a humanized anti-CD3 monoclonal antibody, as well as other potential next-generation anti-CD3 molecules for use in the treatment of autoimmune diseases. As part of the arrangement, we acquired the exclusive rights to the molecule, which was in the development stage (Phase II/III clinical trial for individuals with recent-onset type 1 diabetes) and had no alternative future use. As with many development-phase compounds, launch of the product, if approved, was not expected in the near term. The charge of $44.0 million for acquired IPR&D was deductible for tax purposes and was included as expense in the fourth quarter of 2007.

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. The charge of $25.0 million for acquired IPR&D related to this arrangement was included as expense in the first quarter of 2007 and was deductible for tax purposes.

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

Collaborations

In the second quarter of 2008, we entered into an agreement with an affiliate of TPG-Axon Capital (TPG) for the Phase III development of our gamma-secretase inhibitor and our A-beta antibody, our two lead molecules for the treatment of mild to moderate Alzheimer s disease. Pursuant to the terms of the agreement, both we and TPG will provide funding for the Alzheimer s clinical trials. Funding from TPG will not exceed $325 million and could extend into 2014. In exchange for their funding, TPG may receive success-based milestones totaling $330 million and mid-to high-single-digit royalties that are contingent upon the successful development of the Alzheimer s treatments. The royalties will be paid for approximately eight years after launch of a product. Our reported research and development costs related to the Alzheimer s treatments are reflected net of the at-risk funding we receive from TPG for their share of the development costs. The funding from TPG is not expected to be material in any period.

Note 4: Asset Impairments, Restructuring, and Other Special Charges

As discussed further in Note 11, in the third quarter of 2008, we recorded a charge of $1.48 billion related to the pending Zyprexa® investigations led by the U.S. Attorney for the Eastern District of Pennsylvania, as well as the resolution of a multi-state investigation regarding Zyprexa involving 32 states and the District of Columbia.

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

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

In March 2008, 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. This decision was not a result of any observations during AIR Insulin trials relating to the safety of the product, but rather was a result of increasing uncertainties in the regulatory environment, and a thorough evaluation of the evolving commercial and clinical potential of the product compared to existing medical therapies. As a result of this decision, we halted our ongoing clinical studies and transitioned the AIR Insulin patients in these studies to other appropriate therapies. We have implemented a patient program in the U.S., and other regions of the world where allowed, to provide clinical trial participants with appropriate financial support to fund their medications and diagnostic supplies through the end of 2008.

We recognized asset impairment, restructuring, and other special charges of $145.7 million in the first quarter of 2008. These charges were primarily related to the decision to terminate development of AIR Insulin. Components of these charges included non-cash charges of $40.9 million for the write-down of impaired manufacturing assets that had no use beyond the AIR Insulin program, as well as charges of $91.7 million for estimated contractual obligations and wind-down costs associated with the termination of clinical trials and certain development activities, and costs associated with the patient program to transition participants from AIR Insulin. This amount includes an estimate of Alkermes s wind-down costs for which we were 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 September 30, 2008 for assets and liabilities measured at fair value on a recurring basis, as well as the carrying amount of certain other investments:

			Fair Value Measurements Using		
Description	Carrying Amount	Fair Value	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	$ 1,765.2	$ 1,765.2	$ 543.0	$ 1,222.2	$
Noncurrent investments					
Marketable equity	$ 39.8	$ 39.8	$ 39.8	$	$
Debt securities	1,030.5	1,030.5	449.0	581.5	
Equity method and other investments	116.3	N/A			
	$ 1,186.6				
Risk-management instruments assets	$ 57.2	$ 57.2	$	$ 57.2	$

The fair value of equity method investments and other investments is not readily available.

The fair value of the portion of our available-for-sale securities in an unrealized gain position was $700.3 million at September 30, 2008, with an unrealized gain of $6.8 million. The fair value of our available-for-sale securities in an unrealized loss position was $2.06 billion, with an unrealized loss of $147.1 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 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 for those securities in an unrealized loss position, no other-than-temporary loss exists at September 30, 2008. As of September 30, 2008, we did not hold auction rate securities, collateralized debt obligations, or securities issued by structured investment vehicles.

Note 6: Stock-Based Compensation

In 2008 and 2007, our stock-based compensation expense consisted primarily of performance awards (PAs), shareholder value awards (SVAs), and stock options. We recognized pretax stock-based compensation cost in the amount of $77.9 million and $79.3 million in the third quarter of 2008 and 2007, respectively. In the first nine months of 2008 and 2007, we recognized stock-based compensation expense of $192.7 million and $214.5 million, respectively.

PAs are granted to officers and management and are payable in shares of our common stock. The number of PA shares actually issued, if any, varies depending on the achievement of certain earnings-per-share targets over a one-year 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 September 30, 2008, the total remaining unrecognized

compensation cost

related to nonvested PAs amounted to $47.7 million, which will be amortized over the weighted-average remaining requisite service period of three months.

SVAs are granted to officers and management and are payable in shares of common stock at the end of a three-year period. The number of shares actually issued varies depending on our stock price at the end of the three-year vesting period compared to pre-established target prices. We measure the fair value of the SVA unit on the grant date using a Monte Carlo simulation model. The Monte Carlo simulation model utilizes multiple input variables that determine the probability of satisfying the market condition stipulated in the award grant and calculates the fair value of the award. As of September 30, 2008, the total remaining unrecognized compensation cost related to nonvested SVAs amounted to $59.6 million, which will be amortized over the weighted-average remaining requisite service period of 25 months.

We discontinued issuing stock options beginning in 2007. As of September 30, 2008, the total remaining unrecognized compensation cost related to nonvested stock options amounted to $6.7 million, which will be amortized over the weighted-average remaining requisite service period of four months.

Note 7: Shareholders Equity

As of September 30, 2008, we have purchased $2.58 billion of our previously announced $3.0 billion share repurchase program. During the third 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. The IRS began its examination of tax years 2005-2007 during the third quarter of 2008.

Note 10: Retirement Benefits

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

	Defined Benefit Pension Plans			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
	(Dollars in millions)			
Components of net periodic benefit cost				
Service cost	$ 61.4	$ 62.9	$ 186.8	$ 194.9
Interest cost	102.7	86.5	308.5	258.9
Expected return on plan assets	(151.3)	(134.6)	(455.0)	(403.1)
Amortization of prior service cost	1.8	1.4	5.3	4.0
Recognized actuarial loss	19.2	30.9	57.8	93.1
Net periodic benefit cost	$ 33.8	$ 47.1	$ 103.4	$ 147.8

	Retiree Health Benefit Plans			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
	(Dollars in millions)			
Components of net periodic benefit cost				
Service cost	$ 15.5	$ 17.6	$ 46.6	$ 54.3
Interest cost	26.5	25.3	79.4	76.0
Expected return on plan assets	(29.1)	(25.3)	(88.3)	(77.0)
Amortization of prior service cost	(9.0)	(3.9)	(27.0)	(11.7)
Recognized actuarial loss	15.7	23.8	47.1	70.9
Net periodic benefit cost	$ 19.6	$ 37.5	$ 57.8	$112.5

In 2008, we expect to contribute approximately $80 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 September 30, 2008, we have contributed substantially all of these amounts to our plans.

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):

Cymbalta®: We have received notice that at least four generic drug manufacturers have submitted Abbreviated New Drug Applications (ANDAs) seeking permission to market generic versions of Cymbalta prior to the expiration of our relevant U.S. patents (the earliest of which expires in 2013) and alleging that these patents are either invalid or not infringed. We are currently reviewing the allegations and will take appropriate action to

seek rulings that the patents are valid and infringed.

Gemzar®: Sicor Pharmaceuticals, Inc. (Sicor), Mayne Pharma (USA) Inc. (Mayne), and Sun

Pharmaceutical Industries Inc. (Sun) each submitted an ANDA seeking permission to market generic versions of Gemzar prior to the expiration of our relevant U.S. patents (compound patent expiring in 2010 and method of use patent expiring in 2013), and alleging that these patents are invalid. We filed lawsuits in the U.S. District Court for the Southern District of Indiana against Sicor (February 2006) and Mayne (October 2006 and January 2008), seeking rulings that these patents are valid and are being infringed. The suit against Sicor has been scheduled for trial in July 2009. The statutory stay barring final approval of Sicor s ANDAs has expired; however, Sicor must provide 90 days notice prior to marketing generic Gemzar upon receipt of final approval by the FDA to allow time for us to seek a preliminary injunction. Both suits against Mayne have been administratively closed, and the parties have agreed to be bound by the results of the Sicor suit. In November 2007, Sun filed a declaratory judgment action in the United States District Court for the Eastern District of Michigan, seeking rulings that our method-of-use and compound patents are invalid or unenforceable, or would not be infringed by the sale of Sun s generic product. This trial is scheduled for December 2009.

Alimta®: Teva Parenteral Medicines, Inc. (Teva) and APP Pharmaceuticals, LLC (APP) each submitted ANDAs seeking approval to market generic versions of Alimta prior to the expiration of the relevant U.S. patent (licensed from the Trustees of Princeton University and expiring in 2016), and alleging the patent is invalid. We, along with Princeton, filed lawsuits in the U.S. District Court for the District of Delaware against Teva and APP, seeking rulings that the compound patent is valid and infringed. The court has not set a date for trial in either case.

Evista®: Barr Laboratories, Inc. (Barr), submitted an ANDA in 2002 seeking permission to market a generic version of Evista prior to the expiration of our relevant U.S. patents (expiring in 2012-2017) and alleging that these patents are invalid, not enforceable, or not infringed. In November 2002, we filed a lawsuit against Barr in the U.S. District Court for the Southern District of Indiana, seeking a ruling that these patents are valid, enforceable, and being infringed by Barr. 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 a statutory stay that expires on March 9, 2009.

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. In June 2008, Glenmark agreed to entry of a permanent injunction, enjoining it from selling a generic product prior to the expiration of the U.S. patent. Also in June 2008, Synthon notified us that it has withdrawn its ANDA and agreed to a stipulated dismissal of all outstanding claims. For the remaining defendants, trial is anticipated as early as December 2009.

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

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

In Canada, several generic pharmaceutical manufacturers have challenged the validity of our Zyprexa compound and method-of-use patent (expiring in 2011). In April 2007, the Canadian Federal Court ruled against the first challenger, Apotex Inc. (Apotex), and that ruling was affirmed on appeal in February 2008. In June 2007, the Canadian Federal Court held that an invalidity allegation of a second challenger, Novopharm Ltd. (Novopharm), was justified and denied our request that Novopharm be prohibited from receiving marketing approval for generic olanzapine in Canada. Novopharm began selling generic olanzapine in Canada in the third quarter of 2007. We 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. We have brought similar actions against Pharmascience (August 2007), Sandoz (July 2007), Nu-Pharm (June 2008), and Genpharm (June 2008); none of these suits has been scheduled for trial. Pharmascience has agreed to be bound by the outcome of the Novopharm suit, and, pending the outcome of the lawsuit, we have agreed not to take any further steps to prevent them from coming to market with generic olanzapine tablets, subject to a contingent damages obligation should we be successful against Novopharm.

In Germany, generic pharmaceutical manufacturers Egis-Gyogyszergyar and Neolab Ltd. challenged the validity of our Zyprexa compound and method-of-use patent (expiring in 2011). In June 2007, the German Federal Patent Court held that our patent is invalid. We are appealing the decision to the German Supreme Court, which has scheduled a hearing for December 2008. Generic olanzapine was launched by competitors in Germany in the fourth quarter of 2007. Notwithstanding the Federal Patent Court ruling, we have sought preliminary injunctions against all generic companies who are marketing generic olanzapine products in Germany. In May 2008 the Court of Appeal in Düsseldorf granted an injunction against the first of these generic companies, STADApharm GmbH, as a result of which STADA has had to withdraw its generic olanzapine product from the German market. Preliminary injunction actions against other generic companies in Germany were denied. We continue to pursue these companies in main actions for infringement.

We have received challenges in a number of other countries, including Spain, the United Kingdom (UK), 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 UK, the generic pharmaceutical manufacturer Dr. Reddy s Laboratories (UK) Limited has challenged the validity of our Zyprexa compound and method-of-use patent (expiring in 2011). In October, 2008, the Patents Court in the High Court, London ruled that our patent was valid. We anticipate that Dr. Reddy s will appeal this decision.

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. In addition, the State Medicaid Fraud Control Units of more than 30 states are coordinating with the EDPA in its investigation of any Medicaid-related claims relating to our marketing and promotion of Zyprexa. Twelve other states (Arkansas, Connecticut, Idaho, Louisiana, Minnesota, Mississippi, Montana, New Mexico, Pennsylvania, South Carolina, Utah, and West Virginia) have filed lawsuits over Zyprexa and are not participating in the coordinated investigation. In October 2008, we announced that we are in advanced discussions to resolve the ongoing investigations led by the EDPA, and we recorded a charge of $1.42 billion. The charge reflects our currently estimable exposure with respect to these matters. If the ongoing discussions are successfully concluded, we expect that they would settle the Zyprexa-related federal claims, as well as similar Medicaid-related claims of states participating in the settlement.

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 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 became part of a multistate investigative effort coordinated by an executive committee of attorneys general. In October 2008, we reached a settlement with 32 states and the District of Columbia. While there is no finding that we have violated any provision of the state laws under which the investigations were conducted, we will pay $62 million and undertake certain commitments regarding Zyprexa for a period of six years, through consent decrees filed in the settling states. The 32 states participating in the Multistate agreement are: Alabama, Arizona, California, Delaware, Florida, Hawaii, Illinois, Indiana, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Missouri, Nebraska, Nevada, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Vermont, Washington, and Wisconsin.

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. Except to the extent described above, 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 31,350 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 180 lawsuits in the U.S. covering approximately 1,615 plaintiffs, of which about 130 cases covering about 305 plaintiffs are part of the MDL. The MDL cases have been scheduled for trial in groups, with the earliest trial scheduled to begin March 16, 2009.

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

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

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

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

In December 2004, we were served with two lawsuits brought in state court in Louisiana on behalf of the Louisiana Department of Health and Hospitals, alleging that Zyprexa caused or contributed to diabetes or high blood-glucose levels, and that we improperly promoted the drug. These cases have been removed to federal court and are now part of the MDL proceedings in the Eastern District of New York (EDNY). In these actions, the Department of Health and Hospitals seeks to recover the costs it paid for Zyprexa through Medicaid and other drug-benefit programs, as well as the costs the department alleges it has incurred and will incur to treat Zyprexa-related illnesses. We have been served with similar lawsuits filed by the states of Alaska, Arkansas, Connecticut, Idaho, Minnesota, Mississippi, Montana, New Mexico, Pennsylvania, South Carolina, Utah, and West Virginia in the courts of the respective states. The Connecticut, Louisiana, Minnesota, Mississippi, Montana, New Mexico, and West Virginia cases are part of the MDL proceedings in the EDNY. The Alaska case was settled in March 2008 for a payment of $15.0 million, plus terms designed to ensure, subject to certain limitations and conditions, that Alaska is treated as favorably as certain other states that may settle with us in the future over similar claims. The following cases have been set for trial in 2009: Connecticut in the EDNY in June, Pennsylvania in November, and South Carolina in August, in their respective states.

In 2005, two lawsuits were filed in the EDNY purporting to be nationwide class actions on behalf of all consumers and third-party payors, excluding governmental entities, which have made or will make payments for their members or insured patients being prescribed Zyprexa. These actions have now been consolidated into a single lawsuit, which is brought under certain state consumer protection statutes, the federal civil RICO statute, and common law theories, seeking a refund of the cost of Zyprexa, treble damages, punitive damages, and attorneys fees. Two additional lawsuits were filed in the EDNY in 2006 on similar grounds. In September 2008, Judge Weinstein certified a class consisting of third-party payors, excluding governmental entities and individual consumers. We appealed the certification order, and Judge Weinstein s order denying our motion for summary judgment, in September 2008. In 2007, The Pennsylvania Employees Trust Fund brought claims in state court in Pennsylvania as insurer of Pennsylvania state employees, who were prescribed Zyprexa on similar grounds as described in the New York cases. As with the product liability suits, these lawsuits allege that we inadequately tested for and warned about side effects of Zyprexa and improperly promoted the drug. The Pennsylvania case is set for trial in October 2009.

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

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

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
	(Dollars in millions)			
Interest expense	$ 44.0	$ 55.8	$ 146.4	$ 167.9
Interest income	(53.2)	(49.6)	(156.8)	(157.0)
Joint-venture income				(11.0)
Other	6.7	(56.0)	(44.7)	(89.8)
	$ (2.5)	$(49.8)	$ (55.1)	$ (89.9)

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.

Note 13: Subsequent Events

ImClone Systems, Inc.

We, along with ImClone Sytems, Inc. (ImClone), have approved a definitive merger agreement under which we will acquire ImClone through an all-cash tender offer of $70 per share, or approximately $6.5 billion. This strategic combination will create one of the leading oncology franchises in the biopharmaceutical industry, offering both targeted therapies and oncolytic agents along with a pipeline spanning all phases of clinical development. The combination also expands our biotechnology capabilities. The transaction, which is expected to close in either the fourth quarter of 2008 or the first quarter of 2009, is conditioned upon at least a majority of the outstanding ImClone shares being tendered, as well as clearance under the Hart-Scott-Rodino Antitrust Improvements Act, similar requirements outside the U.S., and other customary closing conditions. In addition, a shareholder lawsuit has been filed seeking to enjoin the closing of the transaction. If we close in the fourth quarter, we will incur a one-time charge to earnings for IPR&D, but it is premature to estimate what that charge would be.

Posilac®

On October 1, 2008, we acquired the worldwide rights to the dairy cow supplement, Posilac (sometribove), as well as the product s supporting operations, from Monsanto Company (Monsanto). The acquisition of Posilac provides us with a product that complements those of our animal health product line. Under the terms of the agreement, we acquired the rights to the Posilac brand, as well as the product s U.S. sales force and manufacturing facility for a $300.0 million upfront payment as well as contingent consideration based on future Posilac sales. The allocation of the purchase price has not been finalized; however, we do not anticipate incurring an IPR&D charge.

This acquisition will be accounted for as a business combination under the purchase method of accounting, which requires the assets acquired and liabilities assumed from Monsanto to be recorded at their respective fair values as of the acquisition date in our consolidated financial statements. The results of operations will be included in our consolidated financial statements from the date of acquisition.

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

OPERATING RESULTS

Executive Overview

I. Financial Results

Worldwide sales increased 14 percent and 13 percent for the third quarter and first nine months of 2008, respectively, driven by the collective growth of Cymbalta, Alimta, Cialis, Humalog, and Gemzar, and by the favorable impact of foreign exchange rates. Third-quarter net loss was $465.6 million and loss per share was $.43 as compared to 2007 net income of $926.3 million and earnings per share of $.85. Net income and earnings per share decreased 26 percent for the first-nine-months of 2008, to $1.56 billion and $1.42, respectively, as compared with the same period of 2007. Net income for the first nine months of 2008 and the first nine months of 2007 was affected by the following significant items:

2008

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

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

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

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

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

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

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

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

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

2007

We incurred a special charge following a settlement with one of our insurance carriers over Zyprexa product liability claims, which led to a reduction of our expected product liability insurance recoveries. This resulted in a charge of $81.3 million (pretax), which decreased earnings per share by $.06 in the third quarter.

We incurred IPR&D charges associated with the acquisition of Hypnion of $291.1 million (no tax benefit) and the acquisition of Ivy of $37.0 million (pretax), which decreased earnings per share by $.29 in the second quarter.

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 in the first quarter.

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 in the first quarter.

II. Late-Stage Pipeline Developments and Business Development Activity in 2008

Pipeline

We, along with our partner Daiichi Sankyo Company, Limited, confirmed that the U.S. Food and Drug Administration (FDA) did not complete its review for the prasugrel New Drug Application (NDA) by the Prescription Drug User Fee Act goal date of September 26, 2008. We continue to have discussions with the FDA regarding the review of this application. We 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 (EMEA) for the same indication.

In September, the FDA approved Alimta, in combination with cisplatin, as a first-line treatment for locally advanced and metastatic non-small cell lung cancer (NSCLC) for patients with nonsquamous histology. 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.

We submitted tadalafil as a treatment for pulmonary arterial hypertension (PAH) to regulatory authorities in both the U.S. and Japan.

The Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion recommending approval of Zypadhera™ (also known as olanzapine long-acting injection) for maintenance treatment of adult patients with schizophrenia sufficiently stabilized during acute treatment with oral olanzapine. The opinion issued by the CHMP will need to be ratified by the European Commission before the new indication is considered approved.

In July, the European Commission approved Cymbalta for the treatment of generalized anxiety disorder (GAD).

In June, the FDA approved Cymbalta for the management of fibromyalgia, a chronic widespread pain disorder.

We submitted a supplemental New Drug Application (sNDA) to the FDA seeking approval for a new indication for Cymbalta for the management of chronic pain.

In May, the FDA approved Strattera for maintenance treatment of attention-deficit hyperactivity disorder (ADHD) in children and adolescents.

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 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 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 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. In the second quarter, we submitted a complete response to the FDA s not-approvable decision.

Business Development

In October, we along with ImClone Systems, Inc. (ImClone), approved a definitive merger agreement to acquire ImClone through an all-cash tender offer of $70 per share, or approximately $6.5 billion. We expect the transaction to close in either the fourth quarter of 2008 or the first quarter of 2009. If we close in the fourth quarter, we will incur a one-time charge to earnings for IPR&D, but it is premature to estimate what that charge would be.

In October, we acquired the worldwide rights to the dairy cow supplement, Posilac (sometribove), as well as the product s supporting operations, from Monsanto Company (Monsanto) for an upfront payment of $300.0 million, as well as contingent consideration based on future Posilac sales. The acquisition of Posilac provides us with a product that complements those of our animal health product line, and will be included in our results of operations from the date of acquisition.

In October, we sold our Greenfield Laboratories site in Greenfield, Indiana, to Covance Inc. We also signed a 10-year service agreement, under which Covance will assume responsibility for our toxicology testing and other R&D support activities at the site.

In August, we acquired SGX for approximately $64 million in cash. The acquisition allows us to integrate SGX s structure-guided drug discovery platform into our drug discovery efforts. It also gives us access to FAST™, SGX s fragment-based, protein structure guided drug discovery technology, and to a portfolio of preclinical oncology compounds focused on a number of kinase targets.

In June, we entered into a licensing and development agreement with TransPharma Medical Ltd. (TransPharma) to acquire rights to its product and related drug delivery system for the treatment of osteoporosis. The product, which is administered transdermally using TransPharma s proprietary technology, is currently in Phase II clinical testing.

In the second quarter, we entered into an agreement with an affiliate of TPG-Axon Capital (TPG) for the Phase III development of our two lead molecules for the treatment of Alzheimer s disease. This agreement provides TPG with success-based milestones and royalties in exchange for clinical trial funding.

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.

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 31,350 claims against us relating to the medication. Approximately 1,615 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. In October 2008, we announced that we are in advanced discussions to resolve the ongoing investigations led by the EDPA, and we recorded a charge of $1.42 billion. The charge reflects our currently estimable exposure with respect to these matters. If the ongoing discussions are successfully concluded, we expect that they would settle the Zyprexa-related federal claims, as well as similar Medicaid-related claims of states participating in the settlement.

Beginning in August 2006, we received civil investigative demands or subpoenas from the attorneys general of a number of states under various state consumer protection laws seeking Zyprexa documents. In October 2008, we reached a settlement with 32 states and the District of Columbia. While there is no finding that we have violated any provision of the state laws under which the investigations were conducted, we will pay $62.0 million and undertake certain commitments regarding Zyprexa for a period of six years, through consent decrees filed in the settling states.

In the third quarter of 2008, we initiated a strategic review of our Tippecanoe Labs facility in Lafayette, Indiana. Options being considered for this site include continuing operations with a revised site mission, exploring opportunities to sell the facility, and ceasing operations altogether. The review is expected to last six to twelve months. No final decisions have been made at this time; however, depending on the decision, we could record significant charges.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), continues to 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

Third-quarter and first-nine-months 2008 sales growth of 14 percent and 13 percent, respectively, was driven primarily by the collective growth of Cymbalta, Alimta, Cialis, Humalog, and Gemzar, and by the favorable impact of foreign exchange rates. Sales in the U.S. increased by $291.9 million, or 12 percent, and $704.4 million, or 10 percent, for the third quarter and first nine months of 2008, respectively, compared with the same periods of 2007. Sales outside the U.S. increased $330.9 million, or 16 percent, and $1.02 billion, or 17 percent, for the third quarter and first nine months of 2008, respectively. For the third quarter of 2008, worldwide sales volume, exchange rates, and selling prices contributed 6 percent, 4 percent, and 3 percent, respectively, to worldwide sales growth (numbers do not add due to rounding). For the first nine months of 2008,

worldwide sales volume, exchange rates, and selling prices contributed 6 percent, 5 percent, and 2 percent, respectively, to worldwide sales growth.

The following tables summarize our net sales activity for the three- and nine-month periods ended September 30, 2008 and 2007:

Product	Three Months Ended September 30, 2008 U.S.[1]	Outside U.S.	Total	Three Months Ended September 30, 2007 Total	Percent Change From 2007
			(Dollars in millions)		
Zyprexa	$ 555.6	$ 633.9	$1,189.5	$ 1,166.1	2
Cymbalta	597.1	119.3	716.4	513.2	40
Gemzar	189.2	251.0	440.2	394.4	12
Humalog	245.1	187.5	432.6	362.5	19
Cialis	139.8	236.8	376.6	311.4	21
Alimta	149.3	164.6	313.9	215.0	46
Animal health products	127.9	149.2	277.1	236.6	17
Humulin	95.1	176.5	271.6	243.3	12
Evista	170.8	94.9	265.7	263.2	1
Forteo	117.0	75.7	192.7	180.5	7
Strattera	109.5	40.0	149.5	130.5	15
Other pharmaceutical products	272.6	311.1	583.7	570.1	2
Total net sales	$2,769.0	$2,440.5	$5,209.5	$ 4,586.8	14

Product	Nine Months Ended September 30, 2008 U.S.[1]	Outside U.S.	Total	Nine Months Ended September 30, 2007 Total	Percent Change From 2007
			(Dollars in millions)		
Zyprexa	$ 1,618.5	$ 1,931.0	$ 3,549.5	$ 3,487.1	2
Cymbalta	1,651.1	324.8	1,975.9	1,474.6	34
Gemzar	548.3	758.2	1,306.5	1,166.9	12
Humalog	733.2	544.6	1,277.8	1,060.4	21
Cialis[2]	391.2	684.5	1,075.7	797.6	35
Alimta	400.8	435.2	836.0	610.0	37
Evista	520.4	286.2	806.6	805.0	
Humulin	279.8	521.0	800.8	711.9	12
Animal health products	352.3	414.6	766.9	666.5	15
Forteo	364.7	219.6	584.3	511.1	14
Strattera	326.4	106.3	432.7	412.6	5

Other pharmaceutical products	809.5	945.3	1,754.8	1,740.2	
Total net sales	$ 7,996.2	$ 7,171.3	$ 15,167.5	$ 13,443.9	13

[1] U.S. sales include sales in Puerto Rico.

[2] Prior to the acquisition of ICOS in January 2007, the Cialis sales shown in the table above represent results only in the territories in which we marketed Cialis exclusively. The remaining sales for that one-month period 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 in our consolidated condensed income statement. Cialis sales for the first nine months of 2008 represent 24 percent

growth over total worldwide sales of $870.3 million for the first nine months of 2007, which includes the joint-venture territory sales.

Product Highlights

Zyprexa, our top-selling product, is a treatment for schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and bipolar maintenance. In the third quarter of 2008, Zyprexa sales in the U.S. increased 3 percent compared with the third quarter of 2007, driven by increased net effective selling prices, offset partially by decreased demand. In the first nine months of 2008, U.S. Zyprexa sales decreased 1 percent compared with the same period of 2007 driven by decreased demand, offset partially by increased prices. Sales outside the U.S. increased 1 percent and 4 percent during the third quarter and first nine months of 2008, respectively, driven by the favorable impact of foreign exchange rates, offset by decreased demand and decreased prices. Demand outside the U.S. was unfavorably impacted by generic competition in Canada and Germany, offset by 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, generalized anxiety disorder, and fibromyalgia, increased 34 percent and 28 percent during the third quarter and first nine months of 2008, respectively, driven primarily by increased demand and, to a lesser extent, increased prices. Sales outside the U.S. increased 73 percent and 74 percent, respectively, driven primarily by increased demand and, to a lesser extent, the favorable impact of foreign exchange rates. Increased demand outside the U.S. reflects both increased demand in established markets, as well as recent launches in new markets.

U.S. sales of Gemzar, a product approved to fight various cancers, increased 14 percent and 11 percent during the third quarter and first nine months of 2008, respectively, driven by increased demand and increased prices. Sales outside the U.S. increased 10 percent and 13 percent, respectively, driven primarily by the favorable impact of foreign exchange rates.

U.S. sales of Humalog, our injectable human insulin analog for the treatment of diabetes, increased 13 percent and 15 percent for the third quarter and first nine months of 2008, respectively, driven by increased demand and, to a lesser extent, increased net effective selling prices. Sales outside the U.S. increased 28 percent and 29 percent during both periods, respectively, driven by increased demand and the favorable impact of exchange rates.

Total worldwide sales of Cialis, a treatment for erectile dysfunction, increased 21 percent and 24 percent during the third quarter and first nine months of 2008, respectively. This comparison includes $72.7 million of sales in the Lilly ICOS joint-venture territories for the one-month period prior to the acquisition of ICOS in January 2007. Prior to the ICOS acquisition, Cialis sales in our territories were reported in revenue, while our 50 percent share of the joint-venture net income was reported in other income net. Total U.S. sales increased 20 percent during the third quarter of 2008, driven by increased prices and, to a lesser extent, increased demand. For the first nine months of 2008, U.S. sales increased 20 percent, driven by increased demand and, to a lesser extent, increased prices. Total sales outside the U.S. increased 22 percent during the third quarter of 2008, driven primarily by the favorable impact of foreign exchange rates and increased demand. For the first nine months of 2008, sales outside the U.S. increased 26 percent, driven primarily by increased demand and the favorable impact of foreign exchange rates.

U.S. sales of Alimta, a treatment for various cancers, increased 35 percent and 24 percent during the third quarter and first nine months of 2008, respectively, driven by increased demand. Alimta

sales outside the U.S. increased 58 percent and 51 percent during the same periods, driven by increased demand and, to a lesser extent, 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, increased 1 percent and remained essentially flat during the third quarter and first nine months of 2008, respectively, driven by increased prices, partially offset by decreased demand. Evista sales outside the U.S. increased 1 percent for the third quarter of 2008, driven by the favorable impact of foreign exchange rates and increased prices, offset by decreased volume. Sales outside the U.S. for the first nine months of 2008 remained essentially flat due to the favorable impact of foreign exchange rates, offset by decreased demand and decreased prices.

U.S. sales of Humulin, an injectable human insulin for the treatment of diabetes, increased by 5 percent and 6 percent, during the third quarter and first nine months of 2008, respectively, driven primarily by higher net effective selling prices. Humulin sales outside the U.S. increased 16 percent for both periods, driven by the favorable impact of exchange rates and increased demand.

U.S. sales of Forteo, an injectable treatment for osteoporosis in postmenopausal women and men at high risk for fracture, decreased 6 percent during the third quarter of 2008, driven by changes in wholesaler buying patterns, offset partially by higher net effective selling prices. For the first nine months of 2008, sales increased 3 percent due to increased prices, offset partially by decreased demand. Forteo sales outside the U.S. grew 36 percent and 41 percent during the same periods, respectively, driven by increased demand and the favorable impact of foreign exchange rates.

U.S. sales of Strattera, a treatment for attention-deficit hyperactivity disorder in children, adolescents, and adults, increased 6 percent during the third quarter of 2008 driven primarily by increased prices. For the first nine months of 2008, sales decreased 4 percent driven by decreased demand, offset partially by increased prices. Strattera sales outside the U.S. increased 49 percent and 43 percent during the same periods, respectively, driven by increased demand and the favorable impact of foreign exchange rates, and for the third quarter of 2008, increased net effective selling prices.

Worldwide sales of Byetta, an injectable product for the treatment of type 2 diabetes, which we market with Amylin Pharmaceuticals (Amylin), increased 22 percent to $201.2 million and 21 percent to $564.9 million, for the third quarter and first nine months of 2008, respectively. 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 25 percent and 23 percent to $109.2 million and $293.1 million during the third quarter and first nine months of 2008, respectively.

Animal health product sales in the U.S. increased 14 percent and 17 percent during the third quarter and first nine months of 2008, respectively, driven by increased demand and the 2007 launch of Comfortis™, a new companion animal product that kills fleas and prevents flea infestations on dogs, and for the first nine months of 2008, the impact of the 2007 acquisition of Ivy Animal Health, Inc. Sales outside the U.S increased 20 percent and 14 percent, compared to the same periods in 2007, driven primarily by increased demand and the favorable impact of foreign exchange rates.

Gross Margin, Costs, and Expenses

For the third quarter of 2008, gross margins as a percent of net sales increased by .8 percentage points, to 77.8 percent, driven by higher product prices and manufacturing expenses growing at a slower rate than sales. For the first nine months of 2008, gross margins as a percentage of net sales decreased by .8 percentage points, to 77.1 percent. This decrease was primarily due to the impact of foreign exchange rates and the inclusion in cost of sales of asset impairments at certain manufacturing facilities of $57.1 million, partially offset by manufacturing expenses growing at a slower rate than sales.

Marketing, selling, and administrative expenses rose 12 percent, to $1.65 billion, and 13 percent, to $4.90 billion, for the third quarter and first nine months of 2008, respectively. This increase was due to increased marketing and sales force expenses, including prelaunch expenses for prasugrel and marketing costs associated with Cymbalta and Evista, the impact of foreign exchange rates, and increased litigation-related expenses. Research and development expenses were $953.0 million and $2.78 billion for the third quarter and first nine months of 2008, respectively, or 18 percent of sales. Compared with the third quarter and first nine months of 2007, research and development expenses increased 13 percent and 10 percent, respectively. This increase was primarily due to increased discovery research and late-stage clinical trial costs, and for the first nine months of 2008, to a $47.0 million expense for a milestone payment made to MacroGenics, Inc. related to progress in the clinical trials of teplizumab, offset by lower prasugrel clinical trial costs. The increase in research and development expenses for the first nine months of 2008 was also offset by the first-quarter 2007 costs associated with the consequences of the FDA s rejection of our appeal of the approvable letter for Arxxant™ and the withdrawal of the Arxxant application in Europe.

Acquired IPR&D charges were $28.0 million and $150.0 million in the third quarter and first nine months of 2008, respectively, compared with no charges for the third quarter of 2007 and $656.6 million for the first nine months of 2007, respectively. We recognized asset impairments, restructuring, and other special charges of $1.66 and $1.89 billion in the third quarter of 2008 and first nine months of 2008, respectively, as compared to $81.3 million and $204.3 million in the third quarter and first nine months of 2007, respectively. See Notes 3, 4, and 11 to the consolidated condensed financial statements for additional information.

Other income net decreased by $47.3 million, to $2.5 million, and by $34.8 million, to $55.1 million, for the third quarter and first nine months of 2008, respectively. Other income net consists of interest expense, interest income, the after-tax operating results of the Lilly ICOS joint venture prior to the 2007 ICOS acquisition, and all other miscellaneous income and expense items.

Interest expense for the third quarter and first nine months of 2008 decreased $11.8 million and $21.5 million, respectively, to $44.0 million and $146.4 million, respectively, driven by lower debt balances and lower interest rates in 2008 as compared with the same periods of 2007, offset partially by lower capitalized interest due to lower construction-in-progress balances.

Interest income for the third quarter of 2008 increased $3.6 million to $53.2 million, driven primarily by higher average cash balances in the third quarter of 2008 as compared to the same period in 2007, offset by lower short-term interest rates. Interest income for the first nine months of 2008 decreased $.2 million to $156.8 million, driven by lower interest rates in 2008, offset by higher cash balances in 2008.

The Lilly ICOS joint venture income prior to the 2007 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 (loss) items for the third quarter and first nine months of 2008 decreased $62.7 million, to a loss of $6.7 million, and $45.1 million, to $44.7 million, respectively, driven by lower out-licensing income and the $10.9 million write-down of certain investment securities in the third quarter of 2008, offset partially by the gains on the sale of investment securities.

We recorded income tax expense of $232.8 million for the third quarter of 2008 despite a net loss before income taxes, due to the uncertainty of the tax treatment of the Zyprexa charges. We recorded income tax expense of $472.3 million, an effective tax rate of 23.3 percent, for the first nine months of 2008, down from 25.7 percent for the first nine months of 2007. In the first quarter of 2008, we recognized a discrete income tax 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. This item reduced the effective tax rate for the first nine months of 2008. Furthermore, the in-process research and development charges in 2007 associated with the

acquisitions of ICOS and Hypnion were not deductible, resulting in higher effective tax rates for 2007.

FINANCIAL CONDITION

As of September 30, 2008, cash, cash equivalents, and short-term investments totaled $6.12 billion compared with $4.83 billion at December 31, 2007. Cash flows from operations of $4.92 billion during the first nine months of 2008 were offset by dividends paid of $1.54 billion, net purchases of property and equipment of $671.5 million, and net purchases of noncurrent investments of $641.9 million.

Total debt at September 30, 2008, was $4.61 billion, a decrease of $395.1 million from December 31, 2007. Subsequent to the announcement of the proposed acquisition of ImClone, Standard & Poor s affirmed our AA/A+ long-term rating and our A-1 short-term rating. Moody s Investors Service placed our Aa3 long-term rating under review for possible downgrade, but affirmed our Prime-1 short-term rating.

We believe that cash generated from operations, along with available cash and cash equivalents, will be sufficient to fund our normal operating needs, including debt service, capital expenditures, costs associated with litigation and government investigations, dividends, and taxes in 2008. We approved a definitive merger agreement under which we will acquire ImClone through an all-cash tender offer of $70 per share, or approximately $6.5 billion. We intend to fund the acquisition, as well as any payments required in connection with the EDPA investigation, with cash and cash equivalents on hand and short-term borrowings through the issuance of commercial paper. We have $1.25 billion of unused committed bank credit facilities, $1.2 billion of which backs our commercial paper program. Additionally, we have obtained commitments to provide a short-term revolving credit facility in the amount of $4.0 billion as back-up, alternative financing. Our access to credit markets has not been adversely affected by the recent illiquidity in the market due to the high credit quality of our short- and long-term debt; however, long-term borrowing costs have increased. 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):

Cymbalta: We have received notice that at least four generic drug manufacturers have submitted Abbreviated New Drug Applications (ANDAs) seeking permission to market generic versions of Cymbalta prior to the expiration of our relevant U.S. patents (the earliest of which expires in 2013) and alleging that these patents are either invalid or not infringed. We are currently reviewing the allegations and will take appropriate action to seek rulings that the patents are valid and infringed.

Gemzar: Sicor Pharmaceuticals, Inc. (Sicor), Mayne Pharma (USA) Inc. (Mayne), and Sun

Pharmaceutical Industries Inc. (Sun) each submitted an Abbreviated New Drug Application (ANDA) seeking permission to market generic versions of Gemzar prior to the expiration of our relevant U.S. patents (compound patent expiring in 2010 and method of use patent expiring in 2013), and alleging that these patents are invalid. We filed lawsuits in the U.S. District Court for the Southern District of Indiana against Sicor (February 2006) and Mayne (October 2006 and January 2008), seeking rulings that these patents are valid and are being infringed. The suit against Sicor has been scheduled for trial in July 2009. The statutory stay barring final approval of Sicor s ANDAs has expired; however, Sicor must provide 90 days notice prior to marketing generic Gemzar upon receipt of final approval by the FDA to allow time for us to seek a preliminary injunction. Both suits against Mayne have been administratively closed, and the parties have agreed to be bound by the results of the Sicor suit. In November 2007, Sun filed a declaratory judgment action in the United States District Court for the Eastern District of Michigan, seeking rulings that our method-of-use and compound patents are invalid or unenforceable, or would not be infringed by the sale of Sun s generic product. This trial is scheduled for December 2009.

Alimta: Teva Parenteral Medicines, Inc. (Teva) and APP Pharmaceuticals, LLC (APP) each submitted ANDAs seeking approval to market generic versions of Alimta prior to the expiration of the relevant U.S. patent (licensed from the Trustees of Princeton University and expiring in 2016), and alleging the patent is invalid. We, along with Princeton, filed lawsuits in the U.S. District Court for the District of Delaware against Teva and APP, seeking rulings that the compound patent is valid and infringed. The court has not set a date for trial in either case.

Evista: Barr Laboratories, Inc. (Barr), submitted an ANDA in 2002 seeking permission to market a generic version of Evista prior to the expiration of our relevant U.S. patents (expiring in 2012-2017) and alleging that these patents are invalid, not enforceable, or not infringed. In November 2002, we filed a lawsuit against Barr in the U.S. District Court for the Southern District of Indiana, seeking a ruling that these patents are valid, enforceable, and being infringed by Barr. 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 a statutory stay that expires on March 9, 2009.

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. In June 2008, Glenmark agreed to entry of a permanent injunction, enjoining it from selling a generic product prior to the expiration of the U.S. patent. Also in June 2008, Synthon notified us that it has withdrawn its ANDA and agreed to a stipulated dismissal of all outstanding claims. For the remaining defendants, trial is anticipated as early as December 2009.

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

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

In Canada, several generic pharmaceutical manufacturers have challenged the validity of our Zyprexa compound and method-of-use patent (expiring in 2011). In April 2007, the Canadian Federal Court ruled against the first challenger, Apotex Inc. (Apotex), and that ruling was affirmed on appeal in February 2008. In June 2007, the Canadian Federal Court held that an invalidity allegation of a second challenger, Novopharm Ltd. (Novopharm), was justified and denied our request that Novopharm be prohibited from receiving marketing approval for generic olanzapine in Canada. Novopharm began selling generic olanzapine in Canada in the third quarter of 2007. We 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. We have brought similar actions against Pharmascience (August 2007), Sandoz (July 2007), Nu-Pharm (June 2008), and Genpharm (June 2008); none of these suits has been scheduled for trial. Pharmascience has agreed to be bound by the outcome of the Novopharm suit, and, pending the outcome of the lawsuit, we have agreed not to take any further steps to prevent them from coming to market with generic olanzapine tablets, subject to a contingent damages obligation should we be successful against Novopharm.

In Germany, generic pharmaceutical manufacturers Egis-Gyogyszergyar and Neolab Ltd. challenged the validity of our Zyprexa compound and method-of-use patent (expiring in 2011). In June 2007, the German Federal Patent Court held that our patent is invalid. We are appealing the decision to the German Supreme Court, which has scheduled a hearing for December 2008. Generic olanzapine was launched by competitors in Germany in the fourth quarter of 2007. Notwithstanding the Federal Patent Court ruling, we have sought preliminary injunctions against all generic companies who are marketing generic olanzapine products in Germany. In May 2008 the Court of Appeal in Düsseldorf granted an injunction against the first of these generic companies, STADApharm GmbH, as a result of which STADA has had to withdraw its generic olanzapine product from the German market. Preliminary injunction actions against other generic companies in Germany were denied. We continue to pursue these companies in main actions for infringement.

We have received challenges in a number of other countries, including Spain, the United Kingdom (UK), 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 UK, the generic pharmaceutical manufacturer Dr. Reddy s Laboratories (UK) Limited has challenged the validity of our Zyprexa compound and method-of-use patent (expiring in 2011). In October, 2008, the Patents Court in the High Court, London ruled that our patent was valid. We anticipate that Dr. Reddy s will appeal this decision.

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. In addition, the State Medicaid Fraud Control Units of more than 30 states are coordinating with the EDPA in its investigation of any Medicaid-related claims relating to our marketing and promotion of Zyprexa. Twelve other states (Arkansas, Connecticut, Idaho, Louisiana, Minnesota, Mississippi, Montana, New Mexico, Pennsylvania, South Carolina, Utah, and West Virginia) have filed lawsuits over Zyprexa and are not participating in the coordinated investigation. In October 2008, we announced that we are in advanced discussions to resolve the ongoing investigations led by the EDPA, and we recorded a charge of $1.42 billion. The charge reflects our currently estimable exposure with respect to these matters. If the ongoing discussions are successfully concluded, we expect that they would settle the Zyprexa-related federal claims, as well as similar Medicaid-related claims of states participating in the settlement.

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 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 became part of a multistate investigative effort coordinated by an executive committee of attorneys general. In October 2008, we reached a settlement with 32 states and the District of Columbia. While there is no finding that we have violated any provision of the state laws under which the investigations were conducted, we will pay $62 million and undertake certain commitments regarding Zyprexa for a period of six years, through consent decrees filed in the settling states. The 32 states participating in the Multistate agreement are: Alabama, Arizona, California, Delaware, Florida, Hawaii, Illinois, Indiana, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Missouri, Nebraska, Nevada, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Vermont, Washington, and Wisconsin.

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. Except to the extent described above, 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 31,350 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 180 lawsuits in the U.S. covering approximately 1,615 plaintiffs, of which about 130 cases covering about 305 plaintiffs are part of the MDL. The MDL cases have been scheduled for trial in groups, with the earliest trial scheduled to begin March 16, 2009.

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

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

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

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

In December 2004, we were served with two lawsuits brought in state court in Louisiana on behalf of the Louisiana Department of Health and Hospitals, alleging that Zyprexa caused or contributed to diabetes or high blood-glucose levels, and that we improperly promoted the drug. These cases have been removed to federal court and are now part of the MDL proceedings in the Eastern District of New York (EDNY). In these actions, the Department of Health and Hospitals seeks to recover the costs it paid for Zyprexa through Medicaid and other drug-benefit programs, as well as the costs the department alleges it has incurred and will incur to treat Zyprexa-related illnesses. We have been served with similar lawsuits filed by the states of Alaska, Arkansas, Connecticut, Idaho, Minnesota, Mississippi, Montana, New Mexico, Pennsylvania, South Carolina, Utah, and West Virginia in the courts of the respective states. The Connecticut, Louisiana, Minnesota, Mississippi, Montana, New Mexico, and West Virginia cases are part of the MDL proceedings in the EDNY. The Alaska case was settled in March 2008 for a payment of $15.0 million, plus terms designed to ensure, subject to certain limitations and conditions, that Alaska is treated as favorably as certain other states that may settle with us in the future over similar claims. The following cases have been set for trial in 2009: Connecticut in the EDNY in June, Pennsylvania in November, and South Carolina in August, in their respective states.

In 2005, two lawsuits were filed in the EDNY purporting to be nationwide class actions on behalf of all consumers and third-party payors, excluding governmental entities, which have made or will make payments for their members or insured patients being prescribed Zyprexa. These actions have now been consolidated into a single lawsuit, which is brought under certain state consumer protection statutes, the federal civil RICO statute, and common law theories, seeking a refund of the cost of Zyprexa, treble damages, punitive damages, and attorneys fees. Two additional lawsuits were filed in the EDNY in 2006 on similar grounds. In September 2008, Judge Weinstein certified a class consisting of third-party payors, excluding governmental entities and individual consumers. We appealed the certification order, and Judge Weinstein s order denying our motion for summary judgment, in September 2008. In 2007, The Pennsylvania Employees Trust Fund brought claims in state court in Pennsylvania as insurer of Pennsylvania state employees, who were prescribed Zyprexa on similar grounds as described in the New York cases. As with the product liability suits, these lawsuits allege that we inadequately tested for and warned about side effects of Zyprexa and improperly promoted the drug. The Pennsylvania case is set for trial in October 2009.

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

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

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

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

FINANCIAL EXPECTATIONS FOR 2008

Our full-year 2008 earnings guidance on a GAAP basis is now $2.44 to $2.49 per share. The change from earlier guidance of $3.79 to $3.94 per share results from the previously mentioned third-quarter 2008 significant items totaling $1.47 per share that are reflected in our financial results, as well as from improved financial performance. Our full-year 2008 guidance does not reflect any impact related to the proposed acquisition of ImClone Systems, Inc., including any potential charges associated with the purchase.

We have also revised other aspects of our previously-issued 2008 full-year financial guidance. Specifically, guidance for gross margin as a percent of sales, other income and deductions, and the effective tax rate has been revised. All other line-item guidance remains unchanged. Sales are still expected to grow in the high-single to low-double digits. As a result of the weakening of foreign currencies, we now expect significant improvement in gross margin as a percent of sales, an increase from prior guidance that gross margin would remain essentially flat. The sum of marketing, selling, and administrative expenses and research and development expenses is still expected to grow in the high-single digits. Marketing, selling, and administrative expenses are still expected to grow in the high-single digits, and research and development expenses are still expected to grow in the high-single to low-double digits. Other income and deductions are now expected to contribute approximately $50 million, a reduction from our previous guidance of less than $100 million. As a result of the Zyprexa charges, the effective tax rate is now expected to be approximately 23 percent.

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/A, 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, Ph.D., president and chief executive officer, and Derica W. Rice, senior vice president and chief financial officer, evaluated our disclosure controls and procedures as of September 30, 2008, and concluded that they are effective.

(b) *Changes in Internal Controls.* During the third 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 matters involving Cymbalta, Gemzar, Alimta, Evista, Strattera, and Xigris

The patent litigation outside the U.S. involving Zyprexa

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

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

That information is incorporated into this Item by reference.

Other Product Liability Litigation

We refer to Part I, Item 3, of our Form 10-K/A 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 70 suits involving approximately 125 claimants. In the thimerosal litigation, we have been named as a defendant in approximately 210 suits with approximately 280 claimants.

Employee Litigation

In April 2006, three former employees and one current employee filed a putative class action against the company in the U.S. District Court for the Southern District of Indiana (*Welch, et al. v. Eli Lilly and Company*, filed April 20, 2006) alleging racial discrimination. Plaintiffs have since amended their complaint twice, adding to the lawsuit a total of 154 individual plaintiffs as well as the national and local chapters of the National Association for the Advancement of Colored People (NAACP). Under the current schedule, the plaintiffs are to file their class certification motion in March 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. As of the close of the opt-in period, fewer than 400 of the over 7,500 potential plaintiffs elected to participate in the lawsuit. We believe this lawsuit is without merit and are prepared to defend against it vigorously.

ImClone Shareholder Litigation

In October 2008, a class action complaint was filed in the Supreme Court of the State of New York, purportedly on behalf of all shareholders of ImClone Systems, Inc. (ImClone), against us, ImClone, and the members of its board of directors. The complaint alleges, among other things, that the members of ImClone s board of directors breached their fiduciary duties to ImClone s shareholders in connection with the transactions contemplated by the merger agreement and failed to provide ImClone s shareholders with material information to make an informed decision as to whether to tender their shares in the offer. In addition, the complaint alleges that Lilly knowingly aided and abetted the alleged wrongdoing of ImClone s board of directors. The complaint seeks, among other relief, injunctive relief preliminarily and permanently enjoining the defendants from proceeding with the offer; a judgment enjoining the defendants from consummating the offer and the merger until certain additional information is provided; and an award to plaintiffs of the costs of the action, including reasonable attorneys and experts fees. We believe that the complaint is without merit and intend to vigorously defend the action.

Other Matters

During 2004 we, along with several other pharmaceutical companies, were named in one consolidated case in California state court brought on behalf of consumers alleging that the conduct of pharmaceutical companies in preventing commercial importation of prescription drugs from outside the United States violated antitrust laws. The case sought restitution for alleged overpayments for pharmaceuticals and an injunction against the allegedly violative conduct. Summary judgment was granted to us and the other defendants. In July 2008, the California Court of Appeals affirmed that decision. Plaintiffs have petitioned the California Supreme Court to accept a further appeal.

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 September 30, 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)
July 2008				$ 419.2
August 2008				419.2
September 2008				419.2
Total				

The amounts presented in columns (a) and (b) above represent purchases of common stock related to our stock-based compensation programs. The amounts presented in columns (c) and (d) in the above table represent activity related to our $3.0 billion share repurchase program announced in March 2000. As of September 30, 2008, we have purchased $2.58 billion related to this program. During the first nine months 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 6. Exhibits

The following documents are filed as exhibits to this Report:

EXHIBIT 10.1	2002 Lilly Stock Plan, as amended effective January 1, 2009
EXHIBIT 10.2	Lilly Directors Deferral Plan, as amended effective October 20, 2008
EXHIBIT 10.3	The Lilly Deferred Compensation Plan, as amended effective January 1, 2009
EXHIBIT 10.4	2007 Change In Control Severance Pay Plan for Select Employees, as amended effective January 1, 2009
EXHIBIT 10.5	2007 Change In Control Severance Pay Plan for Select Employees, as amended effective October 20, 2010
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, Ph.D., 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

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 November 3, 2008	s/ James B. Lootens James B. Lootens Secretary and Deputy General Counsel
Date November 3, 2008	s/ Arnold C. Hanish Arnold C. Hanish Executive Director, Finance, and Chief Accounting Officer

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