SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

Quarterly Report Under Section 13 or 15(d) of the Securities Exchange Act of 1934

FOR THE QUARTER ENDED MARCH 31, 2005

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 ☑ No o

Indicate by check mark whether the Registrant is an accelerated filer as defined in Exchange Act Rule 12b-2.

Yes ☑ No o

The number of shares of common stock outstanding as of April 20, 2005:

Class	Number of Shares Outstanding
Common	1,133,093,133

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

CONSOLIDATED CONDENSED STATEMENTS OF INCOME
(Unaudited)
ELI LILLY AND COMPANY AND SUBSIDIARIES

	Three Months Ended March 31,	
	2005	2004
	(Dollars in millions except per-share data)	
Net sales	$3,497.4	$3,376.9
Cost of sales	859.0	751.7
Research and development	702.2	646.6
Marketing and administrative	1,090.4	1,063.9
Acquired in-process research and development	—	362.3
Interest expense	24.6	9.3
Other income – net	(123.2)	(72.4)
	2,553.0	2,761.4
Income before income taxes	944.4	615.5
Income taxes	207.8	215.1
Net income	$ 736.6	$ 400.4
Earnings per share – basic	$ .68	$ .37
Earnings per share – diluted	$ .68	$ .37
Dividends paid per share	$ .38	$ .355

See Notes to Consolidated Condensed Financial Statements.

CONSOLIDATED CONDENSED BALANCE SHEETS
ELI LILLY AND COMPANY AND SUBSIDIARIES

	March 31, 2005 (Unaudited)	December 31, 2004
	(Dollars in millions)	
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 5,607.7	$ 5,365.3
Short-term investments	12.6	2,099.1
Accounts receivable, net of allowances of $66.0 (2005) and $66.1 (2004)	2,112.4	2,058.7
Other receivables	469.4	494.3
Inventories	2,198.3	2,291.6
Deferred income taxes	501.9	255.3
Prepaid expenses	355.0	271.5
TOTAL CURRENT ASSETS	11,257.3	12,835.8
OTHER ASSETS		
Prepaid pension	2,233.0	2,253.8
Investments	500.6	561.4
Sundry	1,666.9	1,665.1
	4,400.5	4,480.3
PROPERTY AND EQUIPMENT		
Land, buildings, equipment, and construction-in-progress	12,511.9	12,338.9
Less allowances for depreciation	(4,930.0)	(4,788.0)
	7,581.9	7,550.9
	$ 23,239.7	$ 24,867.0
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Short-term borrowings	$ 233.1	$ 2,020.6
Accounts payable	670.5	648.6
Employee compensation	365.9	471.6
Dividends payable	—	414.4
Income taxes payable	2,099.5	1,703.9
Other current liabilities	2,012.7	2,334.6
TOTAL CURRENT LIABILITIES	5,381.7	7,593.7
LONG-TERM DEBT	4,357.0	4,491.9
DEFERRED INCOME TAXES	698.1	620.4
OTHER NONCURRENT LIABILITIES	1,205.1	1,241.1
SHAREHOLDERS' EQUITY		
Common stock	708.6	708.0
Additional paid-in capital	3,227.9	3,119.4
Retained earnings	10,462.4	9,724.6
Employee benefit trust	(2,635.0)	(2,635.0)
Deferred costs-ESOP	(110.6)	(111.9)
Accumulated other comprehensive income	47.6	218.6
	11,700.9	11,023.7
Less cost of common stock in treasury	103.1	103.8
	11,597.8	10,919.9
	$ 23,239.7	$ 24,867.0

See Notes to Consolidated Condensed Financial Statements.

CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES

	Three Months Ended March 31,	
	2005	2004
	(Dollars in millions)	
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income	$ 736.6	$ 400.4
Adjustments to reconcile net income to cash flows from operating activities:		
Changes in operating assets and liabilities	.3	(438.0)
Depreciation and amortization	158.7	147.6
Stock-based compensation expense	108.2	25.2
Change in deferred taxes	(221.8)	13.2
Acquired in-process research and development	—	362.3
Other, net	22.8	66.3
NET CASH PROVIDED BY OPERATING ACTIVITIES	804.8	577.0
CASH FLOWS FROM INVESTING ACTIVITIES		
Net purchases of property and equipment	(242.2)	(463.6)
Net change in short-term investments	2,085.6	(88.5)
Purchase of noncurrent investments	(139.8)	(1,342.2)
Proceeds from sales and maturities of noncurrent investments	187.5	1,018.1
Cash paid for acquisition of Applied Molecular Evolution, net of cash acquired	—	(71.7)
Other, net	(67.6)	1.7
NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES	1,823.5	(946.2)
CASH FLOWS FROM FINANCING ACTIVITIES		
Dividends paid	(413.2)	(384.3)
Issuances of common stock under stock plans	12.5	46.5
Net change in short-term borrowings	(1,885.3)	358.6
Other, net	.9	(2.3)
NET CASH (USED IN) PROVIDED BY FINANCING ACTIVITIES	(2,285.1)	18.5
Effect of exchange rate changes on cash and cash equivalents	(100.8)	4.8
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	242.4	(345.9)
Cash and cash equivalents at January 1	5,365.3	2,756.3
CASH AND CASH EQUIVALENTS AT MARCH 31	$ 5,607.7	$ 2,410.4

See Notes to Consolidated Condensed Financial Statements.

CONSOLIDATED CONDENSED STATEMENTS OF COMPREHENSIVE INCOME
(Unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES

	Three Months Ended March 31,	
	2005	2004
	(Dollars in millions)	
Net income	$ 736.6	$ 400.4
Other comprehensive loss[1]	(171.0)	(24.8)
Comprehensive income	$ 565.6	$ 375.6

1 The significant components of other comprehensive loss were a loss of $138.5 million from foreign currency translation adjustments and net unrealized losses on securities of $22.9 million for the three months ended March 31, 2005, compared with a loss of $39.9 million from cash flow hedges, partially offset by net unrealized gains on securities of $19.7 million for the three months ended March 31, 2004.

See Notes to Consolidated Condensed Financial Statements.

SEGMENT INFORMATION

We operate in one significant business segment – pharmaceutical products. Operations of our animal health business segment are not material and share many of the same economic and operating characteristics as our pharmaceutical products. Therefore, they are included with pharmaceutical products for purposes of segment reporting. Our business segments are distinguished by the ultimate end user of the product: humans or animals. Performance is evaluated based on profit or loss from operations before income taxes. Income before income taxes for the animal health business for the first quarters of 2005 and 2004 were $40.0 million and $53.5 million, respectively.

SALES BY PRODUCT CATEGORY

Worldwide sales by product category for the quarters of 2005 and 2004 were as follows:

	Three Months Ended March 31,	
	2005	2004
	(Dollars in millions)	
Net sales – to unaffiliated customers:		
Neurosciences	$1,427.8	$1,498.1
Endocrinology	1,144.8	1,057.5
Oncology	400.9	294.1
Animal health	195.5	182.4
Cardiovascular	168.1	165.8
Anti-infectives	109.2	125.1
Other pharmaceutical	51.1	53.9
Net sales	$3,497.4	$3,376.9

NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

BASIS OF PRESENTATION

We have prepared the accompanying unaudited consolidated condensed financial statements in accordance with the requirements of Form 10-Q and, therefore, they do not include all information and footnotes necessary for a fair presentation of financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States (GAAP). In our opinion, the financial statements reflect all adjustments (including those that are normal and recurring) that are necessary for a fair presentation of the results of operations for the periods shown. In preparing financial statements in conformity with GAAP, we must make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, and related disclosures at the date of the financial statements and during the reporting period. Actual results could differ from those estimates.

The information included in this Quarterly Report on Form 10-Q should be read in conjunction with our consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2004.

CONTINGENCIES

Three generic pharmaceutical manufacturers, Zenith Goldline Pharmaceuticals, Inc. (Zenith), Dr. Reddy's Laboratories, Ltd. (Reddy), and Teva Pharmaceuticals (Teva), have submitted abbreviated new drug applications (ANDAs) seeking permission to market generic versions of Zyprexa® in various dosage forms several years prior to the expiration of our U.S. patents for the product, alleging that our patents are invalid, unenforceable, or not infringed. We filed suit against the three companies in the U.S. District Court for the Southern District of Indiana, seeking a ruling that the challenges to our compound patent (expiring in 2011) are without merit. The cases have been consolidated. A trial before the district court judge was held in January and February of 2004. On April 14, 2005, the district court upheld our 2011 U.S. patent on Zyprexa. In the case of *Eli Lilly and Company v. Zenith Goldline Pharmaceuticals et al.*, the court ruled in our favor on all accounts, including the patent doctrines of obviousness, double patenting, inequitable conduct, novelty, and public use. We anticipate that appeals will follow. We are confident, and the trial court confirmed, that the generic manufacturers' claims are without merit and we expect to prevail in this litigation. However, it is not possible to predict or determine the outcome of this litigation and, accordingly, we can provide no assurance that we will prevail if the case is appealed. An unfavorable outcome would have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

In October 2002, we were notified that Barr Laboratories, Inc. (Barr), had submitted an ANDA with the FDA seeking permission to market a generic version of Evista® several years prior to the expiration of our U.S. patents covering the product, alleging that the patents are invalid or not infringed. In November 2002, we filed suit against Barr in the U.S. District Court for the Southern District of Indiana seeking a ruling that Barr's challenges to our patents claiming the methods of use and pharmaceutical form (expiring from 2012 to 2017) are without merit. Recently, Barr has also asserted that the method of use patents are unenforceable. On September 28, 2004, the U.S. Patent and Trademark Office issued to us a new patent (expiring in 2017) directed to pharmaceutical compositions containing raloxifene. Barr has challenged this patent, alleging that the patent is invalid, unenforceable, or will not be infringed. This patent has been added to the lawsuit. The suit is in discovery. The trial date previously scheduled for February 2006 has been postponed and no new date has been set at this time. While we believe that Barr's claims are without merit and we expect to prevail, it is not possible to predict or determine the outcome of the litigation. Therefore, we can provide no assurance that we will prevail. An unfavorable outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

In July 2002, we received a grand jury subpoena for documents from the Office of Consumer Litigation, U.S. Department of Justice, related to our marketing and promotional practices and physician communications with respect to Evista. We received subpoenas seeking additional documents in July 2003, July 2004, and August 2004. We continue to cooperate with the government and have provided a broad range of information concerning our U.S. marketing and promotional practices, including documents relating to communications with physicians and the remuneration of physician consultants and advisers. Based upon advanced discussions with the government to resolve this matter, we expensed $36.0 million during the fourth quarter of 2004, which we believe will be sufficient to resolve the matter. Those discussions are ongoing.

In March 2004, the office of the U.S. Attorney for the Eastern District of Pennsylvania advised us that it has commenced a civil investigation related to our U.S. marketing and promotional practices with respect to Zyprexa, Prozac®, and Prozac Weekly™. We are cooperating with the U.S. Attorney in this investigation and are providing a broad range of documents and information related to the investigation, including documents relating to communications with physicians and the remuneration of physician consultants and advisers. It is possible that other Lilly products could become subject to this investigation and that the outcome of

this matter could include criminal charges and fines and/or civil penalties. We cannot predict or determine the outcome of this matter 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, and remuneration of health care professionals comply with promotional laws and regulations.

We have been named in approximately 190 product liability cases in the United States involving approximately 540 claimants alleging a variety of injuries from the use of Zyprexa. Most of the cases allege that the product caused or contributed to diabetes or high blood-glucose levels. The lawsuits seek substantial compensatory and punitive damages and typically accuse us of inadequately testing for and warning about side effects of Zyprexa. Many of the lawsuits also allege that we improperly promoted the drug. We are vigorously defending these suits. Virtually all the federal cases, involving approximately 450 claimants, have been or will be transferred to The Honorable Jack Weinstein in the Federal District Court for the Eastern District of New York for consolidated and coordinated pretrial proceedings. Two cases requesting certification of nationwide class actions on behalf of those who allegedly suffered injuries from the administration of Zyprexa were filed in the Federal District Court for the Eastern District of New York on April 16, 2004, and May 19, 2004, respectively. The cases seek damages for alleged personal injuries and also seek compensation for medical monitoring of individuals who have taken Zyprexa. A lawsuit was also filed that requests a class action on behalf of Iowa residents who took Zyprexa, and that case has been transferred to the federal court in New York. In addition, we have entered into agreements with various plaintiffs' counsel halting the running of the statutes of limitation (tolling agreements) with respect to more than 3,800 individuals who do not have lawsuits on file and may or may not eventually file suits. This provides counsel additional time to evaluate the potential claims. In exchange, the individuals have agreed not to file suits in state courts, and the Plaintiffs Steering Committee agreed to dismiss the personal injury claims in the two pending nationwide class actions. The class action claims seeking medical monitoring for Zyprexa patients are not affected by this agreement.

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. In these actions, which we have removed to federal court, the Department of Health and Hospitals seeks to recover the costs it paid for Zyprexa through Medicaid and other drug benefit programs and the costs the department alleges it has incurred and will incur to treat Zyprexa-related illnesses.

In early 2005, we were served with five lawsuits seeking class action status in Canada on behalf of patients who took Zyprexa. The allegations in these suits are similar to those in the litigation pending in the United States.

In connection with the Zyprexa product liability claims, certain of our insurance carriers have identified potential defenses to their liability under the policies and to date have failed to reimburse us for claim-related costs despite demand of the first-layer carriers for payment. However, in our opinion, the potential defenses identified to date appear to lack substance, and we believe the carriers will ultimately honor their obligations under the policies either voluntarily or after litigation and/or arbitration. In March 2005, we filed suit against several of the carriers in state court in Indiana to obtain reimbursement of costs related to the Zyprexa product liability litigation, which litigation was recently removed to federal court. While we believe our position is meritorious, there can be no assurance that we will prevail.

The number of product liability lawsuits and tolled claims relating to Zyprexa continues to increase, and we cannot predict at this time the additional number of lawsuits and claims that may be asserted. As noted, we are vigorously defending this litigation. However, product litigation of this type is inherently unpredictable, with the risk of excessive verdicts not justified by the evidence. Accordingly, it is possible that the ultimate resolution of the Zyprexa product liability litigation by judgment or settlement could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

We have been named as a defendant in numerous product liability lawsuits involving primarily diethylstilbestrol (DES), thimerosal, and Zyprexa. With respect to current claims, we have accrued for our estimated exposures to the extent they are both probable and estimable based on the information available to us. In addition, we have accrued for certain claims incurred but not filed to the extent we can formulate a reasonable estimate of their costs. We estimate these expenses based primarily on historical claims experience and data regarding product usage. We expect the cash amounts related to the accruals to be paid out over the next several years. A portion of the costs associated with defending and disposing of these suits is covered by insurance. We estimate insurance recoverables based on existing deductibles, coverage limits, our assessment of any defenses to coverage that might be raised by the carriers, and the existing and projected future level of insolvencies among the insurance carriers.

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, taking 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 reached a settlement with our liability insurance carriers providing for coverage for certain environmental liabilities.

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 previously with respect to the U.S. Zyprexa and Evista patent litigation, the Zyprexa, Prozac, and Prozac Weekly marketing and promotional practices investigation, and the Zyprexa product liability litigation, 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.

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).

STOCK-BASED COMPENSATION

We adopted Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment (SFAS 123R), effective January 1, 2005. SFAS 123R requires the recognition of the fair value of stock-based compensation in net income. Stock-based compensation primarily consists of stock options and performance awards. Stock options are granted to employees at exercise prices equal to the fair market value of our stock at the dates of grant. Generally, options fully vest three years from the grant date and have a term of 10 years. Performance awards are granted to officers and key employees and are payable in shares of our common stock. The number of performance award shares actually issued, if any, varies depending upon the achievement of certain earnings-per-share targets. In general, performance awards fully vest at the end of the fiscal year of the grant. We recognize the stock-based compensation expense over the requisite service period of the individual grantees, which generally equals the vesting period. We provide newly issued shares and treasury stock to satisfy stock option exercises and for the issuance of performance awards.

Prior to January 1, 2005, we followed Accounting Principles Board (APB) Opinion 25, Accounting for Stock Issued to Employees, and related interpretations in accounting for our stock-based compensation. Under APB 25, no compensation expense was recognized for stock options since the exercise price of our employee stock options equals the market price of the underlying stock on the date of grant. We have elected the modified prospective transition method for adopting SFAS 123R. Under this method, the provisions of SFAS 123R apply to all awards granted or modified after the date of adoption. In addition, the unrecognized expense of awards not yet vested at the date of adoption, determined under the original provisions of SFAS 123, shall be recognized in net income in the periods after the date of adoption. We recognized compensation cost in the amount of $108.2 million and $25.2 million in the first quarter of 2005 and 2004, respectively, as well as related tax benefits of $32.8 million and $8.8 million, respectively. The amounts for 2004 relate only to expenses for performance awards because no expense was recognized for stock options under APB 25.

As a result of the adoption of SFAS 123R and compensation plan structural changes effective January 1, 2005, the incremental impact on our stock compensation expense caused our income before income taxes and net income for the quarter ended March 31, 2005, to be $86.9 million and $61.6 million ($.06 per share) lower, respectively, than if we had continued to account for our previous equity compensation programs under APB 25.

SFAS 123R requires us to present pro forma information for periods prior to the adoption as if we had accounted for all our employee stock options and performance awards under the fair value method of that statement. For purposes of pro forma disclosure, the estimated fair value of the options and performance awards at the date of the grant is amortized to expense over the requisite service period, which generally equals the vesting period. The following table illustrates the effect on net income and earnings per share for the three months ended March 31, 2004, if we had applied the fair value recognition provisions of SFAS 123R to stock-based employee compensation (dollars in millions, except per-share data).

Net income, as reported	$ 400.4
Add: Stock-based compensation expense included in reported net income, net of related tax effects	16.4
Deduct: Total stock-based employee compensation expense determined under fair-value-based method for all awards, net of related tax effects	(107.7)
Pro forma net income	$ 309.1
Earnings per share:	
Basic, as reported	$ .37
Basic, pro forma	$ .29
Diluted, as reported	$ .37
Diluted, pro forma	$ .29

Beginning with the 2005 stock option grant, we utilized a lattice-based option valuation model for estimating the fair value of the stock options. The lattice model allows the use of a range of assumptions related to volatility, risk-free interest rate, and employee exercise behavior. Expected volatilities utilized in the lattice model are based on implied volatilities from traded options on our stock, historical volatility of our stock price, and other factors. Similarly, the dividend yield is based on historical experience and our estimate of future dividend yields. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. The model incorporates exercise and post-vesting forfeiture assumptions based on an analysis of historical data. The expected life of the 2005 grants is derived from the output of the lattice model.

The weighted-average fair values of the options granted in the first quarter of 2005 were $16.06 per option, determined using the following assumptions:

Dividend yield	2.0%
Weighted-average volatility	27.8%
Range of volatilities	27.6%-30.7%
Risk-free interest rate	2.5% - 4.5%
Weighted-average expected life	7.2 years

As of March 31, 2005, the total remaining unrecognized compensation cost related to non-vested stock options and performance awards amounted to $397.5 million and $123.9 million, respectively, which will be amortized over the weighted-average remaining requisite service period of 2 years and 0.75 years, respectively.

SHAREHOLDERS' EQUITY

As of March 31, 2005, we have purchased $2.08 billion of our previously announced $3.0 billion share repurchase program. During the first quarter of 2005, we did not repurchase any stock pursuant to this program and we do not expect any share repurchases during the remainder of 2005.

RETIREMENT BENEFITS

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

	Defined Benefit Pension Plans		Retiree Health Benefit Plans	
	Three Months Ended March 31,		Three Months Ended March 31,	
	2005	2004	2005	2004
	(Dollars in millions)			
Components of net periodic benefit cost				
Service cost	$ 80.1	$ 59.2	$ 14.7	$ 11.8
Interest cost	74.8	70.9	20.1	17.4
Expected return on plan assets	(110.1)	(97.2)	(17.0)	(14.7)
Amortization of prior service cost	2.0	2.2	(4.0)	(3.9)
Recognized actuarial loss	26.2	20.9	21.6	16.6
Net periodic benefit cost	$ 73.0	$ 56.0	$ 35.4	$ 27.2

We expect to contribute between $130 million and $205 million during 2005 to our defined benefit pension plans and post-retirement health benefit plans. As of March 31, 2005, $51.9 million of contributions have been made to these plans.

IMPLEMENTATION OF NEW FINANCIAL ACCOUNTING PRONOUNCEMENTS

In 2004, the FASB issued FASB Staff Position (FSP) 106-2, which provides guidance regarding accounting for the effects of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). The FSP specifies that, for plans with benefits that are determined to be actuarially equivalent to the Medicare Part D benefits, the plan sponsor will be entitled to a tax-free subsidy under the MMA. We have determined that our plan is actuarially equivalent and, therefore, we are entitled to the subsidy. Following our adoption of the provisions of FSP 106-2 in the second quarter of 2004, we remeasured the accumulated postretirement benefit obligation (APBO) to reflect the effects of the MMA as of the effective date of the MMA (December 8, 2003), and recognized the financial statement effect retroactively. This had no material impact on the APBO, our consolidated financial position, or results of operations.

As discussed previously, we adopted SFAS 123(R) effective January 1, 2005. The adoption of this standard requires the recognition of the fair value of stock-based compensation in net income.

APPLIED MOLECULAR EVOLUTION ACQUISITION

On February 12, 2004, we acquired all the outstanding common stock of Applied Molecular Evolution, Inc. (AME) in a tax-free merger. Under the terms of the merger agreement, each outstanding share of AME common stock was exchanged for our common stock or a combination of cash and our stock valued at $18. The aggregate purchase price of approximately $442.8 million consisted of issuance of 4.2 million shares of our common stock valued at $314.8 million, issuance of 0.7 million replacement options to purchase shares of our common stock in exchange for the remaining outstanding AME options valued at $37.6 million, cash of $85.4 million for AME common stock and options for certain AME employees, and transaction costs of $5.0 million. The fair value of our common stock was derived using a per-share value of $74.14, which was our average closing stock price for February 11 and 12, 2004. The fair value for the options granted was derived using a Black-Scholes valuation method using assumptions consistent with those we used in valuing employee options. Replacement options to purchase our common stock granted as part of this acquisition have terms equivalent to the AME options being replaced.

In addition to acquiring the rights to two compounds currently under development, we expect the acquisition of AME's protein optimization technology to create synergies that will accelerate our ability to discover and optimize biotherapeutic drugs for cancer, critical care, diabetes, and obesity, areas in which proteins are of great therapeutic benefit.

In accordance with SFAS 141, Business Combinations, the acquisition has been accounted for as a purchase business combination. Under the purchase method of accounting, the assets acquired and liabilities assumed from AME at the date of acquisition 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 $9.6 million. Goodwill resulting from this acquisition has been fully allocated to the pharmaceutical products segment. No portion of this goodwill is expected to be deductible for tax purposes. AME's results of operations are included in our consolidated financial statements from the date of acquisition.

As of the date of acquisition, we determined the following estimated fair values for the assets purchased and liabilities assumed. The determination of estimated fair value requires management to make significant estimates and assumptions. We hired independent third parties to assist in the valuation of assets that were difficult to value.

	Estimated Fair Value at February 12, 2004
Cash and short-term investments	$ 38.7
Acquired in-process research and development	362.3
Platform technology	17.9
Goodwill	9.6
Other assets and liabilities - net	14.3
Total estimated purchase price	$ 442.8

The acquired in-process research and development (IPR&D) represents compounds currently under development that have not yet achieved regulatory approval for marketing. The estimated fair value of these intangible assets was derived using a valuation from an independent third party. AME's two lead compounds for the treatment of non-Hodgkin's lymphoma and rheumatoid arthritis represent approximately 80 percent of the estimated fair value of the IPR&D. 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 have been written off by a charge to income immediately subsequent to the acquisition because the compounds do not have any alternative future use. This charge is not deductible for tax purposes. The ongoing activity with respect to each of these compounds under development is not material to our research and development expenses.

There are several methods that can be used to determine the estimated fair value of the acquired IPR&D. We utilized the "income method," which applies a probability weighting to the estimated future net cash flows that are derived from projected sales revenues and estimated costs. These projections are based on factors such as relevant market size, patent protection, historical pricing of similar products, and expected industry trends. The estimated future net cash flows are then discounted to the present value using an appropriate discount rate. This analysis is performed for each project independently. The discount rate we used in valuing the acquired IPR&D projects was 18.75 percent.

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

OPERATING RESULTS

Executive Overview

I. Financial Results

Worldwide sales increased 4 percent in the first quarter of 2005 compared to the first quarter of 2004, despite competitive pressures experienced by Zyprexa in the U.S. We estimate that sales would have increased approximately 7 percent if not for approximately $130 million of reductions in wholesaler inventory levels during the first quarter of 2005 as a result of recently restructured arrangements with our U.S. wholesalers. Gross margins as a percent of sales decreased by 2.3 percentage points, to 75.4 percent. Marketing and administrative expenses increased 2 percent, while research and development expenses increased 9 percent. Net income and diluted earnings per share increased 84 percent in the first quarter of 2005. Net income comparisons between the three-month periods ended March 31, 2005 and 2004 were affected by the impact of the following significant items that are reflected in our financial results (see Notes to Consolidated Condensed Financial Statements for additional information).

- In 2005, we began to expense stock options in accordance with SFAS 123(R). Had we expensed stock options in 2004, our first quarter 2004 net income would have been lower by $91.3 million, which would have decreased earnings per share by $.08 in the quarter.

- We incurred a charge for acquired in-process research and development (IPR&D) of $362.3 million (no tax benefit) in the first quarter of 2004 related to the acquisition of Applied Molecular Evolution, Inc. (AME), which decreased earnings per share by $.33 in that quarter.

II. Recent product launches, product pipeline developments, and other significant events affecting our business:

- We are in the process of rolling out the global launches of a number of new products, which include Alimtaâ, Cialisâ, Cymbalta®, Forteoâ, Stratteraâ, Symbyax®, and Yentreve®. In addition, we have launched new indications or formulations of Alimta, Cymbalta, Gemzar®, Humatrope®, and Zyprexa.

- The U.S. Food and Drug Administration (FDA) approved Cymbalta, a balanced and potent selective serotonin and norepinephrine reuptake inhibitor, for the treatment of major depressive disorder in August 2004. This breakthrough antidepressant, which addresses both the emotional and painful physical symptoms of depression, was launched in the U.S. later that month. In September 2004, following an accelerated review by the FDA, Cymbalta received its second U.S. approval and became the first FDA-approved treatment for pain caused by diabetic peripheral neuropathy. Cymbalta was launched in the United Kingdom and Germany in the first quarter of 2005 for the treatment of major depressive episodes. Other launches in the European Union are expected to occur throughout 2005 and 2006. We also expect that the European Commission will authorize Cymbalta to be marketed for diabetic peripheral neuropathic pain in adults this summer.

- In August 2004, the FDA granted accelerated approval for Alimta for the treatment of locally advanced or metastatic non-small-cell lung cancer. This represented the second approval for Alimta in 2004; the product was approved and launched for malignant pleural mesothelioma in the first quarter. In September, Alimta was granted marketing authorization by the European Commission for the treatment of malignant pleural mesothelioma and as a second-line treatment for non-small-cell lung cancer. Alimta will continue to be launched in a number of European countries in 2005.

- The European Commission granted marketing authorization throughout the European Union for Yentreve for the treatment of moderate-to-severe stress urinary incontinence (SUI) in women. Yentreve has been launched in several European countries and will be available in many additional countries in the coming months. To date, we have received marketing authorization for the product in 29 countries worldwide. In January 2005, we withdrew the New Drug Application from the FDA for duloxetine for the treatment of SUI. This decision was based on discussions with the FDA suggesting the agency is not prepared at this time to grant approval for the product for the treatment of the SUI patient population based on the data package submitted. With our marketing partner, Boehringer Ingelheim, we are continuing to evaluate our options for next steps for the SUI indication in consultation with the FDA. Ongoing clinical trials for the product's treatment of SUI will continue.

- On April 29, 2005, Lilly and Amylin Pharmaceuticals, Inc. announced FDA approval to market Byetta™ (exenatide), the first in a new class of medicines known as incretin mimetics, for the treatment of type 2 diabetes. Byetta will be available in pharmacies by June 1, 2005.

- We recently restructured our arrangements with our U.S. wholesalers. The new arrangements are expected to provide us competitive distribution costs, reduce the speculative wholesaler buying seen in the past, and provide improved data on inventory levels at our U.S. wholesalers.

III. Legal, Regulatory, and Other Matters

Certain generic manufacturers have challenged our U.S. compound patent for Zyprexa and are seeking permission to market generic versions of Zyprexa prior to its patent expiration in 2011. On April 14, 2005, the U.S. District Court in Indianapolis ruled in our favor on all accounts. We expect the generic manufacturers to appeal this decision. We are confident that the generic manufacturers' claims are without merit; however, it is not possible to predict the outcome of this litigation and, accordingly, we can provide no assurance that we will prevail if the case is appealed.

In March 2004, we were notified by the U.S. Attorney's office for the Eastern District of Pennsylvania that it has commenced a civil investigation relating to our U.S. marketing and promotional practices. The products involved include Zyprexa, Prozac, and Prozac Weekly.

We have been named in a number of product liability cases in the United States that allege a variety of injuries from the administration of Zyprexa. Most of the cases allege that the product caused or contributed to diabetes or high blood-glucose levels. The suits seek substantial compensatory and punitive damages and typically accuse the company of inadequately testing for and warning about side effects of Zyprexa. Many of the suits also allege that we improperly promoted the drug. We are vigorously defending these suits.

Sales

First quarter 2005 sales growth of 4 percent compared to the first quarter of 2004 was primarily driven by sales growth of Cymbalta, Alimta, Forteo, and Gemzar. This growth was partially offset by an estimated $130 million of lost sales due to reductions in wholesaler inventory as a result of recently restructuring our arrangements with our U.S. wholesalers, and by decreased sales of Zyprexa. We estimate that sales would have increased approximately 7 percent if not for the reductions in wholesaler inventory levels. Sales in the U.S. decreased by $52.1 million, or 3 percent, for the first quarter of 2005 compared with

the first quarter of 2004. The decline in U.S. sales was driven primarily by the reductions in wholesaler inventory levels and decreased sales of Zyprexa, partially offset by increased sales of Cymbalta and Alimta. Sales outside the U.S. increased $172.5 million, or 12 percent, for the first quarter of 2005, driven primarily by Zyprexa, Alimta, and Gemzar. Worldwide sales volume decreased 1 percent, while exchange rates and selling prices each increased sales by 2 percent (numbers do not add due to rounding).

The following table summarizes our net sales activity for the three-month periods ended March 31, 2005 and 2004:

Product	Three Months Ended March 31, 2005			Three Months Ended March 31, 2004	Percent Change from 2004
	U.S. [1]	Outside U.S.	Total	Total	
	(Dollars in millions)				
Zyprexa	$ 517.4	$ 520.8	$1,038.2	$ 1,098.3	(5)
Gemzar	126.9	177.7	304.6	279.0	9
Humalog	176.2	110.0	286.2	267.2	7
Humulin	104.9	152.0	256.9	249.4	3
Evista	158.6	90.3	248.9	232.8	7
Animal health products	74.6	120.9	195.5	182.4	7
Actos	138.0	30.7	168.7	153.3	10
Strattera	112.4	7.4	119.8	141.1	(15)
Fluoxetine products	57.3	55.2	112.5	165.0	(32)
Anti-infectives	34.7	74.5	109.2	125.1	(13)
Cymbalta	102.4	4.4	106.8	—	N/M
Humatrope	48.1	56.4	104.5	102.8	2
Alimta	63.6	30.3	93.9	11.6	N/M
ReoPro	28.7	48.0	76.7	93.7	(18)
Forteo	42.3	24.5	66.8	40.8	64
Xigris	34.8	24.7	59.5	48.6	22
Cialis[2]	0.4	38.5	38.9	33.3	17
Symbyax	12.4	0.2	12.6	33.7	(63)
Other pharmaceutical products	11.0	86.2	97.2	118.8	(18)
Total net sales	$1,844.7	$ 1,652.7	$3,497.4	$ 3,376.9	4

N/M — Not meaningful

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

2 Cialis had worldwide first-quarter 2005 sales of $150.1 million compared with first-quarter 2004 sales of $108.3 million. The sales shown in the table above represent results in the territories in which we market Cialis exclusively. The remaining sales relate to the joint-venture territories of Lilly ICOS LLC (North America, excluding Puerto Rico, and Europe). Our share of the joint-venture territory sales, net of expenses, is reported in net other income in our consolidated condensed income statement.

Product Highlights

Zyprexa sales in the U.S. decreased 17 percent in the first quarter of 2005 compared with the first quarter of 2004. This decrease was a result of a decline in the underlying demand due to continuing competitive pressures. Sales outside the U.S. increased 9 percent driven by volume growth in a number of major markets and a favorable impact of exchange rates. Excluding the impact of exchange rates, sales of Zyprexa outside the U.S. increased by 4 percent in the first quarter of 2005. We continue to expect a slight decline in our 2005 worldwide Zyprexa sales.

Diabetes care products, composed primarily of Humalogâ, Humulinâ, and Actosâ, had worldwide net sales of $724.6 million in the first quarter of 2005, an increase of 6 percent compared with the same period last year. Diabetes care revenues in the U.S. increased 4 percent, to $428.3 million, primarily driven by price increases for insulins, offset partially by decline in underlying demand due to continued competitive pressures in the insulins market and reductions in wholesaler inventory levels of insulins during the first quarter of 2005. Diabetes care revenues outside the U.S. increased 11 percent, to $296.3 million. Humalog sales increased 5 percent, while Humulin sales decreased 4 percent in the U.S. in the first quarter of 2005. Humalog and Humulin

sales outside the U.S. increased 10 percent and 8 percent, respectively, during the first quarter of 2005. Actos revenues, the majority of which represent service revenues from a copromotion agreement in the U.S. with Takeda Pharmaceuticals North America (Takeda), increased 10 percent in 2005. Actos is manufactured by Takeda Chemical Industries, Ltd., and sold in the U.S. by Takeda. As previously disclosed, since our share of revenue from the agreement with Takeda will vary from quarter to quarter based on contract terms, Actos revenue will not necessarily track with product sales. As a result, it is difficult to make quarterly comparisons for Actos revenue.

Gemzar sales in the first quarter of 2005 decreased 1 percent in the U.S. Although underlying demand increased, sales in the U.S. declined due to reductions in wholesaler inventory levels during the first quarter of 2005. Gemzar sales outside the U.S. increased 18 percent.

Evista sales in the U.S. decreased 1 percent in the first quarter of 2005, due primarily to reductions in wholesaler inventory levels and a decline in U.S. underlying demand resulting from continued competitive pressures, partially offset by price increases. Evista sales outside the U.S. increased 25 percent in the first quarter of 2005 compared with 2004.

Strattera, the only nonstimulant medicine approved for the treatment of attention-deficit hyperactivity disorder (ADHD) in children, adolescents, and adults, generated $119.8 million of sales during the first quarter of 2005 compared with $141.1 million of sales in the first quarter of 2004. Although underlying demand increased, the decline in sales was due to reductions in wholesaler inventory levels during the first quarter of 2005. We expect Strattera sales for 2005 to decrease primarily due to greater than anticipated wholesaler destocking resulting from the recently restructured arrangements with our U.S. wholesalers, as well as sales pressures in the children's ADHD market.

Cymbalta was launched in the U.S. in late August 2004 for the treatment of major depressive disorder and in September 2004 for the treatment of diabetic peripheral neuropathic pain. Cymbalta has been well accepted, generating $106.8 million in sales in the first quarter of 2005, up sequentially from $61.3 million in the fourth quarter of 2004.

Alimta was launched in the U.S. during the first quarter of 2004 for the treatment of malignant pleural mesothelioma and approved during August 2004 for second-line treatment of non-small-cell lung cancer, while in Europe it was approved for both indications in September 2004. For the first quarter of 2005, Alimta generated sales of $93.9 million, representing a sequential increase compared with fourth-quarter 2004 sales of $73.1 million.

Forteo, a treatment for both men and postmenopausal women suffering from osteoporosis, increased 15 percent in the U.S., driven by strong growth in underlying demand, but offset, in part, by wholesaler destocking related to our new arrangements with U.S. wholesalers.

Xigris had first-quarter 2005 sales growth of 8 percent in the U.S., while sales outside the U.S. increased 51 percent during the same period.

Cialis was launched in the U.S. in December 2003. The $150.1 million of worldwide Cialis sales in the first quarter of 2005 comprised $38.9 million of sales in our territories, which are reported in our net sales, and $111.2 million of sales in the joint-venture territories. Within the joint-venture territories, the U.S. sales of Cialis were $42.7 million the first quarter of 2005 compared with $32.8 million in the first quarter of 2004. The increase was due to an increase in the underlying demand, offset partially by reductions in wholesaler inventory levels during the first quarter of 2005.

Symbyax was launched in the U.S. in January 2004. Symbyax combines olanzapine (the active ingredient in Zyprexa) and fluoxetine (the active ingredient in Prozac) to treat bipolar depression. Symbyax is the first FDA-approved medication for this difficult-to-treat condition. Symbyax had sales of $12.6 million in the first quarter of 2005, compared with sales of $15.2 million in the fourth quarter of 2004. Sales of Symbyax in the first quarter of 2004 of $33.7 million benefited from approximately $30 million of initial stocking.

Gross Margin, Costs, and Expenses

For the first quarter of 2005, gross margins declined 2.3 percentage points, to 75.4 percent of net sales. This decrease was primarily due to the impact of foreign exchange rates, increased expenses resulting from the expansion of our manufacturing capacity, and other cost increases, partially offset by improved productivity.

Operating expenses (the aggregate of research and development and marketing and administrative expenses) increased 5 percent for the first quarter of 2005 compared with the first quarter of 2004. Investment in research and development increased 9

percent, to $702.2 million, due to increased clinical trial and development expenses and the adoption of stock option expensing in 2005. Marketing and administrative expenses increased 2 percent, to $1.09 billion, in the first quarter of 2005, primarily attributable to the adoption of stock option expensing in 2005 and the impact of foreign exchange rates, offset partially by ongoing marketing cost-containment measures. Research and development expenses would have increased by 2 percent and marketing and administrative expenses would have decreased by 4 percent if the first-quarter 2004 results had been restated as if stock options had been expensed.

Net other income for the first quarter of 2005 increased $50.8 million, to $123.2 million. This increase was primarily due to income earned from the restructuring of our royalty arrangements with Ligand Pharmaceuticals Incorporated and Cubist Pharmaceuticals, Inc. during the quarter, and a decreased loss from the Lilly ICOS LLC joint venture.

For the first quarters of 2005 and 2004, the effective tax rates were 22.0 percent and 34.9 percent, respectively. The first-quarter 2004 effective tax rate was affected by the charge for acquired IPR&D related to the AME acquisition, which was not deductible for tax purposes.

FINANCIAL CONDITION

As of March 31, 2005, cash, cash equivalents, and short-term investments totaled $5.62 billion compared with $7.46 billion at December 31, 2004. Cash flow from operations of $804.8 million was more than offset by net repayments of short-term debt of $1.89 billion, dividends paid of $413.2 million and net capital expenditures of $242.2 million. Total debt at March 31, 2005, was $4.59 billion, a decrease of $1.92 billion from December 31, 2004. The decrease in debt was primarily due to the reduction of commercial paper using available U.S. funds.

We believe that cash generated from operations, along with available cash and cash equivalents, will be sufficient to fund our operating needs, including debt service, capital expenditures, dividends, and taxes in 2005. We believe that amounts available through our existing commercial paper program should be adequate to fund maturities of short-term borrowings, if necessary. Although we repaid approximately $2 billion of debt in the first quarter of 2005, we will likely incrementally increase our debt during the remainder of 2005 by approximately $1 billion from March 31, 2005 balances, as business needs require. Various risks and uncertainties, including those discussed in the Financial Expectations for 2005 section, may affect our operating results and cash generated from operations.

We have commenced repatriation of the incentive dividends as defined in the American Jobs Creation Act of 2004. We will repatriate a total of approximately $8.00 billion during 2005 pursuant to this Act.

LEGAL AND REGULATORY MATTERS

Three generic pharmaceutical manufacturers, Zenith Goldline Pharmaceuticals, Inc. (Zenith), Dr. Reddy's Laboratories, Ltd. (Reddy), and Teva Pharmaceuticals (Teva), have submitted abbreviated new drug applications (ANDAs) seeking permission to market generic versions of Zyprexa in various dosage forms several years prior to the expiration of our U.S. patents for the product, alleging that our patents are invalid, unenforceable, or not infringed. We filed suit against the three companies in the U.S. District Court for the Southern District of Indiana, seeking a ruling that the challenges to our compound patent (expiring in 2011) are without merit. The cases have been consolidated. A trial before the district court judge was held in January and February of 2004. On April 14, 2005, the district court upheld our 2011 U.S. patent on Zyprexa. In the case of *Eli Lilly and Company v. Zenith Goldline Pharmaceuticals et al.*, the court ruled in our favor on all accounts, including the patent doctrines of obviousness, double patenting, inequitable conduct, novelty, and public use. We anticipate that appeals will follow. We are confident, and the trial court confirmed, that the generic manufacturers' claims are without merit and we expect to prevail in this litigation. However, it is not possible to predict or determine the outcome of this litigation if the case is appealed and, accordingly, we can provide no assurance that we will prevail. An unfavorable outcome would have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

In October 2002, we were notified that Barr Laboratories, Inc. (Barr), had submitted an ANDA with the FDA seeking permission to market a generic version of Evista several years prior to the expiration of our U.S. patents covering the product, alleging that the patents are invalid or not infringed. In November 2002, we filed suit against Barr in the U.S. District Court for the Southern District of Indiana seeking a ruling that Barr's challenges to our patents claiming the methods of use and pharmaceutical form (expiring from 2012 to 2017) are without merit. Recently, Barr has also asserted that the method of use patents are unenforceable. On September 28, 2004, the U.S. Patent and Trademark Office issued to us a new patent (expiring in 2017) directed to pharmaceutical compositions containing raloxifene. Barr has challenged this patent, alleging that the patent is invalid, unenforceable, or will not be infringed. This patent has been added to the lawsuit. The suit is in discovery. The trial date

previously scheduled for February 2006 has been postponed and no new date has been set at this time. While we believe that Barr's claims are without merit and we expect to prevail, it is not possible to predict or determine the outcome of the litigation. Therefore, we can provide no assurance that we will prevail. An unfavorable outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

In March 2004, the office of the U.S. Attorney for the Eastern District of Pennsylvania advised us that it has commenced a civil investigation related to our U.S. marketing and promotional practices with respect to Zyprexa, Prozac, and Prozac Weekly. We are cooperating with the U.S. Attorney in this investigation and are providing a broad range of documents and information related to the investigation, including documents relating to communications with physicians and the remuneration of physician consultants and advisers. It is possible that other Lilly products could become subject to this investigation and that the outcome of this matter could include criminal charges and fines and/or civil penalties. We cannot predict or determine the outcome of this matter 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, and remuneration of health care professionals comply with promotional laws and regulations.

We have been named in approximately 190 product liability cases in the United States involving approximately 540 claimants alleging a variety of injuries from the use of Zyprexa. Most of the cases allege that the product caused or contributed to diabetes or high blood-glucose levels. The lawsuits seek substantial compensatory and punitive damages and typically accuse us of inadequately testing for and warning about side effects of Zyprexa. Many of the lawsuits also allege that we improperly promoted the drug. We are vigorously defending these suits. Virtually all the federal cases, involving approximately 450 claimants, have been or will be transferred to The Honorable Jack Weinstein in the Federal District Court for the Eastern District of New York for consolidated and coordinated pretrial proceedings. Two cases requesting certification of nationwide class actions on behalf of those who allegedly suffered injuries from the administration of Zyprexa were filed in the Federal District Court for the Eastern District of New York on April 16, 2004, and May 19, 2004, respectively. The cases seek damages for alleged personal injuries and also seek compensation for medical monitoring of individuals who have taken Zyprexa. A lawsuit was also filed that requests a class action on behalf of Iowa residents who took Zyprexa, and that case has been transferred to the federal court in New York. In addition, we have entered into agreements with various plaintiffs' counsel halting the running of the statutes of limitation (tolling agreements) with respect to more than 3,800 individuals who do not have lawsuits on file and may or may not eventually file suits. This provides counsel additional time to evaluate the potential claims. In exchange, the individuals have agreed not to file suits in state courts, and the Plaintiffs Steering Committee agreed to dismiss the personal injury claims in the two pending nationwide class actions. The class action claims seeking medical monitoring for Zyprexa patients are not affected by this agreement.

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. In these actions, which we have removed to federal court, the Department of Health and Hospitals seeks to recover the costs it paid for Zyprexa through Medicaid and other drug benefit programs and the costs the department alleges it has incurred and will incur to treat Zyprexa-related illnesses.

In early 2005, we were served with five lawsuits seeking class action status in Canada on behalf of patients who took Zyprexa. The allegations in these suits are similar to those in the litigation pending in the United States.

In connection with the Zyprexa product liability claims, certain of our insurance carriers have identified potential defenses to their liability under the policies and to date have failed to reimburse us for claim-related costs despite demand of the first-layer carriers for payment. However, in our opinion, the potential defenses identified to date appear to lack substance, and we believe the carriers will ultimately honor their obligations under the policies either voluntarily or after litigation and/or arbitration. In March 2005, we filed suit against several of the carriers in state court in Indiana to obtain reimbursement of costs related to the Zyprexa product liability litigation, which litigation was recently removed to federal court. While we believe our position is meritorious, there can be no assurance that we will prevail.

The number of product liability lawsuits and tolled claims relating to Zyprexa continues to increase, and we cannot predict at this time the additional number of lawsuits and claims that may be asserted. As noted, we are vigorously defending this litigation. However, product litigation of this type is inherently unpredictable, with the risk of excessive verdicts not justified by the evidence. Accordingly, it is possible that the ultimate resolution of the Zyprexa product liability litigation by judgment or settlement could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

FINANCIAL EXPECTATIONS FOR 2005

We expect second-quarter 2005 earnings per share of $.65 to $.68, which represents 8 percent to 13 percent growth compared with reported second-quarter 2004 earnings per share of $.60 (which excluded stock option expensing, but included an asset impairment charge of $.08 per share). During the second quarter, it is expected that further inventory reductions will occur at our U.S. wholesalers as a result of our recent restructuring of our wholesaler arrangements. For the full year of 2005, we currently expect earnings per share to be in the range of $2.80 to $2.90 per share, respectively, including the incremental equity compensation expense as a result of expensing stock options (see Notes to the Consolidated Condensed Financial Statements for additional information) and compensation structural changes. For the full year 2005, we expect sales to grow 8 percent to 10 percent (with acceleration in the second half of the year), gross margins as a percentage of sales to decline by roughly 50 basis points to 75 basis points, marketing and administrative expenses to grow in the low single digits, and research and development expenses to grow in the mid-single digits. Further, we expect other income to contribute approximately $175 million to $225 million, and the effective income tax rate to be about 22 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; 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. Other factors that may affect our operations and prospects are discussed in Exhibit 99 to this Form 10-Q. We undertake no duty to update 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.

PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

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 Sidney Taurel, chairman, president, and chief executive officer, and Charles E. Golden, executive vice president and chief financial officer, evaluated our disclosure controls and procedures as of March 31, 2005, and concluded that they are effective.

(b) *Changes in Internal Controls.* During the first quarter of 2005, 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

Certain generic manufacturers have challenged our U.S. compound patent for Zyprexa and are seeking permission to market generic versions of Zyprexa prior to the patent expiration in 2011. The trial regarding the defense of these patents was held in January and February 2004. On April 14, 2005, the U.S. District Court for the Southern District of Indiana upheld our 2011 U.S. patent on Zyprexa, ruling in our favor on all accounts, including the patent doctrines of obviousness, double patenting, inequitable conduct, novelty, and public use. We anticipate that appeals will follow. While we cannot predict or determine the outcome of this litigation if the case is appealed, an unfavorable outcome would have a material adverse effect on our consolidated financial position, liquidity, and results of operations.

In 2002, we were notified that Barr Laboratories, Inc., had challenged our U.S. patents for Evista and are seeking permission to market generic versions of Evista prior to the patent expiration. In November 2002, we filed suit against Barr in the U.S. District Court for the Southern District of Indiana seeking a ruling that Barr's challenges to our patents are without merit. The suit is in discovery. The trial date previously scheduled for February 2006 has been postponed and no new date has been set at this time. While we believe that Barr's claims are without merit and expect to prevail, it is not possible to predict or determine the outcome of the litigation. Therefore, we can provide no assurance that we will prevail. An unfavorable outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

In March 2004, we were notified that the office of the U.S. Attorney for the Eastern District of Pennsylvania has commenced a civil investigation relating to our U.S. marketing and promotional practices. Based on the information provided by the U.S. Attorney's office, we believe that the products involved include Zyprexa, Prozac, and Prozac Weekly. We are cooperating with the government in this investigation. It is possible that the outcome of this investigation could include criminal charges and fines and/or civil penalties. While we cannot predict or determine the outcome of this matter, it is possible that an adverse outcome could have a material adverse effect on our consolidated financial position, liquidity, and results of operations.

We have been named in approximately 190 product liability cases in the United States involving approximately 540 claimants alleging a variety of injuries from the administration of Zyprexa. We have also been named in similar suits brought in Louisiana and Canada. Most of the cases allege that the product caused or contributed to diabetes or high blood-glucose levels. The suits seek substantial compensatory and punitive damages and typically accuse us of inadequately testing for and warning about side effects of Zyprexa, and many of the suits also allege that we improperly promoted the drug. In addition, the potential claims of more than 3,800 individuals are subject to an agreement that tolls the running of the statute of limitations while the potential claims are evaluated. The number of product liability lawsuits and tolled claims relating to Zyprexa continues to increase, and we cannot predict at this time the additional number of lawsuits and claims that may be asserted. As noted, we are vigorously defending this litigation. However, product litigation of this type is inherently unpredictable, with the risk of excessive verdicts not justified by the evidence. Accordingly, it is possible that the ultimate resolution of the Zyprexa product liability litigation by judgment or settlement could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

See Part I, Item 2, Legal and Regulatory Matters, for more information on the above matters.

We refer to Part I, Item 3, of our Form 10-K annual report for 2004 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 125 suits involving approximately 205 claimants. In the thimerosal litigation, we have been named as a defendant in approximately 360 suits with approximately 970 claimants.

As previously disclosed, in 2003 and 2004, four counties in New York (Nassau, Suffolk, Rockland, and Westchester) and the City of New York sued us and many other pharmaceutical manufacturers, claiming in general that as a result of alleged improprieties by the manufacturers in the calculation and reporting of average wholesale prices for purposes of Medicaid reimbursement, the counties overpaid their portion of the cost of pharmaceuticals. In 2005, additional suits have been filed by Erie and numerous other New York counties. The suits seek monetary and other relief, including civil penalties and treble damages. Most of the New York suits are consolidated by agreement in the U.S. District Court for the District of Massachusetts for pretrial proceedings (along with several other suits to which we were not a party). Litigation activity in all of the New York cases was stayed pending a decision on a motion to dismiss in the Suffolk County case, which was decided in our favor on April 8, 2005. Counsel for Suffolk County (also counsel for all but two of the New York municipalities) has indicated that a consolidated, amended pleading will be filed and it is not known whether the amended pleading will seek to replead allegations against us. Also in 2005, the Attorney General for Alabama filed a similar suit naming us and 78 other drug manufacturers. Our obligation to answer the complaint has been stayed. In July 2004, Central Alabama Comprehensive Healthcare, Inc. filed a similar suit in Alabama relating to Public Health Service pricing**.** The suit seeks injunctive and monetary relief. The allegations in the lawsuit are based on a report issued by the Office of the Inspector General for Health and Human Services (OIG) that was subsequently withdrawn by the OIG because it was based on flawed data. We and the other defendants have filed motions to dismiss, which are pending. While we are vigorously defending all these cases, given their early procedural stage, we cannot predict or determine the outcome of this litigation.

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 previously with respect to the U.S. Zyprexa and Evista patent litigation, the Zyprexa, Prozac, and Prozac Weekly marketing and promotional practices investigation, and the Zyprexa product liability litigation, the resolution of all such matters will not have a material adverse effect on our consolidated financial position or liquidity but could possibly be material to the consolidated results of operations in any one accounting period.

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

The following table summarizes the activity related to repurchases of our equity securities during the three-month period ended March 31, 2005:

Period	Total Number of Shares Purchased (a)	Average Price Paid per Share (b)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (c)	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (d)
	(in thousands)			(Dollars in millions)
January 2005	11	$ 55.77	—	$ 920.0
February 2005	4	54.60	—	920.0
March 2005	4	53.80	—	920.0
Total	19		—	

The amounts presented in columns (a) and (b) above represent purchases of common stock related to employee stock option exercises. The amounts presented in columns (c) and (d) in the above table represent activity related to our $3.0 billion share repurchase program announced in March 2000. As of March 31, 2005, we have purchased $2.08 billion related to this program. During the first quarter of 2005, no shares were repurchased pursuant to this program and we do not expect to purchase any shares under this program during the remainder of 2005.

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

We held our annual meeting of shareholders on April 18, 2005. The following is a summary of the matters voted on at the meeting:

(a) The four nominees for director were elected to serve three-year terms ending in 2008, as follows:

Nominee	For	Withhold Vote
George M.C. Fisher	885,384,687	104,724,400
Alfred G. Gilman, M.D., Ph.D.	977,271,565	12,837,522
Karen N. Horn, Ph.D.	884,675,603	105,433,484
Sir John Rose	976,142,528	13,966,559

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

For:	969,446,889
Against:	19,270,252
Abstain:	1,391,946

(c) By the following vote, the shareholders did not approve the shareholder proposal requesting separating the roles of Chairman and Chief Executive Officer:

For:	208,862,246
Against:	643,145,832
Abstain:	4,700,908
Broker Nonvote:	133,400,101

(d) By the following vote, the shareholders did not approve the shareholder proposal requesting that the Board of Directors adopt a policy that does not constrain the reimportation of prescription drugs in the U.S. and prepare a report to shareholders regarding the policy:

For:	29,604,497
Against:	748,333,779
Abstain:	78,770,710
Broker Nonvote:	133,400,101

(e) By the following vote, the shareholders did not approve the shareholder proposal requesting that the Board of Directors prepare a report on the effects on the long-term economic stability of the company and on the risks of liability to legal claims that arise from the company's policy of limiting the availability of the companies products to Canadian wholesalers or pharmacies that allow purchase of its products by U.S. residents:

For:	107,966,209
Against:	669,207,679
Abstain:	79,535,098
Broker Nonvote:	133,400,101

(f) By the following vote, the shareholders did not approve the shareholder proposal requesting that the Company provide a report semiannually describing its policies, procedures, and contributions to political candidates and parties:

For:	50,304,104
Against:	724,628,219
Abstain:	81,776,663
Broker Nonvote:	133,400,101

(g) By the following vote, the shareholders did not approve the shareholder proposal requesting that the Board of Directors adopt a policy that a significant portion of future stock option grants to senior executives be performance-based through indexed options, premium-priced stock options, or performance-vesting options:

For:	236,130,335
Against:	465,067,668
Abstain:	155,510,983
Broker Nonvote:	133,400,101

(h) By the following vote, the shareholders did not approve the shareholder proposal requesting that the Board of Directors commit specifically to using only non-animal methods for certain testing procedures, replace animal-based tests with non-animal methods, and other animal-related testing activities:

For:	9,197,643
Against:	759,975,991
Abstain:	87,535,352
Broker Nonvote:	133,400,101

Item 6. Exhibits

The following documents are filed as exhibits to this Report:

EXHIBIT 11.	Statement re: Computation of Earnings per Share
EXHIBIT 12.	Statement re: Computation of Ratio of Earnings From Continuing Operations to Fixed Charges
EXHIBIT 31.1	Rule 13a-14(a) Certification of Sidney Taurel, Chairman of the Board, President, and Chief Executive Officer
EXHIBIT 31.2	Rule 13a-14(a) Certification of Charles E. Golden, Executive Vice President and Chief Financial Officer
EXHIBIT 32.	Section 1350 Certification
EXHIBIT 99.	Cautionary Statement Under Private Securities Litigation Reform Act of 1995 – “Safe Harbor” for Forward-Looking Disclosures

SIGNATURES

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

ELI LILLY AND COMPANY
(Registrant)

Date May 4, 2005

/s/Alecia A. DeCoudreaux
Alecia A. DeCoudreaux
Secretary and Deputy General Counsel

Date May 4, 2005

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

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INDEX TO EXHIBITS

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EXHIBIT 11. STATEMENT RE: COMPUTATION OF EARNINGS PER SHARE

(Unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES

	Three Months Ended March 31,	
	2005	2004
BASIC		
Net income	$ 736.6	$ 400.4
Average number of common shares outstanding	1,086.6	1,080.3
Contingently issuable shares	.3	—
Adjusted average shares	1,086.9	1,080.3
Basic earnings per share	$ .68	$ .37
DILUTED		
Net income	$ 736.6	$ 400.4
Average number of common shares outstanding	1,086.6	1,080.3
Incremental shares – stock options and contingently issuable shares	2.6	6.7
Adjusted average shares	1,089.2	1,087.0
Diluted earnings per share	$ .68	$ .37

Dollars and shares in millions except per-share data.

EXHIBIT 12. STATEMENT RE: COMPUTATION OF RATIO OF EARNINGS TO FIXED CHARGES

(Unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES
(Dollars in millions)

	Three Months Ended March 31, 2005	Years Ended December 31,				
		2004	2003	2002	2001	2000
Consolidated pretax income	$ 944.4	$2,941.9	$3,261.7	$3,457.7	$3,506.9	$3,858.7
Interest	57.5	162.9	121.9	140.0	253.3	225.4
Less interest capitalized during the period	(32.9)	(111.3)	(60.9)	(60.3)	(61.5)	(43.1)
Earnings	$ 969.0	$2,993.5	$3,322.7	$3,537.4	$3,698.7	$4,041.0
Fixed charges	$ 57.5	$ 162.9	$ 121.9	$ 140.0	$ 253.3	$ 225.4
Ratio of earnings to fixed charges	16.9	18.4	27.3	25.3	14.6	17.9

EXHIBIT 31.1 Rule 13a-14(a) Certification of Sidney Taurel, Chairman of the Board, President, and Chief Executive Officer

CERTIFICATIONS

I, Sidney Taurel, chairman of the board, president, and chief executive officer, certify that:

1. I have reviewed this report on Form 10-Q of Eli Lilly and Company;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: May 3, 2005

By: /s/Sidney Taurel

Sidney Taurel
Chairman of the Board, President,
and Chief Executive Officer

EXHIBIT 31.2 Rule 13a-14(a) Certification of Charles E. Golden, Executive Vice President and Chief Financial Officer

CERTIFICATIONS

I, Charles E. Golden, executive vice president and chief financial officer, certify that:

1. I have reviewed this report on Form 10-Q of Eli Lilly and Company;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: May 3, 2005

By: /s/Charles E. Golden

Charles E. Golden
Executive Vice President
and Chief Financial Officer

EXHIBIT 32. Section 1350 Certification

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Eli Lilly and Company, an Indiana corporation (the "Company"), does hereby certify that, to the best of their knowledge:

The Quarterly Report on Form 10-Q for the quarter ended March 31, 2005 (the "Form 10-Q") of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date May 3, 2005

/s/Sidney Taurel
Sidney Taurel
Chairman of the Board, President, and
Chief Executive Officer

Date May 3, 2005

/s/Charles E. Golden
Charles E. Golden
Executive Vice President and
Chief Financial Officer

EXHIBIT 99. Cautionary Statement Under Private Securities Litigation Reform Act of 1995 – “Safe Harbor” for Forward-Looking Disclosures

Certain forward-looking statements are included in this Form 10-K and may be made by spokespeople based on then-current expectations of management. All forward-looking statements made by us are subject to risks and uncertainties. One can identify forward-looking statements by the use of words such as “expects,” “plans,” “will,” “estimates,” “forecasts,” “projects,” “believes,” “anticipates,” and other words of similar meaning. Forward-looking statements do not relate strictly to historical or current facts. They are likely to address our growth strategy, financial results, regulatory issues, and status of product approvals, development programs, litigation, and investigations.

Certain factors, including but not limited to those listed below, may cause actual results to differ materially from current expectations and historical results.

- Competitive factors can lead to declining demand for our products. These factors include new patented products or expanded indications for existing products introduced by competitors; generic competition as patents on key products expire; and pricing pressures, both in the U.S. and abroad.

- Government health care cost-containment measures can significantly affect our sales and profitability. These include federal, state, and foreign laws and regulations that negatively affect pharmaceutical pricing, such as Medicaid and Medicare; pharmaceutical importation laws; and other laws and regulations that, directly or indirectly, impose governmental controls on the prices at which our products are sold.

- There are many difficulties and uncertainties inherent in new product development and introduction of new products. New product candidates that appear promising in development may fail to reach the market or may have only limited commercial success because of efficacy or safety concerns, inability to obtain necessary regulatory approvals, limited scope of approved uses, difficulty or excessive costs to manufacture, or infringement of the patents or intellectual property rights of others. In addition, it can be very difficult to predict sales growth rates of new products.

- Delays and uncertainties in the FDA approval process and the approval processes in other countries can result in delays in product launches and lost market opportunity.

- Unexpected safety or efficacy concerns can arise with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals, or declining sales.

- Patent challenges, including challenges to our patents by generic pharmaceutical manufacturers under the Hatch-Waxman Act or patent infringement suits brought against us by other patent holders, can cause us to prematurely lose market exclusivity for, or preclude commercialization of, our products. In particular, see Part I, Item 2, “Legal and Regulatory Matters”, for a discussion of Hatch-Waxman Act challenges to our patents for Zyprexa and Evista.

- Changes in inventory levels maintained by pharmaceutical wholesalers can cause reported sales for a particular period to differ significantly from underlying prescriber demand.

- Regulatory issues concerning compliance with current Good Manufacturing Practice (cGMP) regulations for pharmaceutical products can lead to product recalls and seizures, interruption of production, and delays in the approvals of new products pending resolution of the cGMP issues.

- Other legal factors, including product liability or other liability claims, marketing and promotional practices investigations, antitrust and pricing litigation, environmental matters, and privacy regulations can result in significant expense to the company. In particular, See Part I, Item 2, “Legal and Regulatory Matters”, for the discussions of the U.S. marketing practices investigations and the Zyprexa product liability litigation.

- We have experienced difficulties in obtaining product liability insurance due to a very restrictive insurance market, and therefore will be largely self-insured for future product liability losses. In addition, there is no assurance that we will be able to fully collect from our insurance carriers on past claims.

- Changes in tax laws, including laws related to the remittance of foreign earnings or investments in foreign countries with favorable tax rates, and settlements of federal, state, and foreign tax audits, can affect our net income.

- Economic factors over which we have no control, including changes in inflation, interest rates and foreign currency exchange rates, and overall economic conditions in volatile areas can affect our results of operations.

- Changes in accounting standards promulgated by the Financial Accounting Standards Board, the Securities and Exchange Commission, the American Institute of Certified Public Accountants, and the Emerging Issues Task Force can affect reported results.

- Our results can also be affected by internal factors, such as changes in business strategies and the impact of restructurings, asset impairments, technology acquisition and disposition transactions, and business combinations.

We undertake no duty to update forward-looking statements.