



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 JUNE 30, 2004

COMMISSION FILE NUMBER 001-6351

**ELI LILLY AND COMPANY**

(Exact name of Registrant as specified in its charter)

INDIANA  
(State or other jurisdiction of  
incorporation or organization)

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

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

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

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

Yes  No

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

Yes  No

The number of shares of common stock outstanding as of July 20, 2004:

<u>Class</u>	<u>Number of Shares Outstanding</u>
Common	1,130,571,660

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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 June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
	(Dollars in millions, except per-share data)			
Net sales	\$3,556.3	\$3,088.2	\$6,933.2	\$5,977.6
Cost of sales	796.4	643.0	1,548.1	1,264.3
Research and development	684.2	542.5	1,330.8	1,072.1
Marketing and administrative	1,170.2	1,043.3	2,234.1	1,957.8
Acquired in-process research and development	—	—	362.3	—
Asset impairments, restructuring, and other special charges	108.9	—	108.9	353.9
Interest expense	7.5	19.9	16.8	35.4
Other income – net	(49.1)	(48.4)	(121.5)	(87.7)
	<u>2,718.1</u>	<u>2,200.3</u>	<u>5,479.5</u>	<u>4,595.8</u>
Income before income taxes	838.2	887.9	1,453.7	1,381.8
Income taxes	181.3	195.7	396.4	282.6
Net income	<u>\$ 656.9</u>	<u>\$ 692.2</u>	<u>\$1,057.3</u>	<u>\$1,099.2</u>
Earnings per share - basic	<u>\$ .61</u>	<u>\$ .64</u>	<u>\$ .98</u>	<u>\$ 1.02</u>
Earnings per share - diluted	<u>\$ .60</u>	<u>\$ .64</u>	<u>\$ .97</u>	<u>\$ 1.02</u>
Dividends paid per share	<u>\$ .355</u>	<u>\$ .335</u>	<u>\$ .71</u>	<u>\$ .67</u>

See Notes to Consolidated Condensed Financial Statements.

## CONSOLIDATED CONDENSED BALANCE SHEETS

## ELI LILLY AND COMPANY AND SUBSIDIARIES

	June 30, 2004	December 31, 2003
	(Dollars in millions)	
	(Unaudited)	
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 2,396.7	\$ 2,756.3
Short-term investments	1,014.8	957.0
Accounts receivable, net of allowances of \$84.6 (2004) and \$79.5 (2003)	1,973.6	1,854.7
Other receivables	459.3	477.6
Inventories	2,058.9	1,963.0
Deferred income taxes	589.1	500.6
Prepaid expenses	295.8	249.5
<b>TOTAL CURRENT ASSETS</b>	<b>8,788.2</b>	<b>8,758.7</b>
<b>OTHER ASSETS</b>		
Prepaid pension	1,583.1	1,613.3
Investments	3,576.1	3,374.6
Sundry	1,689.3	1,392.5
	<u>6,848.5</u>	<u>6,380.4</u>
<b>PROPERTY AND EQUIPMENT</b>		
Land, buildings, equipment, and construction- in-progress	11,802.0	11,068.0
Less allowances for depreciation	(4,666.9)	(4,529.0)
	<u>7,135.1</u>	<u>6,539.0</u>
	<u>\$22,771.8</u>	<u>\$21,678.1</u>
<b>LIABILITIES AND SHAREHOLDERS'</b>		
<b>EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Short-term borrowings	\$ 1,597.7	\$ 196.5
Accounts payable	788.8	875.9
Employee compensation	411.5	387.4
Dividends payable	400.7	398.3
Income taxes payable	1,723.0	1,749.8
Other liabilities	1,802.0	1,942.7
<b>TOTAL CURRENT LIABILITIES</b>	<b>6,723.7</b>	<b>5,550.6</b>
<b>LONG-TERM DEBT</b>	<b>3,532.0</b>	<b>4,687.8</b>
<b>OTHER NONCURRENT LIABILITIES</b>	<b>2,016.9</b>	<b>1,674.9</b>
<b>COMMITMENTS AND CONTINGENCIES</b>	<b>—</b>	<b>—</b>
<b>SHAREHOLDERS' EQUITY</b>		
Common stock	707.2	702.3
Additional paid-in capital	3,066.4	2,610.0
Retained earnings	9,756.2	9,470.4
Employee benefit trust	(2,635.0)	(2,635.0)
Deferred costs-ESOP	(116.0)	(118.6)
Accumulated other comprehensive loss	(176.8)	(160.1)
	<u>10,602.0</u>	<u>9,869.0</u>
Less cost of common stock in treasury.	102.8	104.2
	<u>10,499.2</u>	<u>9,764.8</u>
	<u>\$22,771.8</u>	<u>\$21,678.1</u>

See Notes to Consolidated Condensed Financial Statements.

## CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS

(Unaudited)

## ELI LILLY AND COMPANY AND SUBSIDIARIES

	Six Months Ended June 30,	
	2004	2003
	(Dollars in millions)	
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net income	\$ 1,057.3	\$ 1,099.2
Adjustments to reconcile net income to cash flows from operating activities:		
Changes in operating assets and liabilities, net of effect of acquisition of Applied Molecular Evolution		
Depreciation and amortization	(549.2)	(370.2)
Change in deferred taxes	297.6	288.6
Acquired in-process research and development	136.1	144.5
Asset impairments, restructuring, and other special charges, net of tax	362.3	—
Other, net	81.7	243.3
	135.4	11.6
<b>NET CASH PROVIDED BY OPERATING ACTIVITIES</b>	<u>1,521.2</u>	<u>1,417.0</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Net purchases of property and equipment	(971.7)	(666.4)
Net change in short-term investments	(47.0)	774.0
Purchase of noncurrent investments	(2,106.5)	(2,697.7)
Proceeds from sales and maturities of noncurrent investments	1,737.4	2,142.6
Cash paid for acquisition of Applied Molecular Evolution, net of cash acquired	(71.7)	—
Other, net	(60.5)	(22.5)
<b>NET CASH USED IN INVESTING ACTIVITIES</b>	<u>(1,520.0)</u>	<u>(470.0)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Dividends paid	(769.2)	(719.1)
Purchase of common stock and other capital transactions	—	(281.1)
Issuances of common stock under stock plans	75.8	45.7
Net change in short-term borrowings	324.1	(237.0)
Net (repayments) issuances of long-term debt	(4.7)	292.4
<b>NET CASH USED IN FINANCING ACTIVITIES</b>	<u>(374.0)</u>	<u>(899.1)</u>
Effect of exchange rate changes on cash and cash equivalents	13.2	43.5
<b>NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</b>	<u>(359.6)</u>	<u>91.4</u>
Cash and cash equivalents at January 1	2,756.3	1,945.9
<b>CASH AND CASH EQUIVALENTS AT JUNE 30</b>	<u>\$ 2,396.7</u>	<u>\$ 2,037.3</u>

See Notes to Consolidated Condensed Financial Statements.

## CONSOLIDATED CONDENSED STATEMENTS OF COMPREHENSIVE INCOME

(Unaudited)

## ELI LILLY AND COMPANY AND SUBSIDIARIES

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
	(Dollars in millions)			
Net income	\$656.9	\$692.2	\$1,057.3	\$1,099.2
Other comprehensive income (loss) <sup>1</sup>	8.2	164.6	(16.6)	229.5
Comprehensive income	<u>\$665.1</u>	<u>\$856.8</u>	<u>\$1,040.7</u>	<u>\$1,328.7</u>

<sup>1</sup> The significant components of other comprehensive income (loss) were gains of \$172.6 million and \$202.7 million from foreign currency translation adjustments for the three months and six months ended June 30, 2003, respectively.

See Notes to Consolidated Condensed Financial Statements.

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## 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 second quarter of 2004 and 2003 was \$35.0 million and \$52.8 million, respectively, and \$88.5 million and \$109.8 million for the six months ended June 30, 2004 and 2003, respectively.

## SALES BY PRODUCT CATEGORY

Worldwide sales by product category for the three months and six months ended June 30, 2004 and 2003 were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
	(Dollars in millions)			
Net sales – to unaffiliated customers				
Neurosciences	\$1,593.1	\$1,361.8	\$3,091.2	\$2,586.8
Endocrinology	1,119.0	967.9	2,176.3	1,904.3
Oncology	313.2	257.8	607.2	498.4
Cardiovascular	179.8	169.4	345.6	334.5
Animal health	179.6	166.5	362.0	339.3
Anti-infectives	118.6	116.0	243.7	238.1
Other pharmaceuticals	53.0	48.8	107.2	76.2
Net sales	<u>\$3,556.3</u>	<u>\$3,088.2</u>	<u>\$6,933.2</u>	<u>\$5,977.6</u>

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 that are necessary for a fair presentation of the results of operations for the periods shown. All such adjustments are of a normal recurring nature. 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, 2003.

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 or not infringed. In April 2001, we filed suit against Zenith 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. We filed similar suits in the same court against Reddy in June 2001 and Teva in September 2002. The cases have been consolidated. A trial before a district court judge in Indianapolis was held in January and February of 2004. A ruling from the trial court is expected in the summer of 2004. Regardless of the trial court's ruling, we anticipate that appeals will follow. If we are unsuccessful at the trial court level, we cannot predict whether any of the generic companies would launch generic versions of Zyprexa prior to a final resolution of any appeals. We believe 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. 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 U.S. Food and Drug Administration (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 method of use and pharmaceutical form (expiring from 2012 to 2017) are without merit. In June 2003, Barr added a challenge to one of our additional patents (expiring in 2017) claiming a component in the pharmaceutical form of Evista. That patent has been added to the lawsuit. The suit is in discovery and the trial is now scheduled to begin on February 13, 2006. 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 July 2002, we received a grand jury subpoena for documents from the Office of Consumer Litigation, 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 and July 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. 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 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 Prozac® and Zyprexa. We are cooperating with the U.S. Attorney in this investigation. It is possible that other Lilly products could become subject to these investigations. We continue to review and enhance policies and procedures designed to ensure that our marketing and promotional practices, physician communications, and remuneration of healthcare professionals comply with promotional laws and regulations. It is possible that the outcome of the above matters could include criminal charges and fines and/or civil penalties. We cannot predict or determine the outcome of the above 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 operation, liquidity, and financial position.

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We have been named as a defendant in numerous product liability lawsuits involving primarily three products, 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, 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.

The litigation accruals and environmental liabilities have been reflected in our consolidated condensed balance sheet at the gross amount of approximately \$218.2 million at June 30, 2004. Estimated insurance recoverables of approximately \$76.6 million at June 30, 2004, have been reflected as assets in the consolidated condensed balance sheet.

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 with respect to the Zyprexa and Evista patent litigation and the marketing and promotional practices investigations, 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 have elected to follow Accounting Principles Board (APB) Opinion 25, Accounting for Stock Issued to Employees, and related interpretations in accounting for our stock options and performance awards. Under APB 25, because the exercise price of our employee stock options equals the market price of the underlying stock on the date of grant, no compensation expense is recognized. However, Statement of Financial Accounting Standards (SFAS) 123, Accounting for Stock-Based Compensation, as amended by SFAS 148, Accounting for Stock-Based Compensation-Transition and Disclosure, requires us to present pro forma information as if we had accounted for 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 vesting period.

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The following table illustrates the effect on net income and earnings per share if we had applied the fair value recognition provisions of SFAS 123 to stock-based employee compensation.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
	(Dollars in millions, except per-share data)			
Net income, as reported	\$656.9	\$692.2	\$1,057.3	\$1,099.2
Add: Compensation expense for stock-based performance awards included in reported net income, net of related tax effects	15.2	7.0	30.4	13.2
Deduct: Total stock-based employee compensation expense determined under fair-value-based method for all awards, net of related tax effects	(74.4)	(61.8)	(148.5)	(126.9)
Pro forma net income	<u>\$597.7</u>	<u>\$637.4</u>	<u>\$ 939.2</u>	<u>\$ 985.5</u>
Earnings per share:				
Basic, as reported	<u>\$ .61</u>	<u>\$ .64</u>	<u>\$ .98</u>	<u>\$ 1.02</u>
Basic, pro forma	<u>\$ .55</u>	<u>\$ .59</u>	<u>\$ .87</u>	<u>\$ .92</u>
Diluted, as reported	<u>\$ .60</u>	<u>\$ .64</u>	<u>\$ .97</u>	<u>\$ 1.02</u>
Diluted, pro forma	<u>\$ .55</u>	<u>\$ .59</u>	<u>\$ .86</u>	<u>\$ .91</u>

#### SHAREHOLDERS' EQUITY

As of June 30, 2004, we have purchased \$2.08 billion of our previously announced \$3.0 billion share repurchase program. During the six months ended June 30, 2004, we did not repurchase any stock pursuant to this program and we do not expect any significant share repurchases during the remainder of 2004.

RETIREMENT BENEFITS

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

	Defined Benefit Pension Plans			
	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
	(Dollars in millions)			
Components of net periodic benefit cost				
Service cost	\$ 61.5	\$ 46.9	\$ 120.7	\$ 93.8
Interest cost	71.1	66.7	142.0	133.4
Expected return on plan assets	(97.6)	(95.0)	(194.8)	(190.0)
Amortization of prior service cost.	2.2	1.9	4.4	3.8
Recognized actuarial loss	21.1	12.1	42.0	24.2
Net periodic benefit cost	\$ 58.3	\$ 32.6	\$ 114.3	\$ 65.2
	Retiree Health Benefit Plans			
	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
	(Dollars in millions)			
Components of net periodic benefit cost				
Service cost	\$ 10.3	\$ 13.0	\$ 22.1	\$ 26.0
Interest cost	15.4	17.2	32.8	34.4
Expected return on plan assets	(14.7)	(13.9)	(29.4)	(27.8)
Amortization of prior service cost.	(3.9)	(3.9)	(7.8)	(7.8)
Recognized actuarial loss	12.6	12.8	29.2	25.6
Net periodic benefit cost	\$ 19.7	\$ 25.2	\$ 46.9	\$ 50.4

We previously disclosed in our consolidated financial statements for the year ended December 31, 2003, that we expected to contribute approximately \$26.0 million to our defined benefit pension plans in 2004 to satisfy minimum funding requirements and an additional \$300.0 million and \$125.0 million of discretionary funding for our defined benefit pension plans and postretirement health benefit plans, respectively. We confirm these full-year 2004 minimum and discretionary funding expectations. As of June 30, 2004, a total of \$30.8 million of contributions has been made to these plans.

IMPLEMENTATION OF NEW FINANCIAL ACCOUNTING PRONOUNCEMENTS

In 2003, the Financial Accounting Standards Board (FASB) issued FASB Interpretation (FIN) 46, Consolidation of Variable Interest Entities. FIN 46 defines a variable interest entity (VIE) as a corporation, partnership, trust, or any other legal structure that does not have equity investors with a controlling financial interest or has equity investors that do not provide sufficient financial resources for the entity to support its activities. FIN 46 requires consolidation of a VIE by the primary beneficiary of the assets, liabilities, and results of activities. FIN 46 also requires certain disclosures by all holders of a significant variable interest in a VIE that are not the primary beneficiary. We do not have any material investments in variable interest entities; therefore, the adoption of this interpretation in the first quarter of 2004 had no material impact on our consolidated financial position or results of operations.

On May 19, 2004, the FASB issued FASB Staff Position (FSP) 106-2, which provides guidance regarding the 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.

## 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, inflammatory diseases, and critical care as well as 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. Although we do not anticipate any significant adjustments, to the extent that our estimates used in the purchase accounting need to be refined, we will do so upon making that determination but not later than one year from the date of acquisition.

	<b>Estimated Fair Value at February 12, 2004</b>
	<b>(Dollars in millions)</b>
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	<u>\$442.8</u>

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.

## ASSET IMPAIRMENTS, RESTRUCTURING, AND OTHER SPECIAL CHARGES

As part of our ongoing strategic review of our manufacturing and research and development strategies, we made decisions during the second quarter of 2004 that resulted in the impairment of certain assets. This review did not result in any closure of facilities or layoffs, but certain assets located at various sites were affected. We have ceased using these assets, their carrying value was written down to zero, and all the assets are being disposed of or their destruction has commenced. The asset impairment charges incurred in the second quarter of 2004 aggregated \$108.9 million and are included in asset impairments, restructuring, and other special charges in our consolidated condensed income statement.

Similarly, in the first quarter of 2003, management approved global manufacturing strategies across our product portfolio to improve plant performance and efficiency, including the outsourcing of production of certain anti-infective products. These decisions resulted in the impairment of certain assets, primarily manufacturing assets in the U.S. This review did not result in any closure of facilities, but certain assets located at various manufacturing sites were affected. We have ceased using these assets and all these assets have been disposed of or their destruction has commenced. The impairment charges were necessary to adjust the carrying value of these assets to zero. These asset impairment charges incurred in the first quarter of 2003 totaled \$114.6 million and are included in asset impairments, restructuring, and other special charges in our consolidated condensed statement of income.

In December 2002, we initiated a plan of eliminating approximately 700 positions worldwide in order to streamline our infrastructure. While a substantial majority of affected employees were successfully placed in other positions in the company, severance expenses were incurred in the first quarter of 2003 for those employees who elected a severance package. The restructuring and other special charges incurred in the first quarter of 2003 were \$52.5 million, consisting primarily of voluntary severance expenses, which have been included in asset impairments, restructuring, and other special charges in our consolidated condensed statement of income. All this charge has been expended.

In August 2001, we licensed from Isis Pharmaceuticals, Inc. (Isis), Affinitak™, a non-small-cell lung cancer drug candidate, and entered into an agreement regarding an ongoing research collaboration. In conjunction with this agreement, we purchased approximately 4.2 million shares of Isis common stock with a cost basis of approximately \$68.0 million and we committed to loan Isis \$100 million over the four-year term of the research agreement. The Isis loan is repayable at the end of the research agreement term in cash or Isis stock, at Isis's option, using a conversion price of \$40 per share. In addition, we committed to loan Isis \$21.2 million for the building of a manufacturing suite for Affinitak. On March 17, 2003, we announced, along with Isis, the results of the Phase III trial that evaluated Affinitak when combined with chemotherapy in patients with advanced non-small-cell lung cancer. No difference was observed in the overall survival of the two groups. Due to this announcement and the decline in Isis's stock price that occurred in the previous 12 months, we concluded in the first quarter of 2003 that our investment in Isis common stock was other-than-temporarily impaired as defined by generally accepted accounting principles. For the same reasons, it was probable that the value of the consideration that we will be eligible to receive from Isis pursuant to the terms of the loan agreements will be less than the carrying amount of the loans. Therefore, in the first quarter of 2003, we recognized an impairment in our investment in Isis common stock of \$55.0 million and a reserve related to the loans of \$92.9 million. In addition, we recognized a charge of \$38.9 million for contractual obligations related to Affinitak. The primary portion of this charge resulted from our supply agreement with Isis. The supply agreement obligated us to pay certain costs associated with work-in-process and raw materials and other costs that were triggered when we canceled our order of Affinitak. The remaining portion of the charge resulted from our contractual obligations related to the conduct of Affinitak clinical trials. Substantially all our contractual obligations have been fulfilled. The stock and loan impairments and other special charges incurred in the first quarter of 2003 related to this relationship totaled \$186.8 million and have been included in the asset impairments, restructuring, and other special charges category in our consolidated condensed statement of income.

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

#### OPERATING RESULTS

##### Executive Overview

##### I. Financial Summary

Net income was \$656.9 million, or \$.60 per share, for the second quarter of 2004 compared with \$692.2 million, or \$.64 per share, for the second quarter of 2003, representing decreases in earnings and earnings per share of 5 percent and 6 percent, respectively. Net income and earnings per share in the second quarter of 2004 were affected by sales growth that was more than offset by costs of goods sold and research and development expenses increasing at a rate greater than sales, as well as the asset impairment

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charges of \$108.9 million discussed above. Net income was \$1.06 billion, or \$.97 per share, for the first half of 2004 compared with \$1.10 billion, or \$1.02 per share, for the first half of 2003, representing decreases in net income and earnings per share of 4 percent and 5 percent, respectively. Net income and earnings per share for the first six months of 2004 were driven by the same factors affecting the second quarter of 2004, as well as the acquired IPR&D charges and related tax effects attributable to the AME acquisition.

Comparisons between the three- and six-month periods ended June 30, 2004 and 2003, are influenced by the following items that are reflected in our operating results (see Notes to Consolidated Condensed Financial Statements for additional information).

### **2004**

- We recognized asset impairment charges of \$108.9 million (pretax), which decreased earnings per share by \$.08 in the second quarter of 2004.
- We incurred a charge for acquired IPR&D of \$362.3 million (no tax benefit) related to the acquisition of AME, which decreased earnings per share by \$.33 in the first quarter of 2004.

### **2003**

- We streamlined our infrastructure in the first quarter of 2003, resulting in severance-related and other charges of \$52.5 million (pretax), which decreased earnings per share by \$.03.
- We recognized asset impairments, primarily relating to manufacturing assets in the U.S., totaling \$114.6 million (pretax) in the first quarter of 2003, which decreased earnings per share by \$.07.
- Separately, we recognized asset impairments and other charges of \$186.8 million (pretax) in the first quarter of 2003 related primarily to our common stock ownership and loan agreements with Isis, which decreased earnings per share by \$.13.

## **II. Recent Product Launches and Late-Stage Product Pipeline Developments**

- We are in the process of rolling out the global launches of seven important products, indications, or formulations – Alimta®, Cialis®, Forteo®, Strattera®, Symbyax™, Zyprexa IntraMuscular, and Zyprexa for bipolar maintenance.
- Duloxetine for the treatment of moderate-to-severe stress urinary incontinence (SUI) in women was recommended for approval by the European Committee for Medicinal Products for Human Use in March. Marketing authorization by the European Commission and subsequent launch of the product is expected later this year.
- The U.S. Food and Drug Administration (FDA) granted full approval in May for Gemzar®, in combination with paclitaxel, for the first-line treatment of patients with metastatic breast cancer.
- Evista was launched during May in Japan as the first selective estrogen receptor modulator for the treatment of osteoporosis in postmenopausal women. Evista was launched in Japan with Chugai Pharmaceutical Co. Ltd., our Japanese marketing partner.
- In late June, Lilly and Amylin Pharmaceuticals, Inc., submitted a New Drug Application to the FDA for regulatory approval of exenatide, the first in a new class of medicines known as incretin mimetics, for the treatment of type 2 diabetes.
- In early August, the FDA approved Cymbalta® for the treatment of major depressive disorder. Cymbalta acts as a reuptake inhibitor of serotonin and norepinephrine to treat the broad range of emotional and physical symptoms of depression. We expect to launch Cymbalta in the U.S. in late August.

## **III. Legal and Regulatory Matters**

- 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. We believe that the products involved include Prozac and Zyprexa.
- In May, the filing of posttrial briefs in the U.S. Zyprexa patent trial was completed. We continue to expect a ruling from the U.S. district court judge this summer.

Additional information regarding certain of these significant events is included in the Notes to Consolidated Condensed Financial Statements and elsewhere in Part I, Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations.

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Sales

Second-quarter and first-half 2004 sales growth of 15 percent and 16 percent, respectively, was primarily driven by increased sales of Zyprexa, Strattera, Evista, Forteo, and Gemzar. Sales in the U.S. increased by \$209.5 million, or 12 percent, and \$413.8 million, or 12 percent, for the second quarter and first half of 2004, respectively, compared with the respective periods of 2003. Sales outside the U.S. increased \$258.6 million, or 20 percent, and \$541.8 million, or 22 percent, for the second quarter and first half of 2004, respectively. Worldwide sales volume in the second quarter of 2004 increased 9 percent, while exchange rates and selling prices increased sales by 4 and 3 percent, respectively (numbers do not add due to rounding). Worldwide sales volume, exchange rates, and selling prices for the first half of 2004 increased 9 percent, 4 percent, and 2 percent, respectively (numbers do not add due to rounding).

The following tables summarize our net sales activity for the three- and six-month periods ended June 30, 2004 and 2003:

Product	Three Months Ended June 30, 2004			Three Months Ended June 30, 2003	Percent Change from 2003
	U.S. <sup>1</sup>	Outside U.S.	Total	Total	
	(Dollars in millions)				
Zyprexa	\$ 696.1	\$ 516.2	\$1,212.3	\$1,045.5	16
Gemzar	129.6	163.7	293.3	254.6	15
Humalog	180.1	105.2	285.3	254.1	12
Evista	170.9	105.7	276.6	223.5	24
Humulin	113.1	146.2	259.3	255.5	1
Animal health products	75.2	104.4	179.6	166.5	8
Strattera	177.3	1.3	178.6	74.8	NM
Fluoxetine products	69.3	60.5	129.8	175.0	(26)
Anti-infectives	29.8	88.8	118.6	116.0	2
Actos	83.9	28.5	112.4	116.3	(3)
ReoPro	53.4	48.4	101.8	94.5	8
Forteo	56.8	8.5	65.3	13.7	NM
Xigris	29.5	19.1	48.6	36.1	35
Cialis <sup>2</sup>	0.4	31.8	32.2	15.6	NM
Alimta	16.6	1.2	17.8	—	NM
Symbyax	7.9	—	7.9	—	NM
Other pharmaceutical products	86.5	150.4	236.9	246.5	(4)
Total net sales	<u>\$1,976.4</u>	<u>\$1,579.9</u>	<u>\$3,556.3</u>	<u>\$3,088.2</u>	<u>15</u>

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Product	Six Months Ended June 30, 2004			Six Months Ended June 30, 2003	Percent Change from 2003
	U.S. <sup>1</sup>	Outside U.S.	Total	Total	
(Dollars in millions)					
Zyprexa	\$1,317.0	\$ 993.6	\$2,310.6	\$2,003.8	15
Gemzar	257.7	314.6	572.3	488.5	17
Humalog	347.7	204.8	552.5	502.9	10
Evista	331.1	178.3	509.4	437.5	16
Humulin	222.2	286.5	508.7	496.5	2
Animal health products	144.6	217.4	362.0	339.3	7
Strattera	317.7	2.0	319.7	129.7	NM
Fluoxetine products	172.8	122.1	294.9	325.0	(9)
Actos	213.9	51.8	265.7	249.5	7
Anti-infectives	57.7	186.0	243.7	238.1	2
ReoPro	98.8	96.7	195.5	187.6	4
Forteo	93.5	12.6	106.1	17.8	NM
Xigris	61.8	35.4	97.2	72.0	35
Cialis <sup>2</sup>	0.7	64.8	65.5	20.5	NM
Symbyax	41.6	—	41.6	—	NM
Alimta	28.2	1.2	29.4	—	NM
Other pharmaceutical products	166.0	292.4	458.4	468.9	(2)
Total net sales	<u>\$3,873.0</u>	<u>\$3,060.2</u>	<u>\$6,933.2</u>	<u>\$5,977.6</u>	<u>16</u>

NM – Not meaningful

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

<sup>2</sup> Cialis had worldwide second-quarter and first-quarter 2004 sales of \$137.2 million and \$108.3 million, respectively, representing a sequential increase of 27 percent. The sales shown in the tables 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-Symbyax franchise sales increased 17 percent, to \$1.22 billion, in the second quarter of 2004 compared with the second quarter of 2003 and 17 percent, to \$2.35 billion, in the first half of 2004 compared with the first half of 2003. Zyprexa sales in the U.S. increased 7 percent in the second quarter of 2004 compared with the second quarter of 2003, despite a decline in underlying demand due to continued competitive pressures. The increase in U.S. Zyprexa sales was due to a reduction in rebate reserves, primarily Medicaid, following a routine review, and also to wholesaler stocking during the second quarter of 2004. As previously described in our 2003 Annual Report on Form 10-K under Application of Critical Accounting Policies, we consider various factors in determining the appropriate accrual for Medicaid rebates, including our rebate payments as a percent of historical sales as well as any significant changes in sales trends, current Medicaid rebate laws and interpretations, the percent of our products that are sold to Medicaid recipients, and our product pricing and current rebate/discount contracts across all customer groups. As a result of our review of these factors in the second quarter of 2004, we determined that our Medicaid rebate reserves needed to be reduced. Excluding the reserve adjustment and wholesaler stocking, U.S. Zyprexa sales would have declined in the second quarter of 2004 compared with the second quarter of 2003. Zyprexa sales in the U.S. increased 5 percent in the first half of 2004 compared with the first half of 2003. Zyprexa sales outside the U.S. increased 31 percent and 33 percent, respectively, for the second quarter and first half of 2004, primarily driven by strong volume growth in a number of major markets due to the continued conversion of older antipsychotic agents to atypicals and the impact of foreign exchange rates. Excluding the impact of exchange rates, sales of Zyprexa outside the U.S. increased by 20 percent for both the second quarter and first half of 2004.

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

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condition. Second-quarter and first-half sales in 2004 were \$7.9 million and \$41.6 million, respectively. Sales in the first quarter of 2004 included approximately \$30 million of wholesaler stocking.

Diabetes care products, composed primarily of Humalog®, Humulin®, and Actos®, had worldwide net sales of \$674.9 million and \$1.36 billion in the second quarter and first half of 2004, respectively, an increase of 5 percent and 6 percent, respectively, compared with the same periods last year. Diabetes care revenues in the U.S. in the second quarter of 2004 decreased 1 percent, to \$391.5 million, while revenues outside the U.S. increased 16 percent, to \$283.4 million. For the first half of 2004, diabetes care revenues in the U.S. decreased 1 percent, to \$804.8 million, while revenues outside the U.S. increased 20 percent, to \$551.2 million. Humalog sales in the U.S. increased 11 percent and 5 percent for the quarter and six-month periods ended June 30, 2004, while sales outside the U.S. for the same periods increased 15 percent and 20 percent, respectively. Humulin sales in the U.S. decreased 9 percent for both the quarter and six-month period ended June 30, 2004, due to continuing competitive pressures, while sales outside the U.S. for the same periods increased 11 percent and 13 percent, respectively. Actos revenues, the majority of which represent service revenues from a copromotion agreement in the U.S. with Takeda Pharmaceuticals North America (Takeda), decreased 3 percent for the second quarter but increased 7 percent for the six-month period ended June 30, 2004. 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.

The growth in Gemzar sales in the second quarter of 2004 comprised a 2 percent decrease in the U.S. and a 34 percent increase outside the U.S. The decline in second-quarter 2004 U.S. Gemzar sales was a result of wholesaler destocking and competitive pressures. For the first half of 2004, Gemzar sales were essentially flat in the U.S. and increased 37 percent outside the U.S. In May 2004, the FDA approved Gemzar, in combination with paclitaxel, as a first-line treatment for metastatic breast cancer.

Evista sales in the U.S. increased 6 percent and 5 percent in the second quarter and first half of 2004, respectively. The U.S. sales growth was due to a price increase in the fourth quarter of 2003 and wholesaler destocking in the second quarter of 2003, offset partially by a decline in U.S. prescription volume resulting from continued declines in the postmenopausal osteoporosis prevention market and continued competitive pressures in the treatment segment. Evista sales outside the U.S. increased 68 percent and 44 percent in the second quarter and first half of 2004, respectively. We launched Evista in Japan in May 2004 for the treatment of osteoporosis in postmenopausal women. The significant increase in sales outside the U.S. in the second quarter of 2004 was primarily due to the launch in Japan and strong growth in a number of other major markets.

Strattera, the only nonstimulant medicine approved for the treatment of ADHD in children, adolescents, and adults, generated \$178.6 million of sales during the second quarter of 2004 compared with \$141.1 million of sales in the first quarter of 2004, representing a sequential increase of 27 percent. Strattera was launched in the U.S. in January 2003 and in the United Kingdom in July 2004.

Forteo, a treatment for severe osteoporosis, was launched in December 2002. Second-quarter 2004 sales were \$65.3 million compared with first-quarter 2004 sales of \$40.8 million, representing a sequential increase of 60 percent.

Xigris® had second-quarter 2004 sales growth of 17 percent in the U.S. compared with 2003, while sales outside the U.S. increased 75 percent during the same period. Xigris sales for the first half of 2004 increased 19 percent and 78 percent in the U.S. and outside the U.S., respectively.

Cialis was launched in the U.S. in December 2003. The \$137.2 million of worldwide Cialis sales in the second quarter of 2004 comprises \$32.2 million of sales in our territories, which are reported in our net sales, and \$105.0 million of sales in the joint-venture territories. The \$245.5 million of worldwide Cialis sales in the first half of 2004 comprises \$65.5 million of sales in our territories and \$180.0 million of sales in the joint-venture territories. Within the joint-venture territories, the U.S. sales of Cialis were \$50.8 million and \$83.6 million for the quarter and six months ended June 30, 2004, respectively.

Alimta, a treatment for malignant pleural mesothelioma, was launched in the U.S. in February 2004 and we have submitted Alimta for approval for second-line non-small-cell lung cancer (NSCLC) in the U.S. In July, the Oncologic Drugs Advisory Committee recommended to the FDA that accelerated approval be granted for Alimta for the second-line treatment of NSCLC. We anticipate FDA approval in the third quarter of 2004. In addition, the European Committee for Medicinal Products for Human Use recommended in June to the European Commission that approval be granted for Alimta, in combination with cisplatin, for the treatment for malignant pleural mesothelioma and, as a monotherapy, for second-line non-small-cell lung cancer. Marketing authorization by the European Commission for both indications is expected later this year.

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### Gross Margin, Costs, and Expenses

For the second quarter of 2004, gross margins declined 1.6 percentage points, to 77.6 percent of net sales, compared with the second quarter of 2003. For the first half of 2004, gross margins declined 1.1 percentage points, to 77.7 percent of net sales, compared with the first half of 2003. This decrease was due to investment in our manufacturing technical capabilities and capacity and the impact of foreign exchange rates, offset partially by a favorable product mix.

Operating expenses (the aggregate of research and development and marketing and administrative expenses) increased 17 percent and 18 percent for the second quarter and first half of 2004, respectively, compared with the same periods of 2003. Investment in research and development increased 26 percent, to \$684.2 million, and 24 percent, to \$1.33 billion, for the second quarter and first half of 2004, respectively, due to increased clinical trial and development expenses and increased incentive compensation and benefits expense. Marketing and administrative expenses increased 12 percent, to \$1.17 billion, and 14 percent, to \$2.23 billion, for the second quarter and first half of 2004, respectively, primarily attributable to selling and marketing expenses in support of the new and anticipated product launches, the impact of foreign exchange rates, and increased incentive compensation and benefits expense.

Interest expense declined despite an increase in our outstanding debt. This decline was caused by increased capitalization of our interest costs as more of our debt supported capital asset construction.

Net other income for the quarter and six-month period ended June 30, 2004, increased \$0.7 million, to \$49.1 million, and \$33.8 million, to \$121.5 million, respectively. The increase in the first half of 2004 was primarily due to income related to a previously assigned patent arrangement of \$30.0 million that was recognized in the first quarter of 2004 and the outlicensing of legacy products, offset partially by an increase in the net loss of the Lilly ICOS LLC joint venture, due primarily to increased marketing costs.

For the second quarter and first half of 2004, the effective tax rates were 21.6 percent and 27.3 percent, respectively, compared with 22.0 percent and 20.5 percent for the respective periods of 2003. The effective tax rate for the first half of 2004 was affected by the charge for acquired IPR&D related to the AME acquisition, which is not deductible for tax purposes.

### FINANCIAL CONDITION

As of June 30, 2004, cash, cash equivalents, and short-term investments totaled \$3.41 billion compared with \$3.71 billion at December 31, 2003. Cash flow from operations for the first half of 2004 of \$1.52 billion was more than offset by dividends paid of \$769.2 million and net capital expenditures of \$971.7 million. Total debt at June 30, 2004, was \$5.13 billion, an increase of \$245.4 million from December 31, 2003. The increase in debt was primarily due to the issuance of commercial paper.

In June 2004, we called for redemption \$825.0 million of long-term debt, effective in early August 2004. As a result, the debt was reclassified as a short-term borrowing on June 30, 2004. The redemption will be initially financed by the issuance of commercial paper.

We believe that cash to be generated from operations in 2004, along with available cash and cash equivalents, will be sufficient to fund most of our remaining 2004 operating needs, including debt service, capital expenditures, and dividends. We will likely issue additional debt in the remainder of 2004 to fund remaining cash requirements and to refinance some of our short-term borrowings. We believe that, if necessary, amounts available through existing commercial paper programs should be adequate to fund maturities of short-term borrowings. Various risks and uncertainties, including those discussed in the Other Matters and Financial Expectations for 2004 sections, may affect our operating results and cash generated from operations.

### OTHER 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 or not infringed. In April 2001, we filed suit against Zenith 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. We filed similar suits in the same court against Reddy in June 2001 and Teva in September 2002. The cases have been consolidated. A trial before a district court judge in Indianapolis was held in January and February of 2004. A ruling from the trial court is expected in the summer of 2004. Regardless of the trial court's ruling, we anticipate that appeals will follow. If we are unsuccessful at the trial court level, we cannot predict whether any of the generic companies would launch generic versions of Zyprexa prior to a final resolution of any

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appeals. We believe 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. An unfavorable outcome would 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, 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 and July 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. 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 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 Prozac and Zyprexa. We are cooperating with the U.S. Attorney in this investigation. It is possible that other Lilly products could become subject to these investigations. We continue to review and enhance policies and procedures designed to ensure that our marketing and promotional practices, physician communications, and remuneration of healthcare professionals comply with promotional laws and regulations. It is possible that the outcome of the above matters could include criminal charges and fines and/or civil penalties. We cannot predict or determine the outcome of the above 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.

### FINANCIAL EXPECTATIONS FOR 2004

For the third quarter of 2004, excluding unusual items, we expect earnings per share to be in the range of \$.67 to \$.68. Including the per-share impact of \$.33 for the acquired IPR&D charge related to the acquisition of AME in the first quarter of 2004 and asset impairments of \$.08 in the second quarter of 2004, we expect earnings per share for 2004 to be in the range of \$2.39 to \$2.44, excluding future unusual items. We are not currently aware of any material unusual items that will occur in the remainder of 2004. For the full-year 2004, we expect low double-digit sales growth. For Zyprexa, we expect continued strong international sales growth in the second half of 2004. In the U.S., Zyprexa's sales in the second half of 2004 are expected to decline compared with the second half of 2003. For the full-year 2004, we continue to anticipate worldwide sales growth for Zyprexa. In addition, for the full-year 2004, we expect gross margins as a percent of sales to decline approximately 1.5 percentage points compared with the prior year, marketing and administrative expenses to grow in the single digits, and research and development expenses to grow in the mid-teens. Further, we expect that other income/deductions (net other income less interest expense) will be approximately \$200 million to \$250 million for 2004. We expect the reported tax rate for 2004 to increase slightly from 2003, due to the nondeductibility of the acquired IPR&D charge related to the AME acquisition in the first quarter of 2004.

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; other regulatory developments and government investigations; and the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals. In particular, as described below under Legal Proceedings, certain generic pharmaceutical manufacturers have challenged our U.S. compound patent for Zyprexa. A trial court decision on the challenge is expected during the summer. If the decision is unfavorable and the generic companies launch generic olanzapine prior to resolution of appeals, our financial results would be very negatively affected.

### 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

Under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, we caution investors that any forward-looking statements or projections made by us, including those made in this document, are based on management's expectations at the time they are made, but they are subject to risks and uncertainties that may cause actual results to differ materially from those

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projected. Economic, competitive, governmental, technological, and other factors that may affect our operations and prospects are discussed above and in Exhibit 99 to this Form 10-Q filing. We have no obligation to update forward-looking statements.

### *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 June 30, 2004, and concluded that they are effective.

(b) *Changes in Internal Controls.* During the second quarter of 2004, 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 and a ruling is expected in the summer of 2004. Regardless of the outcome of the court's ruling, we anticipate that appeals will follow. If we are unsuccessful at the trial court level, it is possible that some of the generic manufacturers would launch generic versions of Zyprexa prior to a final resolution of the appeals. While we cannot predict or determine the outcome of this litigation, an unfavorable outcome would have a material adverse effect on our consolidated financial position, liquidity, and results of operations.

In 2002, the Office of Consumer Litigation, Department of Justice, instituted a grand jury investigation related to our U.S. marketing and promotional practices and physician communications with respect to Evista. That investigation is ongoing. In addition, 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 Prozac and Zyprexa. We are cooperating with the government in these investigations. It is possible that the outcome of these investigations could include criminal charges and fines and/or civil penalties. While we cannot predict or determine the outcome of these matters, it is possible that an adverse outcome could have a material adverse effect on our consolidated financial position, liquidity, and results of operations.

See Part I, Item 2, Other Matters, for more information on the above matters.

In October 2002, we were notified that Barr Laboratories, Inc., had submitted an ANDA with the U.S. Food and Drug Administration (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 method of use and pharmaceutical form (expiring from 2012 to 2017) are without merit. In June 2003, Barr added a challenge to one of our additional patents (expiring in 2017) claiming a component in the pharmaceutical form of Evista. That patent has been added to the lawsuit. The suit is in discovery and the trial is now scheduled to begin on February 13, 2006. 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.

We refer to Part I, Item 3, of our Form 10-K annual report for 2003 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 105 suits involving approximately 160 claimants. In the thimerosal litigation, we have been named as a defendant in approximately 325 suits with approximately 925 claimants.

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We have been named in approximately 60 product liability cases in the United States involving plaintiffs claiming 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. We are vigorously defending these suits. All the federal cases will be transferred to Judge Jack Weinstein in the Federal District Court for the Eastern District of New York for pretrial proceedings. Two motions 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.

In 2003, three counties in New York (Suffolk, Rockland, and Westchester) 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 July of 2004, Central Alabama Comprehensive Healthcare, Inc., in Alabama filed a similar suit relating to Public Health Service pricing. The suits seek monetary and other relief, including civil penalties and treble damages. The three New York county suits have been transferred to the U.S. District Court for the District of Massachusetts for pretrial proceedings (along with several other suits to which Lilly is not a party). The Suffolk County case is now the subject of a pending motion to dismiss, and the Rockland and Westchester cases are stayed pending the resolution of that motion. While we are vigorously defending these cases, given their early procedural stage, we cannot predict or determine the outcome of this litigation, and therefore we can provide no assurance that we will prevail.

We, along with several other pharmaceutical companies, have been named in five cases in Minnesota and one case in New Jersey alleging that the conduct of pharmaceutical companies in preventing commercial importation of prescription drugs from outside the United States violated antitrust laws. While we intend to vigorously defend these suits, 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 above with respect to the Zyprexa and Evista patent litigation and the marketing and promotional practices investigations, 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. Changes in Securities, Use of Proceeds, and Issuer Purchases of Equity Securities*

The following table summarizes the activity related to repurchases of our equity securities during the six-month period ended June 30, 2004:

<b>Period</b>	<b>Total Number of Shares Purchased (a)</b>	<b>Average Price Paid per Share (b)</b>	<b>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (c)</b>	<b>Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (d)</b>
	<b>(in thousands)</b>			<b>(Dollars in millions)</b>
January 2004	11	\$69.25	—	\$920.0
February 2004	73	71.90	—	920.0
March 2004	44	65.62	—	920.0
April 2004	20	67.08	—	920.0
May 2004	17	69.71	—	920.0
June 2004	9	72.62	—	920.0
<b>Total</b>	<b>174</b>			

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 June 30, 2004, we have purchased \$2.08 billion related to this program. During the first half of 2004, no shares were repurchased pursuant to this program and we do not expect to purchase any shares under this program during the remainder of 2004.

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### *Item 6. Exhibits and Reports on Form 8-K*

(a) Exhibits. The following documents are filed as exhibits to this Report:

EXHIBIT 10.1	Lilly Deferred Compensation Plan
EXHIBIT 10.2	Change in Control Severance Pay Plan for Select Employees (amended and restated effective July 1, 2004)
EXHIBIT 10.3	2007 Change in Control Severance Pay Plan for Select Employees
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

(b) Reports on Form 8-K.

We filed a Form 8-K on April 19, 2004, which furnished a copy of our press release announcing our first-quarter financial results as well as informing readers of our upcoming webcast to discuss our first-quarter financial results on the same date.

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 August 5, 2004

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

Date August 5, 2004

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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**The Lilly Deferred Compensation Plan**

(As Amended and Restated as of April 19, 2004)

**Section 1. Establishment of the Plan.**

There is hereby established for the benefit of Participants an unfunded plan of voluntarily deferred compensation known as “The Lilly Deferred Compensation Plan.”

**Section 2. Definitions.**

When used in the Plan, the following terms shall have the definitions set forth in this Section 2:

- 2.1. Base Salary. The term “Base Salary” means the base salary to which a management employee is entitled for services rendered to the Company as a management employee.
  - 2.2. Base Salary Year. The term “Base Salary Year” means each calendar year in which Base Salary deferred under the Plan is earned by a Participant.
  - 2.3. Beneficiary. The term “Beneficiary” means the beneficiary or beneficiaries (including any contingent beneficiary or beneficiaries) designated pursuant to subsection 6.2 hereof.
  - 2.4. Board of Directors. The term “Board of Directors” means the Board of Directors of Eli Lilly and Company.
  - 2.5. Bonus. The term “Bonus” means the payment to which an Eligible Employee is entitled pursuant to the Contingent Compensation Plan, the Senior Executive Bonus Plan or the Lilly Executive Bonus Plan (the EVA Bonus Plan) of the Company or any other similar compensation plan as may from time to time be designated by the Committee.
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2.6. Bonus Year. The term “Bonus Year” means each calendar year in which a Bonus deferred under the Plan is earned by a Participant.

2.7. Committee. The term “Committee” means the committee designated in subsection 9.1 hereof to administer the Plan.

2.8. Company. The term “Company” means Eli Lilly and Company and its affiliates and subsidiaries.

2.9. Company Credit. The term “Company Credit” means an amount computed and credited each calendar year or part thereof to Participants’ accounts as described in Section 5 at a rate that is equal to one hundred twenty percent (120%) of the applicable federal long-term rate, with compounding (as prescribed under Section 1274(d) of the Internal Revenue Code) that was in effect for the month of December immediately preceding the calendar year.

2.10. Disability. The term “Disability” means a condition that the Committee determines (i) is attributable to sickness, injury, or disease and (ii) renders a Participant incapable of engaging in any activity for remuneration or profit commensurate with the Participant’s education, experience, and training.

2.11. Eligible Employee. The term “Eligible Employee” means a management employee of the Company who is designated by the Committee as eligible to defer a Bonus earned in the following year.

2.12. Lilly. The term “Lilly” means Eli Lilly and Company.

2.13. Participant. The term “Participant” means an Eligible Employee who has elected to defer all or part of a Bonus pursuant to the Plan in accordance with Section 3.1 hereof or an SEC Executive Officer who has elected to defer all or part of Base Salary pursuant to the Plan in accordance with Section 3.2 hereof.

2.14. Plan. The term “Plan” means “The Lilly Deferred Compensation Plan” as set forth herein and as it may be amended from time to time.

2.15. Retirement. The term “Retirement” means the first day of the month next following the Participant’s last day of work for the Company, but only if such first day of the month occurs on or after the first to occur of (i) the day on which the Participant attains age 65 or (ii) the day on which the Participant is eligible to commence receiving a monthly retirement benefit under a retirement plan or program maintained by the Company and covering the Participant.

2.16. SEC Executive Officers. The term “SEC Executive Officers” shall mean those officers and employees from time to time designated as Executive Officers for purposes of the proxy statement and Form 10-K.

### **Section 3. Participation.**

3.1. Bonuses. Prior to the beginning of each Bonus Year, the Committee shall select those Eligible Employees who may elect to defer Bonuses pursuant to the Plan. Upon selection by the Committee and before the beginning of the applicable Bonus Year, an Eligible Employee may defer the receipt of a Bonus pursuant to the Plan by filing a written election with the Committee, in a form satisfactory to the Committee, that

- (i) defers payment of a designated amount (of One Thousand Dollars (\$1,000) or more) or percentage of the Bonus, if any, to be earned in the Bonus Year, and
- (ii) specifies the payment option selected by the Participant pursuant to subsection 6.1 hereof.

The amount deferred may not exceed the amount of the Bonus. Except as provided in subsections 6.1 and 6.3 hereof, any election made pursuant to this Section 3 (including any

election made pursuant to paragraphs (i) and (ii), above) with respect to a Bonus Year shall be irrevocable when made.

Selection of an Eligible Employee for deferral of a Bonus during one year does not confer upon the Eligible Employee a right to defer Bonuses for subsequent years. The Eligible Employees who shall be permitted to defer Bonuses pursuant to the Plan shall be selected annually by the Committee. If an Eligible Employee is also an SEC Executive Officer as of the beginning of the Bonus Year, the Eligible Employee may also defer the receipt of Base Salary as provided in Section 3.2.

3.2. Base Salary. Subject to the right of the Committee to limit deferrals described below, prior to the beginning of each Compensation Year, an SEC Executive Officer may defer the receipt of up to one hundred percent (100%) of Base Salary pursuant to the Plan by filing a written election with the Committee, in a form satisfactory to the Committee, that

- (i) defers payment of a designated amount of One Thousand Dollars (\$1,000) or more or a percentage of Base Salary, and
- (ii) specifies the payment option selected by the Participation pursuant to subsection 6.1 hereof.

The amount deferred may not exceed the amount of Base Salary. Except as provided in subsections 6.1 and 6.3 hereof, any election made pursuant to this Section 3 (including any election made pursuant to paragraphs (i) and (ii), above) with respect to a Bonus Year shall be irrevocable when made and shall not be affected by the Participant's ceasing to be an SEC Executive Officer after the beginning of the Bonus Year.

The Committee reserves the right to limit the amount of Deferrals of Base Salary to assure that the Company has sufficient funds to cover taxes, benefit payments, and other necessary and appropriate deductions.

**Section 4. Individual Account.**

The Treasurer of Lilly shall maintain an account in the name of each Participant. In the year following the Bonus Year or Base Salary Year, each Participant's account shall be credited, as of the first day of the month in which Bonuses or Base Salary are paid, with the amount that the Participant has elected to defer hereunder. Each Participant shall be given an annual statement, as of December 31 of each year, showing for each year (i) the amount of Bonuses or Base Salary deferred and (ii) the amount of the Company Credit to the Participant's account.

**Section 5. Accrual of Company Credit.**

The Treasurer of Lilly shall determine the applicable annual rate of Company Credit on or before December 31 of each calendar year. This rate shall be effective for the following calendar year. The Company Credit shall accrue monthly, at one-twelfth of the applicable annual rate, on all amounts credited to the Participant's account, including the Company Credits for prior years. The Company Credit shall not accrue on any amount distributed to the Participant (or to the Participant's Beneficiary) during the month for which the accrual is determined, except where an amount is distributed to a Beneficiary in the month of the Participant's death. The Company Credit for each year shall be credited to each Participant's account as of December 31 of that year and shall be compounded annually.

**Section 6. Payment.**

6.1. Payment Options. The Participant shall select a payment election from the payment options described below. A Participant may elect that his final payment election control over all prior payment elections. The payment option selected by a Participant shall provide for payment to the Participant of the amount credited to the Participant's account in

- (i) a lump sum in January of the second calendar year following the calendar year in which the Participant's employment terminates by reason of Retirement or Disability; or
- (ii) annual installments over a period of two to ten years commencing in January of the second calendar year following the calendar year in which the Participant's employment terminates by reason of Retirement or Disability;

provided, that in no event shall a lump sum be paid or installment payments begin under any payment option before the first January that begins after any Bonus that has been deferred under the payment option has been determined. The Company shall pay the aggregate amounts deferred, together with a proportionate part of the aggregate Company Credit accrued to the date (or dates) of payment, in the manner and on the date(s) specified by the Participant. If a payment option described in paragraph (i), above, has been elected, the amount of the lump sum shall be equal to the amount credited to the Participant's account as of the December 31 next preceding the date of the payment. If the payment option described in paragraph (ii), above, has been elected, the amount of each installment shall be equal to the amount credited to the Participant's account as of the December 31 next preceding the date of the installment payment divided by the number of installment payments that have not yet been made. If the Participant fails to elect a payment option, the amount credited to the Participant's account shall be distributed in a lump sum in accordance with the payment option described in paragraph (i), above. If the amount credited to the Participant's account is less than \$25,000 at any time following the year in which the Participant's employment terminates by reason of Retirement or Disability, the Committee, in its sole discretion, may pay out the amount credited to the Participant's account in a lump sum.

6.2. Payment upon Death. Within a reasonable period of time following the death of a Participant, the balance in the Participant's account shall be paid in a lump sum to the Participant's Beneficiary. For purposes of this subsection 6.2, the balance in the Participant's account shall be determined as of the date of payment. A Participant may designate the Beneficiary, in writing, in a form acceptable to the Committee, and filed with the Committee

before the Participant's death. A Participant may, before the Participant's death, revoke a prior designation of Beneficiary and may also designate a new Beneficiary without the consent of the previously designated Beneficiary, provided that such revocation and new designation (if any) are in writing, in a form acceptable to the Committee, and filed with the Committee before the Participant's death. If the Participant does not designate a Beneficiary, or if no designated Beneficiary survives the Participant, any amount not distributed to the Participant during the Participant's life shall be paid to the Participant's estate in a lump sum in accordance with this subsection 6.2.

6.3. Resignation or Dismissal. Within a reasonable time following termination of a Participant's employment by resignation or dismissal, the balance in the Participant's account shall be paid in a lump sum to the Participant. For purposes of this subsection 6.3, the balance in the Participant's account shall be determined as of a date determined by the Committee in its sole discretion.

6.4. Payment on Unforeseeable Emergency. The Administrator may, in its sole discretion, direct payment to a Participant of all or of any portion of the Participant's Account balance, notwithstanding an election under Section 6.1. above, at any time that it determines that such Participant has an unforeseeable emergency and then only to the extent reasonably necessary to meet the emergency. For purposes of this rule, "unforeseeable emergency" means severe financial hardship to the Participant resulting from a sudden and unexpected illness or accident of the Participant or of a dependent of the Participant, loss of the Participant's property due to casualty, or other similar extraordinary and unforeseeable circumstances arising as a result of events beyond the control of the Participant. The circumstances that will constitute an unforeseeable emergency will depend upon the facts of each case, but, in any case, payment may not be made to the extent that such hardship is or may be relieved —

- (i) Through reimbursement or compensation by insurance or otherwise,

(ii) By liquidation of the Participant's assets, to the extent the liquidation of such assets would not itself cause severe financial hardship, or

(iii) By cessation of deferrals under the Plan.

Examples of what are not considered to be unforeseeable emergencies include the need to send a Participant's child to college or the desire to purchase a home.

6.5. Cash Payments. All payments under the Plan shall be made in cash.

**Section 7. Prohibition Against Transfer.**

The right of a Participant to receive payments under the Plan may not be transferred except by will or applicable laws of descent and distribution. A Participant may not assign, sell, pledge, or otherwise transfer any amount to which he is entitled hereunder prior to transfer or payment thereof to the Participant.

**Section 8. Participant's Rights Unsecured.**

The Plan is unfunded. The right of any Participant to receive payments under the Plan shall be an unsecured claim against the general assets of the Company.

**Section 9. Administration.**

9.1. Committee. The Plan shall be administered by the Compensation and Management Development Committee of the Board of Directors, the members of which shall be selected by the Board of Directors from among its members. No member of the Committee may be a salaried employee of the Company.

9.2. Powers of the Committee. The Committee's powers shall include, but not be limited to, the power

- (i) to select Eligible Employees for participation in the Plan,
- (ii) to interpret the terms and provisions of the Plan and to determine any and all questions arising under the Plan, including, without limitation, the right to remedy possible ambiguities, inconsistencies, or omissions by a general rule or particular decision,
- (iii) to adopt rules consistent with the Plan, and
- (iv) to limit the deferrals of SEC Executive Officers to assure that the Company has sufficient funds to cover taxes, benefit payments, and other necessary or appropriate deductions.

9.3. Finality of Committee Determinations. Determinations by the Committee and any interpretation, rule, or decision adopted by the Committee under the Plan or in carrying out or administering the Plan shall be final and binding for all purposes and upon all interested persons, their heirs, and personal representatives.

9.4. Claims Procedures. Any person making a claim for benefits hereunder shall submit the claim in writing to the Committee. If the Committee denies the claim in whole or in part, it shall issue to the claimant a written notice explaining the reason for the denial and identifying any additional information or documentation that might enable the claimant to perfect the claim. The claimant may, within 60 days of receiving a written notice of denial, submit a written request for reconsideration to the Committee, together with a written explanation of the basis of the request. The Committee shall consider any such request and shall provide the claimant with a written decision together with a written explanation thereof. All interpretations, determinations, and decisions of the committee in respect of any claim shall be final and conclusive.

9.5. Withholding. The Company shall have the right to deduct from all payments hereunder any taxes required by law to be withheld from such payments. The recipients of such payments shall bear all taxes on amounts paid under the Plan to the extent that no taxes are withheld thereon, irrespective of whether withholding is required.

9.6. Incapacity. If the Committee determines that any person entitled to benefits under the Plan is unable to care for his or her affairs because of illness or accident, any payment due (unless a duly qualified guardian or other legal representative has been appointed) may be paid for the benefit of such person to such person's spouse, parent, brother, sister, or other party deemed by the Committee to have incurred expenses for such person.

9.7. Inability to Locate. If the Committee is unable to locate a person to whom a payment is due under the Plan for a period of twelve (12) months, commencing with the first day of the month as of which the payment becomes payable, the total amount payable to such person shall be forfeited.

9.8. Legal Holidays. If any day on (or on or before) which action under the Plan must be taken falls on a Saturday, Sunday, or legal holiday, such action may be taken on (or on or before) the next succeeding day that is not a Saturday, Sunday, or legal holiday; provided, that this subsection 9.8 shall not permit any action that must be taken in one calendar year to be taken in any subsequent calendar year.

**Section 10. No Employment Rights.**

No provision of the Plan or any action taken hereunder by the Company, the Board of Directors, or the Committee shall give any person any right to be retained in the employ of the Company, and the right and power of the Company to dismiss or discharge any Participant is specifically reserved.

**Section 11. Amendment, Suspension, and Termination.**

The Board of Directors shall have the right to amend, suspend, or terminate the Plan at any time. The Committee shall also have the right to amend the Plan, except for subsection 9.1 hereof and this Section 11.

**Section 12. Applicable Law.**

The Plan shall be governed by, and construed in accordance with, the laws of the State of Indiana, except to the extent that such laws are preempted by Federal law.

**Section 13. Effective Date.**

This amendment and restatement of the Plan is effective as of January 1, 2004. Nothing herein shall invalidate or adversely affect any previous election, designation, deferral, or accrual in accordance with the terms of the Plan that were then in effect.

**ELI LILLY AND COMPANY**  
**CHANGE IN CONTROL SEVERANCE PAY PLAN**  
**FOR SELECT EMPLOYEES**  
**(amended and restated effective July 1, 2004)**

**1. PURPOSE**

This Eli Lilly and Company Change in Control Severance Pay Plan For Select Employees has been established by the Company to provide for the payment of severance pay and benefits to Eligible Employees whose employment with a Participating Employer terminates due to certain conditions created by a Change in Control of the Company. The purpose of the Plan is to assure a continuity in operations of the Company during a period of Change in Control by allowing employees to focus on their responsibilities to the Company knowing that they have certain financial security in the event of their termination of employment. The accomplishment of this purpose is in the best interests of the Company and its shareholders. The Plan was originally adopted by the Board on March 1, 1995, was amended and restated by action of the Board effective as of October 15, 2001, and was subsequently amended and restated by action of the Board effective as of July 1, 2004.

**2. DEFINITIONS**

The terms defined in this Section 2 shall have the meanings given below:

- (a) "Annual Base Salary" means the amount of the Eligible Employee's Monthly Base Salary multiplied by twelve (12).
  - (b) "Board" means the Board of Directors of the Company.
  - (c) "Change in Control" has the meaning given in Section 3.
  - (d) "Code" means the Internal Revenue Code of 1986, as amended.
  - (e) "Committee" means the Compensation Committee of the Board, or such other committee appointed by the Board to perform the functions of the Committee under the Plan, provided that at all times the Committee shall be constituted solely of directors who are Continuing Directors (as defined in Section 3) to the extent any such directors remain on the Board and are willing to serve in such capacity.
  - (f) "Covered Termination" has the meaning given in Section 6.
  - (g) "Company" means Eli Lilly and Company, an Indiana corporation.
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- (h) “Eligible Employee” means a Tier I Employee or a Tier II Employee.
- (i) “ERISA” means the Employee Retirement Income Security Act of 1974, as amended.
- (j) “Exchange Act” means the Securities Exchange Act of 1934, as amended.
- (k) “EVA Plan” means the Eli Lilly and Company EVA Bonus Plan, as in effect from time to time, or any similar bonus plan adopted by the Board.
- (l) “Monthly Base Salary” means an Eligible Employee’s gross monthly base salary before any deductions, exclusions or any deferrals or contributions under any Participating Employer plan or program, but excluding bonuses, incentive awards or compensation, employee benefits or any other non-salary form of compensation.
- (m) “Participating Employer” has the meaning given in Section 4.
- (n) “Plan” means this Eli Lilly and Company Change in Control Severance Pay Plan for Select Employees, as amended and restated as provided herein.
- (o) “Severance Multiple” means the number of years represented by the Severance Period for the Eligible Employee.
- (p) “Severance Period” means (i) in the case of Tier I Employees, the three (3) year period immediately following a Covered Termination and (ii) in the case of Tier II Employees, the two (2) year period immediately following a Covered Termination.
- (q) “Tier I Employees” and “Tier II Employees” have the meanings given in Section 5.

### **3. CHANGE IN CONTROL**

For purposes of the Plan, a “Change in Control” of the Company shall be deemed to have occurred upon:

- (a) the acquisition by any “person,” as that term is used in Sections 13(d) and 14(d) of the Exchange Act (other than (i) the Company, (ii) any subsidiary of the Company, (iii) any employee benefit plan or employee stock plan of the Company or a subsidiary of the Company or any trustee or fiduciary with respect to any such plan when acting in that capacity, or (iv) Lilly Endowment, Inc.) of “beneficial ownership,” as defined in Rule 13d-3 under the Exchange Act, directly or indirectly, of 15% or more of the shares of the Company’s capital stock the holders of which have general voting power under ordinary circumstances to elect at least a majority of the Board (or which would have such voting power but for the application of the Indiana Control Shares Statute) (“Voting Stock”); provided, however, that an acquisition of Voting Stock directly from the Company shall not constitute a Change in Control under this Section 3(a);

(b) the first day on which less than two-thirds of the total membership of the Board shall be Continuing Directors (as that term is defined in Article 13(f) of the Company's Articles of Incorporation);

(c) consummation of a merger, share exchange, or consolidation of the Company (a "Transaction"), other than a Transaction which would result in the Voting Stock of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than 60% of the Voting Stock of the Company or such surviving entity immediately after such Transaction;

(d) a complete liquidation of the Company or a sale or disposition of all or substantially all the assets of the Company, other than a sale or disposition of assets to any subsidiary of the Company;

(e) either (i) the Company shall have entered into a definitive agreement with any Person, which, if consummated, would result in a Change in Control as specified in paragraphs (a) through (d) of this Section 3 or (ii) any Person initiates a tender offer or exchange offer to acquire shares of the Voting Stock which, if consummated, would result in a Change in Control as specified in paragraphs (a) through (d) of this Section 3; provided, however, that if the Board shall make a final determination that such agreement, tender offer or exchange offer will not be consummated, the occurrence of any such event shall cease to constitute a Change in Control and the termination of employment of an Eligible Employee after such determination shall not be treated as a Covered Termination on the basis of such event; or

(f) the Board adopts a resolution to the effect that any Person has taken actions which, if consummated, would result in its having acquired effective control of the business and affairs of the Company; provided, however, that if the Board shall make a final determination that such actions will not be consummated, the occurrence of any such event shall cease to constitute a Change in Control and the termination of employment of an Eligible Employee after such determination shall not be treated as a Covered Termination on the basis of such event.

For purposes of this Section 3 only, the term "subsidiary" means a corporation or limited liability company of which the Company owns directly or indirectly fifty (50) percent or more of the voting power.

#### **4. PARTICIPATING EMPLOYERS**

**A. Designation of Participating Employers.** The Company and each subsidiary corporation of which the Company owns directly or indirectly one-hundred (100) percent of the voting power at the time of the Change in Control shall be Participating Employers under the Plan. In addition, the Committee may designate other affiliates of the Company as Participating Employers under the

Plan, from time to time and under such terms and conditions, as shall be specified by an action in writing by the Committee. Such terms and conditions may impose limitations on the extent to which any such affiliate participates in the Plan (including but not limited to the duration of any such participation), but shall not provide rights or benefits to Eligible Employees that are broader than those set forth in the Plan. Any entity that is a Participating Employer at the time of a Change in Control shall continue to be a Participating Employer following a Change in Control, and any person, firm or business that is a successor to the business or interests of a Participating Employer following a Change in Control shall be treated as a Participating Employer under the Plan.

**B. Limitations in Foreign Jurisdictions.** Notwithstanding the foregoing or anything elsewhere in the Plan to the contrary, the Committee shall have the discretionary authority, as specified below, to exclude from participation or limit the participation of any Participating Employer with respect to its Eligible Employees employed outside of the United States. The Committee shall exercise this authority only by an action in writing taken prior to a Change in Control on the basis of a good faith determination that, as a result of the specific effect of applicable local law or practice with respect to the Plan, it would be in the best interests of the Company to so exclude or limit such participation. In addition, to the extent specified by an action in writing prior to a Change in Control, the Committee may offset the benefits provided under the Plan to any such Eligible Employee by benefits under severance arrangements that exist by reason of applicable local law or practice.

## **5. ELIGIBLE EMPLOYEES**

The following individuals shall be eligible to participate in the Plan and shall be considered an Eligible Employee for all purposes hereunder:

(i) “Tier I Employees” - all executive officers (as defined in Rule 3b-7 under the Exchange Act) of the Company immediately prior to the Change in Control, and all employees immediately prior to the Change in Control who were members of the Senior Management Forum of the Company as of April 19, 2004; and

(ii) “Tier II Employees” - all employees of the Participating Employers (other than Tier I Employees) who are classified by the Company as G-6 level (Executive Director) or above (or any successor classifications) immediately prior to the Change in Control.

Any person who is an Eligible Employee in accordance with the foregoing shall continue to be an Eligible Employee (and shall retain his/her status as a Tier I or Tier II Employee for purposes of the Plan) notwithstanding any change in his/her position or classification following a Change in Control, subject to Section 6 hereof relating to certain terminations of employment. The Committee shall notify each Eligible Employee of his/her participation in the Plan and status as a Tier I or Tier II Employee at the time of the Change in Control.

## 6. COVERED TERMINATIONS

**A. General.** An Eligible Employee shall be treated as having suffered a “Covered Termination” hereunder if his/her employment is terminated, within a period of two (2) years immediately following the date of a Change in Control, by a Participating Employer other than for “Cause” or by the Eligible Employee for “Good Reason.”

For purposes of the foregoing, the time periods specified above within which a termination of employment may be treated as a Covered Termination shall commence on the date the Change in Control becomes effective and, with respect to a Change in Control under paragraphs (e) and (f) of Section 3, shall recommence (for the full applicable period) on the date of consummation of the underlying actions. For purposes of the Plan, a termination of employment shall be effective as of the last date of the Eligible Employee’s employment with the Participating Employer.

An Eligible Employee shall not be treated as having suffered a Covered Termination in the event of (1) death, (2) total disability (within the meaning of the Company’s Extended Disability Plan), (3) transfer of employment among Participating Employers (unless such transfer gives rise to a “Good Reason”), (4) involuntary termination by the Participating Employer for “Cause”, (5) voluntary termination by the Eligible Employee other than for Good Reason or (6) a termination of employment for any reason by either the Participating Employer or the Eligible Employee that does not occur during the time periods specified above.

**B. Termination For Cause.** For purposes hereof, the termination of an Eligible Employee’s employment shall be deemed to be a termination for “Cause” if as a result of:

(i) the willful refusal of the Eligible Employee to perform, without legal cause, his/her material duties to the Participating Employer, resulting in demonstrable economic harm to any Participating Employer, which the Eligible Employee has failed to cure after thirty (30) calendar days’ advance written notice from the Company; or

(ii) the conviction of the Eligible Employee by a court of competent jurisdiction of any crime (or the entering of a plea of guilty or nolo contendere to a charge of any crime) constituting a felony.

A termination for Cause shall be communicated to the Eligible Employee in writing by the Participating Employer and shall specify the provisions of the Plan and factual matters relied upon in making the Cause determination.

**C. Termination for Good Reason.** For purposes hereof, an Eligible Employee may terminate his/her employment for “Good Reason” as a result of:

(i) a material diminution in the nature or status of the Eligible Employee’s position, title, reporting relationship, duties, responsibilities or authority, or the assignment to him/her of additional responsibilities that materially increase his/her workload;

(ii) any reduction in the Eligible Employee’s then-current Monthly Base Salary;

(iii) a material reduction in the Eligible Employee's opportunities to earn incentive bonuses below those in effect for the year most recently completed before the date of the Change in Control, taking into account all material bonus factors such as targeted bonus amounts and corporate performance measures;

(iv) a material reduction in the Eligible Employee's employee benefits and coverages (including, without limitation, pension, profit sharing and all welfare, retiree welfare and fringe benefits) that are provided to the Eligible Employee from the benefit levels in effect immediately prior to the Change in Control;

(v) the failure to grant to the Eligible Employee stock options, performance shares or similar equity incentive rights during each twelve (12) month period following the Change in Control on the basis of a number of shares or units and all other material terms (including vesting requirements) at least as favorable to the Eligible Employee as those rights granted to him/her on an annualized average basis for the three (3) year period immediately prior to the Change in Control;

(vi) relocation of the Eligible Employee by more than fifty (50) miles from his/her regularly assigned workplace existing on the date of the Change in Control; or

(vii) any failure by a successor entity to the Company (including any entity that succeeds to the business or assets of the Company) in connection with a Change in Control to assume by operation of law or otherwise the obligations of the Company under the Plan, or any attempted amendment, termination or repudiation of the Plan by such successor entity, other than pursuant to the provisions of Section 14.

A termination for Good Reason shall be communicated to the Participating Employer in writing by the Eligible Employee and shall specify the provisions of the Plan and the factual matters relied upon in making the Good Reason determination.

## **7. SEVERANCE PAYMENT**

The amount of the severance payment to be received by an Eligible Employee whose employment is terminated under conditions constituting a Covered Termination shall equal the applicable Severance Multiple for the Eligible Employee multiplied by the sum of:

(i) the Eligible Employee's Annual Base Salary at the time of Covered Termination (calculated without regard to any reduction in Monthly Base Salary that results in a Good Reason termination) or, if greater, at the time of the Change in Control, *plus*

(ii) the greater of (a) the amount of the Eligible Employee's target annual cash incentive bonus for the year of Covered Termination or (b) the amount of the Eligible

Employee's annual cash incentive bonus earned for the year immediately prior to the Change in Control.

The severance payment to be made hereunder shall be paid to the Eligible Employee in a single lump-sum cash payment, less any required tax withholding, within fifteen (15) calendar days after the date of the Eligible Employee's Covered Termination. Any payment required under this Section 7 or any other provision of the Plan that is not made in a timely manner shall bear interest at a rate equal to one hundred twenty (120) percent of the monthly compounded applicable federal rate, as in effect under Section 1274(d) of the Code for the month in which the payment is required to be made.

#### **8. OTHER SEVERANCE BENEFITS**

In addition to the severance payment provided under Section 7, an Eligible Employee shall be entitled to the following benefits and other rights in the event of his/her Covered Termination:

**A. Welfare Benefits.** The Eligible Employee shall be entitled to continued coverage and benefits for the duration of the applicable Severance Period, at the Company's sole expense for coverage, under all employee welfare benefit plans (including, without limitation, medical, dental, group life, death benefit, dependent life, supplemental life, accidental death and dismemberment, short-term disability and long-term disability plans, health care reimbursement account and dependent day care reimbursement account) of a Participating Employer for which he/she was eligible at the time of Covered Termination (or, if it would provide benefits or other terms more favorable to the Eligible Employee, at the time of the Change in Control), as though his/her termination of employment had not occurred (the "Welfare Continuation Coverages"). All Welfare Continuation Coverages shall apply to the Eligible Employee and any of his/her dependents who would have been eligible for coverage if the Eligible Employee remained employed for the applicable Severance Period. The Company may provide the Eligible Employee with the Welfare Continuation Coverages under arrangements other than its generally applicable welfare benefit plans, provided that the benefit coverages so provided are at least as favorable to the Eligible Employee as coverage under the otherwise applicable Welfare Continuation Coverages, on a coverage by coverage basis, and taking into account all tax consequences to the Eligible Employee. At the expiration of the applicable Severance Period, the Eligible Employee shall be treated as a then terminating employee with respect to the right to elect continued medical and dental coverages in accordance with Section 4980B of the Code (or any successor provision thereto).

**B. Retiree Welfare Benefits.** Following a Covered Termination, the Participating Employer shall continue to provide to the Eligible Employee (subject to normal eligibility requirements as supplemented in the last sentence of this paragraph), and shall not be permitted to terminate or amend in any manner adverse to the Eligible Employee, all retiree medical and dental benefit plans ("Retiree Welfare Plans") that are in effect at the time of Covered Termination (or, if it would provide benefits or other terms more favorable to the Eligible Employee, at the time of the Change in Control). For purposes of determining eligibility for the Retiree Welfare Plans, the Eligible Employee shall receive additional credit for the number of years equal to the Severance Period

applicable to the Eligible Employee for purposes of both age and service requirements under the Retiree Welfare Plans.

**C. Pension Supplement.** The Eligible Employee shall be entitled to the additional pension benefits that would be payable to him/her, under all defined benefit pension plans of a Participating Employer in which he/she is participating at the time of Covered Termination (or, if it would provide benefits or other terms more favorable to the Eligible Employee, at the time of the Change in Control), including all such tax-qualified and supplemental plans, by taking into account under such plans (i) an additional number of years equal to the Severance Period applicable to the Eligible Employee for purposes of the age and service credit of the Eligible Employee under such plans and (ii) the amount of the severance payment to which the Eligible Employee is entitled under Section 7, expressed on an annualized basis for the number of years equal to the Severance Period applicable to the Eligible Employee, for purposes of the compensation credit of the Eligible Employee under such plans (but only to the extent such additional credit would produce a higher benefit for the Eligible Employee than if it were not taken into account). The additional pension benefits provided hereby shall be paid pursuant to a supplemental pension plan of the Company, at the same time and in the same form as pension benefits are otherwise payable to the Eligible Employee (subject to clause (iii) of Section 8.E).

**D. Equity Incentives.** Immediately upon a Covered Termination, (i) any stock options or similar equity-based incentive rights granted to the Eligible Employee under a stock incentive plan of a Participating Employer that are not then fully vested and exercisable shall become fully vested and immediately exercisable, (ii) the Eligible Employee shall be entitled to exercise any stock options or similar equity-based incentive rights until the expiration of their original full term (without regard to any earlier termination otherwise applicable in the event of termination of employment), and (iii) any performance shares or shares of restricted stock granted to the Eligible Employee under a stock incentive plan of a Participating Employer that remain subject to forfeiture, performance conditions or transfer restrictions at such time shall become fully and immediately vested and all such conditions and restrictions shall immediately lapse. In addition, as to any other types of equity-based incentive awards granted to the Eligible Employee under a stock incentive plan of a Participating Employer prior to the date of Covered Termination, any restrictions on exercise, payment or transfer shall immediately lapse, and the Eligible Employee shall have all rights associated with such awards as of the date of Covered Termination. The provisions of this Section 8.D shall apply equally to any awards or rights into which the equity incentive rights described herein are converted or for which such rights are substituted in connection with a Change in Control.

**E. Accrued Rights.** The Eligible Employee shall be entitled to the following payments and benefits in respect of accrued compensation rights at the time of a Covered Termination, in addition to all other rights provided under the Plan: (i) immediate payment of any accrued but unpaid Annual Base Salary through the date of Covered Termination; (ii) payment within fifteen (15) calendar days of Covered Termination of the accrued annual cash bonus for the year in effect on the date of the Covered Termination, determined on the basis of the bonus earned under terms of the applicable bonus plan through the date of termination or, if greater, the pro-rata amount of the target bonus for the period of such year through the date of termination; (iii) payment within fifteen (15) calendar days of Covered Termination of all non-tax-qualified deferred compensation

rights, in lieu of payment in respect of such rights that would otherwise be made at a later date in accordance with the terms of such arrangements, except to the extent such rights are funded by amounts held under an irrevocable grantor trust or other irrevocable commitment of funds by the Company; and (iv) all benefits and rights accrued under the employee benefit plans, fringe benefit programs and payroll practices of a Participating Employer (other than those described in clause (iii) above) in accordance with their terms (including, without limitation, employee pension, employee welfare, incentive bonus and stock incentive plans).

**F. EVA Plan.** Notwithstanding any provision of this Plan or the EVA Plan to the contrary, the following provisions of this Section 8.F shall apply with respect to any interest of an Eligible Employee under the EVA Plan, without duplication by any otherwise applicable provision of this Section 8. The Eligible Employee shall be entitled to the following payments within fifteen (15) days of a Covered Termination: (i) payment of the positive balance, if any, of the amount credited to his/her "Bonus Bank" (or similar bonus bank) under the EVA Plan immediately prior to the Covered Termination, and (ii) payment of the amount of his/her "Target Bonus Amount" (or similar target bonus) for the year in which the Covered Termination occurs, prorated for any partial year of service prior to the Covered Termination. The foregoing payments shall be made without offset of one against the other and without regard to any negative balance that may exist in the Bonus Bank immediately prior to the Covered Termination.

**G. Outplacement; Relocation.** The Eligible Employee shall be provided, at the Company's sole expense, with professional outplacement services selected by the Eligible Employee consistent with his/her duties or profession and of a type and level customary for persons in his/her position; provided, however, that the Company shall not be required to pay fees in connection with the foregoing in an amount greater than fifteen (15) percent of the Eligible Employee's Annual Base Salary for purposes of clause (i) of Section 7. The Company shall honor any prior agreement or understanding with an Eligible Employee who has suffered a Covered Termination to reimburse his/her relocation expenses to the Indianapolis, Indiana metropolitan area or, if it does not result in a greater cost to the Company, to such other location selected by the Eligible Employee.

**H. Indemnification.** With respect to any Eligible Employee who is, immediately prior to a Change in Control or a Covered Termination, indemnified by the Company for his/her service as a director, officer or employee of a Participating Employer, the Company shall indemnify such Eligible Employee to the fullest extent permitted by applicable law, and the Company shall maintain in full force and effect, for the duration of all applicable statute of limitation periods, insurance policies at least as favorable to the Eligible Employee as those maintained by the Company for the benefit of its directors and officers at the time of Change in Control, with respect to all costs, charges and expenses whatsoever (including payment of expenses in advance of final disposition of a proceeding) incurred or sustained by the Eligible Employee in connection with any action, suit or proceeding to which he/she may be made a party by reason of being or having been a director, officer or employee of a Participating Employer or serving or having served any other enterprise as a director, officer or employee at the request of a Participating Employer.

**I. Retention Bonuses and Loans.** Immediately upon a Covered Termination, there shall automatically be forgiven any repayment obligation of the Eligible Employee to the Participating Employer that arises under any retention bonus agreement, forgivable loan or similar

arrangement that provides for the lapse of the Eligible Employee's repayment obligation over time based on continued employment or other conditions (but not under any other loan obligations of the Eligible Employee that do not include forgiveness provisions).

#### **9. EXCISE TAX REIMBURSEMENT**

In the event it shall be determined that any payment, right or distribution by the Company or any other person or entity to or for the benefit of an Eligible Employee is a "parachute payment" within the meaning of Section 280G of the Code, pursuant to the terms of this Plan or otherwise, in connection with, or arising out of, his/her employment with a Participating Employer or a change in ownership or effective control of the Company or a substantial portion of its assets (a "Payment"), and would be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), concurrent with the making of such Payment, the Company shall pay to the Eligible Employee an additional payment (the "Gross-Up Payment") in an amount such that the net amount retained by the Eligible Employee, after deduction of any Excise Tax on such Payment and any federal, state or local income tax and Excise Tax on the Gross-Up Payment shall equal the amount of such Payment. In the event the Internal Revenue Service subsequently may assess or seek to assess from the Eligible Employee an amount of Excise Tax in excess of that determined in accordance with the foregoing, the Company shall pay to the Eligible Employee an additional Gross-Up Payment, calculated as described above in respect of such excess Excise Tax, including a Gross-Up Payment in respect of any interest or penalties imposed by the Internal Revenue Service with respect to such excess Excise Tax. The rights of the Eligible Employee to a Gross-Up Payment under this Section 9 shall apply without regard to whether the Eligible Employee has incurred a Covered Termination and shall apply to all payments whether or not in connection with a Covered Termination.

#### **10. NO MITIGATION OR OFFSET**

The Eligible Employee shall be under no obligation to minimize or mitigate damages by seeking other employment, and the obtaining of any such other employment shall in no event effect any reduction of the Company's obligation to make the payments and provide the benefits required under the Plan. In addition, the Company's obligation to make the payments and provide the benefits required under the Plan shall not be affected by any circumstances, including, without limitation, any set-off, counterclaim, recoupment, defense or other rights which a Participating Employer may have against the Eligible Employee.

#### **11. UNFUNDED STATUS**

The Plan is intended to constitute an employee pension benefit plan under ERISA which is unfunded and is maintained primarily for the purpose of providing deferred compensation for a select group of management or highly compensated employees, and shall be interpreted and administered accordingly. The payments and benefits provided hereunder shall be paid from the general assets of the Company. Nothing herein shall be construed to require the Company to

maintain any fund or to segregate any amount for the benefit of any employee, and no employee or other person shall have any right against, right to, or security or other interest in any fund, account or asset of the Company from which the payment pursuant to the Plan may be made. Consistent with the foregoing, the Company may, in its sole discretion, deposit funds in a grantor trust or otherwise establish arrangements to pay amounts that become due under the Plan, and, notwithstanding anything elsewhere in the Plan to the contrary, the payments and benefits due under the Plan shall be reduced to reflect the amount of any payment made in respect of any Eligible Employee from a grantor trust or other arrangement established for this purpose.

## **12. ADMINISTRATION**

The Committee shall be the named fiduciary of the Plan and the plan administrator for purposes of ERISA. The Committee shall be responsible for the overall operation of the Plan and shall have the fiduciary responsibility for the general operation of the Plan. The Committee may allocate to any one or more of the Company's employees any responsibility the Committee may have under the Plan and may designate any other person or persons to carry out any of the Committee's responsibilities under the Plan. As plan administrator, the Committee shall maintain records pursuant to the Plan's provisions and shall be responsible for the handling, processing and payment of any claims for benefits under the Plan.

## **13. CLAIMS AND DISPUTES**

Within fifteen (15) calendar days of a Covered Termination, the Company shall notify each Eligible Employee whom the Company determines is entitled to payments and benefits under the Plan of his/her entitlement to such payments and benefits. An Eligible Employee who is not so notified may submit a claim for payments and benefits under the Plan in writing to the Company within ninety (90) calendar days after becoming entitled to such benefits as described in Section 6. All such claims shall be approved or denied in writing by the Company within fifteen (15) calendar days after submission.

Any denial of a claim by the Company shall be in writing and shall include: (i) the reason or reasons for the denial; (ii) reference to the pertinent Plan provisions on which the denial is based; (iii) a description of any additional material or information necessary for the Eligible Employee to perfect the claim together with an explanation of why the material or information is necessary; and (iv) an explanation of the Plan's claim review procedure, described below.

An Eligible Employee shall have a reasonable opportunity to appeal a denied claim to the Company for a full and fair review. The Eligible Employee or authorized representative shall have sixty (60) calendar days after receipt of written notification of the denial of claim in which to request a review and to review pertinent documents of the Plan. The Company shall notify the Eligible Employee or his/her authorized representative of the time and place for the claim review. The Company shall issue a decision on the reviewed claim promptly, but no later than fifteen (15) calendar days after receipt of the request for review. The Company's decision shall be in writing

and shall include: (i) the reasons for the decision, and (ii) references to the Plan provisions on which the decision is based.

If the Eligible Employee shall dispute the Company's final decision, the dispute shall be submitted to an arbitration proceeding, conducted before a panel of three arbitrators, in accordance with the rules of the Center for Public Resources (or such other organization selected by mutual agreement of the Company and the Eligible Employee). Such arbitration shall take place in the location most practicably proximate to the Eligible Employee's principal workplace. Judgment may be entered on the arbitrators' award in any court having jurisdiction. Notwithstanding the foregoing, if an Eligible Employee believes the claims procedure or dispute resolution mechanism provided under this Section 13 would be futile or would cause such Eligible Employee irreparable harm, the Eligible Employee may, in his/her sole discretion, elect to enforce his/her rights under the Plan pursuant to Section 502 of ERISA.

The Company shall bear the expense of any enforcement proceeding brought by an Eligible Employee under the Plan and shall reimburse the Eligible Employee for all of his/her reasonable costs and expenses relating to such enforcement proceeding, including, without limitation, reasonable attorneys' fees and expenses, provided that the Eligible Employee is the prevailing party in such proceeding. For purposes hereof, the trier of fact in such enforcement proceeding shall be requested to make a determination as to the reimbursement of the Eligible Employee's costs and expenses as a prevailing party hereunder. In no event shall the Eligible Employee be required to reimburse the Company for any of the costs or expenses relating to such enforcement proceeding.

#### **14. TERM AND AMENDMENT**

The Plan became effective on March 1, 1995 (the "Effective Date") and, by action of the Board as contemplated by the Plan, shall terminate on March 1, 2007 (the "Expiration Date"). Notwithstanding the foregoing, in the event of a Change in Control, the Plan shall continue in effect, and the Expiration Date shall not occur, until the satisfaction of all severance payments and benefits to which Eligible Employees are or may become entitled to under the Plan. The Board shall have the right, by resolution or other written action, to amend the Plan; provided, however, that the Plan may only be amended prior to a Change in Control, and then only to the extent such amendment is of a technical or clarifying nature, or increases the rights or benefits of all affected Eligible Employees, and does not in any manner reduce the rights or benefits of any Eligible Employee, unless the Company has obtained the express written consent, in return for good and valuable consideration, of all affected Eligible Employees in respect of any such amendment.

#### **15. SUCCESSORS AND ASSIGNS**

The Plan shall be binding upon any person, firm or business that is a successor to the business or interests of the Company, whether as a result of a Change in Control of the Company or otherwise. All payments and benefits that become due to an Eligible Employee under the Plan shall inure to the benefit of his/her heirs, assigns, designees or legal representatives.

## **16. ENFORCEABILITY**

The Company intends the Plan to constitute a legally enforceable obligation between it and each Eligible Employee, and that the Plan confer vested rights on each Eligible Employee in accordance with the terms of the Plan, with each Eligible Employee being a third-party beneficiary thereof. Nothing in the Plan, however, shall be construed to confer on any Eligible Employee any right to continue in the employ of a Participating Employer or affect the right of a Participating Employer to terminate the employment or change the terms and conditions of employment of an Eligible Employee, with or without notice or cause, prior to a Change in Control, or to take any such action following a Change in Control, subject to the consequences specified by the Plan.

The Plan shall be construed and enforced in accordance with ERISA and the laws of the State of Indiana to the extent not preempted by ERISA, regardless of the law that might otherwise govern under applicable principles or provisions of choice or conflict of law doctrines. To the extent any provision of the Plan shall be invalid or unenforceable under any applicable law, it shall be considered deleted herefrom and all other provisions of the Plan shall be unaffected and shall continue in full force and effect.

**ELI LILLY AND COMPANY**  
**2007 CHANGE IN CONTROL SEVERANCE PAY PLAN**  
**FOR SELECT EMPLOYEES**

**1. PURPOSE**

This Eli Lilly and Company 2007 Change in Control Severance Pay Plan For Select Employees has been established by the Company to provide for the payment of severance pay and benefits to Eligible Employees whose employment with a Participating Employer terminates due to certain conditions created by a Change in Control of the Company. The purpose of the Plan is to assure a continuity in operations of the Company during a period of Change in Control by allowing employees to focus on their responsibilities to the Company knowing that they have certain financial security in the event of their termination of employment. The accomplishment of this purpose is in the best interests of the Company and its shareholders. The Plan replaces the Change in Control Severance Pay Plan for Select Employees that was originally adopted by the Board on March 1, 1995, and shall become operative immediately upon the expiration of such plan with respect to a Change in Control occurring on or after March 1, 2007.

**2. DEFINITIONS**

The terms defined in this Section 2 shall have the meanings given below:

- (a) "Base Salary" means an Eligible Employee's gross annualized rate of base salary at the time of any determination hereunder, before any deductions, exclusions or any deferrals or contributions under any Participating Employer plan or program, but excluding bonuses, incentive awards or compensation, employee benefits or any other non-salary form of compensation.
  - (b) "Board" means the Board of Directors of the Company.
  - (c) "Change in Control" has the meaning given in Section 3.
  - (d) "Code" means the Internal Revenue Code of 1986, as amended.
  - (e) "Committee" means the Compensation Committee of the Board, or such other committee appointed by the Board to perform the functions of the Committee under the Plan, provided that at all times the Committee shall be constituted solely of directors who are Continuing Directors (as defined in Section 3) to the extent any such directors remain on the Board and are willing to serve in such capacity.
  - (f) "Covered Termination" has the meaning given in Section 6.
  - (g) "Company" means Eli Lilly and Company, an Indiana corporation.
  - (h) "Eligible Employee" means a Tier I Employee or a Tier II Employee.
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(i) "ERISA" means the Employee Retirement Income Security Act of 1974, as amended.

(j) "Exchange Act" means the Securities Exchange Act of 1934, as amended.

(k) "Participating Employer" has the meaning given in Section 4.

(l) "Plan" means this Eli Lilly and Company 2007 Change in Control Severance Pay Plan for Select Employees.

(m) "Retirement Age" means the date the Eligible Employee reaches age 65, unless the Company's senior most officer responsible for the Human Resources department has approved a later date as the Retirement Age for the Eligible Employee.

(n) "Severance Multiple" means the number of years represented by the Severance Period for the Eligible Employee.

(o) "Severance Period" means (i) in the case of Tier I Employees, the three (3) year period immediately following a Covered Termination and (ii) in the case of Tier II Employees, the two (2) year period immediately following a Covered Termination.

(p) "Tier I Employees" and "Tier II Employees" have the meanings given in Section 5.

### **3. CHANGE IN CONTROL**

For purposes of the Plan, a "Change in Control" of the Company shall be deemed to have occurred upon:

(a) the acquisition by any "person," as that term is used in Sections 13(d) and 14(d) of the Exchange Act (other than (i) the Company, (ii) any subsidiary of the Company, (iii) any employee benefit plan or employee stock plan of the Company or a subsidiary of the Company or any trustee or fiduciary with respect to any such plan when acting in that capacity, or (iv) Lilly Endowment, Inc.) of "beneficial ownership," as defined in Rule 13d-3 under the Exchange Act, directly or indirectly, of 15% or more of the shares of the Company's capital stock the holders of which have general voting power under ordinary circumstances to elect at least a majority of the Board (or which would have such voting power but for the application of the Indiana Control Shares Statute) ("Voting Stock"); provided, however, that an acquisition of Voting Stock directly from the Company shall not constitute a Change in Control under this Section 3(a);

(b) the first day on which less than two-thirds of the total membership of the Board shall be Continuing Directors (as that term is defined in Article 13(f) of the Company's Articles of Incorporation);

(c) consummation of a merger, share exchange, or consolidation of the Company (a "Transaction"), other than a Transaction which would result in the Voting Stock of the

Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than 60% of the Voting Stock of the Company or such surviving entity immediately after such Transaction;

(d) a complete liquidation of the Company or a sale or disposition of all or substantially all the assets of the Company, other than a sale or disposition of assets to any subsidiary of the Company;

(e) either (i) the Company shall have entered into a definitive agreement with any Person, which, if consummated, would result in a Change in Control as specified in paragraphs (a) through (d) of this Section 3 or (ii) any Person initiates a tender offer or exchange offer to acquire shares of the Voting Stock which, if consummated, would result in a Change in Control as specified in paragraphs (a) through (d) of this Section 3; provided, however, that if the Board shall make a final determination that such agreement, tender offer or exchange offer will not be consummated, the occurrence of any such event shall cease to constitute a Change in Control and the termination of employment of an Eligible Employee after such determination shall not be treated as a Covered Termination on the basis of such event; or

(f) the Board adopts a resolution to the effect that any Person has taken actions which, if consummated, would result in its having acquired effective control of the business and affairs of the Company; provided, however, that if the Board shall make a final determination that such actions will not be consummated, the occurrence of any such event shall cease to constitute a Change in Control and the termination of employment of an Eligible Employee after such determination shall not be treated as a Covered Termination on the basis of such event.

For purposes of this Section 3 only, the term “subsidiary” means a corporation or limited liability company of which the Company owns directly or indirectly fifty (50) percent or more of the voting power.

#### **4. PARTICIPATING EMPLOYERS**

**A. Designation of Participating Employers.** The Company and each subsidiary corporation of which the Company owns directly or indirectly one-hundred (100) percent of the voting power at the time of the Change in Control shall be Participating Employers under the Plan. In addition, the Committee may designate other affiliates of the Company as Participating Employers under the Plan, from time to time and under such terms and conditions, as shall be specified by an action in writing by the Committee. Such terms and conditions may impose limitations on the extent to which any such affiliate participates in the Plan (including but not limited to the duration of any such participation), but shall not provide rights or benefits to Eligible Employees that are broader than those set forth in the Plan. Any entity that is a Participating Employer at the time of a Change in Control shall continue to be a Participating Employer following a Change in Control, and any person, firm or business that is a successor to the business or interests of a Participating Employer following a Change in Control shall be treated as a Participating Employer under the Plan.

**B. Limitations in Foreign Jurisdictions.** Notwithstanding the foregoing or anything elsewhere in the Plan to the contrary, the Committee shall have the discretionary authority, as

specified below, to exclude from participation or limit the participation of any Participating Employer with respect to individuals employed outside of the United States. The Committee shall exercise this authority only by an action in writing taken prior to a Change in Control on the basis of a good faith determination that, as a result of the specific effect of applicable local law or practice with respect to the Plan or severance benefits generally, it would be in the best interests of the Company to so exclude or limit such participation. In addition, to the extent specified by an action in writing prior to a Change in Control, the Committee may offset the benefits provided under the Plan to any such Eligible Employee by benefits under severance arrangements that exist by reason of applicable local law or practice.

## 5. ELIGIBLE EMPLOYEES

The following individuals shall be eligible to participate in the Plan and shall be considered an Eligible Employee for all purposes hereunder:

(i) "Tier I Employees" - means all executive officers (as defined in Rule 3b-7 under the Exchange Act) of the Company immediately prior to the Change in Control; and

(ii) "Tier II Employees" - means all employees of the Participating Employers, other than Tier I Employees, who are classified by the Company as G-6 level (Executive Director) or above (or any successor classifications) immediately prior to the Change in Control.

Any person who is an Eligible Employee in accordance with the foregoing shall continue to be an Eligible Employee (and shall retain his/her status as a Tier I or Tier II Employee for purposes of the Plan) notwithstanding any change in his/her position or classification following a Change in Control, subject to Section 6 hereof relating to certain terminations of employment. The Committee shall notify each Eligible Employee of his/her participation in the Plan and status as a Tier I or Tier II Employee prior to the Change in Control.

## 6. COVERED TERMINATIONS

**A. General.** An Eligible Employee shall be treated as having suffered a "Covered Termination" hereunder if his/her employment is terminated, within a period of two (2) years immediately following the date of a Change in Control, by a Participating Employer other than for "Cause" or by the Eligible Employee for "Good Reason."

For purposes of the foregoing, the two (2) year time period specified above within which a termination of employment may be treated as a Covered Termination shall commence on the date the Change in Control becomes effective and, with respect to a Change in Control under paragraphs (e) and (f) of Section 3, shall recommence (for the full applicable period) on the date of consummation of the underlying actions. For purposes of the Plan, a termination of employment shall be effective as of the last date of the Eligible Employee's employment with the Participating Employer.

An Eligible Employee shall not be treated as having suffered a Covered Termination in the event of (1) death, (2) total disability (within the meaning of the Company's Extended Disability Plan), (3)

transfer of employment among Participating Employers (unless such transfer gives rise to a “Good Reason”), (4) involuntary termination by the Participating Employer for “Cause”, (5) voluntary termination by the Eligible Employee other than for Good Reason, (6) a termination of employment for any reason by either the Participating Employer or the Eligible Employee that does not occur during the time periods specified above or (7) a termination of employment for any reason by either the Participating Employer or the Eligible Employee after the Eligible Employee reaches Retirement Age.

**B. Termination For Cause.** For purposes hereof, the termination of an Eligible Employee’s employment shall be deemed to be a termination for “Cause” if as a result of:

(i) the willful refusal of the Eligible Employee to perform, without legal cause, his/her material duties to the Participating Employer, resulting in demonstrable economic harm to any Participating Employer, which the Eligible Employee has failed to cure after thirty (30) calendar days’ advance written notice from the Company;

(ii) any act of fraud, dishonesty or gross misconduct of the Eligible Employee resulting in significant economic harm to any Participating Employer or other significant harm to the business reputation of any Participating Employer; or

(iii) the conviction of the Eligible Employee by a court of competent jurisdiction of any crime (or the entering of a plea of guilty or nolo contendere to a charge of any crime) constituting a felony.

A termination for Cause shall be communicated to the Eligible Employee in writing by the Participating Employer and shall specify the provisions of the Plan and factual matters relied upon in making the Cause determination.

**C. Termination for Good Reason.** For purposes hereof, an Eligible Employee may terminate his/her employment for “Good Reason” as a result of:

(i) a material diminution in the nature or status of the Eligible Employee’s position, title, reporting relationship, duties, responsibilities or authority, or the assignment to him/her of additional responsibilities that materially increase his/her workload;

(ii) any reduction in the Eligible Employee’s then-current Base Salary;

(iii) a material reduction in the Eligible Employee’s opportunities to earn incentive bonuses below those in effect for the year most recently completed before the date of the Change in Control, taking into account all material bonus factors such as targeted bonus amounts and corporate performance measures;

(iv) a material reduction in the Eligible Employee’s employee benefits and coverages (including, without limitation, pension, profit sharing and all welfare, retiree welfare and fringe benefits) that are provided to the Eligible Employee from the benefit levels in effect immediately prior to the Change in Control;

(v) the failure to grant to the Eligible Employee stock options, stock units, performance shares or similar incentive rights during each twelve (12) month period following the Change in Control on the basis of a number of shares or units and all other material terms (including vesting requirements) at least as favorable to the Eligible Employee as those rights granted to him/her on an annualized average basis for the three (3) year period immediately prior to the Change in Control;

(vi) relocation of the Eligible Employee by more than fifty (50) miles from his/her regularly assigned workplace existing immediately prior to the date of the Change in Control; or

(vii) any failure by a successor entity to the Company (including any entity that succeeds to the business or assets of the Company) in connection with a Change in Control to assume by operation of law or otherwise the obligations of the Company under the Plan, or any attempted amendment, termination or repudiation of the Plan by such successor entity, other than pursuant to the provisions of Section 15.

For purposes of the foregoing, but without limitation of the Eligible Employee's right to otherwise terminate employment for Good Reason, if the Eligible Employee is in charge of a principal business unit, division or function of the Company immediately prior to a Change in Control, Good Reason shall not be deemed to exist based solely on the fact that the Eligible Employee is not in charge of such principal business unit, division or function of the combined entity following the Change in Control, unless as a result thereof, the Eligible Employee suffers a material diminution in the nature or status of the Eligible Employee's position, title, reporting relationship, duties, responsibilities or authority or suffers some other Good Reason event.

A termination for Good Reason shall be communicated to the Participating Employer in writing by the Eligible Employee within thirty (30) days following his/her knowledge of the circumstances constituting Good Reason, and shall specify the provisions of the Plan and the factual matters relied upon in making the Good Reason determination. The Participating Employer shall have the opportunity to cure the circumstances constituting Good Reason within 15 days following receipt of the such written notice from the Eligible Employee, and if such circumstances are fully cured, such circumstances shall cease to constitute the basis for a Good Reason termination hereunder.

## **7. SEVERANCE PAYMENT**

The amount of the severance payment to be received by an Eligible Employee whose employment is terminated under conditions constituting a Covered Termination shall equal the applicable Severance Multiple for the Eligible Employee multiplied by the sum of:

(i) the Eligible Employee's Base Salary at the time of Covered Termination (calculated without regard to any reduction in Base Salary that results in a Good Reason termination) or, if greater, at the time of the Change in Control, *plus*

(ii) the greater of (a) the amount of the Eligible Employee's target annual cash incentive bonus for the year of Covered Termination or (b) the amount of the Eligible Employee's annual cash incentive bonus earned for the year immediately prior to the Change in Control.

The severance payment to be made hereunder shall be paid to the Eligible Employee in a single lump-sum cash payment, less any required tax withholding, within thirty (30) calendar days after the date of the Eligible Employee's Covered Termination. Any payment required under this Section 7 or any other provision of the Plan that is not made in a timely manner shall bear interest at a rate equal to one hundred twenty (120) percent of the monthly compounded applicable federal rate, as in effect under Section 1274(d) of the Code for the month in which the payment is required to be made.

#### **8. OTHER SEVERANCE BENEFITS**

In addition to the severance payment provided under Section 7, an Eligible Employee shall be entitled to the following benefits and other rights in the event of his/her Covered Termination:

**A. Welfare Benefits.** The Eligible Employee shall be entitled to continued coverage and benefits for the duration of the applicable Severance Period under the Participating Employer's medical and dental plans, group life insurance plans, company-provided death benefit, supplemental life insurance and long-term disability plans for which he/she was eligible at the time of Covered Termination (or, if it would provide benefits or other terms more favorable to the Eligible Employee, at the time of the Change in Control), as though his/her termination of employment had not occurred (the "Welfare Continuation Coverages"). All Welfare Continuation Coverages shall apply to the Eligible Employee and any of his/her dependents who would have been eligible for coverage if the Eligible Employee remained employed for the applicable Severance Period. The Company may provide the Eligible Employee with the Welfare Continuation Coverages under arrangements other than its generally applicable welfare benefit plans, provided that the benefit coverages so provided are at least as favorable to the Eligible Employee as coverage under the otherwise applicable Welfare Continuation Coverages, on a coverage by coverage basis, and taking into account all tax consequences to the Eligible Employee. At the expiration of the applicable Severance Period, the Eligible Employee shall be treated as a then terminating employee with respect to the right to elect continued medical and dental coverages in accordance with Section 4980B of the Code (or any successor provision thereto).

**B. Retiree Welfare Benefits.** For purposes of determining eligibility for the retiree medical and dental plans applicable to Eligible Employee (the "Retiree Welfare Plans"), the Eligible Employee shall receive additional credit for the number of years equal to the Severance Period applicable to the Eligible Employee for purposes of both age and service requirements under the Retiree Welfare Plans, but not beyond the Retirement Age of the Eligible Employee. If an Eligible Employee shall be eligible for participation in the Retiree Welfare Plans at the time of Covered Termination (including by reason of this Section 8.B.), then (i) for the Severance Period, he/she shall be entitled to continue to participate in either the Retiree Welfare Plans or the Welfare Continuation Coverage pursuant to Section 8.A. hereof, whichever provides greater benefits to the Eligible Employee on a coverage by coverage basis, and (ii) following the Severance Period, he/she shall be entitled to continue to participate in the retiree welfare benefit program provided to

retired employees of the Participating Employer generally, or if no such program is provided, the program of the successor entity following the Change in Control, if any.

**C. Pension Supplement.** The Eligible Employee shall be entitled to the additional pension benefits that would be payable to him/her, under all defined benefit pension plans of a Participating Employer in which he/she is participating at the time of Covered Termination (or, if it would provide benefits or other terms more favorable to the Eligible Employee, at the time of the Change in Control), including all such tax-qualified and supplemental plans, by taking into account under such plans (i) an additional number of years equal to the Severance Period applicable to the Eligible Employee for purposes of the age and service credit of the Eligible Employee under such plans and (ii) the amount of the severance payment to which the Eligible Employee is entitled under Section 7, expressed on an annualized basis for the number of years equal to the Severance Period applicable to the Eligible Employee, for purposes of the compensation credit of the Eligible Employee under such plans (but only to the extent such additional credit would produce a higher benefit for the Eligible Employee than if it were not taken into account). The additional pension benefits provided hereby shall be paid pursuant to a supplemental pension plan of the Company, at the same time and in the same form as pension benefits are otherwise payable to the Eligible Employee (subject to clause (iii) of Section 8.E). Notwithstanding the foregoing, the Eligible Employee will only receive additional age, service and compensation credit hereunder until his/her Retirement Age.

**D. Equity Incentives.** Immediately upon a Covered Termination, (i) any stock options, or similar equity-based incentive rights granted to the Eligible Employee under a stock incentive plan of a Participating Employer that are not then fully vested and exercisable shall become fully vested and immediately exercisable, (ii) the Eligible Employee shall be entitled to exercise any stock options or similar equity-based incentive rights until the expiration of three years following the date of the Covered Termination (or until such later date as may be applicable under the terms of the option or other right upon termination of employment), subject to the maximum full term of the option but without regard to any earlier termination otherwise applicable in the event of termination of employment, and (iii) any performance shares, stock units or shares of restricted stock granted to the Eligible Employee under a stock incentive plan of a Participating Employer that remain subject to forfeiture, performance conditions or transfer restrictions at such time shall become fully and immediately vested and all such conditions and restrictions shall immediately lapse. In addition, as to any other types of equity-based incentive awards granted to the Eligible Employee under a stock incentive plan of a Participating Employer prior to the date of Covered Termination, any restrictions on exercise, payment or transfer shall immediately lapse, and the Eligible Employee shall have all rights associated with such awards as of the date of Covered Termination. The provisions of this Section 8.D shall apply equally to any awards or rights into which the equity incentive rights described herein are converted or for which such rights are substituted in connection with a Change in Control.

**E. Accrued Rights.** The Eligible Employee shall be entitled to the following payments and benefits in respect of accrued compensation rights at the time of a Covered Termination, in addition to all other rights provided under the Plan: (i) immediate payment of any accrued but unpaid Base Salary through the date of Covered Termination; (ii) payment within fifteen (15) calendar days of Covered Termination of the accrued annual cash bonus for the year in effect on the date of the Covered Termination, determined on the basis of the bonus earned under terms of the applicable

bonus plan through the date of termination or, if greater, the pro-rata amount of the target annual cash bonus for the period of such year through the date of termination; (iii) payment within fifteen (15) calendar days of Covered Termination of all non-tax-qualified deferred compensation rights, in lieu of payment in respect of such rights that would otherwise be made at a later date in accordance with the terms of such arrangements, except to the extent such rights are funded by amounts held under an irrevocable grantor trust or other irrevocable commitment of funds by the Company; and (iv) all benefits and rights accrued under the employee benefit plans, fringe benefit programs and payroll practices of a Participating Employer (other than those described in clause (iii) above) in accordance with their terms (including, without limitation, employee pension, employee welfare, incentive bonus and stock incentive plans).

**F. Outplacement; Relocation.** The Eligible Employee shall be provided, at the Company's sole expense, with professional outplacement services selected by the Eligible Employee consistent with his/her duties or profession and of a type and level customary for persons in his/her position; provided, however, that the Company shall not be required to pay fees in connection with the foregoing in an amount greater than fifteen (15) percent of the Eligible Employee's Base Salary for purposes of clause (i) of Section 7. The Company shall honor any prior agreement or understanding with an Eligible Employee who has suffered a Covered Termination to reimburse his/her relocation expenses to the Indianapolis, Indiana metropolitan area or, if it does not result in a greater cost to the Company, to such other location selected by the Eligible Employee.

**G. Indemnification.** With respect to any Eligible Employee who is, immediately prior to a Change in Control or a Covered Termination, indemnified by the Company for his/her service as a director, officer or employee of a Participating Employer, the Company shall indemnify such Eligible Employee to the fullest extent permitted by applicable law, and the Company shall maintain in full force and effect, for the duration of all applicable statute of limitation periods, insurance policies at least as favorable to the Eligible Employee as those maintained by the Company for the benefit of its directors and officers at the time of Change in Control, provided that such insurance policies are commercially available from carriers of recognized standing, with respect to all costs, charges and expenses whatsoever (including payment of expenses in advance of final disposition of a proceeding) incurred or sustained by the Eligible Employee in connection with any action, suit or proceeding to which he/she may be made a party by reason of being or having been a director, officer or employee of a Participating Employer or serving or having served any other enterprise as a director, officer or employee at the request of a Participating Employer.

**H. Retention Bonuses and Loans.** Immediately upon a Covered Termination, there shall automatically be forgiven any repayment obligation of the Eligible Employee to the Participating Employer that arises under any retention bonus agreement, forgivable loan or similar arrangement that provides for the lapse of the Eligible Employee's repayment obligation over time based on continued employment or other conditions (but not under any other loan obligations of the Eligible Employee that do not include forgiveness provisions).

#### **9. EXCISE TAX REIMBURSEMENT**

(a) In the event it shall be determined that any payment, right or distribution by the Company or any other person or entity to or for the benefit of an Eligible Employee pursuant to

the terms of this Plan or otherwise, in connection with, or arising out of, his/her employment with a Participating Employer or a change in ownership or effective control of the Company or a substantial portion of its assets (a "Payment") is a "parachute payment" within the meaning of Section 280G of the Code on account of the aggregate value of the Payments due to the Eligible Employee being equal to or greater than three times the "base amount," as defined in Section 280G(b)(3) of the Code, (the "Parachute Threshold") so that the Eligible Employee would be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), concurrent with the making of such Payment, then (i) in the event the aggregate value of the Payments exceeds the Parachute Threshold by less than 3%, one or more Payments shall be reduced so that the aggregate value of the Payments is \$1.00 less than the Threshold Amount, or (ii) in the event that the aggregate value of the Payments exceeds the Parachute Threshold by 3% or more, the Company shall pay to the Eligible Employee an additional payment (the "Gross-Up Payment") in an amount such that the net amount retained by the Eligible Employee, after deduction of any Excise Tax on such Payments and any federal, state or local income tax and Excise Tax on the Gross-Up Payment shall equal the amount of such Payments. In the event the Internal Revenue Service subsequently may assess or seek to assess from the Eligible Employee an amount of Excise Tax in excess of that determined in accordance with the foregoing, the Company shall pay to the Eligible Employee an additional Gross-Up Payment, calculated as described above in respect of such excess Excise Tax, including a Gross-Up Payment in respect of any interest or penalties imposed by the Internal Revenue Service with respect to such excess Excise Tax. The rights of the Eligible Employee to a Gross-Up Payment under this Section 9 shall apply without regard to whether the Eligible Employee has incurred a Covered Termination and shall apply to all payments whether or not in connection with a Covered Termination.

(b) All determinations required to be made under this Section 9, including whether any Payment is a "parachute payment" and whether and when a Gross-Up Payment is required and the amount of such Gross-Up Payment and the assumptions to be utilized in arriving at such determination, shall be made by a nationally recognized accounting firm designated by the Company which is not the auditor of the Company or another party involved in the Change in Control (the "Accounting Firm") and shall be based upon "substantial authority" (within the meaning of Section 6662 of the Code). The Accounting Firm shall provide detailed supporting calculations both to the Company and the Eligible Employee within 15 business days of the receipt of notice from the Company or an Eligible Employee that there has been a Payment, or such earlier time as is requested by the Company. All fees and expenses of the Accounting Firm shall be borne by the Company. Any Gross-Up Payment, as determined pursuant to this Section 9, shall be paid by the Company to the Eligible Employee within five business days of the receipt of the Accounting Firm's determination. Any determination by the Accounting Firm shall be binding upon the Company and the Eligible Employee.

#### **10. RELEASE OF CLAIMS**

All payments and benefits that may be made to an Eligible Employee upon a Covered Termination under the Plan shall be contingent upon the Eligible Employee entering into a general release of employment law claims against the Company in substantially the form attached hereto as Exhibit A, subject to such modifications as may be determined by the Committee in good faith to take into account changes in employment laws or differences in employment laws in other jurisdictions.

## **11. NO MITIGATION OR OFFSET**

The Eligible Employee shall be under no obligation to minimize or mitigate damages by seeking other employment, and the obtaining of any such other employment shall in no event effect any reduction of the Company's obligation to make the payments and provide the benefits required under the Plan. Except as provided in Section 10, the Company's obligation to make the payments and provide the benefits required under the Plan shall not be affected by any circumstances, including, without limitation, any set-off, counterclaim, recoupment, defense or other rights which a Participating Employer may have against the Eligible Employee.

## **12. UNFUNDED STATUS**

The Plan is intended to constitute an employee pension benefit plan under ERISA which is unfunded and is maintained primarily for the purpose of providing deferred compensation for a select group of management or highly compensated employees, and shall be interpreted and administered accordingly. The payments and benefits provided hereunder shall be paid from the general assets of the Company. Nothing herein shall be construed to require the Company to maintain any fund or to segregate any amount for the benefit of any employee, and no employee or other person shall have any right against, right to, or security or other interest in any fund, account or asset of the Company from which the payment pursuant to the Plan may be made. Consistent with the foregoing, the Company may, in its sole discretion, deposit funds in a grantor trust or otherwise establish arrangements to pay amounts that become due under the Plan, and, notwithstanding anything elsewhere in the Plan to the contrary, the payments and benefits due under the Plan shall be reduced to reflect the amount of any payment made in respect of any Eligible Employee from a grantor trust or other arrangement established for this purpose.

## **13. ADMINISTRATION**

The Committee shall be the named fiduciary of the Plan and the plan administrator for purposes of ERISA. The Committee shall be responsible for the overall operation of the Plan and shall have the fiduciary responsibility for the general operation of the Plan. The Committee may allocate to any one or more of the Company's employees any responsibility the Committee may have under the Plan and may designate any other person or persons to carry out any of the Committee's responsibilities under the Plan. As plan administrator, the Committee shall maintain records pursuant to the Plan's provisions and shall be responsible for the handling, processing and payment of any claims for benefits under the Plan.

#### 14. CLAIMS AND DISPUTES

Within fifteen (15) calendar days following a Covered Termination, the Company shall notify each Eligible Employee whom the Company determines is entitled to payments and benefits under the Plan of his/her entitlement to such payments and benefits. An Eligible Employee who is not so notified may submit a claim for payments and benefits under the Plan in writing to the Company within ninety (90) calendar days after becoming entitled to such benefits as described in Section 6. All such claims shall be approved or denied in writing by the Company within fifteen (15) calendar days after submission.

Any denial of a claim by the Company shall be in writing and shall include: (i) the reason or reasons for the denial; (ii) reference to the pertinent Plan provisions on which the denial is based; (iii) a description of any additional material or information necessary for the Eligible Employee to perfect the claim together with an explanation of why the material or information is necessary; and (iv) an explanation of the Plan's claim review procedure, described below.

An Eligible Employee shall have a reasonable opportunity to appeal a denied claim to the Company for a full and fair review. The Eligible Employee or authorized representative shall have sixty (60) calendar days after receipt of written notification of the denial of claim in which to request a review and to review pertinent documents of the Plan. The Company shall notify the Eligible Employee or his/her authorized representative of the time and place for the claim review. The Company shall issue a decision on the reviewed claim promptly, but no later than fifteen (15) calendar days after receipt of the request for review. The Company's decision shall be in writing and shall include: (i) the reasons for the decision, and (ii) references to the Plan provisions on which the decision is based.

If the Eligible Employee shall dispute the Company's final decision, the dispute shall be submitted to an arbitration proceeding, conducted before a panel of three arbitrators, in accordance with the rules of the Center for Public Resources (or such other organization selected by mutual agreement of the Company and the Eligible Employee). Such arbitration shall take place in the location most practicably proximate to the Eligible Employee's principal workplace. Judgment may be entered on the arbitrators' award in any court having jurisdiction. Notwithstanding the foregoing, if an Eligible Employee believes the claims procedure or dispute resolution mechanism provided under this Section 14 would be futile or would cause such Eligible Employee irreparable harm, the Eligible Employee may, in his/her sole discretion, elect to enforce his/her rights under the Plan pursuant to Section 502 of ERISA.

The Company shall bear the expense of any enforcement proceeding brought by an Eligible Employee under the Plan and shall reimburse the Eligible Employee for all of his/her reasonable costs and expenses relating to such enforcement proceeding, including, without limitation, reasonable attorneys' fees and expenses, provided that the Eligible Employee is the prevailing party in such proceeding. For purposes hereof, the trier of fact in such enforcement proceeding shall be requested to make a determination as to the reimbursement of the Eligible Employee's costs and

expenses as a prevailing party hereunder. In no event shall the Eligible Employee be required to reimburse the Company for any of the costs or expenses relating to such enforcement proceeding.

#### **15. TERM AND AMENDMENT**

The Plan shall become effective as on July 1, 2004, but shall only be operative with respect to a Change in Control occurring on or after March 1, 2007, the date as of which the Plan as previously in effect shall have been terminated by action of the Board. The Plan shall continue to be effective until terminated in accordance with this Section 15. The Board shall have the right, by resolution or other written action, to terminate or amend the Plan; provided, however, that the Plan may only be terminated or amended prior to a Change in Control, and then only (i) with respect to an amendment or termination that becomes effective upon the second (2nd) anniversary of notice being given thereof to Eligible Employees generally, or (ii) to the extent any such amendment is of a technical or clarifying nature, or increases the rights or benefits of all affected Eligible Employees, and does not in any manner reduce the rights or benefits of any Eligible Employee, unless the Company has obtained the express written consent, in return for good and valuable consideration, of all affected Eligible Employees in respect of any such amendment. Notwithstanding the foregoing, in the event of a Change in Control, the Plan shall continue in effect, and no termination or amendment of the Plan shall occur, until the satisfaction of all severance payments and benefits to which Eligible Employees are or may become entitled to under the Plan. Upon the occurrence of a Change in Control during the term of the Plan, the Plan shall not be operative with respect to any subsequent Change in Control.

#### **16. SUCCESSORS AND ASSIGNS**

The Plan shall be binding upon any person, firm or business that is a successor to the business or interests of the Company, whether as a result of a Change in Control of the Company or otherwise. Any successor to the Company shall be required to assume the Plan in writing and honor the obligations of the Company and the Participating Employers hereunder. All payments and benefits that become due to an Eligible Employee under the Plan shall inure to the benefit of his/her heirs, assigns, designees or legal representatives.

#### **17. ENFORCEABILITY**

The Company intends the Plan to constitute a legally enforceable obligation between it and each Eligible Employee, and that the Plan confer vested rights on each Eligible Employee in accordance with the terms of the Plan, with each Eligible Employee being a third-party beneficiary thereof. Nothing in the Plan, however, shall be construed to confer on any Eligible Employee any right to continue in the employ of a Participating Employer or affect the right of a Participating Employer to terminate the employment or change the terms and conditions of employment of an Eligible Employee, with or without notice or cause, prior to a Change in Control, or to take any such action following a Change in Control, subject to the consequences specified by the Plan.

The Plan shall be construed and enforced in accordance with ERISA and the laws of the State of Indiana to the extent not preempted by ERISA, regardless of the law that might otherwise govern under applicable principles or provisions of choice or conflict of law doctrines. To the extent any provision of the Plan shall be invalid or unenforceable under any applicable law, it shall be considered deleted herefrom and all other provisions of the Plan shall be unaffected and shall continue in full force and effect.

## EXHIBIT 11. STATEMENT RE: COMPUTATION OF EARNINGS PER SHARE

(Unaudited)

Eli Lilly and Company and Subsidiaries

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
	(Dollars and shares in millions except per- share data)			
<b>BASIC</b>				
Net income	\$ 656.9	\$ 692.2	\$1,057.3	\$1,099.2
Average number of common shares outstanding	1,083.9	1,076.8	1,082.1	1,076.4
Basic earnings per share	\$ .61	\$ .64	\$ .98	\$ 1.02
<b>DILUTED</b>				
Net income	\$ 656.9	\$ 692.2	\$1,057.3	\$1,099.2
Average number of common shares outstanding	1,083.9	1,076.8	1,082.1	1,076.4
Incremental shares – stock options	6.8	5.6	6.8	5.8
Adjusted average shares	1,090.7	1,082.4	1,088.9	1,082.2
Diluted earnings per share	\$ .60	\$ .64	\$ .97	\$ 1.02

## EXHIBIT 12. STATEMENT RE: COMPUTATION OF RATIO OF EARNINGS FROM CONTINUING OPERATIONS TO FIXED CHARGES

(Unaudited)

Eli Lilly and Company and Subsidiaries  
(Dollars in millions)

	Six Months Ended June 30, 2004	Years Ended December 31,				
		2003	2002	2001	2000	1999
Consolidated pretax income from continuing operations	\$1,453.7	\$3,261.7	\$3,457.7	\$3,506.9	\$3,858.7	\$3,245.4
Interest from continuing operations and other fixed charges	66.4	121.9	140.0	253.3	225.4	213.1
Less interest capitalized during the period from continuing operations	(49.6)	(60.9)	(60.3)	(61.5)	(43.1)	(29.3)
Earnings	\$1,470.5	\$3,322.7	\$3,537.4	\$3,698.7	\$4,041.0	\$3,429.2
Fixed charges	\$ 66.4	\$ 121.9	\$ 140.0	\$ 253.3	\$ 225.4	\$ 213.2
Ratio of earnings to fixed charges	22.1	27.3	25.3	14.6	17.9	16.1

**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)) 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) 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
- c) 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 that 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: July 30, 2004

By: s/Sidney Taurel

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

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**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)) 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) 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
- c) 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 that 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: July 30, 2004

By: s/Charles E. Golden

Charles E. Golden  
Executive Vice President  
and Chief Financial Officer

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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 June 30, 2004 (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 July 30, 2004

s/Sidney Taurel

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Sidney Taurel

Chairman of the Board, President, and  
Chief Executive Officer

Date July 30, 2004

s/Charles E. Golden

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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-Q and may be made by spokespersons 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. One can also identify them by the fact that they do not relate strictly to historical or current facts. These statements 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, including new patented products or expanded indications for existing products introduced by competitors, which can lead to declining demand for our products; generic competition as patents on key products expire; and pricing pressures, both in the U.S. and abroad, primarily from managed care groups and government agencies
  - governmental factors, including federal, state, and foreign laws and regulations that affect pharmaceutical pricing, such as Medicaid, Medicare, pharmaceutical importation laws, and other laws and regulations that could, directly or indirectly, impose governmental controls on the prices at which our products are sold or that ease the approval process for generic products
  - the 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, 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, resulting in delays in product launches and lost market opportunity
  - unexpected safety or efficacy concerns arising with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals, or declining sales
  - changes in inventory levels maintained by pharmaceutical wholesalers that can cause reported sales for a particular period to differ significantly from underlying prescriber demand
  - 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, that could cause us to lose market exclusivity for, or preclude commercialization of, our products
  - regulatory issues concerning compliance with current Good Manufacturing Practice (cGMP) regulations for pharmaceutical products that 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, liabilities based on marketing and promotional practices or research practices, antitrust and pricing claims, and environmental matters
  - 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
  - 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, such as Latin America
  - 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
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- 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.