LILLY ELI & CO Form 10-Q August 04, 2006

#### 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, 2006 COMMISSION FILE NUMBER 001-6351 ELI LILLY AND COMPANY

(Exact name of Registrant as specified in its charter)

**INDIANA** 

35-0470950

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification No.)

INDIANA 46005

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 b No o

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer.

Large accelerated filer b 
Accelerated filer o 
Non-accelerated filer o

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

Yes o No b

The number of shares of common stock outstanding as of July 20, 2006:

Class Common Number of Shares Outstanding 1,130,398,796

## 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,		ed	Six Months En June 30,		nded
	2006	200	)5	2006		2005
		(Dollars in mi	llions, excep	t per-share	data)	
Net sales	\$3,866.	9 \$3,66	7.7 \$7	7,581.6	\$7	7,165.1
Cost of sales	860.	6 87	1.3	,667.1	1	1,730.3
Research and development	774.	8 76		,515.6		,464.6
Marketing and administrative	1,237.	9 1,14		2,380.8		2,236.5
Asset impairments, restructuring, and other special		•				
charges		1,07	3.4		1	,073.4
Other income net	(46.	9) (4	5.4)	(79.1)		(144.0)
	2,826.	4 3,80	7.8	5,484.4	6	5,360.8
Income (loss) before income taxes	1,040.	5 (14	0.1) 2	2,097.2		804.3
Income taxes	218.	5 11	1.9	440.4		319.7
Net income (loss)	\$ 822.	0 \$ (25	2.0) \$1	,656.8	\$	484.6
Earnings (loss) per share basic	\$ .7	6 \$ (	\$.23)	1.53	\$	.45
Earnings (loss) per share diluted	\$ .7	6 \$ (	.23) \$	1.53	\$	.44
Dividends paid per share	\$ .4	0 \$	.38 \$	.80	\$	.76
See Notes to Consolidated Condensed Financial Stateme	ents.					

## CONSOLIDATED CONDENSED BALANCE SHEETS Eli Lilly and Company and Subsidiaries

	June 30,	December 31,
	2006	2005
	(Dollars in	millions)
	(Unaudited)	
ASSETS		
CURRENT ASSETS	Φ 2 660 7	ф. 2.00 <i>с</i> <b>7</b>
Cash and cash equivalents	\$ 2,669.7	\$ 3,006.7
Short-term investments	1,921.0	2,031.0
Accounts receivable, net of allowances of \$64.9 (2006) and \$66.3 (2005)	2,101.8	2,313.3
Other receivables	415.0	448.4
Inventories	2,099.2	1,878.0
Deferred income taxes	648.9	756.4
Prepaid expenses	733.0	362.0
TOTAL CURRENT ASSETS	10,588.6	10,795.8
OTHER ASSETS		
Prepaid pension	2,360.8	2,419.6
Investments	1,287.8	1,296.6
Sundry	2,110.4	2,156.3
·		
	5,759.0	5,872.5
PROPERTY AND EQUIPMENT  Land buildings againment and construction in progress	13,568.1	13,136.0
Land, buildings, equipment, and construction-in-progress	·	•
Less allowances for depreciation	(5,480.1)	(5,223.5)
	8,088.0	7,912.5
	\$24,435.6	\$ 24,580.8
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES		
Short-term borrowings	\$ 738.6	\$ 734.7
Accounts payable	648.9	781.3
Employee compensation	374.1	548.8
Dividends payable	438.3	436.5
Income taxes payable	700.9	884.9
Other current liabilities	1,744.5	2,330.1
TOTAL CURRENT LIABILITIES	4,645.3	5,716.3
LONG-TERM DEBT	5,578.0	5,763.5
DEFERRED INCOME TAXES	759.4	695.1
OTHER NONCURRENT LIABILITIES	1,524.4	1,614.0
	1,02	1,011.0

Common stock	707.0	706.9
Additional paid-in capital	3,365.2	3,323.8
Retained earnings	10,817.6	10,027.2
Employee benefit trust	(2,635.0)	(2,635.0)
Deferred costs-ESOP	(103.7)	(106.3)
Accumulated other comprehensive loss	(120.0)	(420.6)
	12,031.1	10,896.0
Less cost of common stock in treasury	102.6	104.1
	11,928.5	10,791.9
	\$24,435.6	\$ 24,580.8

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 2006 2005 (Dollars in millions)	
CASH FLOWS FROM OPERATING ACTIVITIES  Net income	\$ 1,656.8	\$ 484.6
Adjustments to reconcile net income to cash flows from operating activities:	ψ 1,030.0	ψ +0+.0
Changes in operating assets and liabilities	(1,357.3)	(369.0)
Depreciation and amortization	414.0	317.4
Stock-based compensation expense	191.3	208.2
Change in deferred taxes	120.7	(175.9)
Asset impairments, restructuring, and other special charges, net of tax		979.7
Other, net	(83.3)	33.9
NET CASH PROVIDED BY OPERATING ACTIVITIES	042.2	1 479 0
NET CASH PROVIDED BY OPERATING ACTIVITIES	942.2	1,478.9
CASH FLOWS FROM INVESTING ACTIVITIES		
Net purchases of property and equipment	(392.1)	(619.9)
Net change in short-term investments	103.9	1,337.8
Purchase of noncurrent investments	(1,003.2)	(218.1)
Proceeds from sales and maturities of noncurrent investments	906.2	270.8
Other, net	126.9	(145.1)
NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES	(258.3)	625.5
CASH FLOWS FROM FINANCING ACTIVITIES		
Dividends paid	(864.6)	(821.2)
Purchases of common stock	(122.1)	,
Repayment of long-term debt	(100.1)	(94.0)
Issuances of common stock under stock plans	13.9	34.9
Net change in short-term borrowings	4.9	(1,791.9)
Other, net	.2	7.9
NET CASH USED IN FINANCING ACTIVITIES	(1,067.8)	(2,664.3)
	,	,
Effect of exchange rate changes on cash and cash equivalents	46.9	(163.0)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(337.0)	(722.9)
Cash and cash equivalents at January 1	3,006.7	5,365.3

## CASH AND CASH EQUIVALENTS AT JUNE 30

\$ 2,669.7

\$ 4,642.4

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,			ths Ended e 30,
	2006	2005	2006	2005
		(Dollars	in millions)	
Net income (loss)	\$822.0	\$(252.0)	\$1,656.8	\$ 484.6
Other comprehensive income (loss) <sup>1</sup>	170.5	(345.9)	300.7	(517.0)
Comprehensive income (loss)	\$992.5	\$(597.9)	\$1,957.5	\$ (32.4)

The significant components of other comprehensive income (loss) were gains of \$172.5 million and \$223.3 million from foreign currency translation adjustments for the three months and six months ended June 30, 2006, respectively, compared to losses from foreign currency translation adjustments of \$247.9 million and \$386.4 million for the three months and six months ended June 30, 2005, respectively.

Gains from cash flow hedges

were

\$11.5 million

and

\$78.3 million

for the three

months and six

months ended

June 30, 2006,

respectively,

compared to

losses of

\$104.7 million

and

\$114.3 million

from cash flow

hedges for the

three months

and six months

ended June 30,

2005,

respectively.

See Notes to

Consolidated

Condensed

Financial

Statements.

#### SEGMENT INFORMATION

We operate in one significant business segment—pharmaceutical products. Operations of our animal health business segment are not material and share many of the same economic and operating characteristics as our pharmaceutical products. Therefore, they are included with pharmaceutical products for purposes of segment reporting. Our business segments are distinguished by the ultimate end user of the product: humans or animals. Performance is evaluated based on profit or loss from operations before income taxes. Income before income taxes for the animal health business for the second quarter of 2006 and 2005 was \$40.9 million and \$47.3 million, respectively, and \$75.1 million and \$87.3 million for the six months ended June 30, 2006 and 2005, respectively.

#### SALES BY PRODUCT CATEGORY

Worldwide sales by product category for the three months and six months ended June 30, 2005 and 2004 were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2006	2005	2006	2005
Net sales to unaffiliated customers		(Dollars 1	n millions)	
Neurosciences	\$1,686.2	\$1,547.4	\$3,193.3	\$2,975.2
Endocrinology	1,231.2	1,141.8	2,459.8	2,286.5
Oncology	496.7	454.4	965.8	855.3
Animal health	201.0	201.0	399.3	396.5
Cardiovascular	127.5	155.7	270.6	323.8
Anti-infectives	69.6	112.8	157.5	222.0
Other pharmaceuticals	54.7	54.6	135.3	105.8
Net sales	\$3,866.9	\$3,667.7	\$7,581.6	\$7,165.1
	6			

## NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS BASIS OF PRESENTATION

We have prepared the accompanying unaudited consolidated condensed financial statements in accordance with the requirements of Form 10-Q and, therefore, they do not include all information and footnotes necessary for a fair presentation of financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States (GAAP). In our opinion, the financial statements reflect all adjustments (including those that are normal and recurring) that are necessary for a fair presentation of the results of operations for the periods shown. In preparing financial statements in conformity with GAAP, we must make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, and related disclosures at the date of the financial statements and during the reporting period. Actual results could differ from those estimates. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with our consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2005.

#### **CONTINGENCIES**

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

Dr. Reddy s Laboratories, Ltd. (Reddy), Teva Pharmaceuticals, and Zenith Goldline Pharmaceuticals, Inc., which was subsequently acquired by Teva Pharmaceuticals (together, Teva), each submitted abbreviated new drug applications (ANDAs) seeking permission to market generic versions of Zyprexa® prior to the expiration of our relevant U.S. patent (expiring in 2011) and alleging that this patent was invalid or not enforceable. We filed lawsuits against these companies in the U.S. District Court for the Southern District of Indiana, seeking a ruling that the patent is valid, enforceable and being infringed. The district court ruled in our favor on all counts on April 14, 2005. We are now awaiting a decision by the Court of Appeals for the Federal Circuit, which on April 6, 2006, heard Reddy s and Teva s respective appeals of this ruling. We are confident Reddy s and Teva s claims are without merit and we expect to prevail. 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 on appeal. An unfavorable outcome would have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

Barr Laboratories, Inc. (Barr), submitted an ANDA in 2002 seeking permission to market a generic version of Evistaâ prior to the expiration of our relevant U.S. patents (expiring in 2012-2017) and alleging that these patents are invalid, not enforceable, or not infringed. In November 2002, we filed a lawsuit against Barr in the U.S. District Court for the Southern District of Indiana, seeking a ruling that these patents are valid, enforceable, and being infringed by Barr. Teva has also submitted an ANDA seeking permission to market a generic version of Evista. In June 2006, we filed a lawsuit against Teva in the U.S. District Court for the Southern District of Indiana, seeking a ruling that our relevant U.S. patents (expiring in 2012-2014) are valid, enforceable, and being infringed by Teva. No trial date has been set in either case. We believe Barr s and Teva s claims are without merit and we expect to prevail. 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 could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

Sicor Pharmaceuticals, Inc. (Sicor), a subsidiary of Teva, submitted ANDAs in November 2005 seeking permission to market generic versions of Gemzar<sup>®</sup> prior to the expiration of our relevant U.S. patents (expiring in 2010 and 2013), and alleging that these patents are invalid. In February, we filed a lawsuit against Sicor in the U.S. District Court for the Southern District of Indiana, seeking a ruling that these patents are valid and are being infringed by Sicor. In response to our lawsuit, Sicor filed a declaratory judgment action in the U.S. District Court for the Central District of California. No trial date has been set in either matter. We believe Sicor s claims are without merit and we expect to prevail. 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 could have a material adverse impact on our consolidated results of operations. In March 2004, the office of the U.S. Attorney for the Eastern District of Pennsylvania advised us that it has commenced a civil investigation related to our U.S. marketing and promotional practices, including our communications with physicians and remuneration of physician consultants and advisors, with respect to Zyprexa, Prozac®, and Prozac Weekly . In October 2005, the U.S. Attorney s office advised that it is also conducting an inquiry regarding certain rebate agreements we entered into with a pharmacy benefit manager covering Axid®, Evista, Humalogâ, Humulinâ, Prozac, and Zyprexa. The inquiry includes a review of Lilly s Medicaid best price reporting related to the product sales covered by the rebate agreements. We are cooperating with the U.S. Attorney in these investigations, including providing a broad range of documents and information relating to the

investigations. In June 2005, we received a subpoena from the office of the Attorney General, Medicaid Fraud Control Unit, of the State of Florida, seeking production of documents relating to sales of Zyprexa and our marketing and promotional practices with respect to Zyprexa. It is possible that other Lilly products could become subject to investigation and that the outcome of these matters could include criminal charges and fines, penalties, or other monetary or nonmonetary remedies. We cannot predict or determine the outcome of these matters or reasonably estimate the amount or range of amounts of any fines or penalties that might result from an adverse outcome. It is possible, however, that an adverse outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position. We have implemented and continue to review and enhance a broadly based compliance program that includes comprehensive compliance-related activities designed to ensure that our marketing and promotional practices, physician communications, remuneration of health care professionals, managed care arrangements, and Medicaid best price reporting comply with applicable laws and regulations. We have been named as a defendant in a large number of Zyprexa product liability lawsuits in the United States and have been notified of many other claims of individuals who have not filed suit. The lawsuits and unfiled claims (together the claims ) allege a variety of injuries from the use of Zyprexa, with the majority alleging that the product caused or contributed to diabetes or high blood-glucose levels. The claims seek substantial compensatory and punitive damages and typically accuse us of inadequately testing for and warning about side effects of Zyprexa. Many of the claims also allege that we improperly promoted the drug. Almost all of the federal lawsuits are part of a Multi-District Litigation (MDL) proceeding before The Honorable Jack Weinstein in the Federal District Court for the Eastern District of New York (MDL No. 1596). The MDL includes three lawsuits requesting certification of class actions on behalf of those who allegedly suffered injuries from the administration of Zyprexa. We have entered into agreements with various plaintiffs counsel halting the running of the statutes of limitation (tolling agreements) with respect to a

Since June 2005, we have entered into agreements with various claimants attorneys involved in U.S. Zyprexa product liability litigation to settle a majority of the claims. The agreements cover approximately 10,500 claimants, including a large number of previously filed lawsuits (including the three purported class actions mentioned above), tolled claims, and other informally asserted claims. The settlements are being overseen and distributed by court-approved claims administrators. The agreements are subject to certain conditions, including obtaining full releases from a specified number of claimants.

number of claimants who do not have lawsuits on file.

The U.S. Zyprexa product liability claims not subject to these agreements include approximately 1,400 lawsuits in the U.S. covering approximately 7,600 claimants, and approximately 850 tolled claims. In addition, we have been served with a lawsuit seeking class certification in which the members of the purported class are seeking refunds and medical monitoring. Finally, in early 2005, we were served with four lawsuits seeking class action status in Canada on behalf of patients who took Zyprexa. One of these four lawsuits has been certified for residents of Quebec. The allegations in the Canadian actions are similar to those in the litigation pending in the United States. We are prepared to continue our vigorous defense of Zyprexa in all remaining cases.

In December 2004, we were served with two lawsuits brought in state court in Louisiana on behalf of the Louisiana Department of Health and Hospitals, alleging that Zyprexa caused or contributed to diabetes or high blood-glucose levels, and that we improperly promoted the drug. These cases have been removed to federal court and are now part of the MDL proceedings in the Eastern District of New York. In these actions, the Department of Health and Hospitals seeks to recover the costs it paid for Zyprexa through Medicaid and other drug-benefit programs, as well as the costs the department alleges it has incurred and will incur to treat Zyprexa-related illnesses. In 2006, we were served with similar lawsuits filed by the states of Alaska, West Virginia, and Mississippi in the courts of the respective states. In 2005, two lawsuits were filed in the Eastern District of New York purporting to be nationwide class actions on behalf of all consumers and third-party payors, excluding governmental entities, which have made or will make payments for their members or insured patients being prescribed Zyprexa. These actions have now been consolidated into a single lawsuit, which is brought under certain state consumer protection statutes, the federal civil RICO statute, and common law theories, seeking a refund of the cost of Zyprexa, treble damages, punitive damages, and attorneys fees. Four additional lawsuits were filed in 2006: two in the Eastern District of New York, one in the Southern District of Indiana, and one in Indiana state court, all on similar grounds. As with the product liability suits, these lawsuits

allege that we inadequately tested for and warned about side effects of Zyprexa and improperly promoted the drug. We have insurance coverage for a portion of our Zyprexa product liability claims exposure. The third-party insurance carriers have raised defenses to their liability under the policies and are seeking to rescind the policies. The dispute is now the subject of litigation in the federal court in Indianapolis against certain of the carriers and in arbitration in Bermuda against other carriers. While we believe our position is meritorious, there can be no assurance that we will prevail.

In addition, we have been named as a defendant in numerous other product liability lawsuits involving primarily diethylstilbestrol (DES) and thimerosal.

With respect to the product liability claims currently asserted against us, 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 product liability 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. Legal defense costs expected to be incurred in connection with significant product liability loss contingencies are accrued when probable and reasonably estimable. A portion of the costs associated with defending and disposing of these suits is covered by insurance. We record receivables for insurance-related recoveries when it is probable they will be realized. These receivables are classified as a reduction of the litigation charges on the statement of income. We estimate insurance recoverables based on existing deductibles, coverage limits, our assessment of any defenses to coverage that might be raised by the carriers, and the existing and projected future level of insolvencies among the insurance carriers.

In the second quarter of 2005, we recorded a net pre-tax charge of \$1.07 billion for product liability matters. The \$1.07 billion net charge takes into account our estimated recoveries from our insurance coverage related to these matters. The charge covers the following:

The cost of the Zyprexa settlements described above; and,

Reserves for product liability exposures and defense costs regarding currently known and expected claims to the extent we can formulate a reasonable estimate of the probable number and cost of the claims. A substantial majority of these exposures and costs relate to current and expected Zyprexa claims not included in the settlements. We have estimated these charges based primarily on historical claims experience, data regarding product usage, and our historical product liability defense cost experience.

During 2005, \$700.0 million was paid in connection with Zyprexa settlements, while the cash related to other reserves for product liability exposures and defense costs is expected to be paid out over the next several years, including 2006. The timing of our insurance recoveries is uncertain.

We cannot predict with certainty the additional number of lawsuits and claims that may be asserted. In addition, although we believe it is probable, there can be no assurance that the Zyprexa settlements described above will be concluded. The ultimate resolution of Zyprexa product liability and related litigation could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

Because of the nature of pharmaceutical products, it is possible that we could become subject to large numbers of product liability claims for other products in the future. We have experienced difficulties in obtaining product liability insurance due to a very restrictive insurance market, and therefore will be largely self-insured for future product liability losses. In addition, as noted above, there is no assurance that we will be able to fully collect from our insurance carriers on past claims.

In June 2002, we were sued by Ariad Pharmaceuticals, Inc., the Massachusetts Institute of Technology, the Whitehead Institute for Biomedical Research and the President and Fellows of Harvard College in the U.S. District Court for the District of Massachusetts alleging that sales of two of our products, Xigris® and Evista, were inducing the infringement of a patent related to the discovery of a natural cell signaling phenomenon in the human body and seeking royalties on past and future sales of these products. We believe that these allegations are without legal merit and that we will ultimately prevail on these issues. In June 2005, the United States Patent and Trademark Office commenced a re-examination of the patent in order to consider certain issues raised by us relating to the validity of the patent. A jury trial commenced in Boston on April 10, 2006 on the patent validity and infringement issues. On May 4, 2006, the jury issued an initial decision in the case that Xigris and Evista sales infringe the patent. The jury awarded the plaintiffs approximately \$65 million in damages, calculated by applying a 2.3 percent royalty to all U.S. sales of Xigris and Evista from the date of issuance of the patent through the date of trial. We will seek to have the jury verdict overturned by the trial court judge, and if unsuccessful, will appeal the decision to the Court of Appeals for the Federal Circuit. In addition, a separate bench trial with the U.S. District Court of Massachusetts is scheduled to begin on August 7, 2006, and will be held on our contention that the patent is unenforceable and will also consider the patent s improper coverage of natural processes.

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

The litigation accruals and environmental liabilities and the related estimated insurance recoverables have been reflected on a gross basis as liabilities and assets, respectively, on our consolidated balance sheets.

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

#### **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). Loss per-share amounts are presented based on a basic calculation; that is, based on the weighted-average number of outstanding common shares.

#### STOCK-BASED COMPENSATION

We adopted Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment (SFAS 123R), effective January 1, 2005. SFAS 123R requires the recognition of the fair value of stock-based compensation in net income. Stock-based compensation primarily consists of stock options and performance awards. We recognized pretax stock-based compensation cost in the amount of \$91.1 million and \$100.0 million in the second quarter of 2006 and 2005, respectively. In the first half of 2006 and 2005, we recognized stock-based compensation expense of \$191.3 million and \$208.2 million, respectively.

As of June 30, 2006, the total remaining unrecognized compensation cost related to nonvested stock options and performance awards amounted to \$183.4 million and \$102.4 million, respectively, which will be amortized over the weighted-average remaining requisite service periods, which are approximately 19 months and 6 months, respectively. Under our policy, all stock option awards are approved prior to the date of grant and the exercise price is the average of the high and low market price on the date of grant. The Compensation Committee of the Board of Directors approves the value of the award and the date of grant. All option awards for senior management are approved by the Compensation Committee. Options that are awarded as part of annual total compensation for senior management and other employees are made on specific grant dates scheduled in advance. With respect to option awards given to new hires, our policy requires approval of such awards prior to the grant date, and the options are granted on a pre-determined monthly date immediately following the date of hire.

#### **RETIREMENT BENEFITS**

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

	Defined Benefit Pension Plans				
	Three Months Ended June				
	3	0,	Six Months Ended June		
	2006	2005	2006	2005	
		(Dollars i	n millions)		
Components of net periodic benefit cost					
Service cost	\$ 68.8	\$ 74.3	\$ 138.1	\$ 154.4	
Interest cost	81.5	74.2	162.2	149.0	
Expected return on plan assets	(120.8)	(112.9)	(240.2)	(223.0)	
Amortization of prior service cost	1.5	1.9	2.9	3.9	
Recognized actuarial loss	32.8	26.0	63.1	52.2	
Net periodic benefit cost	\$ 63.8	\$ 63.5	\$ 126.1	\$ 136.5	
	10				

	Retiree Health Benefit Plans				
	Three Month	s Ended June			
	30,		Six Months Ended June 30,		
	2006	2005	2006	2005	
		(Dollars	in millions)		
Components of net periodic benefit cost					
Service cost	\$ 16.3	\$ 14.7	\$ 36.0	\$ 29.4	
Interest cost	24.4	20.0	48.8	40.1	
Expected return on plan assets	(23.0)	(18.7)	(45.0)	(35.7)	
Amortization of prior service cost	(3.9)	(4.0)	(7.7)	(8.0)	
Recognized actuarial loss	28.8	21.5	53.9	43.1	
Net periodic benefit cost	\$ 42.6	\$ 33.5	\$ 86.0	\$ 68.9	

In 2006, we expect to contribute approximately \$30 million to our defined benefit pension plans to satisfy minimum funding requirements for the year. In addition, we expect to contribute approximately \$140 million of additional discretionary funding in 2006 to our defined benefit plans. We also expect to contribute approximately \$90 million of discretionary funding to our postretirement health benefit plans during 2006. As of June 30, 2006, \$42.6 million of contributions have been made to these plans and the majority of our remaining expected contributions were made in early July 2006.

#### OTHER INCOME NET

Other income net, was comprised of the following:

		Three Months Ended June 30,		Six Months Ended June 30,	
	2006	2005	2006	2005	
		(Dollars	in millions)		
Interest expense	\$ 65.8	\$ 12.0	\$ 130.8	\$ 36.6	
Interest income	(68.4)	(46.3)	(128.1)	(92.3)	
Joint venture (income) loss	(22.5)	.5	(42.3)	13.1	
Other	(21.8)	(11.6)	(39.5)	(101.4)	
	\$(46.9)	\$(45.4)	\$ (79.1)	\$(144.0)	

The joint venture (income) loss represents our share of the Lilly ICOS LLC joint venture results of operations, net of income taxes.

#### SHAREHOLDERS EQUITY

As of June 30, 2006, we have purchased \$2.58 billion of our previously announced \$3.0 billion share repurchase program. During the six months ended June 30, 2006, we acquired 2.1 million shares pursuant to this program. We do not expect any share repurchases for the remainder of 2006.

#### IMPLEMENTATION OF NEW FINANCIAL ACCOUNTING PRONOUNCEMENTS

In the fourth quarter of 2005, we adopted Financial Accounting Standards Board (FASB) Interpretation (FIN) 47, Accounting for Conditional Asset Retirement Obligations, an interpretation of FASB Statement No. 143. FIN 47 requires us to record the fair value of a liability for conditional asset retirement obligations in the period in which it is incurred, which is adjusted to its present value each subsequent period. In addition, we are required to capitalize a corresponding amount by increasing the carrying amount of the related long-lived asset, which is depreciated over the useful life of the related long-lived asset. The adoption of FIN 47 on December 31, 2005, resulted in a cumulative effect of a change in accounting principle of \$22.0 million, net of income taxes of \$11.8 million.

In July 2006, the FASB issued FIN 48, Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The Interpretation is effective for fiscal years beginning after December 15, 2006; therefore, we will be required to adopt this Interpretation in the first quarter of 2007. We are currently evaluating FIN 48 and have not yet determined the impact, if any, the adoption of this Interpretation will have on our consolidated financial position or results of operations.

#### POTENTIAL ASSET IMPAIRMENTS. RESTRUCTURING, AND OTHER SPECIAL CHARGES

As part of our ongoing efforts to maximize performance and efficiencies, including the streamlining of manufacturing operations and research and development activities, we are discussing the future of three European facilities, including proposals to close the sites, which include two research and development sites and one manufacturing site. Any site closures would be subject to consultations with employee representatives at the affected sites. Following these consultations, which could take several months, final recommendations will be made to the Lilly Board of Directors, which must approve any action. No final decisions have been made about the future of the sites at this time. However, if the proposals proceed, the majority of the 900 employees plus contractors at those sites would be laid off and we would attempt to dispose of the facilities. As a consequence, we would incur severance and impairment charges that would likely be significant.

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

#### **Executive Overview**

#### I. Financial Results

The second-quarter and first-half 2006 net income was \$822.0 million, or \$.76 per share, and \$1.66 billion, or \$1.53 per share, respectively. Second-quarter 2005 net loss and loss per share was \$252.0 million and \$.23. However, net income was \$484.6 million, or \$.44 per share for the first half of 2005. The net loss and loss per share in the second quarter of 2005 was the result of a product liability litigation charge of \$1.07 billion (pretax) in the quarter. In addition to this product liability charge, changes in earnings between the periods were driven primarily by increased sales and decreased cost of sales for the second quarter and first half of 2006, offset partially by decreased total other income in the first half of 2006.

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

Gemzar was approved in the U.S. for the treatment of recurrent ovarian cancer in combination with carboplatin.

We submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for review of ruboxistaurin mesylate (proposed brand name Arxxant<sup>TM</sup>) as an oral medication to reduce the risk of vision loss associated with diabetic retinopathy. The FDA subsequently informed us that our Arxxant application is fileable and will be given a priority review. We also submitted Arxxant for approval in Europe for the same indication.

We submitted a supplemental NDA to the FDA for Cymbaltaâ for the treatment of generalized anxiety disorder. We are also conducting Phase III studies on Cymbalta for the treatment of fibromyalgia, a chronic, often debilitating pain disorder.

We initiated a Phase III clinical trial to study enzastaurin as a maintenance therapy to prevent relapse in patients with diffuse large B-cell lymphoma. Enzastaurin, a targeted oral agent, is also being studied in Phase III trials for the treatment of relapsed glioblastoma multiforme, an aggressive and malignant form of brain cancer.

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

Certain generic manufacturers have challenged our U.S. compound patent for Zyprexa and are seeking permission to market generic versions of Zyprexa prior to its patent expiration in 2011. On April 14, 2005, the U.S. District Court in Indianapolis ruled in our favor on all counts, upholding our patents. The decision has been appealed.

We have reached agreements with claimants—attorneys involved in certain U.S. Zyprexa product liability litigation to settle a majority of the claims against us relating to the medication. A large number of claims remain. As a result of our product liability exposures, the substantial majority of which were related to Zyprexa, we recorded a net pretax charge of \$1.07 billion in the second quarter of 2005.

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. sales, marketing, and promotional practices.

We announced that we are discussing the future of three European facilities, including proposals to close the sites. Any site closures would be subject to consultations with employee representatives at the affected sites and final approval by the Board of Directors. No final decisions have been made at this time. If the sites are closed, the majority of the 900 employees would be laid off and we would record charges that would likely be significant.

In the United States, implementation of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), which provides a prescription drug benefit under the Medicare program, took effect January 1, 2006. While it is difficult to predict the business impact of this legislation, we currently anticipate a modest short-term increase in sales. However, in the long term there is additional risk of increased pricing pressures. While the MMA prohibits the Secretary of Health and Human Services (HHS) from directly negotiating prescription drug prices with manufacturers, we expect continued challenges to that prohibition over the next several years. Also, the MMA retains the authority of the Secretary of HHS to prohibit the importation of prescription drugs, but we expect Congress to consider several measures that could remove that authority and allow for the importation of products into the U.S. regardless of their safety or cost. If adopted, such legislation would likely have a negative effect on our U.S. sales. We believe there is some chance that the new and expanded prescription drug coverage for seniors under the MMA will alleviate the perceived need for a federal importation scheme. Additionally, notwithstanding the federal law prohibiting drug importation, approximately a dozen states have implemented importation schemes for their citizens, usually involving a website that links patients to selected Canadian pharmacies. One state has such a program for its state employees. As a result of the passage of the MMA, aged and disabled patients jointly eligible for Medicare and Medicaid began receiving their prescription drug benefits through the Medicare program, instead of Medicaid, on January 1, 2006. This may relieve some state budget pressures but is unlikely to result in reduced pricing pressures at the state level. A majority of states have implemented supplemental rebates and restricted formularies in their Medicaid programs, and these programs are expected to continue in the post-MMA environment. Moreover, under the 2005 federal Deficit Reduction Act, states will have greater flexibility to impose new cost-sharing requirements on Medicaid beneficiaries for non-preferred prescription drugs that will result in certain beneficiaries bearing more of the cost. Several states also are attempting to extend discounted Medicaid prices to non-Medicaid patients. As a result, we expect pressures on pharmaceutical pricing to continue.

As it relates to the new Medicare program, we announced in the second quarter of 2006 that we have temporarily extended our U.S. patient assistance program, LillyAnswers. The temporary extension of LillyAnswers allows patients who are not enrolled in Medicare Part D access to the LillyAnswers program until December 31, 2006. We also temporarily extended LillyAnswers for patients who have enrolled in a Medicare Part D plan and need assistance for Zyprexa and Forteoâ. We have asked the U.S. Department of Health and Human Services Office of the Inspector General (OIG) for an opinion on our proposal for an Outside Part D patient assistance program (i.e., the LillyMedicareAnswers program) which would provide assistance primarily for Zyprexa and Forteo, beyond the end of this year to patients enrolled in a Medicare Part D plan. We currently anticipate that the specific LillyAnswers program extension involving Zyprexa and Forteo for patients enrolled in a Medicare Part D plan will continue to be available until a decision is rendered by the OIG on our proposal. In order to participate in either the temporary extension as described above or the new proposed LillyMedicareAnswers program, certain eligibility and certification requirements must be met.

International operations also are generally subject to extensive price and market regulations, and there are many proposals for additional cost-containment measures, including proposals that would directly or indirectly impose additional price controls or reduce the value of our intellectual property protection.

## Sales Secor

Second-quarter and first-half 2006 sales growth of 5 and 6 percent, respectively, was driven primarily by sales growth of Cymbalta, Forteo, Alimtaâ, and Byettaâ. The growth comparisons also benefited from an estimated \$160 million of wholesaler destocking in the first six months of 2005 as a result of restructuring our arrangements with our U.S. wholesalers in the first quarter of 2005. Sales in the U.S. increased by \$158.4 million, or 8 percent, and \$349.0 million, or 9 percent, for the second quarter and first half of 2006, respectively, compared with the same periods of 2005. Sales outside the U.S. increased \$40.8 million, or 2 percent, and \$67.4 million, or 2 percent, for the second quarter and first half of 2006, respectively. For the second quarter, sales volume and selling prices each increased sales by 3 percent, while exchange rates decreased sales by 1 percent. For the first six months of 2006, worldwide sales volume and selling prices increased 5 percent and 3 percent, respectively, while exchange rates decreased 2 percent.

The following tables summarize our net sales activity for the three- and six-month periods ended June 30, 2006 and 2005:

		Three Months Ende June 30, 2006	ed	Three Months Ended June 30, 2005	Percent Change from
Product	U.S. <sup>1</sup>	Outside U.S.	Total	Total	2005
		(Dollars in	millions)		
Zyprexa	\$ 542.9	\$ 572.1	\$1,115.0	\$ 1,096.8	2
Gemzar	150.0	193.5	343.5	343.0	0
Humalog	196.6	123.9	320.5	296.2	8
Cymbalta	269.9	40.5	310.4	161.4	92
Evista	175.0	100.5	275.5	261.6	5
Humulin	79.9	139.9	219.8	249.8	(12)
Animal health products	92.7	108.3	201.0	201.0	0
Alimta	87.7	65.3	153.0	111.2	38
Forteo	101.0	45.1	146.1	101.9	43
Strattera	125.9	18.2	144.1	123.5	17
Humatrope	52.0	56.0	108.0	108.9	(1)
Actos	50.9	41.7	92.6	105.0	(12)
Fluoxetine products	39.5	40.5	80.0	114.2	(30)
ReoPro	28.3	44.0	72.3	77.7	(7)
Anti-infectives	3.5	66.1	69.6	112.8	(38)
Byetta	52.1		52.1	3.3	NM
Cialis <sup>2</sup>	0.8	49.7	50.5	45.1	12
Xigris	25.1	23.3	48.4	57.7	(16)
Other pharmaceutical products	23.9	40.6	64.5	96.6	(33)
Total net sales	\$2,097.7	\$1,769.2	\$3,866.9	\$ 3,667.7	5
		Six Months Ended June 30, 2006		Six Months Ended June 30, 2005	Percent Change

				SIX MOHUIS	
				Ended	
	,	Six Months Ende	ed	June 30,	Percent
		June 30, 2006		2005	Change
		Outside			from
Product	U.S. <sup>1</sup>	U.S.	Total	Total	2005
		(Dollars i	n millions)		
Zyprexa	\$1,036.8	\$1,085.6	\$2,122.4	\$ 2,135.0	(1)
Gemzar	299.7	382.6	682.3	647.6	5
Humalog	385.2	239.8	625.0	582.4	7
Cymbalta	475.8	67.9	543.7	268.2	103
Evista	324.1	192.9	517.0	510.5	1
Humulin	168.1	270.2	438.3	506.7	(13)
Animal health products	176.7	222.6	399.3	396.5	1
Strattera	261.2	35.2	296.4	243.2	22
Alimta	165.6	117.6	283.2	205.1	38

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Actos	202.3	79.4	281.7	273.6	3
Forteo	188.2	84.9	273.1	168.7	62
Humatrope	100.2	104.4	204.6	213.4	(4)
Fluoxetine products	75.6	81.8	157.4	226.7	(31)
Anti-infectives	24.3	133.2	157.5	222.0	(29)
ReoPro	57.8	88.6	146.4	154.4	(5)
Cialis <sup>2</sup>	1.9	104.3	106.2	84.0	26
Xigris	52.9	45.7	98.6	117.3	(16)
Byetta	88.0		88.0	3.3	NM
Other pharmaceutical products	48.6	111.9	160.5	206.5	(22)
Total net sales	\$4,133.0	\$3,448.6	\$7,581.6	\$ 7,165.1	6

#### NM Not Meaningful

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

<sup>&</sup>lt;sup>2</sup> Cialisâ had worldwide second-quarter and first-half 2006 sales of \$233.2 million and \$456.1 million, respectively, representing increases of 22 and 34 percent, respectively, compared with the same periods of 2005. 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 other income net in our consolidated condensed statements of income.

#### **Product Highlights**

Zyprexa sales in the U.S. decreased 1 percent and 3 percent in the second quarter and first half of 2006, respectively, compared with the same periods of 2005. This decrease was a result of a decline in the underlying demand, offset in part by higher net effective selling prices. The increase in net effective selling prices was partially due to the transition of certain low income patients from Medicaid to Medicare. Despite the decline in demand as compared to prior year, we are seeing improving U.S. prescription trends. Specifically, Zyprexa s U.S. prescriptions have held steady during the first six months of 2006. Sales of Zyprexa outside the U.S. increased by 5 percent in the second quarter and 2 percent in the first half of 2006, due to increased demand, offset partially by the unfavorable impact of foreign exchange rates.

Diabetes care products, composed primarily of Humalog, Humulin, Actosâ, and Byetta, had worldwide net sales of \$701.7 million and \$1.47 billion in the second quarter and first half of 2006, respectively, an increase of 5 percent compared with the same periods last year. Diabetes care revenues in the U.S. increased 6 percent and 9 percent, to \$392.6 million and \$868.1 million for the second quarter and first half of 2006, led by sales of Byetta. Diabetes care revenues outside the U.S. increased 4 percent and remained flat, to \$309.1 million and \$597.0 million in the second quarter and first half of 2006, respectively. Humalog sales in the U.S. increased 8 percent during both the second quarter and first half of 2006, due to higher prices, which were partially offset by a decline in demand during the second quarter. Humalog sales outside of the U.S. increased 8 percent and 7 percent during the second quarter and first half of 2006, respectively, due primarily to increased demand, offset in part by the unfavorable impact of foreign exchange rates. Humulin sales decreased 22 percent and 19 percent in the U.S. in the second quarter and first half of 2006, respectively, driven primarily by the decline in demand due to continued competitive pressures. Humulin sales outside of the U.S. decreased 5 percent and 10 percent during the second quarter and first half of 2006, respectively, due to decreased demand and the unfavorable impact of foreign exchange rates. Actos revenues, the majority of which represent service revenues from a copromotion agreement in the U.S. with Takeda Pharmaceuticals North America (Takeda), decreased 29 percent and 3 percent in the second quarter and first half of 2006 in the U.S. 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. Our U.S. marketing rights with respect to Actos expire in September 2006; however, we will continue receiving royalties from Takeda. As a result, our U.S. revenues from Actos will decline in 2006 and each subsequent year. Our arrangement in the U.S. ceases after October 2009, although our arrangement outside the U.S. continues. Sales of Byetta, a first-in-class treatment for type 2 diabetes that we market with Amylin Pharmaceuticals and launched in the U.S. in June 2005, were \$98.6 million and \$166.6 million for the second quarter and first half of 2006, respectively. We report as revenue our 50 percent share of Byetta s gross margin and our sales of Byetta s pen delivery devices to Amylin.

Gemzar sales decreased 3 percent and increased 6 percent in the U.S. for the second quarter and first half of 2006, respectively, reflecting decreased demand due to competitive pressures in the second quarter. Gemzar sales outside the U.S. increased 3 and 4 percent for the second quarter and first half of 2006, respectively, due to increased demand, offset partially by the unfavorable impact of foreign exchange rates.

U.S. sales of Cymbalta, a treatment of major depressive disorder and diabetic peripheral neuropathic pain, increased 79 percent and 88 percent in the second quarter and first half of 2006, respectively, reflecting increased demand. Also during the second quarter, Cymbalta s U.S. market share growth accelerated. Specifically, Cymbalta s U.S. share of new prescriptions increased 0.96 percentage points in the second quarter, compared with a 0.35 percentage point gain in the first quarter of 2006, per IMS Health, National Prescription Audit *Plus 7*, July 2006. Sales outside the U.S. reflect international launches in key markets, including Germany, the U.K., Italy, Spain, Mexico, and Brazil. Evista sales in the U.S. increased 7 percent and 1 percent in the second quarter and first half of 2006, respectively, due to price increases in both periods, offset partially by decreased demand in the first half of 2006. Evista sales outside the U.S. increased 2

percent in the second quarter and first half of 2006 compared with the same periods of 2005, due to increased demand, offset partially by lower prices and the unfavorable impact of foreign exchange rates.

Stratteraâ, a treatment for attention-deficit hyperactivity disorder (ADHD) in children, adolescents, and adults, generated increases in U.S. sales of 13 percent and 17 percent for the second quarter and first half of 2006, compared with the same periods in 2005. The sales increases for both periods were primarily due to reductions in the U.S. wholesaler inventory levels in 2005 and higher prices, offset partially by a decline in demand in the U.S. Alimta, a treatment for malignant pleural mesothelioma and second-line treatment of non-small-cell lung cancer, generated increased U.S. sales of 26 percent and 25 percent in the second quarter and first half of 2006, respectively; while sales outside the U.S. increased 56 percent and 63 percent for the same periods in 2005. Forteo, a treatment for severe osteoporosis, increased 43 percent and 67 percent in the U.S. in the second quarter and first half of 2006, respectively; while sales outside the U.S. increased 45 percent and 52 percent for the same periods. Increased sales in the U.S. were due in part to greater access to medical coverage through the MMA program. Cialis sales in the second quarter and first half of 2006 were comprised of \$50.5 million and \$106.2 million of sales in our territories, respectively, which are reported in our net sales, and \$182.7 million and \$349.9 million of sales in the joint-venture territories. Within the joint-venture territories, the U.S. sales of Cialis were \$93.8 million and \$176.3 million in the second quarter and first half of 2006, respectively, compared with \$71.1 million and \$113.9 million in the same periods of 2005. Cialis sales in our territories are reported in revenue, while our 50 percent share of the joint-venture territory sales, net of expenses, is reported in other income net. Cialis sales growth reflects both gains in market share and growth of the erectile dysfunction market during the second quarter and first half of

## Gross Margin, Costs, and Expenses

2006.

For the second quarter of 2006, gross margins increased 1.5 percentage points, to 77.7 percent of net sales, compared with the second quarter of 2005. For the first half of 2006, gross margins increased 2.1 percentage points, to 78.0 percent of net sales, compared with the first half of 2005. This increase was primarily due to favorable product mix and the favorable impact of foreign exchange rates, partially offset by higher manufacturing-related costs. Operating expenses (the aggregate of research and development and marketing and administrative expenses) increased 5 percent for both the second quarter and first half of 2006. Investment in research and development increased 2 percent, to \$774.8 million, and 3 percent, to \$1.52 billion, for the second quarter and first half of 2006, respectively, due primarily to increased discovery research expenses. Marketing and administrative expenses increased 8 percent, to \$1.24 billion, and 6 percent, to \$2.38 billion, for the second quarter and first half of 2006, respectively, primarily due to increased marketing expenses in support of newer products, offset partially by the impact of foreign exchange rates. Other income net consists of interest expense, interest income, the after-tax operating results of the Lilly ICOS joint venture, and all other income and expense items.

Second-quarter and first-half 2006 interest expense increased \$53.8 million, to \$65.8 million, and \$94.2 million to \$130.8 million, respectively, as a result of higher interest rates and less capitalized interest due to the completion in late 2005 of certain manufacturing facilities.

Interest income increased \$22.1 million, to \$68.4 million and \$35.8 million to \$128.1 million for the second quarter and first half of 2006, respectively, due to higher interest rates.

The Lilly ICOS joint-venture income was \$22.5 million in the second quarter of 2006, compared with a loss of \$.5 million in the second quarter of 2005. For the first half of 2006, income was \$42.3 million, compared with a loss of \$13.1 million in the first half of 2005. The increase in both periods was due to increased Cialis sales and decreased selling and marketing expenses.

Net other income and expense items increased \$10.2 million to \$21.8 million for second-quarter 2006 and decreased \$61.9 million to \$39.5 million for first-half 2006. The first-half decrease is largely a result of less income from business development transactions.

We incurred a tax expense of \$218.5 million and \$440.4 million, for the second quarter and first half of 2006, respectively, representing an effective tax rate of 21 percent in both periods. Comparisons to prior year are not meaningful due to the net loss before income taxes experienced in the second quarter of 2005.

#### FINANCIAL CONDITION

As of June 30, 2006, cash, cash equivalents, and short-term investments totaled \$4.59 billion compared with \$5.04 billion at December 31, 2005. Cash flow from operations of \$942.2 million during the first six months of 2006 was more than offset by dividends paid of \$864.6 million, net capital expenditures of \$392.1 million, and repurchases of common stock of \$122.1 million.

Total debt at June 30, 2006, was \$6.32 billion, a decrease of \$181.6 million from December 31, 2005. Our current debt ratings from Standard & Poor s and Moody s remain at AA and Aa3, respectively.

We believe that cash generated from operations, along with available cash and cash equivalents, will be sufficient to fund our operating needs, including debt service, capital expenditures, dividends, and taxes in 2006. We believe that amounts available through our existing commercial paper program should be adequate to fund maturities of short-term borrowings, if necessary. We currently have \$1.23 billion of unused committed bank credit facilities, \$1.20 billion of which backs our commercial paper program. We currently expect to repay approximately \$1.5 billion of debt during 2006, using available cash. Various risks and uncertainties, including those discussed in the Financial Expectations for 2006 section, may affect our operating results and cash generated from operations.

#### LEGAL AND REGULATORY MATTERS

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

Dr. Reddy s Laboratories, Ltd. (Reddy), Teva Pharmaceuticals, and Zenith Goldline Pharmaceuticals, Inc., which was subsequently acquired by Teva Pharmaceuticals (together, Teva), each submitted abbreviated new drug applications (ANDAs) seeking permission to market generic versions of Zyprexa prior to the expiration of our relevant U.S. patent (expiring in 2011) and alleging that this patent was invalid or not enforceable. We filed lawsuits against these companies in the U.S. District Court for the Southern District of Indiana, seeking a ruling that the patent is valid, enforceable and being infringed. The district court ruled in our favor on all counts on April 14, 2005. We are now awaiting a decision by the Court of Appeals for the Federal Circuit, which on April 6, 2006, heard Reddy s and Teva s respective appeals of this ruling. We are confident Reddy s and Teva s claims are without merit and we expect to prevail. 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 on appeal. An unfavorable outcome would have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

Barr Laboratories, Inc. (Barr), submitted an ANDA in 2002 seeking permission to market a generic version of Evista prior to the expiration of our relevant U.S. patents (expiring in 2012-2017) and alleging that these patents are invalid, not enforceable, or not infringed. In November 2002, we filed a lawsuit against Barr in the U.S. District Court for the Southern District of Indiana, seeking a ruling that these patents are valid, enforceable, and being infringed by Barr. Teva has also submitted an ANDA seeking permission to market a generic version of Evista. In June 2006, we filed a lawsuit against Teva in the U.S. District Court for the Southern District of Indiana, seeking a ruling that our relevant U.S. patents (expiring in 2012-2014) are valid, enforceable, and being infringed by Teva. No trial date has been set in either case. We believe Barr s and Teva s claims are without merit and we expect to prevail. 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 could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

Sicor Pharmaceuticals, Inc. (Sicor), a subsidiary of Teva, submitted ANDAs in November 2005 seeking permission to market generic versions of Gemzar prior to the expiration of our relevant U.S. patents (expiring in 2010 and 2013), and alleging that these patents are invalid. In February, we filed a lawsuit against Sicor in the U.S. District Court for the Southern District of Indiana, seeking a ruling that these patents are valid and are being infringed by Sicor. In response to our lawsuit, Sicor filed a declaratory judgment action in the U.S. District Court for the Central District of California. No trial date has been set in either matter. We believe

Sicor s claims are without merit and we expect to prevail. 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 could have a material adverse impact on our consolidated results of operations.

In March 2004, the office of the U.S. Attorney for the Eastern District of Pennsylvania advised us that it has commenced a civil investigation related to our U.S. marketing and promotional practices, including our communications with physicians and remuneration of physician consultants and advisors, with respect to Zyprexa, Prozac, and Prozac Weekly. In October 2005, the U.S. Attorney s office advised that it is also conducting an inquiry regarding certain rebate agreements we entered into with a pharmacy benefit manager covering Axid, Evista, Humalog, Humulin, Prozac, and Zyprexa. The inquiry includes a review of Lilly s Medicaid best price reporting related to the product sales covered by the rebate agreements. We are cooperating with the U.S.

Attorney in these investigations, including providing a broad range of documents and information relating to the investigations. In June 2005, we received a subpoena from the office of the Attorney General, Medicaid Fraud Control Unit, of the State of Florida, seeking production of documents relating to sales of Zyprexa and our marketing and promotional practices with respect to Zyprexa. It is possible that other Lilly products could become subject to investigation and that the outcome of these matters could include criminal charges and fines, penalties, or other monetary or nonmonetary remedies. We cannot predict or determine the outcome of these matters or reasonably estimate the amount or range of amounts of any fines or penalties that might result from an adverse outcome. It is possible, however, that an adverse outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position. We have implemented and continue to review and enhance a broadly based compliance program that includes comprehensive compliance-related activities designed to ensure that our marketing and promotional practices, physician communications, remuneration of health care professionals, managed care arrangements, and Medicaid best price reporting comply with applicable laws and regulations. We have been named as a defendant in a large number of Zyprexa product liability lawsuits in the United States and have been notified of many other claims of individuals who have not filed suit. The lawsuits and unfiled claims (together the claims ) allege a variety of injuries from the use of Zyprexa, with the majority alleging that the product caused or contributed to diabetes or high blood-glucose levels. The claims seek substantial compensatory and punitive damages and typically accuse us of inadequately testing for and warning about side effects of Zyprexa. Many of the claims also allege that we improperly promoted the drug. Almost all of the federal lawsuits are part of a Multi-District Litigation (MDL) proceeding before The Honorable Jack Weinstein in the Federal District Court for the Eastern District of New York (MDL No. 1596). The MDL includes three lawsuits requesting certification of class actions on behalf of those who allegedly suffered injuries from the administration of Zyprexa. We have entered into agreements with various plaintiffs counsel halting the running of the statutes of limitation (tolling agreements) with respect to a number of claimants who do not have lawsuits on file.

Since June 2005, we have entered into agreements with various claimants attorneys involved in U.S. Zyprexa product liability litigation to settle a majority of the claims. The agreements cover approximately 10,500 claimants, including a large number of previously filed lawsuits (including the three purported class actions mentioned above), tolled claims, and other informally asserted claims. The settlements are being overseen and distributed by court-approved claims administrators. The agreements are subject to certain conditions, including obtaining full releases from a specified number of claimants.

The U.S. Zyprexa product liability claims not subject to these agreements include approximately 1,400 lawsuits in the U.S. covering approximately 7,600 claimants, and approximately 850 tolled claims. In addition, we have been served with a lawsuit seeking class certification in which the members of the purported class are seeking refunds and medical monitoring. Finally, in early 2005, we were served with four lawsuits seeking class action status in Canada on behalf of patients who took Zyprexa. One of these four lawsuits has been certified for residents of Quebec. The allegations in the Canadian actions are similar to those in the litigation pending in the United States. We are prepared to continue our vigorous defense of Zyprexa in all remaining cases.

In December 2004, we were served with two lawsuits brought in state court in Louisiana on behalf of the Louisiana Department of Health and Hospitals, alleging that Zyprexa caused or contributed to diabetes or high blood-glucose levels, and that we improperly promoted the drug. These cases have been removed to federal court and are now part of the MDL proceedings in the Eastern District of New York. In these actions, the Department of Health and Hospitals seeks to recover the costs it paid for Zyprexa through Medicaid and other drug-benefit programs, as well as the costs the department alleges it has incurred and will incur to treat Zyprexa-related illnesses. In 2006, we were served with similar lawsuits filed by the states of Alaska, West Virginia, and Mississippi in the courts of the respective states. In 2005, two lawsuits were filed in the Eastern District of New York purporting to be nationwide class actions on behalf of all consumers and third-party payors, excluding governmental entities, which have made or will make payments for their members or insured patients being prescribed Zyprexa. These actions have now been consolidated into a single lawsuit, which is brought under certain state consumer protection statutes, the federal civil RICO statute, and common law theories, seeking a refund of the cost of Zyprexa, treble damages, punitive damages, and attorneys fees. Four additional lawsuits were filed in 2006: two in the Eastern District of New York, one in the Southern District

of Indiana, and one in Indiana state court, all on similar grounds. As with the product liability suits, these lawsuits allege that we inadequately tested for and warned about side effects of Zyprexa and improperly promoted the drug. We have insurance coverage for a portion of our Zyprexa product liability claims exposure. The third-party insurance carriers have raised defenses to their liability under the policies and are seeking to rescind the policies. The dispute is now the subject of litigation in the federal court in Indianapolis against certain of the carriers and in arbitration in Bermuda against other carriers. While we believe our position is meritorious, there can be no assurance that we will prevail.

In addition, we have been named as a defendant in numerous other product liability lawsuits involving primarily diethylstilbestrol (DES) and thimerosal.

With respect to the product liability claims currently asserted against us, 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 product liability 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. Legal defense costs expected to be incurred in connection with significant product liability loss contingencies are accrued when probable and reasonably estimable. A portion of the costs associated with defending and disposing of these suits is covered by insurance. We record receivables for insurance-related recoveries when it is probable they will be realized. These receivables are classified as a reduction of the litigation charges on the statement of income. We estimate insurance recoverables based on existing deductibles, coverage limits, our assessment of any defenses to coverage that might be raised by the carriers, and the existing and projected future level of insolvencies among the insurance carriers.

In the second quarter of 2005, we recorded a net pre-tax charge of \$1.07 billion for product liability matters. The \$1.07 billion net charge takes into account our estimated recoveries from our insurance coverage related to these matters. The charge covers the following:

The cost of the Zyprexa settlements described above; and,

Reserves for product liability exposures and defense costs regarding currently known and expected claims to the extent we can formulate a reasonable estimate of the probable number and cost of the claims. A substantial majority of these exposures and costs relate to current and expected Zyprexa claims not included in the settlements. We have estimated these charges based primarily on historical claims experience, data regarding product usage, and our historical product liability defense cost experience.

During 2005, \$700.0 million was paid in connection with Zyprexa settlements, while the cash related to other reserves for product liability exposures and defense costs is expected to be paid out over the next several years, including 2006. The timing of our insurance recoveries is uncertain.

We cannot predict with certainty the additional number of lawsuits and claims that may be asserted. In addition, although we believe it is probable, there can be no assurance that the Zyprexa settlements described above will be concluded. The ultimate resolution of Zyprexa product liability and related litigation could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

Because of the nature of pharmaceutical products, it is possible that we could become subject to large numbers of product liability claims for other products in the future. We have experienced difficulties in obtaining product liability insurance due to a very restrictive insurance market, and therefore will be largely self-insured for future product liability losses. In addition, as noted above, there is no assurance that we will be able to fully collect from our insurance carriers on past claims.

In June 2002, we were sued by Ariad Pharmaceuticals, Inc., the Massachusetts Institute of Technology, the Whitehead Institute for Biomedical Research and the President and Fellows of Harvard College in the U.S. District Court for the District of Massachusetts alleging that sales of two of our products, Xigris and Evista, were inducing the infringement of a patent related to the discovery of a natural cell signaling phenomenon in the human body and seeking royalties on past and future sales of these products. We believe that these allegations are without legal merit and that we will ultimately prevail on these issues. In June 2005, the United States Patent and Trademark Office commenced a re-examination of the patent in order to consider certain issues raised by us relating to the validity of the patent. A jury trial commenced in Boston on April 10, 2006 on the patent validity and infringement issues. On May 4, 2006, the jury issued an initial decision in the case that Xigris and Evista sales infringe the patent. The jury awarded the plaintiffs approximately \$65 million in damages, calculated by applying a 2.3 percent royalty to all U.S. sales of Xigris and Evista from the date of issuance of the patent through the date of trial. We will seek to have the jury verdict overturned by the trial court judge, and if unsuccessful, will appeal the decision to the Court of Appeals for the Federal Circuit. In addition, a separate bench trial with the U.S. District Court of Massachusetts is scheduled to begin on August 7, 2006, and will be held on our contention that the patent is unenforceable and will also consider the patent s improper coverage of natural processes.

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

The litigation accruals and environmental liabilities and the related estimated insurance recoverables have been reflected on a gross basis as liabilities and assets, respectively, on our consolidated balance sheets.

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

#### FINANCIAL EXPECTATIONS FOR 2006

We expect third-quarter earnings per share of \$.77 to \$.79, representing 5 percent to 8 percent growth compared with third-quarter 2005 earnings per share of \$.73. For the full year of 2006, we expect earnings per share to be in the range of \$3.10 to \$3.20. This guidance excludes future material unusual items, such as any charges related to the three potential European site closures discussed previously. We expect full-year 2006 sales to grow at approximately the low end of our previous guidance of 7 percent to 9 percent. In addition, we expect gross margins as a percent of sales to improve modestly compared with 2005, operating expenses to grow in the mid-single digits in the aggregate, and other income net, to contribute approximately \$175 million to \$275 million. Excluding the tax associated with the potential charges discussed above, we also anticipate the effective tax rate to be approximately 21 percent. In terms of cash flow, we expect capital expenditures to be flat at about \$1.4 billion in 2006.

We caution investors that any forward-looking statements or projections made by us, including those above, are based on management s belief at the time they are made. However, they are subject to risks and uncertainties. Actual results could differ materially and will depend on, among other things, the continuing growth of our currently marketed products; developments with competitive products; the timing and scope of regulatory approvals and the success of our new product launches; asset impairments, restructurings, and acquisitions of compounds under development resulting in acquired in-process research and development charges; foreign exchange rates; wholesaler inventory changes; the outcome of the Zyprexa patent appeal; other regulatory developments, government investigations, patent disputes and litigation; and the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals. Other factors that may affect our operations and prospects are discussed in Item 1A of our 2005 Form 10-K, Risk Factors. We undertake no duty to update these forward-looking statements.

#### AVAILABLE INFORMATION ON OUR WEBSITE

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

#### Item 4. Controls and Procedures

- (a) Evaluation of Disclosure Controls and Procedures. Under applicable SEC regulations, management of a reporting company, with the participation of the principal executive officer and principal financial officer, must periodically evaluate the company s disclosure controls and procedures, which are defined generally as controls and other procedures of a reporting company designed to ensure that information required to be disclosed by the reporting company in its periodic reports filed with the commission (such as this Form 10-Q) is recorded, processed, summarized, and reported on a timely basis.
  - Our management, with the participation of Sidney Taurel, chairman and chief executive officer, and Derica W. Rice, senior vice president and chief financial officer, evaluated our disclosure controls and procedures as of June 30, 2006, and concluded that they are effective.
- (b) Changes in Internal Controls. During the second quarter of 2006, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### PART II. OTHER INFORMATION

Item 1. Legal Proceedings

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

The U.S. patent litigation involving Zyprexa, Evista, and Gemzar

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

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

The legal proceedings we have filed against several of our product liability insurance carriers with respect to our coverage for the Zyprexa product liability claims

That information is incorporated into this Item by reference.

Other Product Liability Litigation

We refer to Part I, Item 3, of our Form 10-K annual report for 2005 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 80 suits involving approximately 170 claimants. In the thimerosal litigation, we have been named as a defendant in approximately 360 suits with approximately 975 claimants. While it is not possible to predict or determine the outcome of the patent, product liability, or other legal actions brought against us or the ultimate cost of environmental matters, we believe that, except as noted above, the resolution of all such matters will not have a material adverse effect on our consolidated financial position or liquidity but could possibly be material to the consolidated results of operations in any one accounting period.

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

The following table summarizes the activity related to repurchases of our equity securities during the three-month period ended June 30, 2006:

			Total Number of	
			Shares Purchased	
			as	Approximate Dollar
				Value of Shares that
			Part of Publicly	May
	Total Number		Announced Plans	
	of	Average Price Paid	or	Yet Be Purchased Under
	Shares			
	Purchased	per Share	Programs	the Plans or Programs
Period	(a)	(b)	(c)	(d)
	(in thousands)		(in thousands)	(Dollars in millions)
April 2006	3	\$53.49		\$419.2
May 2006	15	52.52		419.2
June 2006	10	54.02		419.2
Total	28			

The amounts presented in columns (a) and (b) above include 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 only to our \$3.0 billion share repurchase program announced in March 2000. As of June 30, 2006, we have purchased \$2.58 billion related to this program. During the second quarter of 2006, no shares were repurchased pursuant to this program and we do not expect to purchase any shares under this program during the remainder of 2006.

## Item 6. Exhibits

The following documents are filed as exhibits to this Report:

EXHIBIT 10.	Master Settlement Agreement regarding Zyprexa product liability claims, filed here in its entirety to include its Exhibit A, which was inadvertently omitted from our Form 10-Q for the quarter ended September 30, 2005
EXHIBIT 11.	Statement re: Computation of Earnings (Loss) per Share
EXHIBIT 12.	Statement re: Computation of Ratio of Earnings to Fixed Charges
EXHIBIT 31.1	Rule 13a-14(a) Certification of Sidney Taurel, Chairman of the Board and Chief Executive Officer
EXHIBIT 31.2	Rule 13a-14(a) Certification of Derica W. Rice, Senior Vice President and Chief Financial Officer
EXHIBIT 32.	Section 1350 Certification

#### **SIGNATURES**

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

ELI LILLY AND COMPANY

(Registrant)

Date August 1, 2006 /s/ James B. Lootens

James B. Lootens

Secretary and Deputy General Counsel

Date August 1, 2006 /s/ Arnold C. Hanish

Arnold C. Hanish

Executive Director, Finance, and Chief

Accounting Officer

## INDEX TO EXHIBITS

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Section 1350 Certification

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