MYLAN LABORATORIES INC
Form 10-Q
July 28, 2005

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-Q

þ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d)**
OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2005
OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)**
OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission file number 1-9114

MYLAN LABORATORIES INC.

(Exact name of registrant as specified in its charter)

Pennsylvania	25-1211621
(State of incorporation)	(I.R.S. Employer Identification No.)

1500 Corporate Drive
Canonsburg, Pennsylvania 15317
(Address of principal executive offices)
(Zip Code)
(724) 514-1800
(Registrant s telephone number, including area code)

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 twelve months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES R NO £

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). YES R NO £

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date.

Class of Common Stock	**Outstanding at July 21, 2005**
$0.50 par value	218,601,952

MYLAN LABORATORIES INC. AND SUBSIDIARIES
FORM 10-Q
For the Quarterly Period Ended
June 30, 2005
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PART I. FINANCIAL INFORMATION

Item 1: Financial Statements

Condensed Consolidated Statements of Earnings

MYLAN LABORATORIES INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Earnings

(unaudited; in thousands, except per share amounts)

Three Months Ended June 30,	**2005**	**2004**
Net revenues	$ 323,378	$ 339,012
Cost of sales	155,424	159,259
Gross profit	167,954	179,753
Operating expenses:		
Research & development	25,087	21,495
Selling, general & administrative	71,302	57,746
Litigation, net	12,000	(25,985)
Total operating expenses	108,389	53,256
Earnings from operations	59,565	126,497
Other income, net	5,556	686
Earnings before income taxes	65,121	127,183
Provision for income taxes	22,206	45,150
Net earnings	$ 42,915	$ 82,033
Earnings per common share:		
Basic	$ 0.16	$ 0.31
Diluted	$ 0.16	$ 0.30
Weighted average common shares:		
Basic	269,445	268,553
Diluted	273,262	275,409
Cash dividend declared per common share	$ 0.06	$ 0.03

See Notes to Condensed Consolidated Financial Statements

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Condensed Consolidated Balance Sheets

MYLAN LABORATORIES INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(unaudited; in thousands)

	June 30, 2005	March 31, 2005
Assets		
Current assets:		
Cash and cash equivalents	$ 342,833	$ 137,733
Marketable securities	543,929	670,348
Accounts receivable, net	269,121	297,334
Inventories	261,123	286,267
Deferred income tax benefit	134,454	119,327
Other current assets	15,235	17,443
Total current assets	1,566,695	1,528,452
Property, plant and equipment, net	353,549	336,719
Intangible assets, net	117,395	120,493
Goodwill	102,579	102,579
Other assets	46,813	47,430
Total assets	$ 2,187,031	$ 2,135,673
Liabilities and shareholders equity		
Liabilities		
Current liabilities:		
Trade accounts payable	$ 50,978	$ 78,114
Income taxes payable	47,351	44,123
Other current liabilities	165,773	123,270
Total current liabilities	264,102	245,507
Long-term obligations	19,254	19,325
Deferred income tax liability	23,548	24,905
Total liabilities	306,904	289,737
Shareholders equity		
Common stock	152,448	152,217
Additional paid-in capital	359,920	354,172
Retained earnings	1,835,533	1,808,802
Accumulated other comprehensive earnings	2,351	870
	2,350,252	2,316,061

Less:		
Treasury stock at cost	470,125	470,125
Total shareholders equity	1,880,127	1,845,936
Total liabilities and shareholders equity	$ 2,187,031	$ 2,135,673

See Notes to Condensed Consolidated Financial Statements

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Condensed Consolidated Statements of Cash Flows

MYLAN LABORATORIES INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows
(unaudited; in thousands)

Three Months Ended June 30,	**2005**	**2004**
Cash flows from operating activities:		
Net earnings	$ 42,915	$ 82,033
Adjustments to reconcile net earnings to net cash provided from operating activities:		
Depreciation and amortization	11,505	10,961
Deferred income tax benefit	(17,281)	(6,741)
Net loss from equity method investees	270	1,200
Changes in estimated sales allowances	6,934	8,723
Restructuring provision	10,203	
Other non-cash items	2,975	1,437
Loss (gain) from litigation, net	12,000	(25,985)
Receipts from litigation settlements	2,000	52,035
Changes in operating assets and liabilities:		
Accounts receivable	28,559	(31,345)
Inventories	24,325	5,219
Trade accounts payable	(27,136)	17,204
Income taxes	3,226	38,035
Other operating assets and liabilities, net	5,941	(3,500)
Net cash provided from operating activities	106,436	149,276
Cash flows from investing activities:		
Capital expenditures	(25,142)	(19,500)
Purchase of marketable securities	(250,462)	(249,539)
Proceeds from sale of marketable securities	379,183	196,400
Other items, net	(1,842)	1,970
Net cash provided by (used in) investing activities	101,737	(70,669)
Cash flows from financing activities:		
Cash dividends paid	(8,078)	(8,052)
Proceeds from exercise of stock options	5,005	3,037
Net cash used in financing activities	(3,073)	(5,015)
Net increase (decrease) in cash and cash equivalents	205,100	73,592
Cash and cash equivalents - beginning of period	137,733	101,713
Cash and cash equivalents - end of period	$ 342,833	$ 175,305

Additional disclosures:		
Cash paid for income taxes	$ 36,260	$ 13,983

See Notes to Condensed Consolidated Financial Statements

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Notes to Condensed Consolidated Financial Statements

MYLAN LABORATORIES INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(unaudited; dollars in thousands, except Note 11 and per share amounts)

1. General

In the opinion of management, the accompanying unaudited condensed consolidated financial statements (interim financial statements) of Mylan Laboratories Inc. and subsidiaries (Mylan or the Company) were prepared in accordance with accounting principles generally accepted in the United States of America and the rules and regulations of the Securities and Exchange Commission for reporting on Form 10-Q; therefore, as permitted under these rules, certain footnotes and other financial information included in audited financial statements were condensed or omitted. The interim financial statements contain all adjustments (consisting of only normal recurring adjustments) necessary to present fairly the interim results of operations, financial position and cash flows for the periods presented.

These interim financial statements should be read in conjunction with the Consolidated Financial Statements and Notes thereto in the Company s Annual Report on Form 10-K for the fiscal year ended March 31, 2005.

The interim results of operations for the three months ended June 30, 2005, and the interim cash flows for the three months ended June 30, 2005, are not necessarily indicative of the results to be expected for the full fiscal year or any other future period.

During the first quarter of fiscal 2006, Mylan announced that it was closing Mylan Bertek Pharmaceuticals Inc. (Mylan Bertek), its branded subsidiary (see Note 4). Mylan had previously reported its financial results in two reportable segments, Generic and Brand. With the closure of Mylan Bertek, management now evaluates the business as one segment, pharmaceuticals, and will report as such effective with this first quarter. In accordance with Statement of Financial Accounting Standards (SFAS) No. 131, information for earlier periods shall be restated and reported as one segment.

2. Revenue Recognition and Accounts Receivable

Revenue is recognized for product sales upon shipment when title and risk of loss transfer to the Company s customers and when provisions for estimates, including discounts, rebates, price adjustments, returns, chargebacks and other promotional programs are reasonably determinable. No revisions were made to the methodology used in determining these provisions during the three month period ended June 30, 2005. Accounts receivable are presented net of allowances relating to these provisions. Such allowances were $349,792 and $349,355 as of June 30, 2005, and March 31, 2005. Other current liabilities include $58,269 and $51,772 at June 30, 2005, and March 31, 2005, for certain rebates and other adjustments that are payable to indirect customers.

3. Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board issued SFAS No. 123(R), *Share-Based Payment.* SFAS 123(R) establishes standards for the accounting for transactions in which an entity exchanges its equity instruments for goods and services. Under SFAS 123(R), companies will no longer be able to account for share-based compensation transactions using the intrinsic method in accordance with APB No. 25, *Accounting for Stock Issued to Employees*. Instead, companies will be required to account for such transactions using a fair-value method and to recognize compensation expense over the period during which an employee is required to provide services in exchange for the award. In April 2005, the SEC delayed the effective date of SFAS No. 123(R) to fiscal years beginning after June 15, 2005. Management is currently assessing the impact that adoption of this Statement will have on the Company s Consolidated Financial Statements.

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4. Restructuring

On June 14, 2005, the Company announced that it was closing its branded subsidiary, Mylan Bertek, and transferring the responsibility for marketing Mylan Bertek s products to other Mylan subsidiaries. In conjunction with this restructuring, which is expected to be completed by September 30, 2005, Mylan recorded $10,203, pre-tax, in restructuring charges, during the first quarter of fiscal 2006, of which $231 is included in research and development expense, with the remainder in selling, general and administrative expense. The major components of the restructuring charge and the remaining accrual balance at June 30, 2005, were as follows:

	Non-cash Asset Write-downs	Employee Termination & Severance Costs	Other Exit Costs	Total
Initial charge - quarter ended June 30, 2005	$ 970	6,953	2,280	$10,203
Amounts utilized - quarter ended June 30, 2005	(970)	(4,248)		(5,218)
Accrued restructuring costs - June 30, 2005	$	2,705	2,280	$ 4,985

Employee termination and severance costs are primarily related to involuntary terminations, most of which were with respect to the Mylan Bertek sales force, and represent cash termination payments to be paid to the affected employees as a direct result of the restructuring. Employee termination and severance costs do not represent all of the amounts to be recorded in connection with the separation of the affected employees, as additional costs will be recognized during the second quarter of fiscal 2006 as eligibility requirements are met.

Non-cash asset write-downs consisted primarily of sample inventory that was to be distributed by the Mylan Bertek sales force. Additional amounts with respect to the destruction of existing sample inventory are included in other exit costs. Also included in other exit costs are costs associated with the termination of automobile leases, mostly associated with the Mylan Bertek sales force.

During the second quarter of fiscal 2006, the Company expects to incur an additional estimated $10,000, pre-tax, of costs related to the restructuring such as additional employee termination and severance costs and additional lease termination costs, which will be expensed as incurred.

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5. Balance Sheet Components

Selected balance sheet components consist of the following:

	June 30, 2005	March 31, 2005
Inventories:		
Raw materials	$ 106,927	$ 119,654
Work in process	37,446	39,589
Finished goods	116,750	127,024
	$ 261,123	$ 286,267
Property, plant and equipment:		
Land and improvements	$ 10,574	$ 9,704
Buildings and improvements	169,625	161,050
Machinery and equipment	275,446	269,208
Construction in progress	90,386	85,324
	546,031	525,286
Less - accumulated depreciation	192,482	188,567
	$ 353,549	$ 336,719
Other current liabilities:		
Accrued rebates	$ 58,269	$ 51,772
Payroll and employee benefit plan accruals	30,988	21,251
Royalties and product license fees	8,758	11,446
Legal and professional	29,035	18,148
Cash dividends payable	16,184	8,078
Current portion of long-term obligations	1,586	1,586
Other	20,953	10,989
	$ 165,773	$ 123,270

6. Earnings per Common Share

Basic earnings per common share is computed by dividing net earnings by the weighted average number of common shares outstanding during the period. Diluted earnings per common share is computed by dividing net earnings by the weighted average number of common shares outstanding during the period adjusted for the dilutive effect of stock options and restricted stock outstanding. The effect of dilutive stock options on the weighted average number of common shares outstanding was 3,817,000 and 6,856,000 for the three months ended June 30, 2005 and 2004.

Options to purchase 6,178,000 and 244,300 shares of common stock were outstanding as of June 30, 2005 and 2004, but were not included in the computation of diluted earnings per share for the three months then ended because to do so would have been antidilutive.

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7. Intangible Assets

Intangible assets consist of the following components:

	Weighted Average Life (years)	Original Cost	Accumulated Amortization	Net Book Value
June 30, 2005				
Amortized intangible assets:				
Patents and technologies	19	$ 118,935	$ 50,002	$ 68,933
Product rights and licenses	12	112,033	71,915	40,118
Other	20	14,267	6,706	7,561
		$ 245,235	$ 128,623	116,612
Intangible assets no longer subject to amortization:				
Trademarks				783
				$ 117,395
March 31, 2005				
Amortized intangible assets:				
Patents and technologies	19	$ 118,935	$ 48,478	$ 70,457
Product rights and licenses	12	111,433	69,923	41,510
Other	20	14,267	6,524	7,743
		$ 244,635	$ 124,925	119,710
Intangible assets no longer subject to amortization:				
Trademarks				783
				$ 120,493

Amortization expense for the three months ended June 30, 2005, and 2004 was $3,698 and $4,550 and is expected to be $14,851, $14,603, $14,151, $13,840 and $12,822 for fiscal years 2006 through 2010, respectively.

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8. Comprehensive Earnings

Comprehensive earnings consist of the following:

	Three Months	
Three Months Ended June 30,	**2005**	**2004**
Net earnings	$ 42,915	$ 82,033
Other comprehensive earnings net of tax:		
Net unrealized gain (loss) on marketable securities	1,495	(593)
Reclassification for (gains) losses included in net earnings	(14)	136
	1,481	(457)
Comprehensive earnings	$ 44,396	$ 81,576

Accumulated other comprehensive earnings, as reflected on the balance sheet, is comprised solely of the net unrealized gain on marketable securities, net of deferred income taxes.

9. Common Stock

As of June 30, 2005, and March 31, 2005, there were 600,000,000 shares of common stock authorized with 304,895,945 and 304,434,724 shares issued. Treasury shares held as of both June 30, 2005, and March 31, 2005, were 35,129,643.

On June 14, 2005, Mylan announced a $1,250,000 share buyback, comprised of a modified Dutch Auction self-tender for up to $1,000,000 (which commenced on June 16, 2005) and a $250,000 follow-on share repurchase program in the open market or otherwise, shares under which can be repurchased beginning 10 business days subsequent to the expiration of the Dutch Auction. In the tender offer, shareholders were given the opportunity to tender some or all of their shares at a price not less than $18.00 per share or more than $20.50 per share. Based on the number of shares tendered and the prices specified by the tendering shareholders, Mylan determined the lowest per share price within the range that would enable it to buy up to 48,780,487 shares, or such lesser number of shares as were properly tendered. Additionally, in the event the final purchase price was less than the maximum price of $20.50 per share and more than 48,780,487 shares were tendered, Mylan generally would have the right to purchase up to an additional 2% of its outstanding common stock without extending the tender offer, so that Mylan could repurchase up to $1,000,000 of its common stock.

The tender offer expired on July 15, 2005, and closed on July 21, 2005, at which time the Company announced that it accepted for payment an aggregate of 51,282,051 shares of its common stock at a purchase price of $19.50 per share. These shares represent approximately 19% of the shares outstanding as of July 20, 2005. The 51,282,051 shares are comprised of the 48,780,487 shares Mylan offered to purchase and 2,501,564 shares purchased pursuant to Mylan s right to purchase up to an additional 2%. See Note 12.

Mylan plans to use existing cash reserves to buy back up to an additional $250,000 of its common stock from time to time on the open market or otherwise, commencing on or after August 1, 2005. Upon completion of the self-tender and the open market purchases, and depending on the actual purchase prices, Mylan expects to have repurchased a total of approximately 25% of its shares outstanding at July 20, 2005.

Mylan also announced on June 14, 2005, that it will double its annual dividend from $0.12 per share to $0.24 per share, effective with the dividend to be paid for the first quarter of fiscal 2006.

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10. Stock Option Plans

On July 25, 2003, Mylan shareholders approved the Mylan Laboratories Inc. 2003 Long-Term Incentive Plan (the 2003 Plan). Under the 2003 Plan, 22,500,000 shares of common stock are reserved for issuance to key employees, consultants, independent contractors and non-employee directors of Mylan through a variety of incentive awards including: stock options, stock appreciation rights, restricted shares and units, performance awards, other stock based awards and short-term cash awards.

In accordance with the provisions of SFAS No. 123, *Accounting for Stock-Based Compensation* and SFAS No. 148, *Accounting for Stock-Based Compensation-Transition and Disclosure, an amendment of FASB Statement No. 123*, the Company accounts for stock option plans under the intrinsic-value-based method as defined in APB 25. The following table illustrates the effect on net earnings and earnings per share if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation:

Three Months Ended June 30,		**2005**	**2004**
Net earnings as reported		$ 42,915	$ 82,033
Add:	Stock-based compensation expense included in reported net income, net of related tax effects	979	979
Deduct:	Total compensation expense determined under the fair value based method for all stock awards, net of related tax effects	(933)	(4,652)
Pro forma net earnings		$ 42,961	$ 78,360
Earnings per share:			
Basic as reported		$ 0.16	$ 0.31
Basic pro forma		$ 0.16	$ 0.29
Diluted as reported		$ 0.16	$ 0.30
Diluted pro forma		$ 0.16	$ 0.29

Included in total compensation expense determined under the fair value based method in the first quarter of fiscal 2006, are favorable adjustments totaling $3,200 related to compensation expense which had been previously recognized for employees that were terminated as part of the closing of Mylan Bertek.

11. Contingencies

Legal Proceedings and Investigations

While it is not possible to determine with any degree of certainty the ultimate outcome of the following legal proceedings and investigations, the Company believes that it has meritorious defenses with respect to the claims asserted against it and intends to vigorously defend its position. An adverse outcome in any of these proceedings could have a material adverse effect on the Company s financial position and results of operations.

Omeprazole

In fiscal 2001, Mylan Pharmaceuticals Inc. (MPI), a wholly-owned subsidiary of Mylan Laboratories Inc. (Mylan Labs), filed an ANDA seeking approval from the Food and Drug Administration (FDA) to manufacture, market and sell omeprazole delayed-release capsules, and made Paragraph IV certifications to several patents owned by AstraZeneca PLC (AstraZeneca) that were listed in the FDA s Orange Book . On September 8, 2000,

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AstraZeneca filed suit against MPI and Mylan Labs in the U.S. District Court for the Southern District of New York alleging infringement of several of AstraZeneca s patents. MPI filed multiple motions for summary judgment as to all claims of infringement, and the summary judgment motions remain pending. On May 29, 2003, the FDA approved MPI s ANDA for the 10 mg and 20 mg strengths of omeprazole delayed-release capsules and, on August 4, 2003, Mylan Labs announced that MPI had commenced the sale of omeprazole 10 mg and 20 mg delayed-release capsules. AstraZeneca then amended the pending lawsuit to assert claims against Mylan Labs and MPI, and filed a separate lawsuit against MPI s supplier, Esteve Quimica S.A., for unspecified money damages and a finding of willful infringement which could result in treble damages, injunctive relief, attorneys fees, costs of litigation and such further relief as the court deems just and proper.

Lorazepam and Clorazepate

On June 1, 2005, a jury verdict was rendered against Mylan Labs and MPI in the U.S. District Court for the District of Columbia in the amount of approximately $12.0 million, which has been accrued as of June 30, 2005. The jury found Mylan willfully violated Massachusetts, Minnesota and Illinois state antitrust laws, meaning the amount of the verdict could be trebled, and an award of attorneys fees and litigation costs could be made to the plaintiffs. The case was brought by four health insurers who opted out of earlier class action settlements agreed to by the Company in 2001, and represents the last remaining claims relating to Mylan s 1998 price increases for lorazepam and clorazepate. The Company has filed a motion for judgment as a matter of law, which remains pending before the court. If the Company s post-verdict motion is denied, the Company intends to appeal to the U.S. Court of Appeals for the D.C. circuit.

Pricing and Medicaid Litigation

On September 26, 2003, the Commonwealth of Massachusetts sued Mylan Labs and 12 other generic drug companies alleging unlawful manipulation of reimbursements under the Massachusetts Medicaid program. The lawsuit identified three drug products sold by MPI, and sought equitable relief, attorneys fees, cost of litigation and monetary damages in unspecified sums. The court has dismissed the complaint, without prejudice, and granted Massachusetts leave to amend.

On June 26, 2003, UDL and MPI received requests from the U.S. House of Representatives Energy and Commerce Committee requesting information about certain drug products sold by UDL and MPI, in connection with the Committee s investigation into pharmaceutical reimbursement and rebates under Medicaid. UDL and MPI are cooperating with this inquiry and provided information in response to the Committee s requests in 2003. Several states Attorneys General (AGs) have also sent letters to MPI, UDL and Mylan Bertek Pharmaceuticals Inc., a wholly-owned subsidiary of Mylan Labs, demanding that those companies retain documents relating to Medicaid reimbursement and rebate calculations pending the outcome of unspecified investigations by those AGs into such matters. In addition, in July 2004, Mylan Labs received subpoenas from the AGs of California and Florida in connection with civil investigations purportedly related to price reporting and marketing practices regarding various drugs. Mylan is cooperating with each of these investigations and has begun producing information in response to the subpoenas.

On August 4, 2004, the City of New York filed a civil lawsuit against 44 pharmaceutical companies, including Mylan Labs, in the U.S. District Court for the Southern District of New York alleging violations of federal and state Medicaid laws, Medicaid and common law fraud, breach of contract, other New York statutes and regulations, and unjust enrichment, and on January 26, 2005, the plaintiff filed an amended complaint naming MPI and UDL as defendants. The case has been transferred to the average wholesale prices (AWP) multi-district litigation proceedings pending in the U.S. District Court for the District of Massachusetts for pretrial proceedings. A similar suit was filed by the Commonwealth of Kentucky on November 4, 2004, against Mylan Labs, MPI and approximately 40 other pharmaceutical companies in the Franklin County Circuit Court alleging violations of the Kentucky Consumer Protection Act, the Kentucky Medicaid Fraud Statute, the Kentucky False Advertising Statute, fraud and negligent misrepresentation relating to reporting of AWP. In addition, on December 6, 2004, the State of Wisconsin sued Mylan Labs, MPI and approximately 35 other pharmaceutical companies in the Circuit Court for Dane County, Wisconsin alleging violations of Wisconsin false advertising, price reporting and fraud statutes and, the Wisconsin Trusts and Monopolies Act, and also asserting a claim for unjust enrichment. Nassau County, New York filed a similar complaint in the U.S. District Court for the Eastern District of New York on November 24, 2004

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containing federal and state claims against numerous pharmaceutical companies including Mylan Labs, MPI and UDL. On January 26, 2005, the Counties of Rockland, Suffolk and Westchester filed amended complaints in the U.S. District Court for the District of Massachusetts against approximately 50 pharmaceutical companies, including Mylan Labs, MPI and UDL, alleging violations of federal and state Medicaid laws, Medicaid and common law fraud, breach of contract, other New York statutes and regulations and unjust enrichment. Onondaga County, New York filed a substantially similar complaint in the U.S. District Court for the Northern District of New York in January 2005. In addition to the case filed by Onandaga, Rockland, Suffolk and Westchester Counties, New York, Mylan Labs, MPI and UDL have been named as defendants along with several dozen other drug manufacturers in lawsuits filed by 22 other counties in the State of New York since March 2005, asserting substantially similar claims. On January 26, 2005, the State of Alabama filed suit against 79 pharmaceutical companies, including Mylan Labs, MPI and UDL, in the Circuit Court of Montgomery County, Alabama, alleging that Alabama has been defrauded by false reporting of AWP, WAC and direct prices and asserts claims for fraud, wantonness and unjust enrichment, seeking compensatory and punitive damages and injunctive relief. Similar actions have been filed by the State of Illinois under Illinois law and, on July 20, 2005, by the Florida AG under Florida law, naming Mylan Labs and other pharmaceutical companies as defendants. In addition, the Company has been informed that the State of California will be filing an amended complaint that adds Mylan and other additional companies as defendants in its ongoing pharmaceutical pricing, Medicaid and AWP litigation. In each of these matters, Mylan Labs and its subsidiaries have not yet been required to respond to the complaint or the amended complaint, as applicable. The Company intends to defend these actions vigorously.

By letter dated January 12, 2005, MPI was notified by the U.S. Department of Justice of an investigation concerning MPI s calculations of Medicaid drug rebates. To the best of MPI s information, the investigation is in its early stages. MPI is collecting information requested by the government and is cooperating fully with the government s investigation.

Shareholder Litigation

On November 22, 2004, an individual purporting to be a Mylan Labs shareholder, filed a civil action in the Court of Common Pleas of Allegheny County, Pennsylvania, against Mylan Labs and all members of its Board of Directors alleging that the Board members had breached their fiduciary duties by approving the planned acquisition of King Pharmaceuticals, Inc. (King) and by declining to dismantle the Company s anti-takeover defenses to permit an auction of the Company to Carl Icahn or other potential buyers of the Company, and also alleging that certain transactions between the Company and its directors (or their relatives or companies with which they were formerly affiliated) may have been wasteful. On November 23, 2004, a substantially identical complaint was filed in the same court by another purported Mylan Labs shareholder. The actions are styled as shareholder derivative suits on behalf of Mylan Labs and class actions on behalf of all Mylan Labs shareholders, and have been consolidated by the court under the caption In re Mylan Laboratories Inc. Shareholder Litigation. Mylan Labs and its directors filed preliminary objections seeking dismissal of the complaints. On January 19, 2005, the plaintiffs amended their complaints to add Bear Stearns & Co., Inc., Goldman Sachs & Co., Richard C. Perry, Perry Corp., American Stock Transfer & Trust Company, and John Does 1-100 as additional defendants, and to add claims regarding trading activity by the additional defendants and the implications on Mylan Labs shareholder rights agreement. The plaintiffs are seeking injunctive and declaratory relief and undisclosed damages. Mylan Labs and its directors have not yet been required to respond to the amended complaint.

On December 10, 2004, High River Limited Partnership (High River), an entity controlled by Carl Icahn, filed suit in the U.S. District Court for the Middle District of Pennsylvania against Mylan Labs, its Vice Chairman and Chief Executive Officer Robert J. Coury, Richard C. Perry, Perry Corp. and John Does 1-100 , asserting against the Company a claim for violation of federal securities laws and against the Company and Mr. Coury a claim for alleged breaches of Pennsylvania statutory and common law, in connection with SEC filings and other public statements concerning the planned King acquisition. The complaint also asserted claims under the federal securities laws and Pennsylvania corporate law concerning a possible shareholder vote relating to the proposed merger. On January 27, 2005, the court granted a motion by defendants Perry Corp. and Mr. Perry to transfer the case to the U.S. District Court for the Southern District of New York. Mylan Labs, Mr. Coury and the other defendants filed motions to

dismiss the complaint in its entirety. On May 27, 2005, High River voluntarily dismissed the lawsuit without prejudice.

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On February 22, 2005, High River filed a complaint naming Mylan Labs and its directors in the U.S. District Court for the Middle District of Pennsylvania challenging the validity under Pennsylvania law of amendments to the provisions of the Company s bylaws requiring shareholders to provide advance notice of nominations of directors for election at Mylan Labs annual meeting of shareholders. High River sought a temporary restraining order (TRO) in an attempt to block implementation of the advance notice bylaw. The Court denied High River s motion for a TRO, and High River voluntarily withdrew the case without prejudice. On March 24, 2005, High River filed another complaint in the same court naming the same defendants and seeking substantially the same relief. The second complaint also challenged the validity of the provisions of the Company s bylaws requiring advance notice by shareholders of other business to be conducted at the annual meeting. On June 6, 2005, the Court issued an order, among other things, dismissing the case against the Company s directors and dismissing all claims against Mylan for money damages. On July 22, 2005, High River agreed to the dismissal of the suit without prejudice.

Other Litigation

The Company is involved in various other legal proceedings that are considered normal to its business. While it is not feasible to predict the ultimate outcome of such other proceedings, the Company believes that the ultimate outcome of such other proceedings will not have a material adverse effect on its financial position or results of operations.

12. Subsequent Event

As discussed in Note 9, on June 14, 2005, Mylan announced a $1,250,000 share buyback, comprised of a modified Dutch Auction self- tender for up to $1,000,000 (which commenced on June 16, 2005) and a $250,000 follow-on share repurchase program in the open market or otherwise, shares under which can be repurchased beginning 10 business days subsequent to the closing of the Dutch Auction. The tender offer expired on July 15, 2005, and closed on July 21, 2005, at which time the Company announced that it accepted for payment an aggregate of 51,282,051 shares of its common stock at a purchase price of $19.50 per share.

Mylan financed the Dutch Auction self-tender described above and the related transaction costs through its existing cash reserves as well as the issuance of $500,000 in Senior Notes and borrowings of $275,000 from a senior credit facility. The Senior Notes, which were issued on July 21, 2005, consist of $150,000 of Senior Notes due 2010, and bearing interest at 5 3/4%, and $350,000 of Senior Notes due 2015, and bearing interest at 6 3/8%. The senior credit facility, which was also entered into on July 21, 2005, consists of a $225,000 five-year revolving credit facility, which the Company did not draw upon at closing, but may use for future working capital and general corporate purposes, and a $275,000 five-year term loan which bears interest at LIBOR plus 150 basis points. Also, in connection with the closing of the financing described above, Mylan terminated a $50.0 million revolving line of credit with a commercial bank.

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ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF RESULTS OF OPERATIONS AND FINANCIAL CONDITION

The following discussion and analysis addresses material changes in the results of operations and financial condition of Mylan Laboratories Inc. and Subsidiaries (the Company , Mylan or we) for the periods presented. This discussion and analysis should be read in conjunction with the Consolidated Financial Statements, the related Notes to Consolidated Financial Statements and Management s Discussion and Analysis of Results of Operations and Financial Condition included in the Company s Annual Report on Form 10-K for the fiscal year ended March 31, 2005, the unaudited interim Condensed Consolidated Financial Statements and related Notes included in Item 1 of this Report on Form 10-Q (Form 10-Q) and the Company s other SEC filings and public disclosures.

This Form 10-Q may contain forward-looking statements . These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements may include, without limitation, statements about the Company s market opportunities, strategies, competition and expected activities and expenditures, and at times may be identified by the use of words such as may , will , could , should , would , project , believe , anticipate , expect , plan , estimate , forecast , potential , intend , continue words or comparable words. Forward-looking statements inherently involve risks and uncertainties. Accordingly, actual results may differ materially from those expressed or implied by these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, the risks described below under Risk Factors in this Item 2. The Company undertakes no obligation to update any forward-looking statements for revisions or changes after the date of this Form 10-Q.

Overview

Mylan s financial results for the three months ended June 30, 2005, included net revenues of $323.4 million, net earnings of $42.9 million and earnings per diluted share of $0.16. Comparatively, the three months ended June 30, 2004, included revenues of $339.0 million, net earnings of $82.0 million and earnings per diluted share of $0.30. This represents a decrease of 5% in revenues, 48% in net earnings and 47% in earnings per diluted share when compared to the same prior year period. Included in the first quarter of fiscal 2006 was a charge of $0.03 per diluted share with respect to a contingent legal liability related to previously-disclosed litigation in connection with the Company s lorazepam and clorazepate products. Included in the financial results for the first quarter of fiscal 2005 was $0.06 per diluted share of income from the favorable settlement of other litigation.

Mylan commenced several significant strategic initiatives during the first quarter of fiscal 2006. These include:

Share Buyback On June 14, 2005, Mylan announced a $1.25 billion share buyback, comprised of a modified Dutch Auction self-tender for up to $1.0 billion (which commenced on June 16, 2005) and a $250.0 million follow-on share repurchase program in the open market or otherwise, shares under which can be repurchased beginning 10 business days subsequent to the expiration of the Dutch Auction. In the tender offer, shareholders were given the opportunity to tender some or all of their shares at a price not less than $18.00 per share or more than $20.50 per share. Based on the number of shares tendered and the prices specified by the tendering shareholders, Mylan determined the lowest per share price within the range that would enable it to buy up to 48,780,487 shares, or such lesser number of shares as were properly tendered. Additionally, in the event the final purchase price was less than the maximum price of $20.50 per share and more than 48,780,487 shares were tendered, Mylan generally would have the right to purchase up to an additional 2% of its outstanding common stock without extending the tender offer, so that Mylan can repurchase up to $1.0 billion of its common stock.

The tender offer expired on July 15, 2005, and closed on July 21, 2005, at which time the Company announced that it accepted for payment an aggregate of 51,282,051 shares of its common stock at a purchase price of $19.50 per share. These shares represent approximately 19% of the shares outstanding as of July 20, 2005. The 51,282,051 shares are comprised of the 48,780,487 shares Mylan offered to purchase and 2,501,564 shares purchased pursuant to Mylan s right to purchase up to an additional 2%.

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Mylan plans to use existing cash reserves to buy back up to an additional $250.0 million of its common stock from time to time on the open market or otherwise, commencing on or after August 1, 2005. Upon completion of the self-tender and the open market purchases, and depending on the actual purchase prices, Mylan expects to have repurchased a total of approximately 25% of its shares outstanding at July 20, 2005.

Financing Mylan financed the Dutch Auction self-tender described above and the related transaction costs through its existing cash reserves as well as the issuance of $500.0 million in Senior Notes and borrowings of $275.0 million from a senior credit facility. The Senior Notes, which were issued on July 21, 2005, consist of $150.0 million of Senior Notes due 2010, and bearing interest at 5 3/4%, and $350.0 million of Senior Notes due 2015, and bearing interest at 6 3/8%. The senior credit facility, which was also entered into on July 21, 2005, consists of a $225.0 million five-year revolving credit facility, which the Company did not draw upon at closing, but may use for future working capital and general corporate purposes, and a $275.0 million five-year term loan which bears interest at LIBOR plus 150 basis points.

Planned Outlicensing of Nebivolol Mylan announced that it has decided to out-license nebivolol, its highly anticipated beta-blocker. The nebivolol NDA for a hypertension indication was submitted to the Food and Drug Administration (FDA) in April 2004, and Mylan has now received an Approvable Letter from the FDA. Final approval of nebivolol is contingent upon successfully satisfying additional FDA requirements regarding certain aspects of pre-clinical data and finalization of the labeling. The Company believes that the data from the ongoing pre-clinical study will satisfactorily resolve the FDA s questions and is committed to working diligently with the FDA towards final approval. The Company also entered into a collaboration agreement with Menarini, the European marketer of nebivolol, to use certain data from the SENIORS trial conducted in Europe by Menarini to include in an NDA for a congestive heart failure indication.

Increased Dividend Mylan announced that it doubled its annual dividend from $0.12 per share to $0.24 per share. This dividend increase was effective with the dividend paid for the first quarter of fiscal 2006 which was paid on July 15, 2005.

Closure of Mylan Bertek During the first quarter of fiscal 2006, Mylan announced that it was closing Mylan Bertek Pharmaceuticals Inc. (Mylan Bertek), its branded subsidiary, and transferring responsibility for marketing Mylan Bertek s products to its other subsidiaries, Mylan Pharmaceuticals Inc. (MPI) and UDL Laboratories, Inc. (UDL). In connection with this restructuring, which is expected to be completed by September 30, 2005, the Company incurred a pre-tax charge of approximately $10.2 million in the first quarter of fiscal 2006. The Company expects to incur an additional estimated $10.0 million in the second quarter of fiscal 2006, of costs related to the restructuring such as additional severance and additional lease termination costs, which will be expensed as incurred.

Of the $10.2 million expensed in the current quarter, $0.2 million is included in research and development (R&D) expense, with the remainder in selling, general and administrative (SG&A) expense.

Mylan had previously reported its financial results in two reportable segments; Generic and Brand. With the closure of Mylan Bertek, its branded subsidiary, management now evaluates the business as one segment, pharmaceuticals, and will report as such effective with this first quarter. In accordance with SFAS No. 131, information for earlier periods shall be restated and reported as one segment. A detailed discussion of the Company s financial results follows.

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Results of Operations

Quarter Ended June 30, 2005, Compared to Quarter Ended June 30, 2004

Total Revenues and Gross Profit

Revenues for the current quarter decreased 5% or $15.6 million to $323.4 million compared to $339.0 million in the first quarter of fiscal 2005. Pricing pressure on the Company s product portfolio, most notably omeprazole, carbidopa/levodopa and Amnesteem , is the result of increased competition, and is the primary reason for the decrease in net revenues versus the prior year. As is the case in the generic industry, the entrance into the market of additional competition generally has a negative impact on the volume and pricing of the affected products. In the near term, it is likely that unfavorable pricing will continue to impact certain products in the Company s portfolio.

The decrease due to unfavorable pricing was partially offset by sales of new products which contributed net revenue of $55.0 million in the current quarter, substantially all of which was due to fentanyl, which was launched during the fourth quarter of fiscal 2005. As a result of product mix, the impact of volume on revenue for the quarter was relatively consistent although actual doses shipped decreased by approximately 9% to 3.0 billion.

Consolidated gross profit decreased 7% or $11.8 million to $168.0 million and gross margins decreased to 51.9% from 53%. The decrease in gross margins is primarily the result of the pricing pressure discussed above.

Operating Expenses

Research and development expenses for the current quarter increased 17% or $3.6 million to $25.1 million from $21.5 million in the same prior year period. This increase was due primarily to an increase in the number of ongoing R&D studies, including those with respect to nebivolol.

Selling, general and administrative expenses increased by 23% or $13.6 million to $71.3 million from $57.7 million. This increase is primarily the result of the restructuring charge associated with the closure of Mylan Bertek. The restructuring charge, $10.0 million of which is included in SG&A, consists primarily of $7.0 million of severance and related costs, mostly associated with the Mylan Bertek sales force. Automobile lease termination costs and sample inventory write-offs comprise the balance of the restructuring charge.

Litigation, net

The first quarter of fiscal 2006 included a charge of $12.0 million for a contingent liability with respect to the Company s previously disclosed lorazepam and clorazepate product litigation. In the same prior year period, net gains of $26.0 million were recorded with respect to settlement of other litigation.

Other Income, net

Other income, net of non-operating expenses, was $5.6 million in the first quarter of fiscal 2006 compared to $0.7 million in the same prior year period. The increase is primarily the result of higher interest and dividend income on our investments in marketable securities, as well as less of a loss recorded on our investment in Somerset Pharmaceuticals, Inc. (Somerset).

We own a 50% equity interest in Somerset and account for this investment using the equity method of accounting. The recorded loss in Somerset in the first quarter of fiscal 2006 was $0.3 million compared to $1.4 million in the same prior year period.

Liquidity and Capital Resources

The Company s primary source of liquidity as of and for the quarter ended June 30, 2005, was cash flows from operating activities, which were $106.4 million. Working capital as of June 30, 2005, was $1.3 billion, an increase of $19.6 million from the balance at March 31, 2005. The majority of this increase was the result of higher cash and

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cash equivalents and lower accounts payable, partially offset by lower accounts receivable, net, lower inventories, lower marketable securities and increased accrued expenses.

The decrease in accounts payable is the result of the change in the amount of outstanding checks in excess of cash in our primary disbursement accounts. The Company utilizes a cash management system under which uncleared checks in excess of the cash balance in the bank account at the end of the reporting period are shown as a book cash overdraft. The Company transfers cash on an as-needed basis to fund clearing checks. The Company does not incur any financing charges with respect to this arrangement. At March 31, 2005, approximately $29.4 million was included in accounts payable as a book cash overdraft. No overdraft existed at June 30, 2005.

The decrease in accounts receivable is primarily due to the timing of cash collections during the quarter, primarily with respect to fourth quarter sales of fentanyl. Inventory decreased as the result of normal consumption and lower finished goods primarily as a result of higher than expected orders for one of the Company s products. Accrued expenses increased primarily as a result of a $12.0 million liability recorded with respect to a legal contingency related to the Company s previously announced lorazepam and clorazepate product litigation, a restructuring accrual of $5.0 million, an increase in payroll and payroll related accruals and higher accrued rebates.

During the first quarter of fiscal 2005, Mylan received $52.0 million from the settlement of various lawsuits. Of this amount, approximately $35.0 million related to the settlement of certain patent litigation claims involving omeprazole, and the majority of the remainder related to a settlement reached with respect to mirtazapine.

Cash provided by investing activities for the three months ended June 30, 2005, was $101.7 million. Of the Company s $2.2 billion of total assets at June 30, 2005, $886.8 million was held in cash, cash equivalents and marketable securities. Investments in marketable securities consist primarily of a variety of high credit quality debt securities, including U.S. government, state and local government and corporate obligations. These investments are highly liquid and available for working capital needs. As these instruments mature, the funds are generally reinvested in instruments with similar characteristics.

Capital expenditures during the three months ended June 30, 2005, were $25.1 million. These expenditures were incurred primarily with respect to the Company s previously announced planned expansions. The Company expects capital expenditures for fiscal 2006 to approximate $120.0 million.

Cash used in financing activities was $3.1 million for the three months ended June 30, 2005, and was comprised of proceeds from the exercise of stock options and cash dividends paid. In the first quarter of fiscal 2006, the Board voted to double the amount of the quarterly dividend to 6.0 cents per share from 3.0 cents per share, effective with the dividend paid for the first quarter of fiscal 2006.

On July 21, 2005, Mylan closed a modified Dutch Auction self- tender for approximately $1.0 billion. The Company financed the closing and the related transaction costs through the issuance of $500 million in Senior Notes, $275 million of borrowings under a senior credit facility and existing cash reserves. The Senior Notes, which were issued on July 21, 2005, consist of $150.0 million of Senior Notes due 2010, and bearing interest at 5 3/4%, and $350.0 million of Senior Notes due 2015, and bearing interest at 6 3/8%. The senior credit facility, which was also entered into on July 21, 2005, consists of a $225.0 million five-year revolving credit facility, which the Company did not draw upon at closing, but may use for future working capital and general corporate purposes, and a $275.0 million five-year term loan which bears interest at LIBOR plus 150 basis points. In connection with the closing, the Company incurred approximately $21.0 million in transaction related costs. Also, in connection with the closing of the financing described above, Mylan terminated a $50.0 million revolving line of credit with a commercial bank which had been outstanding throughout the first quarter and up until the date of the above closing. No funds had been advanced under this line of credit.

The Company expects to commence up to a $250.0 million follow-on share repurchase program in the open market or otherwise, beginning on or after August 1, 2005. The Company expects to use existing cash reserves for repurchases under this program.

The Company is involved in various legal proceedings that are considered normal to its business (see Note 11 to Condensed Consolidated Financial Statements). While it is not feasible to predict the outcome of such proceedings,

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an adverse outcome in any of these proceedings could materially affect the Company s financial position and results of operations.

The Company is actively pursuing, and is currently involved in, joint projects related to the development, distribution and marketing of both generic and brand products. Many of these arrangements provide for payments by the Company upon the attainment of specified milestones. While these arrangements help to reduce the financial risk for unsuccessful projects, fulfillment of specified milestones or the occurrence of other obligations may result in fluctuations in cash flows.

The Company is continuously evaluating the potential acquisition of products, as well as companies, as a strategic part of its future growth. Consequently, the Company may utilize current cash reserves or incur additional indebtedness to finance any such acquisitions, which could impact future liquidity.

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards (SFAS) No. 123(R), *Share-Based Payment.* SFAS No. 123(R) establishes standards for the accounting for transactions in which an entity exchanges its equity instruments for goods and services. Under SFAS No. 123(R), companies will no longer be able to account for share-based compensation transactions using the intrinsic method in accordance with APB No. 25, *Accounting for Stock Issued to Employees*. Instead, companies will be required to account for such transactions using a fair-value method and to recognize compensation expense over the period during which an employee is required to provide services in exchange for the award. In April 2005, the SEC delayed the effective date of SFAS No. 123(R) to fiscal years beginning after June 15, 2005. Management is currently assessing the impact that adoption of this Statement will have on the Company s Consolidated Financial Statements.

Risk Factors

The following risk factors could have a material adverse effect on our business, financial position or results of operations and could cause the market value of our common stock to decline. These risk factors may not include all of the important factors that could affect our business or our industry or that could cause our future financial results to differ materially from historic or expected results or cause the market price of our common stock to fluctuate or decline.

OUR FUTURE REVENUE GROWTH AND PROFITABILITY ARE DEPENDENT UPON OUR ABILITY TO DEVELOP AND/OR LICENSE, OR OTHERWISE ACQUIRE, AND INTRODUCE NEW PRODUCTS ON A TIMELY BASIS IN RELATION TO OUR COMPETITORS PRODUCT INTRODUCTIONS. OUR FAILURE TO DO SO SUCCESSFULLY COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Our future revenues and profitability will depend, to a significant extent, upon our ability to successfully develop and/or license, or otherwise acquire, and commercialize new generic and patent or statutorily protected (usually brand) pharmaceutical products in a timely manner. Product development is inherently risky, especially for new drugs for which safety and efficacy have not been established, and the market is not yet proven. Likewise, product licensing involves inherent risks including uncertainties due to matters that may affect the achievement of milestones, as well as the possibility of contractual disagreements with regard to terms such as license scope or termination rights. The development and commercialization process, particularly with regard to new drugs, also requires substantial time, effort and financial resources. We may not be successful in commercializing any of the products that we are developing or licensing (including, without limitation, nebivolol) on a timely basis, if at all, which could adversely affect our product introduction plans, financial position and results of operations and could cause the market value of our common stock to decline.

FDA approval is required before any prescription drug product, including generic drug products, can be marketed. The process of obtaining FDA approval to manufacture and market new and generic pharmaceutical products is rigorous, time-consuming, costly and largely unpredictable. We may be unable to obtain requisite FDA

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approvals on a timely basis for new generic or brand products that we may develop, license or otherwise acquire. Also, for products pending approval, we may obtain raw materials or produce batches of inventory to be used in efficacy and bioequivalency testing, as well as in anticipation of the product s launch. In the event that FDA approval is denied or delayed we could be exposed to the risk of this inventory becoming obsolete. The timing and cost of obtaining FDA approvals could adversely affect our product introduction plans, financial position and results of operations and could cause the market value of our common stock to decline.

The ANDA approval process often results in the FDA granting final approval to a number of ANDAs for a given product at the time a patent claim for a corresponding brand product or other market exclusivity expires. This often forces us to face immediate competition when we introduce a generic product into the market. Additionally, ANDA approvals often continue to be granted for a given product subsequent to the initial launch of the generic product. These circumstances generally result in significantly lower prices, as well as reduced margins, for generic products compared to brand products. New generic market entrants generally cause continued price and margin erosion over the generic product life cycle.

The Waxman-Hatch Act provides for a period of 180 days of generic marketing exclusivity for each ANDA applicant that is first to file an ANDA containing a certification of invalidity, non-infringement or unenforceability related to a patent listed with respect to a reference drug product, commonly referred to as a Paragraph IV certification. During this exclusivity period, which under certain circumstances may be required to be shared with other applicable ANDA sponsors with Paragraph IV certifications, the FDA cannot grant final approval to other ANDA sponsors holding applications for the same generic equivalent. If an ANDA containing a Paragraph IV certification is successful and the applicant is awarded exclusivity, it generally results in higher market share, net revenues and gross margin for that applicant. Even if we obtain FDA approval for our generic drug products, if we are not the first ANDA applicant to challenge a listed patent for such a product, we may lose significant advantages to a competitor that filed its ANDA containing such a challenge. The same would be true in situations where we are required to share our exclusivity period with other ANDA sponsors with Paragraph IV certifications. Such situations could have a material adverse effect on our ability to market that product profitably and on our financial position and results of operations, and the market value of our common stock could decline.

OUR APPROVED PRODUCTS MAY NOT ACHIEVE EXPECTED LEVELS OF MARKET ACCEPTANCE, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR PROFITABILITY, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Even if we are able to obtain regulatory approvals for our new pharmaceutical products, generic or brand, the success of those products is dependent upon market acceptance. Levels of market acceptance for our new products could be impacted by several factors, including:

the availability of alternative products from our competitors;

the price of our products relative to that of our competitors;

the timing of our market entry;

the ability to market our products effectively to the retail level; and

the acceptance of our products by government and private formularies.

Some of these factors are not within our control. Our new products may not achieve expected levels of market acceptance. Additionally, continuing studies of the proper utilization, safety and efficacy of pharmaceutical products are being conducted by the industry, government agencies and others. Such studies, which increasingly employ sophisticated methods and techniques, can call into question the utilization, safety and efficacy of previously marketed products. For example, on July 15, 2005, the FDA issued a Public Health Advisory regarding the safe use of transdermal fentanyl patches, a product we currently market, the loss of revenues of which could have a significant impact on our business. In some cases, studies have resulted, and may in the future result, in the discontinuance of

product marketing. These situations, should they occur, could have a material adverse effect on our profitability, financial position and results of operations, and the market value of our common stock could decline.

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A RELATIVELY SMALL GROUP OF PRODUCTS MAY REPRESENT A SIGNIFICANT PORTION OF OUR NET REVENUES OR NET EARNINGS FROM TIME TO TIME. IF THE VOLUME OR PRICING OF ANY OF THESE PRODUCTS DECLINES, IT COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Sales of a limited number of our products often represent a significant portion of our net revenues and net earnings. If the volume or pricing of our largest selling products declines in the future, our business, financial position and results of operations could be materially adversely affected, and the market value of our common stock could decline.

WE FACE VIGOROUS COMPETITION FROM OTHER PHARMACEUTICAL MANUFACTURERS THAT THREATENS THE COMMERCIAL ACCEPTANCE AND PRICING OF OUR PRODUCTS, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Our competitors may be able to develop products and processes competitive with or superior to our own for many reasons, including that they may have:

- proprietary processes or delivery systems;
- larger research and development and marketing staffs;
- larger production capabilities in a particular therapeutic area;
- more experience in preclinical testing and human clinical trials;
- more products; or
- more experience in developing new drugs and financial resources, particularly with regard to brand manufacturers.

Any of these factors and others could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

BECAUSE THE PHARMACEUTICAL INDUSTRY IS HEAVILY REGULATED, WE FACE SIGNIFICANT COSTS AND UNCERTAINTIES ASSOCIATED WITH OUR EFFORTS TO COMPLY WITH APPLICABLE REGULATIONS. SHOULD WE FAIL TO COMPLY WE COULD EXPERIENCE MATERIAL ADVERSE EFFECTS ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS, AND THE MARKET VALUE OF OUR COMMON STOCK COULD DECLINE.

The pharmaceutical industry is subject to regulation by various federal and state governmental authorities. For instance, we must comply with FDA requirements with respect to the manufacture, labeling, sale, distribution, marketing, advertising, promotion and development of pharmaceutical products. Failure to comply with FDA and other governmental regulations can result in fines, disgorgement, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the FDA s review of NDAs or ANDAs, enforcement actions, injunctions and criminal prosecution. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals. Although we have internal regulatory compliance programs and policies and have had a favorable compliance history, there is no guarantee that these programs, as currently designed, will meet regulatory agency standards in the future. Additionally, despite our efforts at compliance, there is no guarantee that we may not be deemed to be deficient in some manner in the future. If we were deemed to be deficient in any significant way, our business, financial position and results of operations could be materially affected and the market value of our common stock could decline.

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In addition to the new drug approval process, the FDA also regulates the facilities and operational procedures that we use to manufacture our products. We must register our facilities with the FDA. All products manufactured in those facilities must be made in a manner consistent with current good manufacturing practices (cGMP). Compliance with cGMP regulations requires substantial expenditures of time, money and effort in such areas as production and quality control to ensure full technical compliance. The FDA periodically inspects our manufacturing facilities for compliance. FDA approval to manufacture a drug is site-specific. Failure to comply with cGMP regulations at one of our manufacturing facilities could result in an enforcement action brought by the FDA which could include withholding the approval of NDAs, ANDAs or other product applications of that facility. If the FDA were to require one of our manufacturing facilities to cease or limit production, our business could be adversely affected. Delay and cost in obtaining FDA approval to manufacture at a different facility also could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

We are subject, as are generally all manufacturers, to various federal, state and local laws regulating working conditions, as well as environmental protection laws and regulations, including those governing the discharge of materials into the environment. Although we have not incurred significant costs associated with complying with environmental provisions in the past, if changes to such environmental laws and regulations are made in the future that require significant changes in our operations or if we engage in the development and manufacturing of new products requiring new or different environmental controls, we may be required to expend significant funds. Such changes could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

OUR REPORTING AND PAYMENT OBLIGATIONS UNDER THE MEDICAID REBATE PROGRAM AND OTHER GOVERNMENTAL PRICING PROGRAMS ARE COMPLEX AND MAY INVOLVE SUBJECTIVE DECISIONS. ANY DETERMINATION OF FAILURE TO COMPLY WITH THOSE OBLIGATIONS COULD SUBJECT US TO PENALTIES AND SANCTIONS WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS, AND THE MARKET VALUE OF OUR COMMON STOCK COULD DECLINE.

The regulations regarding reporting and payment obligations with respect to Medicaid reimbursement and rebates are complex, and as discussed elsewhere in this Form 10-Q, we and other pharmaceutical companies are defendants in a number of suits filed by state attorneys general and have been notified of an investigation by the U.S. Department of Justice with respect to Medicaid reimbursement and rebates. We believe we are properly and accurately calculating and reporting the amounts owed in respect of Medicaid and other governmental pricing programs; however, our calculations are subject to review and challenge by the applicable governmental agencies, and it is possible that any such review could result in material changes. In addition, because our processes for these calculations and the judgements involved in making these calculations involve, and will continue to involve, subjective decisions, these calculations are subject to the risk of errors.

In addition, as also disclosed in this Form 10-Q, a number of state and federal government agencies are conducting investigations of manufacturers reporting practices with respect to AWP, in which they have suggested that reporting of inflated AWP has led to excessive payments for prescription drugs. We and numerous other pharmaceutical companies have been named as defendants in various actions relating to pharmaceutical pricing issues and whether allegedly improper actions by pharmaceutical manufacturers led to excessive payments by Medicare and/or Medicaid.

Any governmental agencies that have commenced, or may commence, an investigation of the Company could impose, based on a claim of violation of fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from federal health care programs (including Medicaid and Medicare). Some of the applicable laws may impose liability even in the absence of specific intend to defraud. Furthermore, should there be ambiguity with regard to how to properly calculate and report payments and even in the absence of any such ambiguity a governmental authority may take a position contrary to a position we have taken, and may impose civil and/or criminal sanctions. Any such penalties or sanctions could have a material adverse effect on our business, financial position and results or operations and could cause the market value of our common stock to decline.

WE EXPEND A SIGNIFICANT AMOUNT OF RESOURCES ON RESEARCH AND DEVELOPMENT EFFORTS THAT MAY NOT LEAD TO SUCCESSFUL PRODUCT INTRODUCTIONS. FAILURE TO SUCCESSFULLY INTRODUCE PRODUCTS INTO THE MARKET COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS, AND THE MARKET VALUE OF OUR COMMON STOCK COULD DECLINE.

Much of our development effort is focused on technically difficult-to-formulate products and/or products that require advanced manufacturing technology. We conduct research and development primarily to enable us to manufacture and market FDA-approved pharmaceuticals in accordance with FDA regulations. Typically, research

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expenses related to the development of innovative compounds and the filing of NDAs are significantly greater than those expenses associated with ANDAs. As we continue to develop new products, our research expenses will likely increase. Because of the inherent risk associated with research and development efforts in our industry, particularly with respect to new drugs (including, without limitation, nebivolol), our research and development expenditures may not result in the successful introduction of FDA approved new pharmaceutical products. Also, after we submit an NDA or ANDA, the FDA may request that we conduct additional studies and as a result, we may be unable to reasonably determine the total research and development costs to develop a particular product. Finally, we cannot be certain that any investment made in developing products will be recovered, even if we are successful in commercialization. To the extent that we expend significant resources on research and development efforts and are not able, ultimately, to introduce successful new products as a result of those efforts, our business, financial position and results of operations may be materially adversely affected, and the market value of our common stock could decline.

A SIGNIFICANT PORTION OF OUR NET REVENUES ARE DERIVED FROM SALES TO A LIMITED NUMBER OF CUSTOMERS. ANY SIGNIFICANT REDUCTION OF BUSINESS WITH ANY OF THESE CUSTOMERS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS, AND THE MARKET VALUE OF OUR COMMON STOCK COULD DECLINE.

A significant portion of our net revenues are derived from sales to a limited number of customers. As such, a reduction in or loss of business with one customer, or if one customer were to experience difficulty in paying us on a timely basis, our business, financial position and results of operations could be materially adversely affected, and the market value of our common stock could decline.

THE USE OF LEGAL, REGULATORY AND LEGISLATIVE STRATEGIES BY COMPETITORS, BOTH BRAND AND GENERIC, INCLUDING SO-CALLED AUTHORIZED GENERICS AND CITIZEN S PETITIONS, AS WELL AS THE POTENTIAL IMPACT OF PROPOSED LEGISLATION, MAY INCREASE OUR COSTS ASSOCIATED WITH THE INTRODUCTION OR MARKETING OF OUR GENERIC PRODUCTS, COULD DELAY OR PREVENT SUCH INTRODUCTION AND/OR SIGNIFICANTLY REDUCE OUR PROFIT POTENTIAL. THESE FACTORS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Our competitors, both brand and generic, often pursue strategies to prevent or delay competition from generic alternatives to brand products. These strategies include, but are not limited to:

- entering into agreements whereby other generic companies will begin to market a so-called authorized generic , a generic equivalent of a branded product, at the same time generic competition initially enters the market;
- filing citizen s petitions with the FDA, including timing the filings so as to thwart generic competition by causing delays of our product approvals;
- seeking to establish regulatory and legal obstacles that would make it more difficult to demonstrate bioequivalence;
- initiating legislative efforts in various states to limit the substitution of generic versions of brand pharmaceuticals;
- filing suits for patent infringement that automatically delay FDA approval of many generic products;
- introducing next-generation products prior to the expiration of market exclusivity for the reference product, which often materially reduces the demand for the first generic product for which we seek FDA approval;

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obtaining extensions of market exclusivity by conducting clinical trials of brand drugs in pediatric populations or by other potential methods as discussed below;

persuading the FDA to withdraw the approval of brand name drugs for which the patents are about to expire, thus allowing the brand name company to obtain new patented products serving as substitutes for the products withdrawn; and

seeking to obtain new patents on drugs for which patent protection is about to expire.

The Food and Drug Modernization Act of 1997 includes a pediatric exclusivity provision that may provide an additional six months of market exclusivity for indications of new or currently marketed drugs if certain agreed upon pediatric studies are completed by the applicant. Brand companies are utilizing this provision to extend periods of market exclusivity.

Some companies have lobbied Congress for amendments to the Waxman-Hatch legislation that would give them additional advantages over generic competitors. For example, although the term of a company s drug patent can be extended to reflect a portion of the time an NDA is under regulatory review, some companies have proposed extending the patent term by a full year for each year spent in clinical trials, rather than the one-half year that is currently permitted.

If proposals like these were to become effective, our entry into the market and our ability to generate revenues associated with new products may be delayed, reduced or eliminated, which could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

THE INDENTURE FOR OUR SENIOR NOTES AND OUR SENIOR CREDIT FACILITY IMPOSE SIGNIFICANT OPERATING AND FINANCIAL RESTRICTIONS, WHICH MAY PREVENT US FROM CAPITALIZING ON BUSINESS OPPORTUNITIES AND TAKING SOME ACTIONS. THESE FACTORS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

The indenture for our Senior Notes and senior credit facility impose significant operating and financial restrictions on us. These restrictions will limit the ability of us and our subsidiaries to, among other things, incur additional indebtedness, make investments, sell assets, incur certain liens, enter into agreements restricting our subsidiaries ability to pay dividends, or merge or consolidate. In addition, our senior credit facility requires us to maintain specified financial ratios. We cannot assure you that these covenants will not adversely affect our ability to finance our future operations or capital needs or to pursue available business opportunities. A breach of any of these covenants or our inability to maintain the required financial ratios could result in a default under the related indebtedness. If a default occurs, the relevant lenders could elect to declare the indebtedness, together with accrued interest and other fees, to be immediately due and payable and proceed against any collateral securing that indebtedness. These factors could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

OUR ABILITY TO SERVICE OUR DEBT AND MEET OUR CASH REQUIREMENTS DEPENDS ON MANY FACTORS, SOME OF WHICH ARE BEYOND OUR CONTROL. THESE FACTORS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Our ability to satisfy our obligations, including our Senior Notes and our senior credit facility, will depend on our future operating performance and financial results, which will be subject, in part, to factors beyond our control, including interest rates and general economic, financial and business conditions. If we are unable to generate sufficient cash flow, we may be required to: refinance all or a portion of our debt, including the notes and our senior credit facility; obtain additional financing in the future for acquisitions, working capital, capital expenditures and general corporate or other purposes; redirect a substantial portion of our cash flow to debt service, which as a result, might not

be available for our operations or other purposes; sell some of our assets or operations; reduce or delay capital expenditures; or revise or delay our operations or strategic plans. If we are required to take any of these actions, it could have a material adverse effect on our business, financial condition or results of operations. In addition, we cannot assure you that we would be able to take any of these actions, that these actions would enable us to continue to satisfy our capital requirements or that these actions would be permitted under the terms of our senior credit facility and the indenture governing the notes. The increased leverage resulting from the financing of our Dutch Auction self-tender offer through our notes offering and our senior credit facility could have certain material adverse

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effects on us, including limiting our ability to obtain additional financing and reducing cash available for our operations and acquisitions. As a result, our ability to withstand competitive pressures may be decreased and, we may be more vulnerable to economic downturns, which in turn could reduce our flexibility in responding to changing business, regulatory and economic conditions. These factors could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

WE DEPEND ON THIRD-PARTY SUPPLIERS AND DISTRIBUTORS FOR THE RAW MATERIALS, PARTICULARLY THE CHEMICAL COMPOUND(S) COMPRISING THE ACTIVE PHARMACEUTICAL INGREDIENT, THAT WE USE TO MANUFACTURE OUR PRODUCTS, AS WELL AS CERTAIN FINISHED GOODS. A PROLONGED INTERRUPTION IN THE SUPPLY OF SUCH PRODUCTS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS, AND THE MARKET VALUE OF OUR COMMON STOCK COULD DECLINE.

We typically purchase the active pharmaceutical ingredient (i.e. the chemical compounds that produce the desired therapeutic effect in our products), and other materials and supplies that we use in our manufacturing operations, as well as certain finished products, from many different foreign and domestic suppliers.

Additionally, we maintain safety stocks in our raw materials inventory, and in certain cases where we have listed only one supplier in our applications with the FDA, have received FDA approval to use alternative suppliers should the need arise. However, there is no guarantee that we will always have timely and sufficient access to a critical raw material or finished product. A prolonged interruption in the supply of a single-sourced raw material, including the active ingredient, or finished product could cause our financial position and results of operations to be materially adversely affected, and the market value of our common stock could decline. In addition, our manufacturing capabilities could be impacted by quality deficiencies in the products which our suppliers provide, which could have a material adverse effect on our business, financial position and results of operations, and the market value of our common stock could decline.

WE USE SEVERAL MANUFACTURING FACILITIES TO MANUFACTURE OUR PRODUCTS. HOWEVER, A SIGNIFICANT NUMBER OF OUR PRODUCTS ARE PRODUCED AT ONE LOCATION. PRODUCTION AT THIS FACILITY COULD BE INTERRUPTED, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Although we have other facilities, we produce a significant number of our products at our largest manufacturing facility. A significant disruption at that facility, even on a short-term basis, could impair our ability to produce and ship products to the market on a timely basis, which could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

WE MAY EXPERIENCE DECLINES IN THE SALES VOLUME AND PRICES OF OUR PRODUCTS AS THE RESULT OF THE CONTINUING TREND TOWARD CONSOLIDATION OF CERTAIN CUSTOMER GROUPS, SUCH AS THE WHOLESALE DRUG DISTRIBUTION AND RETAIL PHARMACY INDUSTRIES, AS WELL AS THE EMERGENCE OF LARGE BUYING GROUPS. THE RESULT OF SUCH DEVELOPMENTS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

We make a significant amount of our sales to a relatively small number of drug wholesalers and retail drug chains. These customers represent an essential part of the distribution chain of generic pharmaceutical products. Drug wholesalers and retail drug chains have undergone, and are continuing to undergo, significant consolidation. This consolidation may result in these groups gaining additional purchasing leverage and consequently increasing the product pricing pressures facing our business. Additionally, the emergence of large buying groups representing independent retail pharmacies and the prevalence and influence of managed care organizations and similar institutions potentially enable those groups to attempt to extract price discounts on our products. The result of these developments may have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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WE MAY BE UNABLE TO PROTECT OUR INTELLECTUAL AND OTHER PROPRIETARY PROPERTY IN AN EFFECTIVE MANNER, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Although our brand products may have patent protection, this may not prevent other companies from developing functionally equivalent products or from challenging the validity or enforceability of our patents. If our patents are found to be non-infringed, invalid or not enforceable, we could experience an adverse effect on our ability to commercially promote patented products. We could be required to enforce our patent or other intellectual property rights through litigation, which can be protracted and involve significant expense and an inherently uncertain outcome. Any negative outcome could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

OUR COMPETITORS OR OTHER THIRD PARTIES MAY ALLEGE THAT WE ARE INFRINGING THEIR INTELLECTUAL PROPERTY, FORCING US TO EXPEND SUBSTANTIAL RESOURCES IN RESULTING LITIGATION, THE OUTCOME OF WHICH IS UNCERTAIN. ANY UNFAVORABLE OUTCOME OF SUCH LITIGATION COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Companies that produce brand pharmaceutical products routinely bring litigation against ANDA applicants that seek FDA approval to manufacture and market generic forms of their branded products. These companies allege patent infringement or other violations of intellectual property rights as the basis for filing suit against an ANDA applicant. Likewise, patent holders may bring patent infringement suits against companies that are currently marketing and selling their approved generic products. Litigation often involves significant expense and can delay or prevent introduction or sale of our generic products.

There may also be situations where the Company uses its business judgment and decides to market and sell products, notwithstanding the fact that allegations of patent infringement(s) by our competitors have not been finally resolved by the courts. The risk involved in doing so can be substantial because the remedies available to the owner of a patent for infringement include, among other things, damages measured by the profits lost by the patent owner and not by the profits earned by the infringer. In the case of a willful infringement, the definition of which is unclear, such damages may be trebled. Moreover, because of the discount pricing typically involved with bioequivalent products, patented brand products generally realize a substantially higher profit margin than bioequivalent products. An adverse decision in a case such as this or in other similar litigation could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

WE MAY EXPERIENCE REDUCTIONS IN THE LEVELS OF REIMBURSEMENT FOR PHARMACEUTICAL PRODUCTS BY GOVERNMENTAL AUTHORITIES, HMOS OR OTHER THIRD-PARTY PAYERS. ANY SUCH REDUCTIONS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Various governmental authorities and private health insurers and other organizations, such as HMOs, provide reimbursement to consumers for the cost of certain pharmaceutical products. Demand for our products depends in part on the extent to which such reimbursement is available. Third-party payers increasingly challenge the pricing of pharmaceutical products. This trend and other trends toward the growth of HMOs, managed health care and legislative health care reform create significant uncertainties regarding the future levels of reimbursement for pharmaceutical products. Further, any reimbursement may be reduced in the future, perhaps to the point that market demand for our products declines. Such a decline could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

LEGISLATIVE OR REGULATORY PROGRAMS THAT MAY INFLUENCE PRICES OF PRESCRIPTION DRUGS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS,

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FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Current or future federal or state laws and regulations may influence the prices of drugs and, therefore, could adversely affect the prices that we receive for our products. Programs in existence in certain states seek to set prices of all drugs sold within those states through the regulation and administration of the sale of prescription drugs. Expansion of these programs, in particular, state Medicaid programs, or changes required in the way in which Medicaid rebates are calculated under such programs, could adversely affect the price we receive for our products and could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

WE ARE INVOLVED IN VARIOUS LEGAL PROCEEDINGS AND CERTAIN GOVERNMENT INQUIRIES AND MAY EXPERIENCE UNFAVORABLE OUTCOMES OF SUCH PROCEEDINGS OR INQUIRIES, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

We are involved in various legal proceedings and certain government inquiries, including, but not limited to, patent infringement, product liability, breach of contract and claims involving Medicaid and Medicare reimbursements, some of which are described in our periodic reports and involve claims for, or the possibility of fines and penalties involving, substantial amounts of money or for other relief. If any of these legal proceedings or inquiries were to result in an adverse outcome, the impact could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

With respect to product liability, the Company maintains commercial insurance to protect against and manage a portion of the risks involved in conducting its business. Although we carry insurance, we believe that no reasonable amount of insurance can fully protect against all such risks because of the potential liability inherent in the business of producing pharmaceuticals for human consumption. To the extent that a loss occurs, depending on the nature of the loss and the level of insurance coverage maintained, it could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

WE ENTER INTO VARIOUS AGREEMENTS IN THE NORMAL COURSE OF BUSINESS WHICH PERIODICALLY INCORPORATE PROVISIONS WHEREBY WE INDEMNIFY THE OTHER PARTY TO THE AGREEMENT. IN THE EVENT THAT WE WOULD HAVE TO PERFORM UNDER THESE INDEMNIFICATION PROVISIONS, IT COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

In the normal course of business, we periodically enter into employment, legal settlement, and other agreements which incorporate indemnification provisions. We maintain insurance coverage which we believe will effectively mitigate our obligations under these indemnification provisions. However, should our obligation under an indemnification provision exceed our coverage or should coverage be denied, our business, financial position and results of operations could be materially affected and the market value of our common stock could decline.

OUR ACQUISITION STRATEGIES IN GENERAL INVOLVE A NUMBER OF INHERENT RISKS. THESE RISKS COULD CAUSE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE A DECLINE IN THE MARKET VALUE OF OUR COMMON STOCK.

We continually seek to expand our product line through complementary or strategic acquisitions of other companies, products and assets, and through joint ventures, licensing agreements or other arrangements. Acquisitions, joint ventures and other business combinations involve various inherent risks, such as assessing accurately the values, strengths, weaknesses, contingent and other liabilities, regulatory compliance and potential profitability of acquisition or other transaction candidates. Other inherent risks include the potential loss of key personnel of an acquired business, our inability to achieve identified financial and operating synergies anticipated to result from an acquisition or other transaction and unanticipated changes in business and economic conditions

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affecting an acquisition or other transaction. International acquisitions, and other transactions, could also be affected by export controls, exchange rate fluctuations, domestic and foreign political conditions and the deterioration in domestic and foreign economic conditions.

We may be unable to realize synergies or other benefits expected to result from acquisitions, joint ventures and other transactions or investments we may undertake, or be unable to generate additional revenue to offset any unanticipated inability to realize these expected synergies or benefits. Realization of the anticipated benefits of acquisitions or other transactions could take longer than expected, and implementation difficulties, market factors and the deterioration in domestic and global economic conditions could alter the anticipated benefits of any such transactions. These factors could cause a material adverse effect on our business, financial position and results of operations and could cause a decline in the market value of our common stock.

OUR FUTURE SUCCESS IS HIGHLY DEPENDENT ON OUR CONTINUED ABILITY TO ATTRACT AND RETAIN KEY PERSONNEL. ANY FAILURE TO ATTRACT AND RETAIN KEY PERSONNEL COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Because our success is largely dependent on the scientific nature of our business, it is imperative that we attract and retain qualified personnel in order to develop new products and compete effectively. If we fail to attract and retain key scientific, technical or management personnel, our business could be affected adversely. Additionally, while we have employment agreements with certain key employees in place, their employment for the duration of the agreement is not guaranteed. If we are unsuccessful in retaining all of our key employees, it could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

RECENT DECISIONS BY THE FDA, CURRENT BRAND TACTICS AND OTHER FACTORS BEYOND OUR CONTROL HAVE PLACED OUR BUSINESS UNDER INCREASING PRESSURE, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

We believe that certain recent FDA rulings are contrary to multiple sections of the Federal Food, Drug, and Cosmetic Act and the Administrative Procedures Act, the FDA s published regulations and the legal precedent on point. These decisions call into question the rules of engagement in our industry and have added a level of unpredictability that may materially adversely affect our business and the generic industry as a whole. While we remain in an intense battle with regard to these recent decisions as well as current brand tactics that undermine Congressional intent, we cannot guarantee that we will prevail. If we are not successful, our business, financial position and results of operations could suffer and the market value of our common stock could decline.

WE HAVE BEGUN THE IMPLEMENTATION OF AN ENTERPRISE RESOURCE PLANNING SYSTEM. AS WITH ANY IMPLEMENTATION OF A SIGNIFICANT NEW SYSTEM, DIFFICULTIES ENCOUNTERED COULD RESULT IN BUSINESS INTERRUPTIONS, AND COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

We have begun the implementation of an enterprise resource planning (ERP) system to enhance operating efficiencies and provide more effective management of our business operations. Implementations of ERP systems and related software carry risks such as cost overruns, project delays and business interruptions and delays. If we experience a material business interruption as a result of our ERP implementation, it could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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WE MUST MAINTAIN ADEQUATE INTERNAL CONTROLS AND BE ABLE, ON AN ANNUAL BASIS, TO PROVIDE AN ASSERTION AS TO THE EFFECTIVENESS OF SUCH CONTROLS. FAILURE TO MAINTAIN ADEQUATE INTERNAL CONTROLS OR TO IMPLEMENT NEW OR IMPROVED CONTROLS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Effective internal controls are necessary for the Company to provide reasonable assurance with respect to its financial reports. We are spending a substantial amount of management time and resources to comply with changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new Securities and Exchange Commission (SEC) regulations and the New York Stock Exchange rules. In particular, Section 404 of the Sarbanes-Oxley Act of 2002 requires management s annual review and evaluation of our internal control systems, and attestations as to the effectiveness of these systems by our independent public accounting firm. If we fail to maintain the adequacy of our internal controls, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting. Additionally, internal control over financial reporting may not prevent or detect misstatements because of its inherent limitations, including the possibility of human error, the circumvention or overriding of controls, or fraud. Therefore, even effective internal controls can provide only reasonable assurance with respect to the preparation and fair presentation of financial statements. In addition, projections of any evaluation of effectiveness of internal control over financial reporting to future periods are subject to the risk that the control may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. If the Company fails to maintain the adequacy of its internal controls, including any failure to implement required new or improved controls, this could have a material adverse effect on our business, financial position and results of operations, and the market value of our common stock could decline.

THERE ARE INHERENT UNCERTAINTIES INVOLVED IN ESTIMATES, JUDGMENTS AND ASSUMPTIONS USED IN THE PREPARATION OF FINANCIAL STATEMENTS IN ACCORDANCE WITH GAAP. ANY FUTURE CHANGES IN ESTIMATES, JUDGEMENTS AND ASSUMPTIONS USED OR NECESSARY REVISIONS TO PRIOR ESTIMATES, JUDGMENTS OR ASSUMPTIONS COULD LEAD TO A RESTATEMENT WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

The consolidated and condensed consolidated financial statements included in the periodic reports we file with the SEC are prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). The preparation of financial statements in accordance with GAAP involves making estimates, judgments and assumptions that affect reported amounts of assets (including intangible assets), liabilities, revenues, expenses and income. Estimates, judgments and assumptions are inherently subject to change in the future and any necessary revisions to prior estimates, judgements or assumptions could lead to a restatement. Any such changes could result in corresponding changes to the amounts of assets (including goodwill and other intangible assets), liabilities, revenues, expenses and income. Any such changes could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Company is subject to market risk primarily from changes in the market values of investments in its marketable debt securities. In addition to marketable debt and equity securities, investments are made in overnight deposits, money market funds and marketable securities with maturities of less than three months. These instruments are classified as cash equivalents for financial reporting purposes and have minimal or no interest rate risk due to their short-term nature.

The following table summarizes the investments in marketable debt and equity securities which subject the Company to market risk at June 30, 2005 and March 31, 2005:

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(in thousands)	June 30, 2005	March 31, 2005
Debt securities	$ 539,482	$ 667,170
Equity securities	4,447	3,178
	$ 543,929	$ 670,348

The primary objectives for the marketable debt securities investment portfolio are liquidity and safety of principal. Investments are made to achieve the highest rate of return while retaining principal. Our investment policy limits investments to certain types of instruments issued by institutions and government agencies with investment-grade credit ratings. At June 30, 2005, the Company had invested $539.5 million in marketable debt securities, of which $146.7 million will mature within one year and $392.8 million will mature after one year. The short duration to maturity creates minimal exposure to fluctuations in market values for investments that will mature within one year. However, a significant change in current interest rates could affect the market value of the remaining $392.8 million of marketable debt securities that mature after one year. A 5% change in the market value of the marketable debt securities that mature after one year would result in a $19.6 million change in marketable debt securities.

On July 21, 2005, the Company issued $500.0 million in Senior Notes with fixed interest rates and borrowed $275.0 million under a senior credit facility with a variable interest rate based on the prime rate or LIBOR. Also on July 21, 2005, the Company entered into a $225.0 million revolving credit facility, any borrowings under which will bear interest at a variable rate based on the prime rate or LIBOR. At this time no amounts have been drawn under this facility. As a result of these borrowings the Company will be subject to market risk (Interest Rate Risk).

ITEM 4. CONTROLS AND PROCEDURES

An evaluation was performed under the supervision and with the participation of the Company s management, including the Chief Executive Officer and the Chief Financial Officer, of the effectiveness of the design and operation of the Company s disclosure controls and procedures as of June 30, 2005. Based upon that evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that the Company s disclosure controls and procedures were effective. In addition, during the period covered by this report, there have been no significant changes in the Company s internal controls or in other factors that could significantly affect these controls, and no corrective actions taken with regard to significant deficiencies or material weaknesses in such controls. No change in the Company s internal control over financial reporting occurred during the last fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company s internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

For a description of the material pending legal proceedings to which the Company is a party, please see our Annual Report on Form 10-K for the year ended March 31, 2005. During the quarter ended June 30, 2005, there were no new material legal proceedings or material developments with respect to pending proceedings other than as described below. While it is not possible to determine with any degree of certainty the ultimate outcome of the following matters, the Company believes that it has meritorious defenses with respect to the claims asserted against it and intends to vigorously defend its position. An adverse outcome in any of these proceedings could have a material adverse effect on the Company s financial position and results of operations.

Lorazepam and Clorazepate

On June 1, 2005, a jury verdict was rendered against Mylan Labs and MPI in the U.S. District Court for the District of Columbia in the amount of approximately $12.0 million, which has been accrued as of June 30, 2005. The jury found Mylan willfully violated Massachusetts, Minnesota and Illinois state antitrust laws, meaning the amount of the verdict could be trebled, and an award of attorneys fees and litigation costs could be made to the plaintiffs. The case was brought by four health insurers who opted out of earlier class action settlements agreed to by the Company in 2001, and represents the last remaining claims relating to Mylan s 1998 price increases for lorazepam and clorazepate.

The Company has filed a motion for judgment as a matter of law, which remains pending before the court. If the Company s post-verdict motion is denied, the Company intends to appeal to the U.S. Court of Appeals for the D.C. circuit.

Shareholder Litigation

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On November 22, 2004, an individual purporting to be a Mylan Labs shareholder, filed a civil action in the Court of Common Pleas of Allegheny County, Pennsylvania, against Mylan Labs and all members of its Board of Directors alleging that the Board members had breached their fiduciary duties by approving the planned acquisition of King Pharmaceuticals, Inc. (King) and by declining to dismantle the Company s anti-takeover defenses to permit an auction of the Company to Carl Icahn or other potential buyers of the Company, and also alleging that certain transactions between the Company and its directors (or their relatives or companies with which they were formerly affiliated) may have been wasteful. On November 23, 2004, a substantially identical complaint was filed in the same court by another purported Mylan Labs shareholder. The actions are styled as shareholder derivative suits on behalf of Mylan Labs and class actions on behalf of all Mylan Labs shareholders, and have been consolidated by the court under the caption In re Mylan Laboratories Inc. Shareholder Litigation. Mylan Labs and its directors filed preliminary objections seeking dismissal of the complaints. On January 19, 2005, the plaintiffs amended their complaints to add Bear Stearns & Co., Inc., Goldman Sachs & Co., Richard C. Perry, Perry Corp., American Stock Transfer & Trust Company, and John Does 1-100 as additional defendants, and to add claims regarding trading activity by the additional defendants and the implications on Mylan Labs shareholder rights agreement. The plaintiffs are seeking injunctive and declaratory relief and undisclosed damages. Mylan Labs and its directors have not yet been required to respond to the amended complaint.

On December 10, 2004, High River Limited Partnership (High River), an entity controlled by Carl Icahn, filed suit in the U.S. District Court for the Middle District of Pennsylvania against Mylan Labs, its Vice Chairman and Chief Executive Officer Robert J. Coury, Richard C. Perry, Perry Corp. and John Does 1-100 , asserting against the Company a claim for violation of federal securities laws and against the Company and Mr. Coury a claim for alleged breaches of Pennsylvania statutory and common law, in connection with SEC filings and other public statements concerning the planned King acquisition. The complaint also asserted claims under the federal securities laws and Pennsylvania corporate law concerning a possible shareholder vote relating to the proposed merger. On January 27, 2005, the court granted a motion by defendants Perry Corp. and Mr. Perry to transfer the case to the U.S. District Court for the Southern District of New York. Mylan Labs, Mr. Coury and the other defendants filed motions to dismiss the complaint in its entirety. On May 27, 2005, High River voluntarily dismissed the lawsuit without prejudice.

On February 22, 2005, High River filed a complaint naming Mylan Labs and its directors in the U.S. District Court for the Middle District of Pennsylvania challenging the validity under Pennsylvania law of amendments to the provisions of the Company s bylaws requiring shareholders to provide advance notice of nominations of directors for election at Mylan Labs annual meeting of shareholders. High River sought a temporary restraining order (TRO) in an attempt to block implementation of the advance notice bylaw. The Court denied High River s motion for a TRO, and High River voluntarily withdrew the case without prejudice. On March 24, 2005, High River filed another complaint in the same court naming the same defendants and seeking substantially the same relief. The second complaint also challenged the validity of the provisions of our bylaws requiring advance notice by shareholders of other business to be conducted at the annual meeting. On June 6, 2005, the Court issued an order, among other things, dismissing the case against our directors and dismissing all claims against us for money damages. On July 22, 2005, High River agreed to the dismissal of the suit without prejudice.

Other Litigation

The Company is involved in various other legal proceedings that are considered normal to its business. While it is not feasible to predict the ultimate outcome of such other proceedings at this time, the Company believes that the ultimate outcome of such other proceedings will not have a material adverse effect on its financial position or results of operations.

ITEM 6. EXHIBITS

3.1	Amended and Restated Articles of Incorporation of the registrant, as amended to date, filed as Exhibit 3.1 to the Form 10-Q for the quarterly period ended June 30, 2003, and incorporated herein by reference.
3.2	

Bylaws of the Registrant, as amended to date, filed as Exhibit 3.2 to the Form 10-Q for the quarterly period ended September 30, 2003, and incorporated herein by reference.

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4.1(a)	Rights Agreement dated as of August 22, 1996, between the registrant and American Stock Transfer & Trust Company, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on September 3, 1996, and incorporated herein by reference.
4.1(b)	Amendment to Rights Agreement dated as of November 8, 1999, between the registrant and American Stock Transfer & Trust Company, filed as Exhibit 1 to Form 8-A/A filed with the SEC on March 31, 2000, and incorporated herein by reference.
4.1(c)	Amendment No. 2 to Rights Agreement dated as of August 13, 2004, between the registrant and American Stock Transfer & Trust Company, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on August 16, 2004, and incorporated herein by reference.
4.1(d)	Amendment No. 3 to Rights Agreement dated as of September 8, 2004, between the registrant and American Stock Transfer & Trust Company, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on September 9, 2004, and incorporated herein by reference.
4.1(e)	Amendment No. 4 to Rights Agreement dated as of December 2, 2004, between the registrant and American Stock Transfer & Trust Company, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on December 3, 2004, and incorporated herein by reference.
31.1	Certification of CEO pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of CFO pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32	Certification of CEO and CFO pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Report on Form 10-Q for the quarterly period ended June 30, 2005, to be signed on its behalf by the undersigned thereunto duly authorized.

Mylan Laboratories Inc.
(Registrant)

July 28, 2005 By: /s/ Robert J. Coury

Robert J. Coury
Vice Chairman and Chief Executive Officer

July 28, 2005 /s/ Edward J. Borkowski

Edward J. Borkowski
Chief Financial Officer
(*Principal financial officer)*

July 28, 2005 /s/ Gary E. Sphar

Gary E. Sphar
Vice President, Corporate Controller
(*Principal accounting officer)*

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EXHIBIT INDEX

31.1	Certification of CEO pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of CFO pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32	Certification of CEO and CFO pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.