

MYLAN LABORATORIES INC

Form 10-Q

February 09, 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 December 31, 2004

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  
(State of incorporation)

25-1211621  
(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 þ NO o

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

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  
February 3, 2005**

\$0.50 par value

269,241,972

**MYLAN LABORATORIES INC. AND SUBSIDIARIES**

**FORM 10-Q  
For the Quarterly Period Ended  
December 31, 2004**

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**Table of Contents****MYLAN LABORATORIES INC. AND SUBSIDIARIES****Condensed Consolidated Statements of Earnings**

(unaudited; in thousands, except per share amounts)

Period Ended December 31,	Three Months		Nine Months	
	2004	2003	2004	2003
Revenues:				
Net revenues	\$ 290,972	\$ 336,543	\$ 936,939	\$ 1,027,344
Other revenue		13,243		13,910
Total revenues	290,972	349,786	936,939	1,041,254
Cost of sales	155,625	150,602	466,586	456,933
Gross profit	135,347	199,184	470,353	584,321
Operating expenses:				
Research & development	23,167	25,248	66,704	73,933
Selling & marketing	19,661	18,027	59,552	53,137
General & administrative	43,537	33,096	121,080	95,016
Litigation settlements, net		(2,676)	(25,985)	(24,345)
Total operating expenses	86,365	73,695	221,351	197,741
Earnings from operations	48,982	125,489	249,002	386,580
Other income, net	3,699	4,194	6,295	14,727
Earnings before income taxes	52,681	129,683	255,297	401,307
Provision for income taxes	17,911	45,065	89,840	141,548
Net earnings	\$ 34,770	\$ 84,618	\$ 165,457	\$ 259,759
Earnings per common share:				
Basic	\$ 0.13	\$ 0.32	\$ 0.62	\$ 0.97
Diluted	\$ 0.13	\$ 0.31	\$ 0.60	\$ 0.94
Weighted average common shares:				
Basic	269,165	268,560	268,888	269,141
Diluted	273,139	276,881	273,826	276,478
Cash dividend declared per common share	\$ 0.03	\$ 0.03	\$ 0.09	\$ 0.07

See Notes to Condensed Consolidated Financial Statements

**Table of Contents****MYLAN LABORATORIES INC. AND SUBSIDIARIES****Condensed Consolidated Balance Sheets**

(unaudited; in thousands)

	December 31, 2004	March 31, 2004
Assets		
Current assets:		
Cash and cash equivalents	\$ 183,313	\$ 101,713
Marketable securities	651,952	585,445
Accounts receivable, net	196,390	191,094
Inventories	292,385	320,797
Deferred income tax benefit	84,083	78,477
Other current assets	31,567	40,315
Total current assets	1,439,690	1,317,841
Property, plant and equipment, net	316,902	273,051
Intangible assets, net	123,274	134,601
Goodwill	102,579	102,579
Other assets	46,149	47,218
Total assets	\$ 2,028,594	\$ 1,875,290
Liabilities and shareholders' equity		
Liabilities		
Current liabilities:		
Trade accounts payable	\$ 60,857	\$ 40,639
Income taxes payable		23,837
Other current liabilities	108,742	109,292
Total current liabilities	169,599	173,768
Long-term obligations	18,747	19,130
Deferred income tax liability	25,222	22,604
Total liabilities	213,568	215,502
Shareholders' equity		
Common stock	152,185	151,777
Additional paid-in capital	352,533	338,143
Retained earnings	1,778,745	1,637,497
Accumulated other comprehensive earnings	1,688	2,496
	2,285,151	2,129,913

Less:		
Treasury stock at cost	470,125	470,125
Total shareholders' equity	1,815,026	1,659,788
Total liabilities and shareholders' equity	\$ 2,028,594	\$ 1,875,290

See Notes to Condensed Consolidated Financial Statements



**Table of Contents****MYLAN LABORATORIES INC. AND SUBSIDIARIES****Condensed Consolidated Statements of Cash Flows**

(unaudited; in thousands)

Nine Months Ended December 31,	2004	2003
Cash flows from operating activities:		
Net earnings	\$ 165,457	\$ 259,759
Adjustments to reconcile net earnings to net cash provided from operating activities:		
Depreciation and amortization	33,426	32,718
Deferred income tax (benefit) expense	(1,883)	25,942
Net earnings from equity method investees	2,146	2,774
Cash received from Somerset		10,000
Changes in estimated sales allowances	2,934	(6,773)
Gain on sale of building		(5,000)
Other non-cash items	6,558	(1,643)
Gain from litigation settlements, net	(25,985)	(24,345)
Receipts from (payments for) litigation settlements, net	42,985	(16,630)
Changes in operating assets and liabilities:		
Accounts receivable	(12,806)	(13,039)
Inventories	28,412	(73,828)
Trade accounts payable	20,218	(2,368)
Income taxes	(22,009)	34,328
Other operating assets and liabilities, net	(17,230)	(12,910)
Net cash provided from operating activities	222,223	208,985
Cash flows from investing activities:		
Capital expenditures	(63,205)	(88,979)
Purchase of marketable securities	(607,144)	(581,139)
Proceeds from sale of marketable securities	539,345	441,791
Liquidation of equity investment		7,269
Proceeds from sale of building		12,000
Other items	5,204	(1,498)
Net cash used in investing activities	(125,800)	(210,556)
Cash flows from financing activities:		
Cash dividends paid	(24,184)	(17,980)
Purchase of common stock		(133,088)
Proceeds from exercise of stock options	9,361	24,369
Net cash used in financing activities	(14,823)	(126,699)
Net increase (decrease) in cash and cash equivalents	81,600	(128,270)
Cash and cash equivalents - beginning of period	101,713	258,902

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Cash and cash equivalents - end of period	\$ 183,313	\$ 130,632
Additional disclosures:		
Cash paid for income taxes	\$ 115,192	\$ 81,279
Non-cash financing activities:		
Issuance of restricted stock	\$	\$ 11,740

See Notes to Condensed Consolidated Financial Statements

**Table of Contents****MYLAN LABORATORIES INC. AND SUBSIDIARIES****Notes to Condensed Consolidated Financial Statements**

(unaudited; in thousands, except share 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, 2004.

Certain prior year amounts were reclassified to conform to the current year presentation. Such reclassifications had no impact on reported net earnings, earnings per share or shareholders' equity.

The interim results of operations for the three and nine months ended December 31, 2004, and the interim cash flows for the nine months ended December 31, 2004, are not necessarily indicative of the results to be expected for the full fiscal year or any other future period.

**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 and nine month periods ended December 31, 2004. Accounts receivable are presented net of allowances relating to these provisions. Such allowances were \$269,044 and \$264,170 as of December 31, 2004, and March 31, 2004. Other current liabilities include \$26,238 and \$28,178 at December 31, 2004, and March 31, 2004, for certain rebates and other adjustments that are payable to indirect customers.

The following is a rollforward of the most significant provisions for estimated sales allowances during the nine months ended December 31, 2004:

	Balance March 31, 2004	Checks/Credits Issued to Third Parties	Provisions Recorded in Current Period	Balance December 31, 2004
Chargebacks	\$ 144,121	\$ (652,086)	\$ 651,271	\$ 143,306
Customer performance and promotions	\$ 61,058	\$ (144,753)	\$ 148,474	\$ 64,779
Returns	\$ 45,311	\$ (27,346)	\$ 25,610	\$ 43,575

**Table of Contents****3. Recent Accounting Pronouncements**

In December 2004, the Financial Accounting Standards Board ( FASB ) issued Statement of Financial Accounting Standards ( 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 Accounting Principles Board Opinion ( 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. The provisions of SFAS 123 (R) are effective for periods beginning after June 15, 2005, and apply to all awards that vest after the required effective date and to awards that are granted, modified, repurchased, or cancelled after that date. Management is currently assessing the impact that adoption of this Statement will have on the Company's Consolidated Financial Statements.

**4. Balance Sheet Components**

Selected balance sheet components consist of the following:

	December 31, 2004	March 31, 2004
Inventories:		
Raw materials	\$ 124,324	\$ 149,048
Work in process	37,626	34,511
Finished goods	130,435	137,238
	\$ 292,385	\$ 320,797
Property, plant and equipment:		
Land and improvements	\$ 9,761	\$ 9,704
Buildings and improvements	148,118	132,983
Machinery and equipment	259,573	240,594
Construction in progress	82,178	54,181
	499,630	437,462
Less accumulated depreciation	182,728	164,411
	\$ 316,902	\$ 273,051
Other current liabilities:		
Accrued rebates	\$ 26,238	\$ 28,178
Payroll and employee benefit plan accruals	35,913	20,644
Royalties and product license fees	9,689	20,493
Legal and professional	15,203	13,650
Cash dividends payable	8,076	8,052
Current portion of long-term obligations	1,604	1,586

Other	12,019	16,689
	\$ 108,742	\$ 109,292

## 5. 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 3,974,000 and 8,321,000 for the three months ended December 31, 2004 and 2003 and 4,938,000 and 7,337,000 for the nine months ended December 31, 2004 and 2003.

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Options to purchase 6,804,000 and 35,000 shares of common stock were outstanding as of December 31, 2004 and 2003, 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.

## 6. Intangible Assets

Intangible assets consist of the following components:

	Weighted Average Life (years)	Original Cost	Accumulated Amortization	Net Book Value
December 31, 2004				
Amortized intangible assets:				
Patents and technologies	19	\$ 117,435	\$ 46,934	\$ 70,501
Product rights and licenses	12	111,433	67,367	44,066
Other	20	14,267	6,343	7,924
		\$ 243,135	\$ 120,644	122,491
Intangible assets no longer subject to amortization:				
Trademarks				783
				\$ 123,274
March 31, 2004				
Amortized intangible assets:				
Patents and technologies	19	\$ 117,435	\$ 42,304	\$ 75,131
Product rights and licenses	12	109,333	59,111	50,222
Other	20	14,267	5,802	8,465
		\$ 241,035	\$ 107,217	133,818
Intangible assets no longer subject to amortization:				
Trademarks				783
				\$ 134,601

Amortization expense for the nine months ended December 31, 2004, and 2003 was \$13,427 and \$15,003 and is expected to be \$14,341, \$14,063, \$13,611, \$13,300 and \$12,282 for fiscal years 2006 through 2010, respectively.



**Table of Contents****7. Comprehensive Earnings**

Comprehensive earnings consist of the following:

Period Ended December 31,	Three Months		Nine Months	
	2004	2003	2004	2003
Net earnings	\$ 34,770	\$ 84,618	\$ 165,457	\$ 259,759
Other comprehensive earnings net of tax:				
Net unrealized (loss) gain on marketable securities	(490)	(891)	(893)	1,722
Reclassification for (gains) losses included in net earnings	(29)	(1,953)	85	(2,228)
	(519)	(2,844)	(808)	(506)
Comprehensive earnings	\$ 34,251	\$ 81,774	\$ 164,649	\$ 259,253

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.

**8. Common Stock**

As of December 31, 2004, and March 31, 2004, there were 600,000,000 shares of common stock authorized with 304,369,702 and 303,553,121 shares issued. Treasury shares held as of both December 31, 2004, and March 31, 2004, were 35,129,643.

In May 2002, the Board of Directors approved a Stock Repurchase Program to purchase up to 22,500,000 shares of the Company's outstanding common stock. During the nine months ended December 31, 2003, the Company purchased 6,458,700 shares for approximately \$133,088. The Stock Repurchase Program was completed on November 18, 2003.



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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. Upon approval of the 2003 Plan, the Mylan Laboratories Inc. 1997 Incentive Stock Option Plan was frozen and no further grants of stock options will be made under that plan.

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:

Period ended December 31,	Three Months		Nine Months	
	2004	2003	2004	2003
Net earnings as reported	\$ 34,770	\$ 84,618	\$ 165,457	\$ 259,759
Add: Stock-based compensation expense included in reported net income, net of related tax effects	986	985	2,937	1,403
Deduct: Total compensation expense determined under the fair value based method for all stock awards, net of related tax effects	(3,789)	(6,611)	(12,578)	(19,030)
Pro forma net earnings	\$ 31,967	\$ 78,992	\$ 155,816	\$ 242,132
Earnings per share:				
Basic as reported	\$ 0.13	\$ 0.32	\$ 0.62	\$ 0.97
Basic pro forma	\$ 0.12	\$ 0.29	\$ 0.58	\$ 0.90
Diluted as reported	\$ 0.13	\$ 0.31	\$ 0.60	\$ 0.94
Diluted pro forma	\$ 0.12	\$ 0.29	\$ 0.57	\$ 0.88

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Segment net revenues represent revenues from unrelated third parties. For the Generic and Brand Segments, segment profit represents segment gross profit less direct research and development, selling and marketing and general and administrative expenses. Corporate/Other includes certain general and administrative expenses, such as legal expenditures, litigation settlements and non-operating income and expense.

The following table presents the results of operations for each of the Company's operating segments:

Period Ended December 31,	Three Months		Nine Months	
	2004	2003	2004	2003
Consolidated:				
Total revenues	\$ 290,972	\$ 349,786	\$ 936,939	\$ 1,041,254
Pretax earnings	52,681	129,683	255,297	401,307
Generic:				
Total revenues	\$ 238,357	\$ 277,446	\$ 753,572	\$ 832,157
Segment profit	79,967	130,449	289,184	395,103
Brand:				
Total revenues	\$ 52,615	\$ 72,340 <sup>1</sup>	\$ 183,367	\$ 209,097 <sup>1</sup>
Segment profit	3,392	17,052	28,023	38,514
Corporate/Other:				
Loss	\$ (30,678)	\$ (17,818)	\$ (61,910)	\$ (32,310)

<sup>1</sup> Includes \$13,243 and \$13,910 related to the sale of the U.S. and Canadian rights for sertaconazole nitrate 2% cream in the three and nine months ended December 31, 2003.

**11. Contingencies**

*(Dollar amounts in this Note 11 are as stated)*

**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. No amounts have been accrued at December 31, 2004, with respect to any of these matters.

**Omeprazole**

In fiscal 2001, Mylan Pharmaceuticals Inc. ( MPI ), a wholly-owned subsidiary of Mylan Laboratories Inc. ( Mylan Labs ), filed an Abbreviated New Drug Application ( 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, 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 a motion for summary judgment as to all claims of infringement, and the summary judgment motion remains 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.

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( Esteve ), 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.

In November 2002, MPI filed suit in the U.S. District Court for the District of Delaware against Kremers Urban Development Company ( KUDCo ) and several other companies affiliated with Schwarz Pharma AG (the Schwarz Pharma Group ) alleging KUDCo and the Schwarz Pharma Group are infringing U.S. patent 5,626,875 (the 875 Patent ) in connection with KUDCo's manufacture and sale of omeprazole capsules in the U.S. KUDCo and the Schwarz Pharma Group asserted defenses and counterclaims in that action alleging the inventors listed on the 875 patent are not the actual inventors of the invention described therein, and further seeking money damages alleging the infringement action was not proper. On August 7, 2003, KUDCo and an individual filed a lawsuit against MPI and Esteve in the U.S. District Court for the District of Columbia asserting claims that were not asserted in the Delaware action. During the first quarter of fiscal 2005, a settlement was agreed to with respect to the cases involving MPI, KUDCo and the Schwarz Pharma Group, and these lawsuits have been dismissed, with prejudice. Under the settlement, MPI received a payment of \$37,500,000, a portion of which represented the reimbursement of legal expenses.

*Paclitaxel*

In June 2001, Tapestry Pharmaceuticals, Inc. (formerly NAPRO Biotherapeutics Inc.) ( Tapestry ) and Abbott Laboratories Inc. ( Abbott ) filed suit against Mylan Labs, MPI and UDL Laboratories Inc. ( UDL ), also a wholly-owned subsidiary of Mylan Labs, in the U.S. District Court for the Western District of Pennsylvania alleging that the manufacture, use and sale of MPI's paclitaxel product, which MPI began selling in July 2001, infringes certain patents owned by Tapestry and allegedly licensed to Abbott. During the first quarter of fiscal 2005, all parties agreed to a settlement of this case and the lawsuit has been dismissed, with prejudice. MPI paid \$9,000,000 pursuant to the settlement.

***Pricing and Medicaid Litigation and Investigations***

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 identifies three drug products sold by MPI, and seeks equitable relief, attorneys' fees, cost of litigation and monetary damages in unspecified sums. All defendants have joined in a motion to dismiss the complaint. The court has not yet ruled on the motion to dismiss.

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 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

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misrepresentation relating to reporting of average wholesale prices (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 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. Also 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. In each case, the plaintiff seeks money damages and civil penalties in unspecified amounts and declaratory and injunctive relief, and in each matter Mylan Labs and its subsidiaries have not yet been required to respond to the complaint or the amended complaint, as applicable.

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. The government has not asked MPI for information.

## ***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*. 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' preliminary objections seeking dismissal of the complaints are pending before the court.

On December 10, 2004, High River Limited Partnership, 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 asserts 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 have filed motions to dismiss the

complaint in its entirety, which motions are currently pending before the court.

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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.

12. Pending Acquisition of King Pharmaceuticals

*(Dollar amounts in this Note 12 are as stated)*

On July 23, 2004, the Company entered into an Agreement and Plan of Merger ( Agreement ) to acquire King Pharmaceuticals, Inc. ( King ) in a stock-for-stock transaction. King is a branded pharmaceutical company headquartered in Bristol, Tennessee.

Under the terms of the Agreement, each of King's shareholders will receive .9 shares of Mylan common stock for every common share of King held upon closing. At July 22, 2004, King had approximately 241,400,000 shares of common stock issued and outstanding, which would translate into approximately 217,300,000 shares of Mylan's common stock being issued to the King shareholders. In addition, at July 22, 2004, King had approximately 6,700,000 outstanding options, which would translate into approximately 6,000,000 shares of Mylan's common stock being reserved upon closing for exercise of such options after the date the acquisition is consummated. The Agreement contains a provision whereby if the acquisition is not completed, either party may be obligated to pay a termination fee of \$85,000,000 under certain limited circumstances.

The acquisition contemplated under the Agreement, which was approved by the Boards of Directors of Mylan and King, is subject to customary closing conditions, and would qualify as a tax-free reorganization for U.S. federal income tax purposes.

During the third quarter of fiscal 2005, King announced that it would restate previously reported financial results for 2002, 2003 and the first six months of 2004, and that it was evaluating whether financial results for any earlier periods require restatement. Any restatement of King's financial statements results in a failure to satisfy a condition of Mylan's obligation to close the acquisition of King. In January 2005, Mylan announced that while it was monitoring and reviewing King's accounting issues and a number of other matters concerning King, in light of timing issues, Mylan believed it was highly unlikely that the parties would be able to consummate the merger contemplated by the Agreement by February 28, 2005, which is the date in the Agreement after which generally either Mylan or King may terminate the Agreement.

Mylan also indicated that, in light of its ongoing review, Mylan believed it was unlikely that Mylan would consummate the acquisition of King on the terms, including the economic terms, set forth in the Agreement. While the Company's continued assessment may lead to a renegotiation of the Agreement, there can be no assurance that a revised agreement will be reached or that any transaction will occur.

As of December 31, 2004, the Company has incurred certain acquisition related costs in the amount of approximately \$12,000,000 which are recorded in the accompanying condensed consolidated balance sheet within other current assets. In the event that the acquisition is terminated, these costs would be expensed in the period in which the termination occurs.



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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, 2004, 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 December 31, 2004, included net revenues of \$291.0 million, net earnings of \$34.8 million and earnings per diluted share of \$0.13. Comparatively, the three months ended December 31, 2003, included revenues of \$349.8 million, net earnings of \$84.6 million and earnings per diluted share of \$0.31. This represents a decrease of 17% in revenues, 59% in net earnings and 58% in earnings per diluted share when compared to the same prior year period. The principal items impacting the results of the current quarter were:

**Competition on omeprazole subsequent to launch** During the past year, additional generic competition has entered the omeprazole market. In general, additional generic competition usually results in lower pricing and volume. Competition caused significantly lower pricing on omeprazole sales compared to the prior year, during which the product was launched. However, greater volume was realized due primarily to expanding the customer base which helped to partially offset the impact of the unfavorable pricing. In addition to other generics, Mylan faced competition on omeprazole from an over-the-counter product and other competing branded products.

**Competition on carbidopa/levodopa** For the past several years, Mylan had been the only generic market entrant for carbidopa/levodopa. During fiscal 2005, however, several additional generic competitors have launched carbidopa/levodopa. Similar to omeprazole, this additional competition has had negative implications on pricing as well as volume related to carbidopa/levodopa sales.

**Unexpected delay of fentanyl launch** In the third quarter of fiscal 2004, Mylan received final FDA approval for its fentanyl transdermal system, the generic equivalent of Alza Corporation's (Alza) Duragesic®. Mylan was, therefore, prepared to launch this product upon patent expiration in July 2004. However, the FDA in June 2004, rescinded Mylan's final Abbreviated New Drug Application (ANDA) approval. The actions of the FDA prevented Mylan from launching fentanyl in July 2004, which was expected to contribute significantly to fiscal 2005 net revenues and net earnings. Subsequent to December 31, 2004, on January 28, 2005, the

FDA granted Mylan final approval for fentanyl, following the denial of the pending citizen's petitions. Mylan launched the product immediately after receiving this approval. However, the pre-marketing of fentanyl by certain competitors, who represented that they would be in the market at market formation, despite not having a tentative or final approval from the FDA, coupled with strategies used by the authorized generic, caused what the Company believes was irrational pricing of fentanyl at market formation. Mylan believes that there could be further price erosion as additional competitors enter the fentanyl market.

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Consolidated gross profit for the current quarter decreased 32% or \$63.8 million to \$135.3 million and gross margins decreased to 47% from 57% when compared to the same prior year period. These decreases were realized by both the Generic and Brand Segments.

Generic Segment third quarter net revenues decreased 14% or \$39.1 million to \$238.4 million, while gross profit decreased \$46.3 million or 30% to \$107.2 million when compared to the same prior year period. Generic operating income decreased as well, primarily as a result of the decrease in gross profit. Brand Segment third quarter revenues decreased 27% or \$19.7 million to \$52.6 million and gross profit decreased 38% or \$17.5 million to \$28.1 million. Brand Segment operating income decreased 80% or \$13.7 million, also as a result of lower gross profit. Brand Segment results for the third quarter of fiscal 2004 included \$13.2 million from the sale of the U.S. and Canadian rights for sertaconazole nitrate 2% cream ( sertaconazole ). A more thorough discussion of operating results by segment is provided under the heading Results of Operations .

### *Pending Acquisition of King Pharmaceuticals*

On July 23, 2004, the Company entered into an Agreement and Plan of Merger ( Agreement ) to acquire King Pharmaceuticals, Inc. ( King ) in a stock-for-stock transaction. Under the terms of the Agreement, each of King s shareholders will receive .9 shares of Mylan common stock for every common share of King held upon closing. The acquisition contemplated under the Agreement, which was approved by the Boards of Directors of Mylan and King, is subject to customary closing conditions and would qualify as a tax-free reorganization for U.S. federal income tax purposes.

During the third quarter of fiscal 2005, King announced that it would restate previously reported financial results for 2002, 2003 and the first six months of 2004, and that it was evaluating whether financial results for any earlier periods require restatement. Any restatement of King s financial statements results in a failure to satisfy a condition of Mylan s obligation to close the acquisition of King. In January 2005, Mylan announced that while it was monitoring and reviewing King s accounting issues and a number of other matters concerning King, in light of timing issues, Mylan believed it was highly unlikely that the parties would be able to consummate the merger contemplated by the Agreement by February 28, 2005, which is the date in the Agreement after which generally either Mylan or King may terminate the Agreement.

Mylan also indicated that, in light of its ongoing review, Mylan believed it was unlikely that Mylan would consummate the acquisition of King on the terms, including the economic terms, set forth in the Agreement. While the Company s continued assessment may lead to a renegotiation of the Agreement, there can be no assurance that a revised agreement will be reached or that any transaction will occur.

### *EMSAM®*

In December 2004, Somerset Pharmaceuticals, Inc., in which Mylan owns a 50% equity interest, entered into an agreement with Bristol-Myers Squibb for the commercialization and distribution of Somerset s EMSAM (selegiline transdermal system). Somerset received an Approvable letter from the FDA for EMSAM in February 2004, and if approved by the FDA, EMSAM would be the first transdermal treatment for major depressive disorder.

**Table of Contents****Results of Operations**

The following table illustrates the financial results for the consolidated company and by operating segment:

(in thousands)

Period Ended December 31, Consolidated:	Three Months		Nine Months	
	2004	2003	2004	2003
Total revenues	\$ 290,972	\$ 349,786	\$ 936,939	\$ 1,041,254
Gross profit	135,347	199,184	470,353	584,321
Research and development	23,167	25,248	66,704	73,933
Selling and marketing	19,661	18,027	59,552	53,137
General and administrative	43,537	33,096	121,080	95,016
Litigation settlements		(2,676)	(25,985)	(24,345)
Other income, net	3,699	4,194	6,295	14,727
 Pretax earnings	 \$ 52,681	 \$ 129,683	 \$ 255,297	 \$ 401,307
 Generic Segment:				
Total revenues	\$ 238,357	\$ 277,446	\$ 753,572	\$ 832,157
Gross profit	107,249	153,582	367,136	461,249
Research and development	18,071	14,436	50,880	42,077
Selling and marketing	3,108	2,743	8,979	8,260
General and administrative	6,103	5,954	18,093	15,809
 Segment profit	 \$ 79,967	 \$ 130,449	 \$ 289,184	 \$ 395,103
 Brand Segment:				
Total revenues	\$ 52,615	\$ 72,340	\$ 183,367	\$ 209,097
Gross profit	28,098	45,602	103,217	123,072
Research and development	5,096	10,812	15,824	31,856
Selling and marketing	16,553	15,284	50,573	44,877
General and administrative	3,057	2,454	8,797	7,825
 Segment profit	 \$ 3,392	 \$ 17,052	 \$ 28,023	 \$ 38,514
 Corporate/Other:				
Loss	\$ (30,678)	\$ (17,818)	\$ (61,910)	\$ (32,310)

*Segment total revenues represent revenues from unrelated third parties. For the Generic and Brand Segments, segment profit represents segment gross profit less direct research and development, selling and marketing and general and administrative expenses. Corporate/Other includes certain general and administrative expenses, such as legal expenditures, litigation settlements and non-operating income and expense.*

Quarter Ended December 31, 2004, Compared to Quarter Ended December 31, 2003

*Total Revenues and Gross Profit*

Revenues for the current quarter decreased 17% or \$58.8 million to \$291.0 million compared to \$349.8 million in the third quarter of fiscal 2004. In arriving at net revenues, gross revenues are reduced by provisions for estimates, including discounts, customer performance and promotions, price adjustments, returns and chargebacks. See

Application of Critical Accounting Policies in the Company's Form 10-K for the fiscal year ended March 31,

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2004, for a thorough discussion of its methodology with respect to such provisions. For the quarter ended December 31, 2004, the most significant amounts charged against gross revenues were for chargebacks in the amount of \$213.3 million and customer performance and promotions in the amount of \$48.0 million. For the quarter ended December 31, 2003, chargebacks of \$218.6 million and customer performance and promotions of \$46.5 million were charged against gross revenues.

The decrease in net revenues was realized by both the Generic Segment, for which revenues decreased 14% or \$39.1 million to \$238.4 million, and the Brand Segment, for which revenues decreased 27% or \$19.7 million to \$52.6 million.

With respect to Generic net revenues, the decrease in revenues was the result of increased pressure on pricing, including the effect of additional competition, on the Company's product portfolio. Omeprazole, which was launched during the second quarter of fiscal 2004, experienced significantly lower pricing as a direct result of additional generic competition. Despite the additional competition, omeprazole sales volume increased due primarily to expanding the customer base and capitalizing on a higher generic conversion rate, and Mylan was able to establish its position as market leader, based on omeprazole prescriptions dispensed. On an overall basis however, Generic volume shipped for the quarter decreased nearly 2% to 2.8 billion doses compared with the same prior year period.

Increased competition also resulted in unfavorable pricing on carbidopa/levodopa. As is the case in the generic industry, the entrance into the market of other generic 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.

New products launched subsequent to December 31, 2003, contributed net revenues of \$11.8 million in the third quarter of fiscal 2005. By comparison, new products in the third quarter of fiscal 2004 contributed net revenues of \$29.5 million, largely due to omeprazole.

For the Brand Segment, revenues for the third quarter decreased 27% or \$19.7 million to \$52.6 million from \$72.3 million in the same prior year period. Included in revenues for the third quarter of fiscal 2004 was \$13.2 million related to the sale of sertaconazole. Unfavorable pricing, the result of increased competition on Amnesteem, was primarily responsible for the remainder of the decrease in revenues.

Consolidated gross profit decreased 32% or \$63.8 million to \$135.3 million and gross margins decreased to 47% from 57%. For the Generic Segment, gross profit decreased to \$107.2 million from \$153.6 million while gross margins decreased to 45% from 55% in the third quarter of fiscal 2004. The decrease in Generic Segment gross margin is primarily the result of additional generic competition on certain products, primarily omeprazole and carbidopa/levodopa.

For the Brand Segment, gross profit decreased 38% or \$17.5 million to \$28.1 million from \$45.6 million and gross margins decreased from 63% to 53%. The decrease in Brand gross margin was primarily the result of the sale of sertaconazole in the prior year. Excluding the effects of this sale, the decrease in Brand Segment gross margin during the third quarter of fiscal 2005 was not significant.

*Operating Expenses*

Research and development ( R&D ) expenses for the current quarter decreased 8% or \$2.1 million to \$23.2 million from \$25.2 million. The Brand Segment, for which R&D expenses decreased 53% or \$5.7 million to \$5.1 million, was responsible for the overall decrease, partially offset by a 25% increase in R&D expenses in the Generic Segment to \$18.1 million. The decrease in Brand Segment R&D expenses is primarily the result of the completion, during fiscal

2004, of the Phase III clinical studies for nebivolol, for which a New Drug Application ( NDA ) was submitted to the FDA on April 30, 2004, and accepted for filing by the FDA on June 29, 2004. The increase in Generic Segment R&D expenses was due primarily to an increase in the number of current R&D projects.

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Selling and marketing expenses for the current quarter increased 9% or \$1.6 million to \$19.7 million from \$18.0 million. The Brand Segment was primarily responsible for this increase, due primarily to pre-marketing costs associated with neбиволол.

General and administrative ( G&A ) expenses for the quarter increased 32% or \$10.4 million to \$43.5 million from \$33.1 million. Of this increase, \$9.7 million was attributable to higher corporate expenses, with increased consulting costs and higher payroll and payroll related costs contributing equally to the increase. Consulting cost increased due to the announced (but not completed) acquisition and integration of King and the implementation of an enterprise resource planning system.

*Other Income, net*

Other income, net of non-operating expenses, was \$3.7 million in the third quarter of fiscal 2005 compared to \$4.2 million in the same prior year period.

**Nine Months Ended December 31, 2004, Compared to Nine Months Ended December 31, 2003**

*Total Revenues and Gross Profit*

Revenues for the nine months ended December 31, 2004, decreased 10% or \$104.3 million to \$936.9 million, compared to \$1.04 billion in the corresponding period of fiscal 2004. In arriving at net revenues, gross revenues are reduced by provisions for estimates, including discounts, customer performance and promotions, price adjustments, returns and chargebacks. See Application of Critical Accounting Policies in the Company's Form 10-K for the fiscal year ended March 31, 2004, for a thorough discussion of its methodology with respect to such provisions. For the nine months ended December 31, 2004, the most significant amounts charged against gross revenues were for chargebacks in the amount of \$651.3 million and customer performance and promotions in the amount of \$148.5 million. For the nine months ended December 31, 2003, chargebacks of \$615.4 million and customer performance and promotions of \$159.6 million were charged against gross revenues. The increase in the amounts charged against gross revenues for chargebacks in the current year is primarily the result of pricing pressures on certain products in the Company's portfolio, most notably omeprazole and carbidopa/levodopa, as well as a shift in the percentage of sales in the current year to customers to whom chargebacks are applicable.

The decrease in net revenues was realized by both the Generic Segment, for which revenues decreased 9% or \$78.6 million to \$753.6 million, and the Brand Segment for which revenues decreased 12% or \$25.7 million to \$183.4 million.

The decrease in Generic net revenues was primarily the result of overall unfavorable pricing, partially offset by increased sales of certain other products, including new product sales of \$38.0 million. Additional generic competition on omeprazole and carbidopa/levodopa were the primary reasons for the unfavorable pricing as well as the overall decrease in sales. Despite the additional competition, omeprazole did realize favorable volume as a result of nine months of sales in fiscal 2005 as compared to two months of sales in the same prior year period. In addition, Mylan expanded its customer base on omeprazole and capitalized on a higher generic conversion rate. Overall, Generic Segment volume for the nine months ended December 31, 2004, increased approximately 5% to 8.7 billion doses shipped.

For the Brand Segment, revenues for the nine months ended December 31, 2004, decreased 12% or \$25.7 million to \$183.4 million from \$209.1 million in the same prior year period. Excluding sertaconazole, the decrease in sales of \$11.8 million was primarily driven by increased competition on certain products such as Amnesteem, Digitek® and Acticin®, partially offset by higher revenues from phenytoin.



Consolidated gross profit for the first nine months of fiscal 2005 decreased 20% or \$114.0 million to \$470.4 million and gross margins decreased to 50% from 56%. For the Generic Segment, gross profit decreased to \$367.1 million from \$461.2 million while gross margins decreased to 49% from 55% for the nine months ended December 31, 2004. The decrease in Generic Segment gross margin is primarily the result of the impact on pricing of additional generic competition on certain products, as discussed above.

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For the Brand Segment, gross profit decreased 16% or \$19.9 million to \$103.2 million from \$123.1 million while gross margins decreased from 59% to 56%. However, excluding sertaconazole, Brand Segment gross margins for the nine months ended December 31, 2004, increased slightly. This increase is primarily the result of favorable product mix, with phenytoin comprising a higher percentage of sales, and Amnesteem, which contributes lower gross margins as a result of royalties paid under a supply and distribution agreement, comprising a smaller percentage of sales.

### *Operating Expenses*

R&D expenses for the current year to date period decreased 10% or \$7.2 million to \$66.7 million from \$73.9 million. The Brand Segment, for which R&D expenses decreased 50% or \$16.0 million to \$15.8 million, was responsible for the overall decrease, partially offset by a 21% increase in R&D expenses in the Generic Segment to \$50.9 million. The decrease in Brand Segment R&D expenses is primarily the result of the completion, during fiscal 2004, of the Phase III clinical studies for nebivolol. For the Generic Segment, a greater number of current R&D projects resulted in \$4.5 million more R&D expense in the current year, and payroll and payroll related costs increased \$3.4 million, accounting for a majority of the overall increase.

Selling and marketing expenses for fiscal 2005 increased 12% or \$6.4 million to \$59.6 million from \$53.1 million. The Brand Segment was primarily responsible for this increase, due primarily to costs incurred with respect to nebivolol and the launch of Apokyn .

G&A expenses for the nine months ended December 31, 2004, increased 27% or \$26.1 million to \$121.1 million from \$95.0 million. Of this increase, \$22.8 million was attributable to higher corporate expenses. For Corporate G&A expenses, the majority of the increase is due equally to higher payroll and payroll related costs, and increased consulting expenses, including legal expenses. Consulting expenses increased as a result of the announced (but not completed) acquisition and integration of King and the implementation of an enterprise resource planning system. Legal expenses continue to be an integral part of the Company's ability to continue to deliver new generic products to the market.

### *Litigation Settlements*

Net gains of \$26.0 million were recorded in the first nine months of fiscal 2005 with respect to the settlement of various lawsuits. In June 2004, Mylan received \$37.5 million in settlement of certain patent litigation claims involving omeprazole. A portion of this settlement represented reimbursement of legal fees and expenses related to the litigation. Partially offsetting this gain, Mylan agreed, also in June 2004, to a \$9.0 million settlement resolving all pending litigation with respect to paclitaxel. Net gains of \$24.3 million, also from the settlement of litigation, were recorded in the first nine months of the prior year.

### *Other Income, net*

Other income, net of non-operating expenses, was \$6.3 million in fiscal 2005 compared to \$14.7 million in the same prior year period. The prior year results included a gain of \$5.0 million on the sale of an office building.

## **Liquidity and Capital Resources**

The Company's primary source of liquidity continues to be cash flows from operating activities, which were \$222.2 million for the nine months ended December 31, 2004. Working capital as of December 31, 2004, was \$1.27 billion, an increase of \$126.0 million from the balance at March 31, 2004. The majority of this increase was the result of higher cash and cash equivalents and marketable securities, partially offset by lower inventories. The decrease in inventory corresponds to the overall increase in sales volume experienced during the nine months ended

December 31, 2004, as well as lower inventories carried with respect to certain products. Trade accounts payable increased \$20.2 million and income taxes payable decreased \$23.8 million, primarily due to the timing of cash payments.

In the prior year, inventory at December 31, 2003, increased from March 31, 2003, due to new product launches and planned production increases in order to meet forecasted demand. The effect on cash of the increase in working

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capital items, primarily inventory, along with the favorable impact of net cash from litigation settlements, were primarily responsible for the increase in cash from operations during the nine months ended December 31, 2004.

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 \$17.0 million related to lawsuits which were settled in prior periods.

During the second quarter of fiscal 2005, Mylan paid \$9.0 million to resolve all pending litigation with respect to paclitaxel.

Cash used in investing activities for the nine months ended December 31, 2004, was \$125.8 million. Of the Company's \$2.0 billion of total assets at December 31, 2004, \$835.3 million was held in cash, cash equivalents and marketable securities. Investments in marketable securities consists 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 nine months ended December 31, 2004, were \$63.2 million. These expenditures were incurred primarily with respect to the Company's planned expansions. As such expansions continue, capital expenditures are expected to be approximately \$80.0 million to \$100.0 million for fiscal 2005, primarily due to the timing of payments and the delay of certain projects as the Company assesses the announced (but not completed) acquisition and integration of King.

Cash used in financing activities was \$14.8 million for the nine months ended December 31, 2004. Included in financing activities in the prior year was \$133.1 million to purchase shares of the Company's stock under a stock repurchase program. This program was completed on November 18, 2003.

In the third quarter of fiscal 2004, the Board voted to increase the quarterly dividend 35% to 3.0 cents per share. Dividend payments totaled \$24.2 million during the nine months ended December 31, 2004.

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, 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 from operating activities.

In order to provide additional operating leverage, if necessary, the Company maintains a revolving line of credit with a commercial bank providing for borrowings of up to \$50.0 million. As of December 31, 2004, no funds have been advanced under this line of credit. Additionally, 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. On July 23, 2004, the Company entered into an Agreement to acquire King in a stock-for-stock transaction, for which the Company expects to continue to incur acquisition related costs.



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### Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board ( FASB ) issued Statement of Financial Accounting Standards ( SFAS ) No. (R), *Share-Based Payment*. SFAS 123® establishes standards for the accounting for transactions in which an entity exchanges its equity instruments for goods and services. Under SFAS 123®, companies will no longer be able to account for share-based compensation transactions using the intrinsic method in accordance with Accounting Principles Board Opinion ( 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. The provisions of SFAS 123 ® are effective for periods beginning after June 15, 2005, and apply to all awards that vest after the required effective date and to awards that are granted, modified, repurchased, or cancelled after that date. 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. 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. Please refer to our other periodic reports filed with the Securities and Exchange Commission ( SEC ) including our Annual Report on Form 10-K for the fiscal year ended March 31, 2004, and our Quarterly Reports on Form 10-Q for the quarters ended June 30, 2004 and September 30, 2004. Lastly, please note that the risk factors included in our periodic reports are reviewed and updated for each filing, and from time to time we may supplement or highlight an existing risk factor.

**OUR FUTURE REVENUE GROWTH AND PROFITABILITY ARE DEPENDENT UPON OUR ABILITY TO DEVELOP AND 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 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 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 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

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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, the FDA cannot grant final approval to any other generic equivalent. If an ANDA containing a Paragraph IV certification is successful, 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 who filed its ANDA containing such a challenge. Such a situation 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. In some cases, these 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.

**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.

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**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.

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

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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.**

As previously discussed 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. Although the regulations regarding reporting and payment obligations are complex, 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 judgments involved in making these calculations involve, and will continue to involve, subjective decisions, these calculations are subject to the risk of errors. 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 intent 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 of 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 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, 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

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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 OR COULD DELAY OR PREVENT SUCH INTRODUCTION. 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;

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

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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, 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 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 GENERIC 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 generic 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**





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**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.

**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, our brand products 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 who 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 who 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**

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**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 healthcare and legislative healthcare 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, 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 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

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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 ANNOUNCED (BUT NOT COMPLETED) ACQUISITION OF KING PHARMACEUTICALS INVOLVES A NUMBER OF INHERENT RISKS, 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.**

On July 23, 2004, we entered into an Agreement and Plan of Merger to acquire King Pharmaceuticals, Inc. ( King ) in a stock-for-stock transaction. The consummation of the acquisition requires the satisfaction of certain conditions to the acquisition that are beyond our control. Should the acquisition occur the anticipated synergies and other benefits from the acquisition may not be achieved, and the integration of the two businesses may involve challenges and costs, all of which could result in the costs of the acquisition exceeding its realized benefits. Furthermore, we cannot predict, among other things: the effect of any changes in customer and supplier relationships and customer purchasing patterns; the impact and effects of legal or regulatory proceedings, actions or changes; general market perception of the transaction; exposure to lawsuits and contingencies associated with the acquisition; our ability to retain key employees; and other uncertainties and matters beyond our control. In addition, if the acquisition is not completed, we may be obligated to pay an \$85 million termination fee under certain limited circumstances. We are also responsible for financial advisory, legal, accounting and other fees which must be paid even if the acquisition is not completed. Certain of the above factors could have 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 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.**

In addition to the King acquisition, 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 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,

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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 GENERICS 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.**

If recent FDA rulings should stand, which rulings we believe 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, then our business and the generic industry as a whole could be materially adversely affected. 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 operation 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.

**UNDER REGULATIONS REQUIRED BY THE SARBANES-OXLEY ACT OF 2002, AN ADVERSE OPINION ON INTERNAL CONTROLS COULD BE ISSUED BY OUR AUDITOR, AND THIS 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.**

Section 404 of the Sarbanes-Oxley Act of 2002 requires us to provide an assessment of the effectiveness of internal control over financial reporting beginning with our Annual Report of Form 10-K for the fiscal year ending March 31, 2005. Our auditors are required to audit both the design and operating effectiveness of our internal controls and management's assessment of the design and the effectiveness of its internal controls. Although no known material weaknesses exist at this time, this will be the first year that we have undergone an audit of our internal controls and procedures, and it is possible that material weaknesses could be found. If we are unable to remediate the weaknesses, management may be required to disclose that material weaknesses exist, and the auditors could be required to issue an adverse opinion on our internal controls, 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.

**THERE ARE INHERENT UNCERTAINTIES INVOLVED IN ESTIMATES, JUDGMENTS AND ASSUMPTIONS USED IN THE PREPARATION OF FINANCIAL STATEMENTS IN ACCORDANCE**



**WITH GAAP. ANY CHANGES IN ESTIMATES, JUDGMENTS AND ASSUMPTIONS USED 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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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 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 December 31, 2004 and March 31, 2004:

	December 31, 2004	March 31, 2004
<i>(in thousands)</i>		
Debt securities	\$ 648,501	\$ 581,212
Equity securities	3,451	4,233
	\$ 651,952	\$ 585,445

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 December 31, 2004, the Company had invested \$648.5 million in marketable debt securities, of which \$152.8 million will mature within one year and \$495.7 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 \$495.7 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 \$24.8 million change in marketable debt securities.

**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 December 31, 2004. 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.

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**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, 2004, as supplemented by the disclosure in our Quarterly Reports on Form 10-Q for the quarters ended June 30, 2004 and September 30, 2004. During the quarter ended December 31, 2004, 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. No amounts have been accrued at December 31, 2004, with respect to any of these matters.

**Pricing and Medicaid Litigation and Investigations**

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 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 average wholesale prices. 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 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. Also 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. In each case, the plaintiff seeks money damages and civil penalties in unspecified amounts and declaratory and injunctive relief, and in each matter Mylan Labs and its subsidiaries have not yet been required to respond to the complaint or the amended complaint, as applicable.

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. The government has not asked MPI for information.

***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

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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*. On January 19, 2005, 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 preliminary objections seeking dismissal of the complaints are pending before the court.

On December 10, 2004, High River Limited Partnership, 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 the 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 asserts 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 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 have filed motions to dismiss the complaint in its entirety, which motions are currently pending before the court.

## **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.
- 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.
- 10.1 Amendment No. 1 to Transition and Succession Agreement dated as of December 2, 2004, between the registrant and Robert J. Coury.
- 10.2 Amendment No. 1 to Transition and Succession Agreement dated as of December 2, 2004, between the registrant and Edward J. Borkowski.

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- 10.3 Amendment No. 1 to Transition and Succession Agreement dated as of December 2, 2004, between the registrant and Louis J. DeBone.
- 10.4 Amendment No. 1 to Transition and Succession Agreement dated as of December 2, 2004, between the registrant and Margaret A. McKenna.
- 10.5 Amendment No. 1 to Transition and Succession Agreement dated as of December 2, 2004, between the registrant and John P. O'Donnell.
- 10.6 Amendment No. 1 to Transition and Succession Agreement dated as of December 2, 2004, between the registrant and Stuart A. Williams.
- 10.7 Retirement Benefit Agreement dated as of December 31, 2004, between the registrant and Robert J. Coury.
- 10.8 Retirement Benefit Agreement dated as of December 31, 2004, between the registrant and Edward J. Borkowski.
- 10.9 Retirement Benefit Agreement dated as of December 31, 2004, between the registrant and Stuart A. Williams.
- 10.10 Amended and Restated Retirement Benefit Agreement dated as of December 31, 2004, between the registrant and Louis J. DeBone.
- 10.11 Amended and Restated Retirement Benefit Agreement dated as of December 31, 2004, between the registrant and John P. O'Donnell.
- 10.12 Mylan Laboratories Inc. Severance Plan.
- 10.13 Description of the registrant's Director Compensation Arrangements in effect as of February 9, 2005.
- 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 December 31, 2004, to be signed on its behalf by the undersigned thereunto duly authorized.

Mylan Laboratories Inc.  
(Registrant)

February 9, 2005

By: /s/ Robert J. Coury

Robert J. Coury  
Vice Chairman and Chief  
Executive Officer

February 9, 2005

/s/ Edward J. Borkowski

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

February 9, 2005

/s/ Gary E. Sphar

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

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