MYLAN LABORATORIES INC
Form 10-Q
November 04, 2005

Table of Contents

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 September 30, 2005

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from ___to ___

Commission file number 1-9114
MYLAN LABORATORIES INC.
(Exact name of registrant as specified in its charter)

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

1500 Corporate Drive
Canonsburg, Pennsylvania 15317
(Address of principal executive offices)
(Zip Code)

(724) 514-1800
(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding twelve months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
YES 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 by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
YES o NO þ

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 October 31, 2005
$0.50 par value	215,310,557

MYLAN LABORATORIES INC. AND SUBSIDIARIES
FORM 10-Q

For the Quarterly Period Ended
September 30, 2005
INDEX

Table of Contents

MYLAN LABORATORIES INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Earnings
(unaudited; in thousands, except per share amounts)

	Three Months		Six Months	
Period Ended September 30,	2005	2004	2005	2004
Net revenues	$ 297,994	$ 306,955	$ 621,372	$ 645,967
Cost of sales	154,763	151,702	310,307	310,961
Gross profit	143,231	155,253	311,065	335,006
Operating expenses:				
Research & development	28,159	22,042	53,245	43,537
Selling, general & administrative	57,089	59,688	128,271	117,434
Litigation settlements, net			12,000	(25,985)
Total operating expenses	85,248	81,730	193,516	134,986
Earnings from operations	57,983	73,523	117,549	200,020
Interest expense	8,942		8,942	
Other income, net	4,347	1,910	9,903	2,596
Earnings before income taxes	53,388	75,433	118,510	202,616
Provision for income taxes	17,618	26,779	39,825	71,929
Net earnings	$ 35,770	$ 48,654	$ 78,685	$ 130,687
Earnings per common share:				
Basic	$ 0.16	$ 0.18	$ 0.32	$ 0.49
Diluted	$ 0.16	$ 0.18	$ 0.31	$ 0.48
Weighted average common shares:				
Basic	225,042	268,945	247,244	268,749
Diluted	229,259	272,930	251,261	274,170
Cash dividend declared per common share	$ 0.06	$ 0.03	$ 0.12	$ 0.06

See Notes to Condensed Consolidated Financial Statements

Table of Contents

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

	September 30, 2005	March 31, 2005
Assets		
Current assets:		
Cash and cash equivalents	$ 182,091	$ 137,733
Marketable securities	449,422	670,348
Accounts receivable, net	239,049	297,334
Inventories	255,413	286,267
Deferred income tax benefit	127,926	119,327
Other current assets	12,763	17,443
Total current assets	1,266,664	1,528,452
Property, plant and equipment, net	371,072	336,719
Intangible assets, net	114,308	120,493
Goodwill	102,579	102,579
Other assets	59,440	47,430
Total assets	$ 1,914,063	$ 2,135,673
Liabilities and shareholders equity		
Liabilities		
Current liabilities:		
Trade accounts payable	$ 75,451	$ 78,114
Income taxes payable	5,333	44,123
Current portion of long-term obligations & long-term debt	4,336	1,586
Cash dividends payable	12,905	8,078
Other current liabilities	171,231	113,606
Total current liabilities	269,256	245,507
Long-term debt	772,250	
Other long-term obligations	19,700	19,325
Deferred income tax liability	22,196	24,905
Total liabilities	1,083,402	289,737
Shareholders equity		
Common stock	152,937	152,217
Additional paid-in capital	372,047	354,172
Retained earnings	1,858,398	1,808,802
Accumulated other comprehensive earnings	3,373	870

		2,386,755	2,316,061
Less:			
Treasury stock at cost		1,556,094	470,125
Total shareholders equity		830,661	1,845,936
Total liabilities and shareholders equity	$	1,914,063	$ 2,135,673

See Notes to Condensed Consolidated Financial Statements

Table of Contents

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

Six Months Ended September 30,	**2005**	**2004**
Cash flows from operating activities:		
Net earnings	$ 78,685	$ 130,687
Adjustments to reconcile net earnings to net cash provided from operating activities:		
Depreciation and amortization	23,928	22,049
Deferred income tax benefit	(12,657)	(5,351)
Net loss from equity method investees	948	2,334
Changes in estimated sales allowances	7,737	6,682
Restructuring provision	19,646	
Other non-cash items	6,456	3,582
Loss (gain) from litigation, net	12,000	(25,985)
Receipts from litigation settlements	2,000	42,985
Changes in operating assets and liabilities:		
Accounts receivable	61,383	(28,315)
Inventories	30,035	24,193
Trade accounts payable	(2,604)	2,136
Income taxes	(38,790)	(10,811)
Other operating assets and liabilities, net	6,311	(6,675)
Net cash provided from operating activities	195,078	157,511
Cash flows from investing activities:		
Capital expenditures	(51,313)	(38,197)
Purchase of marketable securities	(440,844)	(485,781)
Proceeds from sale of marketable securities	665,458	399,275
Other items, net	(1,704)	1,653
Net cash provided by (used in) investing activities	171,597	(123,050)
Cash flows from financing activities:		
Cash dividends paid	(24,262)	(16,112)
Payment of financing fees	(13,900)	
Proceeds from long-term debt	775,000	
Purchase of common stock	(1,081,011)	
Proceeds from exercise of stock options	16,635	8,050
Increase in outstanding checks in excess of cash in disbursement accounts	5,221	
Net cash used in financing activities	(322,317)	(8,062)
Net increase in cash and cash equivalents	44,358	26,399
Cash and cash equivalents beginning of period	137,733	101,713

Cash and cash equivalents	end of period	$ 182,091	$ 128,112
Additional disclosures:			
Cash paid for income taxes		$ 91,272	$ 88,326
Interest paid		$	$

See Notes to Condensed Consolidated Financial Statements

Table of Contents

MYLAN LABORATORIES INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements
(unaudited; dollars in thousands, except Note 12 and per share amounts)

1. General

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

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

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

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

2. Revenue Recognition and Accounts Receivable

Revenue is recognized for product sales upon shipment when title and risk of loss transfer to the Company s customers and when provisions for estimates, including discounts, rebates, price adjustments, returns, chargebacks and other promotional programs are reasonably determinable. No revisions were made to the methodology used in determining these provisions during the three and six month periods ended September 30, 2005. Accounts receivable are presented net of allowances relating to these provisions. Such allowances were $344,920 and $349,355 as of September 30, 2005, and March 31, 2005. Other current liabilities include $63,944 and $51,772 at September 30, 2005, and March 31, 2005, for certain rebates and other adjustments that are payable to indirect customers.

3. Recent Accounting Pronouncements

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

Table of Contents

4. Restructuring

On June 14, 2005, the Company announced that it was closing its branded subsidiary, Mylan Bertek, and transferring the responsibility for marketing Mylan Bertek s products to other Mylan subsidiaries. In conjunction with this restructuring, the Company incurred restructuring charges of $9,443, pre-tax, and $19,646, pre-tax, during the three and six months ended September 30, 2005. Of the $9,443 recorded in the second quarter, $758 is included in research and development expense, with the remainder in selling, general and administrative expense. For the six months ended September 30, 2005, $990 is included in research and development expense, with the remainder in selling, general and administrative expense. The major components of the restructuring charge and the remaining accrual balance at September 30, 2005, were as follows:

	Non-cash Asset Write-downs	Employee Termination & Severance Costs	Other Exit Costs	Total
Initial charge quarter ended June 30, 2005	$ 970	6,953	2,280	$ 10,203
Amounts utilized quarter ended June 30, 2005	(970)	(4,248)		(5,218)
Accrued restructuring costs June 30, 2005	$	2,705	2,280	$ 4,985
Additional charge quarter ended September 30, 2005	$ 667	7,754	1,022	$ 9,443
Amounts utilized quarter ended September 30, 2005	(667)	(1,839)	(1,260)	(3,766)
Accrued restructuring costs September 30, 2005	$	8,620	2,042	$ 10,662

Employee termination and severance costs are primarily related to involuntary terminations, most of which were with respect to the Mylan Bertek sales force, and represent cash termination payments to be paid to the affected employees as a direct result of the restructuring. Exit costs consist primarily of lease termination costs incurred as a result of the restructuring.

As of September 30, 2005, the Company s restructuring was substantially complete. The majority of the remaining accrued restructuring costs, most of which relate to employee termination and severance costs, are expected to be paid during the third quarter of fiscal 2006.

Table of Contents

5. Balance Sheet Components

Selected balance sheet components consist of the following:

	September 30, 2005	March 31, 2005
Inventories:		
Raw materials	$ 102,614	$ 119,654
Work in process	37,790	39,589
Finished goods	115,009	127,024
	$ 255,413	$ 286,267
Property, plant and equipment:		
Land and improvements	$ 10,639	$ 9,704
Buildings and improvements	168,913	161,050
Machinery and equipment	275,247	269,208
Construction in progress	113,513	85,324
	568,312	525,286
Less accumulated depreciation	197,240	188,567
	$ 371,072	$ 336,719
Other current liabilities:		
Accrued rebates	$ 63,944	$ 51,772
Payroll and employee benefit plan accruals	34,510	21,251
Royalties and product license fees	8,955	11,446
Legal and professional	23,900	18,148
Other	39,922	10,989
	$ 171,231	$ 113,606

6. Earnings per Common Share

Basic earnings per common share is computed by dividing net earnings by the weighted average number of common shares outstanding during the period. Diluted earnings per common share is computed by dividing net earnings by the weighted average number of common shares outstanding during the period adjusted for the dilutive effect of stock options and restricted stock outstanding. The effect of dilutive stock options and restricted stock on the weighted average number of common shares outstanding was 4,217,000 and 3,985,000 for the three months ended September 30, 2005 and 2004, and 4,017,000 and 5,421,000 for the six months ended September 30, 2005 and 2004.

Options to purchase 5,402,000 and 6,857,000 shares of common stock were outstanding as of September 30, 2005 and 2004, but were not included in the computation of diluted earnings per share for the three months then ended because to do so would have been antidilutive.

Table of Contents

7. Intangible Assets

Intangible assets consist of the following components:

	Weighted Average Life (years)	Original Cost	Accumulated Amortization	Net Book Value
September 30, 2005				
Amortized intangible assets:				
Patents and technologies	19	$ 118,935	$ 51,666	$ 67,269
Product rights and licenses	12	112,633	73,758	38,875
Other	20	14,267	6,886	7,381
		$ 245,835	$ 132,310	113,525
Intangible assets no longer subject to amortization:				
Trademarks				783
				$ 114,308
March 31, 2005				
Amortized intangible assets:				
Patents and technologies	19	$ 118,935	$ 48,478	$ 70,457
Product rights and licenses	12	111,433	69,923	41,510
Other	20	14,267	6,524	7,743
		$ 244,635	$ 124,925	119,710
Intangible assets no longer subject to amortization:				
Trademarks				783
				$ 120,493

Amortization expense for the six months ended September 30, 2005, and 2004, was $7,385 and $8,989 and is expected to be $14,851, $14,603, $14,151, $13,840 and $12,822 for fiscal years 2006 through 2010, respectively.

8. Long-Term Debt

A summary of long-term debt is as follows:

	September 30, 2005	March 31, 2005
Senior Notes (A)	$ 500,000	$
Senior Credit Facility (B)	275,000	
	775,000	

Less: current portion			2,750	
Total long term debt		$	772,250	$

(A) On July 21, 2005, the Company issued $500,000 in Senior Notes, which consist of $150,000 of Senior Notes due August 15, 2010, and bearing interest at 5 3/4 % per annum and $350,000 of Senior Notes due August 15, 2015 (collectively the Notes), and bearing interest at 6 3/8% per annum. Interest is payable semi-annually on February 15 and August 15, commencing February 15, 2006. The proceeds from the Notes were used to finance a portion of the Dutch Auction self-tender described in Note 10.

Table of Contents

In connection with the Notes offering, the Company entered into a registration rights agreement, as described below.

Prior to maturity, the Company may, under certain circumstances, redeem the Notes in whole or in part at prices specified in the bond indenture governing the notes. Upon a change of control (as defined in the indenture governing the Notes) of the Company, each holder of the Notes may require the Company to purchase all or a portion of such holder s Notes at 101% of the principal amount of such Notes, plus accrued and unpaid interest.

The Notes are senior unsecured obligations of

the Company and rank junior to all of the Company s secured obligations. The Notes are guaranteed jointly and severally on a full and unconditional senior unsecured basis by all of the Company s wholly owned domestic subsidiaries except a captive insurance company, which is considered to be a minor subsidiary. Also, the assest and operations of Mylan Laboratories Inc. (Mylan Labs), the parent company, are not material, and as such condensed consolidating financial information for the parent and subsidiaries is not provided.

The Notes indenture contain covenants that, among other things, (a) limit the ability of the Company to incur additional

secured indebtedness, (b) make investments or other restricted payments, (c) pay dividends on, redeem or repurchase the Company s capital stock, (d) engage in sale-leaseback transactions and (e) consolidate, merge or transfer all or substantially all of its assets. Certain of the covenants contained in the indenture will no longer be applicable or will be less restrictive if the Company achieves investment grade ratings as outlined in the indenture.

In connection with the completion of the Notes offering, the Company entered into a registration rights agreement (the Registration Rights Agreement), dated July 21, 2005. The Registration Rights

Agreement requires the Company to use its reasonable best efforts (i) to file with the SEC a registration statement covering an offer to exchange the Notes for freely tradeable notes with substantially similar terms within 120 days of the issue date of the Notes (the Closing Date), (ii) to cause such registration statement to be declared effective by the SEC within 210 days of the Closing Date, (iii) to keep such registration statement effective until the exchange offer is consummated, (iv) to consummate the exchange offer within 240 days of the Closing Date and (v) if such registration statement is not declared effective, or if the exchange offer is not consummated, on the dates specified for

such effectiveness or consummation, or if certain other events occur, to file a shelf registration statement for the resale of the Notes. If the Company fails to meet the requirements of the Registration Rights Agreement outlined above, during the periods specified, the Company will incur additional interest on the Notes until such registration defaults are cured in an amount equal to 0.25%, per annum of the principal amount of the Notes for each 90 day period of default up to a maximum increase of 1.0% over the original interest rates of the Notes.

(B) On July 21, 2005, the Company entered into a $500,000 senior secured credit facility (the Credit Facility). The Credit

Facility consists of a $225,000 five-year revolving credit facility (the Revolving Credit Facility), which the Company intends to use for working capital and general corporate purposes, and a $275,000 five-year term loan (the Term Loan), the proceeds of which were used to fund a portion of the Dutch Auction self-tender described in Note 10. Loans under the Revolving Credit Facility bear interest at a rate equal to either LIBOR plus 1.25% per annum or prime plus 0.25% per annum, at the Company s option and the Term Loan bears interest at a rate equal to LIBOR plus 1.50% per annum or prime plus 0.50% per annum also at the Company s option. The Term Loan interest rate in

effect at September 30, 2005 was 5.40%. The Company is required to pay a fee on the unused portion of the Revolving Credit Facility of 0.50% per annum. At September 30, 2005, no borrowings were outstanding under the Revolving Credit Facility.

The Term Loan will amortize at a rate of 1% per year for the first four years, with the balance paid in four equal quarterly installments thereafter. Subject to exceptions, the Credit Facility has mandatory prepayments with respect to certain proceeds of asset sales, debt issuances, equity issuances and with respect to the Company s excess cash flows. Also, the Term Loan may be prepaid without penalty at any time in

whole or in part at the Company s option. Because the amount of mandatory prepayment varies from quarter to quarter and cannot be reasonably estimated, only the 1% per year amortization is included on the balance sheet as a current liability.

Table of Contents

The Company s obligations under the Credit Facility are guaranteed jointly and severally on a full and unconditional senior secured basis by all of the Company s wholly owned domestic subsidiaries except a captive insurance company, which is considered to be a minor subsidiary. The obligations under the Credit Facility are also collateralized by a first priority lien on, and pledge of, 100% of the equity interests of certain of the Company s wholly owned domestic subsidiaries and 65% of the equity interests of each of the Company s foreign subsidiaries.

The Credit Facility includes covenants that (a) require the Company to maintain a minimum

interest coverage ratio and a maximum total leverage ratio, (b) place limitations on the Company s ability to incur debt, grant liens, carry out mergers, acquisitions and asset sales and make investments and (c) place limitations on the Company s ability to pay dividends or make other restricted payments.

All debt issuance costs associated with the Notes and the Credit Facility are being amortized over the life of the related debt. The total unamortized amounts of $13,994 are included in other assets in the consolidated balance sheets.

At September 30, 2005, the carrying value of the Company s long-term debt approximated fair value.

Principal maturities of the Notes and Credit Facility for the next five years and thereafter, as of September 30, 2005, are as follows:

Year 1	$ 2,750
Year 2	2,750
Year 3	2,750
Year 4	2,750
Year 5	198,000
Thereafter	566,000
	$ 775,000

9. Comprehensive Earnings

Comprehensive earnings consist of the following:

	Three Months		Six Months	
Period Ended September 30,	2005	2004	2005	2004
Net earnings	$ 35,770	$ 48,654	$ 78,685	$ 130,687
Other comprehensive earnings net of tax:				
Net unrealized gain (loss) on marketable securities	900	190	2,395	(403)
Reclassification for (gains) losses included in net earnings	123	(22)	108	114
	1,023	168	2,503	(289)

Comprehensive earnings	$ 36,793	$ 48,822	$ 81,188	$ 130,398

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.

10. Common Stock

As of September 30, 2005, and March 31, 2005, there were 600,000,000 shares of common stock authorized with 305,873,958 and 304,434,724 shares issued. Treasury shares held as of September 30, 2005 were 90,744,394, and 35,129,643 at March 31, 2005.

Table of Contents

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

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

Additionally, during the three months ended September 30, 2005, the Company purchased 4,332,700 shares for approximately $78,378, on the open market under the follow-on repurchase program.

11. Stock Option Plans

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

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

	Three Months		Six Months	
Period ended September 30,	2005	2004	2005	2004
Net income, as reported	$ 35,770	$ 48,654	$ 78,685	$ 130,687
Add: Stock-based compensation expense included in reported net income, net of related tax effects	981	972	1,960	1,951
Deduct: Total compensation expense determined under the fair value based method for all stock awards, net of related tax effects	(2,213)	(4,041)	(3,146)	(8,693)
Pro forma net income	$ 34,538	$ 45,585	$ 77,499	$ 123,945
Earnings per share:				
Basic as reported	$ 0.16	$ 0.18	$ 0.32	$ 0.49
Basic pro forma	$ 0.15	$ 0.17	$ 0.31	$ 0.46
Diluted as reported	$ 0.16	$ 0.18	$ 0.31	$ 0.48

Diluted	pro forma	$	0.15	$	0.17	$	0.31	$	0.45

Table of Contents

12. Contingencies

Legal Proceedings

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

Omeprazole

In fiscal 2001, Mylan Pharmaceuticals Inc. (MPI), a wholly-owned subsidiary of Mylan Labs, filed an ANDA seeking approval from the Food and Drug Administration (FDA) to manufacture, market and sell omeprazole delayed-release capsules, and made Paragraph IV certifications to several patents owned by AstraZeneca PLC (AstraZeneca) that were listed in the FDA s Orange Book . On September 8, 2000, AstraZeneca filed suit against MPI and Mylan Labs in the U.S. District Court for the Southern District of New York alleging infringement of several of AstraZeneca s patents. MPI filed multiple motions for summary judgment as to all claims of infringement, and the summary judgment motions remain pending. On May 29, 2003, the FDA approved MPI s ANDA for the 10 mg and 20 mg strengths of omeprazole delayed-release capsules and, on August 4, 2003, Mylan Labs announced that MPI had commenced the sale of omeprazole 10 mg and 20 mg delayed-release capsules. AstraZeneca then amended the pending lawsuit to assert claims against Mylan Labs and MPI, and filed a separate lawsuit against MPI s supplier, Esteve Quimica S.A., for unspecified money damages and a finding of willful infringement which could result in treble damages, injunctive relief, attorneys fees, costs of litigation and such further relief as the court deems just and proper. MPI has certain indemnity obligations to Esteve in connection with this litigation. MPI, Esteve and the other generic manufacturers who are co-defendants in the case have filed motions for summary judgment of non-infringement and patent invalidity. Those motions remain pending before the court.

Lorazepam and Clorazepate

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

Pricing and Medicaid Litigation

On June 26, 2003, MPI and UDL Laboratories Inc., a subsidiary of Mylan Labs (UDL), received requests from the U.S. House of Representatives Energy and Commerce Committee seeking information about certain 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, 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. As noted below, both California and Florida subsequently filed suits against Mylan, and the Company believes any further requests for information and disclosures will be made as part of that litigation.

Table of Contents

Beginning in September 2003, Mylan Labs, MPI and/or UDL, together with many other U.S. pharmaceutical companies, have been named in a series of civil lawsuits filed by State AGs and municipal bodies within the State of New York alleging generally that the defendants defrauded the State Medicaid systems by allegedly reporting Average Wholesale Prices (AWP) and/or Wholesale Acquisition Costs that exceeded the actual selling price of the defendants prescription drugs. To date, Mylan Labs, MPI and UDL have been named as defendants in substantially similar civil lawsuits filed by the AGs of Alabama, California, Florida, Illinois, Kentucky, Massachusetts, Mississippi and Wisconsin, and also by the City of New York and approximately 30 counties across New York State. Several of these cases have been transferred to the AWP multi-district litigation proceedings pending in the U.S. District Court for the District of Massachusetts for pretrial proceedings. Others of these cases will likely be litigated in the state courts in which they were filed. Each of the cases seeks an unspecified amount in money damages, civil penalties and/or treble damages, counsel fees and costs and injunctive relief. In each of these matters, Mylan Labs and its subsidiaries either have not yet been required to respond to the complaints or have motions to dismiss pending. The Company previously reported that the U.S. District Court for the District of Massachusetts had dismissed the complaint filed by the Massachusetts AG without prejudice and with leave to amend. The Massachusetts AG has since filed an amended complaint which has survived motions to dismiss, and Mylan Labs intends to answer, denying liability. Mylan Labs and its subsidiaries intend to defend each of these actions vigorously.

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

Shareholder Litigation

On November 22, 2004, an individual purporting to be a Mylan Labs shareholder filed a civil action in the Court of Common Pleas of Allegheny County, Pennsylvania, against Mylan Labs and all members of its Board of Directors alleging that the Board members had breached their fiduciary duties by approving the planned acquisition of King Pharmaceuticals, Inc. (King) and by declining to dismantle the Company s anti-takeover defenses to permit an auction of the Company to Carl Icahn or other potential buyers of the Company, and also alleging that certain transactions between the Company and its directors (or their relatives or companies with which they were formerly affiliated) may have been wasteful. On November 23, 2004, a substantially identical complaint was filed in the same court by another purported Mylan Labs shareholder. The actions were styled as shareholder derivative suits on behalf of Mylan Labs and class actions on behalf of all Mylan Labs shareholders, and were consolidated by the court under the caption In re Mylan Laboratories Inc. Shareholder Litigation. Mylan Labs and its directors filed preliminary objections seeking dismissal of the complaints. On January 19, 2005, the plaintiffs amended their complaints to add Bear Stearns & Co., Inc., Goldman Sachs & Co., Richard C. Perry, Perry Corp., American Stock Transfer & Trust Company, and John Does 1-100 as additional defendants, and to add claims regarding trading activity by the additional defendants and the implications on Mylan Labs shareholder rights agreement. On October 26, 2005, the court approved the voluntary dismissal of these cases by the plaintiffs, with prejudice.

Other Litigation

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

13. Subsequent Event

On November 4, 2005, the Company announced that it has signed an agreement with Vernalis plc for the sale of the U.S. and Canadian rights for Apokyn®, Mylan s product for the acute, intermittent treatment of hypomobility, off episodes associated with advanced Parkinson s disease. Under the terms of the agreement, the Company will receive a cash payment of $23,000 and Vernalis will assume obligations, including completion of certain phase IV studies. In addition, Mylan has agreed to provide certain transitional services, including supply chain management and customer service assistance.

Table of Contents

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

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

This Form 10-Q may contain forward-looking statements . These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements may include, without limitation, statements about the Company s market opportunities, strategies, competition and expected activities and expenditures, and at times may be identified by the use of words such as may , could , should , would , project , believe , anticipate , expect , plan , estimate , forecast , potential , intend , continue and variati 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 September 30, 2005, included net revenues of $298.0 million, net earnings of $35.8 million and earnings per diluted share of $0.16. Comparatively, the three months ended September 30, 2004, included net revenues of $307.0 million, net earnings of $48.7 million and earnings per diluted share of $0.18. This represents a decrease of 3% in revenues, 26% in net earnings and 12% in earnings per diluted share when compared to the same prior year period. The current quarter results include approximately $0.03 per share, net of tax, of restructuring costs related to the closure of Mylan Bertek Pharmaceuticals Inc. (Mylan Bertek).

For the six months ended September 30, 2005, Mylan reported net revenues of $621.4 million, net earnings of $78.7 million and earnings per diluted share of $0.31. For the first six months of fiscal 2005, net revenues were $646.0 million, net earnings were $130.7 million and earnings per diluted share were $0.48. This represents a decrease of 4% in revenues, 40% in net earnings and 34% in earnings per diluted share when compared to the prior fiscal year. Included in the current year results are $0.03 per diluted share, net of tax, with respect to a contingent legal liability related to previously-disclosed litigation in connection with the Company s lorazepam and clorazepate products, and $0.05 per diluted share, net of tax, of restructuring costs. Included in the financial results for the first six months of fiscal 2005 was $0.06 per diluted share, net of tax, of income from the favorable settlement of other litigation. A more detailed discussion of the Company s financial results of the three and six month periods ended September 30, 2005, can be found under the section titled Results of Operations .

Significant developments which have occurred during the second quarter include:

Share Buyback On July 21, 2005, Mylan closed on its modified Dutch Auction self- tender and accepted for payment, for an aggregate purchase price of approximately $1.0 billion, 51,282,051 shares of its common stock at a price of $19.50 per share.

Subsequent to the completion of the Dutch Auction self-tender, Mylan repurchased 4,332,700 shares of its common stock on the open market for an aggregate purchase price of $78.4 million under a previously announced open market follow-on repurchase. In total, the Company plans to buy back up to $250.0 million of its common stock (inclusive of the $78.4 million) from time to time on the open market or otherwise.

Table of Contents

Financing The share buyback described above was financed through Mylan s existing cash reserves as well as $500.0 million in Senior Notes and a $275.0 million borrowing under a $500.0 million senior credit facility. The Senior Notes, which were issued on July 21, 2005, consist of $150.0 million of Senior Notes due 2010, and bearing interest at 5 3/4% per annum, and $350.0 million of Senior Notes due 2015, and bearing interest at 6 3/8% per annum. The senior credit facility, which was also entered into on July 21, 2005, consists of a $225.0 million five-year revolving credit facility, which the Company expects to use for working capital and general corporate purposes, and a $275.0 million five-year term loan. The term loan bears interest at LIBOR plus 150 basis points or prime plus 50 basis points at the Company s option. The interest rate in effect on the term loan at September 30, 2005, was 5.40%. No borrowings were outstanding under the revolving credit facility at September 30, 2005.

Recent FDA Approvals Mylan received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for amlodipine besylate tablets in the 2.5 mg, 5 mg and 10 mg dosage strengths. Amlodipine besylate tablets are the generic equivalent of Pfizer s Norvasc® Tablets, which had U.S. sales of approximately 2.6 billion for the 12-month period ended September 30, 2005. The FDA has confirmed that Mylan was the first generic company to file an ANDA on all strengths of Norvasc and is therefore eligible for 180 days of market exclusivity, which will begin to run from the earlier of the commercial launch of the Mylan product or a final court decision concerning the pending litigation between Pfizer and Mylan.

Also, during the second quarter, Mylan received tentative FDA approval for its ANDA for ondansetron hydrochloride tablets, 4 mg, 8 mg, 16 mg, and 24 mg strengths. Ondansetron HCl tablets are the generic version of GlaxoSmithKline s Zofran® Tablets, which had sales of approximately $600 million for the 12-month period ended September 30, 2005.

Oxybutynin Litigation On September 28, 2005, Mylan announced that the federal district court in the Northern District of West Virginia ruled in favor of Mylan in its oxybutynin patent litigation with Alza Corporation, a subsidiary of Johnson & Johnson. Mylan is the first generic company to file ANDAs with the FDA for 5 mg and 10 mg Ditropan XL®. The Company will be eligible for 180 days of market exclusivity upon final FDA approval, which has been requested. Ditropan XL® had U.S. sales of approximately $350 million in the 5 mg and 10 mg strengths during the 12-month period ended September 30, 2005.

Closure of Mylan Bertek During the first quarter of fiscal 2006, Mylan announced that it was closing Mylan Bertek, its branded subsidiary and transferring responsibility for selling Mylan Bertek s products to its other subsidiaries, Mylan Pharmaceuticals, Inc. (MPI) and UDL Laboratories, Inc. (UDL). In connection with this restructuring, the Company incurred restructuring charges of $9.4 million and $19.6 million in the second quarter and six-month period, of which $8.6 million and $18.6 million, respectively, was included in selling, general and administrative (SG&A) expense. These costs primarily relate to employee termination and severance costs associated with the Mylan Bertek sales force, along with lease termination costs and asset write-downs. As of September 30, 2005, the restructuring was substantially completed.

Results of Operations

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

Total Revenues and Gross Profit

Net revenues for the current quarter decreased by 3% or $9.0 million to $298.0 million from $307.0 million in the same prior year period. This decrease was the result of overall unfavorable pricing partially offset by revenue from new products. The pricing pressure on the Company s product portfolio, most notably on omeprazole and carbidopa/levodopa, was the result of increased competition, and was the primary factor for the decrease in net revenues. As is the case in the generic industry, the entrance into the market of additional competition generally has a negative impact on the volume and pricing of the affected products. In the near term, it is likely that unfavorable pricing will continue to impact certain products in the Company s portfolio.

Table of Contents

Products launched subsequent to October 1, 2004, helped to offset some of the impact from the unfavorable pricing discussed above. New products contributed net revenues of $34.0 million during the second quarter, substantially all of which was due to the Company s launch of its fentanyl transdermal system in January 2005.

Doses shipped for the second quarter increased by approximately 4% to 3.3 billion.

Consolidated gross profit decreased 8% or $12.0 million to $143.2 million and gross margins decreased to 48.1% from 50.6%. The decrease in gross margins was primarily the result of the pricing pressure discussed above.

Operating Expenses

Research and development (R&D) expenses for the current quarter increased 28% or $6.1 million to $28.2 million from $22.1 million in the same prior year period. This increase was due primarily to an increase in the number of ongoing R&D studies, including those with respect to nebivolol, the Company s next-generation beta blocker.

SG&A expenses decreased by 4% or $2.6 million to $57.1 million from $59.7 million. This decrease is primarily the result of savings, mostly payroll and payroll related, as a result of the closure of Mylan Bertek. Partially offsetting these costs savings is $8.6 million in restructuring charges recorded in the current quarter. The restructuring charge consists primarily of employee termination and severance costs, mostly associated with the Mylan Bertek sales force.

Interest Expense

During the second quarter of fiscal 2006, Mylan completed the financing of $500.0 million in Senior Notes and a $500.0 million senior credit facility. Interest expense related to this financing was $8.9 million in the second quarter. Included in interest expense is a commitment fee on the unused portion of the revolving credit facility and the amortization of debt issuance costs.

Other Income, net

Other income, net of non-operating expenses, was $4.3 million in the second quarter of fiscal 2006 compared to $1.9 million in the same prior year period. The increase is primarily the result of higher interest and dividend income on our investments in marketable securities, as well as less of a loss recorded on our investment in Somerset Pharmaceuticals, Inc. (Somerset).

We own a 50% equity interest in Somerset and account for this investment using the equity method of accounting. The recorded loss in Somerset in the second quarter of fiscal 2006 was $0.7 million compared to $1.4 million in the same prior year period.

Six Months Ended September 30, 2005, Compared to Six Months Ended September 30, 2004

Total Revenues and Gross Profit

Net revenues for the six months ended September 30, 2005 decreased by 4% or $24.6 million to $621.4 million from $646.0 million in the same prior year period. This decrease was the result of overall unfavorable pricing partially offset by increased volume and revenue from new products. As a result of continued competition, omeprazole, carbidopa/levodopa and Amnesteem were principally responsible for the price erosion in the Company s product portfolio. As is the case in the generic industry, the entrance into the market of additional competition generally has a negative impact on the volume and pricing of the affected products. In the near term, it is likely that unfavorable pricing will continue to impact certain products in the Company s portfolio.

In total for the six months ended September 30, 2005, doses shipped decreased by approximately 3% to 6.2 billion. Despite the decrease in doses, the impact of volume on revenue was favorable as a result of a more favorable product mix.

Table of Contents

Also helping to partially offset the unfavorable pricing is revenue from new products. New products contributed net revenues of $88.1 million in the current fiscal year, substantially all of which is due to fentanyl.

Consolidated gross profit decreased 7% or $23.9 million to $311.1 million and gross margins decreased to 50.1% from 51.9%. The decrease in gross margins is primarily the result of the pricing pressure discussed above, partially offset by the favorable contribution from new products.

Operating Expenses

R&D expenses for the six months ended September 30, 2005 increased 22% or $9.7 million to $53.2 million from $43.5 million in the same prior year period. This increase was due primarily to an increase in the number of ongoing R&D studies, including those with respect to nebivolol. Also included in R&D in the current year was $1.0 million of restructuring costs.

SG&A expenses increased by 9% or $10.8 million to $128.3 million from $117.4 million. This increase was primarily the result of the restructuring charge of $18.6 million recorded in the current period. The restructuring charge consists primarily of employee termination and severance costs, mostly associated with the Mylan Bertek sales force, as well as asset write-downs and lease termination costs. Savings, primarily payroll and payroll related, realized as a result of the restructuring partially offset the increase in SG&A in the current year.

Litigation, net

The six months ended September 30, 2005, included a charge of $12.0 million for a contingent liability with respect to the Company s previously disclosed lorazepam and clorazepate product litigation. In the same prior year period, net gains of $26.0 million were recorded with respect to settlement of other litigation.

Interest Expense

During the second quarter of fiscal 2006, Mylan completed the financing of $500.0 million in Senior Notes and a $500.0 million senior credit facility. Interest expense related to this financing was $8.9 million for the six months ended September 30, 2005. Included in interest expense is a commitment fee on the unused portion of the revolving credit facility and the amortization of debt issuance costs.

Other Income, net

Other income, net of non-operating expenses, was $9.9 million in the first half of fiscal 2006 compared to $2.6 million in the same prior year period. The increase is primarily the result of higher interest and dividend income on our investments in marketable securities, as well as less of a loss recorded on our investment in Somerset.

We own a 50% equity interest in Somerset and account for this investment using the equity method of accounting. The recorded loss in Somerset for the first six months of fiscal 2006 was $0.9 million compared to $2.8 million in the same prior year period.

Liquidity and Capital Resources

The Company s primary source of liquidity continues to be cash flows from operating activities, which were $195.1 million for the six months ended September 30, 2005. Changes in operating assets and liabilities yielded $56.3 million in operating cash, primarily due to a decrease in accounts receivable, net, and lower inventories, partially offset by a decrease in accrued income taxes payable.

The decrease in accounts receivable is primarily due to the timing of cash collections since the end of fiscal 2005, primarily with respect to the fourth quarter sales of fentanyl. Inventory decreased as the result of normal consumption and lower overall inventory levels. The decrease in accrued income taxes payable was the result of the timing of tax payments.

Table of Contents

Cash provided by investing activities for the six months ended September 30, 2005, was $171.6 million. Of the Company s $1.9 billion of total assets at September 30, 2005, $631.5 million was held in cash, cash equivalents and marketable securities. Investments in marketable securities consist 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. During the second quarter, the Company utilized a portion of its existing cash, along with the proceeds from the issuance of debt, to finance certain transactions described below.

Capital expenditures during the six months ended September 30, 2005, were $51.3 million. These expenditures were incurred primarily with respect to the Company s previously announced planned expansions. The Company expects capital expenditures for fiscal 2006 to approximate $120.0 million.

Cash used in financing activities was $322.3 million for the six months ended September 30, 2005. A total of $1.08 billion was used during the period to repurchase Mylan common stock. Of this, $1.0 billion was used to repurchase shares as part of the Company s modified Dutch Auction self- tender, with the remainder used to pay for expenses related to the self-tender and to repurchase shares under a previously announced open market follow-on repurchase program. During the second quarter, approximately 4.3 million shares were repurchased under the repurchase program for approximately $78.4 million. The Company anticipates that it will repurchase the remaining amount of shares allowable under the follow-on repurchase program, throughout the remainder of fiscal 2006.

Cash proceeds of $775.0 million from the issuance of debt were received in the current year, and used to partially finance the stock buybacks described above. Financing fees of $13.9 million were paid during the six months ended September 30, 2005, in order to obtain this financing.

Also included in cash flows from financing activities are proceeds of $16.6 million from the exercise of stock options and cash dividends paid of $24.3 million. In the first quarter of fiscal 2006, the Board voted to double the amount of the quarterly dividend to 6.0 cents per share from 3.0 cents per share, effective with the dividend paid for the first quarter of fiscal 2006.

The Company is involved in various legal proceedings that are considered normal to its business (see Note 12 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.

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.

Table of Contents

Contractual Obligations

The following table summarizes our contractual obligations at September 30, 2005 and the effect that such obligations are expected to have on our liquidity and cash flows in future periods:

As of September 30, 2005 (in thousands)	Total	Less than One Year	One - Three Years	Three - Five Years	Thereafter
Operating leases	$ 11,085	$ 3,629	$ 6,636	$ 604	$ 216
Long-term debt	775,000	2,750	8,250	264,000	500,000
Other long-term obligations	19,325	1,821	5,463	3,642	8,399
Revolving credit facility					
Letters of credit	775	775			
	$ 806,185	$ 8,975	$ 20,349	$ 268,246	$ 508,615

We lease certain real property under various operating lease arrangements that expire generally over the next four years. These leases generally provide us with the option to renew the lease at the end of the lease term. We have also entered into agreements to lease vehicles which are typically 24 to 36 months in length.

Long-term debt consists of $500.0 million in Senior Notes and a $275.0 million borrowing under a $500.0 million senior credit facility. The Senior Notes, which were issued on July 21, 2005, consist of $150.0 million of Senior Notes due 2010, and bearing interest at 5 3/4% per annum, and $350.0 million of Senior Notes due 2015, and bearing interest at 6 3/8% per annum. The senior credit facility, which was also entered into on July 21, 2005, consists of a $225.0 million five-year revolving credit facility, which the Company expects to use for working capital and general corporate purposes, and a $275.0 million five-year term loan. The term loan bears interest at LIBOR plus 150 basis points or prime plus 50 basis points at the Company s option. The interest rate in effect on the term loan at September 30, 2005 was 5.40%. No borrowings were outstanding under the revolving credit facility at September 30, 2005.

Other long-term obligations, primarily deferred compensation, consist of the discounted future payments under individually negotiated agreements with certain key employees and directors.

In addition to the above, the Company has entered into various product licensing and development agreements. In some of these arrangements, we provide funding for the development of the product or to obtain rights to the use of the patent, through milestone payments, in exchange for marketing and distribution rights to the product. Because milestones represent the completion of specific contractual events and it is uncertain if and when these milestones will be achieved, such contingencies have not been recorded on the Company s consolidated balance sheet. In the event that all projects are successful, milestone and development payments of approximately $9.5 million would be paid.

The Company periodically enters into licensing agreements with other pharmaceutical companies for the manufacture, marketing and/or sale of pharmaceutical products. These agreements generally call for the Company to pay a percentage of amounts earned from the sale of the product as a royalty.

Other than discussed above the Company does not have material financial guarantees or other contractual commitments that are reasonably likely to adversely affect liquidity. The Company does not have any special purpose entities or off-balance sheet financing arrangements.

We have entered into employment and other agreements with certain executives that provide for compensation and certain other benefits. These agreements provide for severance payments under certain circumstances.

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards (SFAS) No. 123(R), *Share-Based Payment.* SFAS No. 123(R) establishes standards for the accounting for transactions in which an entity exchanges its equity instruments for goods and services. Under SFAS No. 123(R), companies will

no longer be able to account for share-based compensation transactions using the intrinsic

Table of Contents

method in accordance with APB No. 25, *Accounting for Stock Issued to Employees*. Instead, companies will be required to account for such transactions using a fair-value method and to recognize compensation expense over the period during which an employee is required to provide services in exchange for the award. In April 2005, the SEC delayed the effective date of SFAS No. 123(R) to fiscal years beginning after June 15, 2005. Management is currently assessing the impact that adoption of this Statement will have on the Company s Consolidated Financial Statements.

Risk Factors

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

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

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

FDA approval is required before any prescription drug product, including generic drug products, can be marketed. The process of obtaining FDA approval to manufacture and market new and generic pharmaceutical products is rigorous, time-consuming, costly and largely unpredictable. We may be unable to obtain requisite FDA approvals on a timely basis for new generic or brand products that we may develop, license or otherwise acquire. Also, for products pending approval, we may obtain raw materials or produce batches of inventory to be used in efficacy and bioequivalency testing, as well as in anticipation of the product s launch. In the event that FDA approval is denied or delayed we could be exposed to the risk of this inventory becoming obsolete. The timing and cost of obtaining FDA approvals could adversely affect our product introduction plans, financial position and results of operations and could cause the market value of our common stock to decline.

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

The Waxman-Hatch Act provides for a period of 180 days of generic marketing exclusivity for each ANDA applicant that is first to file an ANDA containing a certification of invalidity, non-infringement or unenforceability related to a patent listed with respect to a reference drug product, commonly referred to as a Paragraph IV certification. During this exclusivity period, which under certain circumstances may be required to be shared with

Table of Contents

other applicable ANDA sponsors with Paragraph IV certifications, the FDA cannot grant final approval to other ANDA sponsors holding applications for the same generic equivalent. If an ANDA containing a Paragraph IV certification is successful and the applicant is awarded exclusivity, it generally results in higher market share, net revenues and gross margin for that applicant. Even if we obtain FDA approval for our generic drug products, if we are not the first ANDA applicant to challenge a listed patent for such a product, we may lose significant advantages to a competitor that filed its ANDA containing such a challenge. The same would be true in situations where we are required to share our exclusivity period with other ANDA sponsors with Paragraph IV certifications. Such situations could have a material adverse effect on our ability to market that product profitably and on our financial position and results of operations, and the market value of our common stock could decline.

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

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

the availability of alternative products from our competitors;

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

the timing of our market entry;

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

the acceptance of our products by government and private formularies.

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

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.

Table of Contents

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 material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to

decline.

Table of Contents

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

The regulations regarding reporting and payment obligations with respect to Medicaid reimbursement and rebates and other governmental programs are complex, and as discussed elsewhere in this Form 10-Q, we and other pharmaceutical companies are defendants in a number of suits filed by state attorneys general and have been notified of an investigation by the U.S. Department of Justice with respect to Medicaid reimbursement and rebates. Our calculations and methodologies are currently being reviewed internally and likewise are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews 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 and complex methodologies, these calculations are subject to the risk of errors.

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

Any governmental agencies that have commenced, or may commence, an investigation of the Company could impose, based on a claim of violation of fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from federal health care programs (including Medicaid and Medicare). Some of the applicable laws may impose liability even in the absence of specific 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

Table of Contents

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

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

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

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

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

entering into agreements whereby other generic companies will begin to market a so-called authorized generic , a generic equivalent of a branded product, at the same time generic competition initially enters the market;

filing citizen s petitions with the FDA, including timing the filings so as to thwart generic competition by causing delays of our product approvals;

seeking to establish regulatory and legal obstacles that would make it more difficult to demonstrate bioequivalence;

initiating legislative efforts in various states to limit the substitution of generic versions of brand pharmaceuticals;

filing suits for patent infringement that automatically delay FDA approval of many generic products;

introducing next-generation products prior to the expiration of market exclusivity for the reference product, which often materially reduces the demand for the first generic product for which we seek FDA approval;

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

Table of Contents

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

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

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

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

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

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

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

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

Our ability to satisfy our obligations, including our Senior Notes and our senior credit facility, will depend on our future operating performance and financial results, which will be subject, in part, to factors beyond our control, including interest rates and general economic, financial and business conditions. If we are unable to generate sufficient cash flow, we may be required to: refinance all or a portion of our debt, including the notes and our senior credit facility; obtain additional financing in the future for acquisitions, working capital, capital expenditures and general corporate or other purposes; redirect a substantial portion of our cash flow to debt service, which as a result, might not be available for our operations or other purposes; sell some of our assets or operations; reduce or delay capital expenditures; or revise or delay our operations or strategic plans. If we are required to take any of these actions, it could have a material adverse effect on our business, financial condition or results of operations.

26

Table of Contents

In addition, we cannot assure you that we would be able to take any of these actions, that these actions would enable us to continue to satisfy our capital requirements or that these actions would be permitted under the terms of our senior credit facility and the indenture governing the notes. The increased leverage resulting from the financing of our Dutch Auction self-tender offer through our notes offering and our senior credit facility could have certain material adverse effects on us, including limiting our ability to obtain additional financing and reducing cash available for our operations and acquisitions. As a result, our ability to withstand competitive pressures may be decreased and, we may be more vulnerable to economic downturns, which in turn could reduce our flexibility in responding to changing business, regulatory and economic conditions. These factors could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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

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

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

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

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

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

We make a significant amount of our sales to a relatively small number of drug wholesalers and retail drug chains. These customers represent an essential part of the distribution chain of generic pharmaceutical products. Drug wholesalers and retail drug chains have undergone, and are continuing to undergo, significant consolidation.

Table of Contents

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

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

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

There may also be situations where the Company uses its business judgment and decides to market and sell products, notwithstanding the fact that allegations of patent infringement(s) 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 subjective, such damages may be trebled. Moreover, because of the discount pricing typically involved with bioequivalent products, patented brand products generally realize a substantially higher profit margin than bioequivalent products. An adverse decision in a case such as this or in other similar litigation could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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

Various governmental authorities and private health insurers and other organizations, such as HMOs, provide reimbursement to consumers for the cost of certain pharmaceutical products. Demand for our products depends in part on the extent to which such reimbursement is available. Third-party payers increasingly challenge the pricing of pharmaceutical products. This trend and other trends toward the growth of HMOs, managed health care and legislative health care reform create significant uncertainties regarding the future levels of reimbursement for

Table of Contents

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

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

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

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

Table of Contents

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, while we have employment agreements with certain key employees in place, their employment for the duration of the agreement is not guaranteed. If we are unsuccessful in retaining all of our key employees, it could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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

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

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

We have begun the implementation of an enterprise resource planning (ERP) system to enhance operating efficiencies and provide more effective management of our business operations. Implementations of ERP systems and related software carry risks such as cost overruns, project delays and business interruptions and delays. If we

30

Table of Contents

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.

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

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

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

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Company is subject to market risk from changes in the market values of investments in its marketable debt securities and interest rate risk from changes in interest rates associated with its long term debt.

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.

Table of Contents

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

(in thousands)	September 30, 2005	March 31, 2005
Debt securities	$ 442,761	$ 667,170
Equity securities	6,661	3,178
	$ 449,422	$ 670,348

The primary objectives for the marketable debt securities investment portfolio are liquidity and safety of principal. Investments are made to achieve the highest rate of return while retaining principal. Our investment policy limits investments to certain types of instruments issued by institutions and government agencies with investment-grade credit ratings. At September 30, 2005, the Company had invested $442.8 million in marketable debt securities, of which $116.4 million will mature within one year and $326.4 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 $326.4 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 $16.3 million change in marketable debt securities.

On July 21, 2005, the Company issued $500.0 million in Senior Notes with fixed interest rates and borrowed $275.0 million under a term loan as part of a senior credit facility with a variable interest rate based on the prime rate or LIBOR. Also on July 21, 2005, the Company entered into a $225.0 million revolving credit facility, any borrowings under which will bear interest at a variable rate based on the prime rate or LIBOR. At this time no amounts have been drawn under the revolving credit facility.

Generally, the fair market value of fixed interest rate debt will decrease as interest rates rise and increase as interest rates fall. As of September 30, 2005, the carrying value of our long term debt approximated fair value. A 10% change in interest rates on the term loan would result in a change in interest expense of approximately $1.5 million per year.

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

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

Table of Contents

Lorazepam and Clorazepate

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

Pricing and Medicaid Litigation

On 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 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. As noted below, both California and Florida subsequently filed suits against Mylan, and the Company believes any further requests for information and disclosures will be made as part of that litigation.

Beginning in September 2003, Mylan Labs, MPI and/or UDL, together with many other U.S. pharmaceutical companies, have been named in a series of civil lawsuits filed by State Attorneys General and municipal bodies within the State of New York alleging generally that the defendants defrauded the State Medicaid systems by allegedly reporting Average Wholesale Prices (AWP) and/or Wholesale Acquisition Costs that exceeded the actual selling price of the defendants prescription drugs. To date, Mylan Labs, MPI and UDL have been named as defendants in substantially similar civil lawsuits filed by the AGs of Alabama, California, Florida, Illinois, Kentucky, Massachusetts, Mississippi and Wisconsin, and also by the City of New York and approximately 30 counties across New York State. Several of these cases have been transferred to the AWP multi-district litigation proceedings pending in the U.S. District Court for the District of Massachusetts for pretrial proceedings. Others of these cases will likely be litigated in the state courts in which they were filed. Each of the cases seeks an unspecified amount in money damages, civil penalties and/or treble damages, counsel fees and costs and injunctive relief. In each of these matters, Mylan Labs and its subsidiaries either have not yet been required to respond to the complaints or have motions to dismiss pending. The Company previously reported that the U.S. District Court for the District of Massachusetts had dismissed the complaint filed by the Massachusetts AG without prejudice and with leave to amend. The Massachusetts AG has since filed an Amended Complaint which has survived motions to dismiss, and Mylan Labs intends to answer, denying liability. Mylan Labs and its subsidiaries intend to defend each of these actions vigorously.

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

Shareholder Litigation

On November 22, 2004, an individual purporting to be a Mylan Labs shareholder, filed a civil action in the Court of Common Pleas of Allegheny County, Pennsylvania, against Mylan Labs and all members of its Board of Directors alleging that the Board members had breached their fiduciary duties by approving the planned acquisition of King Pharmaceuticals, Inc. (King) and by declining to dismantle the Company s anti-takeover defenses to

Table of Contents

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 were styled as shareholder derivative suits on behalf of Mylan Labs and class actions on behalf of all Mylan Labs shareholders, and were consolidated by the court under the caption In re Mylan Laboratories Inc. Shareholder Litigation. Mylan Labs and its directors filed preliminary objections seeking dismissal of the complaints. On January 19, 2005, the plaintiffs amended their complaints to add Bear Stearns & Co., Inc., Goldman Sachs & Co., Richard C. Perry, Perry Corp., American Stock Transfer & Trust Company, and John Does 1-100 as additional defendants, and to add claims regarding trading activity by the additional defendants and the implications on Mylan Labs shareholder rights agreement. On October 26, 2005, the court approved the voluntary dismissal of these cases by the plaintiffs, with prejudice.

Other Litigation

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

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

(a) Not applicable.

(b) Not applicable.

(c) Issuer Purchases of Equity Securities:

During the quarter ending September 30, 2005, the Company repurchased 55,614,751 shares of common stock as follows:

Period	Total number of shares purchased	Average price paid per share	Total number of Shares purchased as part of publicly announced plans or programs	Approximate dollar value of shares that may be purchased under the program
July 1, 2005 - July 31, 2005	51,282,051	$19.50	51,282,051(1)	
August 1, 2005 - August 31, 2005	4,182,700	$18.05	4,182,700(2)	$ 174,488,534
September 1, 2005 - September 30, 2005	150,000	$18.53	150,000(2)	$ 171,708,914

(1) On June 14, 2005, Mylan announced a modified Dutch Auction self-tender for up to $1.0 billion, which commenced on June 16, 2005. The tender offer

expired on July 15, 2005, and closed on July 21, 2005, at which time the Company announced that it accepted for payment an aggregate of 51,282,051 shares of its common stock at a purchase price of $19.50 per share.

(2) On June 14, 2005, in connection with the announcement of the modified Dutch Auction (see (1) above), Mylan announced a $250 million follow-on share repurchase program in the open market or otherwise.

Table of Contents

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 3.1 to the Report of Form 8-K filed on February 22, 2005, 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.
4.2	Indenture, dated as of July 21, 2005, between the registrant and The Bank of New York, as trustee, as filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on July 27, 2005, and incorporated herein by reference.
4.3	Registration Rights Agreement, dated as of July 21, 2005, among the registrant, the Guarantors party thereto and Merrill Lynch, Pierce, Fenner & Smith Incorporated, BNY Capital Markets, Inc., KeyBanc Capital Markets (a Division of McDonald Investments Inc.), PNC Capital Markets, Inc. and SunTrust Capital Markets, Inc., as filed as Exhibit 4.2 to the Report on Form 8-K filed with the SEC on July 27, 2005, and incorporated herein by reference.
10.1	Credit Agreement, dated as of July 21, 2005, among the registrant and a syndicate of bank lenders, including Merrill Lynch & Co., Merrill Lynch, Pierce, Fenner and Smith Incorporated, as sole lead arranger, sole bookrunner and syndication agent, Keybank National Association, PNC Bank, National Association, Suntrust Bank and The Bank of New York, as co-documentation agents, and Merrill Lynch Capital Corporation, as administrative agent, as filed as Exhibit 99.1 to the Report on Form 8-K filed with the SEC on July 27, 2005, and incorporated herein by reference.
31.1	Certification of CEO pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of CFO pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

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

Table of Contents

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 September 30, 2005, to be signed on its behalf by the undersigned thereunto duly authorized.

Mylan Laboratories Inc.
(Registrant)

November 4, 2005

By: /s/ Robert J. Coury
Robert J. Coury
Vice Chairman and Chief Executive Officer

November 4, 2005

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

November 4, 2005

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

Table of Contents

EXHIBIT INDEX

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