MYLAN LABORATORIES INC
Form 10-Q
November 03, 2006

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, 2006

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** *(Address of principal executive offices)*	**15317** *(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 a large accelerated filer, an accelerated filer or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act.
Large Accelerated Filer þ Accelerated Filer o Non-Accelerated Filer o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES o NO 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, 2006
$0.50 par value	211,990,589

MYLAN LABORATORIES INC. AND SUBSIDIARIES

FORM 10-Q
For the Quarterly Period Ended
September 30, 2006

INDEX

Table of Contents

MYLAN LABORATORIES INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Earnings

Period Ended September 30,	Three Months		Six Months	
	2006	2005	2006	2005
	(Unaudited; in thousands, except per share amounts)			
Revenues				
Net revenues	$ 357,766	$ 296,613	$ 706,555	$ 617,622
Other revenues	8,891	1,381	16,241	3,750
Total revenues	366,657	297,994	722,796	621,372
Cost of sales	170,567	154,763	338,506	310,307
Gross profit	196,090	143,231	384,290	311,065
Operating expenses:				
Research and development	22,696	28,253	43,921	53,432
Selling, general and administrative	50,348	56,995	100,173	128,084
Litigation settlements, net	(11,500)		(11,500)	12,000
Total operating expenses	61,544	85,248	132,594	193,516
Earnings from operations	134,546	57,983	251,696	117,549
Interest expense	10,441	8,942	20,801	8,942
Other (expense) income, net	(2,222)	4,347	7,362	9,903
Earnings before income taxes	121,883	53,388	238,257	118,510
Provision for income taxes	44,342	17,618	85,129	39,825
Net earnings	$ 77,541	$ 35,770	$ 153,128	$ 78,685
Earnings per common share:				
Basic	$ 0.37	$ 0.16	$ 0.73	$ 0.32
Diluted	$ 0.36	$ 0.16	$ 0.71	$ 0.31
Weighted average common shares outstanding:				
Basic	210,999	225,042	210,477	247,244
Diluted	215,077	229,259	214,934	251,261
Cash dividend declared per common share	$ 0.06	$ 0.06	$ 0.12	$ 0.12

See Notes to Condensed Consolidated Financial Statements

Table of Contents

MYLAN LABORATORIES INC. AND SUBSIDIARIES

Condensed Consolidated Balance Sheets

	September 30, 2006	March 31, 2006
	(Unaudited; in thousands)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 159,786	$ 150,124
Marketable securities	451,882	368,003
Accounts receivable, net	252,515	242,193
Inventories	303,267	279,008
Deferred income tax benefit	145,606	137,672
Prepaid expenses and other current assets	20,030	14,900
Total current assets	1,333,086	1,191,900
Property, plant and equipment, net	439,431	406,875
Intangible assets, net	96,153	105,595
Goodwill	102,579	102,579
Other assets	64,412	63,577
Total assets	$ 2,035,661	$ 1,870,526
LIABILITIES AND SHAREHOLDERS EQUITY		
Liabilities		
Current liabilities:		
Trade accounts payable	$ 61,075	$ 76,859
Income taxes payable	18,565	12,963
Current portion of long-term obligations	1,586	4,336
Cash dividends payable	12,713	12,605
Other current liabilities	166,015	158,487
Total current liabilities	259,954	265,250
Deferred revenue	90,031	89,417
Long-term debt	687,000	685,188
Other long-term obligations	23,105	22,435
Deferred income tax liability	18,748	20,585
Total liabilities	1,078,838	1,082,875
Shareholders equity		
Preferred stock		
Common stock	155,471	154,575
Additional paid-in capital	461,321	418,954
Retained earnings	2,066,812	1,939,045

Accumulated other comprehensive earnings	2,264	2,450
	2,685,868	2,515,024
Less:		
Treasury stock at cost	1,729,045	1,727,373
Total shareholders equity	956,823	787,651
Total liabilities and shareholders equity	$ 2,035,661	$ 1,870,526

See Notes to Condensed Consolidated Financial Statements

Table of Contents

MYLAN LABORATORIES INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Cash Flows

	Six Months Ended September 30,	
	2006	2005
	(Unaudited; in thousands)	
Cash flows from operating activities:		
Net earnings	$ 153,128	$ 78,685
Adjustments to reconcile net earnings to net cash provided from operating activities:		
Depreciation and amortization	23,887	23,928
Stock-based compensation expense	12,835	
Net (income) loss from equity method investees	(5,038)	948
Change in estimated sales allowances	19,919	7,737
Restructuring provision		19,646
Deferred income tax benefit	(7,687)	(12,657)
Other non-cash items, net	7,313	6,456
Litigation settlements	(11,500)	12,000
Receipts from litigation settlements	13,508	2,000
Cash received from Somerset	5,500	
Changes in operating assets and liabilities:		
Accounts receivable	(36,609)	61,383
Inventories	(24,259)	30,035
Trade accounts payable	(8,180)	(2,604)
Income taxes	7,319	(38,790)
Deferred revenue	(8,504)	
Other operating assets and liabilities, net	14,552	6,311
Net cash provided by operating activities	156,184	195,078
Cash flows from investing activities:		
Capital expenditures	(49,798)	(51,313)
Purchase of marketable securities	(403,789)	(440,844)
Proceeds from sale of marketable securities	318,482	665,458
Other investing items, net	(896)	(1,704)
Net cash (used in) provided by investing activities	(136,001)	171,597
Cash flows from financing activities:		
Cash dividends paid	(25,253)	(24,262)
Payment of financing fees	(1,782)	(13,900)
Proceeds from long-term debt	187,000	775,000
Payments on long-term debt	(187,938)	
Purchase of common stock		(1,081,011)
	(7,605)	5,221

(Decrease) increase in outstanding checks in excess of cash in disbursement accounts		
Tax benefit of stock-based compensation	3,353	
Proceeds from exercise of stock options	21,704	16,635
Net cash used in financing activities	(10,521)	(322,317)
Net increase in cash and cash equivalents	9,662	44,358
Cash and cash equivalents beginning of period	150,124	137,733
Cash and cash equivalents end of period	$ 159,786	$ 182,091
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Income taxes	$ 78,122	$ 91,272
Interest	$ 21,788	$

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 per share amounts)

MYLAN LABORATORIES INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements (Continued)

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, 2006.

The interim results of operations for the three and six months ended September 30, 2006, and the interim cash flows for the six months ended September 30, 2006, are not necessarily indicative of the results to be expected for the full fiscal year or any other future period.

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

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, 2006. Accounts receivable are presented net of allowances relating to these provisions. Such allowances were $408,908 and $381,800 as of September 30, 2006 and March 31, 2006. Other current liabilities include $53,185 and $60,374 at September 30, 2006, and March 31, 2006, for certain rebates and other adjustments that are payable to indirect customers.

3. Recent Accounting Pronouncements

In July 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes-an Interpretation of FASB Statement 109* (FIN 48), which clarifies the accounting for uncertain tax positions. This Interpretation provides that the tax effects from an uncertain tax position be recognized in the Company s financial statements, only if the position is more likely than not of being sustained upon audit, based on the technical merits of the position. The provisions of FIN 48 will be effective for Mylan as of the beginning of fiscal 2008. The Company is currently evaluating the impact of adopting FIN 48 on its consolidated financial statements.

4. Pending Acquisition

On August 28, 2006, Mylan entered into a Share Purchase Agreement (the Share Purchase Agreement) to acquire, through MP Laboratories (Mauritius) Ltd, its wholly-owned indirect subsidiary, approximately 51.5% of the outstanding share capital of Matrix Laboratories Limited (Matrix), a publicly traded Indian company. Matrix is engaged in the manufacture of active pharmaceutical ingredients (APIs) and solid oral dosage forms and is based in Hyderabad, India. Pursuant to the Share Purchase Agreement, Mylan has agreed to pay a cash purchase price of 306 rupees per share (or approximately $6.58 per share at the August 28, 2006, exchange rate), for shares held by the selling shareholders, Mr. Prasad Nimmagadda, Prasad Nimmagadda-HUF, G2 Corporate Services Limited, India Newbridge Investments Limited (Newbridge Investments), India Newbridge Coinvestment

Table of Contents

Limited (Newbridge Coinvestment), India Newbridge Partners FDI Limited (Newbridge Partners and, together with Newbridge Investments and Newbridge Coinvestment, the Newbridge Selling Shareholders), Maxwell (Mauritius) Pte. Limited and Spandana Foundation (collectively, the Selling Shareholders).

In accordance with applicable Indian law, the Company has also made a public announcement for an open offer to acquire up to an additional 20% of the outstanding shares of Matrix (the Public Offer) from Matrix s shareholders (other than the Selling Shareholders). The price in the Public Offer will be 306 rupees per share, in accordance with applicable Indian regulations.

Mr. Prasad Nimmagadda, the Newbridge Selling Shareholders and Maxwell (Mauritius) Pte. Limited have agreed to use a portion of the proceeds from their sale of Matrix shares, approximately $164,000 in the aggregate, to acquire shares of Mylan common stock in a private sale at a price of $20.85 per share, which is conditioned upon the closing of the Share Purchase Agreement and other customary closing conditions. Assuming the open offer is fully subscribed, and taking into account the private sale of Mylan common stock, the net cash to be paid, excluding transaction costs, is expected to be approximately $572,000. The transaction will be funded using Mylan s existing revolving credit facility and cash on hand.

Mylan and certain of the Selling Shareholders have entered into a Shareholders Agreement (the Mylan Shareholders Agreement) relating to their share ownership of Mylan, which agreement will be effective upon the closing of the private sale of the Mylan shares. The Mylan Shareholders Agreement requires registration of the Mylan shares, restricts transfer of the Mylan shares by Mr. Prasad Nimmagadda for a limited period of time, provides for the Company, using its reasonable best efforts, to nominate Mr. Prasad Nimmagadda to the Company s Board of Directors for a certain period of time, and restricts Mr. Prasad Nimmagadda from competing with Matrix s pharmaceutical business for a certain period of time.

The consummation of the acquisition of Matrix shares from the Selling Shareholders is subject to regulatory approval in India and other closing conditions. The consummation of the acquisition of shares in the Public Offer is also subject to regulatory approval in India. The parties anticipate that the transaction will be completed by the end of fiscal 2007. Matrix will remain a publicly traded company in India and will continue to operate on an independent basis.

In conjunction with this planned transaction, on August 26, 2006, the Company entered into a foreign exchange forward contract to purchase Indian rupees with U.S. dollars. The contract is contingent upon the close of the potential Matrix acquisition. The purpose of the forward contract is to mitigate the risk of foreign currency exposure related to the pending transaction.

The Company accounts for this instrument under the provisions of Statement of Financial Accounting Standards No. 133, *Accounting for Derivative Instruments and Hedging Activities* (SFAS 133). This instrument does not qualify for hedge accounting treatment under SFAS 133 and therefore was required to be adjusted to fair value with the change in the fair value of the instrument recorded in current earnings. At September 30, 2006, the Company recorded a loss of $7,800 related to this deal contingent forward contract. This amount is included as other income (expense), net in the Condensed Consolidated Statement of Earnings for both periods ended September 30, 2006.

5. Stock Based Incentive Plan

Mylan s shareholders approved the *Mylan Laboratories Inc. 2003 Long-Term Incentive Plan* on July 25, 2003, and approved certain amendments on July 28, 2006 (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. Awards are granted at the market price of the shares underlying the options at the date of the grant and generally become exercisable over periods ranging from three to four years and generally expire in ten years.

Table of Contents

The Company adopted SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS 123R), effective April 1, 2006. SFAS 123R requires the recognition of the fair value of stock-based compensation in net earnings. Prior to April 1, 2006, the Company accounted for its stock options using the intrinsic value method of accounting provided under Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, (APB 25), and related Interpretations, as permitted by SFAS No. 123, *Accounting for Share Based Compensation*, (SFAS 123).

Mylan adopted the provisions of SFAS 123R, using the modified prospective transition method. Under this method, compensation expense recognized in the three and six month period ended September 30, 2006 of fiscal 2007 includes: (a) compensation cost for all share-based payments granted prior to April 1, 2006, but for which the requisite service period had not been completed as of April 1, 2006, based on the grant date fair value, estimated in accordance with the original provisions of SFAS 123, and (b) compensation cost for all share-based payments granted subsequent to April 1, 2006, based on the grant date fair value estimated in accordance with the provisions of SFAS 123R. Results for prior periods have not been restated.

The previously disclosed pro forma effects of recognizing the estimated fair value of stock-based employee compensation for the three and six months ended September 30, 2005, were as follows:

Period Ended September 30,	**Three Months 2005**	**Six Months 2005**
	(In thousands)	
Net earnings as reported	$ 35,770	$ 78,685
Add: Stock-based compensation expense included in reported net income, net of related tax effects	638	1,274
Deduct: Total compensation expense determined under the fair value based method for all stock awards, net of related tax effects	(1,438)	(2,045)
Pro forma net earnings	$ 34,970	$ 77,914
Earnings per share:		
Basic as reported	$ 0.16	$ 0.32
Basic pro forma	$ 0.15	$ 0.31
Diluted as reported	$ 0.16	$ 0.31
Diluted pro forma	$ 0.15	$ 0.31

Upon approval of the 2003 Plan, the *Mylan Laboratories Inc. 1997 Incentive Stock Option Plan* (the 1997 Plan) was frozen, and no further grants of stock options will be made under that plan. However, there are stock options outstanding from the 1997 Plan, expired plans and other plans assumed through acquisitions.

Table of Contents

The following table summarizes stock option activity:

	Number of Shares Under Option	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (In thousands)
Outstanding at March 31, 2006	21,358,670	$ 15.16		
Options granted	438,400	22.46		
Options exercised	(1,791,101)	12.12		
Options forfeited	(577,278)	17.08		
Outstanding at September 30, 2006	19,428,691	$ 15.55	6.40	$ 90,965
Vested and expected to vest at September 30, 2006	19,124,433	$ 15.51	6.35	$ 90,356
Options exercisable at September 30, 2006	12,988,863	$ 14.10	5.57	$ 79,063

A summary of the status of the Company s nonvested restricted stock and restricted stock unit awards is presented below:

Restricted Stock Awards	Number of Restricted Stock Awards	Weighted Average Grant-Date Fair Value
Nonvested at March 31, 2006	507,962	$ 24.69
Granted	199,161	23.27
Released	(472,500)	24.85
Forfeited		
Nonvested at September 30, 2006	234,623	$ 23.12

Of the 199,161 awards granted in fiscal 2007, approximately 135,000 are performance based. The remaining awards vest ratably over three years.

As of September 30, 2006, the Company had $25,300 of total unrecognized compensation expense, net of estimated forfeitures, related to all of its stock based awards, which will be recognized over the remaining weighted average period of 1.6 years. The total intrinsic value of options exercised during the three and six month periods ended

September 30, 2006 was $10,216 and $13,971. The total fair value of all options which vested during the three and six month periods ended September 30, 2006, was $26,300 and $33,500.

As a result of the adoption of SFAS 123R, the Company recognized stock-based compensation expense of $6,029 and $12,835 for the three and six months ended September 30, 2006. The impact of recognizing the compensation expense related to SFAS 123R on basic and diluted earnings per share for the three and six months ended September 30, 2006, was $0.02 and $0.04.

With respect to options granted under the Company s stock-based compensation plan, the fair value of each option grant was estimated at the date of grant using the Black-Scholes option pricing model. Black-Scholes utilizes assumptions related to volatility, the risk-free interest rate, the dividend yield and employee exercise behavior. Expected volatilities utilized in the model are based mainly on the historical volatility of the Company s stock price and other factors. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. The model incorporates exercise and post-vesting forfeiture assumptions based on an analysis of historical

Table of Contents

data. The expected lives of the grants are derived from historical and other factors. The assumptions used are as follows:

Period Ended September 30,	Six Months 2006
Volatility	36.0%
Risk-free interest rate	4.9%
Dividend yield	1.1%
Expected term of options (in years)	4.1
Forfeiture rate	3.0%
Weighted average grant date fair value per option	$ 7.17

6. Restructuring

On June 14, 2005, the Company announced that it was closing its branded subsidiary, Mylan Bertek Pharmaceuticals, Inc. (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 and $19,646, pre-tax, during the three and six months ended September 30, 2005. Of this, $1,000 is included in research and development expense, with the remainder in selling, general and administrative expense. As of March 31, 2006, the Company s restructuring was complete.

7. Balance Sheet Components

Selected balance sheet components consist of the following:

	September 30, 2006	March 31, 2006
	(In thousands)	
Inventories:		
Raw materials	$ 129,759	$ 98,259
Work in process	46,230	36,073
Finished goods	127,278	144,676
	$ 303,267	$ 279,008
Property, plant and equipment:		
Land and improvements	$ 13,331	$ 10,639
Buildings and improvements	216,608	175,343
Machinery and equipment	307,381	287,202
Construction in progress	127,455	144,429
	664,775	617,613
Less: accumulated depreciation	225,344	210,738

	$ 439,431	$ 406,875
Other current liabilities:		
Payroll and employee benefit plan accruals	$ 40,949	$ 24,323
Accrued rebates	53,185	60,374
Royalties and product license fees	5,465	9,320
Deferred revenue	8,107	17,225
Legal and professional	30,526	30,074
Accrued interest	4,312	3,989
Other	23,471	13,182
	$ 166,015	$ 158,487

Table of Contents

8. 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 4,078,000 and 4,217,000 for the three months ended September 30, 2006 and 2005, and 4,457,000 and 4,017,000 for the six months ended September 30, 2006 and 2005.

Options to purchase 2,167,000 and 5,402,000 shares of common stock were outstanding as of September 30, 2006 and 2005, 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.

9. Intangible Assets

Intangible assets consist of the following components:

	Weighted Average Life (Years)	Original Cost	Accumulated Amortization	Net Book Value
		(In thousands)		
September 30, 2006				
Amortized intangible assets:				
Patents and technologies	20	$ 118,935	$ 57,945	$ 60,990
Product rights and licenses	12	102,006	74,287	27,719
Other	20	14,267	7,606	6,661
		$ 235,208	$ 139,838	95,370
Intangible assets no longer subject to amortization:				
Trademarks				783
				$ 96,153
March 31, 2006				
Amortized intangible assets:				
Patents and technologies	20	$ 118,935	$ 54,836	$ 64,099
Product rights and licenses	12	111,135	77,444	$ 33,691
Other	20	14,267	7,245	$ 7,022
		$ 244,337	$ 139,525	104,812
Intangible assets no longer subject to amortization:				
Trademarks				783
				$ 105,595

Amortization expense for the six months ended September 30, 2006, and 2005, was $6,703 and $7,385 and is expected to be $14,407, $13,637, $13,460, $12,411 and $11,259 for fiscal years 2007 through 2011, respectively.

Table of Contents

10. Long-Term Debt

A summary of long-term debt is as follows:

	September 30 2006	March 31 2006
	(In thousands)	
Senior Notes(A)	$ 500,000	$ 500,000
Credit Facilities(B)	187,000	187,938
	687,000	687,938
Less: Current portion		2,750
Total long-term debt	$ 687,000	$ 685,188

(A) On July 21, 2005, the Company issued $500,000 in Senior Notes, which consisted of $150,000 of Senior Notes due August 15, 2010, and bearing interest at 53/4% per annum (the 2010 Restricted Notes) and $350,000 of Senior Notes due August 15, 2015, and bearing interest at 63/8% per annum (the 2015 Restricted Notes , and collectively the Restricted Notes). The Restricted Notes were exchanged on January 14, 2006, in accordance with a registration rights agreement in a transaction consummated on January 19, 2006. The form and terms of the registered notes (the Notes) are identical in all material respects to the original notes.

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 assets 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 contains covenants that, among other things, limit the ability of the Company to (a) 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.

(B) On July 21, 2005, the Company entered into a $500,000 senior secured credit facility (the Credit Facility). The Credit Facility consisted of a $225,000 five-year revolving credit facility (the Revolving Credit Facility), which the Company intended to use for working capital and general corporate purposes, and a $275,000 five-year term loan (the Term Loan).

On July 24, 2006, the Company completed the refinancing of its existing credit facility by entering into a credit agreement for a new five-year $700,000 senior unsecured revolving credit facility (the New Facility). Borrowings totaling $187,000 were made under the New Facility and, along with existing cash, were used to repay the Term Loan. At September 30, 2006 these borrowings bear interest at a rate equal to LIBOR plus 0.60% per annum, which equates to 5.98%. The spread over LIBOR for these borrowings will subsequently be adjusted based upon the Company s total leverage ratio as discussed below. The remaining unused portion of the New Facility is available for working capital and general corporate purposes, including acquisitions.

At the Company s option, additional loans under the New Facility will bear interest at either a rate equal to LIBOR plus an applicable margin of 0.60% or at a base rate, which is defined as the higher of the rate announced

Table of Contents

publicly by the administrative agent, from time to time, as its prime rate or 0.5% above the federal funds rate. In the case of the applicable margin for advances based on LIBOR, the applicable margin may increase or decrease, within a range from 0.40% to 0.70%, based on the Company s total leverage ratio. In addition, the Company is required to pay a facility fee on average daily amount of the commitments (whether used or unused) of the New Facility at a rate, which ranges from 0.10% to 0.175%, based on the Company s total leverage ratio.

The Company s obligations under the New Facility are guaranteed on a senior unsecured basis by all of the Company s direct and indirect domestic subsidiaries, except a captive insurance company.

The New 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 subsidiaries ability to incur debt, (c) place limitations on the Company s and the Company s subsidiaries ability to grant liens, carry out mergers, consolidations and sales of all or substantially all of its assets and (d) place limitations on the Company s and the Company s subsidiaries ability to pay dividends or make other restricted payments. The New Facility contains customary events of default, including nonpayment, misrepresentation, breach of covenants and bankruptcy.

All financing fees associated with the Company s borrowings are being amortized over the life of the related debt. The total unamortized amounts of $13,198 and $12,813 are included in other assets in the Condensed Consolidated Balance Sheets at September 30, 2006 and March 31, 2006.

At September 30, 2006 the fair value of the Notes was approximately $487,000. The New Facility s fair value approximated carrying value at September 30, 2006. At March 31, 2006, the carrying value of the Company s long-term debt approximated fair value.

Principal maturities of the Notes and the New Facility are as follows:

	(In thousands)
Fiscal	
2008	$
2009	
2010	
2011	150,000
2012	187,000
Thereafter	350,000
	$ 687,000

11. Comprehensive Earnings

Comprehensive earnings consist of the following:

	Three Months		Six Months	
Period Ended September 30,	**2006**	**2005**	**2006**	**2005**
	(In thousands)			

Net earnings	$ 77,541	$ 35,770	$ 153,128	$ 78,685
Other comprehensive earnings net of tax:				
Net unrealized (loss) gain on marketable securities	(18)	900	(916)	2,395
Reclassification for (gains) losses included in net earnings	(5)	123	730	108
	(23)	1,023	(186)	2,503
Comprehensive earnings	$ 77,518	$ 36,793	$ 152,942	$ 81,188

Table of Contents

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.

12. Common Stock

As of September 30, 2006, and March 31, 2006, there were 600,000,000 shares of common stock authorized with 310,941,352 and 309,150,251 shares issued. Treasury shares held as of September 30, 2006 and March 31, 2006 were 99,028,399, and 98,971,431.

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 and a $250,000 follow-on share repurchase program. The Dutch Auction self-tender 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 follow-on repurchase was completed during fiscal 2006 through the purchase of 12,595,200 shares for approximately $250,000 on the open market.

13. 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 Abbreviated New Drug Application (ANDA) seeking approval from the 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. 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. (Esteve), for unspecified money damages and a finding of willful infringement, which could result in treble damages, injunctive relief, attorneys fees, costs of litigation and such further relief as the court deems just and proper. 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 filed motions for summary judgment of non-infringement and patent invalidity. On January 12, 2006, those motions were denied, and a non-jury trial regarding liability only commenced on April 3, 2006, and was completed on June 14, 2006.

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 $12,000, which has been accrued for by the Company. The jury found Mylan willfully violated Massachusetts, Minnesota and Illinois state antitrust laws in connection with API

supply agreements entered into between the Company and its API supplier and broker for two drugs, lorazepam and clorazepate, in 1997, and subsequent price increases on these drugs in 1998. In post-trial filings, the plaintiffs have requested that the verdict be trebled. Plaintiffs are also seeking an award of attorneys fees, litigation costs and interest on the judgment in unspecified amounts. The case was brought by four health

Table of Contents

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 filed a motion for judgment as a matter of law, a motion for a new trial and a motion to reduce verdict, all of which remain pending before the court. If the Company s post-verdict motions are 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. (UDL), a subsidiary of Mylan Labs, received requests from the U.S. House of Representatives Energy and Commerce Committee (the Committee) seeking information about certain products sold by MPI and UDL in connection with the Committee s investigation into pharmaceutical reimbursement and rebates under Medicaid. MPI and UDL cooperated with this inquiry and provided information in response to the Committee s requests in 2003. Several states attorneys general (AG) 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.

Beginning in September 2003, Mylan Labs, MPI and/or UDL, together with many other 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/or UDL have been named as defendants in substantially similar civil lawsuits filed by the AGs of Alabama, California, Florida, Illinois, Kentucky, Massachusetts, Mississippi, Missouri, Hawaii, Alaska and Wisconsin and also by the city of New York and approximately 40 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, with the exception of the California, Florida, Missouri and Hawaii AG actions and the actions brought by various counties in New York, excluding the actions brought by Erie, Oswego and Schenectady counties, Mylan Labs, MPI and/or UDL have answered the respective complaints denying liability. Mylan Labs and its subsidiaries intend to defend each of these actions vigorously.

Department of Justice Medicaid Rebate Investigation

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 ongoing. MPI is collecting information requested by the government and is cooperating fully with the government s investigation.

Modafinil Antitrust Litigation and FTC Inquiry

Beginning in April 2006, Mylan Labs, along with four other drug manufacturers, has been named in a series of civil lawsuits filed in the Eastern District of Pennsylvania by a variety of plaintiffs purportedly representing direct and indirect purchasers of the drug modafinil and one action brought by Apotex, Inc., a manufacturer of generic drugs seeking approval to market a generic modafinil product. These actions allege violations of federal and state laws in connection with the defendants settlement of patent litigation relating to modafinil. These actions are in their

preliminary stages, and with the exception of the action brought by Apotex, Inc., Mylan Labs has not yet been

Table of Contents

required to respond to any complaint. Mylan Labs has filed a motion to dismiss the Apotex action, which is pending. Mylan Labs intends to defend each of these actions vigorously. In addition, by letter dated July 11, 2006, Mylan was notified by the U.S. Federal Trade Commission (FTC) of an investigation relating to the settlement of the modafinil patent litigation. In its letter, the FTC requested certain information from Mylan Labs, MPI and Mylan Technologies, Inc. pertaining to the patent litigation and the settlement thereof. Mylan is collecting information requested by the government and is cooperating with the government s investigation.

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.

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, 2006, 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 Part II, Item 1A. 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, 2006, included total revenues of $366.7 million, net earnings of $77.5 million and earnings per diluted share of $0.36. Comparatively, the three months ended September 30, 2005, included total revenues of $298.0 million, net earnings of $35.8 million and earnings per diluted share of $0.16. This represents an increase of 23% in total revenues, 117% in net earnings and 125% in earnings per diluted share when compared to the same prior year period. Included in earnings per share for the second quarter of fiscal 2007 is stock based compensation expense totaling $0.02 per share as a result of the Company s adoption of Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), *Share-Based Payment* (SFAS 123R), a mark to market loss on a foreign exchange forward contract of $0.02 per share and a gain of $0.03 per share related to the favorable settlement of certain litigation. Included in earnings per share in the second quarter of fiscal 2006 was $0.03 per share related to restructuring costs associated with the closure of Mylan s subsidiary, Mylan Bertek Pharmaceuticals Inc. (Mylan Bertek).

For the six months ended September 30, 2006, Mylan reported total revenues of $722.8 million, net earnings of $153.1 million and earnings per diluted share of $0.71. For the first six months of fiscal 2006, total revenues were $621.4 million, net earnings were $78.7 million and earnings per diluted share were $0.31. This represents an increase of 16% in total revenues, 95% in net earnings and 129% in earnings per diluted share when compared to the prior period. Stock based compensation costs of $0.04 per share are included in the results for the six months ended September 30, 2006, as a result of the adoption of SFAS 123R, as is $0.02 per share of a mark to market loss on a foreign exchange forward contract and a gain of $0.03 per share related to the favorable settlement of certain litigation. Included in the prior year results are $0.03 per diluted share, with respect to a contingent legal liability related to previously-disclosed litigation in connection with the Company s lorazepam and clorazepate products, and $0.05 per diluted share of restructuring costs. A more detailed discussion of the Company s financial results of the three and six month periods ended September 30, 2006, can be found under the section titled Results of Operations .

Significant developments which have occurred during the second quarter include:

Matrix Acquisition On August 28, 2006, Mylan announced that it will acquire up to 71.5% of the shares outstanding of Matrix Laboratories Limited (Matrix), a publicly traded Indian company, for 306 rupees per Matrix share. Under the terms of the transaction, Mylan will purchase 51.5% of Matrix s shares outstanding pursuant to an agreement with certain selling shareholders and will make an open offer to

Table of Contents

acquire up to an additional 20% of the outstanding shares of Matrix. Assuming the open offer is fully subscribed, the total purchase price, excluding transaction costs, is expected to be approximately $736.0 million.

Mylan and Matrix together will have approximately 5,100 employees in 10 countries. Matrix will provide Mylan with a significant presence in important emerging pharmaceutical markets, including India, China and Africa, as well as a European footprint and distribution network through Matrix s Docpharma subsidiary. This transaction will combine Matrix s active pharmaceutical ingredient and drug development business with Mylan s expertise in finished dosage forms. The transaction will also expand Mylan s high-barrier-to-entry product capabilities, particularly in the area of anti-virals.

The consummation of the acquisition of Matrix shares is subject to regulatory approval in India and other closing conditions. The parties anticipate that the transaction will be completed by the end of fiscal 2007.

This transaction will be funded using Mylan s existing revolving credit facility and cash on hand. Approximately $164.0 million of the funds received by three of the selling shareholders will be used to purchase shares of Mylan common stock resulting in net cash to be paid of approximately $572.0M.

Refinancing of Credit Facility On July 24, 2006, the Company completed the refinancing of its Credit Facility by entering into a credit agreement for a new five-year $700.0 million senior unsecured revolving credit facility (the New Facility). Borrowings totaling $187.0 million were made under the New Facility and were used to repay an existing term loan. The remaining unused portion of the New Facility is available for working capital and general corporate purposes, including acquisitions.

Other Recent Developments Mylan notes the following developments related to the products listed below:

Oxybutynin On September 6, 2006, the U.S. Court of Appeals for the Federal Circuit upheld a district court decision that Mylan s oxybutynin products do not infringe a patent for Ditropan XL® and that the patent was invalid. Mylan has received tentative approval and is currently awaiting final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Applications (ANDAs) for the 5mg and 10mg strengths of oxybutynin. Oxybutynin is the generic version of Alza s Ditropan XL. Mylan is the first generic company to file an ANDA for these two strengths, and will therefore be eligible for 180-days of market exclusivity upon commercial launch. The 5mg and 10mg strengths represent more than 80% of the approximately $380 million in U.S. sales during the 12-month period ended June 30, 2006, according to IMS Health. The Company also entered into exclusive supply agreements with Ortho-McNeil Pharmaceuticals, Inc. and Alza Corporation, which would allow for Mylan to launch the 15mg strength of Ditropan XL under certain circumstances.

Topiramate On September 11, 2006, Mylan received final approval from the FDA on its ANDA for topiramate tablets, 25mg, 100mg and 200mg. Topiramate tablets are the generic version of Ortho-McNeil s Topamax® Tablets, which had U.S. sales of approximately $1.37 billion for the three strengths listed above for the 12-month period ended June 30, 2006 according to IMS Health. Mylan also received tentative approval for the 50mg strength of Topiramate. The FDA has confirmed that Mylan was the first generic company to file on the 25mg, 100mg, and 200mg strengths of topiramate and is therefore eligible for 180 days of market exclusivity. The FDA has indicated that the exclusivity will begin to run from the earlier of the commercial launch of the Mylan product or a court decision from which no appeal can be taken. However Ortho-McNeil has been granted a preliminary injunction which effectively prohibits Mylan from launching its product until the earlier of a court decision with respect to all issues of validity and infringement, or patent expiration.

Amlodipine Besylate On October 19, 2006, Mylan reported that the U.S. District Court for the Western District of Pennsylvania granted a motion to dismiss the 909 patent from the patent infringement litigation between Pfizer and Mylan concerning amlodipine besylate tablets thereby removing the 909 as a patent that Pfizer can assert against Mylan. The 909 patent was one of two patents covered in the litigation scheduled to begin on November 28, 2006. Amlodipine besylate tablets are the generic version of Pfizer s Norvasc® Tablets, which had U.S. sales of approximately $2.7 billion for the 12-month period

Table of Contents

ended June 30, 2006, according to IMS Health. As previously announced, the FDA has granted Mylan final approval for its ANDA for amlodipine besylate tablets, 2.5mg (base), 5mg (base) and 10mg (base). The FDA also confirmed that Mylan was the first generic company to file on all strengths of Norvasc Tablets and is therefore eligible for 180 days of market exclusivity. The FDA has indicated that the exclusivity 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.

Results of Operations

Quarter Ended September 30, 2006, Compared to Quarter Ended September 30, 2005

Total Revenues and Gross Profit

Total revenues for the current quarter increased by 23% or $68.7 million to $366.7 million from $298.0 million in the same prior year period. This increase was driven by both increased volume and stable pricing. During the quarter fentanyl continued to be the only AB-rated generic alternative to Duragesic® on the market and accounted for approximately 20% of net sales. As a result of a continued shift from brand to generic, fentanyl contributed favorably to both pricing and volume.

Excluding fentanyl, Mylan s product portfolio realized overall stable pricing and volume. In total, doses shipped increased by 6% to approximately 3.5 billion.

Other revenue for the quarter ended September 30, 2006, consisted primarily of amounts recognized with respect to Apokyn®, which was sold in the prior year, with the remainder related to other business development activities.

Consolidated gross profit increased 37% or $52.9 million to $196.1 million and gross margins increased to 53.5% from 48.1%. A significant portion of gross profit was generated by fentanyl sales which contribute margins well in excess of most other products in our portfolio. Absent any changes to market dynamics or significant new competition for fentanyl, the Company expects the product to continue to be a significant contributor to sales and gross profit. As is the case in the generic industry, the entrance into the market of other generic competition generally has a negative impact on the volume and pricing of the affected products.

Operating Expenses

Research and development (R&D) expenses for the current quarter decreased 20% or $5.6 million to $22.7 million from $28.3 million in the same prior year period. This decrease was due primarily to a decline in the number of ongoing R&D studies, including those with respect to nebivolol, which was outlicensed in the fourth quarter of fiscal 2006.

Selling, General and Administrative (SG&A) expenses decreased by 12% or $6.6 million to $50.3 million from $56.9 million. This decrease is primarily the result of savings, mostly payroll and payroll related, as a result of the closure of Mylan Bertek in the prior year. Included in SG&A in the prior year was $8.6 million of restructuring costs, related to the Mylan Bertek closure. Partially offsetting these favorable items is $3.3 million in stock based compensation cost recognized as a result of the Company s adoption of SFAS 123R in the first quarter of fiscal 2007.

Litigation, net

The second quarter of fiscal 2007 included a gain of $11.5 million related to the favorable settlement of certain litigation.

Interest Expense

Interest expense related to the Company s outstanding borrowings was $10.4 million in the second quarter of fiscal 2007, which is an increase of $1.5 million from second quarter of fiscal 2006. The Company s borrowings were outstanding for the entire second quarter of fiscal 2007, compared to only a portion of the second quarter of

Table of Contents

fiscal 2006. 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 (Expense) Income, net

Other expense, net, was $2.2 million in the second quarter of fiscal 2007 compared to $4.3 million of income in the same prior year period. The change is primarily the result of an unfavorable, non-cash $7.8 million mark to market adjustment on a foreign currency forward contract related to the pending acquisition of Matrix. The purpose of the forward contract was to fix the exchange rate on the rupee denominated acquisition price that Mylan will be required to pay at the time of closing. In accordance with SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, this derivative instrument is marked to market each period with any change in the fair value reported in current earnings. As of October 31, 2006, exchange rates had fluctuated such that the mark to market fair value adjustment of this forward contract on such date would have been favorable.

Income Tax Expense

The Company s effective tax rate has increased in the current quarter to 36.4% from 33.0% in the same period of the prior year. This increase is due to higher pre-tax income, which results in higher state taxes, and fewer deductions for research and development when compared to fiscal 2006.

Six Months Ended September 30, 2006, Compared to Six Months Ended September 30, 2005

Total Revenues and Gross Profit

Total revenues for the six months ended September 30, 2006 increased by 16% or $101.4 million to $722.8 million from $621.4 million in the same prior year period.

Net revenues increased by $88.9 million to $706.6 million, which was the result of overall stable pricing as well as increased volume. Fentanyl continues to be the main driver behind these increases and has accounted for over 20% of net revenues through the first half of fiscal 2007.

Exclusive of fentanyl, the remaining product portfolio experienced both overall stable pricing and increased volume. In total, doses shipped for the six month period ended September 30, 2006 were approximately 6.9 billion, an increase of 11% over the same period of the prior year.

Other revenue for the six month period ended September 30, 2006, consisted primarily of amounts recognized with respect to Apokyn®, which was sold in the prior year, with the remainder related to other business development activities.

Consolidated gross profit increased 24% or $73.2 million to $384.3 million from $311.1 million, and gross margins increased to 53.2% from 50.1%. A significant portion of gross profit was comprised of fentanyl which contributes margins well in excess of most other products in our portfolio. Absent any changes to market dynamics or significant new competition for fentanyl, the Company expects the product to continue to be a significant contributor to sales and gross profit. As is the case in the generic industry, the entrance into the market of other generic competition generally has a negative impact on the volume and pricing of the affected products.

Operating Expenses

R&D expenses for the six months ended September 30, 2006 decreased 18% or $9.5 million to $43.9 million from $53.4 million in the same prior year period. This decrease was due primarily to a decline in the number of ongoing R&D studies, including those with respect to nebivolol, which was outlicensed in the prior year. Also included in R&D in the prior year was $1.0 million of restructuring costs.

SG&A expenses decreased by 22% or $27.8 million to $100.2 million from $128.0 million. This decrease was primarily the result of the restructuring charge of $18.6 million recorded in the prior period. This restructuring charge consisted 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. Cost savings derived as a result of the restructuring accounted for the remaining decrease.

Table of Contents

Litigation, net

The six months ended September 30, 2006, included a favorable settlement of litigation for $11.5 million. In the same period of the prior year, there was a charge recorded in the amount of $12.0 million for a contingent liability with respect to the Company s previously disclosed lorazepam and clorazepate product litigation.

Interest Expense

Interest expense for the six months ended September 30, 2006 totaled $20.8 million compared to $8.9 million for the same period of the prior year. The Company has had their financing outstanding for the entire first half of fiscal 2007, while it was only completed during the second quarter of fiscal 2006. 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 (Expense) Income, net

Other income, net, was $7.4 million in the first half of fiscal 2007 compared to $9.9 million in the same prior year period. The change is primarily the result of an unfavorable, non-cash $7.8 million, mark to market adjustment on a foreign currency forward contract related to the pending acquisition of Matrix. The purpose of the forward contract was to fix the exchange rate on the rupee denominated acquisition price that Mylan will be required to pay at the time of closing. In accordance with SFAS 133, this derivative instrument is marked to market each period with any change in the fair value reported in current earnings. As of October 31, 2006, exchange rates had fluctuated such that the mark to market fair value adjustment of this forward contract would have been favorable. Partially, offsetting this adjustment was income related to our investment in Somerset Pharmaceuticals, Inc. (Somerset). We own a 50% equity interest in and account for this investment using the equity method of accounting. During the first quarter of fiscal 2007, Mylan received a cash payment from Somerset of approximately $5.5 million. The amount in excess of the carrying value of our investment in Somerset, approximately $5.0 million, was recorded as equity income.

Income Tax Expense

The Company s effective tax rate increased for the first half of fiscal 2007 to 35.7% from 33.6% in the same period of the prior year. This increase is due to higher pre-tax income, which results in higher state taxes, and fewer deductions for research and development when compared to fiscal 2006.

Liquidity and Capital Resources

The Company s primary source of liquidity continues to be cash flows from operating activities, which were $156.2 million for the six months ended September 30, 2006. Working capital as of September 30, 2006, was $1.1 billion compared to $926.7 million at March 31, 2006. This increase is primarily the result of increased receivables, due to the timing of cash collections and shipments, an increase in inventory due to aligning production to forecasted volumes, and an increase in marketable securities.

Cash used in investing activities for the six months ended September 30, 2006, was $136.0 million. Of the Company s $2.0 billion of total assets at September 30, 2006, $611.7 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.

Capital expenditures during the six months ended September 30, 2006, were $49.8 million. These expenditures were incurred primarily with respect to the Company s previously announced planned expansions and the implementation of an integrated ERP system. The Company expects capital expenditures for fiscal 2007 to approximate $135.0 million.

Cash used in financing activities was $10.5 million for the six months ended September 30, 2006. As part of the refinancing of the Company s debt completed in July 2006, $187.0 million dollars was borrowed under the new credit facility and used along with existing cash to repay an existing term loan.

Table of Contents

Also included in cash flows from financing activities are proceeds of $21.7 million from the exercise of stock options and cash dividends paid of $25.3 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 13 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. On August 28, 2006, the Company announced that it will acquire up to 71.5% of the shares outstanding of Matrix, for 306 rupees per Matrix share, or approximately $736.0 million. Approximately $164.0 million of funds received by three of the selling shareholders will be used to purchase shares of Mylan common stock resulting in net cash to be paid of approximately $572.0 million. This transaction is expected to be funded through the credit facility and cash on hand.

Recent Accounting Pronouncements

In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement 109* (FIN 48), which clarifies the accounting for uncertain tax positions. This Interpretation provides that the tax effects from an uncertain tax position be recognized in the Company s financial statements, only if the position is more likely than not of being sustained upon audit, based on the technical merits of the position. The provisions of FIN 48 will be effective for Mylan as of the beginning of fiscal 2008. The Company is currently evaluating the impact of adopting FIN 48 on our consolidated financial statements.

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, interest rate risk from changes in interest rates associated with its long term debt and foreign currency exchange rate risk as a result of its pending acquisition of up to 71.5% of the shares outstanding of Matrix. In addition to marketable debt and equity securities, investments are made in overnight deposits, money market funds and marketable securities with maturities of less than three months. These instruments are classified as cash equivalents for financial reporting purposes and have minimal or no interest rate risk due to their short-term nature.

The following table summarizes the investments in marketable debt and equity securities which subject the Company to market risk at September 30, 2006 and March 31, 2006:

	September 30, 2006	**March 31, 2006**
	(In thousands)	

Debt securities	$ 448,069	$ 362,458
Equity securities	3,813	5,545
	$ 451,882	$ 368,003

Marketable Debt Securities

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

Table of Contents

policy limits investments to certain types of instruments issued by institutions and government agencies with investment-grade credit ratings. At September 30, 2006, the Company had invested $448.1 million in marketable debt securities, of which $79.1 million will mature within one year and $369.0 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 $369.0 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 $18.5 million change in marketable debt securities.

Long-Term Debt

On July 21, 2005, the Company issued $500.0 million in Senior Notes with fixed interest rates (which were exchanged for registered notes, as described previously) and, on July 24, 2006, entered into a five-year $700.0 million senior unsecured revolving credit facility (the 2006 Credit Facility). Loans under the 2006 Credit Facility bear interest at a rate equal to either LIBOR plus an applicable margin of 0.60% or at a base rate, which is defined as the higher of the rate announced publicly by the administrative agent, from time to time, as its prime rate or 0.5% above the federal funds rate. In the case of the applicable margin for advances based on LIBOR, the applicable margin may increase or decrease, within a range from 0.40% to 0.70%, based on the Company s total leverage ratio. In addition, the Company is required to pay a facility fee on average daily amount of the commitments (whether used or unused) of the Credit Facility at a rate, which ranges from 0.10% to 0.175%, based on the Company s total leverage ratio. On July 24, 2006, the Company borrowed $187.0 million under the 2006 Credit Facility and used the proceeds to repay the aggregate principal amount outstanding under the Company s previous credit agreement, dated as of July 21, 2005 (the Previous Credit Agreement), among the Company, the lenders and other financial institutions party thereto and Merrill Lynch Capital Corporation, as administrative agent. The interest rate on the 2006 Credit Facility at September 30, 2006 was 5.98%.

Generally, the fair market value of fixed interest rate debt will decrease as interest rates rise and increase as interest rates fall. At September 30, 2006 the fair value of the Notes were approximately $487.0 million. The 2006 Credit Facility s fair value approximated carrying value at September 30, 2006. At March 31, 2006, the carrying value of our total long-term debt approximated fair value. A 10% change in interest rates on the 2006 Credit Facility would result in a change in interest expense of approximately $1.1 million per year.

Foreign Exchange Forward Contract

In conjunction with the planned acquisition of Matrix, on August 26, 2006, the Company entered into a foreign exchange forward contract to purchase Indian rupees with U.S. dollars. The contract is contingent upon the close of the potential acquisition. The purpose of the contract is to mitigate the risk of foreign currency exposure related to the pending transaction. The value of the foreign exchange contract fluctuates depending on the value of the U.S. dollar compared to the Indian rupee. At September 30, 2006, for every one percent change in the value of the U.S. dollar compared to the Indian rupee, the value of the foreign exchange contract will fluctuate by approximately $6.0 million. On September 30, 2006, the mark to market value of our foreign exchange contract resulted in a loss of $7.8 million. We expect the foreign exchange contract to be settled concurrent with our payment of the purchase price for Matrix upon closing of the transaction.

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, 2006. Based upon that evaluation, the Chief

Executive Officer and the Chief Financial Officer concluded that the Company s disclosure controls and procedures were effective. 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.

Table of Contents

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, 2006. During the quarter ended September 30, 2006, 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 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 Abbreviated New Drug Application (ANDA) seeking approval from the 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. 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. (Esteve), for unspecified money damages and a finding of willful infringement, which could result in treble damages, injunctive relief, attorneys fees, costs of litigation and such further relief as the court deems just and proper. 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 filed motions for summary judgment of non-infringement and patent invalidity. On January 12, 2006, those motions were denied, and a non-jury trial regarding liability only commenced on April 3, 2006, and was completed on June 14, 2006.

Pricing and Medicaid Litigation

On June 26, 2003, MPI and UDL Laboratories Inc. (UDL), a subsidiary of Mylan Labs, received requests from the U.S. House of Representatives Energy and Commerce Committee (the Committee) seeking information about certain products sold by MPI and UDL in connection with the Committee s investigation into pharmaceutical reimbursement and rebates under Medicaid. MPI and UDL cooperated with this inquiry and provided information in response to the Committee s requests in 2003. Several states attorneys general (AG) 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.

Beginning in September 2003, Mylan Labs, MPI and/or UDL, together with many other 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/or UDL have been named as defendants in substantially similar civil lawsuits filed by the AGs of Alabama, California, Florida, Illinois, Kentucky, Massachusetts, Mississippi, Missouri, Hawaii, Alaska and Wisconsin and also by the city of New York and approximately 40 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

Table of Contents

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, with the exception of the California, Florida, Missouri and Hawaii AG actions and the actions brought by various counties in New York, excluding the actions brought by Erie, Oswego and Schenectady counties, Mylan Labs, MPI and/or UDL have answered the respective complaints denying liability. Mylan Labs and its subsidiaries intend to defend each of these actions vigorously.

Department of Justice Medicaid Rebate Investigation

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 ongoing. MPI is collecting information requested by the government and is cooperating fully with the government s investigation.

Modafinil Antitrust Litigation and FTC Inquiry

Beginning in April 2006, Mylan Labs, along with four other drug manufacturers, has been named in a series of civil lawsuits filed in the Eastern District of Pennsylvania by a variety of plaintiffs purportedly representing direct and indirect purchasers of the drug modafinil and one action brought by Apotex, Inc., a manufacturer of generic drugs seeking approval to market a generic modafinil product. These actions allege violations of federal and state laws in connection with the defendants settlement of patent litigation relating to modafinil. These actions are in their preliminary stages, and with the exception of the action brought by Apotex, Inc., Mylan Labs has not yet been required to respond to any complaint. Mylan Labs has filed a motion to dismiss the Apotex action, which is pending. Mylan Labs intends to defend each of these actions vigorously. In addition, by letter dated July 11, 2006, Mylan was notified by the U.S. Federal Trade Commission (FTC) of an investigation relating to the settlement of the modafinil patent litigation. In its letter, the FTC requested certain information from Mylan Labs, MPI and Mylan Technologies, Inc. pertaining to the patent litigation and the settlement thereof. Mylan is collecting information requested by the government and is cooperating with the government s investigation.

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.

ITEM 1A. ***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

Table of Contents

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, or a partner, 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, or a partner, 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 bioequivalence testing, as well as in anticipation of the product s launch. In the event that FDA approval is denied or delayed we could be exposed to the risk of this inventory becoming obsolete. The timing and cost of obtaining FDA approvals could adversely affect our product introduction plans, financial position and results of operations and could cause the market value of our common stock to decline.

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

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

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

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

- the availability of alternative products from our competitors;

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

the timing of our market entry;

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

the acceptance of our products by government and private formularies.

Table of Contents

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 or other risk management programs such as the need for a patient registry. 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, GROSS PROFIT 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, gross profit and net earnings. If the volume or pricing of our largest selling products declines in the future, our business, financial position and results of operations could be materially adversely affected, and the market value of our common stock could decline.

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

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

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

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

BECAUSE THE PHARMACEUTICAL INDUSTRY IS HEAVILY REGULATED, WE FACE SIGNIFICANT COSTS AND UNCERTAINTIES ASSOCIATED WITH OUR EFFORTS TO COMPLY WITH APPLICABLE

REGULATIONS. SHOULD WE FAIL TO COMPLY WE COULD EXPERIENCE MATERIAL ADVERSE EFFECTS ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS, AND THE MARKET VALUE OF OUR COMMON STOCK COULD DECLINE.

The pharmaceutical industry is subject to regulation by various federal and state governmental authorities. For instance, we must comply with FDA requirements with respect to the manufacture, labeling, sale, distribution, marketing, advertising, promotion and development of pharmaceutical products. Failure to comply with FDA and other governmental regulations can result in fines, disgorgement, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the FDA s review of

Table of Contents

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.

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 Average Wholesale Prices (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.

Table of Contents

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

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

Much of our development effort is focused on technically difficult-to-formulate products and/or products that require advanced manufacturing technology. We conduct research and development primarily to enable us to manufacture and market FDA-approved pharmaceuticals in accordance with FDA regulations. Typically, research expenses related to the development of innovative compounds and the filing of NDAs are significantly greater than those expenses associated with ANDAs. As we continue to develop new products, our research expenses will likely increase. Because of the inherent risk associated with research and development efforts in our industry, particularly with respect to new drugs (including, without limitation, nebivolol), our, or a partner s, 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