

MYLAN INC.
Form 10-Q
November 04, 2008

Table of Contents

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

Form 10-Q

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2008**
- OR**
- 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 INC.

(Exact name of registrant as specified in its charter)

Pennsylvania

(State of incorporation)

25-1211621

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

**1500 Corporate Drive
Canonsburg, Pennsylvania**

(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 No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

Accelerated filer

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

Edgar Filing: MYLAN INC. - Form 10-Q

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, 2008
\$0.50 par value	304,701,486

MYLAN INC. AND SUBSIDIARIES

FORM 10-Q
For the Quarterly Period Ended
September 30, 2008

INDEX

	Page Number
PART I. CONDENSED FINANCIAL INFORMATION	
Item 1:	
Condensed Consolidated Financial Statements	
<u>Condensed Consolidated Statements of Operations Three and Nine Months Ended September 30, 2008 and 2007 (unaudited)</u>	3
<u>Condensed Consolidated Balance Sheets September 30, 2008 and December 31, 2007 (unaudited)</u>	4
<u>Condensed Consolidated Statements of Cash Flows Nine Months Ended September 30, 2008 and 2007 (unaudited)</u>	5
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	6
Item 2:	
<u>Management's Discussion and Analysis of Results of Operations and Financial Condition</u>	29
Item 3:	
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	42
Item 4:	
<u>Controls and Procedures</u>	43
PART II. OTHER INFORMATION	
Item 1:	
<u>Legal Proceedings</u>	43
Item 1A:	
<u>Risk Factors</u>	47
Item 6:	
<u>Exhibits</u>	65
SIGNATURES	67
<u>EX-31.1</u>	
<u>EX-31.2</u>	
<u>EX-32</u>	

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

	Period Ended September 30,			
	Three Months		Nine Months	
	2008	2007	2008	2007
	(Unaudited; in thousands, except per share amounts)			
Revenues:				
Net revenues	\$ 1,191,010	\$ 472,400	\$ 3,440,680	\$ 1,498,809
Other revenues	465,838	4,691	493,750	11,865
Total revenues	1,656,848	477,091	3,934,430	1,510,674
Cost of sales	745,711	255,450	2,258,863	757,478
Gross profit	911,137	221,641	1,675,567	753,196
Operating expenses:				
Research and development	74,721	33,577	239,320	102,145
Acquired in-process research and development				147,000
Goodwill impairment			385,000	
Selling, general and administrative	275,584	97,016	787,953	236,684
Litigation settlements, net		(848)		(4,810)
Total operating expenses	350,305	129,745	1,412,273	481,019
Earnings from operations	560,832	91,896	263,294	272,177
Interest expense	87,553	23,107	264,789	67,010
Other income, net	5,766	166,832	20,583	140,923
Earnings before income taxes and minority interest	479,045	235,621	19,088	346,090
Income tax provision	272,438	88,498	197,378	190,455
Earnings (loss) before minority interest	206,607	147,123	(178,290)	155,635
Minority interest income	(151)	(2,704)	(2,266)	(2,630)
Net earnings (loss) before preferred dividends	206,758	149,827	(176,024)	158,265
Preferred dividends	34,759		104,236	
Net earnings (loss) available to common shareholders	\$ 171,999	\$ 149,827	\$ (280,260)	\$ 158,265
Earnings (loss) per common share:				
Basic	\$ 0.56	\$ 0.60	\$ (0.92)	\$ 0.66
Diluted	\$ 0.45	\$ 0.60	\$ (0.92)	\$ 0.65

Edgar Filing: MYLAN INC. - Form 10-Q

Weighted average common shares outstanding:				
Basic	304,449	248,660	304,305	241,432
Diluted	458,350	250,500	304,305	244,252
Cash dividend declared per common share:	\$	\$	\$	\$ 0.12

See Notes to Condensed Consolidated Financial Statements

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

	September 30, 2008	December 31,2007
	(Unaudited; in thousands, except share and per share amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 655,666	\$ 484,202
Restricted cash	44,828	
Available for sale securities	48,010	91,361
Accounts receivable, net	1,250,894	1,132,121
Inventories	1,119,946	1,063,840
Deferred income tax benefit	176,837	192,113
Prepaid expenses and other current assets	121,778	95,664
Total current assets	3,417,959	3,059,301
Property, plant and equipment, net	1,051,095	1,102,932
Intangible assets, net	2,677,615	2,978,706
Goodwill	3,282,990	3,855,971
Deferred income tax benefit	56,912	18,703
Other assets	537,748	337,563
Total assets	\$ 11,024,319	\$ 11,353,176
LIABILITIES AND SHAREHOLDERS EQUITY		
Liabilities		
Current liabilities:		
Trade accounts payable	\$ 582,052	\$ 608,070
Short-term borrowings	176,108	144,355
Income taxes payable	264,838	169,518
Current portion of long-term debt and other long-term obligations	111,261	410,934
Other current liabilities	687,837	669,474
Total current liabilities	1,822,096	2,002,351
Deferred revenue	21,181	122,870
Long-term debt	5,210,807	4,706,716
Other long-term obligations	246,068	206,672
Deferred income tax liability	715,568	876,816
Total liabilities	8,015,720	7,915,425
Minority interest	29,644	34,325

Edgar Filing: MYLAN INC. - Form 10-Q

Shareholders' equity			
Preferred stock - par value \$0.50 per share			
Shares authorized: 5,000,000			
Shares issued: 2,139,000 as of September 30, 2008 and December 31, 2007		1,070	1,070
Common stock - par value \$0.50 per share			
Shares authorized: 600,000,000			
Shares issued: 395,368,062 and 395,260,355 as of September 30, 2008 and December 31, 2007		197,684	197,630
Additional paid-in capital		3,866,860	3,785,729
Retained earnings		634,344	922,857
Accumulated other comprehensive (loss) earnings		(138,349)	83,044
		4,561,609	4,990,330
Less treasury stock - at cost			
Shares: 90,642,110 and 90,885,188 as of September 30, 2008 and December 31, 2007		1,582,654	1,586,904
Total shareholders' equity		2,978,955	3,403,426
Total liabilities and shareholders' equity	\$	11,024,319	\$ 11,353,176

See Notes to Condensed Consolidated Financial Statements

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

	Nine Months Ended September 30,	
	2008	2007
	(Unaudited; in thousands)	
Cash flows from operating activities:		
Net (loss) earnings before preferred dividends	\$ (176,024)	\$ 158,265
Adjustments to reconcile net (loss) earnings before preferred dividend to net cash provided by operating activities:		
Depreciation and amortization	327,791	78,713
Stock-based compensation expense	23,188	15,380
In-process research and development		147,000
Minority interest	(2,266)	(2,630)
Net income from equity method investees	(3,165)	(4,579)
Change in estimated sales allowances	22,115	79,720
Deferred income tax benefit	(76,154)	(38,504)
Impairment loss on goodwill	385,000	
Other non-cash items	24,812	14,204
Litigation settlements, net		39,342
Gain on foreign exchange contract		(85,046)
Changes in operating assets and liabilities:		
Accounts receivable	(135,293)	(213,992)
Inventories	(98,812)	14,030
Trade accounts payable	(35)	(12,167)
Income taxes	92,346	33,163
Deferred revenue	(110,021)	8,357
Other operating assets and liabilities, net	(24,309)	(3,294)
Net cash provided by operating activities	249,173	227,962
Cash flows from investing activities:		
Capital expenditures	(101,699)	(137,371)
Acquisition of Matrix, net of cash acquired of \$10,943		(550,448)
Increase in restricted cash	(44,828)	
Purchase of available for sale securities	(17,509)	(292,213)
Proceeds from sale of available for sale securities	60,109	405,178
Other items, net	4,716	(2,165)
Net cash used in investing activities	(99,211)	(577,019)
Cash flows from financing activities:		
Cash dividends paid	(102,736)	(42,610)
Payment of financing fees	(13,954)	(13,547)
Proceeds from issuance of common stock, net		657,678

Edgar Filing: MYLAN INC. - Form 10-Q

Purchase of bond hedge	(161,173)	(126,000)
Proceeds from issuance of warrants	62,560	45,360
Change in short-term borrowings, net	46,054	4,210
Proceeds from long-term debt	581,547	1,369,251
Payment of long-term debt	(392,213)	(691,349)
Proceeds from exercise of stock options	1,098	20,602
Change in outstanding checks in excess of cash disbursements accounts		36,016
Other items, net	(260)	3,324
Net cash provided by financing activities	20,923	1,262,935
Effect on cash and cash equivalents of changes in exchange rates	579	2,883
Net increase in cash and cash equivalents	171,464	916,761
Cash and cash equivalents beginning of period	484,202	286,880
Cash and cash equivalents end of period	\$ 655,666	\$ 1,203,641

See Notes to Condensed Consolidated Financial Statements

Table of Contents

MYLAN INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements (Unaudited)

1. General

In the opinion of management, the accompanying unaudited condensed consolidated financial statements (interim financial statements) of Mylan 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 the 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 Transition Report on Form 10-KT/A for the nine months ended December 31, 2007. Effective October 2, 2007, the Company amended its bylaws to change its fiscal year from beginning on April 1st and ending on March 31st, to beginning on January 1st and ending on December 31st.

The interim results of operations and interim cash flows for the nine months ended September 30, 2008 are not necessarily indicative of the results to be expected for the full fiscal year or any other future period.

2. Revenue Recognition and Accounts Receivable

Revenue is recognized for product sales 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 nine-month period ended September 30, 2008. Accounts receivable are presented net of allowances relating to these provisions. Such allowances were \$409.4 million and \$423.2 million as of September 30, 2008 and December 31, 2007, respectively. Other current liabilities include \$249.4 million and \$213.5 million at September 30, 2008, and December 31, 2007, for certain rebates and other adjustments that are payable to indirect customers.

In January 2006, the Company announced an agreement with Forest Laboratories Holdings, Ltd. (Forest), a wholly-owned subsidiary of Forest Laboratories, Inc., for the commercialization, development and distribution of Bystolic[™] in the United States and Canada (the 2006 Agreement). Under the terms of that agreement, Mylan received a \$75.0 million up-front payment and \$25.0 million upon approval of the product. Such amounts were being deferred until the commercial launch of the product and were to be amortized over the remaining term of the license agreement. Mylan also had the potential to earn future milestones and royalties on Bystolic sales and an option to co-promote the product, while Forest assumed all future development and selling and marketing expenses.

In February 2008, Mylan executed an agreement with Forest whereby Mylan sold to Forest its rights to Bystolic (the Amended Agreement). Under the terms of the Amended Agreement, Mylan received a one-time cash payment of \$370.0 million, which was deferred along with the \$100.0 million received under the 2006 Agreement, and retained its contractual royalties for three years, through 2010. Mylan's obligations under the 2006 Agreement to supply Bystolic to Forest were unchanged by the Amended Agreement. Mylan believes that these supply obligations represented significant continuing involvement as Mylan remained contractually obligated to manufacture the product for Forest while the product is being commercialized. As a result of this continuing involvement, Mylan had been amortizing the \$470.0 million of deferred revenue ratably through 2020 pending the transfer of manufacturing responsibility that was

anticipated to occur in the second half of 2008.

In September 2008, Mylan completed the transfer of all manufacturing responsibilities for the product to Forest and Mylan's current supply obligations have therefore been eliminated. The Company believes that it no longer has significant continuing involvement and that the earnings process has been completed. As such, the remaining deferred revenue of \$455.0 million was recognized and included in other revenues in the Company's Condensed Consolidated Statements of Operations.

Table of Contents

MYLAN INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements (Unaudited) (Continued)

Future royalties are considered to be contingent consideration and are recognized in other revenues as earned upon sales of the product by Forest. Such royalties are recorded at the net royalty rates specified in the Amended Agreement.

3. Recent Accounting Pronouncements

In June 2008, the Financial Accounting Standards Board (FASB) issued FASB Staff Position (FSP) No. EITF 03-6-1, *Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities* (FSP No. EITF 03-6-1). FSP No. EITF 03-6-1 states that unvested share-based payment awards that contain nonforfeitable rights to dividends or dividend equivalents (whether paid or unpaid) are participating securities and shall be included in the computation of earnings per share pursuant to the two-class method. FSP No. EITF 03-6-1 is effective for fiscal years beginning after December 15, 2008. The Company is currently evaluating the impact of adopting FSP No. EITF 03-6-01 on its consolidated financial statements.

In May 2008, the FASB issued FSP No. APB 14-a, *Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement)* (FSP No. APB 14-a). Under the new rules for convertible debt instruments (including our Senior Convertible Notes) that may be settled entirely or partially in cash upon conversion, an entity should separately account for the liability and equity components of the instrument in a manner that reflects the issuer's economic interest cost. The effect of the new rules for the debentures is that the equity component would be included in the paid-in-capital section of stockholders' equity on our consolidated balance sheet and the value of the equity component would be treated as original issue discount for purposes of accounting for the debt component of the Senior Convertible Notes. FSP No. APB 14-a will be effective for fiscal years beginning after December 15, 2008, and for interim periods within those fiscal years, with retrospective application required. Higher interest expense would result through the accretion of the discounted carrying value of the Senior Convertible Notes to their face amount over the term of the Senior Convertible Notes. Prior period interest expense will also be higher than previously reported interest expense due to retrospective application. Early adoption is not permitted. The Company is currently evaluating the proposed new rules and the impact of adopting FSP No. APB 14-a on its consolidated financial statements.

In April 2008, the FASB issued FSP No. FAS 142-3, *Determination of the Useful Life of Intangible Assets* (FSP No. FAS 142-3). FSP No. FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement of Financial Accounting Standards (SFAS) No. 142, *Goodwill and Other Intangible Assets*, (SFAS No. 142) in order to improve the consistency between the useful life of a recognized intangible asset under SFAS No. 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS No. 141(R), *Business Combinations*, and other accounting principles generally accepted in the United States (GAAP). FSP No. FAS 142-3 is effective for fiscal years beginning after December 15, 2008. The Company is currently evaluating the impact of adopting FSP No. FAS 142-3 on its consolidated financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements an amendment of ARB No. 51* (SFAS No. 160). SFAS No. 160 amends Accounting Research Bulletin No. 51, *Consolidated Financial Statements*, to establish accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. This standard defines a noncontrolling interest, sometimes called a minority interest, as the portion of equity in a subsidiary not attributable, directly or indirectly, to a parent.

SFAS No. 160 requires, among other items, that a noncontrolling interest be included in the consolidated balance sheet within equity separate from the parent's equity; consolidated net income to be reported at amounts inclusive of both the parent's and noncontrolling interest's shares and, separately, the amounts of consolidated net income attributable to the parent and noncontrolling interest all on the consolidated statement of operations; and if a subsidiary is deconsolidated, any retained noncontrolling equity investment in the former subsidiary be measured at fair value and a gain or loss be recognized in net income based on such fair value. SFAS No. 160 is effective for fiscal years beginning after December 15, 2008. The Company is currently evaluating the potential impact of adopting SFAS No. 160 on its consolidated financial statements.

Table of Contents**MYLAN INC. AND SUBSIDIARIES****Notes to Condensed Consolidated Financial Statements (Unaudited) (Continued)**

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities* an amendment of FASB Statement No. 133 (SFAS No. 161). SFAS No. 161 requires enhanced disclosures about an entity's derivative and hedging activities, including (i) how and why an entity uses derivative instruments, (ii) how derivative instruments and related hedged items are accounted for under SFAS No. 133, and (iii) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. This standard is effective for fiscal years beginning after November 15, 2008. Management is currently assessing the impact on the disclosures on the Company's consolidated financial statements.

In March 2008, the Emerging Issues Task Force (EITF) issued EITF No. 07-5, *Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity's Own Stock* (EITF No. 07-5). EITF No. 07-5 states that if an instrument (or an embedded feature) has the characteristics of a derivative instrument under paragraphs 6-9 of SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, and is indexed to an entity's own stock, it is necessary to evaluate whether it is classified in stockholders' equity (or would be classified in stockholders' equity if it were a freestanding instrument). EITF No. 07-5 is effective for fiscal years beginning after December 15, 2008. The Company is currently evaluating the impact of adopting EITF No. 07-5 on its consolidated financial statements.

On January 1, 2008, the Company adopted SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* including an amendment of FASB Statement No. 115 (SFAS No. 159). SFAS No. 159 permits entities to choose to measure many financial instruments and certain other assets and liabilities at fair value on an instrument-by-instrument basis (the fair value option) with changes in fair value reported in earnings. The Company already records marketable securities at fair value in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities* (SFAS No. 115), and derivative contracts and hedging activities at fair value in accordance with SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities, as amended* (SFAS No. 133). The adoption of SFAS No. 159 did not have a material impact on the Company's Condensed Consolidated Financial Statements as management did not elect the fair value option for any other financial instrument or certain other assets and liabilities.

On January 1, 2008, the Company adopted Statement 133 Implementation Issue No. E23, *Hedging - General: Issues Involving the Application of the Shortcut Method under Paragraph 58* (Issue No. E23). Issue No. E23 provides guidance on certain practice issues related to the application of the shortcut method by amending paragraph 68 of SFAS No. 133 with respect to the conditions that must be met in order to apply the shortcut method for assessing hedge effectiveness of interest rate swaps. In addition to applying the provisions of Issue No. E23 on hedging arrangements designated on or after January 1, 2008, an assessment was required to be made on January 1, 2008 to determine whether preexisting hedging arrangements met the provisions of Issue No. E23 as of their original inception. Management performed such an assessment and determined that the adoption of Issue No. E23 did not have a material impact on preexisting hedging arrangements.

In March 2007, the EITF issued EITF No. 06-10, *Accounting for Collateral Assignment Split-Dollar Life Insurance Arrangements* (EITF No. 06-10). Under the provisions of EITF No. 06-10, an employer is required to recognize a liability for the postretirement benefit related to a collateral assignment split-dollar life insurance arrangement with the employee. The provisions of EITF No. 06-10 also require an employer to recognize and measure the asset in a collateral assignment split-dollar life insurance arrangement based on the nature and substance of the arrangement. The Company adopted the provisions of EITF No. 06-10 as of January 1, 2008. As a result of the adoption, the Company recognized a liability of \$8.3 million, representing the present value of the future premium payments to be

made under the existing policies. In accordance with the transition provisions of EITF No. 06-10, this amount was recorded as a direct decrease to retained earnings.

In March 2007, the EITF issued EITF No. 06-04, *Accounting for Deferred Compensation and Postretirement Benefit Aspects of Endorsed Split-Dollar Life Insurance Arrangements* (EITF No. 06-4), which concludes that an employer should recognize a liability for post-employment benefits promised an employee based on the substantive arrangement between the employer and the employee. The Company adopted the provisions of EITF No. 06-04 as of January 1, 2008. The adoption of EITF No. 06-04 did not have a material impact on the Company's Condensed Consolidated Financial Statements.

Table of Contents**MYLAN INC. AND SUBSIDIARIES****Notes to Condensed Consolidated Financial Statements (Unaudited) (Continued)****4. Acquisitions**

On October 2, 2007, Mylan completed its acquisition of Merck KGaA's generic business (the former Merck Generics business) and paid a purchase price of approximately \$7.0 billion. In accordance with SFAS No. 141, *Business Combinations* (SFAS No. 141), the Company used the purchase method of accounting to account for this transaction. Under the purchase method of accounting, the assets acquired and liabilities assumed in the transaction were recorded at the date of acquisition at the estimate of their respective fair values. The purchase price plus acquisition costs exceeded the estimate of fair values of acquired assets and assumed liabilities.

The Company has finalized the purchase price allocation and plans to exit certain activities of the former Merck Generics business as of September 30, 2008. As a result, the Company has a \$72.1 million reserve at September 30, 2008 related to involuntary termination benefits and certain other exit costs accounted for in accordance with EITF No. 95-3, *Recognition of Liabilities in Conjunction with a Purchased Business Combination* (EITF No. 95-3).

The operating results of the former Merck Generics business have been included in Mylan's Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2008. The following is a summary of the unaudited pro forma results of operations for the three and nine months ended September 30, 2007 and assumes the acquisition occurred on January 1, 2007. This summary of the unaudited pro forma results of operations is not necessarily indicative of what Mylan's results of operations would have been had the former Merck Generics business been acquired at the beginning of the period indicated, nor does it purport to represent results of operations for any future period.

The unaudited pro forma financial information for the periods below include the following material, non-recurring charges directly attributable to the accounting for the acquisition: amortization of the step-up of inventory of \$28.9 million for the three-month period; amortization of the step-up of inventory of \$103.9 million and an acquired in-process research and development charge of \$1.3 billion in the nine-month period. In addition, the pro forma financial information for the periods presented includes the effects of the preferred and common stock offerings, which closed in November 2007, the proceeds of which were used to repay certain temporary financing.

	Three Months Ended September 30, 2007 (In thousands, except per share data)	Nine Months Ended September 30, 2007
Total revenues	\$ 1,085,051	\$ 3,346,804
Net income (loss) before preferred dividends	26,854	(1,479,824)
Preferred dividends	34,759	104,236
Net loss available to common shareholders	\$ (7,905)	\$ (1,584,060)

Loss per common share:

Edgar Filing: MYLAN INC. - Form 10-Q

Basic	\$	(0.03)	\$	(5.37)
Diluted	\$	(0.03)	\$	(5.37)
Weighted average common shares outstanding:				
Basic		302,160		294,932
Diluted		302,160		294,932

In July 2008, Mylan purchased from Watson Pharmaceutical Inc. a 50% interest in the outstanding shares of Somerset Pharmaceuticals, Inc. Mylan had previously owned the other 50% of Somerset and had accounted for the investment using the equity method. This acquisition was not material to our statements of financial position, results of operations, or cash flows.

Table of Contents

MYLAN INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements (Unaudited) (Continued)

5. Impairment of Long-lived Assets Including Goodwill

On February 27, 2008, the Company announced that it was reviewing strategic alternatives for its specialty business, Dey, including the potential sale of the business. This decision was based upon several factors, including a strategic review of the business, the expected performance of the Perforomist[™] product, where anticipated growth was determined to be slower than expected and the timeframe to reach peak sales was determined to be longer than was originally anticipated.

As a result of our ongoing review of strategic alternatives, we determined that it was more likely than not that the business would be sold or otherwise disposed of significantly before the end of its previously estimated useful life. Accordingly, a recoverability test of Dey's long-lived assets was performed during the three months ended March 31, 2008 in accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS No. 144). The Company included both cash flow projections and estimated proceeds from the eventual disposition of the long-lived assets. The estimated undiscounted future cash flows exceeded the book values of the long-lived assets and, as a result, no impairment charge was recorded.

Upon the closing of the former Merck Generics business transaction, Dey was defined as the Specialty Segment under the provisions of SFAS No. 131, *Disclosures About Segments of an Enterprise and Related Information* (SFAS No. 131). Dey is also considered a reporting unit under the provisions of SFAS No. 142. Upon closing of the transaction, the Company allocated \$711.2 million of goodwill to Dey.

The Company tests goodwill for possible impairment on an annual basis and at any other time events occur or circumstances indicate that the carrying amount of goodwill may be impaired. As the Company had determined that it was more likely than not that the business would be sold or otherwise disposed of significantly before the end of its previously estimated useful life, the Company was required during the three months ended March 31, 2008 to assess whether any portion of its recorded goodwill balance was impaired.

The first step of the SFAS No. 142 impairment analysis consisted of a comparison of the fair value of the reporting unit with its carrying amount, including the goodwill. The Company performed extensive valuation analyses, utilizing both income and market approaches, in its goodwill assessment process. The following describes the valuation methodologies used to derive the estimated fair value of the reporting unit.

Income Approach: To determine fair value, the Company discounted the expected future cash flows of the reporting unit, using a discount rate, which reflected the overall level of inherent risk and the rate of return an outside investor would expect to earn. To estimate cash flows beyond the final year of its model, the Company used a terminal value approach. Under this approach, the Company used estimated operating income before interest, taxes, depreciation and amortization in the final year of its model, adjusted to estimate a normalized cash flow, applied a perpetuity growth assumption, and discounted by a perpetuity discount factor to determine the terminal value. The Company incorporated the present value of the resulting terminal value into its estimate of fair value.

Market-Based Approach: To corroborate the results of the income approach described above, Mylan estimated the fair value of its reporting unit using several market-based approaches, including the guideline company method which focuses on comparing its risk profile and growth prospects to a select group of publicly traded companies with reasonably similar guidelines.

Based on the SFAS No. 142 step one analysis that was performed for Dey, the Company determined that the carrying amount of the net assets of the reporting unit was in excess of its estimated fair value. As such, the Company was required to perform the step two analysis for Dey, in order to determine the amount of any goodwill impairment. The step two analysis consisted of comparing the implied fair value of the goodwill with the carrying amount of the goodwill, with an impairment charge resulting from any excess of the carrying value of the goodwill over the implied fair value of the goodwill based on a hypothetical allocation of the estimated fair value to the net assets. Based on the second step analysis, the Company concluded that \$385.0 million of the goodwill recorded at Dey was impaired. As a result, the Company recorded a non-cash goodwill impairment charge of \$385.0 million

Table of Contents**MYLAN INC. AND SUBSIDIARIES****Notes to Condensed Consolidated Financial Statements (Unaudited) (Continued)**

during the three months ended March 31, 2008, which represented its best estimate as of March 31, 2008. The allocation discussed above was performed only for purposes of assessing goodwill for impairment; accordingly, Mylan has not adjusted the net book value of the assets and liabilities on the Company's Condensed Consolidated Balance Sheet, other than goodwill, as a result of this process.

The determination of the fair value of the reporting unit required the Company to make significant estimates and assumptions that affect the reporting unit's expected future cash flows. These estimates and assumptions primarily include, but are not limited to, the discount rate, terminal growth rates, operating income before depreciation and amortization, and capital expenditures forecasts. Due to the inherent uncertainty involved in making these estimates, actual results could differ from those estimates. In addition, changes in underlying assumptions would have a significant impact on either the fair value of the reporting unit or the goodwill impairment charge.

The hypothetical allocation of the fair value of the reporting unit to individual assets and liabilities within the reporting unit also requires the Company to make significant estimates and assumptions. The hypothetical allocation requires several analyses to determine the estimate of the fair value of assets and liabilities of the reporting unit. Refer to Note 9 for a rollforward of the Company's goodwill.

In September 2008, following the completion of the comprehensive review of strategic alternatives for Dey, the Company announced its decision to retain the Dey business. This decision includes a plan to realign the business, including positioning the Company to divest Dey's current facilities over the next two years. (See Note 15 to the Condensed Consolidated Financial Statements).

6. Stock-Based Incentive Plan

Mylan's shareholders approved the *2003 Long-Term Incentive Plan* on July 25, 2003, and approved certain amendments on July 28, 2006 and April 25, 2008 (as amended, the *2003 Plan*). Under the 2003 Plan, 37,500,000 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 fair value of the shares underlying the options at the date of the grant, generally become exercisable over periods ranging from three to four years, and generally expire in ten years. In the amended 2003 Plan, no more than 5,000,000 shares may be issued as restricted shares, restricted units, performance shares and other stock-based awards.

Upon approval of the 2003 Plan, the *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.

The following table summarizes stock option activity:

	Number of Shares	Weighted Average Exercise Price
--	-------------------------	--

	Under Option	per Share
Outstanding at December 31, 2007	20,830,536	\$ 16.15
Options granted	4,037,133	11.50
Options exercised	(107,707)	10.20
Options forfeited	(1,269,151)	16.53
Outstanding at September 30, 2008	23,490,811	\$ 15.37
Vested and expected to vest at September 30, 2008	22,817,106	\$ 15.40
Options exercisable at September 30, 2008	14,940,310	\$ 15.88

Table of Contents**MYLAN INC. AND SUBSIDIARIES****Notes to Condensed Consolidated Financial Statements (Unaudited) (Continued)**

As of September 30, 2008, options outstanding, options vested and expected to vest, and options exercisable had average remaining contractual terms of 6.15 years, 6.07 years and 4.67 years, respectively. Also at September 30, 2008, options outstanding, options vested and expected to vest and options exercisable had aggregate intrinsic values of \$1.5 million, \$1.4 million and \$0.7 million, respectively.

A summary of the status of the Company's nonvested restricted stock and restricted stock unit awards as of September 30, 2008 and the changes during the nine-month period ended September 30, 2008, are presented below:

Restricted Stock Awards	Number of Restricted Stock Awards		Weighted Average Grant-Date Fair Value per Share
Nonvested at December 31, 2007	1,295,347	\$	16.95
Granted	1,696,856		11.30
Released	(359,917)		15.59
Forfeited	(66,219)		14.81
Nonvested at September 30, 2008	2,566,067	\$	13.46

As of September 30, 2008, the Company had \$47.1 million 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 1.94 years. The total intrinsic value of stock-based awards exercised and restricted stock units converted during the nine months ended September 30, 2008 and 2007 was \$4.6 million and \$13.7 million. The total intrinsic value of stock-based awards exercised and restricted stock units converted during the nine months ended September 30, 2008 and 2007 was \$0.3 million for each period.

Table of Contents**MYLAN INC. AND SUBSIDIARIES****Notes to Condensed Consolidated Financial Statements (Unaudited) (Continued)****7. Balance Sheet Components**

Selected balance sheet components consist of the following:

	September 30, 2008	December 31, 2007
	(In thousands)	
Inventories:		
Raw materials	\$ 277,397	\$ 255,744
Work in process	185,033	160,918
Finished goods	657,516	647,178
	\$ 1,119,946	\$ 1,063,840
Property, plant and equipment:		
Land and improvements	\$ 61,006	\$ 62,824
Buildings and improvements	599,602	583,097
Machinery and equipment	1,002,464	980,340
Construction in progress	80,460	125,682
	1,743,532	1,751,943
Less accumulated depreciation	692,437	649,011
	\$ 1,051,095	\$ 1,102,932
Other current liabilities:		
Payroll and employee benefit plan accruals	\$ 146,950	\$ 136,232
Accrued rebates	249,451	213,500
Other	291,436	319,742
Total	\$ 687,837	\$ 669,474

8. Earnings per Common Share

Basic earnings (loss) per share excludes dilution and is computed by dividing net earnings (loss) available to common shareholders by the weighted average number of shares outstanding during the period. Diluted earnings (loss) per share is computed by dividing net earnings (loss) available to common shareholders by the weighted average number of shares outstanding during the period increased by the number of additional shares that would have been outstanding if the impact is dilutive.

With respect to the Company's convertible preferred stock, the Company considered the effect on diluted earnings per share of the preferred stock conversion feature using the if-converted method. The preferred stock is convertible into between 125,234,172 shares and 152,785,775 shares of our common stock, subject to anti-dilution adjustments, depending on the average stock price of our common stock over the 20 trading-day period ending on the third trading day prior to conversion. For the three-month period ended September 30, 2008, the preferred stock conversion was dilutive and therefore was included in the denominator of the computation of diluted earnings per share. Additionally, when the if-converted method is dilutive, the preferred share dividend is added back to the numerator. For the nine-month period ended September 30, 2008, the preferred stock conversion would have been anti-dilutive and, as such, was not assumed in the computation of diluted earnings per share.

Table of Contents**MYLAN INC. AND SUBSIDIARIES****Notes to Condensed Consolidated Financial Statements (Unaudited) (Continued)**

Basic and diluted earnings (loss) per common share is calculated as follows:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2008	2007	2008	2007
	(In thousands, except per share amounts)			
Basic earnings (loss) available to common shareholders (numerator):				
Net earnings (loss) before preferred dividends	\$ 206,758	\$ 149,827	\$ (176,024)	\$ 158,265
Less: Preferred stock dividends	34,759		104,236	
Net earnings (loss) available to common shareholders	\$ 171,999	\$ 149,827	\$ (280,260)	\$ 158,265
Shares (denominator):				
Weighted average shares outstanding	304,449	248,660	304,305	241,432
Basic earnings (loss) per common share	\$ 0.56	\$ 0.60	\$ (0.92)	\$ 0.66
Dilutive earnings (loss) available to common shareholders (numerator):				
Net earnings (loss) available to common shareholders	\$ 171,999	\$ 149,827	\$ (280,260)	\$ 158,265
Add: Preferred stock dividend	34,759			
Income available to common shareholders and assumed conversions	\$ 206,758	\$ 149,827	\$ (280,260)	\$ 158,265
Shares (denominator):				
Stock-based awards	1,115	1,840		2,820
Preferred stock conversion	152,786			
Total dilutive shares outstanding assuming conversion	458,350	250,500	304,305	244,252
Diluted earnings (loss) per common share	\$ 0.45	\$ 0.60	\$ (0.92)	\$ 0.65

Additional stock options or restricted stock awards representing 18.6 million and 12.1 million shares were outstanding for the nine months ended September 30, 2008 and 2007, but were not included in the computation of diluted earnings per share because the effect would be anti-dilutive.

Edgar Filing: MYLAN INC. - Form 10-Q

During the nine months ended September 30, 2008, the Company paid dividends of \$102.7 million on the preferred stock. On October 30, 2008, the Company announced that a quarterly dividend of \$16.25 per share was declared (based on the annual dividend rate of 6.5% and a liquidation preference of \$1,000 per share) payable on November 17, 2008, to the holders of preferred stock of record as of October 31, 2008.

Table of Contents**MYLAN INC. AND SUBSIDIARIES****Notes to Condensed Consolidated Financial Statements (Unaudited) (Continued)****9. Goodwill and Intangible Assets**

A rollforward of goodwill from December 31, 2007 to September 30, 2008 is as follows:

	Total (In thousands)
Goodwill balance at December 31, 2007	\$ 3,855,971
Impairment loss on goodwill	(385,000)
Foreign currency translation and other	(187,981)
Goodwill balance at September 30, 2008	\$ 3,282,990

Included in foreign currency translation and other is approximately \$74.2 million net decrease to goodwill related to the finalization of the purchase price allocation. Finalization of the purchase price allocation consisted of net adjustments to deferred tax liabilities, adjustments to certain asset fair values, and additional restructuring liabilities.

Intangible assets consist of the following components:

	Weighted Average Life (Years)	Original Cost	Accumulated Amortization	Net Book Value
		(In thousands)		
September 30, 2008				
Amortized intangible assets:				
Patents and technologies	20	\$ 118,926	\$ 70,126	\$ 48,800
Product rights and licenses	10	2,893,695	367,093	2,526,602
Other	8	129,678	27,465	102,213
		\$ 3,142,299	\$ 464,684	\$ 2,677,615
December 31, 2007				
Amortized intangible assets:				
Patents and technologies	20	\$ 118,926	\$ 65,578	\$ 53,348
Product rights and licenses	10	2,961,712	152,865	2,808,847
Other	8	129,031	12,520	116,511
		\$ 3,209,669	\$ 230,963	\$ 2,978,706

Amortization expense for the nine months ended September 30, 2008 and 2007 was \$235.0 million and \$36.6 million, and is expected to be \$75.0 million for the remainder of 2008, and \$295.0 million, \$288.0 million, \$279.0 million and \$263.0 million for years 2009 through 2012, respectively. In addition to amortization, the majority of the change to the net book value of intangible assets during the nine months ended September 30, 2008 is due to foreign exchange fluctuations.

10. Financial Instruments and Risk Management

Interest Rate Risk

During the nine months ended September 30, 2008, we executed an incremental \$500.0 million of notional interest rate swaps in order to fix the interest rate on a portion of our U.S. Tranche B Term Loans. These swaps are designated as cash flow hedges of the variability of interest expense related to our variable rate debt and fix a rate of 5.44% until March 2010. In October 2008, the Company executed an additional \$500.0 million of notional interest rate swaps in order to fix the interest rate on a portion of our U.S. Tranche B Term Loans. These swaps fix a rate of

Table of Contents**MYLAN INC. AND SUBSIDIARIES****Notes to Condensed Consolidated Financial Statements (Unaudited) (Continued)**

6.03% on our variable rate debt until December 2010 and are designated as a cash flow hedge of expected future borrowings under the Credit Agreement.

Fair Value Measurement

Effective September 30, 2008, the Company adopted FSP No. FAS 157-3, *Determining the Fair Value of a Financial Asset when the Market for that Asset is not Active*, (FSP No. FAS 157-3). FAS No. FAS 157-3 clarifies the application of SFAS No. 157, *Fair Value Measurements*, (SFAS No. 157) in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. The Company's adoption of FSP No. FAS 157-3 had no impact on the Company's Condensed Consolidated Financial Statements.

On January 1, 2008, the Company adopted SFAS No. 157 for financial assets and liabilities and any other assets and liabilities carried at fair value. This pronouncement defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. The Company's adoption of SFAS No. 157 did not have a material effect on the Company's Condensed Consolidated Financial Statements for financial assets and liabilities and any other assets and liabilities carried at fair value.

As defined in SFAS No. 157, fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, SFAS No. 157 establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value.

Financial assets and liabilities carried at fair value as of September 30, 2008 are classified in the table below in one of the three categories described above:

Financial Assets

Level 1	Level 2	Level 3	Total
(In thousands)			

Edgar Filing: MYLAN INC. - Form 10-Q

Municipal bonds	\$	\$ 5,136	\$	\$ 5,136
Other available-for-sale fixed income investments		32,634		32,634
Equity securities	1,165			1,165
Foreign exchange derivative assets		8,992		8,992
Interest rate swap derivative assets		8,072		8,072
Purchased cash convertible note hedge		211,025		211,025
Auction rate securities(2)			9,075	9,075
Total assets at fair value(1)	\$ 1,165	\$ 265,859	\$ 9,075	\$ 276,099

Table of Contents**MYLAN INC. AND SUBSIDIARIES****Notes to Condensed Consolidated Financial Statements (Unaudited) (Continued)**

Financial Liabilities

	Level 1	Level 2	Level 3	Total
Foreign exchange derivative liabilities	\$	\$ 3,453	\$	\$ 3,453
Interest rate swap derivative liabilities		13,960		13,960
Cash conversion feature of cash convertible notes		211,025		211,025
Total liabilities at fair value(1)	\$	\$ 228,438	\$	\$ 228,438

(1) The Company chose not to elect the fair value option as prescribed by SFAS No. 159 for its financial assets and liabilities that had not been previously carried at fair value. Therefore, material financial assets and liabilities not carried at fair value, such as short-term and long-term debt obligations and trade accounts receivable and payable, are still reported at their carrying values.

(2) There have been no changes to the fair value of these securities during the quarter ended September 30, 2008.

Due to the lack of observable market quotes on the Company's auction rate securities (ARS) portfolio, the Company utilizes valuation models that rely exclusively on Level 3 inputs, including those that are based on expected cash flow streams and collateral values. The Company has approximately \$9.1 million in ARS, which were subject to a failed auction in May 2008. These ARS continue to pay interest according to their terms. The securities were issued by a state educational loan authority and are backed by student loans. The state educational loan authority has requested and received required consent from bondholders to amend the existing indentures governing the securities to add a call provision, which permits the securities to be called at par after August 1, 2008. The Company does not believe these securities are subject to any other than temporary impairment as the Company has the intent and the ability to hold these securities until maturity or until called.

For financial assets and liabilities that utilize Level 2 inputs, the Company utilizes both direct and indirect observable price quotes, including the LIBOR yield curve, foreign exchange forward prices, and bank price quotes. Below is a summary of valuation techniques for Level 1 and Level 2 financial assets and liabilities:

Municipal bonds valued at the quoted market price from broker or dealer quotations or transparent pricing sources at the reporting date.

Other available-for-sale fixed income investments valued at the quoted market price from broker or dealer quotations or transparent pricing sources at the reporting date.

Equity Securities valued using quoted stock prices from the London Exchange at the reporting date and translated to U.S. dollars at prevailing spot exchange rates.

Interest rate swap derivative assets and liabilities valued using the LIBOR yield curve at the reporting date. Counterparties to these contracts are highly rated financial institutions, none of which experienced any significant downgrades in the nine months ended September 30, 2008, that would reduce the receivable amount owed, if any, to the Company.

Foreign exchange derivative assets and liabilities valued using quoted forward foreign exchange prices at the reporting date. Counterparties to these contracts are highly rated financial institutions, none of which experienced any significant downgrades in the nine months ended September 30, 2008, that would reduce the receivable amount owed, if any, to the Company.

Cash Conversion Feature of Cash Convertible Notes and Purchased Convertible Note Hedge valued using quoted prices for the Company's cash convertible notes and the quoted yield on the Company's other long-term debt at the reporting date. Counterparties to the Purchased Convertible Note Hedge are highly rated financial institutions, none of which experienced any significant downgrades in the nine months ended September 30, 2008, that would reduce the receivable amount owed, if any, to the Company.

Table of Contents**MYLAN INC. AND SUBSIDIARIES****Notes to Condensed Consolidated Financial Statements (Unaudited) (Continued)**

Although the Company has not elected the fair value option for financial assets and liabilities existing at January 1, 2008 or transacted in the nine months ended September 30, 2008, any future transacted financial asset or liability will be evaluated for the fair value election as prescribed by SFAS No. 159 and adjusted to fair value as determined under the provisions of SFAS No. 157.

11. Long-Term Debt

A summary of long-term debt is as follows:

	September 30, 2008	December 31, 2007
	(In thousands)	
U.S. Tranche A Term Loans(A)	\$ 300,781	\$ 312,500
Euro Tranche A Term Loans(A)	487,180	516,127
U.S. Tranche B Term Loans(A)	2,536,830	2,556,000
Euro Tranche B Term Loans(A)	752,654	773,273
Revolving Facility(B)		300,000
Senior Convertible Notes	600,000	600,000
Cash Convertible Notes(C)	625,801	
Other(D)	15,822	54,194
	5,319,068	5,112,094
Less: Current portion	108,261	405,378
Total long-term debt	\$ 5,210,807	\$ 4,706,716

Details of the interest rates in effect at September 30, 2008 and December 31, 2007, on the outstanding borrowings under the Term Loans are in the table below:

	September 30, 2008		
	Outstanding	Basis	Rate
	(Dollars in thousands)		
U.S. Tranche A Term Loans	300,781	LIBOR + 3%	6.75%
Euro Tranche A Term Loans	487,180	EURIBO + 3%	8.01%
U.S. Tranche B Term Loans			
Swapped to Fixed Rate March 2010(1)	500,000	Fixed	5.44%
Swapped to Fixed Rate December 2010(1)	1,000,000	Fixed	7.37%
Floating Rate	1,036,830	LIBOR + 3.25%	7.00%

Total U.S. Tranche B Term Loans	2,536,830		
Euro Tranche B Term Loans	752,654	EURIBO + 3.25%	8.26%

(1) Designated as a cash flow hedge of expected future borrowings under the Senior Credit Agreement

Table of Contents**MYLAN INC. AND SUBSIDIARIES****Notes to Condensed Consolidated Financial Statements (Unaudited) (Continued)**

	December 31, 2007		
	Outstanding	Basis	Rate
	(Dollars in thousands)		
U.S. Tranche A Term Loans	312,500	LIBOR + 3.25%	8.31%
Euro Tranche A Term Loans	516,127	EURIBO + 3.25%	7.75%
U.S. Tranche B Term Loans			
Swapped to Fixed Rate December 2010	1,000,000	Fixed	7.37%
Floating Rate	1,556,000	LIBOR + 3.25%	8.31%
Total U.S. Tranche B Term Loans	2,556,000		
Euro Tranche B Term Loans	773,273	EURIBO + 3.25%	7.75%

Mandatory minimum repayments remaining on the outstanding borrowings under the term loans and convertible notes at September 30, 2008 are as follows for each of the periods ending December 31st:

	U.S. Tranche A Term Loans	Euro Tranche A Term Loans	U.S. Tranche B Term Loans	Euro Tranche B Term Loans	Senior Convertible Notes	Cash Convertible Notes (C)	Total
	(In thousands)						
2008	\$ 3,906	\$ 6,328	\$ 6,390	\$ 1,896	\$	\$	\$ 18,520
2009	31,250	50,616	25,560	7,583			115,009
2010	46,875	75,924	25,560	7,583			155,942
2011	62,500	101,232	25,560	7,583			196,875
2012	78,125	126,540	25,560	7,583	600,000		837,808
2013	78,125	126,540	25,560	7,583			237,808
Thereafter			2,402,640	712,843		625,801	3,741,284
Total	\$ 300,781	\$ 487,180	\$ 2,536,830	\$ 752,654	\$ 600,000	\$ 625,801	\$ 5,303,246

(A) During the nine months ended September 30, 2008, the Company paid \$11.7 million on the U.S. Tranche A Term Loans, 13.1 (\$18.6) million on the Euro Tranche A Term Loans, \$19.2 million on the U.S. Tranche B Term Loans, and 3.9 (\$5.6) million on the Euro Tranche B Term Loans.

(B) On September 15, 2008, outstanding borrowings under the Revolving Facility were repaid in the amount of \$300.0 million. The revolving credit facility expires in October 2013.

- (C) On September 15, 2008, Mylan entered into a purchase agreement relating to the sale by the Company of \$575.0 million aggregate principal amount of Cash Convertible Notes due 2015 (Cash Convertible Notes). The Cash Convertible Notes bear stated interest at a rate of 3.75% per year, accruing from September 15, 2008. The effective interest rate at September 30, 2008 is 9.5%. Interest is payable semi-annually in arrears on March 15 and September 15 of each year, beginning on March 15, 2009. The Cash Convertible Notes will mature on September 15, 2015, subject to earlier repurchase or conversion. Holders may convert their notes subject to certain conversion provisions determined by, among other, the market price of the Company's common stock, specified distributions to common shareholders, a fundamental change, and certain time periods specified in the purchase agreement. The Cash Convertible Notes have an initial conversion reference rate of 75.0751 shares of common stock per \$1,000 principal amount (equivalent to an initial conversion reference price of \$13.32 per share), subject to adjustment, with the principal amount and remainder payable in cash. The Cash Convertible Notes are not convertible into our common stock or any other securities under any circumstance.

On September 15, 2008, concurrent with the sale of the Cash Convertible Notes, Mylan entered into a convertible note hedge and warrant transaction with certain counterparties. The net cost of the transactions was \$98.6 million. The cash convertible note hedge is comprised of purchased cash-settled call options that are

Table of Contents**MYLAN INC. AND SUBSIDIARIES****Notes to Condensed Consolidated Financial Statements (Unaudited) (Continued)**

expected to reduce the Company's exposure to potential cash payments required to be made by Mylan upon the cash conversion of the Cash Convertible Notes. Concurrent with entering into the purchased cash-settled call options, the Company entered into respective warrant transactions with the counterparties pursuant to which the Company will have sold to each counterparty warrants for the purchase of shares of our common stock. Pursuant to the warrant transactions, the Company will sell to the counterparties warrants to purchase in the aggregate up to approximately 43.2 million shares of Mylan common stock, subject to anti-dilution adjustments substantially similar to the anti-dilution adjustments for the Cash Convertible Notes, which under most circumstances represents the maximum number of shares that underlie the conversion reference rate for the Cash Convertible Notes. The warrants may not be exercised prior to the maturity of the Cash Convertible Notes.

Pursuant to the call option transactions, if the market price per share of the Company's common stock at the time of cash conversion of any Cash Convertible Notes is above the strike price of the purchased cash settlement call options, such call options will, in most cases, entitle us to receive from the counterparties in the aggregate the same amount of cash as we would be required to issue to the holder of the cash converted notes in excess of the principal amount thereof. The sold warrants have an exercise price of \$20.00 (which represents an exercise price of approximately 80% higher than the market price per share of \$11.10) and are net share settled, meaning that Mylan will issue a number of shares per warrant corresponding to the difference between our share price at each warrant expiration date and the exercise price.

The purchased call options and sold warrants are separate contracts entered into by us with the counterparties, are not part of the notes and do not affect the rights of holders under the Cash Convertible Notes. Holders of the Cash Convertible Notes will not have any rights with respect to the purchased call options or the sold warrants. The purchased cash-settled call options meet the definition of derivatives under SFAS No. 133. As such, the instrument will be marked to market each period. In addition, the liability associated with the cash conversion feature of the Cash Convertible Notes will be marked to market each period. At September 30, 2008, the \$625.8 million consists of \$414.8 million of debt (\$575.0 million face amount, net of \$160.2 million discount) and a liability with a fair value of \$211.0 million related to the bifurcated conversion feature. The purchased call options are assets recorded at their fair value of \$211.0 million within other assets in the Condensed Consolidated Balance Sheet at September 30, 2008. The warrants meet the definition of derivatives under SFAS No. 133, however, because these instruments have been determined to be indexed to the Company's own stock (in accordance with the guidance of EITF Issue No. 01-6, *The Meaning of Indexed to a Company's Own Stock*) and have been recorded in stockholders' equity in the Company's Condensed Consolidated Balance Sheet (as determined under EITF Issue No. 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*) the instruments are exempt from the scope of SFAS No. 133 and are not subject to the fair value provisions of that standard.

- (D) At December 31, 2007, other debt included the Matrix borrowings under a Euro-denominated Facility (Facility B). On March 31, 2008, Facility B was repaid in the amount of 24.5 million (\$39.4 million).

At September 30, 2008, and December 31, 2007, the fair value of the Senior Convertible Notes was approximately \$458.0 million and \$545.5 million. Subsequent to September 30, 2008, the fair value of the Senior Convertible Notes has continued to decrease and at October 31, 2008 was approximately \$392.3 million.

At September 30, 2008, the fair value of the Cash Convertible Notes was approximately \$350.2 million. Subsequent to September 30, 2008, the fair value of the Cash Convertible Notes has increased and at October 31, 2008 was approximately \$429.4 million.

Table of Contents**MYLAN INC. AND SUBSIDIARIES****Notes to Condensed Consolidated Financial Statements (Unaudited) (Continued)****12. Comprehensive Earnings**

Comprehensive earnings consists of the following:

	Three Months Ended September 30,	
	2008	2007
	(In thousands)	
Net earnings	\$ 206,758	\$ 149,827
Other comprehensive (loss) earnings, net of tax:		
Foreign currency translation adjustments	(388,310)	1,148
Change in unrecognized losses and prior service cost related to post-retirement plans	791	170
Net unrecognized gain on derivatives	(3,562)	
Unrealized (losses) gains on available for sale securities		
Net unrealized (losses) gains on available for sale securities	(694)	870
Less: Reclassification for gains (losses) included in net earnings	8 (686)	(344) 526
Other comprehensive (loss) earnings, net of tax:	(391,767)	1,844
Comprehensive (loss) earnings, net of tax	\$ (185,009)	\$ 151,671

	Nine Months Ended September 30,	
	2008	2007
	(In thousands)	
Net (loss) earnings	\$ (176,024)	\$ 158,265
Other comprehensive (loss) earnings, net of tax:		
Foreign currency translation adjustments	(223,480)	12,348
Change in unrecognized losses and prior service cost related to post-retirement plans	1,568	340
Net unrecognized gain on derivatives	1,061	
Unrealized (losses) on available for sale securities		
Net unrealized losses on available for sale securities	(616)	(1,453)
Less: Reclassification for gains (losses) included in net earnings	74 (542)	(71) (1,524)
Other comprehensive (loss) earnings, net of tax:	(221,393)	11,164
Comprehensive (loss) earnings, net of tax	\$ (397,417)	\$ 169,429

Table of Contents**MYLAN INC. AND SUBSIDIARIES****Notes to Condensed Consolidated Financial Statements (Unaudited) (Continued)**

Accumulated other comprehensive earnings, as reflected on the balance sheet, is comprised of the following:

	September 30, 2008	December 31, 2007
	(In thousands)	
Net unrealized gain in available for sale securities	\$ 292	\$ 834
Change in unrecognized losses and prior service cost related to post-retirement plans	(367)	(1,935)
Net unrecognized losses on derivatives	(3,662)	(4,723)
Foreign currency translation adjustments	(134,612)	88,868
Accumulated other comprehensive (loss) income	\$ (138,349)	\$ 83,044

13. Income Taxes

The Company adopted FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes – an Interpretation of FASB Statement 109* (FIN 48) effective April 1, 2007. FIN 48 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 total amount of unrecognized tax benefits was \$144.3 million and \$77.6 million as of September 30, 2008 and December 31, 2007. The increase in the FIN 48 reserve was due primarily to potential exposures identified as part of an on-going global transfer pricing study of \$34.6 million and a stewardship study of \$13.4 million. Accrued interest and penalties related to these potential exposures increased from \$24.4 million at December 31, 2007 to \$30.8 million at September 30, 2008.

It is anticipated that the amount of unrecognized tax benefits will change in the next 12 months; however, these changes are not expected to have a significant impact on the results of operations, cash flows or the financial position of the Company. Most notably, it is anticipated that a significant portion of the FIN 48 reserve generated this quarter, as a result of the stewardship study, will reverse in the fourth quarter of 2008.

The effective tax rate in 2008 has been largely effected by the sale of Bystolic, operating losses and the non-deductible impairment charge related to Dey.

The statute of limitations for tax years ending 2005 through 2007 remain open to examination by the Internal Revenue Service. Examinations have been completed for all federal returns through the March 31, 2007 filing as part of the Compliance Assurance Process. The major state taxing jurisdictions applicable to the Company remain open from 2004 through 2007.

14. Segment Information

The Company previously had two reportable segments, the Mylan Segment and the Matrix Segment . With the acquisition of the former Merck Generics business, Mylan now has three reportable segments: the Generics Segment , the Specialty Segment , and the Matrix Segment . The Generics Segment primarily develops, manufactures, sells and distributes generic or branded generic pharmaceutical products in tablet, capsule or transdermal patch form. The Specialty Segment engages mainly in the manufacture and sale of branded specialty nebulized and injectable products. The Matrix Segment engages mainly in the manufacture and sale of active pharmaceutical ingredients (APIs) and the distribution of certain branded generic products. Additionally, certain general and administrative expenses, as well as litigation settlements, and non-operating income and expenses are reported in Corporate/Other. In accordance with SFAS No. 131, information for earlier periods has been recast.

The Company s chief operating decision maker evaluates the performance of its reportable segments based on total revenues and segment profitability (loss). For the Generics, Specialty, and Matrix Segments, segment profitability (loss) represents segment gross profit less direct research and development expenses and direct selling, general and administrative expenses. Amortization of intangible assets as well as other purchase accounting related items including the write-off of in-process research and development and the amortization of the inventory

Table of Contents**MYLAN INC. AND SUBSIDIARIES****Notes to Condensed Consolidated Financial Statements (Unaudited) (Continued)**

step-up are excluded from segment profitability (loss). Items below the earnings from operations line on the Company's Condensed Consolidated Statements of Operations are not presented by segment, since they are excluded from the measure of segment profitability (loss) reviewed by the Company's chief operating decision maker. The Company does not report depreciation expense, total assets and capital expenditures by segment as such information is not used by the chief operating decision maker.

The accounting policies of the segments are the same as those described in the Summary of Significant Accounting Policies included in the Company's Transition Report on Form 10-KT/A for the nine months ended December 31, 2007. Intersegment revenues are accounted for at current market values.

The table below presents segment information for the periods identified and provides a reconciliation of segment information to total consolidated information.

Three Months Ended September 30, 2008	Generics Segment(1)	Specialty Segment	Matrix Segment	Corporate/ Other(3)	Consolidated
	(In thousands)				
Total revenues					
Third party	\$ 1,441,152	\$ 125,444	\$ 90,252	\$	\$ 1,656,848
Intersegment	1,195	5,151	17,824	(24,170)	
Total	1,442,347	130,595	108,076	(24,170)	\$ 1,656,848
Segment profitability	\$ 720,126	\$ 28,177	\$ 10,260	\$ (197,731)	\$ 560,832
Nine Months Ended September 30, 2008	Generics Segment(1)	Specialty Segment(2)	Matrix Segment	Corporate/ Other(3)	Consolidated
Total revenues					
Third party	\$ 3,343,418	\$ 308,482	\$ 282,530	\$	\$ 3,934,430
Intersegment	1,797	27,547	47,801	(77,145)	
Total	3,345,215	336,029	330,331	(77,145)	\$ 3,934,430
Segment profitability (loss)	\$ 1,152,365	\$ (334,604)	\$ 20,212	\$ (574,679)	\$ 263,294
Three Months Ended September 30, 2007	Generics Segment	Specialty Segment	Matrix Segment	Corporate/ Other(3)	Consolidated
Total revenues					
Third party	\$ 397,044	\$	\$ 80,047	\$	\$ 477,091
Intersegment			6,165	(6,165)	

Edgar Filing: MYLAN INC. - Form 10-Q

Total	397,044		86,212	(6,165)	\$ 477,091
Segment profitability	\$ 168,014	\$	\$ 1,321	\$ (77,439)	\$ 91,896
Nine Months Ended September 30, 2007	Generics Segment	Specialty Segment	Matrix Segment	Corporate/Other(3)	Consolidated
Total revenues					
Third party	\$ 1,259,912	\$	\$ 250,762	\$	\$ 1,510,674
Intersegment			31,724	(31,724)	
Total	1,259,912		282,486	(31,724)	\$ 1,510,674
Segment profitability	\$ 607,999	\$	\$ 17,035	\$ (352,857)	\$ 272,177

- (1) Generics total third-party revenues and segment profitability (loss) includes \$455.0 million and \$468.1 million for the three and nine months, respectively, of revenue related to the sale of Bystolic product rights.
- (2) Specialty segment loss for the nine months ended September 30, 2008 includes a \$385.0 million non-cash goodwill impairment charge.
- (3) Corporate/Other includes corporate overhead, certain purchase accounting items, intercompany eliminations and charges not directly attributable to segments.

Table of Contents**MYLAN INC. AND SUBSIDIARIES****Notes to Condensed Consolidated Financial Statements (Unaudited) (Continued)****15. Restructuring**

The Company's Condensed Consolidated Balance Sheet as of September 30, 2008, includes a \$72.1 million restructuring reserve, which relates to certain estimated exit costs associated with the acquisition of the former Merck Generics business. The plans related to these exit activities have now been finalized. Payments of approximately \$5.0 million were made during the nine months ended September 30, 2008, of which \$2.9 million were severance costs and the remaining \$2.1 million were other exit costs.

The Company announced its intent to restructure certain activities and incur certain related exit costs unrelated to the former Merck Generics business acquisition. At September 30, 2008, the Company met all the criteria in SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* (SFAS No. 146), and has recorded a reserve for such activities of approximately \$0.7 million. This restructuring charge is included in operating expenses in the Company's Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2008. As finalization of the plan is still in progress, the Company has not yet estimated the total amount expected to be incurred in connection with such activities. However, Mylan expects the majority of such costs will relate to one-time termination benefits and certain asset write-downs and could be significant.

As discussed in Note 5, the Company is planning to realign the Dey business. As a result, the Company expects to incur one-time termination benefits and acceleration of depreciation expense related to the planned disposition of Dey's current facilities. The Company has yet to finalize the plan and therefore not yet estimated the total amount expected to be incurred with respect to such activities but the amount could be significant.

16. Contingencies

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. The Company is also party to certain litigation matters, some of which are described below, for which Merck KGaA has agreed to indemnify the Company, under the terms of the Share Purchase Agreement by which Mylan acquired the former Merck Generics business. An adverse outcome in any of these proceedings, or the inability or denial of Merck KGaA to pay an indemnified claim, could have a material adverse effect on the Company's financial position and results of operations.

Omeprazole

On May 17, 2000, Mylan Pharmaceuticals Inc. (MPI) filed an Abbreviated New Drug Application (ANDA) seeking approval from the U.S. Food and Drug Administration (FDA) to manufacture, market and sell omeprazole delayed-release capsules and on August 8, 2000 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 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 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 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. MPI has certain indemnity obligations to Esteve in connection with this litigation. On May 31, 2007, the district court ruled in Mylan s and Esteve s favor by finding that the asserted patents were not infringed by Mylan s/Esteve s products. On July 18, 2007, AstraZeneca appealed the decision to the United States Court of Appeals for the Federal Circuit. On June 10, 2008, the appellate court issued a judgment and decision affirming the district court s finding of noninfringement and the mandate was issued on July 1, 2008.

Table of Contents**MYLAN INC. AND SUBSIDIARIES****Notes to Condensed Consolidated Financial Statements (Unaudited) (Continued)*****Lorazepam and Clorazepate***

On June 1, 2005, a jury verdict was rendered against Mylan, MPI, and co-defendants Cambrex Corporation and Gyma Laboratories in the U.S. District Court for the District of Columbia (D.C.) in the amount of approximately \$12.0 million, which has been accrued for by the Company. The jury found that Mylan and its co-defendants willfully violated Massachusetts, Minnesota and Illinois state antitrust laws in connection with API supply agreements entered into between the Company and its API supplier (Cambrex) and broker (Gyma) for two drugs, lorazepam and clorazepate, in 1997, and subsequent price increases on these drugs in 1998. The case was brought by four health insurers who opted out of earlier class action settlements agreed to by the Company in 2001 and represents the last remaining antitrust claims relating to Mylan's 1998 price increases for lorazepam and clorazepate. Following the verdict, the Company filed a motion for judgment as a matter of law, a motion for a new trial, a motion to dismiss two of the insurers and a motion to reduce the verdict. On December 20, 2006, the Company's motion for judgment as a matter of law and motion for a new trial were denied and the remaining motions were denied on January 24, 2008. In post-trial filings, the plaintiffs requested that the verdict be trebled and that request was granted on January 24, 2008. On February 6, 2008, a judgment was issued against Mylan and its co-defendants in the total amount of approximately \$69.0 million, some or all of which may be subject to indemnification obligations by Mylan. Plaintiffs are also seeking an award of attorneys' fees and litigation costs in unspecified amounts and prejudgment interest of approximately \$9.0 million. The Company and its co-defendants have appealed to the U.S. Court of Appeals for the D.C. Circuit. The appeals have been held in abeyance pending a ruling on the motion for prejudgment interest. In connection with the Company's appeal of the lorazepam Judgment, the company submitted a surety bond underwritten by a third-party insurance company in the amount of \$74.5 million. This surety bond is secured by a pledge of a \$40.0 million cash deposit (which is included as restricted cash on the Company's Condensed Consolidated Balance Sheet as of September 30, 2008) and an irrevocable letter of credit for \$34.5 million issued under the Senior Credit Agreement. On October 27, 2008, a U.S. magistrate judge issued a report recommending the granting of plaintiffs' motion for prejudgment interest. The report also recommends requiring the surety bond amount to be increased to include prejudgment interest. Mylan intends to submit objections to the magistrate judge's recommendations after which the district court will determine whether to accept or reject those recommendations. If the magistrate's recommendations on prejudgment interest are accepted, Mylan intends to contest these rulings as part of its pending appeal.

Pricing and Medicaid Litigation

On June 26, 2003, MPI and UDL Laboratories Inc. (UDL) 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 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, MPI and/or UDL, together with many other pharmaceutical companies, have been named in 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, MPI and/or UDL have been named as defendants in substantially similar civil lawsuits filed by the AGs of Alabama, Alaska, California, Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Massachusetts, Mississippi, Missouri, South Carolina, Texas, Utah and Wisconsin and also by the city of New York

Table of Contents

MYLAN INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements (Unaudited) (Continued)

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 recently filed Kansas case, Mylan, MPI and/or UDL have either moved to dismiss the complaints or have answered the complaints denying liability. Mylan and its subsidiaries intend to defend each of these actions vigorously.

In May 2008, an amended complaint was filed in the U.S. District Court for the District of Massachusetts by a plaintiff on behalf of the United States of America, against Mylan, MPI, UDL and several other generic manufacturers. The original complaint was filed under seal in April 2000, and Mylan, MPI and UDL were added as parties in February 2001. The claims against Mylan, MPI, UDL and the other generic manufacturers were severed from the April 2000 complaint (which remains under seal) as a result of the federal government's decision not to intervene in the action as to those defendants. The complaint alleges violations of the False Claims Act and sets forth allegations substantially similar to those alleged in the state AG cases mentioned in the preceding paragraph and purports to seek recovery of any and all alleged overpayment of the federal share under the Medicaid program. Mylan has moved to dismiss the complaint and intends to defend the action vigorously.

In addition, by letter dated January 12, 2005, MPI was notified by the U.S. Department of Justice of an investigation concerning calculations of Medicaid drug rebates. The investigation involves whether MPI and UDL may have violated the False Claims Act or other laws by classifying certain authorized generics launched in the 1990's and early 2000's as non-innovator rather than innovator drugs for purposes of Medicaid and other federal healthcare programs until 2005. MPI and UDL deny the government's allegations and deny that they engaged in any wrongful conduct. Based on our understanding of the government's allegations, the alleged difference in rebates for the MPI and UDL products currently at issue may be up to approximately \$100.0 million, which includes interest. Remedies under the False Claims Act could include treble damages and penalties. MPI and UDL have been cooperating fully with the government's investigation and are currently in discussions with the government about a possible resolution of the matter. Additionally, the Company believes that it has contractual and other rights to recover from the innovator a substantial portion of any payments that MPI and UDL may remit to the government. The Company has not recorded any amounts in the consolidated financial statements related to this matter.

Dey, L.P. is a defendant currently in lawsuits brought by the state AG's of Arizona, California, Florida, Illinois, Iowa, Kansas, Kentucky, Mississippi, Pennsylvania, South Carolina (on behalf of the state and the state health plan), Utah and Wisconsin and the city of New York and approximately 40 New York counties. Dey is also named as a defendant in several class actions brought by consumers and third-party payors. Dey has reached a settlement of most of these class actions, which has been preliminarily approved by the court. Additionally, the U.S. federal government filed a claim against Dey, L.P. in August 2006. These cases all generally allege that Dey falsely reported certain price information concerning certain drugs marketed by Dey. Dey intends to defend each of these actions vigorously. In conjunction with the former Merck Generics business acquisition by Mylan, Mylan is entitled to indemnification by Merck KGaA for these Dey pricing related suits.

Modafinil Antitrust Litigation and FTC Inquiry

Beginning in April 2006, Mylan, along with four other drug manufacturers, has been named as a defendant in 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 a third-party payor 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 motions to dismiss each action are pending, with the exception of the third-party payor action, in which Mylan's response to the complaint is not due until the motions filed in the other cases have been decided. Mylan intends to defend each of these actions vigorously. In addition, by

Table of Contents**MYLAN INC. AND SUBSIDIARIES****Notes to Condensed Consolidated Financial Statements (Unaudited) (Continued)**

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, MPI and Mylan Technologies Inc. (MTI) pertaining to the patent litigation and the settlement thereof. On March 29, 2007, the FTC issued a subpoena, and on April 26, 2007, the FTC issued a civil investigative demand to Mylan requesting additional information from the Company relating to the investigation. Mylan is cooperating fully with the government 's investigation and completed all requests for information. On February 13, 2008, the FTC filed a lawsuit against Cephalon in the U.S. District Court for the District of Columbia and the case has subsequently been transferred to the U.S. District Court for the Eastern District of Pennsylvania. Mylan is not named as a defendant in the FTC 's lawsuit, although the complaint includes certain allegations pertaining to the Mylan/Cephalon settlement.

Litigation related to the former Merck Generics Business

Generics UK Ltd. is accused of having been involved in pricing agreements pertaining to certain drugs during the years 1996 to 2000. Generics UK Ltd. was able to settle civil claims for damages brought by the Health Service in England and Wales out of court, without any admission of liability. Additional claims have been filed against Generics UK Ltd. and others by health authorities in Scotland and Northern Ireland totaling £21.0 (\$38.2) million exclusive of interest. In addition to these civil claims, in 2006 criminal proceedings were filed in Southwark Crown Court against Generics UK Ltd. and other companies, as well as against a number of individuals who were alleged to be responsible for decision making in the companies. In early 2008, the House of Lords ruled that a price fixing cartel was not at the relevant times a criminal offense. The case was remanded back to the Crown Court for the prosecution to make an application to amend the indictment. On July 11, 2008, the Crown Court refused to allow the prosecution 's application, quashed the indictment and denied the prosecution 's application for permission to appeal. On July 17, 2008, the prosecution applied to the Court of Appeal (Criminal Division) for permission to appeal. A hearing to decide the prosecution 's application is due to take place in December 2008.

The Company has approximately \$129.7 million recorded in other liabilities related to the litigation involving Dey and Generics UK Ltd. As stated above, in conjunction with the former Merck Generics business acquisition, Mylan is entitled to indemnification from Merck KGaA under the Share Purchase Agreement. As a result, the Company has recorded approximately \$130.8 million in other assets.

Digitek® Recall

On April 25, 2008, Actavis Totowa LLC, a division of Actavis Group, announced a voluntary, nationwide recall of all lots and all strengths of Digitek® (digoxin tablets USP). Digitek is manufactured by Actavis and distributed in the United States by MPI and UDL. The Company has tendered its defense and indemnity in all lawsuits and claims arising from this event to Actavis, and Actavis has accepted that tender, subject to a reservation of rights. While the Company is unable to estimate total potential costs with any degree of certainty, such costs could be significant. To date, approximately 120 lawsuits have been filed against Mylan, UDL and Actavis pertaining to the recall. An adverse outcome in these lawsuits, or the inability or denial of Actavis to pay on an indemnified claim could have a materially negative impact on our financial position and results of operations.

Levetiracetam

In March 2004, Mylan Laboratories, Inc. and MPI, along with Dr. Reddy's Laboratories, Inc., were named in a civil lawsuit filed in the Northern District of Georgia by UCB Society Anonyme and UCB Pharma, Inc. (UCB) alleging infringement of U.S. Patent No. 4,943,639 relating to levetiracetam tablets. This litigation was settled in October 2007. Under the terms of the settlement, Mylan has the right to market 250 mg, 500 mg, and 750 mg levetiracetam tablets in the United States beginning on November 1, 2008, provided that UCB obtains pediatric exclusivity for its product and Mylan obtains final approval for its ANDA from the FDA. Pediatric exclusivity has been granted. In addition, by letter dated November 19, 2007, Mylan was notified by the FTC of an investigation

Table of Contents

MYLAN INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements (Unaudited) (Continued)

relating to the settlement of the levetiracetam patent litigation. In its letter, the FTC requested certain information from Mylan pertaining to the patent litigation and the settlement thereof. On April 9, 2008, the FTC issued a civil investigative demand to Mylan requesting additional information from Mylan relating to the investigation. Mylan is cooperating fully with the government's investigation and has complied with all requests for information.

Other Litigation

The Company is involved in various other legal proceedings that are considered normal to its business, including certain proceedings assumed as a result of the former Merck Generics business acquisition. 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 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 Transition Report on Form 10-KT/A for the nine-month period ended December 31, 2007, the unaudited interim Condensed Consolidated Financial Statements and related Notes included in Part I, 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 various 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.

Executive Overview

We are a leading global pharmaceutical company and have developed, manufactured, marketed, licensed and distributed high quality generic, branded and branded generic pharmaceutical products for more than 45 years. As a result of our acquisition of the former Merck Generics business in October 2007 and the acquisition of a controlling interest in Matrix in January 2007, we are the third largest generic pharmaceutical company in the world based on 2007 combined calendar year revenues, a leader in branded specialty pharmaceuticals and the third largest active pharmaceutical ingredient (API) manufacturer with respect to the number of drug master files, or DMFs, filed with regulatory agencies. We hold a leading generics sales position in four of the world's largest pharmaceutical markets: the United States, the United Kingdom (U.K.), France and Japan, and we also hold leading sales positions in several other key generics markets, including Australia, Belgium, Italy, Portugal and Spain.

Mylan previously had two reportable segments, the Mylan Segment and the Matrix Segment. With the acquisition of the former Merck Generics business, Mylan now has three reportable segments: the Generics Segment, the Specialty Segment, and the Matrix Segment. The former Mylan Segment is included within the Generics Segment. Additionally, certain general and administrative expenses, as well as litigation settlements, and non-operating income and expenses are reported in Corporate/Other. In accordance with Statement of Financial Accounting Standards (SFAS) No. 131, *Disclosures about Segments of an Enterprise and Related Information* (SFAS No. 131), information for earlier periods has been recast.

The measure of profitability (loss) used by the Company with respect to segments is gross profit less direct research and development expenses (R&D) and direct selling, general and administrative expenses (SG&A). The amortization of intangible assets, as well as certain purchase accounting related items, including the write-off of in-process research and development and the amortization of the inventory step-up, are excluded from segment profitability (loss).

Bystolic

In January 2006, the Company announced an agreement with Forest Laboratories Holdings, Ltd. (Forest), a wholly-owned subsidiary of Forest Laboratories, Inc., for the commercialization, development and distribution of Bystolic™ in the United States and Canada (the 2006 Agreement). Under the terms of that agreement, Mylan received a \$75.0 million up-front payment and \$25.0 million upon approval of the product. Such amounts were being deferred until the commercial launch of the product and were to be amortized over the remaining term of the

Table of Contents

license agreement. Mylan also had the potential to earn future milestones and royalties on Bystolic sales and an option to co-promote the product, while Forest assumed all future development and selling and marketing expenses.

In February 2008, Mylan executed an agreement with Forest whereby Mylan sold to Forest its rights to Bystolic (the Amended Agreement). Under the terms of the Amended Agreement, Mylan received a one-time cash payment of \$370.0 million, which was deferred along with the \$100.0 million received under the 2006 Agreement, and retained its contractual royalties for three years, through 2010. Mylan's obligations under the 2006 Agreement to supply Bystolic to Forest were unchanged by the Amended Agreement. Mylan believes that these supply obligations represented significant continuing involvement as Mylan remained contractually obligated to manufacture the product for Forest while the product is being commercialized. As a result of this continuing involvement, Mylan had been amortizing the \$470.0 million of deferred revenue ratably through 2020 pending the transfer of manufacturing responsibility that was anticipated to occur in the second half of 2008.

In September 2008, Mylan completed the transfer of all manufacturing responsibilities for the product to Forest and Mylan's current supply obligations have therefore been eliminated. The Company believes that it no longer has significant continuing involvement and that the earnings process has been completed. As such, the remaining deferred revenue of \$455.0 million was recognized and included in other revenues in the Company's Condensed Consolidated Statements of Operations.

Future royalties are considered to be contingent consideration and are recognized in other revenue as earned upon sales of the product by Forest. Such royalties are recorded at the net royalty rates specified in the Amended Agreement.

Issuance of Cash Convertible Notes

On September 15, 2008, Mylan announced that it completed the sale of \$575.0 million of 3.75% Cash Convertible Notes due 2015 (Cash Convertible Notes). The Cash Convertible Notes were sold in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended (the Securities Act). The amount includes \$75.0 million of notes sold pursuant to the initial purchasers' exercise of their overallotment option.

The Cash Convertible Notes, which are unsecured, will pay interest semi-annually at a rate of 3.75% per annum and will mature on September 15, 2015. The Cash Convertible Notes are convertible under certain circumstances into cash at an initial conversion reference rate of 75.0751 shares of Mylan's common stock per \$1,000 principal amount of notes (which is equal to an initial conversion reference price of approximately \$13.32 per share). The Cash Convertible Notes are not convertible into shares of Mylan common stock or any other securities.

The offering generated net proceeds, after deducting the initial purchasers' discount and estimated offering expenses, of approximately \$562.0 million. Of these net proceeds, approximately \$98.6 million was used to fund the net cost of convertible note hedge and warrant transactions. Mylan used \$300.0 million of the remaining net proceeds to pay down outstanding borrowings under its senior secured revolving credit facility and expects to use the remainder to pay down our senior term loan facilities in late December to avoid triggering prepayment penalties under such facilities.

Women's Health

On August 6, 2008, Mylan announced that it completed an agreement with Famy Care Ltd, a global, India-based manufacturing leader of women's health care products, to develop and supply 22 oral contraceptive (OC) medicines to customers in the United States. The agreement also provides Mylan with a right of first refusal for additional oral contraceptive products and certain additional markets, including Australia and Japan. Currently, total U.S. OC market sales are approximately \$3.3 billion, according to IMS. Of the 42 OC products available, 31 are sold generically.

Table of Contents***Goodwill Impairment***

On February 27, 2008, the Company announced that it was reviewing strategic alternatives for its specialty business, Dey, including the potential sale of the business. This decision was based upon several factors, including a strategic review of the business, the expected performance of the Perforomist™ product, where anticipated growth was determined to be slower than expected and the timeframe to reach peak sales was determined to be longer than was originally anticipated.

As a result of our ongoing review of strategic alternatives, we determined that it was more likely than not that the business would be sold or otherwise disposed of significantly before the end of its previously estimated useful life. Accordingly, a recoverability test of Dey's long-lived assets was performed during the three months ended March 31, 2008 in accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS No. 144). We included both cash flow projections and estimated proceeds from the eventual disposition of the long-lived assets. The estimated undiscounted future cash flows exceeded the book values of the long-lived assets and, as a result, no impairment charge was recorded.

Upon the closing of the former Merck Generics business transaction, Dey was defined as the Specialty Segment under the provisions of SFAS No. 131. Dey is also considered a reporting unit under the provisions of SFAS No. 142, *Goodwill and Other Intangible Assets* (SFAS No. 142). Upon closing of the transaction, the Company allocated \$711.2 million of goodwill to Dey.

The Company tests goodwill for possible impairment on an annual basis and at any other time events occur or circumstances indicate that the carrying amount of goodwill may be impaired. As we had determined that it was more likely than not that the business would be sold or otherwise disposed of significantly before the end of its previously estimated useful life, the Company was required during the three months ended March 31, 2008 to assess whether any portion of its recorded goodwill balance was impaired.

The first step of the SFAS No. 142 impairment analysis consisted of a comparison of the fair value of the reporting unit with its carrying amount, including the goodwill. We performed extensive valuation analyses, utilizing both income and market approaches, in our goodwill assessment process. The following describes the valuation methodologies used to derive the estimated fair value of the reporting unit.

Income Approach: To determine fair value, we discounted the expected future cash flows of the reporting unit. We used a discount rate, which reflects the overall level of inherent risk and the rate of return an outside investor would expect to earn. To estimate cash flows beyond the final year of our model, we used a terminal value approach. Under this approach, we used estimated operating income before interest, taxes, depreciation and amortization in the final year of our model, adjusted to estimate a normalized cash flow, applied a perpetuity growth assumption, and discounted by a perpetuity discount factor to determine the terminal value. We incorporated the present value of the resulting terminal value into our estimate of fair value.

Market-Based Approach: To corroborate the results of the income approach described above, we estimated the fair value of our reporting unit using several market-based approaches, including the guideline company method which focuses on comparing our risk profile and growth prospects to a select group of publicly traded companies with reasonably similar guidelines.

Based on the SFAS No. 142 step one analysis that was performed for Dey, the Company determined that the carrying amount of the net assets of the reporting unit was in excess of its estimated fair value. As such, the Company was required to perform the step two analysis for Dey, in order to determine the amount of any goodwill impairment. The step two analysis consisted of comparing the implied fair value of the goodwill with the carrying amount of the

goodwill, with an impairment charge resulting from any excess of the carrying value of the goodwill over the implied fair value of the goodwill based on a hypothetical allocation of the estimated fair value to the net assets. Based on the second step analysis, the Company concluded that \$385.0 million of the goodwill recorded at Dey was impaired. As a result, the Company recorded a non-cash goodwill impairment charge of \$385.0 million during the three months ended March 31, 2008, which represented our best estimate as of March 31, 2008. The allocation discussed above was performed only for purposes of assessing goodwill for impairment; accordingly, we have not adjusted the net book value of the assets and liabilities on the Company's Condensed Consolidated Balance Sheet, other than goodwill, as a result of this process.

Table of Contents

The determination of the fair value of the reporting unit required the Company to make significant estimates and assumptions that affect the reporting unit's expected future cash flows. These estimates and assumptions primarily include, but are not limited to, the discount rate, terminal growth rates, operating income before depreciation and amortization, and capital expenditures forecasts. Due to the inherent uncertainty involved in making these estimates, actual results could differ from those estimates. In addition, changes in underlying assumptions would have a significant impact on either the fair value of the reporting unit or the goodwill impairment charge.

The hypothetical allocation of the fair value of the reporting unit to individual assets and liabilities within the reporting unit also requires the Company to make significant estimates and assumptions. The hypothetical allocation requires several analyses to determine the estimate of the fair value of assets and liabilities of the reporting unit.

In September 2008, following the completion of the comprehensive review of strategic alternatives for Dey, the Company announced its decision to retain the Dey business. This decision includes a plan to realign the business, including positioning the Company to divest Dey's current facilities over the next two years. (See Note 15 to the Condensed Consolidated Financial Statements). The Company has yet to finalize the plan and therefore not yet estimated the total amount expected to be incurred with respect to such activities but the amount could be significant.

Financial Summary

Mylan's financial results for the three months ended September 30, 2008, included total revenues of \$1.66 billion compared to \$477.1 million for the three months ended September 30, 2007. This represents an increase in revenues of \$1.18 billion. Consolidated gross profit for the current quarter was \$911.1 million compared to \$221.6 million in the same prior year period, an increase of \$689.5 million. For the current quarter, operating earnings of \$560.8 million were realized compared to \$91.9 million for the prior year three months ended September 30, 2007.

The net earnings before preferred dividends for the current quarter was \$206.8 million compared to net earnings of \$149.8 million in the comparable prior year period. This translates into earnings per diluted common share of \$0.45 for the three months ended September 30, 2008, compared to earnings per diluted common share of \$0.60 for the comparable three-month period. The results were affected by the following items:

Three Months Ended September 30, 2008:

The recognition of \$455.0 million of previously deferred revenue related to Mylan's sale of the product rights of Bystolic;

\$105.4 million, which consisted primarily of incremental amortization related to purchased intangible assets and the amortization of the inventory step-up (\$23.9 million, pre-tax) associated with the acquisition of the former Merck Generics business; and

152.8 million shares of common stock assumed outstanding for the full quarter under the if-converted method related to the convertible preferred stock issuance in November 2007. (See Note 8 to the Condensed Consolidated Financial Statements).

Three Months Ended September 30, 2007:

\$12.4 million of similar purchase accounting related items recorded primarily with respect to the Matrix acquisition.

In addition to the above, the earnings per diluted common share in the current quarter was impacted by the issuance of 55.4 million shares of common stock in November 2007. A more detailed discussion of the Company's financial results can be found below in the section titled "Results of Operations".

Mylan's financial results for the nine months ended September 30, 2008, include total revenues of \$3.93 billion compared to \$1.51 billion for the nine months ended September 30, 2007. This represents an increase in revenues of

Table of Contents

\$2.42 billion. Consolidated gross profit for the nine months ended September 30, 2008 was \$1.68 billion compared to \$753.2 million in the same prior year period, an increase of \$922.4 million. For the nine months ended September 30, 2008, operating earnings of \$263.3 million was realized compared to \$272.2 million for the same prior year period.

The net loss available to common shareholders for the nine months ended September 30, 2008 was \$280.3 million compared to net earnings of \$158.3 million in the comparable prior year period. This translates into a loss per diluted common share of \$0.92 for the nine months ended September 30, 2008, compared to earnings per diluted common share of \$0.65 for the comparable nine-month period. The results were affected by the following items:

Nine Months Ended September 30, 2008:

The recognition of \$468.1 million of previously deferred revenue related to Mylan's sale of product rights of Bystolic;

\$335.7 million, which consisted primarily of incremental amortization related to purchased intangible assets and the amortization of the inventory step-up (\$89.6 million, pre-tax) associated with the acquisition of the former Merck Generics business;

A non-cash impairment loss on the goodwill of the Specialty Segment of \$385.0 million (pre-tax); and

A \$104.2 million (pre-tax and after-tax) dividend on the 6.50% mandatory convertible preferred stock.

Nine Months Ended September 30, 2007:

\$53.1 million of similar purchase accounting related items recorded primarily with respect to the Matrix acquisition; and

The write-off of acquired in-process research and development related to the Matrix acquisition of \$147.0 million (pre-tax and after-tax).

In addition to the above, the loss per diluted common share in the first nine months of 2008 was impacted by the issuance of 26.2 million shares of common stock in March 2007 and the issuance of 55.4 million shares of common stock in November 2007. Because the first offering occurred in March 2007, the loss per common share for the nine months ended September 30, 2007 did not bear the full impact of the new shares. However, these 26.2 million shares, as well as the additional 55.4 million shares were outstanding for the full nine months ended September 30, 2008. A more detailed discussion of the Company's financial results can be found below in the section titled "Results of Operations".

Results of Operations

Three Months Ended September 30, 2008, Compared to Three Months Ended September 30, 2007

Total Revenues and Gross Profit

For the current quarter, Mylan reported total revenues of \$1.66 billion compared to \$477.1 million in the same prior year period. This represents an increase of \$1.18 billion. The acquisition of the former Merck Generics business contributed revenues of \$687.2 million, of which \$561.7 million are included in the Generics Segment and \$125.4 million are included in the Specialty Segment. Also included in total revenues for the quarter is \$455.0 million of previously deferred revenue recognized related to the sale of our rights of Bystolic. Excluding the effects of the

former Merck Generics business acquisition and the Bystolic revenue, total sales for the three months ended September 30, 2008 were \$514.6 million. This represents an increase of approximately 8% or \$37.5 million over the comparable prior year period. Matrix contributed third-party revenues of \$90.3 million compared to \$80.0 million in the comparable prior year three-month period.

Gross profit for the three months ended September 30, 2008 was \$911.1 million and gross margins were 55.0%. For the three months ended September 30, 2007, gross profit was \$221.6 million and gross margins were 46.5%. Gross profit is impacted by certain purchase accounting related items recorded during the three months

Table of Contents

ended September 30, 2008 of approximately \$105.4 million, which consisted primarily of incremental amortization related to purchased intangible assets and the amortization of the inventory step-up associated with the acquisition of the former Merck Generics business. Excluding these items, as well as the Bystolic revenue, gross margins would have been approximately 46.7%. Prior year gross profit is also impacted by similar purchase accounting related items recorded primarily with respect to the Matrix acquisition in the amount of \$12.4 million. Excluding such items, gross margins in the prior year would have been approximately 49.1%.

The decrease in gross margins excluding the above items, is primarily due to the fact that, on average, the newly acquired former Merck Generics business particularly in countries outside of the United States, contribute margins that are lower than those realized by Mylan's domestic subsidiaries.

Generics Segment

For the current quarter, the Generics Segment reported total revenues of \$1.44 billion. Generics Segment total revenues are derived from sales primarily in or from the U.S. and Canada (collectively, North America), Europe, the Middle East and Africa (collectively, EMEA) and Australia, Japan and New Zealand (collectively, Asia Pacific).

Total revenues from North America were \$910.8 million for the three-month period ended September 30, 2008 compared to \$397.0 million for the three months ended September 30, 2007, representing an increase of \$513.8 million. In the current quarter, revenue of \$455.0 million is the result of the sale of Bystolic, as discussed above and revenue of \$30.7 million is the result of the acquisition of the former Merck Generics business. Excluding the impact of these items, total North America revenues increased by \$28.1 million or 7%. This increase is the result of new products, partially offset by unfavorable pricing. Volume had little impact on the change in revenues as doses shipped during the quarter, excluding the impact of the acquisition, increased by approximately 1%.

Fentanyl, Mylan's AB-rated generic alternative to Duragesic[®], continued to contribute significantly to the financial results. Despite the entrance into the market of additional generic competition in August 2007, volumes in the current quarter increased compared to the comparable prior year period as Mylan was able to supply to the market while certain competitors recalled their versions of the fentanyl patch. The Company expects additional competition in the future that may impact pricing and market share. The entrance into the market of additional generic competition upon Mylan's loss of exclusivity on amlodipine also had an unfavorable impact on the current quarter sales as compared to the prior year period. As is the case in the generic industry, the entrance into the market of additional competition generally has a negative impact on the volume and pricing of the affected products. In order to offset decreases in sales as a result of additional competition, generic pharmaceutical manufacturers must be able to successfully bring to market new products. During the three months ended September 30, 2008, new products contributed \$67.9 million to total revenues, with paroxetine being the most significant.

Total revenues from EMEA were \$393.9 million for the three months ended September 30, 2008, all of which were the result of the acquisition of the former Merck Generics business. Within EMEA, approximately 70% of net revenues are derived from the three largest markets: France, the U.K. and Germany.

Total revenues from Asia Pacific were \$137.6 million for the current quarter, all of which were the result of the acquisition of the former Merck Generics business. The majority of revenues from Asia Pacific are contributed by Alphapharm, Mylan's Australian subsidiary, with the remainder comprised of sales in Japan and New Zealand.

Certain markets in which the Company does business have recently undergone, some for the first time, or will soon undergo, government-imposed price reductions or similar pricing pressures on pharmaceutical products. This is true in France and Australia, though this issue is not limited to solely these markets. In addition, a number of markets in which we operate have implemented or may implement tender systems for generic pharmaceuticals in an effort to

lower prices. Such measures are likely to have a negative impact on sales and gross profit in these markets. However, some pro-generic government initiatives in certain markets could help to offset some of this unfavorability by potentially increasing generic substitution.

For the three months ended September 30, 2008, segment profitability for the Generics Segment was \$720.1 million compared to \$168.0 million in the comparable three month period. Of the current year amount, approximately \$455.0 million is a result of the recognition of the Bystolic revenue and \$70.2 million is due to the

Table of Contents

acquisition of the former Merck Generics business. Excluding these amounts, segment profitability increased by \$26.9 million as a result of higher sales and gross profit as discussed above.

Specialty Segment

For the current quarter, the Specialty Segment reported total revenues of \$130.6 million, of which \$125.4 million represented sales to third parties. The Specialty Segment consists of Dey, an entity acquired as part of the former Merck Generics business acquisition that focuses on the development, manufacturing and marketing of specialty pharmaceuticals in the respiratory and severe allergy markets. The most significant contributor to the Specialty Segment revenues and profitability is EpiPen, an epinephrine auto-injector, which is used in the treatment of severe allergies. EpiPen is the number one prescribed treatment for severe allergic reactions, with a market share of over 95%.

Segment profitability for the Specialty Segment for the three months ended September 30, 2008 was \$28.2 million.

Matrix Segment

For the three months ended September 30, 2008, the Matrix Segment reported total revenues of \$108.1 million, of which \$90.3 million represented third-party sales compared to total revenues of \$86.2 million, of which \$80.0 million represented third-party sales during the comparable period of the prior year. Approximately 70% of the Matrix Segment's third-party net revenues come from the sale of API and intermediates, approximately 20% comes from the distribution of branded generic products in Europe, and the majority of the remainder comes from the sale of Matrix's finished dosage form (FDF) anti-retroviral (ARV) products. Matrix launched its FDF business in late calendar year 2007. In addition to its net revenue, Matrix realized other revenue of \$13.9 million through intersegment product development agreements. Intersegment net revenue consists of API sales to the Generics Segment primarily in conjunction with Mylan's vertical integration strategy.

Segment profitability for the Matrix Segment for the current quarter was \$10.3 million compared to \$1.3 million in the comparable three-month period. An increase in revenue and gross profit, partially offset by higher R&D resulted in the increase in segment profitability.

Operating Expenses

R&D expense for the three months ended September 30, 2008 was \$74.7 million compared to \$33.6 million in the same prior year period. For the current quarter, R&D expense includes approximately \$32.4 million related to the newly acquired former Merck Generics business, all of which was incremental to the prior year. Excluding these amounts, R&D expense increased by \$8.8 million or 26.1%. Payments incurred with respect to product development, including those made to Famy Care Ltd, in conjunction with the Company's women's health care products initiative, were primarily responsible for the increase.

SG&A expense for the current quarter was \$275.6 million compared to \$97.0 million for the same period in the prior year, an increase of \$178.6 million. For the current quarter, SG&A expense includes approximately \$152.9 million related to the newly acquired former Merck Generics business, all of which was incremental to the prior year. Excluding these amounts, SG&A expense increased by \$25.6 million or 26.4%.

This increase was primarily realized by Corporate/Other. The increase in Corporate/Other SG&A expense is due primarily to an increase in professional and consulting fees associated primarily with the ongoing integration of the former Merck Generics business, as well as higher payroll and payroll related costs due to the build-up of additional corporate infrastructure, also a direct result of the former Merck Generics business acquisition.

Interest Expense

Interest expense for the three months ended September 30, 2008 totaled \$87.6 million compared to \$23.1 million for the three months ended September 30, 2007. The increase is due to the additional debt incurred to finance the acquisition of the former Merck Generics business.

Table of Contents*Other Income, net*

Other income, net, was \$5.8 million in the current quarter, comprised mostly of dividend and interest income, compared to \$166.8 million in the comparable three-month period. The comparable quarter of 2007 included a \$142.5 million non-cash mark to market unrealized gain on a deal-contingent foreign currency option contract that was entered into for the then pending acquisition of the former Merck Generics business. Excluding this unrealized gain, the decrease in other income, net, in the current quarter is due primarily to lower interest and dividend income as a result of lower cash and available for sale securities.

Income Tax Expense

The Company recognized income tax expense of \$272.4 million for the three-month period ended September 30, 2008 compared to \$88.5 million in the comparable prior year quarter.

Nine Months Ended September 30, 2008, Compared to Nine Months Ended September 30, 2007*Total Revenues and Gross Profit*

For the nine months ended September 30, 2008, Mylan reported total revenues of \$3.93 billion compared to \$1.51 billion in the same prior year period. This represents an increase of \$2.42 billion. The acquisition of the former Merck Generics business contributed revenues of \$1.99 billion, of which \$1.68 billion are included in the Generics Segment and \$308.5 million are included in the Specialty Segment. Also included in total revenues for the current year is \$468.1 million of previously deferred revenue recognized related to the sale of our rights of Bystolic. Excluding the effects of the former Merck Generics business acquisition and the Bystolic revenue, total sales for the nine months ended September 30, 2008 were \$1.47 billion. This represents a decrease of approximately 2.5% or \$38.1 million over the comparable prior year period. Matrix contributed third-party revenues of \$282.5 million compared to \$250.8 million in the comparable prior year nine-month period.

Gross profit for the nine months ended September 30, 2008 was \$1.68 billion and gross margins were 42.6%. For the nine months ended September 30, 2007, gross profit was \$753.2 million and gross margins were 49.9%. Gross profit is impacted by certain purchase accounting related items recorded during the nine months ended September 30, 2008 of approximately \$335.7 million, which consisted primarily of incremental amortization related to purchased intangible assets and the amortization of the inventory step-up associated with the acquisition of the former Merck Generics business. Excluding these items, as well as the Bystolic revenue, gross margins would have been approximately 44.5%. Prior year gross profit is also impacted by similar purchase accounting related items recorded with respect to the Matrix acquisition in the amount of \$53.1 million. Excluding such items, gross margins in the prior year would have been approximately 53.4%.

The decrease in gross margins excluding the above items related to certain purchase accounting related expenses for the acquisition of the former Merck Generics business and Matrix, as well as the revenue from Bystolic. Margins were negatively impacted by the loss of exclusivity on certain products. Products generally contribute most significantly to gross margin at the time of their launch and even more so in periods of market exclusivity or limited generic competition. For a period of time during the nine months ended September 30, 2007, Mylan had exclusivity on both amlodipine and oxybutynin. Additionally, the decrease in gross margin is due to the fact that, on average, the newly acquired former Merck Generics business, particularly in countries outside of the United States, contribute margins that are lower than those realized by Mylan domestic subsidiaries.

Generics Segment

For the nine months ended September 30, 2008, the Generics Segment reported total revenues of \$3.35 billion. Total revenues from North America were \$1.76 billion for the nine-month period ended September 30, 2008 compared to \$1.26 billion for the nine months ended September 30, 2007, representing an increase of \$504.8 million. In the current nine-month period, revenue of \$97.9 million is the result of the acquisition of the former Merck Generics business and \$468.1 million is the result of the sale of Bystolic, as discussed above. Excluding the impact of these items, total North America revenues decreased by \$61.2 million or 5%. This decrease is the result of unfavorable pricing as discussed below, partially offset by new product revenue and increased volume, as doses shipped during the nine months, excluding the impact of the acquisition, increased by 8% to 12.2 billion.

Table of Contents

Fentanyl continued to contribute significantly to the financial results despite the entrance into the market of additional generic competition in August 2007. As expected, the additional competition had an unfavorable impact on fentanyl pricing. The Company expects additional competition in the future that may impact pricing and market share. However, this was offset by increased volumes of fentanyl which Mylan was able to supply to the market as certain competitors recalled their versions of the fentanyl patch. Additional generic competition resulted in unfavorable pricing on several other significant products in the Company's portfolio. For two of these, amlodipine and oxybutynin, Mylan had market exclusivity for a portion of the prior year. As is the case in the generic industry, the entrance into the market of additional competition generally has a negative impact on the volume and pricing of the affected products. Helping to offset some of the unfavorable pricing experienced in the current year were products launched subsequent to September 30, 2007, which contributed revenues of \$154.0 million.

Total revenues from EMEA were \$1.17 billion for the nine months ended September 30, 2008, all of which were the result of the acquisition of the former Merck Generics business. Within EMEA, approximately 70% of net revenues are derived from the three largest markets: France, the U.K. and Germany.

Total revenues from Asia Pacific were \$407.9 million for the nine months ended September 30, 2008, all of which were the result of the acquisition of the former Merck Generics business. The majority of revenues from Asia Pacific are contributed by Alphapharm, Mylan's Australian subsidiary, with the remainder comprised of sales in Japan and New Zealand.

Certain markets in which the Company does business have recently undergone, some for the first time, or will soon undergo, government-imposed price reductions or similar pricing pressures on pharmaceutical products. This is true in France and Australia, though this issue is not limited to solely these markets. In addition, a number of markets in which we operate have implemented or may implement tender systems for generic pharmaceuticals in an effort to lower prices. Such measures are likely to have a negative impact on sales and gross profit in these markets. However, some pro-generic government initiatives in certain markets could help to offset some of this unfavorability by potentially increasing generic substitution.

For the nine months ended September 30, 2008, segment profitability for the Generics Segment was \$1.15 billion compared to \$608.0 million in the comparable nine month period. Of the current year amount, approximately \$468.1 million is related to the sale of Bystolic product rights and \$176.1 million is due to the acquisition of the former Merck Generics business. Excluding these amounts, segment profitability decreased by \$99.8 million. This decrease is the result of lower revenues and gross profit, as discussed above, as well as increased R&D expense, as further explained below.

Specialty Segment

For the nine months ended September 30, 2008, the Specialty Segment reported total revenues of \$336.0 million, of which \$308.5 million represented sales to third parties. The Specialty Segment consists of Dey, an entity acquired as part of the former Merck Generics business acquisition that focuses on the development, manufacturing and marketing of specialty pharmaceuticals in the respiratory and severe allergy markets. The most significant contributor to the Specialty Segment revenues and profitability is EpiPen, an epinephrine auto-injector, which is used in the treatment of severe allergies. EpiPen is the number one prescribed treatment for severe allergic reactions with a market share of over 95%.

Segment loss for the Specialty Segment for the nine months ended September 30, 2008 was \$334.6 million, which includes the first quarter \$385.0 million non-cash goodwill impairment charge.

Matrix Segment

For the nine months ended September 30, 2008, the Matrix Segment reported total revenues of \$330.3 million, of which \$282.5 million represented third-party sales compared to total revenues of \$282.5 million, of which \$250.8 million represented third-party sales during the prior year comparable period. Approximately 60% of the Matrix Segment's third-party net revenues comes from the sale of API and intermediates, approximately 20% comes from the distribution of branded generic products in Europe, and the majority of the remainder comes from the sale of Matrix's FDF ARV products. Matrix launched its FDF business in late calendar year 2007. In addition to

Table of Contents

its net revenue, Matrix realized other revenue of \$37.0 million through intersegment product development agreements. Intersegment net revenue consists of API sales to the Generics Segment primarily in conjunction with Mylan's vertical integration strategy.

Segment profitability for the Matrix Segment for the current nine-month period was \$20.2 million compared to \$17.0 million in the comparable nine-month period. In the current year, higher revenues and gross profit, partially offset by higher operating expenses, resulted in the year over year increase in segment profitability.

Operating Expenses

R&D expense for the nine months ended September 30, 2008 was \$239.3 million compared to \$102.1 million in the same prior year period. For the nine months ended September 30, 2008, R&D expense includes approximately \$116.6 million related to the newly acquired former Merck Generics business, all of which was incremental to the prior year. Excluding these amounts, R&D expense increased by \$20.5 million or 20.1% primarily as a result of increased ANDA and other regulatory submissions, payments incurred with respect to product development, including those made to Famy Care Ltd, in conjunction with the Company's women's health care products initiative, and higher expenses from Matrix's launch of its FDF franchise.

During the nine months ended September 30, 2007, the Company recognized a charge of \$147.0 million to write-off acquired in-process R&D associated with the Matrix acquisition. This amount represents the fair value of purchased in-process technology for research projects that, as of the closing date of the acquisition, had not reached technological feasibility and had no alternative future use.

SG&A expense for the nine months ended September 30, 2008 was \$788.0 million compared to \$236.7 million for the same period in the prior year, an increase of \$551.3 million. For the nine months, SG&A expense includes approximately \$458.5 million related to the newly acquired former Merck Generics business, all of which was incremental to the prior year. Excluding these amounts, SG&A expense increased by \$92.7 million or 39.2%. This increase was primarily realized by Corporate/Other. The increase in Corporate/Other SG&A expense is due primarily to an increase in professional and consulting fees as well as higher payroll and payroll related costs. The increase in professional and consulting fees is associated primarily with the ongoing integration of the former Merck Generics business. The increase in payroll and related costs is principally attributable to the build-up of additional corporate infrastructure as a direct result of the former Merck Generics business acquisition.

Interest Expense

Interest expense for the nine months ended September 30, 2008 totaled \$264.8 million compared to \$67.0 million for the nine months ended September 30, 2007. The increase is due to the additional debt incurred to finance the acquisition of the former Merck Generics business.

Other Income, net

Other income, net, was \$20.6 million for the nine months ended September 30, 2008, compared to \$140.9 million in the comparable nine-month period. The comparable period of 2007 included a \$85.0 million non-cash mark to market unrealized gain on a deal-contingent foreign currency option contract that was entered into for the then pending acquisition of the former Merck Generics business. Excluding this unrealized gain, the decrease in other income, net, in the current year is due primarily to lower interest and dividend income as a result of lower cash and available-for-sale securities.

Income Tax Expense

For the nine-month period ending September 30, 2008, the income tax expense was \$197.4 million as compared to \$190.5 million for the comparable nine-month period in the prior year. The effective tax rate in 2008 has been largely influenced by the gain on the sale of Bystolic, operating losses and the non-deductible goodwill impairment charge related to Dey. The effective tax rate reported in the prior year was impacted by the write-off of acquired in-process research and development related to the Matrix acquisition.

Table of Contents

Liquidity and Capital Resources

Cash flows from operating activities were \$249.2 million for the nine months ended September 30, 2008, consisting primarily of net income (after the non-cash add-backs for depreciation and amortization expense and the \$385.0 million of goodwill impairment related to Dey), offset by a decrease in deferred revenue of \$110.0 million, driven by the recognition of previously deferred amounts related to the sale of Bystolic rights, the deferred tax benefit of \$76.2 million and a net usage of cash through changes in working capital items.

A higher accounts receivable balance at September 30, 2008, resulted in a net usage of cash, and is the result of increased sales and the timing of cash collections from our customers. Inventory balances also increased during the nine-month period in line with forecasted production plans. An increase in accrued income taxes payable, due to the timing of tax payments, resulted in a net increase to operating cash.

Cash used in investing activities was \$99.2 million for the nine months ended September 30, 2008. Net sales of investments in available for sale securities, which consist of a variety of high-credit quality debt securities, including U.S. government, state and local government and corporate obligations, generated a net \$42.6 million in cash. These investments are highly liquid and available for working capital and other needs. As these instruments mature, the funds are generally reinvested in instruments with similar characteristics.

Capital expenditures during the nine months ended September 30, 2008 were \$101.7 million. These expenditures were incurred primarily for equipment, including with respect to the Company's previously announced planned expansions and integration plans with respect to the former Merck Generics business acquisition. Also included in investing activities was a cash outflow of \$40.0 million to secure a surety bond with respect to the Company's lorazepam and clorazepate litigation.

Cash provided by financing activities was \$20.9 million for the nine months ended September 30, 2008. Cash dividends of \$102.7 million were paid on the Company's 6.50% mandatory convertible preferred stock. In September of 2008, Mylan issued \$575.0 million in Cash Convertible Notes, which accounts for the majority of our total proceeds from long term debt of \$581.5 million. In conjunction with this offering, the Company entered into a convertible note hedge and warrant transaction that resulted in a net outflow of \$98.6 million. Of the net proceeds received from these transactions \$300.0 million were used to repay outstanding indebtedness. In total, debt repayments of \$392.2 million were made during the nine months ended September 30, 2008.

The convertible note hedge and warrant transactions were entered into between the Company and certain counterparties. The cash convertible note hedge is comprised of purchased cash-settled call options. The sale of the warrants resulted in cash proceeds of \$62.6 million which was used along with the proceeds from the issuance of the Cash Convertible Notes, to purchase the bond hedge for approximately \$161.2 million. Subject to the conversion provisions outlined in the Cash Convertible Notes Purchase Agreement, the Cash Convertible Notes have an initial conversion reference rate of 75.0751 shares of common stock per \$1,000 principal amount (equivalent to an initial conversion reference price of \$13.32 per share), subject to adjustment, with the principal amount and remainder payable in cash. The Cash Convertible Notes are not convertible into our common stock or any other securities under any circumstance (See Note 11 to our Condensed Consolidated Financial Statements).

The Company is involved in various legal proceedings that are considered normal to its business (See Note 16 to our 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.

Edgar Filing: MYLAN INC. - Form 10-Q

The Company's Condensed Consolidated Balance Sheet as of September 30, 2008, includes a \$72.1 million restructuring reserve, which relates to certain estimated exit costs associated with the acquisition of the former Merck Generics business. The plans related to these exit activities have now been finalized. Payments of approximately \$5.0 million were made during the nine months ended September 30, 2008, of which \$2.9 million were severance costs and the remaining \$2.1 million were for other exit costs.

The Company announced its intent to restructure certain activities and incur certain related exit costs unrelated to the former Merck Generics business acquisition. At September 30, 2008, the Company met all the criteria in SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* (SFAS No. 146), and has

Table of Contents

recorded a reserve for such activities of approximately \$0.7 million. This restructuring charge is included in operating expenses in the Company's Condensed Consolidated Statement of Operations for the nine months ended September 30, 2008. As finalization of the plan is still in progress, the Company has not yet estimated the total amount expected to be incurred in connection with such activities. However, Mylan expects the majority of such costs will relate to one-time termination benefits and certain asset write-downs and could be significant.

As discussed in the Executive Overview, the Company is planning to realign the Dey business. As a result, the Company expects to incur one-time termination benefits and acceleration of depreciation expense related to the planned disposition of Dey's current facilities. The Company has yet to finalize the plan and therefore not yet estimated the total amount expected to be incurred with respect to such activities but the amount could be significant.

The Company is actively pursuing, and is currently involved in, joint projects related to the development, distribution and marketing of both generic and branded 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. In addition, on an ongoing basis, the Company reviews its operations including the evaluation of potential divestitures of products and businesses as part of our future strategy. Any divestitures could impact future liquidity.

Mandatory minimum repayments remaining on the outstanding borrowings under the term loans and convertible notes at September 30, 2008 are as follows for each of the periods ending December 31st below:

	U.S. Tranche A Term Loans	Euro Tranche A Term Loans	U.S. Tranche B Term Loans	Euro Tranche B Term Loans	Senior Convertible Notes	Cash Convertible Notes	Total
(In thousands)							
2008	\$ 3,906	\$ 6,328	\$ 6,390	\$ 1,896	\$	\$	\$ 18,520
2009	31,250	50,616	25,560	7,583			115,009
2010	46,875	75,924	25,560	7,583			155,942
2011	62,500	101,232	25,560	7,583			196,875
2012	78,125	126,540	25,560	7,583	600,000		837,808
2013	78,125	126,540	25,560	7,583			237,808
Thereafter			2,402,640	712,843		625,801	3,741,284
Total	\$ 300,781	\$ 487,180	\$ 2,536,830	\$ 752,654	\$ 600,000	\$ 625,801	\$ 5,303,246

Recent Accounting Pronouncements

In June 2008, the Financial Accounting Standards Board (FASB) issued FASB Staff Position (FSP) No. EITF 03-6-1, *Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities* (FSP

No. EITF 03-6-1). FSP No. EITF 03-6-1 states that unvested share-based payment awards that contain nonforfeitable rights to dividends or dividend equivalents (whether paid or unpaid) are participating securities and shall be included in the computation of earnings per share pursuant to the two-class method. FSP No. EITF 03-6-1 is effective for fiscal years beginning after December 15, 2008. The Company is currently evaluating the impact of adopting FSP No. EITF 03-6-01 on its consolidated financial statements.

In May 2008, the FASB issued FSP No. APB 14-a, *Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement)* (FSP No. APB 14-a). Under the new rules for convertible debt instruments (including our Senior Convertible Notes) that may be settled entirely or partially in cash upon conversion, an entity should separately account for the liability and equity components of the instrument in a manner that reflects the issuer's economic interest cost. The effect of the new rules for the debentures is that the equity component would be included in the paid-in-capital section of stockholders' equity on our consolidated

Table of Contents

balance sheet and the value of the equity component would be treated as original issue discount for purposes of accounting for the debt component of the Senior Convertible Notes. FSP No. APB 14-a will be effective for fiscal years beginning after December 15, 2008, and for interim periods within those fiscal years, with retrospective application required. Higher interest expense would result through the accretion of the discounted carrying value of the Senior Convertible Notes to their face amount over the term of the Senior Convertible Notes. Prior period interest expense will also be higher than previously reported interest expense due to retrospective application. Early adoption is not permitted. The Company is currently evaluating the proposed new rules and the impact of adopting FSP No. APB 14-a on its consolidated financial statements.

In April 2008, the FASB issued FSP No. FAS 142-3, *Determination of the Useful Life of Intangible Assets* (FSP No. FAS 142-3). FSP No. FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB SFAS No. 142 in order to improve the consistency between the useful life of a recognized intangible asset under SFAS No. 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS No. 141(R) and other accounting principles generally accepted in the United States, (GAAP). FSP No. FAS 142-3 is effective for fiscal years beginning after December 15, 2008. The Company is currently evaluating the impact of adopting FSP No. FAS 142-3 on its consolidated financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements an amendment of ARB No. 51* (SFAS No. 160). SFAS No. 160 amends Accounting Research Bulletin No. 51, *Consolidated Financial Statements*, to establish accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. This standard defines a noncontrolling interest, sometimes called a minority interest, as the portion of equity in a subsidiary not attributable, directly or indirectly, to a parent. SFAS No. 160 requires, among other items, that a noncontrolling interest be included in the consolidated balance sheet within equity separate from the parent's equity; consolidated net income to be reported at amounts inclusive of both the parent's and noncontrolling interest's shares and, separately, the amounts of consolidated net income attributable to the parent and noncontrolling interest all on the consolidated statement of operations; and if a subsidiary is deconsolidated, any retained noncontrolling equity investment in the former subsidiary be measured at fair value and a gain or loss be recognized in net income based on such fair value. SFAS No. 160 is effective for fiscal years beginning after December 15, 2008. The Company is currently evaluating the potential impact of adopting SFAS No. 160 on its consolidated financial statements.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities an amendment of FASB Statement No. 133* (SFAS No. 161). SFAS No. 161 requires enhanced disclosures about an entity's derivative and hedging activities, including (i) how and why an entity uses derivative instruments, (ii) how derivative instruments and related hedged items are accounted for under SFAS No. 133, and (iii) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. This standard is effective for fiscal years beginning after November 15, 2008. Management is currently assessing the impact on the disclosures on the Company's consolidated financial statements.

In March 2008, the Emerging Issues Task Force (EITF) issued EITF No. 07-5, *Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity's Own Stock* (EITF No. 07-5). EITF No. 07-5 states that if an instrument (or an embedded feature) has the characteristics of a derivative instrument under paragraphs 6-9 of SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, and is indexed to an entity's own stock, it is necessary to evaluate whether it is classified in stockholders' equity (or would be classified in stockholders' equity if it were a freestanding instrument). EITF No. 07-5 is effective for fiscal years beginning after December 15, 2008. The Company is currently evaluating the impact of adopting EITF No. 07-5 on its consolidated financial statements.

On January 1, 2008, the Company adopted SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities including an amendment of FASB Statement No. 115* (SFAS No. 159). SFAS No. 159 permits entities to choose to measure many financial instruments and certain other assets and liabilities at fair value on an instrument-by-instrument basis (the fair value option) with changes in fair value reported in earnings. The Company already records marketable securities at fair value in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities* (SFAS No. 115), and derivative contracts and hedging

Table of Contents

activities at fair value in accordance with SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities, as amended* (SFAS No. 133). The adoption of SFAS No. 159 did not have a material impact on the Company's Condensed Consolidated Financial Statements as management did not elect the fair value option for any other financial instrument or certain other assets and liabilities.

On January 1, 2008, the Company adopted Statement 133 Implementation Issue No. E23, *Hedging – General: Issues Involving the Application of the Shortcut Method under Paragraph 58* (Issue No. E23). Issue No. E23 provides guidance on certain practice issues related to the application of the shortcut method by amending paragraph 68 of SFAS No. 133 with respect to the conditions that must be met in order to apply the shortcut method for assessing hedge effectiveness of interest rate swaps. In addition to applying the provisions of Issue No. E23 on hedging arrangements designated on or after January 1, 2008, an assessment was required to be made on January 1, 2008 to determine whether preexisting hedging arrangements met the provisions of Issue No. E23 as of their original inception. Management performed such an assessment and determined that the adoption of Issue No. E23 did not have a material impact on preexisting hedging arrangements.

In March 2007, the EITF issued EITF No. 06-10, *Accounting for Collateral Assignment Split-Dollar Life Insurance Arrangements* (EITF No. 06-10). Under the provisions of EITF No. 06-10, an employer is required to recognize a liability for the postretirement benefit related to a collateral assignment split-dollar life insurance arrangement with the employee. The provisions of EITF No. 06-10 also require an employer to recognize and measure the asset in a collateral assignment split-dollar life insurance arrangement based on the nature and substance of the arrangement. The Company adopted the provisions of EITF No. 06-10 as of January 1, 2008. As a result of the adoption, the Company recognized a liability of \$8.3 million, representing the present value of the future premium payments to be made under the existing policies. In accordance with the transition provisions of EITF No. 06-10, this amount was recorded as a direct decrease to retained earnings.

In March 2007, the EITF issued EITF No. 06-04, *Accounting for Deferred Compensation and Postretirement Benefit Aspects of Endorsed Split-Dollar Life Insurance Arrangements* (EITF No. 06-4), which concludes that an employer should recognize a liability for post-employment benefits promised an employee based on the substantive arrangement between the employer and the employee. The Company adopted the provisions of EITF No. 06-04 as of January 1, 2008. The adoption of EITF No. 06-04 did not have a material impact on the Company's Condensed Consolidated Financial Statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

For a discussion of the Company's market risk, see Item 7A. Quantitative and Qualitative Disclosures About Market Risk in the Company's Transition Report filed on Form 10-KT/A for the nine months ended December 31, 2007.

During the nine months ended September 30, 2008, we executed an incremental \$500.0 million of notional interest rate swaps in order to fix the interest rate on a portion of our U.S. Tranche B Term Loans. These swaps are designated as cash flow hedges of the variability of interest expense related to our variable rate debt and fix a rate of 5.44% until March 2010. In October 2008, the Company executed an additional \$500.0 million of notional interest rate swaps in order to fix the interest rate on a portion of our U.S. Tranche B Term Loans. These swaps fix a rate of 6.03% on our variable rate debt until December 2010 and are designated as a cash flow hedge of expected future borrowings under the Credit Agreement.

The purchased cash-settled call options entered into as part of the Cash Convertible Notes meet the definition of derivatives under SFAS No. 133. As such, the instrument will be marked to market each period. In addition, the liability associated with the cash conversion feature of the Cash Convertible Notes will be marked to market each period. At September 30, 2008, the \$625.8 million liability recorded for the Cash Convertible Notes consists of

\$414.8 million of debt (\$575.0 million face amount, net of \$160.2 million discount) and a liability with a fair value of \$211.0 million related to the bifurcated conversion feature. The purchased call options are assets recorded at their fair value of \$211.0 million within other assets in the Condensed Consolidated Balance Sheet at September 30, 2008.

Table of Contents

At September 30, 2008, the fair value of the Cash Convertible Notes was approximately \$350.2 million. Subsequent to September 30, 2008, the fair value of the Cash Convertible Notes has increased and at October 31, 2008 was approximately \$429.4 million.

At September 30, 2008, and December 31, 2007, the fair value of the Senior Convertible Notes was approximately \$458.0 million and \$545.5 million. Subsequent to September 30, 2008, the fair value of the Senior Convertible Notes has continued to decrease and at October 31, 2008 was approximately \$392.3 million.

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, 2008. Based upon that evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective.

By the end of the third quarter, the various support services provided by Merck KGaA under the transitional services agreement, under which various support services were being provided by Merck KGaA, were terminated as planned. These services were being performed primarily in the EMEA region. Upon termination, the Company is now performing such services utilizing enhanced support systems.

No significant issues were noted from this transition. There were no other changes in our internal control over financial reporting that occurred during the quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. 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. The Company is also party to certain litigation matters, some of which are described below, for which Merck KGaA has agreed to indemnify the Company, under the terms of the Share Purchase Agreement by which Mylan acquired the former Merck Generics business. An adverse outcome in any of these proceedings, or the inability or denial of Merck KGaA to pay an indemnified claim, could have a material adverse effect on the Company's financial position and results of operations.

Omeprazole

On May 17, 2000, Mylan Pharmaceuticals Inc. (MPI) filed an Abbreviated New Drug Application (ANDA) seeking approval from the U.S. Food and Drug Administration (FDA) to manufacture, market and sell omeprazole delayed-release capsules and on August 8, 2000 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 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 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 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. MPI has certain

indemnity obligations to Esteve in connection with this litigation. On May 31, 2007, the district court ruled in Mylan's and Esteve's favor by finding that the asserted patents were not infringed by Mylan's/Esteve's products. On July 18, 2007, AstraZeneca appealed the decision to the United States Court of Appeals for the Federal Circuit. On June 10, 2008, the appellate court issued a judgment and decision affirming the district court's finding of noninfringement and the mandate was issued on July 1, 2008.

Table of Contents***Lorazepam and Clorazepate***

On June 1, 2005, a jury verdict was rendered against Mylan, MPI, and co-defendants Cambrex Corporation and Gyma Laboratories in the U.S. District Court for the District of Columbia (D.C.) in the amount of approximately \$12.0 million, which has been accrued for by the Company. The jury found that Mylan and its co-defendants willfully violated Massachusetts, Minnesota and Illinois state antitrust laws in connection with API supply agreements entered into between the Company and its API supplier (Cambrex) and broker (Gyma) for two drugs, lorazepam and clorazepate, in 1997, and subsequent price increases on these drugs in 1998. The case was brought by four health insurers who opted out of earlier class action settlements agreed to by the Company in 2001 and represents the last remaining antitrust claims relating to Mylan's 1998 price increases for lorazepam and clorazepate. Following the verdict, the Company filed a motion for judgment as a matter of law, a motion for a new trial, a motion to dismiss two of the insurers and a motion to reduce the verdict. On December 20, 2006, the Company's motion for judgment as a matter of law and motion for a new trial were denied and the remaining motions were denied on January 24, 2008. In post-trial filings, the plaintiffs requested that the verdict be trebled and that request was granted on January 24, 2008. On February 6, 2008, a judgment was issued against Mylan and its co-defendants in the total amount of approximately \$69.0 million, some or all of which may be subject to indemnification obligations by Mylan. Plaintiffs are also seeking an award of attorneys' fees and litigation costs in unspecified amounts and prejudgment interest of approximately \$9.0 million. The Company and its co-defendants have appealed to the U.S. Court of Appeals for the D.C. Circuit. The appeals have been held in abeyance pending a ruling on the motion for prejudgment interest. In connection with the Company's appeal of the lorazepam Judgment, the company submitted a surety bond underwritten by a third-party insurance company in the amount of \$74.5 million. This surety bond is secured by a pledge of a \$40.0 million cash deposit (which is included as restricted cash on the Company's Condensed Consolidated Balance Sheet as of September 30, 2008) and an irrevocable letter of credit for \$34.5 million issued under the Senior Credit Agreement. On October 27, 2008, a U.S. magistrate judge issued a report recommending the granting of plaintiffs' motion for prejudgment interest. The report also recommends requiring the surety bond amount to be increased to include prejudgment interest. Mylan intends to submit objections to the magistrate judge's recommendations after which the district court will determine whether to accept or reject those recommendations. If the magistrate's recommendations on prejudgment interest are accepted, Mylan intends to contest these rulings as part of its pending appeal.

Pricing and Medicaid Litigation

On June 26, 2003, MPI and UDL Laboratories Inc. (UDL) 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 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, MPI and/or UDL, together with many other pharmaceutical companies, have been named in 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, MPI and/or UDL have been named as defendants in substantially similar civil lawsuits filed by the AGs

of Alabama, Alaska, California, Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Massachusetts, Mississippi, Missouri, South Carolina, Texas, Utah 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 recently filed Kansas case, Mylan, MPI and/or UDL have either moved to dismiss the complaints or have answered the complaints denying liability. Mylan and its subsidiaries intend to defend each of these actions vigorously.

In May 2008, an amended complaint was filed in the U.S. District Court for the District of Massachusetts by a plaintiff on behalf of the United States of America, against Mylan, MPI, UDL and several other generic manufacturers. The original complaint was filed under seal in April 2000, and Mylan, MPI and UDL were added as parties in February 2001. The claims against Mylan, MPI, UDL and the other generic manufacturers were severed from the April 2000 complaint (which remains under seal) as a result of the federal government's decision not to intervene in the action as to those defendants. The complaint alleges violations of the False Claims Act and sets forth allegations substantially similar to those alleged in the state AG cases mentioned in the preceding paragraph and purports to seek recovery of any and all alleged overpayment of the federal share under the Medicaid program. Mylan has moved to dismiss the complaint and intends to defend the action vigorously.

In addition, by letter dated January 12, 2005, MPI was notified by the U.S. Department of Justice of an investigation concerning calculations of Medicaid drug rebates. The investigation involves whether MPI and UDL may have violated the False Claims Act or other laws by classifying certain authorized generics launched in the 1990's and early 2000's as non-innovator rather than innovator drugs for purposes of Medicaid and other federal healthcare programs until 2005. MPI and UDL deny the government's allegations and deny that they engaged in any wrongful conduct. Based on our understanding of the government's allegations, the alleged difference in rebates for the MPI and UDL products currently at issue may be up to approximately \$100.0 million, which includes interest. Remedies under the False Claims Act could include treble damages and penalties. MPI and UDL have been cooperating fully with the government's investigation and are currently in discussions with the government about a possible resolution of the matter. Additionally, the Company believes that it has contractual and other rights to recover from the innovator a substantial portion of any payments that MPI and UDL may remit to the government. The Company has not recorded any amounts in the consolidated financial statements related to this matter.

Dey, L.P. is a defendant currently in lawsuits brought by the state AG's of Arizona, California, Florida, Illinois, Iowa, Kansas, Kentucky, Mississippi, Pennsylvania, South Carolina (on behalf of the state and the state health plan), Utah and Wisconsin and the city of New York and approximately 40 New York counties. Dey is also named as a defendant in several class actions brought by consumers and third-party payors. Dey has reached a settlement of most of these class actions, which has been preliminarily approved by the court. Additionally, the U.S. federal government filed a claim against Dey, L.P. in August 2006. These cases all generally allege that Dey falsely reported certain price information concerning certain drugs marketed by Dey. Dey intends to defend each of these actions vigorously. In conjunction with the former Merck Generics business acquisition by Mylan, Mylan is entitled to indemnification by Merck KGaA for these Dey pricing related suits.

Modafinil Antitrust Litigation and FTC Inquiry

Beginning in April 2006, Mylan, along with four other drug manufacturers, has been named as a defendant in 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 a third-party payor 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 motions to dismiss each action are pending, with the exception of the third-party payor action, in which Mylan's response to the complaint is not due until the motions filed in the other cases have been decided. Mylan 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, MPI and Mylan Technologies Inc. (MTI) pertaining to the patent litigation and the settlement thereof. On March 29, 2007, the FTC issued a subpoena, and on April 26, 2007, the FTC issued a civil investigative demand to Mylan requesting additional information from the Company relating to the investigation. Mylan is cooperating fully with the government s investigation and completed all requests for information. On February 13, 2008, the FTC filed a lawsuit against Cephalon in the U.S. District Court for the District of Columbia and the case has subsequently

Table of Contents

been transferred to the U.S. District Court for the Eastern District of Pennsylvania. Mylan is not named as a defendant in the FTC's lawsuit, although the complaint includes certain allegations pertaining to the Mylan/Cephalon settlement.

Litigation related to the former Merck Generics Business

Generics UK Ltd. is accused of having been involved in pricing agreements pertaining to certain drugs during the years 1996 to 2000. Generics UK Ltd. was able to settle civil claims for damages brought by the Health Service in England and Wales out of court, without any admission of liability. Additional claims have been filed against Generics UK Ltd. and others by health authorities in Scotland and Northern Ireland totaling £21.0 (\$38.2) million exclusive of interest. In addition to these civil claims, in 2006 criminal proceedings were filed in Southwark Crown Court against Generics UK Ltd. and other companies, as well as against a number of individuals who were alleged to be responsible for decision making in the companies. In early 2008, the House of Lords ruled that a price fixing cartel was not at the relevant times a criminal offense. The case was remanded back to the Crown Court for the prosecution to make an application to amend the indictment. On July 11, 2008, the Crown Court refused to allow the prosecution's application, quashed the indictment and denied the prosecution's application for permission to appeal. On July 17, 2008, the prosecution applied to the Court of Appeal (Criminal Division) for permission to appeal. A hearing to decide the prosecution's application is due to take place in December 2008.

The Company has approximately \$129.7 million recorded in other liabilities related to the litigation involving Dey and Generics UK Ltd. As stated above, in conjunction with the former Merck Generics business acquisition, Mylan is entitled to indemnification from Merck KGaA under the Share Purchase Agreement. As a result, the Company has recorded approximately \$130.8 million in other assets.

Digitek® Recall

On April 25, 2008, Actavis Totowa LLC, a division of Actavis Group, announced a voluntary, nationwide recall of all lots and all strengths of Digitek® (digoxin tablets USP). Digitek is manufactured by Actavis and distributed in the United States by MPI and UDL. The Company has tendered its defense and indemnity in all lawsuits and claims arising from this event to Actavis, and Actavis has accepted that tender, subject to a reservation of rights. While the Company is unable to estimate total potential costs with any degree of certainty, such costs could be significant. To date, approximately 120 lawsuits have been filed against Mylan, UDL and Actavis pertaining to the recall. An adverse outcome in these lawsuits, or the inability or denial of Actavis to pay on an indemnified claim could have a materially negative impact on our financial position and results of operations.

Levetiracetam

In March 2004, Mylan Laboratories, Inc. and MPI, along with Dr. Reddy's Laboratories, Inc., were named in a civil lawsuit filed in the Northern District of Georgia by UCB Society Anonyme and UCB Pharma, Inc. (UCB) alleging infringement of U.S. Patent No. 4,943,639 relating to levetiracetam tablets. This litigation was settled in October 2007. Under the terms of the settlement, Mylan has the right to market 250 mg, 500 mg, and 750 mg levetiracetam tablets in the United States beginning on November 1, 2008, provided that UCB obtains pediatric exclusivity for its product and Mylan obtains final approval for its ANDA from the FDA. Pediatric exclusivity has been granted. In addition, by letter dated November 19, 2007, Mylan was notified by the FTC of an investigation relating to the settlement of the levetiracetam patent litigation. In its letter, the FTC requested certain information from Mylan pertaining to the patent litigation and the settlement thereof. On April 9, 2008, the FTC issued a civil investigative demand to Mylan requesting additional information from Mylan relating to the investigation. Mylan is cooperating fully with the government's investigation and has complied with all requests for information.

Other Litigation

The Company is involved in various other legal proceedings that are considered normal to its business, including certain proceedings assumed as a result of the former Merck Generics business acquisition. 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 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.

CURRENT ECONOMIC CONDITIONS MAY ADVERSELY AFFECT OUR INDUSTRY, BUSINESS AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

The global economy is currently undergoing a period of unprecedented volatility, and the future economic environment may continue to be less favorable than that of recent years. This has led, and could further lead, to reduced consumer spending in the foreseeable future, and this may include spending on healthcare. While generic drugs present an ideal alternative to higher-priced branded products, our sales could be negatively impacted if patients forego obtaining healthcare. In addition, reduced consumer spending may drive us and our competitors to decrease prices. These conditions may adversely affect our industry, business and results of operations and may cause the market value of our common stock to decline.

OUR ACQUISITION OF THE FORMER MERCK GENERICS BUSINESS INVOLVES A NUMBER OF INTEGRATION RISKS. THESE RISKS COULD CAUSE 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 acquisition of the former Merck Generics business involves a number of integration risks, including but not limited to:

- difficulties in successfully integrating the facilities, operations and personnel of the former Merck Generics business with our historical business and corporate culture;
- difficulties in achieving identified financial and operating synergies;
- diversion of management's attention from our ongoing business concerns to integration matters;
- the potential loss of key personnel or customers;
- difficulties in consolidating information technology platforms and corporate infrastructure;
- difficulties in transitioning the former Merck Generics business and products from the Merck name to achieve a global brand alignment;
- our substantial indebtedness and assumed liabilities;
- the incurrence of significant additional capital expenditures, operating expenses and non-recurring acquisition-related charges;
- challenges in operating in other markets outside of the United States that are new to us; and

unanticipated effects of export controls, exchange rate fluctuations, domestic and foreign political conditions or domestic and foreign economic conditions.

These factors could impair our growth and ability to compete, require us to focus additional resources on integration of operations rather than other profitable areas, or otherwise cause a material adverse effect on our business, financial position and results of operations and could cause a decline in the market value of our common stock.

Table of Contents

WE MAY FAIL TO REALIZE THE EXPECTED COST SAVINGS, GROWTH OPPORTUNITIES AND OTHER BENEFITS ANTICIPATED FROM THE ACQUISITIONS OF THE FORMER MERCK GENERICS BUSINESS AND A CONTROLLING INTEREST IN MATRIX.

The success of the acquisitions of the former Merck Generics business and a controlling interest in Matrix will depend, in part, on our ability to realize anticipated cost savings, revenue synergies and growth opportunities from integrating the businesses. We expect to benefit from operational cost savings resulting from the consolidation of capabilities and elimination of redundancies as well as greater efficiencies from increased scale and market integration.

There is a risk, however, that the businesses may not be combined in a manner that permits these costs savings or synergies to be realized in the time currently expected, or at all. This may limit or delay our ability to integrate the companies' manufacturing, research and development, marketing, organizations, procedures, policies and operations. In addition, a variety of factors, including, but not limited to, wage inflation and currency fluctuations, may adversely affect our anticipated cost savings and revenues.

Also, we may be unable to achieve our anticipated cost savings and synergies without adversely affecting our revenues. If we are not able to successfully achieve these objectives, the anticipated benefits of these acquisitions may not be realized fully, or at all, or may take longer to realize than expected. These factors could impair our growth and ability to compete, require us to focus additional resources on integration of operations rather than other profitable areas, or otherwise cause a material adverse effect on our business, financial position and results of operations and could cause a decline in the market value of our common stock.

WE HAVE GROWN AT A VERY RAPID PACE. OUR INABILITY TO PROPERLY MANAGE OR SUPPORT THIS GROWTH MAY HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

We have grown very rapidly over the past few years, through our acquisitions of the former Merck Generics business and a controlling interest in Matrix. This growth has put significant demands on our processes, systems and people. We expect to make significant investments in additional personnel, systems and internal control processes to help manage our growth. Attracting, retaining and motivating key employees in various departments and locations to support our growth is critical to our business, and competition for these people can be intense. If we are unable to hire and retain qualified employees and if we do not continue to invest in systems and processes to manage and support our rapid growth, there may be a material adverse effect on our business, financial position and results of operations, and the market value of our common stock could decline.

OUR GLOBAL EXPANSION THROUGH THE ACQUISITIONS OF THE FORMER MERCK GENERICS BUSINESS AND A CONTROLLING INTEREST IN MATRIX EXPOSES US TO ADDITIONAL RISKS WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

With our recent acquisitions of the former Merck Generics business and a controlling interest in Matrix, our operations extend to numerous countries outside the United States. Operating globally exposes us to certain additional risks including, but not limited to:

compliance with a variety of national and local laws of countries in which we do business, including restrictions on the import and export of certain intermediates, drugs and technologies;

changes in laws, regulations, and practices affecting the pharmaceutical industry and the healthcare system, including but not limited to imports, exports, manufacturing, cost, pricing, reimbursement, approval, inspection, and delivery of healthcare;

fluctuations in exchange rates for transactions conducted in currencies other than the functional currency;

Table of Contents

adverse changes in the economies in which we operate as a result of a slowdown in overall growth, a change in government or economic liberalization policies, or financial, political or social instability in such countries that affects the markets in which we operate, particularly emerging markets;

wage increases or rising inflation in the countries in which we operate;

supply disruptions, and increases in energy and transportation costs;

natural disasters, including droughts, floods and earthquakes in the countries in which we operate;

communal disturbances, terrorist attacks, riots or regional hostilities in the countries in which we operate; and

government uncertainty, including as a result of new or changed laws and regulations.

We also face the risk that some of our competitors have more experience with operations in such countries or with international operations generally. Certain of the above factors could have a material adverse effect on our business, financial position and results of operations and could cause a decline in the market value of our common stock.

OUR 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 pharmaceutical products in a timely manner. Product development is inherently risky, especially for new drugs for which safety and efficacy have not been established and the market is not yet proven. Likewise, product licensing involves inherent risks including uncertainties due to matters that may affect the achievement of milestones, as well as the possibility of contractual disagreements with regard to terms such as license scope or termination rights. The development and commercialization process, particularly with regard to new drugs, also requires substantial time, effort and financial resources. We, or a partner, may not be successful in commercializing any of such products on a timely basis, if at all, which could adversely affect our business, financial position and results of operations and could cause the market value of our common stock to decline.

Before any prescription drug product, including generic drug products, can be marketed, marketing authorization approval is required by the relevant regulatory authorities and/or national regulatory agencies (for example the FDA in the United States and the European Medicines Agency (or EMA) in the European Union (or EU)). The process of obtaining regulatory approval to manufacture and market new and generic pharmaceutical products is rigorous, time consuming, costly and largely unpredictable. Outside the United States, the approval process may be more or less rigorous, and the time required for approval may be longer or shorter than that required in the United States. Bioequivalency studies conducted in one country may not be accepted in other countries, and the approval of a pharmaceutical product in one country does not necessarily mean that the product will be approved in another country. We, or a partner, may be unable to obtain requisite approvals on a timely basis for new generic or branded products that we may develop, license or otherwise acquire. Moreover, if we obtain regulatory approval for a drug it may be limited with respect to the indicated uses and delivery methods for which the drug may be marketed, which could in turn restrict our potential market for the drug. 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 regulatory approval is denied or delayed, we could be exposed to the risk of this inventory becoming obsolete. The timing and cost of obtaining regulatory approvals could adversely affect our product introduction plans, business, financial position and results of operations and could cause the market value of our common stock to decline.

Table of Contents

The approval process for generic pharmaceutical products often results in the relevant regulatory agency granting final approval to a number of generic pharmaceutical products at the time a patent claim for a corresponding branded product or other market exclusivity expires. This often forces us to face immediate competition when we introduce a generic product into the market. Additionally, further generic 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 branded products. New generic market entrants generally cause continued price and margin erosion over the generic product life cycle.

In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman 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, the applicant generally enjoys higher market share, net revenues and gross margin for that product. 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 business, financial position and results of operations, and the market value of our common stock could decline.

In Europe, there is no exclusivity period for the first generic. The EMA or national regulatory agencies may grant marketing authorizations to any number of generics. However, if there are other relevant patents when the core patent expires, for example, new formulations, the owner of the original brand pharmaceutical may be able to obtain preliminary injunctions in certain European jurisdictions preventing launch of the generic product, if the generic company did not commence proceedings in a timely manner to invalidate any relevant patents prior to launch of its generic.

In addition, in jurisdictions other than the United States, we may face similar regulatory hurdles and constraints. If we are unable to navigate our products through all of the regulatory hurdles we face in a timely manner it could adversely affect our product introduction plans, business, financial position and results of operations and could cause the market value of our common stock to decline.

IF THE INTERCOMPANY TERMS OF CROSS BORDER ARRANGEMENTS WE HAVE AMONG OUR SUBSIDIARIES ARE DETERMINED TO BE INAPPROPRIATE, OUR TAX LIABILITY MAY INCREASE, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

We have potential tax exposures resulting from the varying application of statutes, regulations and interpretations which include exposures on intercompany terms of cross border arrangements among our subsidiaries in relation to various aspects of our business, including manufacturing, marketing, sales and delivery functions. Although our cross border arrangements between affiliates are based upon internationally accepted standards, tax authorities in various jurisdictions may disagree with and subsequently challenge the amount of profits taxed in their country, which may result in increased tax liability, including accrued interest and penalties, which would cause our tax expense to increase. This could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Table of Contents

OUR APPROVED PRODUCTS MAY NOT ACHIEVE EXPECTED LEVELS OF MARKET ACCEPTANCE, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR PROFITABILITY, BUSINESS, 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 branded, 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 but not limited to:

- the availability of alternative products from our competitors;
- the price of our products relative to that of our competitors;
- the timing of our market entry;
- the ability to market our products effectively to the retail level; and
- the acceptance of our products by government and private formularies.

Some of these factors are not within our control. Additionally, continuing studies of the proper utilization, safety and efficacy of pharmaceutical products are being conducted by the industry, government agencies and others. Such studies, which increasingly employ sophisticated methods and techniques, can call into question the utilization, safety and efficacy of previously marketed products. In some cases, 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, business, financial position and results of operations, and could cause the market value of our common stock to 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. SUCH COMPETITION COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

The generic pharmaceutical industry is highly competitive. We face competition from many U.S. and foreign manufacturers, some of whom are significantly larger than we are. Our competitors may be able to develop products and processes competitive with or superior to our own for many reasons, including but not limited to the possibility 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

Table of Contents

more experience in developing new drugs and greater financial resources, particularly with regard to manufacturers of branded products.

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 governmental authorities. For instance, we must comply with requirements of the FDA and similar requirements of similar agencies in our other markets with respect to the manufacture, labeling, sale, distribution, marketing, advertising, promotion and development of pharmaceutical products. Failure to comply with regulations of the FDA and other regulators 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 applicable regulator's review of our submissions, enforcement actions, injunctions and criminal prosecution. Under certain circumstances, the regulators may also have 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 Europe we must also comply with regulatory requirements with respect to the manufacture, labeling, sale, distribution, marketing, advertising, promotion and development of pharmaceutical products. Some of these requirements are contained in EU regulations and governed by the EMA. Other requirements are set down in national laws and regulations of the EU Member States. Failure to comply with the regulations can result in a range of fines, penalties, product recalls/suspensions or even criminal liability. Similar laws and regulations exist in most of the markets in which we operate.

In addition to the new drug approval process, government agencies also regulate the facilities and operational procedures that we use to manufacture our products. We must register our facilities with the FDA and other similar regulators. Products manufactured in our facilities must be made in a manner consistent with current good manufacturing practices, or 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 and other agencies periodically inspect our manufacturing facilities for compliance. Regulatory 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 or other regulatory bodies which could include withholding the approval of our submissions or other product applications of that facility. If any regulatory body 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 or other regulatory 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. We are also required to comply with data protection and data privacy rules in many countries. 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

Table of Contents

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 MEDICARE AND/OR MEDICAID REBATE PROGRAM AND OTHER GOVERNMENTAL PURCHASING AND REBATE PROGRAMS ARE COMPLEX AND MAY INVOLVE SUBJECTIVE DECISIONS THAT COULD CHANGE AS A RESULT OF NEW BUSINESS CIRCUMSTANCES, NEW REGULATORY GUIDANCE, OR ADVICE OF LEGAL COUNSEL. 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 Medicare and/or Medicaid reimbursement and rebates and other governmental programs are complex. As discussed elsewhere in this Form 10-Q and other reports we file with the SEC, 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 United States Department of Justice with respect to Medicaid reimbursement and rebates. While we cannot predict the outcome of the investigation, possible remedies which the United States government could seek include treble damages, civil monetary penalties and exclusion from the Medicare and Medicaid programs. In connection with such an investigation, the United States government may also seek a Corporate Integrity Agreement (administered by the Office of Inspector General of HHS) with us which could include ongoing compliance and reporting obligations. 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, they are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in material changes. Further, effective October 1, 2007, the Centers for Medicaid and Medicare Services, or CMS, adopted new rules for Average Manufacturer's Price, or AMP, based on the provisions of the Deficit Reduction Act of 2005, or DRA. One significant change as a result of the DRA is that AMP will be disclosed to the public. AMP was historically kept confidential by the government and participants in the Medicaid program. Disclosing AMP to competitors, customers, and the public at large could negatively affect our leverage in commercial price negotiations.

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

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

Table of Contents

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 approved pharmaceuticals in accordance with applicable regulations. Typically, research expenses related to the development of innovative compounds and the filing of marketing authorization applications for innovative compounds (such as NDAs in the United States) are significantly greater than those expenses associated with the development of and filing of marketing authorization applications for generic products (such as ANDAs in the United States and abridged applications in Europe). 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, Bystolic), our, or a partner's, research and development expenditures may not result in the successful introduction of new pharmaceutical products approved by the relevant regulatory bodies. Also, after we submit a marketing authorization application for a new compound or generic product, the relevant regulatory authority 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 IS 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 is derived from sales to a limited number of customers. If we were to experience a significant reduction in or loss of business with one such customer, or if one such customer were to experience difficulty in paying us on a timely basis, our business, financial position and results of operations could be materially adversely affected, and the market value of our common stock could decline.

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

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

Edgar Filing: MYLAN INC. - Form 10-Q

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

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

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

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

Table of Contents

filing suits for patent infringement that may delay regulatory approval of many generic products;

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

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

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

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

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

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

WE HAVE SUBSTANTIAL INDEBTEDNESS AND WILL BE REQUIRED TO APPLY A SUBSTANTIAL PORTION OF OUR CASH FLOW FROM OPERATIONS TO SERVICE OUR INDEBTEDNESS. OUR SUBSTANTIAL INDEBTEDNESS MAY HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

We incurred significant indebtedness to fund a portion of the consideration for our acquisition of the former Merck Generics business. Our high level of indebtedness could have important consequences, including but not limited to:

increasing our vulnerability to general adverse economic and industry conditions;

requiring us to dedicate a substantial portion of our cash flow from operations and proceeds of any equity issuances to payments on our indebtedness, thereby reducing the availability of cash flow to fund working capital, capital expenditures, acquisitions and investments and other general corporate purposes;

making it difficult for us to optimally capitalize and manage the cash flow for our businesses;

limiting our flexibility in planning for, or reacting to, changes in our businesses and the markets in which we operate;

making it difficult for us to meet the leverage and interest coverage ratios required by our Senior Credit Agreement;

limiting our ability to borrow money or sell stock to fund our working capital, capital expenditures, acquisitions and debt service requirements and other financing needs;

increasing our vulnerability to increases in interest rates in general because a substantial portion of our indebtedness bears interest at floating rates;

requiring us to sell assets in order to pay down debt; and

placing us at a competitive disadvantage to our competitors that have less debt.

If we do not have sufficient cash flow to service our indebtedness, we may need to refinance all or part of our existing indebtedness, borrow more money or sell securities, some or all of which may not be available to us at acceptable terms or at all. In addition, we may need to incur additional indebtedness in the future in the ordinary course of business. Although the terms of our Senior Credit Agreement allow us to incur additional debt, this is subject to certain limitations which may preclude us from incurring the amount of indebtedness we otherwise

Table of Contents

desire. In addition, if we incur additional debt, the risks described above could intensify. Furthermore, the global credit markets are currently experiencing an unprecedented contraction. If current pressures on credit continue or worsen, future debt financing may not be available to us when required or may not be available on acceptable terms, and as a result we may be unable to grow our business, take advantage of business opportunities, respond to competitive pressures or satisfy our obligations under our indebtedness. Any of the foregoing could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

WE MAY DECIDE TO SELL ASSETS WHICH COULD ADVERSELY AFFECT OUR PROSPECTS AND OPPORTUNITIES FOR GROWTH, AND WHICH COULD AFFECT OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

We may from time to time consider selling certain assets if we determine that such assets are not critical to our strategy, or if we believe the opportunity to monetize the asset is attractive, or in order to reduce indebtedness, or for other reasons. We have explored and will continue to explore the sale of certain non-core assets. Although our intention is to engage in asset sales only if they advance our overall strategy, any such sale could reduce the size or scope of our business, our market share in particular markets or our opportunities with respect to certain markets, products or therapeutic categories. We also continue to review the carrying value of manufacturing and intangible assets for indications of impairment as circumstances require. Future events and decisions may lead to asset impairments and/or related costs. As a result, any such sale or impairment could have an adverse effect on our business, prospects and opportunities for growth, financial position and results of operations and could cause the market value of our common stock to decline.

OUR CREDIT FACILITIES AND ANY ADDITIONAL INDEBTEDNESS WE INCUR IN THE FUTURE IMPOSE, OR MAY IMPOSE, SIGNIFICANT OPERATING AND FINANCIAL RESTRICTIONS, WHICH MAY PREVENT US FROM CAPITALIZING ON BUSINESS OPPORTUNITIES. THESE FACTORS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

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

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

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

Table of Contents

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

We utilize controlled substances in certain of our current products and products in development and therefore must meet the requirements of the Controlled Substances Act of 1970 and the related regulations administered by the Drug Enforcement Administration, or DEA, in the United States as well as similar laws in other countries where we operate. These laws relate to the manufacture, shipment, storage, sale and use of controlled substances. The DEA and other regulatory agencies limit the availability of the active ingredients used in certain of our current products and products in development and, as a result, our procurement quota of these active ingredients may not be sufficient to meet commercial demand or complete clinical trials. We must annually apply to the DEA and other regulatory agencies for procurement quota in order to obtain these substances. Any delay or refusal by the DEA or such regulatory agencies in establishing our procurement quota for controlled substances could delay or stop our clinical trials or product launches, or could cause trade inventory disruptions for those products that have already been launched, 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 EFFORTS TO TRANSITION THE FORMER MERCK GENERICS BUSINESS SUBSIDIARIES AWAY FROM THE MERCK NAME INVOLVE INHERENT RISKS AND MAY RESULT IN GREATER THAN EXPECTED COSTS OR IMPEDIMENTS, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

We have a license from Merck KGaA to continue using the Merck name, including in product names, in respect of the former Merck Generics businesses for a transitional period of two years after the closing of the acquisition. We are engaged in efforts to transition in an orderly manner away from the Merck name and to achieve global brand alignment. Re-branding may prove to be costly, especially in markets where the former Merck Generics business name has strong dominance or significant equity locally. In addition, brand migration poses risks of both business disruption and customer confusion. Our customer outreach and similar efforts may not mitigate fully the risks of the name changes, which may lead to reductions in revenues in some markets. These losses may have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

In addition, in limited circumstances, entities we acquired in the acquisition of the former Merck Generics business are party to litigation and/or subject to investigation in matters under which we are entitled to indemnification by Merck KGaA. However, there are risks inherent in such indemnities and, accordingly, there can be no assurance that we will receive the full benefits of such indemnification.

OUR BUSINESS IS HIGHLY DEPENDENT UPON MARKET PERCEPTIONS OF US, OUR BRANDS AND THE SAFETY AND QUALITY OF OUR PRODUCTS. OUR BUSINESS OR BRANDS COULD BE SUBJECT TO NEGATIVE PUBLICITY, 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.

Market perceptions of our business are very important to us, especially market perceptions of our brands and the safety and quality of our products. If we, or our brands, suffer from negative publicity, or if any of our products or similar products which other companies distribute are proven to be, or are claimed to be, harmful to consumers then this could have a material adverse effect on our business, financial position and results of operations and could cause

Table of Contents

the market value of our common stock to decline. Also, because we are dependant on market perceptions, negative publicity associated with illness or other adverse effects resulting from our products could have a material adverse impact on our business, financial position and results of operations and could cause the market value of our common stock to decline.

WE HAVE A LIMITED NUMBER OF MANUFACTURING FACILITIES PRODUCING A SUBSTANTIAL PORTION OF OUR PRODUCTS. PRODUCTION AT ANY ONE OF THESE FACILITIES COULD BE INTERRUPTED, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

A substantial portion of our capacity as well as our current production is attributable to a limited number of manufacturing facilities. A significant disruption at any one of those facilities, even on a short-term basis, could impair our ability to produce and ship products to the market on a timely basis, which could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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

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

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

Companies that produce brand pharmaceutical products routinely bring litigation against ANDA or similar applicants that seek regulatory approval to manufacture and market generic forms of their branded products. These companies allege patent infringement or other violations of intellectual property rights as the basis for filing suit against an ANDA or similar applicant. Likewise, patent holders may bring patent infringement suits against companies that are currently marketing and selling their approved generic products. Litigation often involves significant expense and can delay or prevent introduction or sale of our generic products. If patents are held valid and infringed by our products in a particular jurisdiction, we would, unless we could obtain a license from the patent holder, need to cease selling in

that jurisdiction and may need to deliver up or destroy existing stock in that jurisdiction.

There may also be situations where the Company uses its business judgment and decides to market and sell products, notwithstanding the fact that allegations of patent infringement(s) have not been finally resolved by the

Table of Contents

courts. The risk involved in doing so can be substantial because the remedies available to the owner of a patent for infringement may include, among other things, damages measured by the profits lost by the patent owner and not necessarily by the profits earned by the infringer. In the case of a willful infringement, the definition of which is subjective, such damages may be trebled. Moreover, because of the discount pricing typically involved with bioequivalent products, patented branded products generally realize a substantially higher profit margin than bioequivalent products. An adverse decision in a case such as this or in other similar litigation could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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

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

In Germany, recent legislative changes have been introduced which are aimed at reducing costs for the German statutory health insurance, or SHI, scheme. The measure is likely to have an impact upon marketing practice and reimbursement of drugs and may increase pressure on competition and reimbursement margins. These 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.

In the UK, the Office of Fair Trading produced recommendations in February 2007 that suggested that the UK should include off patent brands in its value based pricing structure in addition to Generics, for the reimbursement of pharmaceutical products. The desired effect is to reduce the difference between the reimbursement levels of off patent brands and Generics. This will increase the Generics Industry ability to compete with off patent brands on a level playing field. Generics [UK] Ltd. and the BGMA (British Generics Manufacturers Association) support the OFT in this recommendation.

In addition, a number of markets in which we operate (including, most recently, the Netherlands) have implemented or may implement tender systems for generic pharmaceuticals in an effort to lower prices. Under such tender systems, manufacturers submit bids which establish prices for generic pharmaceutical products. Upon winning the tender, the winning company will receive a preferential reimbursement for a period of time. The tender system often results in companies underbidding one another by proposing low pricing in order to win the tender.

Certain other countries may consider the implementation of a tender system. Even if a tender system is ultimately not implemented, the anticipation of such could result in price reductions. Failing to win tenders, or the implementation of similar systems in other markets leading to further price declines, could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to

decline.

Table of Contents

LEGISLATIVE OR REGULATORY PROGRAMS THAT MAY INFLUENCE PRICES OF PHARMACEUTICAL PRODUCTS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

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

In order to control expenditure on pharmaceuticals, most member states in the EU regulate the pricing of products and, in some cases, limit the range of different forms of pharmaceuticals available for prescription by national health services. These controls can result in considerable price differences between member states.

On July 18, 2008, the Australian government mandated a 25% price reduction on pharmaceutical products sold in Australia. Such a widespread price reduction of this magnitude is unprecedented in Australia and, as such, pharmaceutical companies are dealing with uncertainties as to how the market will react. As these uncertainties are resolved or if other countries in which we operate enact similar measures, they could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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

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

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

The European Commission is conducting a pharmaceutical sector inquiry involving approximately 100 companies concerning the introduction of innovative and generic medicines. Mylan's subsidiary, Mylan SAS, has responded to questionnaires and has produced documents and other information in connection with the inquiry. The Commission has not alleged that the Company or any of its subsidiaries have engaged in any unlawful practices. However, if this inquiry was to result in an adverse outcome, the impact could have a material adverse effect on our business, financial

position and results of operations and could cause the market value of our common stock to decline.

WE ENTER INTO VARIOUS AGREEMENTS IN THE NORMAL COURSE OF BUSINESS WHICH PERIODICALLY INCORPORATE PROVISIONS WHEREBY WE INDEMNIFY THE OTHER PARTY

Table of Contents

TO THE AGREEMENT. IN THE EVENT THAT WE WOULD HAVE TO PERFORM UNDER THESE INDEMNIFICATION PROVISIONS, IT COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

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

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

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

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

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

ANY FUTURE ACQUISITIONS OR DIVESTITURES WOULD INVOLVE A NUMBER OF INHERENT RISKS. THESE RISKS COULD CAUSE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

We may continue to seek to expand our product line through complementary or strategic acquisitions of other companies, products or assets, or through joint ventures, licensing agreements or other arrangements or may determine to divest certain products or assets. Any such acquisitions, joint ventures or other business combinations may involve significant challenges in integrating the new company's operations, and divestitures could be equally challenging. Either process may prove to be complex and time consuming and require substantial resources and effort. It may also disrupt our ongoing businesses, which may adversely affect our relationships with customers, employees, regulators and others with whom we have business or other dealings.

We may be unable to realize synergies or other benefits expected to result from any acquisitions, joint ventures or other transactions or investments we may undertake, or be unable to generate additional revenue to offset any unanticipated inability to realize these expected synergies or benefits. Realization of the anticipated benefits of acquisitions or other transactions could take longer than expected, and implementation difficulties, unforeseen

Table of Contents

expenses, complications and delays, market factors or a deterioration in domestic and global economic conditions could alter the anticipated benefits of any such transactions. We may also compete for certain acquisition targets with companies having greater financial resources than us or other advantages over us that may prevent us from acquiring a target. These factors could impair our growth and ability to compete, require us to focus additional resources on integration of operations rather than other profitable areas, otherwise cause 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.

MATRIX, AN IMPORTANT PART OF OUR BUSINESS, IS LOCATED IN INDIA AND IT IS SUBJECT TO REGULATORY, ECONOMIC, SOCIAL AND POLITICAL UNCERTAINTIES IN INDIA. THESE RISKS COULD CAUSE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

In recent years, Matrix has benefited from many policies of the Government of India and the Indian state governments in the states in which it operates, which are designed to promote foreign investment generally, including significant tax incentives, liberalized import and export duties and preferential rules on foreign investment and repatriation. There is no assurance that such policies will continue. Various factors, such as changes in the current federal government, could trigger significant changes in India's economic liberalization and deregulation policies and disrupt business and economic conditions in India generally and our business in particular.

In addition, our financial performance and the market price of our securities may be adversely affected by general economic conditions and economic and fiscal policy in India, including changes in exchange rates and controls, interest rates and taxation policies, as well as social stability and political, economic or diplomatic developments affecting India in the future. In particular, India has experienced significant economic growth over the last several years, but faces major challenges in sustaining that growth in the years ahead. These challenges include the need for substantial infrastructure development and improving access to healthcare and education. Matrix's ability to recruit, train and retain qualified employees and develop and operate its manufacturing facilities could be adversely affected if India does not successfully meet these challenges.

Southern Asia has, from time to time, experienced instances of civil unrest and hostilities among neighboring countries, including India and Pakistan. Such military activity or terrorist attacks in the future could influence the Indian economy by disrupting communications and making travel more difficult. Resulting political tensions could create a greater perception that investments in companies with Indian operations involve a high degree of risk, and that there is a risk of disruption of services provided by companies with Indian operations, which could have a material adverse effect on our share price and/or the market for Matrix's products. Furthermore, if India were to become engaged in armed hostilities, particularly hostilities that were protracted or involved the threat or use of nuclear weapons, Matrix might not be able to continue its operations. We generally do not have insurance for losses and interruptions caused by terrorist attacks, military conflicts and wars. These risks could cause 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.

MOVEMENTS IN FOREIGN CURRENCY EXCHANGE RATES 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.

A significant portion of our revenues, indebtedness and our costs are denominated in foreign currencies including the Australian dollar, the British pound, the Canadian dollar, the Euro, the Indian rupee and the Japanese Yen. We report our financial results in U.S. dollars. Our results of operations and, in some cases, cash flows, could be adversely affected by certain movements in exchange rates. From time to time, we may implement currency hedges intended to

reduce our exposure to changes in foreign currency exchange rates. However, our hedging strategies may not be successful, and any of our unhedged foreign exchange payments will continue to be subject to market fluctuations. These risks could cause a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Table of Contents

IF WE FAIL TO ADEQUATELY PROTECT OR ENFORCE OUR INTELLECTUAL PROPERTY RIGHTS, THEN WE COULD LOSE REVENUE UNDER OUR LICENSING AGREEMENTS OR LOSE SALES TO GENERIC COPIES OF OUR BRANDED PRODUCTS. THESE RISKS COULD CAUSE 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 success, particularly in our specialty business, depends in part on our ability to obtain, maintain and enforce patents, and protect trade secrets, know-how and other proprietary information. Our ability to commercialize any branded product successfully will largely depend upon our ability to obtain and maintain patents of sufficient scope to prevent third parties from developing substantially equivalent products. In the absence of patent and trade secret protection, competitors may adversely affect our branded products business by independently developing and marketing substantially equivalent products. It is also possible that we could incur substantial costs if we are required to initiate litigation against others to protect or enforce our intellectual property rights.

We have filed patent applications covering composition of, methods of making, and/or methods of using, our branded products and branded product candidates. We may not be issued patents based on patent applications already filed or that we file in the future and if patents are issued, they may be insufficient in scope to cover our branded products. The issuance of a patent in one country does not ensure the issuance of a patent in any other country. Furthermore, the patent position of companies in the pharmaceutical industry generally involves complex legal and factual questions and has been and remains the subject of much litigation. Legal standards relating to scope and validity of patent claims are evolving. Any patents we have obtained, or obtain in the future, may be challenged, invalidated or circumvented. Moreover, the United States Patent and Trademark Office or any other governmental agency may commence interference proceedings involving our patents or patent applications. Any challenge to, or invalidation or circumvention of, our patents or patent applications would be costly, would require significant time and attention of our management, could cause 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 SPECIALTY BUSINESS DEVELOPS, FORMULATES, MANUFACTURES AND MARKETS BRANDED PRODUCTS THAT ARE SUBJECT TO RISKS. THESE RISKS COULD CAUSE 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 branded products, developed, formulated, manufactured and marketed by our specialty business may be subject to the following risks, among others:

limited patent life, or the loss of patent protection;

competition from generic products;

reductions in reimbursement rates by third-party payors;

importation by consumers;

product liability;

drug development risks arising from typically greater research and development investments than generics; and

unpredictability with regard to establishing a market.

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

WE MUST MAINTAIN ADEQUATE INTERNAL CONTROLS AND BE ABLE, ON AN ANNUAL BASIS, TO PROVIDE AN ASSERTION AS TO THE EFFECTIVENESS OF SUCH CONTROLS. FAILURE TO MAINTAIN ADEQUATE INTERNAL CONTROLS OR TO IMPLEMENT NEW OR IMPROVED CONTROLS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS,

Table of Contents

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

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

On October 2, 2007 we acquired the former Merck Generics business. For purposes of management's evaluation of our internal control over financial reporting as of December 31, 2007, we elected to exclude the former Merck Generics business from the scope of management's assessment as permitted by guidance provided by the SEC.

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

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

Table of Contents

WE ARE SUBJECT TO THE U.S. FOREIGN CORRUPT PRACTICES ACT AND SIMILAR WORLDWIDE ANTI-BRIBERY LAWS, WHICH IMPOSE RESTRICTIONS AND MAY CARRY SUBSTANTIAL PENALTIES. ANY VIOLATIONS OF THESE LAWS, OR ALLEGATIONS OF SUCH VIOLATIONS, COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

The U.S. Foreign Corrupt Practices Act and similar anti-bribery laws in other jurisdictions generally prohibit companies and their intermediaries from making improper payments to officials for the purpose of obtaining or retaining business. Our policies mandate compliance with these anti-bribery laws, which often carry substantial penalties. We operate in jurisdictions that have experienced governmental corruption to some degree, and, in certain circumstances, strict compliance with anti-bribery laws may conflict with certain local customs and practices. We cannot assure you that our internal control policies and procedures always will protect us from reckless or other inappropriate acts committed by our affiliates, employees or agents. Violations of these laws, or allegations of such violations, could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

ITEM 6. EXHIBITS

- 3.1(a) Amended and Restated Articles of Incorporation of the registrant, as amended, filed as Exhibit 3.1 to the Form 10-Q for the quarterly period ended June 30, 2003, and incorporated herein by reference.
- 3.1(b) Amendment to Amended and Restated Articles of Incorporation of the registrant, filed as Exhibit 3.2 to the Report on Form 8-K filed with the SEC on October 5, 2007, and incorporated herein by reference.
- 3.1(c) Amendment to Amended and Restated Articles of Incorporation of the registrant, filed as Exhibit 3.1 to the Report on Form 8-K filed with the SEC on November 20, 2007, and incorporated herein by reference.
- 3.2 Bylaws of the registrant, as amended to date, filed as Exhibit 3.1 to the Report of Form 8-K filed on October 5, 2007, and incorporated herein by reference.
- 4.1(a) Rights Agreement dated as of August 22, 1996, between the registrant and American Stock Transfer & Trust Company, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on September 3, 1996, and incorporated herein by reference.
- 4.1(b) Amendment to Rights Agreement dated as of November 8, 1999, between the registrant and American Stock Transfer & Trust Company, filed as Exhibit 1 to Form 8-A/A filed with the SEC on March 31, 2000, and incorporated herein by reference.
- 4.1(c) Amendment No. 2 to Rights Agreement dated as of August 13, 2004, between the registrant and American Stock Transfer & Trust Company, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on August 16, 2004, and incorporated herein by reference.
- 4.1(d) Amendment No. 3 to Rights Agreement dated as of September 8, 2004, between the registrant and American Stock Transfer & Trust Company, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on September 9, 2004, and incorporated herein by reference.
- 4.1(e) Amendment No. 4 to Rights Agreement dated as of December 2, 2004, between the registrant and American Stock Transfer & Trust Company, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on December 3, 2004, and incorporated herein by reference.
- 4.1(f) Amendment No. 5 to Rights Agreement dated as of December 19, 2005, between the registrant and American Stock Transfer & Trust Company, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on December 19, 2005, and incorporated herein by reference.
- 4.2(a) Indenture, dated as of July 21, 2005, between the registrant and The Bank of New York, as trustee, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on July 27, 2005, and incorporated herein by reference.

- 4.2(b) Second Supplemental Indenture, dated as of October 1, 2007, among the registrant, the Subsidiaries of the registrant listed on the signature page thereto and The Bank of New York, as trustee, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on October 5, 2007, and incorporated herein by reference.

Table of Contents

- 4.3 Registration Rights Agreement, dated as of July 21, 2005, among the registrant, the Guarantors party thereto and Merrill Lynch, Pierce, Fenner & Smith Incorporated, BNY Capital Markets, Inc., KeyBank Capital Markets (a Division of McDonald Investments Inc.), PNC Capital Markets, Inc. and SunTrust Capital Markets, Inc., filed as Exhibit 4.2 to the Report on Form 8-K filed with the SEC on July 27, 2005, and incorporated herein by reference.
- 4.4 Indenture, dated as of September 15, 2008, among the registrant, the guarantors named therein and Bank of New York Mellon as trustee, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on September 15, 2008, and incorporated herein by reference.
- 10.1 3.75% Cash Convertible Notes due 2015 Purchase Agreement dated September 9, 2008, among the registrant and the initial purchaser named therein, filed as Exhibit 1.1 to the Report on Form 8-K filed with the SEC on September 15, 2008, and incorporated herein by reference.
- 10.2 Confirmation of OTC Convertible Note Hedge Transaction dated September 9, 2008, among the registrant, Merrill Lynch International and Merrill Lynch, Pierce, Fenner & Smith Incorporated, filed as Exhibit 10.1 to the Report on Form 8-K filed with the SEC on September 15, 2008, and incorporated herein by reference.
- 10.3 Confirmation of OTC Convertible Note Hedge Transaction dated September 9, 2008, between the registrant and Wells Fargo Bank, National Association, filed as Exhibit 10.2 to the Report on Form 8-K filed with the SEC on September 15, 2008, and incorporated herein by reference.
- 10.4 Confirmation of OTC Warrant Transaction dated September 9, 2008, among the registrant, Merrill Lynch International and Merrill Lynch, Pierce, Fenner & Smith Incorporated, filed as Exhibit 10.3 to the Report on Form 8-K filed with the SEC on September 15, 2008, and incorporated herein by reference.
- 10.5 Confirmation of OTC Warrant Transaction dated September 9, 2008, between the registrant and Wells Fargo Bank, National Association, filed as Exhibit 10.4 to the Report on Form 8-K filed with the SEC on September 15, 2008, and incorporated herein by reference.
- 10.6 Amendment to Confirmation of OTC Warrant Transaction dated September 15, 2008 among the registrant, Merrill Lynch International and Merrill Lynch, Pierce, Fenner & Smith Incorporated, filed as Exhibit 10.5 to the Report on Form 8-K filed with the SEC on September 15, 2008, and incorporated herein by reference.
- 10.7 Amendment to Confirmation of OTC Warrant Transaction dated September 15, 2008, between the registrant and Wells Fargo Bank, National Association, filed as Exhibit 10.6 to the Report on Form 8-K filed with the SEC on September 15, 2008, and incorporated herein by reference.
- 10.8 Amendment to Confirmation of OTC Warrant Transaction dated as of September 9, 2008 among Mylan Inc., Merrill Lynch International and Merrill Lynch, Pierce, Fenner & Smith Incorporated, filed as Exhibit 10.7 to the Report on Form 8-K filed with the SEC on September 15, 2008, and incorporated herein by reference.
- 10.9 Amendment to Confirmation of OTC Warrant Transaction dated as of September 9, 2008 among Mylan Inc., Merrill Lynch International and Merrill Lynch, Pierce, Fenner & Smith Incorporated, filed as Exhibit 10.8 to the Report on Form 8-K filed with the SEC on September 15, 2008, and incorporated herein by reference.
- 10.10 Calculation Agent Agreement dated September 9, 2008, among the registrant, Wells Fargo Bank, National Association and Goldman Sachs International, filed as Exhibit 10.9 to the Report on Form 8-K filed with the SEC on September 15, 2008, and incorporated herein by reference.
- 31.1 Certification of CEO pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of CFO pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32 Certification of CEO and CFO pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Report on Form 10-Q for the quarterly period ended September 30, 2008, to be signed on its behalf by the undersigned thereunto duly authorized.

Mylan Inc.
(Registrant)

By: /s/ Robert J. Coury

Robert J. Coury
Vice Chairman and Chief Executive Officer

November 3, 2008

/s/ Edward J. Borkowski
Edward J. Borkowski
Executive Vice President and Chief Financial Officer
(Principal financial officer)

November 3, 2008

/s/ Daniel C. Rizzo, Jr.
Daniel C. Rizzo, Jr.
Senior Vice President and Corporate Controller
(Principal accounting officer)

November 3, 2008

Table of Contents

EXHIBIT INDEX

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