

MYLAN INC.  
Form 10-Q  
July 29, 2010

**Table of Contents**

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 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 June 30, 2010**
- 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 or other jurisdiction  
of incorporation or organization)*

**25-1211621**

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

**1500 Corporate Drive, Canonsburg, Pennsylvania 15317**

*(Address of principal executive offices)*

**(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 12 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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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

Edgar Filing: MYLAN INC. - Form 10-Q

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

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

<b>Class of Common Stock</b>	<b>Outstanding at July 26, 2010</b>
\$0.50 par value	309,360,933

---

**MYLAN INC. AND SUBSIDIARIES**

**INDEX TO FORM 10-Q  
For the Quarterly Period Ended  
June 30, 2010**

	<b>Page</b>	
<b>PART I FINANCIAL INFORMATION</b>		
ITEM 1.	Condensed Consolidated Financial Statements (unaudited) <u>Condensed Consolidated Statements of Operations Three and Six Months Ended June 30, 2010 and 2009</u>	3
	<u>Condensed Consolidated Balance Sheets June 30, 2010 and December 31, 2009</u>	4
	<u>Condensed Consolidated Statements of Cash Flows Six Months Ended June 30, 2010 and 2009</u>	5
	<u>Notes to Condensed Consolidated Financial Statements</u>	6
<u>ITEM 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	29
<u>ITEM 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	39
<u>ITEM 4.</u>	<u>Controls and Procedures</u>	39
<b>PART II OTHER INFORMATION</b>		
<u>ITEM 1.</u>	<u>Legal Proceedings</u>	40
<u>ITEM 1A.</u>	<u>Risk Factors</u>	43
<u>ITEM 5.</u>	<u>Other Information</u>	63
<u>ITEM 6.</u>	<u>Exhibits</u>	63
<b><u>SIGNATURES</u></b>		65
<u>EX-10.1</u>		
<u>EX-31.1</u>		
<u>EX-31.2</u>		
<u>EX-32</u>		
<u>EX-101 INSTANCE DOCUMENT</u>		
<u>EX-101 SCHEMA DOCUMENT</u>		
<u>EX-101 CALCULATION LINKBASE DOCUMENT</u>		
<u>EX-101 LABELS LINKBASE DOCUMENT</u>		
<u>EX-101 PRESENTATION LINKBASE DOCUMENT</u>		

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

	<b>Period Ended June 30,</b>			
	<b>Three Months</b>		<b>Six Months</b>	
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>
	<b>(Unaudited; in thousands, except per share amounts)</b>			
Revenues:				
Net revenues	\$ 1,356,543	\$ 1,255,798	\$ 2,634,648	\$ 2,424,160
Other revenues	11,993	11,179	26,261	52,733
Total revenues	1,368,536	1,266,977	2,660,909	2,476,893
Cost of sales	826,686	739,210	1,602,762	1,423,393
Gross profit	541,850	527,767	1,058,147	1,053,500
Operating expenses:				
Research and development	66,787	74,016	128,084	132,853
Selling, general and administrative	268,373	279,672	524,134	521,344
Litigation settlements, net	12,104	(634)	12,838	(2,751)
Total operating expenses	347,264	353,054	665,056	651,446
Earnings from operations	194,586	174,713	393,091	402,054
Interest expense	78,402	78,172	152,449	163,175
Other (expense) income, net	(15,239)	25,308	(14,167)	29,498
Earnings before income taxes and noncontrolling interest	100,945	121,849	226,475	268,377
Income tax provision	14,012	26,178	45,272	63,632
Net earnings	86,933	95,671	181,203	204,745
Net (earnings) loss attributable to the noncontrolling interest	(705)	(2,801)	881	(5,816)
Net earnings attributable to Mylan Inc. before preferred dividends	86,228	92,870	182,084	198,929
Preferred dividends	34,759	34,759	69,518	69,518
Net earnings attributable to Mylan Inc. common shareholders	\$ 51,469	\$ 58,111	\$ 112,566	\$ 129,411
Earnings per common share attributable to Mylan Inc. common shareholders:				
Basic	\$ 0.17	\$ 0.19	\$ 0.37	\$ 0.42

Edgar Filing: MYLAN INC. - Form 10-Q

Diluted	\$	0.16	\$	0.19	\$	0.36	\$	0.42
Weighted average common shares outstanding:								
Basic		308,968		304,991		307,982		304,784
Diluted		314,407		306,256		313,177		305,759

See Notes to Condensed Consolidated Financial Statements

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

	<b>June 30, 2010</b>	<b>December 31,</b>
	<b>(Unaudited; in thousands, except share and per share amounts)</b>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 809,421	\$ 380,516
Restricted cash	48,063	47,965
Marketable securities	23,791	27,559
Accounts receivable, net	1,249,017	1,234,634
Inventories	1,096,365	1,114,219
Deferred income tax benefit	260,742	248,917
Prepaid expenses and other current assets	141,929	231,576
Total current assets	3,629,328	3,285,386
Property, plant and equipment, net	1,091,674	1,122,648
Intangible assets, net	2,132,266	2,384,848
Goodwill	3,131,135	3,331,247
Deferred income tax benefit	42,947	36,610
Other assets	570,468	640,995
Total assets	\$ 10,597,818	\$ 10,801,734
<b>LIABILITIES AND EQUITY</b>		
Liabilities		
Current liabilities:		
Trade accounts payable	\$ 527,844	\$ 518,252
Short-term borrowings	161,593	184,352
Income taxes payable	100,419	69,122
Current portion of long-term debt and other long-term obligations	10,061	9,522
Deferred income tax liability	1,285	1,986
Other current liabilities	828,333	934,913
Total current liabilities	1,629,535	1,718,147
Long-term debt	5,047,384	4,984,987
Other long-term obligations	465,745	485,905
Deferred income tax liability	476,198	467,497
Total liabilities	7,618,862	7,656,536
Equity		
Mylan Inc. shareholders' equity		

Edgar Filing: MYLAN INC. - Form 10-Q

Preferred stock par value \$0.50 per share		
Shares authorized: 5,000,000		
Shares issued: 2,139,000	1,070	1,070
Common stock par value \$0.50 per share		
Shares authorized: 1,500,000,000		
Shares issued: 399,252,737 and 396,683,892 as of June 30, 2010 and December 31, 2009	199,626	198,342
Additional paid-in capital	3,880,285	3,834,674
Retained earnings	772,699	660,130
Accumulated other comprehensive (loss) earnings	(317,358)	11,807
	4,536,322	4,706,023
Noncontrolling interest	12,272	14,052
Less: treasury stock at cost		
Shares: 89,899,071 and 90,199,152 as of June 30, 2010 and December 31, 2009	1,569,638	1,574,877
Total equity	2,978,956	3,145,198
Total liabilities and equity	\$ 10,597,818	\$ 10,801,734

See Notes to Condensed Consolidated Financial Statements



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

	<b>Six Months Ended June 30,</b>	
	<b>2010</b>	<b>2009</b>
	<b>(Unaudited; in thousands)</b>	
Cash flows from operating activities:		
Net earnings	\$ 181,203	\$ 204,745
Adjustments to reconcile net earnings to net cash provided by operating activities:		
Depreciation and amortization	204,933	193,361
Stock-based compensation expense	15,617	14,652
Change in estimated sales allowances	26,062	36,911
Deferred income tax benefit	(56,522)	(76,619)
Other non-cash items	92,660	25,965
Litigation settlements, net	12,838	(2,751)
Changes in operating assets and liabilities:		
Accounts receivable	(106,844)	48,643
Inventories	(44,027)	22,221
Trade accounts payable	54,869	(63,172)
Income taxes	120,796	27,487
Other operating assets and liabilities, net	(142,450)	(95,227)
Net cash provided by operating activities	359,135	336,216
Cash flows from investing activities:		
Capital expenditures	(53,300)	(53,007)
Change in restricted cash		(16,029)
Cash paid for acquisitions	(4,999)	(173,359)
Proceeds from sale of equity-method investee		23,333
Purchase of marketable securities	(1,676)	(1,086)
Proceeds from sale of marketable securities	6,303	13,205
Other items, net	(720)	620
Net cash used in investing activities	(54,392)	(206,323)
Cash flows from financing activities:		
Cash dividends paid	(69,518)	(69,518)
Payment of financing fees	(20,394)	
Change in short-term borrowings, net	(22,374)	(18,736)
Proceeds from issuance of long-term debt	1,250,000	
Payment of long-term debt	(1,001,507)	(172,164)
Proceeds from exercise of stock options	36,007	1,417
Other items, net		(23)
Net cash provided by (used in) financing activities	172,214	(259,024)

Edgar Filing: MYLAN INC. - Form 10-Q

Effect on cash of changes in exchange rates	(48,052)	1,461
Net increase (decrease) in cash and cash equivalents	428,905	(127,670)
Cash and cash equivalents beginning of period	380,516	557,147
Cash and cash equivalents end of period	\$ 809,421	\$ 429,477

See Notes to Condensed Consolidated Financial Statements

**Table of Contents**

**MYLAN INC. AND SUBSIDIARIES**

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

**1. General**

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 ( GAAP ) and the rules and regulations of the Securities and Exchange Commission ( SEC ) for reporting on Form 10-Q; therefore, as permitted under these rules, certain footnotes and other financial information included in audited financial statements were condensed or omitted. The interim financial statements contain all adjustments (consisting of only normal recurring adjustments) necessary to present fairly the interim results of operations, financial position and cash flows for the periods presented.

These interim financial statements should be read in conjunction with the Consolidated Financial Statements and Notes thereto in the Company s Annual Report on Form 10-K, for the year ended December 31, 2009.

The interim results of operations for the three and six months ended June 30, 2010 and the interim cash flows for the six months ended June 30, 2010 are not necessarily indicative of the results to be expected for the full fiscal year or any other future period. The Company computes its provision for income taxes in the first three quarters of the year using an estimated effective tax rate for the full year. The estimated annual effective tax rate for 2010 includes an estimate of the full-year effect of foreign tax credits that the Company anticipates it will claim against its 2010 U.S. tax liabilities. The Company did not claim foreign tax credits against its 2009 U.S. tax liabilities. Certain reclassifications of prior year amounts have been made to conform to the current year presentation.

**2. Revenue Recognition and Accounts Receivable**

Mylan recognizes revenue for product sales when title and risk of loss pass to its customers and when provisions for estimates, including discounts, rebates, price adjustments, returns, chargebacks and other promotional programs, are reasonably determinable. Accounts receivable are presented net of allowances relating to these provisions. No revisions were made to the methodology used in determining these provisions during the six months ended June 30, 2010. Such allowances were \$637.2 million and \$607.9 million at June 30, 2010 and December 31, 2009. Other current liabilities include \$235.0 million and \$238.2 million at June 30, 2010 and December 31, 2009, for certain rebates and other adjustments that are paid to indirect customers.

**3. Recent Accounting Pronouncements**

In October 2009, the Financial Accounting Standards Board ( FASB ) issued revised accounting guidance for multiple-deliverable revenue arrangements. The amended guidance requires that consideration received be allocated at the inception of the arrangement to all deliverables using the relative selling price method and provides for expanded disclosures related to such arrangements. It is effective for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

**4. Acquisition of the Remaining Interest in Matrix Laboratories Limited**

On March 26, 2009, the Company announced plans to buy the remaining public interest in Matrix Laboratories Limited ( Matrix ) from its minority shareholders pursuant to a voluntary delisting offer. At the time, the Company owned approximately 71.2% of Matrix through a wholly-owned subsidiary and controlled more than 76% of its voting

rights. During the calendar year ended December 31, 2009, the Company completed the purchase of an additional portion of the remaining interest from minority shareholders of Matrix, bringing both the Company's total ownership and control to over 96%. During the six months ended June 30, 2010, Mylan completed the purchase of an additional portion of the remaining interest from minority shareholders of Matrix, for cash of approximately \$5.0 million, bringing both the Company's total ownership and control to approximately 97%.

**Table of Contents****MYLAN INC. AND SUBSIDIARIES****Notes to Condensed Consolidated Financial Statements (Unaudited) (Continued)****5. Stock-Based Incentive Plan**

Mylan's shareholders have approved the *2003 Long-Term Incentive Plan* (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. Stock option 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 2003 Plan, no more than 8,000,000 shares may be issued as restricted shares, restricted units, performance shares and other stock-based awards.

Upon approval of the 2003 Plan, no further grants of stock options have been made under any other plan. However, there are stock options outstanding from frozen or expired plans and other plans assumed through acquisitions.

The following table summarizes stock option activity:

	<b>Number of Shares Under Option</b>	<b>Weighted Average Exercise Price per Share</b>
Outstanding at December 31, 2009	26,268,678	\$ 15.22
Options granted	2,071,039	20.98
Options exercised	(2,575,185)	14.04
Options forfeited	(672,247)	14.65
Outstanding at June 30, 2010	25,092,285	\$ 15.83
Vested and expected to vest at June 30, 2010	23,890,685	\$ 15.86
Options exercisable at June 30, 2010	16,419,989	\$ 15.92

As of June 30, 2010, options outstanding, options vested and expected to vest, and options exercisable had average remaining contractual terms of 5.88 years, 5.75 years and 4.42 years, respectively. Also at June 30, 2010, options outstanding, options vested and expected to vest and options exercisable had aggregate intrinsic values of \$53.5 million, \$50.5 million and \$33.1 million, respectively.

A summary of the status of the Company's nonvested restricted stock and restricted stock unit awards as of June 30, 2010 and the changes during the six-month period ended June 30, 2010, are presented below:

<b>Number of Restricted</b>	<b>Weighted Average Grant-Date</b>
---------------------------------	--

	<b>Stock Awards</b>		<b>Fair Value per Share</b>
Nonvested at December 31, 2009	2,464,600	\$	12.78
Granted	816,359		21.20
Released	(395,942)		12.07
Forfeited	(110,338)		12.53
Nonvested at June 30, 2010	2,774,679	\$	15.38

As of June 30, 2010, the Company had \$47.4 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 1.77 years. The total intrinsic value of stock-based awards exercised and restricted stock units converted during the six months ended June 30, 2010 and June 30, 2009 was \$27.2 million and \$7.4 million.

**Table of Contents****MYLAN INC. AND SUBSIDIARIES****Notes to Condensed Consolidated Financial Statements (Unaudited) (Continued)****6. Balance Sheet Components**

Selected balance sheet components consist of the following:

	<b>June 30, 2010</b>	<b>December 31, 2009 (In thousands)</b>
Inventories:		
Raw materials	\$ 301,052	\$ 287,128
Work in process	204,614	198,280
Finished goods	590,699	628,811
	\$ 1,096,365	\$ 1,114,219
Property, plant and equipment:		
Land and improvements	\$ 68,052	\$ 69,614
Buildings and improvements	622,933	625,303
Machinery and equipment	1,167,528	1,145,464
Construction in progress	108,854	118,410
	1,967,367	1,958,791
Less accumulated depreciation	875,693	836,143
	\$ 1,091,674	\$ 1,122,648
Other current liabilities:		
Payroll and employee benefit plan accruals	\$ 139,534	\$ 188,743
Accrued rebates	235,023	238,161
Fair value of financial instruments	43,646	66,420
Legal and professional accruals, including litigation reserves	240,108	218,813
Other	170,022	222,776
	\$ 828,333	\$ 934,913

**7. Earnings per Common Share attributable to Mylan Inc.**

Basic earnings per common share is computed by dividing net earnings attributable to Mylan Inc. common shareholders by the weighted average number of shares outstanding during the period. Diluted earnings per common share is computed by dividing net earnings attributable to Mylan Inc. 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 related to potentially dilutable securities or instruments, 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 the Company's common stock, subject to anti-dilution adjustments, depending on the average stock price of the Company's common stock over the 20 trading-day period ending on the third trading day prior to conversion. For the three and six months ended June 30, 2010 and June 30, 2009, the if-converted method is anti-dilutive; therefore, the preferred stock conversion is excluded from 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 per common share attributable to Mylan Inc. are calculated as follows:

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>
	<b>(In thousands, except per share amounts)</b>			
<b>Basic earnings attributable to Mylan Inc. common shareholders (numerator):</b>				
Net earnings attributable to Mylan Inc. before preferred dividends	\$ 86,228	\$ 92,870	\$ 182,084	\$ 198,929
Less: Preferred dividends	34,759	34,759	69,518	69,518
Net earnings attributable to Mylan Inc. common shareholders	\$ 51,469	\$ 58,111	\$ 112,566	\$ 129,411
<b>Shares (denominator):</b>				
Weighted average shares outstanding	308,968	304,991	307,982	304,784
Basic earnings per common share attributable to Mylan Inc.	\$ 0.17	\$ 0.19	\$ 0.37	\$ 0.42
<b>Diluted earnings attributable to Mylan Inc. common shareholders (numerator):</b>				
Net earnings attributable to Mylan Inc. common shareholders	\$ 51,469	\$ 58,111	\$ 112,566	\$ 129,411
Add: Preferred dividends				
Earnings attributable to Mylan Inc. common shareholders and assumed conversions	\$ 51,469	\$ 58,111	\$ 112,566	\$ 129,411
<b>Shares (denominator):</b>				
Weighted average shares outstanding	308,968	304,991	307,982	304,784
Stock-based awards and warrants	5,439	1,265	5,195	975
Preferred stock conversion				
Total dilutive shares outstanding	314,407	306,256	313,177	305,759
Diluted earnings per common share attributable to Mylan Inc.	\$ 0.16	\$ 0.19	\$ 0.36	\$ 0.42

Additional stock options or restricted stock awards representing 3.9 million and 18.7 million shares were outstanding at June 30, 2010 and 2009, but were not included in the computation of diluted earnings per share because the effect

would be anti-dilutive.

During the six months ended June 30, 2010, the Company paid dividends of \$69.5 million on the preferred stock. On July 19, 2010, 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 August 16, 2010, to the holders of preferred stock of record as of August 1, 2010. The preferred stock will automatically convert into common stock on November 15, 2010, and the last dividend payment is expected on that date.

**Table of Contents****MYLAN INC. AND SUBSIDIARIES****Notes to Condensed Consolidated Financial Statements (Unaudited) (Continued)****8. Goodwill and Intangible Assets**

A rollforward of goodwill from December 31, 2009 to June 30, 2010 is as follows:

	<b>Generics Segment</b>	<b>Specialty Segment (In thousands)</b>	<b>Total</b>
Goodwill	\$ 3,009,740	\$ 706,507	\$ 3,716,247
Accumulated impairment losses <sup>(1)</sup>		(385,000)	(385,000)
Balance at December 31, 2009	\$ 3,009,740	\$ 321,507	\$ 3,331,247
Foreign currency translation	(200,112)		(200,112)
Balance at June 30, 2010	\$ 2,809,628	\$ 321,507	\$ 3,131,135

<sup>(1)</sup> Represents the only impairment charge recognized by the Company under the currently effective accounting guidance.

Intangible assets consist of the following components:

	<b>Weighted Average Life (Years)</b>	<b>Original Cost</b>	<b>Accumulated Amortization (Dollars in thousands)</b>	<b>Net Book Value</b>
<b>June 30, 2010</b>				
Amortized intangible assets:				
Patents and technologies	20	\$ 122,926	\$ 80,737	\$ 42,189
Product rights and licenses	10	2,784,154	770,760	2,013,394
Other <sup>(1)</sup>	8	175,563	98,880	76,683
		\$ 3,082,643	\$ 950,377	\$ 2,132,266
<b>December 31, 2009</b>				
Amortized intangible assets:				
Patents and technologies	20	\$ 122,926	\$ 77,717	\$ 45,209
Product rights and licenses	10	2,902,045	657,050	2,244,995
Other <sup>(1)</sup>	8	170,426	75,782	94,644

\$ 3,195,397      \$                      810,549      \$ 2,384,848

(1) Other intangibles consist principally of customer lists and contracts.

Amortization expense, which is classified within cost of sales on the Company's Condensed Consolidated Statements of Operations, for the six months ended June 30, 2010 and 2009 was \$140.6 million and \$133.4 million, and is expected to be \$132.3 million for the remainder of 2010, and \$259.2 million, \$252.6 million, \$246.9 million and \$239.3 million for the years ended December 31, 2011 through 2014, respectively.

## **9. Financial Instruments and Risk Management**

### ***Financial Risks***

The Company is exposed to certain financial risks relating to its ongoing business operations. The primary financial risks that are managed by using derivative instruments are foreign currency risk, interest rate risk and equity risk.

**Table of Contents**

**MYLAN INC. AND SUBSIDIARIES**

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

In order to manage foreign currency risk, Mylan enters into foreign exchange forward contracts to mitigate risk associated with changes in spot exchange rates of mainly non-functional currency denominated assets or liabilities. The foreign exchange forward contracts are measured at fair value and reported as current assets or current liabilities on the Condensed Consolidated Balance Sheets. Any gains or losses on the foreign exchange forward contracts are recognized in earnings in the period incurred in the Condensed Consolidated Statements of Operations.

During the six months ended June 30, 2010, the Company executed a series of forward contracts to hedge foreign currency denominated sales from certain international subsidiaries. These contracts are designated as cash flow hedges to manage foreign currency risk and are measured at fair value and reported as current assets or current liabilities on the Condensed Consolidated Balance Sheets. Any changes in fair value are included in earnings or deferred through accumulated other comprehensive earnings (loss) ( AOCE ), depending on the nature and effectiveness of the offset.

As of June 30, 2010 and December 31, 2009, the Company had 679.2 million of borrowings under its senior credit agreement (the Senior Credit Agreement ) that are designated as a hedge of its net investment in certain Euro-functional currency subsidiaries to manage foreign currency risk. The U.S. Dollar equivalent of such amount was \$833.0 million at June 30, 2010 and \$978.1 million at December 31, 2009. Borrowings designated as hedges of net investments are marked to market using the current spot exchange rate as of the end of the period, with gains and losses included in the foreign currency translation adjustment component of AOCE on the Condensed Consolidated Balance Sheet until the sale or substantial liquidation of the underlying net investments.

The Company enters into interest rate swaps in order to manage interest rate risk associated with the Company's floating-rate debt. These interest rate swaps are designated as cash flow hedges. The Company's interest rate swaps fix the interest rate on a portion of the Company's variable-rate U.S. Tranche B Term Loans and Euro Tranche B Term Loans under the terms of its Senior Credit Agreement. Derivative contracts designated as hedges to manage interest rate risk are measured at fair value and reported as current assets or current liabilities on the Condensed Consolidated Balance Sheets. Any changes in fair value are included in earnings or deferred through AOCE, depending on the nature and effectiveness of the offset.

In conjunction with the notes offering during the current quarter and the associated prepayment of term debt (see Note 10), the Company terminated certain interest rate swaps that had previously fixed the interest rate on a portion of the Company's variable-rate U.S. Tranche B Term Loans. As a result, during the current quarter, approximately \$7.4 million that had previously been classified in AOCE was recognized into other (expense) income, net. As of June 30, 2010 and December 31, 2009, the total notional amount of the Company's floating-rate debt interest rate swaps was \$1.2 billion and \$2.3 billion.

Certain derivative contracts entered into by the Company are governed by Master Agreements, which contain credit-risk-related contingent features which would allow the counterparties to terminate the contracts early and request immediate payment should the Company trigger an event of default on other specified borrowings. The aggregate fair value of all derivative instruments with credit-risk-related contingent features that are in a liability position at June 30, 2010 is \$37.9 million. The Company is not subject to any obligations to post collateral under derivative contracts.

The Company's most significant credit exposure arises from the convertible note hedge on its Cash Convertible Notes. At June 30, 2010, the convertible note hedge had a total fair value of \$347.9 million, which reflects the maximum loss that would be incurred should the parties fail to perform according to the terms of the contract. The counterparties are

highly rated diversified financial institutions with both commercial and investment banking operations. The counterparties are required to post collateral against this obligation should they be downgraded below thresholds specified in the contract. Eligible collateral is comprised of a wide range of financial securities with a valuation discount percentage reflecting the associated risk.

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

The Company regularly reviews the creditworthiness of its financial counterparties and does not expect to incur a significant loss from failure of any counterparties to perform under any agreements.

**Derivatives Designated as Hedging Instruments  
Fair Values of Derivative Instruments**

(In thousands)	<b>Liability Derivatives</b>			
	<b>June 30, 2010</b>		<b>December 31, 2009</b>	
	<b>Balance Sheet Location</b>	<b>Fair Value</b>	<b>Balance Sheet Location</b>	<b>Fair Value</b>
Interest rate swaps	Other current liabilities	\$ 37,862	Other current liabilities	\$ 62,607
Foreign currency forward contracts	Other current liabilities	2,575	Other current liabilities	
Foreign currency borrowings	Long-term debt	832,980	Long-term debt	978,059
<b>Total</b>		<b>\$ 873,417</b>		<b>\$ 1,040,666</b>

**Derivatives Not Designated as Hedging Instruments  
Fair Values of Derivative Instruments**

(In thousands)	<b>Asset Derivatives</b>			
	<b>June 30, 2010</b>		<b>December 31, 2009</b>	
	<b>Balance Sheet Location</b>	<b>Fair Value</b>	<b>Balance Sheet Location</b>	<b>Fair Value</b>
Foreign currency forward contracts	Prepaid expenses and other current assets	\$ 2,823	Prepaid expenses and other current assets	\$ 8,793
Purchased cash convertible note hedge	Other assets	347,900	Other assets	410,600
<b>Total</b>		<b>\$ 350,723</b>		<b>\$ 419,393</b>

	<b>Liability Derivatives</b>			
	<b>June 30, 2010</b>		<b>December 31, 2009</b>	
	<b>Balance Sheet Location</b>	<b>Fair Value</b>	<b>Balance Sheet Location</b>	<b>Fair Value</b>

**(In thousands)**

Foreign currency forward contracts	Other current liabilities	\$ 3,209	Other current liabilities	\$ 5,694
Cash conversion feature of Cash				
Convertible Notes	Long-term debt	347,900	Long-term debt	410,600
<b>Total</b>		<b>\$ 351,109</b>		<b>\$ 416,294</b>



Table of Contents**MYLAN INC. AND SUBSIDIARIES****Notes to Condensed Consolidated Financial Statements (Unaudited) (Continued)****The Effect of Derivative Instruments on the Condensed Consolidated Statements of Operations  
Derivatives in Cash Flow Hedging Relationships**

	<b>Amount of Gain or (Loss) Recognized in AOCE (Net of Tax) on Derivative (Effective Portion)</b>			
	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>
<b>(In thousands)</b>				
Foreign currency forward contracts	\$ (7,748)	\$	\$ (2,863)	\$
Interest rate swaps	(971)	6,039	3,041	6,049
<b>Total</b>	<b>\$ (8,719)</b>	<b>\$ 6,039</b>	<b>\$ 178</b>	<b>\$ 6,049</b>

	<b>Location of Gain or (Loss) Reclassified from AOCE into Earnings (Effective Portion)</b>	<b>Amount of Gain or (Loss) Reclassified from AOCE into Earnings (Effective Portion)</b>			
		<b>Three Months Ended</b>		<b>Six Months Ended</b>	
		<b>June 30,</b>		<b>June 30,</b>	
		<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>
<b>(In thousands)</b>					
Foreign currency forward contracts	Net revenues	\$ 468	\$	\$ 879	\$
Interest rate swaps	Interest expense	(6,271)	(11,190)	(22,358)	(20,370)
<b>Total</b>		<b>\$ (5,803)</b>	<b>\$ (11,190)</b>	<b>\$ (21,479)</b>	<b>\$ (20,370)</b>

During the three and six months ended June 30, 2010, a gain of \$1.2 million was recognized in other (expense) income, net, related to the foreign currency forward contracts for ineffectiveness. There was no gain or loss recognized into earnings on derivatives with cash flow hedging relationships for ineffectiveness during the three or six months ended June 30, 2009.

**The Effect of Derivative Instruments on the Condensed Consolidated Statement of Operations  
Derivatives in Net Investment Hedging Relationships**

	<b>Amount of Gain or (Loss) Recognized in AOCE (Net of Tax) on Derivative (Effective Portion)</b>			
	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>
<b>(In thousands)</b>				
Foreign currency borrowings	\$ 53,394	\$ (35,745)	\$ 89,058	\$ (2,450)
<b>Total</b>	<b>\$ 53,394</b>	<b>\$ (35,745)</b>	<b>\$ 89,058</b>	<b>\$ (2,450)</b>

There was no gain or loss recognized into earnings on derivatives with net investment hedging relationships during the three or six months ended June 30, 2010 or 2009.

Table of Contents

## MYLAN INC. AND SUBSIDIARIES

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

**The Effect of Derivative Instruments on the Condensed Consolidated Statement of Operations**  
**Derivatives Not Designated as Hedging Instruments**

	Location of Gain or (Loss) Recognized in Earnings on Derivatives	Amount of Gain or (Loss) Recognized in Earnings on Derivatives			
		Three Months Ended June 30,		Six Months Ended June 30,	
		2010	2009	2010	2009
<b>(In thousands)</b>					
Foreign currency forward contracts	Other (expense) income, net	\$ (8,210)	\$ (10,462)	\$ (23,151)	\$ (2,542)
Cash conversion feature of Cash Convertible Notes	Other (expense) income, net	183,800	55,925	62,700	(22,425)
Purchased cash convertible note hedge	Other (expense) income, net	(183,800)	(55,925)	(62,700)	22,425
<b>Total</b>		\$ (8,210)	\$ (10,462)	\$ (23,151)	\$ (2,542)

***Fair Value Measurement***

Fair value is based on the price that would be received from the sale of an identical asset or paid to transfer an identical liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, a fair value hierarchy has been established 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 identical assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

*Level 2:* Observable market-based inputs other than quoted prices in active markets for identical assets or liabilities.

*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.

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

Financial assets and liabilities carried at fair value are classified in the tables below in one of the three categories described above:

	<b>Level 1</b>	<b>June 30, 2010</b>		<b>Total</b>
		<b>Level 2</b>	<b>Level 3</b>	
		<b>(In thousands)</b>		
<b>Financial Assets:</b>				
<b>Trading securities:</b>				
Equity securities – exchange traded funds	\$ 1,577	\$	\$	\$ 1,577
Total trading securities	\$ 1,577	\$	\$	\$ 1,577
<b>Available-for-sale fixed income investments:</b>				
U.S. Treasuries	\$	\$ 12,561	\$	\$ 12,561
Corporate bonds		3,738		3,738
Agency mortgage-backed securities		2,253		2,253
Other		3,039		3,039
Total available-for-sale fixed income investments	\$	\$ 21,591	\$	\$ 21,591
<b>Available-for-sale equity securities:</b>				
Biosciences industry	\$ 623	\$	\$	\$ 623
Total available-for-sale equity securities	\$ 623	\$	\$	\$ 623
Foreign exchange derivative assets	\$	2,823	\$	\$ 2,823
Purchased cash convertible note hedge		347,900		347,900
Total assets at fair value <sup>(1)</sup>	\$ 2,200	\$ 372,314	\$	\$ 374,514
<b>Financial Liabilities:</b>				
Foreign exchange derivative liabilities	\$	\$ 5,784	\$	\$ 5,784
Interest rate swap derivative liabilities		37,862		37,862
Cash conversion feature of cash convertible notes		347,900		347,900
Total liabilities at fair value <sup>(1)</sup>	\$	\$ 391,546	\$	\$ 391,546

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

	<b>Level 1</b>	<b>December 31, 2009</b>		<b>Total</b>
		<b>Level 2</b>	<b>Level 3</b>	
		<b>(In thousands)</b>		
<b>Financial Assets:</b>				
Available-for-sale fixed income investments	\$	\$ 26,485	\$	\$ 26,485
Available-for-sale equity securities	1,074			1,074
Foreign exchange derivative assets		8,793		8,793
Purchased cash convertible note hedge		410,600		410,600
<b>Total assets at fair value<sup>(1)</sup></b>	<b>\$ 1,074</b>	<b>\$ 445,878</b>	<b>\$</b>	<b>\$ 446,952</b>
<b>Financial Liabilities:</b>				
Foreign exchange derivative liabilities	\$	\$ 5,694	\$	\$ 5,694
Interest rate swap derivative liabilities		62,607		62,607
Cash conversion feature of cash convertible notes		410,600		410,600
<b>Total liabilities at fair value<sup>(1)</sup></b>	<b>\$</b>	<b>\$ 478,901</b>	<b>\$</b>	<b>\$ 478,901</b>

<sup>(1)</sup> The Company chose not to elect the fair value option 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.

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:

*Trading securities* valued at the quoted market price from broker or dealer quotations or transparent pricing sources at the reporting date.

*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.

*Available-for-sale 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/EURIBOR yield curves at the reporting date. Counterparties to these contracts are highly rated financial institutions, none of which experienced any significant downgrades during the six months ended June 30, 2010, 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 during the six months ended June 30, 2010 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, its implied volatility 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 during the six months ended June 30, 2010, 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, any future transacted financial asset or liability will be evaluated for the fair value election.

**10. Long-Term Debt**

On May 19, 2010, the Company issued \$550.0 million aggregate principal amount of 7.625% Senior Notes due 2017 (the 2017 Notes ) and \$700.0 million aggregate principal amount of 7.875% Senior Notes due 2020 (the 2020 Notes ) in a private offering exempt from the registration requirements of the Securities Act of 1933 (the Securities Act ) to qualified institutional buyers in accordance with Rule 144A and to persons outside of the United States pursuant to Regulation S under the Securities Act. The 2017 Notes and 2020 Notes are the Company's senior unsecured obligations and are guaranteed on a senior unsecured basis by certain of the Company's domestic subsidiaries.

The 2017 Notes bear interest at a rate of 7.625% per year, accruing from May 19, 2010. Interest on the 2017 Notes is payable semiannually in arrears on January 15 and July 15 of each year, beginning on January 15, 2011. The 2017 Notes will mature on July 15, 2017, subject to earlier repurchase or redemption in accordance with the terms of the indenture. The 2020 Notes bear interest at a rate of 7.875% per year, accruing from May 19, 2010. Interest on the 2020 Notes is payable semiannually in arrears on January 15 and July 15 of each year, beginning on January 15, 2011. The 2020 Notes will mature on July 15, 2020, subject to earlier repurchase or redemption in accordance with the terms of the indenture.

The Company may redeem some or all of the 2017 Notes at any time prior to July 15, 2014, and some or all of the 2020 Notes at any time prior to July 15, 2015, in each case at a price equal to 100% of the principal amount redeemed plus accrued and unpaid interest, if any, to the redemption date and an applicable make-whole premium set forth in the indenture. On or after July 15, 2014 in the case of the 2017 Notes, and on or after July 15, 2015 in the case of the 2020 Notes, the Company may redeem some or all of the 2017 Notes and 2020 Notes of such series at redemption prices set forth in the indenture, plus accrued and unpaid interest, if any, to the redemption date. In addition, at any time prior to July 15, 2013, the Company may redeem up to 35% of the aggregate principal amount of either series of the 2017 Notes and 2020 Notes at a specified redemption price set forth in the indenture with the net cash proceeds of certain equity offerings. If the Company experiences certain change of control events, it must offer to repurchase the 2017 Notes and 2020 Notes at 101% of their principal amount, plus accrued and unpaid interest, if any, to the repurchase date.

The Company used \$1.0 billion of the net proceeds of the 2017 Notes and 2020 Notes offering to repay a portion of the U.S. Tranche B Term Loans due under the terms of its Senior Credit Agreement.

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

A summary of long-term debt is as follows:

	<b>June 30,</b>	<b>December 31, 2009</b>
	<b>2010</b>	<b>(In thousands)</b>
U.S. Tranche A Term Loans(A)	\$ 156,250	\$ 156,250
Euro Tranche A Term Loans(A)	214,874	252,299
U.S. Tranche B Term Loans(A)	1,453,760	2,453,760
Euro Tranche B Term Loans(A)	618,106	725,760
Senior Convertible Notes(B)	551,775	538,693
Cash Convertible Notes(C)	793,827	847,136
2017 Notes	550,000	
2020 Notes	700,000	
Other	15,954	17,437
	5,054,546	4,991,335
Less: Current portion	7,162	6,348
Total long-term debt	\$ 5,047,384	\$ 4,984,987

- (A) All 2010 and 2011 mandatory principal payments due under the Senior Credit Agreement were prepaid during 2009. During the quarter ended June 30, 2010, the Company also prepaid \$1.0 billion of the outstanding U.S. Tranche B Term Loans, using a portion of the net proceeds of the 2017 Notes and the 2020 Notes.
- (B) At June 30, 2010, the \$551.8 million of debt is net of a \$48.2 million discount. At December 31, 2009, the \$538.7 million debt is net of a \$61.3 million discount.
- (C) At June 30, 2010, the \$793.8 million consists of \$445.9 million of debt (\$575.0 million face amount, net of \$129.1 million discount) and the bifurcated conversion feature with a fair value of \$347.9 million recorded as a liability within long-term debt in the Condensed Consolidated Balance Sheet at June 30, 2010. Additionally, the Company has purchased call options, which are recorded as assets at their fair value of \$347.9 million within other assets in the Condensed Consolidated Balance Sheet at June 30, 2010. At December 31, 2009, the \$847.1 million consisted of \$436.5 million of debt (\$575.0 million face amount, net of \$138.5 million discount) and the bifurcated conversion feature with a fair value of \$410.6 million recorded as a liability within other long-term obligations in the Condensed Consolidated Balance Sheet. The purchased call options are assets recorded at their fair value of \$410.6 million within other assets in the Condensed Consolidated Balance Sheet at December 31, 2009.

As of June 30, 2010, because the closing price of our common stock for at least 20 trading days in the period of 30 consecutive trading days ending on the last trading day in the June 30, 2010 period, was more than 130% of the applicable conversion reference price of \$13.32 at June 30, 2010, the \$575.0 million of Cash Convertible



Notes was currently convertible. Although the Company's experience is that convertible debentures are not normally converted by investors until close to their maturity date, it is possible that debentures could be converted prior to their maturity date if, for example, a holder perceives the market for the debentures to be weaker than the market for the common stock. Upon an investor's election to convert, the Company is required to pay the full conversion value in cash. The amount payable per \$1,000 notional bond would be calculated as the product of (1) the conversion reference rate (currently 75.0751) and (2) the average Daily Volume Weighted Average Price per share of common stock for a specified period following the conversion date. Any payment above the principal amount is matched by a convertible note hedge.

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

Details of the interest rates in effect at June 30, 2010 and December 31, 2009, on the outstanding borrowings under the Term Loans are in the table below:

	<b>Outstanding</b>	<b>June 30, 2010 Basis (In thousands)</b>	<b>Rate</b>
U.S. Tranche A Term Loans	\$ 156,250	LIBOR + 2.75%	3.13%
Euro Tranche A Term Loans	\$ 214,874	EURIBO + 2.75%	3.22%
U.S. Tranche B Term Loans			
Swapped to Fixed Rate December 2010 <sup>(1)(2)</sup>	\$ 500,000	Fixed	6.03%
Swapped to Fixed Rate March 2010 <sup>(1)</sup>	500,000	Fixed	5.38%
Floating Rate	453,760	LIBOR + 3.25%	3.63%
Total U.S. Tranche B Term Loans	\$ 1,453,760		
Euro Tranche B Term Loans			
Swapped to Fixed Rate March 2010 <sup>(1)</sup>	\$ 245,280	Fixed	5.38%
Floating Rate	372,826	EURIBO + 3.25%	3.72%
Total Euro Tranche B Term Loans	\$ 618,106		
		<b>December 31, 2009 Basis (In thousands)</b>	<b>Rate</b>
U.S. Tranche A Term Loans	\$ 156,250	LIBOR + 2.75%	3.00%
Euro Tranche A Term Loans	\$ 252,299	EURIBO + 2.75%	3.19%
U.S. Tranche B Term Loans			
Swapped to Fixed Rate December 2010 <sup>(1)(2)</sup>	\$ 500,000	Fixed	6.03%
Swapped to Fixed Rate March 2010 <sup>(1)</sup>	500,000	Fixed	5.44%
Swapped to Fixed Rate December 2010 <sup>(1)</sup>	1,000,000	Fixed	7.37%
Floating Rate	453,760	LIBOR + 3.25%	3.50%
Total U.S. Tranche B Term Loans	\$ 2,453,760		
Euro Tranche B Term Loans			
Swapped to Fixed Rate March 2010 <sup>(1)</sup>	\$ 288,000	Fixed	5.38%
Floating Rate	437,760	EURIBO + 3.25%	3.83%
Total Euro Tranche B Term Loans	\$ 725,760		

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

(2) This interest rate swap has been extended to December 2012 at a rate of 6.60%, effective January 2011

At June 30, 2010 and December 31, 2009, the fair value of the Senior Convertible Notes was approximately \$602.5 million and \$612.8 million. At June 30, 2010 and December 31, 2009, the fair value of the Cash Convertible Notes was approximately \$818.2 million and \$879.8 million.

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

Mandatory minimum repayments remaining on the outstanding borrowings under the term loans and notes at June 30, 2010, excluding the discounts and conversion features, are as follows for each of the periods ending December 31:

	<b>U.S. Tranche A Term Loans</b>	<b>Euro Tranche A Term Loans</b>	<b>U.S. Tranche B Term Loans</b>	<b>Euro Tranche B Term Loans</b>	<b>Senior Convertible Notes</b>	<b>Cash Convertible Notes</b>	<b>2017 Notes</b>	<b>2020 Notes</b>	<b>Total</b>
	<b>(In thousands)</b>								
10	\$	\$	\$	\$	\$	\$	\$	\$	\$
11									
12	78,125	107,437		6,439	600,000				792,000
13	78,125	107,437		6,439					192,000
14			1,453,760	605,228					2,058,988
15						575,000			575,000
hereafter							550,000	700,000	1,250,000
total	\$ 156,250	\$ 214,874	\$ 1,453,760	\$ 618,106	\$ 600,000	\$ 575,000	\$ 550,000	\$ 700,000	\$ 4,867,992

**11. Comprehensive (Loss) Earnings**

Comprehensive (loss) earnings consists of the following:

	<b>Three Months Ended June 30,</b>	
	<b>2010</b>	<b>2009</b>
	<b>(In thousands)</b>	
Net earnings	\$ 86,933	\$ 95,671
Other comprehensive (loss) earnings, net of tax, as applicable:		
Foreign currency translation adjustments	(263,935)	322,222
Change in unrecognized (losses) gains and prior service cost related to post-retirement plans	(1,765)	281
Net unrecognized (loss) gain on derivatives	(8,719)	6,039
Unrealized gains on available-for-sale securities		
Net unrealized gains on available-for-sale securities	98	226
Less: Reclassification for gains included in net earnings	158	45
	256	271
Total other comprehensive (loss) earnings, net of tax, as applicable:	(274,163)	328,813
Comprehensive (loss) earnings	(187,230)	424,484

Edgar Filing: MYLAN INC. - Form 10-Q

Comprehensive earnings attributable to the noncontrolling interest	(705)	(2,962)
Comprehensive (loss) earnings attributable to Mylan Inc.	\$ (187,935)	\$ 421,522

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

	<b>Six Months Ended June 30,</b>	
	<b>2010</b>	<b>2009</b>
	<b>(In thousands)</b>	
Net earnings	\$ 181,203	\$ 204,745
Other comprehensive (loss) earnings, net of tax, as applicable:		
Foreign currency translation adjustments	(333,332)	103,293
Change in unrecognized gains and prior service cost related to post-retirement plans	3,520	220
Net unrecognized gain on derivatives	178	6,049
Unrealized gains on available-for-sale securities		
Net unrealized gains on available-for-sale securities	313	378
Less: Reclassification for gains included in net earnings	157	161
	470	539
Total other comprehensive (loss) earnings, net of tax, as applicable:	(329,164)	110,101
Comprehensive (loss) earnings	(147,961)	314,846
Comprehensive loss (earnings) attributable to the noncontrolling interest	881	(5,865)
Comprehensive (loss) earnings attributable to Mylan Inc.	\$ (147,080)	\$ 308,981

Accumulated other comprehensive (loss) earnings, as reflected on the Condensed Consolidated Balance Sheets, is comprised of the following:

	<b>June 30,</b>	<b>December 31, 2009</b>
	<b>2010</b>	<b>(In thousands)</b>
Net unrealized gain on available-for-sale securities, net of tax	\$ 1,345	\$ 875
Net unrecognized gains (losses) and prior service cost related to post-retirement plans, net of tax	107	(3,413)
Net unrecognized losses on derivatives, net of tax	(39,103)	(39,281)
Foreign currency translation adjustment	(279,707)	53,626
Accumulated other comprehensive (loss) earnings	\$ (317,358)	\$ 11,807

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

A summary of the change in shareholders equity for the six months ended June 30, 2010 and 2009 is as follows:

	<b>Total Mylan Inc. Shareholders Equity</b>	<b>Noncontrolling Interest (In thousands)</b>	<b>Total</b>
December 31, 2009	\$ 3,131,146	\$ 14,052	\$ 3,145,198
Net income (loss)	182,084	(881)	181,203
Other comprehensive loss	(329,164)		(329,164)
Dividends paid on preferred stock	(69,518)		(69,518)
Stock option activity	36,007		36,007
Stock compensation expense	15,617		15,617
Purchase of subsidiary shares from noncontrolling interest	(4,376)	(623)	(4,999)
Tax benefit of stock option plans	3,310		3,310
Other	1,578	(276)	1,302
June 30, 2010	\$ 2,966,684	\$ 12,272	\$ 2,978,956
December 31, 2008	\$ 2,757,733	\$ 29,108	\$ 2,786,841
Net income	198,929	5,816	204,745
Other comprehensive income	110,052	49	110,101
Dividends paid on preferred stock	(69,518)		(69,518)
Stock option activity	1,417		1,417
Stock compensation expense	14,652		14,652
Impact on additional paid-in capital of equity transaction	(115,210)		(115,210)
Purchase of subsidiary shares from noncontrolling interest		(19,299)	(19,299)
Other	(2,002)	561	(1,441)
June 30, 2009	\$ 2,896,053	\$ 16,235	\$ 2,912,288

**13. Segment Information**

Mylan previously had three reportable segments, Generics, Specialty and Matrix. The Matrix Segment consisted of Matrix, which was previously a publicly traded company in India, in which Mylan held a 71.2% ownership stake. Following the acquisition of additional interests in Matrix and its related delisting from the Indian stock exchanges, Mylan has two reportable segments, Generics and Specialty. Mylan changed its segment disclosure to align with how the business is being managed after those changes. The former Matrix Segment is included within the Generics

Segment. Information for earlier periods has been recast.

The Generics Segment primarily develops, manufactures, sells and distributes generic or branded generic pharmaceutical products in tablet, capsule or transdermal patch form, as well as active pharmaceutical ingredients ( API ). The Specialty Segment engages mainly in the manufacture and sale of branded specialty nebulized and injectable products.

The Company s chief operating decision maker evaluates the performance of its reportable segments based on total revenues and segment profitability. For the Generics and Specialty Segments, segment profitability represents segment gross profit less direct research and development expenses and direct selling, general and administrative expenses. Certain general and administrative and research and development expenses not allocated to the segments,



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

as well as reserves for litigation settlements, impairment charges and other expenses not directly attributable to the segments, are reported in Corporate/Other. Additionally, amortization of intangible assets, and other purchase accounting related items, as well as any other significant special items, are included in Corporate/Other. 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 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 Annual Report on Form 10-K for the year ended December 31, 2009. 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.

	<b>Generics Segment</b>	<b>Specialty Segment</b>	<b>Corporate / Other<sup>(1)</sup></b>	<b>Consolidated</b>
	<b>(In thousands)</b>			
<b><u>Three Months Ended June 30, 2010</u></b>				
Total revenues				
Third party	\$ 1,242,655	\$ 125,881	\$	\$ 1,368,536
Intersegment	1,502	17,216	(18,718)	
Total	\$ 1,244,157	\$ 143,097	\$ (18,718)	\$ 1,368,536
Segment profitability	\$ 333,253	\$ 35,315	\$ (173,982)	\$ 194,586

	<b>Generics Segment</b>	<b>Specialty Segment</b>	<b>Corporate / Other<sup>(1)</sup></b>	<b>Consolidated</b>
<b><u>Six Months Ended June 30, 2010</u></b>				
Total revenues				
Third party	\$ 2,450,516	\$ 210,393	\$	\$ 2,660,909
Intersegment	31,921	33,730	(65,651)	
Total	\$ 2,482,437	\$ 244,123	\$ (65,651)	\$ 2,660,909
Segment profitability	\$ 658,587	\$ 55,119	\$ (320,615)	\$ 393,091

	<b>Generics Segment</b>	<b>Specialty Segment</b>	<b>Corporate / Other<sup>(1)</sup></b>	<b>Consolidated</b>
--	-----------------------------	------------------------------	--	---------------------

**Three Months Ended June 30, 2009**

Total revenues				
Third party	\$ 1,144,201	\$ 122,776	\$	\$ 1,266,977
Intersegment	1,804	7,090	(8,894)	
Total	\$ 1,146,005	\$ 129,866	\$ (8,894)	\$ 1,266,977
Segment profitability	\$ 322,536	\$ 29,794	\$ (177,617)	\$ 174,713

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

	<b>Generics Segment</b>	<b>Specialty Segment</b>	<b>Corporate / Other<sup>(1)</sup></b>	<b>Consolidated</b>
<b><u>Six Months Ended June 30, 2009</u></b>				
Total revenues				
Third party	\$ 2,274,721	\$ 202,172	\$	\$ 2,476,893
Intersegment	18,228	11,420	(29,648)	
Total	\$ 2,292,949	\$ 213,592	\$ (29,648)	\$ 2,476,893
Segment profitability	\$ 700,018	\$ 31,695	\$ (329,659)	\$ 402,054

- (1) Includes certain corporate general and administrative and research and development expenses; reserves for litigation settlements; certain intercompany transactions, including eliminations; amortization of intangible assets and certain purchase-accounting items; impairment charges; and other expenses not directly attributable to segments.

**14. Restructuring**

Included in other current liabilities in the Company's Condensed Consolidated Balance Sheets as of June 30, 2010 and December 31, 2009 are restructuring reserves totaling \$23.4 million and \$39.3 million. Of these amounts, \$16.5 million and \$27.0 million, as of June 30, 2010 and December 31, 2009, relate to certain estimated exit costs associated with the acquisition of the former Merck Generics business, and the remainder of each balance relates to the Company's intention to restructure certain other activities and incur certain related exit costs.

The plans related to the exit activities associated with the former Merck Generics business were finalized during calendar year 2008. During the six months ended June 30, 2010, payments of \$10.5 million were made against the reserve, of which \$4.5 million was for severance costs and the remaining \$6.0 million was for other exit costs. Of the remaining accrual, approximately \$12.2 million relates to additional severance and related costs, \$2.0 million relates to costs associated with the previously announced rationalization and optimization of the Company's global manufacturing and research and development platforms, and the remainder consists of other exit costs.

In addition, the Company has announced its intent to restructure certain activities and incur certain related exit costs, including costs related to the realignment of the Dey business and the right-sizing of certain businesses in markets outside of the U.S. Accordingly, the Company has recorded a reserve for such activities, of which approximately \$6.9 million remains at June 30, 2010. During the six months ended June 30, 2010, the Company recorded restructuring charges of approximately \$3.4 million, nearly all of which relates to severance and related costs. Spending during the six months, primarily related to severance, amounted to approximately \$8.5 million.

**15. 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 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, results of operations and cash flows.

***Lorazepam and Clorazepate***

On June 1, 2005, a jury verdict was rendered against Mylan, Mylan Pharmaceuticals Inc. ( MPI ), and co-defendants Cambrex Corporation and Gyma Laboratories in the U.S. District Court for the District of Columbia in

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

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, which, in the case of three of the plaintiffs, reflects trebling of the compensatory damages in the original verdict (approximately \$11 million in total) and, in the case of the fourth plaintiff, reflects their amount of the compensatory damages in the original jury verdict plus doubling this compensatory damage award as punitive damages assessed against each of the defendants (approximately \$58 million in total), 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 \$8.0 million. The Company and its co-defendants have appealed to the U.S. Court of Appeals for the D.C. Circuit and have challenged the verdict as legally erroneous on multiple grounds. The appeals were held in abeyance pending a ruling on the motion for prejudgment interest, which has been granted. Mylan intends to contest this ruling along with the liability finding and other damages awards as part of its pending appeal, which is proceeding in the Court of Appeals for the D.C. Circuit. 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 Sheets) and an irrevocable letter of credit for \$34.5 million issued under the Senior Credit Agreement.

***Pricing and Medicaid Litigation***

Beginning in September 2003, Mylan, MPI and/or UDL Laboratories Inc. (UDL), together with many other pharmaceutical companies, have been named in civil lawsuits filed by state attorneys general (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 and/or Wholesale Acquisition Costs that exceeded the actual selling price of the defendants' prescription drugs, causing state programs to overpay pharmacies and other providers. 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 cases seeks money damages, civil penalties and/or double, treble or punitive damages, counsel fees and costs, equitable relief and/or injunctive relief. Certain of these cases may go to trial in 2010. Mylan and its subsidiaries have denied liability and intend to defend each of these actions vigorously. On January 27, 2010, in the New York Counties cases, the U.S. District Court for the District of Massachusetts granted the plaintiffs' motion for partial summary judgment as to liability under New York Social Services Law § 145-b against Mylan and several other defendants. The District Court has not ruled on the

remaining issues of liability and damages. On February 8, 2010, Mylan, and a majority of the other defendants, filed a motion to amend the court's decision, requesting the court to certify a question of New York state law pertaining to the court's finding of requisite causation under the Social Services Law to the First Circuit Court of Appeals, so that the defendants could in turn request that the First Circuit

**Table of Contents**

**MYLAN INC. AND SUBSIDIARIES**

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

Court of Appeals certify the question to the New York Court of Appeals. The District Court denied this motion on May 4, 2010.

In May 2008, an amended complaint was filed in the U.S. District Court for the District of Massachusetts by a private 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 nationwide recovery of any and all alleged overpayment of the federal share under the Medicaid program, as well as treble damages and civil penalties. In February 2010, the Company reached an agreement in principle to settle this case (except for the claims related to the California federal share) and the Texas state action mentioned above. This settlement is contingent upon the execution of definitive settlement documents and court approval. The settlement would resolve a significant portion of the damages claims asserted against Mylan, MPI and UDL in the various pending pricing litigations. In addition, Mylan has reached agreement in principle to settle the Hawaii state action, which settlement is contingent upon the execution of definitive settlement documents. With regard to the remaining state actions, the Company continues to believe that it has meritorious defenses and will continue to vigorously defend itself in those actions. The Company has accrued \$160 million in connection with the above-mentioned settlement in principle and the remaining state actions. The Company reviews the status of these actions on an ongoing basis, and from time to time, the Company may settle or otherwise resolve these matters on terms and conditions that management believes are in the best interests of the Company. There are no assurances that settlements can be reached on acceptable terms or that adverse judgments, if any, in the remaining litigation will not exceed the amounts reserved.

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 involved whether MPI and UDL may have violated the False Claims Act by classifying certain authorized generics as non-innovator rather than innovator drugs for purposes of Medicaid and other federal healthcare programs on sales from 2000 through 2004. MPI and UDL denied the government's allegations and denied that they engaged in any wrongful conduct. On October 19, 2009, a lawsuit, filed in March 2004 by a private relator, in which the federal government subsequently intervened, was unsealed by the U.S. District Court for the District of New Hampshire. That same day, MPI and UDL announced that they had entered into a settlement agreement with the federal government, relevant states and the relator for approximately \$121.0 million, resolving both the lawsuit and the U.S. Department of Justice investigation. A stipulation of dismissal with prejudice has been filed with the court. The resolution of the matter did not include any admission or finding of wrongdoing on the part of either MPI or UDL. The Company has recovered approximately \$50 million of the settlement amount based on overpayments resulting from adjusted net sales during the relevant timeframe.

Dey is a defendant currently in lawsuits brought by the state AGs of California, Illinois, Kentucky, Pennsylvania and Wisconsin, as well as three 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 these class actions, which has been preliminarily approved by the court. Additionally, a complaint was filed under seal by a plaintiff on behalf of the United States of America against Dey in August 1997. In August 2006, the Government filed its complaint-in-intervention and the case was unsealed in September 2006. Dey's motion for partial summary judgment in that case is pending, as is the

Government's cross-motion. The Government has asserted that Dey is jointly liable with a codefendant and seeks recovery of alleged overpayments, together with treble damages, civil penalties and equitable relief. These cases all generally allege that Dey falsely reported certain price information concerning certain drugs marketed by Dey, that Dey caused false claims to be made to Medicaid and to Medicare, and that Dey caused Medicaid and Medicare to make overpayments on those claims. Certain of these cases may go to trial in 2010. Dey intends to defend each of these actions vigorously. The Company has approximately \$97.8 million recorded in other liabilities related to the



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

price-related litigation involving Dey. As stated above, in conjunction with the acquisition of the former Merck Generics business, Mylan is entitled to indemnification from Merck KGaA. As a result, the Company has recorded approximately \$97.8 million in other assets.

***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, the Northern District of Ohio and a lawsuit originally filed in Tennessee state court 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. On March 29, 2010, the Court in the Eastern District of Pennsylvania denied the defendants' motions to dismiss. 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. 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 has cooperated 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. On July 1, 2010, the FTC issued a third party subpoena to Mylan requesting documents in connection with its lawsuit against Cephalon. Mylan is in the process of responding to the subpoena. Mylan is not named as a defendant in the FTC's lawsuit, although the complaint includes certain allegations pertaining to the Mylan/Cephalon settlement.

***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 was 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. There are approximately 1,008 cases pending against Mylan, UDL and Actavis pertaining to the recall. Most of these cases have been transferred to the multi-district litigation proceedings pending in the U.S. District Court for the Southern District of West Virginia for pretrial proceedings. The remainder of these cases will likely be litigated in the state courts in which they were filed. Certain of these cases may go to trial in 2010. 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 the Company's financial position, results of operations or cash flows.

***EU Commission Proceedings***

On or around July 3, 2009, the European Commission (the EU Commission or the Commission) stated that it had initiated antitrust proceedings pursuant to Article 11(6) of Regulation No. 1/2003 and Article 2(1) of Regulation No. 773/2004 to explore possible infringement of Articles 81 and 82 EC and Articles 53 and 54 of the EEA Agreement by Les Laboratoires Servier (Servier) as well as possible infringement of Article 81 EC by Matrix

and four other companies, each of which entered into agreements with Servier relating to the product perindopril. Matrix is cooperating with the EU Commission in connection with the investigation. The EU Commission stated that the initiation of proceedings does not imply that the Commission has conclusive proof of an infringement but merely signifies that the Commission will deal with the case as a matter of priority. No statement of objections has been filed against Matrix in connection with its investigation. On August 5, 2009,

**Table of Contents**

**MYLAN INC. AND SUBSIDIARIES**

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

Matrix and Generics [U.K.] Ltd. received requests for information from the EU Commission in connection with this matter, and both companies have responded. By letters dated February 17, 2010, the EU Commission served additional requests for information on Matrix and Mylan S.A.S. The companies have responded to these requests.

In addition, the EU Commission is conducting a pharmaceutical sector inquiry involving approximately 100 companies concerning the introduction of innovative and generic medicines. Mylan S.A.S. has responded to the questionnaires received in connection with the sector inquiry and has produced documents and other information in connection with the inquiry.

On October 6, 2009, the Company received notice that the EU Commission was initiating an investigation pursuant to Article 20(4) of Regulation No. 1/2003 to explore possible infringement of Articles 81 and 82 EC by the Company and its affiliates. Mylan S.A.S., acting on behalf of its Mylan affiliates, has produced documents and other information in connection with the inquiry. The Company and Mylan S.A.S. received an additional request for information with the same case reference on December 18, 2009 and have responded to the questionnaire. An additional request was received on March 18, 2010. Mylan S.A.S. has responded to this request. Mylan is cooperating with the Commission in connection with the investigation. No statement of objections has been filed against Mylan in connection with the investigation.

***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 acquisition of the former Merck Generics business. While it is not feasible to predict the ultimate outcome of such other proceedings, the ultimate outcome of any such proceeding is not expected to have a material adverse effect on its financial position, results of operations or cash flows.

**16. Subsequent Event**

On July 14, 2010, the Company entered into an agreement to acquire Bioniche Pharma Holdings Limited ( Bioniche Pharma ), a privately held, global injectable pharmaceutical company, for \$550.0 million in cash. Most of Bioniche Pharma's sales are derived in the U.S. commercial marketplace. The company manufactures and sells a diverse portfolio of products across several therapeutic areas for the hospital setting, including analgesics/anesthetics, orthopedics, oncology, and urology.

Mylan is not assuming any of Bioniche Pharma's outstanding debt or acquiring the company's cash as part of the transaction. Mylan expects to finance this transaction using a combination of cash on hand and available borrowings. The closing of this transaction is conditioned upon regulatory approvals and other customary closing conditions and is expected to occur within 60 days of signing the agreement.

**Table of Contents****ITEM 2. *MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS***

The following discussion and analysis addresses material changes in the financial condition and results of operations 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 Financial Condition and Results of Operations included in the Company's Annual Report on Form 10-K for the year ended December 31, 2009, the unaudited interim Condensed Consolidated Financial Statements and related Notes included in Part I ITEM 1 of this Quarterly Report on Form 10-Q (Form 10-Q) and our other Securities and Exchange Commission (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 our 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, be, anticipate, expect, plan, estimate, forecast, potential, intend, continue and variations of these words or other 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 filing date of this Form 10-Q.

***Executive Overview***

Mylan is the world's third largest producer of generic and specialty pharmaceuticals, offering one of the industry's broadest and highest quality product portfolios, a robust pipeline and a global commercial footprint that spans more than 140 countries and territories. Employing over 15,500 people, Mylan has attained leading positions in key international markets through its wide array of dosage forms and delivery systems, significant manufacturing capacity, global scale and commitment to customer service. Through its Matrix Laboratories Limited (Matrix) subsidiary, Mylan controls one of the world's largest active pharmaceutical ingredient (API) manufacturers with respect to the number of drug master files filed with regulatory agencies. This relationship makes Mylan one of only two global generics companies with a comprehensive, vertically integrated supply chain.

Mylan previously had three reportable segments, Generics, Specialty and Matrix. The Matrix Segment consisted of Matrix, which was previously a publicly traded company in India, in which Mylan held a 71.2% ownership stake. Following the acquisition of additional interests in Matrix, beginning in 2009, and its related delisting from the Indian stock exchanges, Mylan now has two reportable segments, Generics and Specialty. Mylan revised its segment disclosure to align with how the business is being managed after those changes. The former Matrix Segment is included within the Generics Segment. Information for earlier periods has been recast.

Generics primarily develops, manufactures, sells and distributes generic or branded generic pharmaceutical products in tablet, capsule or transdermal patch form, as well as API. Specialty engages mainly in the manufacture and sale of branded specialty nebulized and injectable products. We also report in Corporate/Other certain research and development expenses, general and administrative expenses, litigation settlements, amortization of intangible assets and certain purchase-accounting items, impairment charges, and other items not directly attributable to the segments.

***Issuance of Senior Notes***

During the quarter ended June 30, 2010, we issued \$550.0 million of 7.625% Senior Notes due 2017 (the 2017 Notes ) and \$700.0 million of 7.875% Senior Notes due 2020 (the 2020 Notes ). These notes were issued in a private offering exempt from the registration requirements of the Securities Act of 1933 to qualified institutional buyers in accordance with Rule 144A and to persons outside of the United States pursuant to Regulation S under the Securities Act. The 2017 Notes and 2020 Notes are the Company's senior unsecured obligations and are guaranteed on a senior unsecured basis by certain of the Company's domestic subsidiaries.

**Table of Contents**

The 2017 Notes bear interest at a rate of 7.625% per year, accruing from May 19, 2010. Interest on the 2017 Notes is payable semiannually in arrears on January 15 and July 15 of each year, beginning on January 15, 2011. The 2017 Notes will mature on July 15, 2017, subject to earlier repurchase or redemption in accordance with the terms of the indenture. The 2020 Notes bear interest at a rate of 7.875% per year, accruing from May 19, 2010. Interest on the 2020 Notes is payable semiannually in arrears on January 15 and July 15 of each year, beginning on January 15, 2011. The 2020 Notes will mature on July 15, 2020, subject to earlier repurchase or redemption in accordance with the terms of the indenture.

The Company used \$1.0 billion of the net proceeds of the 2017 Notes and 2020 Notes offering to repay a portion of the U.S. Tranche B Term Loans due under the terms of its senior credit agreement ( Senior Credit Agreement ).

*Pending Acquisition of Bioniche Pharma Holdings Limited*

On July 14, 2010, the Company entered into an agreement to acquire Bioniche Pharma Holdings Limited ( Bioniche Pharma ), a privately held, global injectable pharmaceutical company, for \$550.0 million in cash. Most of Bioniche Pharma's sales are derived in the U.S. commercial marketplace. The company manufactures and sells a diverse portfolio of products across several therapeutic areas for the hospital setting, including analgesics/anesthetics, orthopedics, oncology, and urology.

Mylan is not assuming any of Bioniche Pharma's outstanding debt or acquiring the company's cash as part of the transaction. Mylan expects to finance this transaction using a combination of cash on hand and available borrowings. The closing of this transaction is conditioned upon regulatory approvals and other customary closing conditions and is expected to occur within 60 days of signing the agreement.

*Financial Summary*

For the three months ended June 30, 2010, Mylan reported total revenues of \$1.37 billion compared to \$1.27 billion for the three months ended June 30, 2009. This represents an increase in revenues of \$101.6 million, or 8.0%. Consolidated gross profit for the current quarter was \$541.9 million compared to \$527.8 million in the comparable prior year period, an increase of \$14.1 million, or 3%. For the current quarter, earnings from operations of \$194.6 million were realized compared to \$174.7 million for the three months ended June 30, 2009. The impact of foreign currency translation on consolidated sales for the current quarter was not significant.

The net earnings attributable to Mylan Inc. common shareholders for the three months ended June 30, 2010 were \$51.5 million, which translates into earnings per diluted share of \$0.16. In the same prior year period, the net earnings attributable to Mylan Inc. common shareholders were \$58.1 million, which translates into earnings per diluted share of \$0.19. A more detailed discussion of the company's financial statements can be found below in the section titled Results of Operations.

Included in the results for the three months ended June 30, 2010 and 2009 are the following items of note:

*Three months ended June 30, 2010:*

Amortization, primarily related to purchased intangible assets associated with acquisitions, of \$71.3 million;

Interest of \$13.5 million, primarily related to the accretion of the discounts on our convertible debt instruments;

Charges, related to the refinancing, of \$15.0 million, primarily swap termination fees and the write-off of deferred financing costs included in other (expense) income, net;

Net unfavorable litigation charges of \$12.1 million;

Additional costs, primarily restructuring, totaling \$18.4 million; and

A tax effect of \$53.1 million related to the above items and other taxes.

*Three months ended June 30, 2009:*

Amortization, primarily related to purchased intangible assets associated with acquisitions, of \$70.1 million;

Interest of \$10.7 million relating to the accretion of the discounts on our convertible debt instruments;

**Table of Contents**

Net favorable litigation of \$0.6 million;

A charge of \$18.0 million related to an up-front payment made with respect to the Company's execution of a co-development agreement;

A net gain of approximately \$10.4 million on the termination of two joint ventures;

Additional costs, primarily restructuring, related to the integration of acquired entities, and other costs, totaling \$11.0 million; and

A tax effect of \$44.2 million related to the above items and other taxes.

Mylan's financial results for the six months ended June 30, 2010 include total revenues of \$2.66 billion compared to \$2.48 billion for the six months ended June 30, 2009, representing an increase of \$184.0 million, or 7.4%. Translating total revenues for the six months ended June 30, 2010 at prior year exchange rates would have resulted in year-over-year growth, excluding the effect of foreign currency of approximately \$120 million, or 5%. Consolidated gross profit for the six months ended June 30, 2010 was \$1.06 billion compared to \$1.05 billion in the same prior year period. For the six months ended June 30, 2010, earnings from operations of \$393.1 million were realized compared to \$402.1 million for the same prior year period.

The net earnings attributable to Mylan Inc. common shareholders for the six months ended June 30, 2010 were \$112.6 million, which translates into earnings per diluted share of \$0.36. In the same prior year period, net earnings attributable to Mylan Inc. common shareholders were \$129.4 million, which translates into earnings per diluted share of \$0.42. A more detailed discussion of the Company's financial statements can be found below in the section titled Results of Operations.

Included in the results for the six months ended June 30, 2010 and 2009 are the following items of note:

*Six months ended June 30, 2010:*

Amortization, primarily related to purchased intangible assets associated with acquisitions, of \$143.0 million;

Interest of \$24.4 million, primarily related to the accretion of discounts on our convertible debt instruments;

Net unfavorable litigation charges of \$12.8 million;

Charges, related to the refinancing, of \$15.0 million, primarily swap termination fees and the write-off of deferred financing costs included in other (expense) income, net;

Additional costs, primarily restructuring, totaling \$30.5 million; and

A tax effect of \$86.2 million related to the above items and other taxes.

*Six months ended June 30, 2009:*

Amortization, primarily related to purchased intangible assets associated with acquisitions, of \$139.1 million;



Other revenues of approximately \$28.5 million resulting from the cancellation of product development agreements for which the revenue had been previously deferred;

Interest of \$20.9 million relating to the accretion of the discounts on our convertible debt instruments;

Net favorable litigation of \$2.8 million;

A charge of \$18.0 million related to an up-front payment made with respect to the Company's execution of a co-development agreement;

A net gain of approximately \$10.4 million on the termination of two joint ventures;

Additional costs, primarily restructuring, related to the integration of acquired entities, and other costs, totaling \$35.1 million; and

A tax effect of \$72.4 million related to the above items and other taxes.

**Table of Contents****Results of Operations*****Three Months Ended June 30, 2010, Compared to Three Months Ended June 30, 2009****Total Revenues and Gross Profit*

For the current quarter, Mylan reported total revenues of \$1.37 billion compared to \$1.27 billion in the comparable prior year period. Total revenues include both net revenues and other revenues from third parties. Third party net revenues for the current quarter were \$1.36 billion compared to \$1.26 billion for the same prior year period, representing an increase of \$100.7 million, or 8%. The impact of foreign currency translation on consolidated sales for the current quarter was not significant.

Other third party revenues for the current quarter were \$12.0 million compared to \$11.2 million in the same prior year period, an increase of \$0.8 million.

Gross profit for the three months ended June 30, 2010 was \$541.9 million, and gross margins were 39.6%. For the three months ended June 30, 2009, gross profit was \$527.8 million, and gross margins were 41.7%. Gross profit for the current quarter is impacted by certain purchase accounting related items recorded during the three months ended June 30, 2010, of approximately \$71.3 million, which consisted primarily of amortization related to purchased intangible assets associated with acquisitions. Excluding such items, gross margins would have been approximately 44.8%. Prior year gross profit is also impacted by similar purchase accounting related items in the amount of \$70.1 million. Excluding such items, gross margins in the prior year would have been approximately 47.2%.

The decrease in gross margins, excluding the items noted above, can generally be attributed to the impact of the timing of significant product launches. During the first quarter of 2009, Mylan launched divalproex sodium extended-release ( divalproex ER ) tablets, the generic version of Abbott Laboratories' Depak<sup>®</sup> ER. Products generally contribute most significantly to gross margin at the time of their launch and even more so in periods of market exclusivity, as was the case with divalproex ER, or in periods of limited generic competition.

*Generics Segment*

For the current quarter, Generics third party net revenues were \$1.23 billion compared to \$1.13 billion in the comparable prior year period, an increase of \$98.4 million, or 8.7%. Translating Generics third party net revenues for the current quarter at prior year comparative period exchange rates would have resulted in year-over-year growth, excluding the effect of foreign currency of approximately \$96 million, or 8%. The impact of foreign currency was not significant as the unfavorable impact of the Euro devaluation was almost fully offset by the strengthening of the Indian Rupee, Japanese Yen, Australian Dollar and Canadian Dollar against the U.S. Dollar. Generics sales are primarily in or from the U.S. and Canada (collectively North America ), Europe, Middle East and Africa (collectively, EMEA ) and India, Australia, Japan, and New Zealand (collectively, Asia Pacific ).

Third party net revenues from North America were \$588.8 million for the current quarter, compared to \$525.5 million for the comparable prior year period, representing an increase of \$63.3 million, or 12.0%. However, excluding the effect of foreign currency, calculated as described above, the increase was approximately \$59 million, or 11%. New products launched in the U.S. and Canada contributed sales of \$91.9 million. Additionally, volume on certain existing products increased primarily as a result of Mylan's ability to remain a source of stable supply as certain competitors experienced regulatory and supply issues. Partially offsetting these increases was unfavorable pricing on certain other existing products, including divalproex ER. Additional generic competition on divalproex ER entered the market in August 2009. As such, sales of divalproex ER in the current quarter were significantly lower than the comparable

prior year quarter.

Fentanyl, our AB-rated generic alternative to Duragesic<sup>®</sup>, continued to contribute to both net revenues and gross profit despite the entrance into the market of additional generic competition. Sales of fentanyl have remained relatively strong primarily due to Mylan's ability to continue to be a stable and reliable source of supply to the market. 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. Competition on fentanyl in the future could have an unfavorable impact on pricing and market share.

**Table of Contents**

Third party net revenues from EMEA were \$378.6 million for the three-month period ended June 30, 2010, compared to \$392.7 million for the comparable prior year period, a decrease of \$14.1 million, or 3.6%. However, foreign currency translation had a negative impact on sales for the current quarter, reflecting the weakening of the Euro against the U.S. Dollar. Translating current quarter third party net revenues from EMEA at prior year exchange rates would have resulted in year-over-year growth excluding the effect of foreign currency of approximately \$11 million, or 3%. This increase was driven by new product launches in several markets totaling approximately \$30.7 million, as well as favorable market dynamics in certain countries, including, most significantly, Italy, partially offset by unfavorable pricing in other European markets.

In Italy, third party sales almost doubled on a constant currency basis, driven by successful new product launches and increased market penetration, which resulted in increased volume, as well as certain regulatory changes that positively affected pricing in the generics market.

In Spain, excluding the effect of foreign currency, new product launches more than offset the impact of certain recent regulatory actions that had a negative impact on pricing across the portfolio. In France, however, competitive pressure resulted in lower pricing which more than offset the favorable contribution from new products and increased sales of existing products, and resulted in a net decrease in third party local currency sales.

Certain markets in which we do business have recently undergone government-imposed price reductions, thereby increasing pricing pressures on pharmaceutical products. This is true in Australia as well as several European countries. Such measures, along with the tender systems discussed below, 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.

A number of markets in which we operate have implemented or may implement tender systems for generic pharmaceuticals in an effort to lower prices. Generally speaking, tender systems can have an unfavorable impact on revenue and profitability. 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. While certain of our subsidiaries, including those in the U.K. and the Netherlands, have benefited from recent tenders, sales in Germany continue to be negatively affected by the implementation of tender systems in that country.

In Asia Pacific, third party net revenues were \$265.1 million for the three-month period ended June 30, 2010, compared to \$215.9 million for the comparable prior year period, an increase of \$49.2 million, or 22.8%. However, excluding the effect of foreign currency, calculated as described above, the increase was approximately \$27 million, or 12%. This increase is primarily driven by higher third party sales in India and Japan.

In India, the increase in third party net revenues is due to double-digit growth, excluding the effect of foreign currency, in sales of both anti-retroviral ( ARV ) finished dosage form ( FDF ) generic products, which are used in the treatment of HIV/AIDS and API. In addition to third party sales, the Asia Pacific region also supplies both FDF generic products and API to Mylan subsidiaries in conjunction with Mylan's vertical integration strategy. Intercompany revenues recognized by the Asia Pacific region were \$33.9 million for the three months ended June 30, 2010, compared to \$10.0 million in the comparable prior year period. These intercompany sales eliminate within and, therefore, are not included in Generics or consolidated net revenues.

*Specialty Segment*

For the current quarter, Specialty reported third party net revenues of \$124.0 million, an increase of \$2.3 million, or 1.9%, over the comparable prior year period of \$121.7 million. The most significant contributor to Specialty Segment revenues continues to be the EpiPen® Auto-injector, which is used in the treatment of severe allergic reactions. Globally, the EpiPen Auto-injector is the number one epinephrine auto-injector for the treatment of severe allergic reactions with world-wide market share of approximately 91%. In the U.S., the EpiPen Auto-injector is the number one prescribed treatment for severe allergic reactions with market share of approximately 96%.

**Table of Contents**

Intercompany sales by Specialty totaled \$17.2 million in the current quarter compared to \$7.1 million in the same prior year period. The increase is due to the fact that, beginning in 2010, certain generic products previously sold to third parties by Specialty are now sold to Mylan subsidiaries in North America who, in turn, sell the products to third parties. Excluding the sale of such products from 2009 third party net revenues would have resulted in an increase in third party net revenues in the current quarter of \$17.6 million or 14.0%.

*Operating Expenses*

Research and development ( R&D ) expense for the three months ended June 30, 2010 was \$66.8 million, compared to \$74.0 million in the same prior year period, a decrease of \$7.2 million. This decrease was primarily the result of a charge of \$18.0 million in the prior year related to an up-front payment made with respect to the Company's execution of a co-development agreement. Excluding this item, R&D expense increased, primarily in Generics, as a result of increased product development activity.

Selling, general and administrative ( SG&A ) expense for the current quarter was \$268.4 million, compared to \$279.7 million for the same prior year period, a decrease of \$11.3 million. This decrease is the result of charges, recorded in the prior year, with respect to certain restructuring initiatives, and the subsequent cost savings that have resulted.

*Interest Expense*

Interest expense for the three months ended June 30, 2010, totaled \$78.4 million, compared to \$78.2 million for the three months ended June 30, 2009. In March 2009, we pre-paid all of our required 2010 principal payments on our term debt, and in December 2009, we pre-paid all of our required 2011 principal payments on our term debt. The effect of the pre-payments was offset by the effect of the debt offering in the current period. Included in interest expense for the current quarter and the comparable prior year period are \$11.4 million and \$10.7 million of accretion of the discounts on our convertible debt instruments.

*Other (Expense) Income, net*

Other (expense) income, net, was expense of \$15.2 million in the current quarter compared to income of \$25.3 million in the comparable prior year period. Included in the current quarter are charges associated with the termination of certain interest rate swaps totaling \$7.4 million and the write-off of previously deferred financing fees of \$7.6 million, in conjunction with the debt offering during the quarter. In the prior year quarter, other (expense) income consisted primarily of a favorable adjustment of \$13.9 million to the restructuring reserve as a result of a reduction in the estimated remaining spending on accrued projects, as well as a net gain of \$10.4 million realized on the termination of two joint ventures.

*Income Tax Expense*

We recorded income tax expense of \$14.0 million in the current quarter compared to \$26.2 million in the prior year quarter. The decrease in tax expense is driven by a decrease in taxable income, as well as a decrease in the effective tax rate. The effective rate for the current year quarter was 13.9%, versus 21.4% in the comparable prior year period. The decrease in the effective rate was largely due to reductions in certain tax reserves stemming from statutory and other changes.

***Six Months Ended June 30, 2010, Compared to Six Months Ended June 30, 2009***

*Total Revenues and Gross Profit*

For the current six-month period, Mylan reported total revenues of \$2.66 billion compared to \$2.48 billion in the comparable prior year period. Total revenues include both net revenues and other revenues from third parties. Third party net revenues for the current six months were \$2.63 billion compared to \$2.42 billion for the same prior year period, representing an increase of \$210.5 million, or 8.7%. Sales were favorably impacted by the effect of foreign currency translation, primarily reflecting stronger functional currencies in certain of Mylan's subsidiaries, primarily those in Australia, Japan, India and Canada, compared to the U.S. Dollar. The impact of foreign currency

**Table of Contents**

translation related to the Euro was insignificant between the two comparative periods. Translating current year third party net revenues at prior year exchange rates would have resulted in year-over-year growth excluding foreign currency of approximately \$146 million, or 6%.

Other revenues from third parties for the six months ended June 30, 2010 were \$26.3 million compared to \$52.7 million in the same prior year period, a decrease of \$26.5 million, or 50.2%. During the six months ended June 30, 2009, within Generics, we recognized \$26.0 million of incremental revenue resulting from the cancellation of product development agreements for which the revenue had been previously deferred. There was no such revenue recognized during the current year period.

Gross profit for the six months ended June 30, 2010 was \$1.06 billion, and gross margins were 39.8%. For the six months ended June 30, 2009, gross profit was \$1.05 billion, and gross margins were 42.5%. Gross profit for the current year to date period is impacted by certain purchase accounting related items recorded during the six months ended June 30, 2010, of approximately \$143.0 million, which consisted primarily of amortization related to purchased intangible assets associated with acquisitions. Excluding such items, gross margins would have been approximately 45.1%. Prior year gross profit is also impacted by similar purchase accounting related items in the amount of \$139.1 million. Excluding such items, gross margins in the prior year would have been approximately 48.1%.

The decrease in gross margins, excluding the items noted above, can generally be attributed to the impact of the timing of significant product launches. During the first quarter of 2009, Mylan launched divalproex ER. Products generally contribute most significantly to gross margin at the time of their launch and even more so in periods of market exclusivity, as was the case with divalproex ER, or in periods of limited generic competition.

*Generics Segment*

For the six months ended June 30, 2010, Generics reported third party net revenues of \$2.43 billion, compared to \$2.22 billion in the comparable prior year period, an increase of \$204.8 million, or 9.2%. Excluding the effect of foreign currency, calculated as described above, the increase was approximately \$141 million, or 6%.

Third party net revenues from North America were \$1.14 billion for the six-month period, compared to \$1.07 billion for the comparable prior year period, representing an increase of \$66.3 million, or 6.2%. Excluding the effect of foreign currency, calculated as described above, the increase was approximately \$55 million, or 5%. This increase was driven by sales contributed from new products in the U.S. and Canada in the amount of \$148.5 million, and increased revenues on certain products as a result of Mylan's ability to remain a source of stable supply as certain competitors experienced regulatory and supply issues. Partially offsetting these increases were decreases in certain other existing products, such as divalproex ER. Additional generic competition on divalproex ER entered the market in August 2009. As such, sales of divalproex ER in the current year were significantly lower than in the prior year.

Fentanyl, our AB-rated generic alternative to Duragesic®, continued to contribute to both net revenues and gross profit despite the entrance into the market of additional generic competition. Sales of fentanyl have remained relatively strong primarily due to Mylan's ability to continue to be a stable and reliable source of supply to the market. 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. Competition on fentanyl in the future could have an unfavorable impact on pricing and market share.

Third party net revenues from EMEA were \$785.5 million for the six-month period ended June 30, 2010, compared to \$746.4 million for the comparable prior year period, an increase of \$39.1 million, or 5.2%. The increase in EMEA third party net revenues was driven by new product launches in several European markets, which totaled approximately \$61.1 million, as well as favorable market dynamics in certain countries, particularly Italy and the



U.K., partially offset by unfavorable pricing. The impact of foreign currency translation on EMEA sales for the current six-month period was not significant.

In Italy, the increase in third party sales was driven by successful new product launches and increased market penetration, which resulted in increased volume, as well as certain regulatory changes that positively affected pricing in the generics market.

## **Table of Contents**

In the U.K., prior year third party sales were negatively impacted by excess supply in the market at that time. Since the second quarter of 2009, these supply issues have been resolved, which led to the increases in revenue in the current year. Also contributing to the increase in U.K. sales in the current year was a successful bid on a recent government tender.

While the U.K. benefitted from its recent tender, sales in Germany continue to be negatively affected by the implementation of tender systems in that country. Current year to date revenues were negatively impacted by the price reductions as a result of these tenders, as well as general pricing pressure on its non-tender business and the loss of exclusivity on certain Statutory Health Insurance contracts.

In Spain, excluding the effect of foreign currency, new product launches more than offset the impact of certain recent regulatory actions that had a negative impact on pricing across the portfolio.

In France, competitive pricing pressures drove a decrease in third party sales in the current year versus the prior year comparable period. The impact on pricing more than offset increases due to new product launches and increased sales of existing products.

Certain markets in which we do business have recently undergone government-imposed price reductions, thereby increasing pricing pressures on pharmaceutical products. This is true in Australia as well as several European countries. Such measures, along with the tender systems discussed above, 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.

In Asia Pacific, third party net revenues were \$501.2 million for the six-month period ended June 30, 2010, compared to \$401.8 million for the comparable prior year period, an increase of \$99.4 million, or 24.7%. However, excluding the effect of foreign currency, calculated as described above, the increase was approximately \$47 million, or 12%. This increase is primarily driven by higher third party sales from India and Japan.

In India, the increase in third party net revenues is due to double-digit growth, excluding the effect of foreign currency, in sales of both ARV FDF generic products and API. In addition to third party sales, the Asia Pacific region also supplies both FDF generic products and API to Mylan subsidiaries in conjunction with Mylan's vertical integration strategy. Intercompany revenues recognized by the Asia Pacific region were \$64.0 million for the six months ended June 30, 2010, compared to \$20.2 million in the comparable prior year period. These intercompany sales eliminate within and, therefore, are not included in Generics or consolidated net revenues.

### *Specialty Segment*

For the six months ended June 30, 2010, Specialty reported third party net revenues of \$206.7 million, an increase of \$5.7 million, or 2.8% over the comparable prior year period of \$201.0 million. The most significant contributor to Specialty revenues continues to be the EpiPen<sup>®</sup> Auto-injector, which is used in the treatment of severe allergic reactions. Globally, the EpiPen Auto-injector is the number one epinephrine auto-injector for the treatment of severe allergic reactions with world-wide market share of approximately 91%. In the U.S., the EpiPen Auto-injector is the number one prescribed treatment for severe allergic reactions with market share of approximately 96%.

Intercompany sales of product by Specialty totaled \$33.7 million in the current six-month period compared to \$11.4 million in the same prior year period. As in the quarter, the increase is due to the fact that, beginning in 2010, certain generic products previously sold to third parties by Specialty are now sold to Mylan subsidiaries in North America who, in turn, sell the products to third parties. Excluding the sale of such products from 2009 third party net revenues would have resulted in an increase in third party net revenues in the current year of \$39.4 million or

18.7%.

In addition to the continued strong sales of the EpiPen Auto-injector, the increase in third-party sales was driven by increased sales of Perforomist® Solution, Dey's maintenance therapy for patients with moderate to severe chronic obstructive pulmonary disease.

## **Table of Contents**

### *Operating Expenses*

R&D expense for the six months ended June 30, 2010 was \$128.1 million, compared to \$132.9 million in the same prior year period, a decrease of \$4.8 million. This decrease is primarily the result of an up-front payment of \$18.0 million made in the prior year, related to our execution of a co-development agreement, offset partially by increases in certain other R&D costs and an unfavorable effect of foreign exchange.

SG&A expense for the six months ended June 30, 2010 was \$524.1 million, compared to \$521.3 million for the same prior year period, an increase of \$2.8 million. This increase is due to the effect of foreign exchange. Excluding this effect, SG&A decreased mainly due to fewer restructuring costs in the current year and the cost savings realized by previously implemented restructuring programs.

### *Interest Expense*

Interest expense for the six months ended June 30, 2010, totaled \$152.4 million, compared to \$163.2 million for the six months ended June 30, 2009. In March 2009, we pre-paid all of our required 2010 principal payments on our term debt, and in December 2009, we pre-paid all of our required 2011 principal payments on our term debt, which, along with lower overall interest rates, drove the decrease in interest expense, which was partially offset by the effect of the debt offering in the current period. Included in interest expense for the current six months and the comparable prior year period are \$22.4 million and \$20.9 million of accretion of the discounts on our convertible debt instruments.

### *Other (Expense) Income, net*

Other (expense) income, net was expense of \$14.1 million in the current six-month period compared to income of \$29.5 million in the comparable prior year period. Included in the current year are charges associated with the termination of certain interest rate swaps totaling \$7.4 million and the write-off of previously deferred financing fees of \$7.6 million, in conjunction with the debt offering during the current period. The prior year period includes a favorable adjustment of \$13.9 million to the restructuring reserve as a result of a reduction in the estimated remaining spending on accrued projects, as well as a net gain of \$10.4 million realized on the termination of two joint ventures.

### *Income Tax Expense*

We recorded income tax expense of \$45.3 million in the six months ended June 30, 2010 compared to \$63.6 million in the comparable prior year period. The decrease in tax expense is driven by a decrease in taxable income, as well as a decrease in the effective tax rate. The effective rate for the current year period was 20.0%, versus 23.7% in the comparable prior year period. The decrease in the effective rate was largely due to the utilization of certain foreign tax credits.

### *Liquidity and Capital Resources*

Our primary source of liquidity is cash provided by operations, which was \$359.1 million for the six months ended June 30, 2010. Included in this amount is approximately \$98.8 million representing a tax refund received in the first quarter. We believe that cash provided by operating activities will continue to allow us to meet our needs for working capital, capital expenditures, interest and principal payments on debt obligations, preferred stock dividend payments and other cash needs over the next several years. Nevertheless, our ability to satisfy our working capital requirements and debt service obligations, or fund planned capital expenditures, will substantially depend upon our future operating performance (which will be affected by prevailing economic conditions), and financial, business and other factors, some of which are beyond our control. During the six months ended June 30, 2010, changes in operating assets and liabilities resulted in a net cash outflow of \$117.7 million, primarily due to the timing of the collection of cash receipts

from our customers.

Cash used in investing activities for the six months ended June 30, 2010 was \$54.4 million, consisting primarily of capital expenditures. Capital expenditures were \$53.3 million, and were made primarily for equipment,

**Table of Contents**

including a portion related to our previously announced planned expansions and integration plans. Capital expenditures for the year 2010 are expected to be approximately \$250.0 million.

Cash provided by financing activities was \$172.2 million for the six months ended June 30, 2010. In May of 2010, we completed a private placement of \$550.0 million aggregate principal amount of 7.625% Senior Notes due 2017 and \$700.0 million aggregate principal amount of 7.875% Senior Notes due 2020. We used \$1.0 billion of the net proceeds from the private placement to repay a portion of our outstanding term loans. Additionally, we paid cash dividends of \$69.5 million on our 6.5% mandatory convertible preferred stock. The preferred stock will automatically convert into common stock on November 15, 2010, and the last dividend payment is expected on that date.

As of June 30, 2010, because the closing price of our common stock for at least 20 trading days in the period of 30 consecutive trading days ending on the last trading day in the June 30, 2010 period was more than 130% of the applicable conversion reference price of \$13.32 at June 30, 2010, the \$575.0 million of Cash Convertible Notes were currently convertible. Although the Company's experience is that convertible debentures are not normally converted by investors until close to their maturity date, it is possible that debentures could be converted prior to their maturity date if, for example, a holder perceives the market for the debentures to be weaker than the market for the common stock. Upon an investor's election to convert, the Company is required to pay the full conversion value in cash. The amount payable per \$1,000 notional bond would be calculated as the product of (1) the conversion reference rate and (2) the average Daily Volume Weighted Average Price per share of common stock for a specified period following the conversion date. Any payment above the principal amount is matched by a convertible note hedge.

We are involved in various legal proceedings that are considered normal to our business. While it is not possible to predict the outcome of such proceedings, an adverse outcome in any of these proceedings could materially affect our financial position and results of operations. Additionally, for certain contingencies assumed in conjunction with the acquisition of the former Merck Generics business, Merck KGaA, the seller, has indemnified Mylan. The inability or denial of Merck KGaA to pay on an indemnified claim could have a material adverse effect on our financial position, results of operations or cash flows.

Our Condensed Consolidated Balance Sheet as of June 30, 2010 includes restructuring reserves of \$23.4 million. Spending against this balance, which consists primarily of severance and related costs and costs associated with the previously announced rationalization and optimization of our global manufacturing and research and development platforms, is expected to occur over the next two years, with the majority in 2010.

On July 19, 2010, 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 August 16, 2010, to the holders of preferred stock of record as of August 1, 2010.

We are actively pursuing, and are 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 us 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.

We are continuously evaluating the potential acquisition of products, as well as companies, as a strategic part of our future growth. Consequently, we 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, we review our operations including the evaluation of potential divestitures of products and businesses as part of our future strategy. Any divestitures could impact future liquidity. In July 2010, we entered into an agreement to acquire Bioniche Pharma, a privately held, global injectable pharmaceutical company, for \$550.0 million in cash. Though the transaction remains

subject to customary closing conditions, we believe Bioniche Pharma will provide Mylan not only an immediate entry into the North American injectables market but also a platform for future growth opportunities.

At June 30, 2010 and December 31, 2009, we had \$83.2 million and \$77.5 million, respectively, outstanding under existing letters of credit. Additionally, as of June 30, 2010, we had \$46.7 million available under the \$100.0 million subfacility on our Senior Credit Agreement for the issuance of letters of credit.

**Table of Contents**

Mandatory minimum repayments remaining on the outstanding borrowings under the term loans and notes at June 30, 2010, excluding the discounts and conversion features, are as follows for each of the periods ending December 31:

	<b>U.S. Tranche A Term Loans</b>	<b>Euro Tranche A Term Loans</b>	<b>U.S. Tranche B Term Loans</b>	<b>Euro Tranche B Term Loans</b>	<b>Senior Convertible Notes (In thousands)</b>	<b>Cash Convertible Notes</b>	<b>2017 Notes</b>	<b>2020 Notes</b>	<b>Total</b>
10	\$	\$	\$	\$	\$	\$	\$	\$	\$
11									
12	78,125	107,437		6,439	600,000				792,000
13	78,125	107,437		6,439					192,000
14			1,453,760	605,228					2,058,988
15						575,000			575,000
hereafter							550,000	700,000	1,250,000
total	\$ 156,250	\$ 214,874	\$ 1,453,760	\$ 618,106	\$ 600,000	\$ 575,000	\$ 550,000	\$ 700,000	\$ 4,867,994

The Senior Credit Agreement contains customary affirmative covenants for facilities of this type, including covenants pertaining to the delivery of financial statements, notices of default and certain other information, maintenance of business and insurance, collateral matters and compliance with laws, as well as customary negative covenants for facilities of this type, including limitations on the incurrence of indebtedness and liens, mergers and certain other fundamental changes, investments and loans, acquisitions, transactions with affiliates, dispositions of assets, payments of dividends and other restricted payments, prepayments or amendments to the terms of specified indebtedness and changes in lines of business. The Senior Credit Agreement contains financial covenants requiring maintenance of a minimum interest coverage ratio and a senior leverage ratio, both of which are defined within the agreement. We have been compliant with the financial covenants during the six months ended June 30, 2010.

**Recent Accounting Pronouncements**

In October 2009, the FASB issued revised accounting guidance for multiple-deliverable revenue arrangements. The amended guidance requires that consideration received be allocated at the inception of the arrangement to all deliverables using the relative selling price method and provides for expanded disclosures related to such arrangements. It is effective for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The Company is currently evaluating the impact of adoption on its 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 Annual Report filed on Form 10-K.

**ITEM 4. CONTROLS AND PROCEDURES**



An evaluation was performed under the supervision and with the participation of the Company's management, including the Principal Executive Officer and the Principal Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of June 30, 2010. Based upon that evaluation, the Principal Executive Officer and the Principal Financial Officer concluded that the Company's disclosure controls and procedures were effective.

Management has not identified any changes in the Company's internal control over financial reporting that occurred during the quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

**Table of Contents****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 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, results of operations and cash flows.

***Lorazepam and Clorazepate***

On June 1, 2005, a jury verdict was rendered against Mylan, Mylan Pharmaceuticals Inc. ( MPI ), and co-defendants Cambrex Corporation and Gyma Laboratories in the U.S. District Court for the District of Columbia 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, which, in the case of three of the plaintiffs, reflects trebling of the compensatory damages in the original verdict (approximately \$11 million in total) and, in the case of the fourth plaintiff, reflects their amount of the compensatory damages in the original jury verdict plus doubling this compensatory damage award as punitive damages assessed against each of the defendants (approximately \$58 million in total), 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 \$8.0 million. The Company and its co-defendants have appealed to the U.S. Court of Appeals for the D.C. Circuit and have challenged the verdict as legally erroneous on multiple grounds. The appeals were held in abeyance pending a ruling on the motion for prejudgment interest, which has been granted. Mylan intends to contest this ruling along with the liability finding and other damages awards as part of its pending appeal, which is proceeding in the Court of Appeals for the D.C. Circuit. 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 Sheets) and an irrevocable letter of credit for \$34.5 million issued under the Senior Credit Agreement.

***Pricing and Medicaid Litigation***

Beginning in September 2003, Mylan, MPI and/or UDL Laboratories Inc. ( UDL ), together with many other pharmaceutical companies, have been named in civil lawsuits filed by state attorneys general ( 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 and/or Wholesale Acquisition Costs that exceeded the actual selling price of the defendants prescription drugs, causing state programs to overpay pharmacies and other providers. 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

**Table of Contents**

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 money damages, civil penalties and/or double, treble or punitive damages, counsel fees and costs, equitable relief and/or injunctive relief. Certain of these cases may go to trial in 2010. Mylan and its subsidiaries have denied liability and intend to defend each of these actions vigorously. On January 27, 2010, in the New York Counties cases, the U.S. District Court for the District of Massachusetts granted the plaintiffs' motion for partial summary judgment as to liability under New York Social Services Law § 145-b against Mylan and several other defendants. The District Court has not ruled on the remaining issues of liability and damages. On February 8, 2010, Mylan, and a majority of the other defendants, filed a motion to amend the court's decision, requesting the court to certify a question of New York state law pertaining to the court's finding of requisite causation under the Social Services Law to the First Circuit Court of Appeals, so that the defendants could in turn request that the First Circuit Court of Appeals certify the question to the New York Court of Appeals. The District Court denied this motion on May 4, 2010.

In May 2008, an amended complaint was filed in the U.S. District Court for the District of Massachusetts by a private 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 nationwide recovery of any and all alleged overpayment of the federal share under the Medicaid program, as well as treble damages and civil penalties. In February 2010, the Company reached an agreement in principle to settle this case (except for the claims related to the California federal share) and the Texas state action mentioned above. This settlement is contingent upon the execution of definitive settlement documents and court approval. The settlement would resolve a significant portion of the damages claims asserted against Mylan, MPI and UDL in the various pending pricing litigations. In addition, Mylan has reached agreement in principle to settle the Hawaii state action, which settlement is contingent upon the execution of definitive settlement documents. With regard to the remaining state actions, the Company continues to believe that it has meritorious defenses and will continue to vigorously defend itself in those actions. The Company has accrued \$160 million in connection with the above-mentioned settlement in principle and the remaining state actions. The Company reviews the status of these actions on an ongoing basis, and from time to time, the Company may settle or otherwise resolve these matters on terms and conditions that management believes are in the best interests of the Company. There are no assurances that settlements can be reached on acceptable terms or that adverse judgments, if any, in the remaining litigation will not exceed the amounts reserved.

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 involved whether MPI and UDL may have violated the False Claims Act by classifying certain authorized generics as non-innovator rather than innovator drugs for purposes of Medicaid and other federal healthcare programs on sales from 2000 through 2004. MPI and UDL denied the government's allegations and denied that they engaged in any wrongful conduct. On October 19, 2009, a lawsuit, filed in March 2004 by a private relator, in which the federal government subsequently intervened, was unsealed by the U.S. District Court for the District of New Hampshire. That same day, MPI and UDL announced that they had entered into a settlement agreement with the federal government, relevant states and the relator for approximately \$121.0 million, resolving both the lawsuit and the U.S. Department of Justice investigation. A stipulation of dismissal with prejudice has been filed with the court. The resolution of the matter did not include any admission or finding of wrongdoing on the part of either MPI or UDL. The Company has recovered approximately \$50 million of the settlement amount based on overpayments resulting from adjusted net sales during the relevant timeframe.

Dey is a defendant currently in lawsuits brought by the state AGs of California, Illinois, Kentucky, Pennsylvania and Wisconsin, as well as three 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 these class actions, which has been preliminarily approved by the court. Additionally, a complaint was filed under seal by a plaintiff on

**Table of Contents**

behalf of the United States of America against Dey in August 1997. In August 2006, the Government filed its complaint-in-intervention and the case was unsealed in September 2006. Dey's motion for partial summary judgment in that case is pending, as is the Government's cross-motion. The Government has asserted that Dey is jointly liable with a codefendant and seeks recovery of alleged overpayments, together with treble damages, civil penalties and equitable relief. These cases all generally allege that Dey falsely reported certain price information concerning certain drugs marketed by Dey, that Dey caused false claims to be made to Medicaid and to Medicare, and that Dey caused Medicaid and Medicare to make overpayments on those claims. Certain of these cases may go to trial in 2010. Dey intends to defend each of these actions vigorously. The Company has approximately \$97.8 million recorded in other liabilities related to the price-related litigation involving Dey. As stated above, in conjunction with the acquisition of the former Merck Generics business, Mylan is entitled to indemnification from Merck KGaA. As a result, the Company has recorded approximately \$97.8 million in other assets.

***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, the Northern District of Ohio and a lawsuit originally filed in Tennessee state court 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. On March 29, 2010, the Court in the Eastern District of Pennsylvania denied the defendants' motions to dismiss. 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. 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 has cooperated 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. On July 1, 2010, the FTC issued a third party subpoena to Mylan requesting documents in connection with its lawsuit against Cephalon. Mylan is in the process of responding to the subpoena. Mylan is not named as a defendant in the FTC's lawsuit, although the complaint includes certain allegations pertaining to the Mylan/Cephalon settlement.

***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 was 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. There are approximately 1,008 cases pending against Mylan, UDL and Actavis pertaining to the recall. Most of these cases have been transferred to the multi-district litigation proceedings pending in the U.S. District Court for the Southern District of West Virginia for pretrial proceedings. The remainder of these cases will likely be litigated in the state courts in which they were filed. Certain of these cases may go to trial in 2010. 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 the Company's financial position, results of operations or cash flows.

***EU Commission Proceedings***

Edgar Filing: MYLAN INC. - Form 10-Q

On or around July 3, 2009, the European Commission (the EU Commission or the Commission ) stated that it had initiated antitrust proceedings pursuant to Article 11(6) of Regulation No. 1/2003 and Article 2(1) of Regulation No. 773/2004 to explore possible infringement of Articles 81 and 82 EC and Articles 53 and 54 of the EEA Agreement by Les Laboratoires Servier ( Servier ) as well as possible infringement of Article 81 EC by

## **Table of Contents**

Matrix and four other companies, each of which entered into agreements with Servier relating to the product perindopril. Matrix is cooperating with the EU Commission in connection with the investigation. The EU Commission stated that the initiation of proceedings does not imply that the Commission has conclusive proof of an infringement but merely signifies that the Commission will deal with the case as a matter of priority. No statement of objections has been filed against Matrix in connection with its investigation. On August 5, 2009, Matrix and Generics [U.K.] Ltd. received requests for information from the EU Commission in connection with this matter, and both companies have responded. By letters dated February 17, 2010, the EU Commission served additional requests for information on Matrix and Mylan S.A.S. The companies have responded to these requests.

In addition, the EU Commission is conducting a pharmaceutical sector inquiry involving approximately 100 companies concerning the introduction of innovative and generic medicines. Mylan S.A.S. has responded to the questionnaires received in connection with the sector inquiry and has produced documents and other information in connection with the inquiry.

On October 6, 2009, the Company received notice that the EU Commission was initiating an investigation pursuant to Article 20(4) of Regulation No. 1/2003 to explore possible infringement of Articles 81 and 82 EC by the Company and its affiliates. Mylan S.A.S., acting on behalf of its Mylan affiliates, has produced documents and other information in connection with the inquiry. The Company and Mylan S.A.S. received an additional request for information with the same case reference on December 18, 2009 and have responded to the questionnaire. An additional request was received on March 18, 2010. Mylan S.A.S. has responded to this request. Mylan is cooperating with the Commission in connection with the investigation. No statement of objections has been filed against Mylan in connection with the investigation.

### ***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 acquisition of the former Merck Generics business. While it is not feasible to predict the ultimate outcome of such other proceedings, the ultimate outcome of any such proceeding is not expected to have a material adverse effect on its financial position, results of operations or cash flows.

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

Over the past few years, the global economy has undergone a period of unprecedented volatility, and the economic environment may continue to be less favorable than that of past 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, financial position and results of operations and may cause the market value of our common stock to decline.





**Table of Contents**

***OUR INTEGRATION OF ACQUIRED BUSINESSES INVOLVES A NUMBER OF 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.***

There are a number of operational risks associated with the integration of acquired businesses, including Bioniche Pharma (upon completion). These risks include, but are not limited to, difficulties in achieving identified financial and operating synergies, cost savings, revenue synergies and growth opportunities; difficulties in consolidating information technology platforms, business applications and corporate infrastructure; our substantial indebtedness and assumed liabilities; challenges in operating in other markets outside of the U.S. that are new to us; and the 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.

***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 Matrix, and we have recently announced the planned acquisition of Bioniche Pharma. This growth has put significant demands on our processes, systems and people. We expect to make further 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 are 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 FOOTPRINT 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.***

Our operations extend to numerous countries outside the U.S. 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;

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;

**Table of Contents**

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. Any 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.

***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 UNCERTAINTIES CREATE RISKS WHICH 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 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. Our ability to recruit, train and retain qualified employees and develop and operate our manufacturing facilities in India 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, and within the countries themselves. Rioting, 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 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**

***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.

***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 BUSINESS, 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 Food and Drug Administration ( FDA ) in the U.S. and the European Medicines Agency ( EMA ) in the 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 U.S., 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 U.S. 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.

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

**Table of Contents**

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 U.S., 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 abbreviated new drug application ( 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 European Medicines Agency 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 other jurisdictions outside the U.S., 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.

***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. We also partner with third parties to develop products. Typically, research expenses related to the development of innovative compounds and the filing of marketing authorization applications for innovative compounds (such NDAs in the U.S.) 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 U.S. and abridged applications in Europe). As we and our partners continue to develop new products, our research expenses will likely increase. Because of the inherent risk associated with research and development efforts in our industry, particularly with respect to new drugs, our, 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

**Table of Contents**

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.

***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.

***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 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.

***THE ILLEGAL DISTRIBUTION AND SALE BY THIRD PARTIES OF COUNTERFEIT VERSIONS OF OUR PRODUCTS OR OF STOLEN PRODUCTS COULD HAVE A NEGATIVE IMPACT ON OUR REPUTATION AND 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 drug supply has been increasingly challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the Internet. The World Health Organization estimates that more than 10% of medications being sold globally are counterfeit.

Third parties may illegally distribute and sell counterfeit versions of our products, which do not meet the rigorous manufacturing and testing standards that our products undergo. Counterfeit products are frequently unsafe

**Table of Contents**

or ineffective, and can be potentially life-threatening. Counterfeit medicines may contain harmful substances, the wrong dose of the API or no API at all. However, to distributors and users, counterfeit products may be visually indistinguishable from the authentic version.

Reports of adverse reactions to counterfeit drugs or increased levels of counterfeiting could materially affect patient confidence in the authentic product. It is possible that adverse events caused by unsafe counterfeit products will mistakenly be attributed to the authentic product. In addition, thefts of inventory at warehouses, plants or while in-transit which are not properly stored and which are sold through unauthorized channels could adversely impact patient safety, our reputation and our business.

Public loss of confidence in the integrity of pharmaceutical products as a result of counterfeiting or theft could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

***IF WE OR ANY PARTNER 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 or any partner's 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 or any partner's 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 U.S. 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.

***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;

**Table of Contents**

larger production capabilities in a particular therapeutic area;

more experience in preclinical testing and human clinical trials;

more products; or

more experience in developing new drugs and 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.

***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:

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;

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 U.S., 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 a new drug application 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 U.S., 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.

**Table of Contents**

***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, INCLUDING IN AN AT-RISK LAUNCH SITUATION, 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 courts (i.e., an at-risk launch situation). 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.

***OUR SPECIALTY BUSINESS DEVELOPS, FORMULATES, MANUFACTURES OR IN-LICENSES 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 (or alternatively, in-licensed) 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.



In addition, developing and commercializing branded products is generally more costly than generic products. If such business expenditures do not ultimately result in the launch of commercially successful brand products, or if any of the risks above were to occur, there could be a material adverse effect on our business, financial position and results of operations and the market value of our common stock could decline.

**Table of Contents**

***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 from time to time 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.

***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.

***WE DEPEND TO A LARGE EXTENT 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 COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.***

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

Additionally, we maintain safety stocks in our raw materials inventory and, in certain cases where we have listed only one supplier in our applications with 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 business, 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 ( DEA ) in the U.S. 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

**Table of Contents**

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.

***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.

***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

**Table of Contents**

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 similar standards in each territory in which we manufacture. Compliance with such 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 good manufacturing practices 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 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. 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 ( AMP ) based on the provisions of the Deficit Reduction Act of 2005 ( DRA ). While the matter remains subject to litigation and proposed legislation, one potential significant change as a result of the DRA is that AMP would need to 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 ( 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

**Table of Contents**

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.

***WE MAY EXPERIENCE REDUCTIONS IN THE LEVELS OF REIMBURSEMENT FOR PHARMACEUTICAL PRODUCTS BY GOVERNMENTAL AUTHORITIES, HMOS OR OTHER THIRD-PARTY PAYERS. IN ADDITION, THE USE OF TENDER SYSTEMS COULD REDUCE PRICES FOR OUR PRODUCTS OR REDUCE OUR MARKET OPPORTUNITIES. 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 U.K. National Health Service and the German statutory health insurance scheme) and private health insurers and other organizations, such as health maintenance organizations ( HMOs ) in the U.S., 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 U.S., 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 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.

***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



U.S. 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

**Table of Contents**

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.

Several countries in which we operate have implemented, or plan to implement, government mandated price reductions, including but not limited to Spain, Portugal, Italy, Australia, Japan and Canada. When such price cuts occur, pharmaceutical companies have generally experienced significant declines in revenues and profitability and uncertainties continue to exist within the market. Such price reductions could have an adverse effect on our business, and as uncertainties are resolved or if other countries in which we operate enact similar measures, they could have a further material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

***HEALTHCARE REFORM LEGISLATION 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 recent years, there have been numerous initiatives on the federal and state levels for comprehensive reforms affecting the payment for, the availability of and reimbursement for healthcare services in the U.S., and it is likely that federal and state legislatures and health agencies will continue to focus on health care reform in the future. The Patient Protection and Affordable Care Act (H.R. 3590; Public Law 111-148) ( PPACA ) and The Health Care and Education and Reconciliation Act of 2010 (H.R. 4872), which amends the PPACA (collectively the Health Reform Laws ), were signed into law in March 2010. While the Health Reform Laws may increase the number of patients who have insurance coverage for our products, they also include provisions such as the assessment of a pharmaceutical manufacturer fee and an increase in the amount of rebates that manufacturers pay for coverage of their drugs by Medicaid programs.

We are unable to predict the future course of federal or state healthcare legislation. The Health Reform Laws and further changes in the law or regulatory framework that reduce our revenues or increase our costs could also have a material adverse effect on our business, financial condition and results of operations and cash flows, and could cause the market value of our common stock to decline.

Additionally, we encounter similar regulatory and legislative issues in most other countries. In the EU and some other international markets, the government provides health care at low cost to consumers and regulates pharmaceutical prices, patient eligibility or reimbursement levels to control costs for the government-sponsored health care system. This international system of price regulations may lead to inconsistent prices. Within the EU and in other countries, the availability of our products in some markets at lower prices undermines our sales in some markets with higher prices. Additionally, certain countries set prices by reference to the prices in other countries where our products are marketed. Thus, our inability to secure adequate prices in a particular country may also impair our ability to obtain acceptable prices in existing and potential new markets, and may create the opportunity for third party cross border trade.

If significant additional reforms are made to the U.S. healthcare system, or to the healthcare systems of other markets in which we operate, those reforms 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

**Table of Contents**

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.

In addition, in limited circumstances, entities we acquired in the acquisition of the former Merck Generics business are party to litigation 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, which could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

***IF 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.

***UNANTICIPATED CHANGES IN OUR TAX PROVISIONS OR EXPOSURE TO ADDITIONAL INCOME TAX LIABILITIES 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 to income taxes in the U.S. and many foreign jurisdictions. Significant judgment is required in determining our worldwide provision for income taxes. In the ordinary course of business, there are many transactions and calculations where the ultimate tax determination is uncertain. The final determination of any tax audits or related litigation could be materially different from our historical income tax provisions and accruals. Additionally, changes in the effective tax rate as a result of a change in the mix of earnings in countries with differing statutory tax rates, changes in our overall profitability, changes in the valuation of deferred tax assets and liabilities, the results of audits and the examination of previously filed tax returns by taxing authorities and continuing assessments of our tax exposures could impact our tax liabilities and affect our income tax expense, 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.



**Table of Contents**

***CHANGES IN INCOME TAX LAWS AND TAX RULINGS MAY HAVE A SIGNIFICANTLY ADVERSE IMPACT ON OUR EFFECTIVE TAX RATE AND INCOME TAX EXPENSE, 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.***

In February 2010, the Obama administration released its fiscal year 2011 budget, which reintroduced, in somewhat modified form, several proposals originally proposed in May 2009 to change U.S. income tax rules, including proposals for U.S. international tax reform. The proposals would, among other things, limit the use of foreign tax credits to reduce residual U.S. income tax on non-U.S. source income and defer the deduction of interest attributable to non-U.S. source income of foreign subsidiaries. Each of these proposals would be effective only for taxable years beginning after December 31, 2010. We cannot determine whether these proposals will be enacted into law or what, if any, changes will be made to such proposals prior to their being enacted into law. If enacted, and depending on its precise terms, such legislation could materially increase our overall effective income tax rate and income tax expense. 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.

The Tax Extenders Act of 2009 includes legislation which would extend, for one year, 49 expiring tax provisions. On May 20, 2010, a new tax extenders bill, the American Jobs and Tax Loophole Closing Act of 2010, was introduced. This bill was passed by the House on May 28, 2010 and is now pending action in the Senate. The total impact to the Company of an extension of these expiring tax provisions is currently unknown due to the potential impact of revenue offsets, which may be included in the final version of this legislation, if enacted. If enacted, and depending on its precise terms, such legislation could materially increase our overall effective income tax rate and income tax expense. 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.

***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 COULD LEAD TO ADVERSE CONSEQUENCES THAT 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 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;

restricting us from exploiting business opportunities;

increasing our cost of borrowings; and

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

**Table of Contents**

Our ability to service our indebtedness will depend on our future operating performance and financial results, which will be subject, in part, to factors beyond our control, including interest rates and general economic, financial and business conditions. If we 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 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 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 from time to time consider selling certain assets if (a) we determine that such assets are not critical to our strategy, or (b) we believe the opportunity to monetize the asset is attractive or for various reasons including we want to reduce indebtedness. 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, SENIOR UNSECURED NOTES, OTHER OUTSTANDING INDEBTEDNESS 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, senior unsecured notes, other outstanding indebtedness 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 certain dividends, prepay other indebtedness, sell assets, incur certain liens, enter into agreements with our affiliates or restricting our subsidiaries ability to pay dividends, 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.

**Table of Contents**

***THE TOTAL AMOUNT OF INDEBTEDNESS RELATED TO OUR OUTSTANDING CASH CONVERTIBLE NOTES WILL INCREASE IF OUR STOCK PRICE INCREASES. IN ADDITION, OUR OUTSTANDING SENIOR NOTES SETTLEMENT VALUE INCREASES AS OUR STOCK PRICE INCREASES, ALTHOUGH WE DO NOT ACCOUNT FOR THIS AS AN INCREASE IN INDEBTEDNESS. ALSO, WE HAVE ENTERED INTO NOTE HEDGES AND WARRANT TRANSACTIONS IN CONNECTION WITH THE SENIOR CONVERTIBLE NOTES AND CASH CONVERTIBLE NOTES IN ORDER TO HEDGE SOME OF THE RISK ASSOCIATED WITH THE POTENTIAL INCREASE OF INDEBTEDNESS AND SETTLEMENT VALUE. SUCH TRANSACTIONS HAVE BEEN CONSUMMATED WITH CERTAIN COUNTERPARTIES, MAINLY HIGHLY RATED FINANCIAL INSTITUTIONS. ANY INCREASE IN INDEBTEDNESS, NET EXPOSURE RELATED TO THE RISK OR FAILURE OF ANY COUNTERPARTIES TO PERFORM THEIR OBLIGATIONS, COULD HAVE ADVERSE EFFECTS ON US, INCLUDING UNDER OUR DEBT AGREEMENTS, 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.***

Under applicable accounting rules, the cash conversion feature that is a term of the Cash Convertible Notes must be recorded as a liability on our balance sheet and periodically marked to fair value. If our stock price increases, the liability associated with the cash conversion feature would increase and, because this liability must be periodically marked to fair value on our balance sheet, the total amount of indebtedness related to the notes that is shown on our balance sheet would also increase. This could have adverse effects on us, including under our existing and any future debt agreements. For example, our senior credit facilities contain covenants that restrict our ability to incur debt, make capital expenditures, pay dividends and make investments if, among other things, our leverage ratio, exceeds certain levels. In addition, the interest rate we pay under our senior credit facilities increases if our leverage ratio increases. Because the leverage ratio under our senior credit facilities is calculated based on a definition of total indebtedness as defined under accounting principles generally accepted in the United States of America ( GAAP ), if the amount of our total indebtedness were to increase, our leverage ratio would also increase. As a result, we may not be able to comply with such covenants in the future, which could, among other things, restrict our ability to grow our business, take advantage of business opportunities or respond to competitive pressures. 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 the notes and our common stock to decline.

Although the conversion feature under our Senior Convertible Notes is not marked to market, the conversion feature also increases as the price of our common stock increases. If our stock price increases, the settlement value of the conversion feature increases.

In connection with the issuance of the Cash Convertible Notes and Senior Convertible Notes, we entered into note hedge and warrant transactions with certain financial institutions, each of which we refer to as a counterparty. The Cash Convertible Note hedge is comprised of purchased cash-settled call options that are expected to reduce our exposure to potential cash payments required to be made by us upon the cash conversion of the notes. The Senior Convertible Notes hedge is comprised of call options that are expected to reduce our exposure to the settlement value (issuance of common stock) upon the conversion of the notes. We have also entered into respective warrant transactions with the counterparties pursuant to which we will have sold to each counterparty warrants for the purchase of shares of our common stock. Together, each of the note hedges and warrant transactions are expected to provide us with some protection against increases in our stock price over the conversion price per share. However, there is no assurance that these transactions will remain in effect at all times. Also, although we believe the counterparties are highly rated financial institutions, there are no assurances that the counterparties will be able to perform their respective obligations under the agreement we have with each of them. Any net exposure related to conversion of the notes or any failure of the counterparties to perform their obligations under the agreements we have with them 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**

***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, including Bioniche Pharma, products or assets, including those in rapidly developing economies, 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, including tax, expected to result from any acquisitions, including Bioniche Pharma, 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 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, or 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.

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

In the normal course of business, we periodically enter into employment, legal settlement, and other agreements which incorporate indemnification provisions. We maintain insurance coverage which we believe will effectively mitigate our obligations under 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 adversely 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.

**Table of Contents**

***WE ARE IN THE PROCESS OF ENHANCING AND FURTHER DEVELOPING OUR GLOBAL ENTERPRISE RESOURCE PLANNING SYSTEMS AND ASSOCIATED BUSINESS APPLICATIONS. AS WITH ANY ENHANCEMENTS OF SIGNIFICANT SYSTEMS, 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 enhancing and further developing our global enterprise resource planning ( ERP ) systems and associated applications to provide more operating efficiencies and effective management of our business operations. Such changes to 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 enhancements, it could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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

Effective internal controls are necessary for the Company to provide reasonable assurance with respect to its financial reports. We are spending a substantial amount of management time and resources to comply with changing laws, regulations and standards relating to corporate governance and public disclosure. In the U.S. such changes include the Sarbanes-Oxley Act of 2002, Securities and Exchange Commission ( SEC ) regulations and the NASDAQ listing standards. 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.

***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 OR CHARGES, INCLUDING IMPAIRMENT CHARGES, 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 GAAP. The preparation of financial statements in accordance with GAAP involves making estimates, judgments and assumptions that affect reported amounts of assets, liabilities, revenues, expenses and income. Estimates, judgments and assumptions are inherently subject to change in the future and any necessary revisions to prior estimates, judgments or assumptions could lead to a restatement.

**Table of Contents**

Furthermore, although we have recorded reserves for lawsuits based on estimates of probable future costs, such lawsuits could result in substantial further costs. 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 liabilities, revenues, expenses and income. Any such changes could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

In addition, a significant amount of our total assets are related to acquired intangible assets and goodwill. Such assets require impairment testing periodically and/or under certain circumstances. Impairment testing requires the use of significant estimates, judgments and assumptions, which involve inherent uncertainty. Any future changes to estimates, judgments and assumptions used in impairment testing could lead to impairment charges, 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.

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

- 3.1 Amended and Restated Articles of Incorporation of the registrant, as amended to date, filed as Exhibit 3.1 to the Report on Form 10-Q for the quarter ended June 30, 2009, and incorporated herein by reference.
- 3.2 Bylaws of the registrant, as amended to date, filed as Exhibit 3.2 to the Report on Form 10-Q for the quarter ended June 30, 2009, 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



Edgar Filing: MYLAN INC. - Form 10-Q

Exhibit 4.1 to the Report on Form 8-K filed with the SEC on October 5, 2007, and incorporated herein by reference.

- 4.3 Registration Rights Agreement, dated as of July 21, 2005, among the registrant, the Guarantors party thereto and Merrill Lynch, Pierce, Fenner & Smith Incorporated, BNY Capital Markets, Inc., KeyBanc Capital Markets (a Division of McDonald Investments Inc.), PNC Capital Markets, Inc. and SunTrust Capital Markets, Inc., 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.

**Table of Contents**

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.
4.5	Indenture, dated as of May 19, 2010, among the registrant, the guarantors named therein and The Bank of New York Mellon as trustee, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on May 19, 2010, and incorporated herein by reference.
10.1	Purchase Agreement, dated as of May 12, 2010, among the registrant, the guarantors named therein and Goldman, Sachs & Co., as representative of the several purchasers named therein.
10.2	Share Purchase Agreement, dated as of July 14, 2010, by and among Mylan Inc., Mylan Luxembourg L3 S.C.S., Bioniche Pharma Holdings Limited, the shareholders party thereto and the optionholders party thereto, filed as Exhibit 2.1 to the Report on Form 8-K filed with the SEC on July 16, 2010, and incorporated herein by reference.
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Mylan Inc.  
(Registrant)

By: /s/ Robert J. Coury

Robert J. Coury  
Chairman and Chief Executive Officer  
(Principal Executive Officer)

July 29, 2010

/s/ John D. Sheehan

John D. Sheehan  
Executive Vice President and Chief Financial Officer  
(Principal Financial Officer)

July 29, 2010

/s/ Daniel C. Rizzo, Jr.

Daniel C. Rizzo, Jr.  
Senior Vice President, Chief Accounting Officer and  
Corporate Controller  
(Principal Accounting Officer)

July 29, 2010

**Table of Contents**

**EXHIBIT INDEX**

10.1	Purchase Agreement, dated as of May 12, 2010, among the registrant, the guarantors named therein and Goldman, Sachs & Co., as representative of the several purchasers named therein.
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase