MYLAN INC. Form 10-Q October 28, 2010

UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, DC 20549

Form 10-Q

DESCRIPTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2010

OR

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

For the transition period from to

Commission File Number 1-9114

MYLAN INC.

(Exact name of registrant as specified in its charter)

Pennsylvania

25-1211621

(State or other jurisdiction of incorporation or organization)

(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 b No o

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 b No o

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 b Non-accelerated filer o (Do not check if a smaller reporting company) Accelerated filer o Smaller reporting company o

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

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

Class of Common Stock Outstanding at October 22, 2010

\$0.50 par value

309,730,799

MYLAN INC. AND SUBSIDIARIES

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

		Page
	PART I FINANCIAL INFORMATION	
ITEM 1.	Condensed Consolidated Financial Statements (unaudited)	
	Condensed Consolidated Statements of Operations Three and Nine Months Ended	
	September 30, 2010 and 2009	3
	Condensed Consolidated Balance Sheets September 30, 2010 and December 31,	
	<u>2009</u>	4
	Condensed Consolidated Statements of Cash Flows Nine Months Ended	
	<u>September 30, 2010 and 2009</u>	5
	Notes to Condensed Consolidated Financial Statements	6
<u>ITEM 2.</u>	Management s Discussion and Analysis of Financial Condition and Results of	
	<u>Operations</u>	32
ITEM 3.	Quantitative and Qualitative Disclosures About Market Risk	43
<u>ITEM 4.</u>	Controls and Procedures	43
	PART II OTHER INFORMATION	
<u>ITEM 1.</u>	Legal Proceedings	44
ITEM 1A.	Risk Factors	47
<u>ITEM 5.</u>	Other Information	67
<u>ITEM 6.</u>	<u>Exhibits</u>	67
SIGNATURES		69
EX-10.1		
EX-31.1 EX-31.2		
EX-32		
EX-101 INSTANCE DOC		
EX-101 SCHEMA DOCU		
EX-101 CALCULATION EX-101 LABELS LINKB	LINKBASE DOCUMENT ASE DOCUMENT	
•	N LINKBASE DOCUMENT	
	-	

MYLAN INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Operations

	Period Ended September 30,							
	Three Months			Nine Months				
		2010		2009		2010		2009
		(Unaudite	d; ir	thousands,	exce	pt per share	amo	ounts)
Revenues:								
Net revenues	\$	1,344,999	\$	1,255,708	\$	3,979,648	\$	3,679,868
Other revenues		10,114		8,366		36,375		61,100
Total revenues		1,355,113		1,264,074		4,016,023		3,740,968
Cost of sales		775,056		759,094		2,377,818		2,182,488
Gross profit		580,057		504,980		1,638,205		1,558,480
Operating expenses:								
Research and development		71,992		69,812		200,076		202,665
Selling, general and administrative		272,285		259,609		796,420		780,953
Litigation settlements, net		1,462		114,281		14,299		111,530
Total operating expenses		345,739		443,702		1,010,795		1,095,148
Earnings from operations		234,318		61,278		627,410		463,332
Interest expense		87,536		77,034		239,985		240,209
Other (expense) income, net		(15,269)		243		(29,437)		29,741
Earnings (loss) before income taxes and								
noncontrolling interest		131,513		(15,513)		357,988		252,864
Income tax (benefit) provision		(12,026)		(11,092)		33,245		52,539
Net earnings (loss) Net (earnings) loss attributable to the		143,539		(4,421)		324,743		200,325
noncontrolling interest		(356)		(841)		525		(6,658)
Net earnings (loss) attributable to Mylan Inc.								
before preferred dividends		143,183		(5,262)		325,268		193,667
Preferred dividends		34,759		34,759		104,276		104,276
Net earnings (loss) attributable to Mylan Inc.								
common shareholders	\$	108,424	\$	(40,021)	\$	220,992	\$	89,391
Earnings (loss) per common share attributable to Mylan Inc. common shareholders:								
Basic	\$	0.35	\$	(0.13)	\$	0.72	\$	0.29

Edgar Filing: MYLAN INC Form 10-0	Edgar	Filing:	MYL	AN INC.	- Form	10-C
-----------------------------------	-------	---------	-----	---------	--------	------

Diluted	\$ 0.33	\$ (0.13)	\$ 0.71	\$ 0.29
Weighted average common shares outstanding: Basic	309,446	305,285	308,470	304,951
Diluted	437,921	305,285	313,014	306,086

See Notes to Condensed Consolidated Financial Statements

3

MYLAN INC. AND SUBSIDIARIES

Condensed Consolidated Balance Sheets

	September 30, 2010 December 31 (Unaudited; in thousands, except share and per share amou			
ASSETS				
Current assets: Cash and cash equivalents Restricted cash Marketable securities Accounts receivable, net Inventories Deferred income tax benefit Prepaid expenses and other current assets	\$	610,921 23,813 30,108 1,251,862 1,221,765 247,917 76,899	\$	380,516 47,965 27,559 1,234,634 1,114,219 248,917 231,576
Total current assets Property, plant and equipment, net Intangible assets, net Goodwill Deferred income tax benefit Other assets		3,463,285 1,150,750 2,562,387 3,568,519 44,204 617,896		3,285,386 1,122,648 2,384,848 3,331,247 36,610 640,995
Total assets	\$	11,407,041	\$	10,801,734
Liabilities Current liabilities: Trade accounts payable Short-term borrowings Income taxes payable Current portion of long-term debt and other long-term obligations Deferred income tax liability Other current liabilities Total current liabilities Long-term debt Other long-term obligations	\$	551,329 150,795 56,863 7,741 1,335 954,278 1,722,341 5,212,229 460,123	\$	518,252 184,352 69,122 9,522 1,986 934,913 1,718,147 4,984,987 485,905
Deferred income tax liability		469,408		467,497
Total liabilities		7,864,101		7,656,536
Equity Mylan Inc. shareholders equity				

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: 399,344,974 and 396,683,892 as of September 30, 2010		
and December 31, 2009	199,672	198,342
Additional paid-in capital	3,890,333	3,834,674
Retained earnings	881,123	660,130
Accumulated other comprehensive earnings	124,268	11,807
	5,096,466	4,706,023
Noncontrolling interest	12,812	14,052
Less: treasury stock at cost		
Shares: 89,718,669 and 90,199,152 as of September 30, 2010 and		
December 31, 2009	1,566,338	1,574,877
Total equity	3,542,940	3,145,198
Total liabilities and equity	\$ 11,407,041	\$ 10,801,734

See Notes to Condensed Consolidated Financial Statements

4

MYLAN INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Cash Flows

	Nine Months Ended 2010 (Unaudited; in			2009
Cash flows from operating activities:				
Net earnings	\$	324,743	\$	200,325
Adjustments to reconcile net earnings to net cash provided by operating				
activities:				
Depreciation and amortization		309,872		296,949
Stock-based compensation expense		24,156		23,591
Change in estimated sales allowances		6,096		62,288
Deferred income tax benefit		(78,450)		(82,036)
Other non-cash items		104,486		51,284
Litigation settlements, net		14,299		111,530
Changes in operating assets and liabilities:				
Accounts receivable		64,721		48,390
Inventories		(69,340)		11,188
Trade accounts payable		8,365		(57,854)
Income taxes		80,883		(59,038)
Deferred revenue		20,602		(24,029)
Other operating assets and liabilities, net		(73,485)		(36,038)
Net cash provided by operating activities		736,948		546,550
Cash flows from investing activities:				
Capital expenditures		(96,270)		(83,135)
Change in restricted cash		24,856		(22,861)
Cash paid for acquisitions, net		(556,112)		(211,209)
Proceeds from sale of property, plant and equipment		4,947		
Proceeds from sale of equity-method investee				23,333
Purchase of marketable securities		(7,835)		(4,278)
Proceeds from sale of marketable securities		4,739		14,970
Other items, net		4,975		237
Net cash used in investing activities		(620,700)		(282,943)
Cash flows from financing activities:				
Cash dividends paid		(104,276)		(104,276)
Payment of financing fees		(23,704)		
Change in short-term borrowings, net		(45,036)		(260)
Proceeds from issuance of long-term debt		1,569,300		6,236
Payment of long-term debt	(1	1,305,224)		(153,315)
Proceeds from exercise of stock options		37,215		8,803

Edgar Filing: MYLAN INC. - Form 10-Q

Net cash provided by (used in) financing activities	128,275	(242,812)
Effect on cash of changes in exchange rates	(14,118)	6,469
Net increase in cash and cash equivalents Cash and cash equivalents beginning of period	230,405 380,516	27,264 557,147
Cash and cash equivalents end of period	\$ 610,921	\$ 584,411

See Notes to Condensed Consolidated Financial Statements

5

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 nine months ended September 30, 2010 and the interim cash flows for the nine months ended September 30, 2010 are not necessarily indicative of the results to be expected for the full fiscal year or any other future period. The Company computed its provision for income taxes in the first three quarters of the year using an estimated effective tax rate for the full year with consideration to certain discrete tax items which occurred within the interim periods. In the three months ended September 30, 2010, the Company realized a tax benefit on positive earnings as a result of the release of several tax reserves, due to favorable tax rulings received from certain taxing authorities, as well as the expiration of certain statutes of limitations during the three-month period. 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, sales allowances, 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 nine months ended September 30, 2010 except as discussed below. Such allowances were \$586.2 million and \$607.9 million at September 30, 2010 and December 31, 2009. Other current liabilities include \$266.0 million and \$238.2 million at September 30, 2010 and December 31, 2009, for certain sales allowances and other adjustments that are paid to indirect customers.

During the current quarter, Mylan launched minocycline hydrochloride extended release (minocycline ER) tablets, the generic version of Medicis Pharmaceuticals Corporation s Solody ER. After receiving final approval from the U.S. Food and Drug Administration on July 20, 2010, Mylan commenced immediate shipment of the product. Mylan also reached settlement and license agreements with Medicis Pharmaceuticals Corporation (Medicis) resolving patent litigation relating to minocycline ER, and the Company has ceased additional distribution. Pursuant to the terms of the agreements, Medicis will release Mylan from any liability related to the prior sales of the product, and Mylan will have the right to market minocycline ER in the U.S. beginning in November 2011, or earlier under certain circumstances.

As a result of significant uncertainties surrounding the pricing and market conditions with respect to this product, the Company is not able to reasonably estimate the amount of potential price adjustments, including product returns. Therefore, revenues on shipments of this product are currently being deferred until the resolution of such uncertainties. At the present time, such uncertainties are resolved upon our customers—sale of this product. As a result, the Company is recognizing revenue only upon our customers—sale of this product.

6

MYLAN INC. AND SUBSIDIARIES

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

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.

In April 2010, the FASB issued revised accounting guidance for the milestone method of revenue recognition. The amended guidance is effective for fiscal years beginning on or after June 15, 2010. It provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research and development transactions. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

4. Acquisitions

Termination of Joint Ventures

During the nine months ended September 30, 2009, Matrix and Aspen Pharmacare Holdings Limited (Aspen) terminated two joint ventures in which each held a 50% share; Astrix Laboratories Limited (Astrix) and Fine Chemicals Corporation (FCC). Under the agreed upon terms, Matrix sold its 50% interest in FCC to Aspen for \$23.3 million. At the same time, a wholly-owned subsidiary of Mylan purchased from Aspen its 50% interest in Astrix for \$38.9 million. These transactions resulted in a net gain of approximately \$10.4 million, which is included in other (expense) income, net, in the Condensed Consolidated Statements of Operations for the nine months ended September 30, 2009. As of the date of purchase, June 1, 2009, the results of Astrix were consolidated with those of Mylan.

The Company accounted for the acquisition of the remaining 50% of Astrix using the purchase method of accounting. Under the purchase method of accounting, the assets acquired and liabilities assumed in the transaction were recorded at their respective fair values.

Biologics Agreement

On June 29, 2009, Mylan announced that it has executed a definitive agreement with Biocon Limited (Biocon), a publicly traded company on the Indian stock exchanges, for an exclusive collaboration on the development, manufacturing, supply and commercialization of multiple, high value generic biologic compounds for the global marketplace.

As part of this collaboration, Mylan and Biocon will share development, capital and certain other costs to bring products to market. Mylan will have exclusive commercialization rights in the U.S., Canada, Japan, Australia, New Zealand and in the European Union and European Free Trade Association countries through a profit sharing arrangement with Biocon. Mylan will have co-exclusive commercialization rights with Biocon in all other markets around the world. In conjunction with executing this agreement, Mylan recorded an \$18.0 million research and development charge in the nine months ended September 30, 2009 related to its up-front, non-refundable obligation

pursuant to the agreement.

Bioniche Pharma

On September 7, 2010, the Company completed the acquisition of 100% of the outstanding equity in Bioniche Pharma Holdings Limited (Bioniche Pharma), a privately held, global injectable pharmaceutical company. The Company financed the transaction using a combination of cash on hand and long-term borrowings (see Note 10). In accordance with the FASB accounting guidance regarding business combinations, the Company used the purchase

7

MYLAN INC. AND SUBSIDIARIES

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

method of accounting to account for this transaction. Under the purchase method of accounting, the assets acquired and liabilities assumed in the transaction were recorded at the date of acquisition at the estimate of their respective fair values.

Bioniche Pharma manufactures and sells a diverse portfolio of products across several therapeutic areas for the hospital setting, including analgesics/anesthetics, orthopedics, oncology, and urology, with most of the company s sales made to customers in the U.S. The operating results of Bioniche Pharma from September 7, 2010 are included in the Condensed Consolidated Financial Statements as part of Mylan s Generics Segment.

The purchase price of \$543.7 million has been allocated to the assets acquired and liabilities assumed for the former Bioniche Pharma business as of the acquisition date as follows:

(In thousands)

Current assets (excluding inventories)	\$ 41,680
Inventories	28,500
Property, plant and equiptment, net	16,211
Identified intangible assets	186,000
In-process research and development	143,000
Goodwill	207,390
Total assets acquired	622,781
Current liabilities	(37,389)
Deferred tax liabilities	(36,910)
Other non-current liabilities	(4,746)
Net assets acquired	\$ 543,736

The allocation of the purchase price is not yet final, primarily related to certain income tax-related accounts. The amount allocated to acquired in-process research and development represents an estimate of the fair value of purchased in-process technology for research projects that, as of the closing date of the acquisition, had not reached technological feasibility and had no alternative future use. The fair value of the acquired in-process technology and research projects was based on the excess earnings method, which utilizes forecasts of expected cash inflows (including estimates for ongoing costs) and other contributory charges, on a project-by-project basis, and will be tested for impairment in accordance with FASB accounting guidance.

The identified intangible assets of \$186.0 million are comprised of product rights and licenses that have a weighted average useful life of approximately nine years. The goodwill of \$207.4 million arising from the acquisition consists largely of the value of the employee workforce and the value of products to be developed in the future. All of the goodwill was assigned to Mylan s Generics Segment. None of the goodwill recognized is expected to be deductible for income tax purposes.

Acquisition costs of \$10.9 million and \$12.5 million were expensed in the three and nine months ended September 30, 2010.

Pro Forma financial results

The operating results of Bioniche Pharma have been included in Mylan s Condensed Consolidated Statement of Operations since September 7, 2010. The following table represents supplemental unaudited pro forma information as if the acquisition of Bioniche Pharma had occurred on January 1, 2010 for the three and nine months ended September 30, 2010 and on January 1, 2009 for the three and nine months ended September 30, 2009. This summary of the unaudited pro forma results of operations is not necessarily indicative of what Mylan s results

8

MYLAN INC. AND SUBSIDIARIES

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

of operations would have been had Bioniche Pharma been acquired at the beginning of each annual period presented and may not be indicative of future performance.

The unaudited pro forma financial information for the periods below includes the following charges directly attributable to the accounting for the acquisition: amortization of the step-up of inventory of \$12.0 million for the nine months ended September 30, 2010 and 2009; amortization on intangibles of \$5.2 million for the quarters ended September 30, 2009 and 2010; and amortization on intangibles of \$15.6 million for the nine-month periods ended September 30, 2009 and 2010. In addition, the unaudited pro forma financial information for the periods presented includes the effects of certain additional borrowings used to purchase Bioniche Pharma as if they occurred on January 1, 2010 and 2009.

			Months Ended otember 30,					hs Ended ber 30,	
		2010		2009		2010		2009	
		(Unaudite	ed; ir	n thousands,	exc	ept per shar	e am	ounts)	
Total revenues	\$	1,386,730	\$	1,286,589	\$	4,127,302	\$	3,800,616	
Net earnings (loss) attributable to Mylan Inc. before preferred dividends Preferred dividends		136,521 34,759		(7,685) 34,759		305,021 104,276		178,521 104,276	
Net earnings (loss) attributable to Mylan Inc. common shareholders	\$	101,762	\$	(42,444)	\$	200,745	\$	74,245	
Earnings (loss) per common share attributable to Mylan Inc. common shareholders	Ф	0.22	ф	(0.14)	Φ.	0.65	Ф	0.24	
Basic	\$	0.33	\$	(0.14)	\$	0.65	\$	0.24	
Diluted	\$	0.31	\$	(0.14)	\$	0.64	\$	0.24	
Weighted average common shares outstanding: Basic		309,446		305,285		308,470		304,951	
Diluted		437,921		305,285		313,014		306,086	

Matrix

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 nine months ended September 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%.

In addition, during the three months ended September 30, 2010, approximately \$10.0 million was paid as part of the purchase consideration for a finished dosage form manufacturing facility in India.

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

9

MYLAN INC. AND SUBSIDIARIES

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

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:

	Number of Shares Under Option	Weighted Average Exercise Price per Share			
Outstanding at December 31, 2009 Options granted Options exercised Options forfeited	26,268,678 2,408,039 (2,667,422) (908,190)	\$	15.22 20.54 14.00 14.91		
Outstanding at September 30, 2010	25,101,105	\$	15.87		
Vested and expected to vest at September 30, 2010	24,019,159	\$	15.89		
Options exercisable at September 30, 2010	17,529,098	\$	15.88		

As of September 30, 2010, options outstanding, options vested and expected to vest, and options exercisable had average remaining contractual terms of 5.67 years, 5.55 years and 4.43 years, respectively. Also at September 30, 2010, options outstanding, options vested and expected to vest and options exercisable had aggregate intrinsic values of \$83.5 million, \$79.4 million and \$56.5 million, respectively.

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

	Number of Restricted Stock Awards	Weighted Average Grant-Date Fair Value per Share		
Nonvested at December 31, 2009	2,464,600	\$	12.78	
Granted	816,359		21.20	
Released	(670,557)		13.57	

Forfeited (133,180) 12.46

Nonvested at September 30, 2010 2,477,222 \$ 15.37

As of September 30, 2010, the Company had \$39.9 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 1.68 years. The total intrinsic value of stock-based awards exercised and restricted stock units converted during the nine months ended September 30, 2010 and September 30, 2009 was \$32.6 million and \$11.1 million.

10

MYLAN INC. AND SUBSIDIARIES

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

6. Balance Sheet Components

Selected balance sheet components consist of the following:

	Sep	otember 30, 2010 (In the	Dece ousands	mber 31, 2009
Inventories: Raw materials Work in process	\$	317,619 235,647	\$	287,128 198,280
Finished goods		668,499		628,811
	\$	1,221,765	\$	1,114,219
Property, plant and equipment:				
Land and improvements	\$	71,536	\$	69,614
Buildings and improvements		651,176		625,303
Machinery and equipment		1,220,804		1,145,464
Construction in progress		135,514		118,410
		2,079,030		1,958,791
Less accumulated depreciation		928,280		836,143
	\$	1,150,750	\$	1,122,648
Other current liabilities:				
Payroll and employee benefit plan accruals	\$	176,799	\$	188,743
Accrued sales allowances		265,979		238,161
Legal and professional accruals, including litigation reserves		232,896		218,813
Fair value of financial instruments		43,129		66,420
Other		235,475		222,776
	\$	954,278	\$	934,913

7. Earnings (Loss) per Common Share attributable to Mylan Inc.

Basic earnings (loss) 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 (loss) 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, which will occur on November 15, 2010. For the three months ended September 30, 2010, the if-converted method is dilutive; therefore, the preferred stock conversion is included in the computation of diluted earnings per share. For the nine months ended September 30, 2010 and the three and nine months ended September 30, 2009, the if-converted method is anti-dilutive; therefore, the preferred stock conversion is excluded from the computation of diluted earnings per share.

11

MYLAN INC. AND SUBSIDIARIES

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

Basic and diluted earnings (loss) per common share attributable to Mylan Inc. are calculated as follows:

	r	Three Mon Septen 2010 (In the	ıber	· 30, 2009	Nine Months Ended September 30, 2010 2009 t per share amounts)				
Basic earnings (loss) attributable to Mylan Inc. common shareholders (numerator): Net earnings (loss) attributable to Mylan Inc. before preferred dividends Less: Preferred dividends	\$	143,183 34,759	\$	(5,262) 34,759	\$	325,268 104,276	\$	193,667 104,276	
Net earnings (loss) attributable to Mylan Inc. common shareholders	\$	108,424	\$	(40,021)	\$	220,992	\$	89,391	
Shares (denominator): Weighted average shares outstanding		309,446		305,285		308,470		304,951	
Basic earnings (loss) per common share attributable to Mylan Inc.	\$	0.35	\$	(0.13)	\$	0.72	\$	0.29	
Diluted earnings (loss) attributable to Mylan Inc. common shareholders (numerator): Net earnings (loss) attributable to Mylan Inc. common shareholders Add: Preferred dividends	\$	108,424 34,759	\$	(40,021)	\$	220,992	\$	89,391	
Earnings (loss) attributable to Mylan Inc. common shareholders and assumed conversions	\$	143,183	\$	(40,021)	\$	220,992	\$	89,391	
Shares (denominator): Weighted average shares outstanding Stock-based awards and warrants Preferred stock conversion		309,446 3,241 125,234		305,285		308,470 4,544		304,951 1,135	
Total dilutive shares outstanding		437,921		305,285		313,014		306,086	
Diluted earnings (loss) per common share attributable to Mylan Inc.	\$	0.33	\$	(0.13)	\$	0.71	\$	0.29	

Additional stock options or restricted stock awards representing 7.5 million and 19.2 million shares were outstanding at September 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 nine months ended September 30, 2010, the Company paid dividends of \$104.3 million on the preferred stock. On October 19, 2010, the Company announced that the last quarterly dividend of \$16.25 per share had been declared (based on the annual dividend rate of 6.5% and a liquidation preference of \$1,000 per share) and is payable on November 15, 2010, to the holders of preferred stock of record as of November 1, 2010. The preferred stock will also automatically convert into common stock on November 15, 2010.

12

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 September 30, 2010 is as follows:

	-	Generics Segment	Specialty Segment (In thousands)			Total
Goodwill Accumulated impairment losses ⁽¹⁾	\$	3,009,740	\$	706,507 (385,000)	\$	3,716,247 (385,000)
Balance at December 31, 2009 Goodwill acquired during the year ⁽²⁾ Foreign currency translation	\$	3,009,740 207,390 29,882	\$	321,507	\$	3,331,247 207,390 29,882
Balance at September 30, 2010	\$	3,247,012	\$	321,507	\$	3,568,519

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

Intangible assets consist of the following components:

	Weighted Average Life (Years)			Ar	ecumulated mortization nousands)	Net Book Value		
September 30, 2010 Amortized intangible assets: Patents and technologies Product rights and licenses Other ⁽¹⁾	20 10 8	\$	122,926 3,251,430 143,716	\$	82,150 964,040 52,495	\$	40,776 2,287,390 91,221	
		\$	3,518,072	\$	1,098,685		2,419,387	
In-process research and development							143,000	
						\$	2,562,387	

⁽²⁾ Allocation of goodwill acquired through the acquisition of Bioniche Pharma (see Note 4).

December 31, 2009

Amortized intangible assets:				
Patents and technologies	20	\$ 122,926	\$ 77,717	\$ 45,209
Product rights and licenses	10	2,913,475	672,999	2,240,476
Other ⁽¹⁾	8	158,996	59,833	99,163
		\$ 3,195,397	\$ 810,549	\$ 2,384,848

Amortization expense, which is classified within cost of sales on the Company s Condensed Consolidated Statements of Operations, for the nine months ended September 30, 2010 and 2009 was \$209.9 million and \$204.3 million, and is expected to be \$76.1 million for the remainder of 2010, and \$292.1 million, \$285.4 million, \$279.7 million and \$272.1 million for the years ended December 31, 2011 through 2014, respectively.

In conjunction with the acquisition of Bioniche Pharma, we acquired \$143.0 million of in-process research and development assets. Acquired in-process research and development assets are not currently being amortized. As

13

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

MYLAN INC. AND SUBSIDIARIES

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

products in development are approved for sale, amounts will be allocated to product rights and licenses and will be amortized over the estimated useful life. Such in-process research and development will be subject to periodic impairment testing under FASB guidance.

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.

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 nine months ended September 30, 2010, the Company entered into forecasted 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 September 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 \$927.6 million at September 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 in May 2010 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 nine months ended September 30, 2010, charges of approximately \$7.4 million that had previously been classified in AOCE were recognized into other (expense) income, net. As of September 30, 2010 and December 31, 2009, the total notional amount of the Company s

floating-rate debt interest rate swaps was \$1.27 billion and \$2.29 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 such contracts that are in a liability position at September 30, 2010 is \$39.6 million. The Company is not subject to any obligations to post collateral under derivative contracts.

14

MYLAN INC. AND SUBSIDIARIES

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

The Company maintains significant credit exposure arising from the convertible note hedge on its Cash Convertible Notes. At September 30, 2010, the convertible note hedge had a total fair value of \$391.1 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.

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

	Asset Derivatives								
	September 30,	2010		December 31,	2009				
	Balance Sheet		Balance Sheet	Foi.					
(In thousands)	Location	Fair	· Value	Location	Fair Value				
Foreign currency forward contracts	Prepaid expenses and other current assets	\$	6,490	Prepaid expenses and other current assets	\$				
Total		\$	6,490		\$				

	Liability Derivatives								
	September :	30, 20 1	10	December	09				
	Balance Sheet		Balance Sheet						
	Location	Location Fair Value		Location	F	Tair Value			
(In thousands)									
Interest rate swaps	Other current			Other current					
	liabilities	\$	39,597	liabilities	\$	62,607			
Foreign currency borrowings	Long-term debt		927,594	Long-term debt		978,059			
Total		\$	967,191		\$	1,040,666			

Derivatives Not Designated as Hedging Instruments Fair Values of Derivative Instruments

Asset Derivatives

			120000	11,0001,00			
	September 30	201	0	December 31, 2009			
	Balance Sheet		Balance Sheet				
	Location	Location Fair Value		Location	Fair Value		
(In thousands)							
Foreign currency forward contracts	Prepaid expenses and			Prepaid expenses and			
	other current assets	\$	3,690	other current assets	\$	8,793	
Purchased cash convertible note							
hedge	Other assets		391,100	Other assets		410,600	
Total		¢	204 700		Φ	410 202	
Total		Þ	394,790		Э	419,393	

MYLAN INC. AND SUBSIDIARIES

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

	Liability Derivatives								
	September 30,	201	0	December 31, 2009					
	Balance Sheet			Balance Sheet	103	• \$7.1			
(In thousands)	Location	Fa	iir Value	Location	Fa	iir Value			
Foreign currency forward contracts Cash conversion feature of Cash	Other current liabilities	\$	3,532	Other current liabilities	\$	5,694			
Convertible Notes	Long-term debt		391,100	Long-term debt		410,600			
Total		\$	394,632		\$	416,294			

The Effect of Derivative Instruments on the Condensed Consolidated Statements of Operations Derivatives in Cash Flow Hedging Relationships

Amount of Gain

	or (Loss) Recognized in AOCE (Net of Tax) on Derivative (Effective Portion)									
	Т		nths Ended aber 30, 2009		Nine Months Ended September 30, 2010 2009					
(In thousands)		2010	2009		2010		2009			
Foreign currency forward contracts Interest rate swaps	\$	9,293 7,440	\$ (5,112)	\$	6,430 10,481	\$	937			
Total	\$	16,733	\$ (5,112)) \$	16,911	\$	937			

		Amount of Gain						
	Location of Gain or			or (Lo	ss) Re	eclassified		
	(Loss) Reclassifed	from AOCE into Earnings					S	
	from AOCE	(Effective Portion)						
		Tł	Three Months Ended Nine Months En					
	into Earnings	into Earnings September 30,				Septen	mber 30,	
	(Effective Portion)	2	2010	2009		2010	2009	
(In thousands)								
	Net revenues	\$	(232)	\$	\$	647	\$	

Total		\$ (6,075)	\$ (14,047)	\$ (27,554)	\$ (34,417)
contracts Interest rate swaps	Interest expense	(5,843)	(14,047)	(28,201)	(34,417)
Foreign currency forward					

	Location of Loss Excluded from the		Amount of Loss Excluded from the Assessment of Hedge Effectiveness				
	Assessment of	Three Months Ended September 30,			Nine Months Ended September 30,		
(In thousands)	Hedge Effectiveness		2010	2009		2010	2009
Foreign currency forward contracts	Other (expense) income, net	\$	(4,971)	\$	\$	(3,721)	\$
Total		\$	(4,971)	\$	\$	(3,721)	\$
	1	6					

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 in Net Investment Hedging Relationships

Amount of Gain
or (Loss) Recognized
in AOCE (Net of Tax)
on Derivative
(Effective Portion)
anded Nine Months En
0, September 30

	(Effective Portion)									
	Three Mon Septem		Nine Months Ended September 30,							
(In thousands)	2010	2009	2	2010		2009				
Foreign currency borrowings	\$ (58,079)	\$ (28,906)	\$	30,979	\$	(31,356)				
Total	\$ (58,079)	\$ (28,906)	\$	30,979	\$	(31,356)				

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

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	Three Months Ended September 30,					Nine Months Ended September 30,		
(In thousands)	Derivatives		2010		2009		2010		2009
Foreign currency forward contracts Cash conversion feature of	Other (expense) income, net Other (expense)	\$	(4,590)	\$	(15,461)	\$	(27,741)	\$	(18,003)
Cash Convertible Notes Purchased cash convertible	income, net Other (expense)		(43,200)		90,725		19,500		113,150
note hedge	income, net		43,200		(90,725)		(19,500)		(113,150)
Total		\$	(4,590)	\$	(15,461)	\$	(27,741)	\$	(18,003)

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.

17

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:

	Ι	evel 1	September Level 2 (In thous		Level 3		
Financial Assets: Trading securities:							
Equity securities exchange traded funds	\$	3,037	\$		\$	\$	3,037
Total trading securities	\$	3,037	\$		\$	\$	3,037
Available-for-sale fixed income investments: U.S. Treasuries Corporate bonds Agency mortgage-backed securities Other	\$		\$	12,704 8,722 2,087 2,976	\$	\$	12,704 8,722 2,087 2,976
Total available-for-sale fixed income investments	\$		\$	26,489	\$	\$	26,489
Available-for-sale equity securities: Biosciences industry	\$	582	\$		\$	\$	582
Total available-for-sale equity securities	\$	582	\$		\$	\$	582
Foreign exchange derivative assets Purchased cash convertible note hedge	\$			10,180 391,100	\$	\$	10,180 391,100
Total assets at fair value ⁽¹⁾	\$	3,619	\$	427,769	\$	\$	431,388
Financial Liabilities: Foreign exchange derivative liabilities Interest rate swap derivative liabilities Cash conversion feature of cash convertible notes	\$		\$	3,532 39,597 391,100	\$	\$	3,532 39,597 391,100
Total liabilities at fair value ⁽¹⁾	\$		\$	434,229	\$	\$	434,229

MYLAN INC. AND SUBSIDIARIES

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

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

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 nine months ended September 30, 2010, that would reduce the receivable amount owed, if any, to the Company.

⁽¹⁾ 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.

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 nine months ended September 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 nine months ended September 30, 2010, that would reduce the receivable amount owed, if any, to the Company.

19

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 Senior Notes) and \$700.0 million aggregate principal amount of 7.875% Senior Notes due 2020 (the 2020 Senior 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. During the quarter ended September 30, 2010, the Company privately placed \$300.0 million aggregate principal amount of senior notes through a reopening of the 2020 Senior Notes. The notes were issued at a price of 105.5%, giving an effective yield to maturity of 7.087%. The 2017 Senior Notes and 2020 Senior 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 Senior Notes bear interest at a rate of 7.625% per year, accruing from May 19, 2010. Interest on the 2017 Senior Notes is payable semiannually in arrears on January 15 and July 15 of each year, beginning on January 15, 2011. The 2017 Senior Notes will mature on July 15, 2017, subject to earlier repurchase or redemption in accordance with the terms of the indenture. The 2020 Senior Notes bear interest at a rate of 7.875% per year, accruing from May 19, 2010. Interest on the 2020 Senior Notes is payable semiannually in arrears on January 15 and July 15 of each year, beginning on January 15, 2011. The 2020 Senior 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 Senior Notes at any time prior to July 15, 2014, and some or all of the 2020 Senior 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 Senior Notes, and on or after July 15, 2015 in the case of the 2020 Senior Notes, the Company may redeem some or all of the 2017 Senior Notes and 2020 Senior 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 Senior Notes and 2020 Senior 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 Senior Notes and 2020 Senior Notes at 101% of their principal amount, plus accrued and unpaid interest, if any, to the repurchase date.

The Company used approximately \$1.00 billion of the net proceeds of the initial 2017 Senior Notes and 2020 Senior Notes offering to repay a portion of the U.S. Tranche B Term Loans due under the terms of its Senior Credit Agreement. Also, during the quarter ended September 30, 2010, the Company repaid approximately \$300.0 million of debt under the Senior Credit Agreement, by repaying the remaining balance of the U.S. Tranche A Term Loans and a portion of the U.S. Tranche B Term Loans.

20

MYLAN INC. AND SUBSIDIARIES

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

A summary of long-term debt is as follows:

	Sep	tember 30, 2010 (In the	December 31, 2009 ousands)		
U.S. Tranche A Term Loans(A)	\$		\$	156,250	
Euro Tranche A Term Loans(A)		239,281		252,299	
U.S. Tranche B Term Loans(A)		1,310,010		2,453,760	
Euro Tranche B Term Loans(A)		688,313		725,760	
Senior Convertible Notes(B)		558,550		538,693	
Cash Convertible Notes(C)		841,906		847,136	
2017 Senior Notes		550,000			
2020 Senior Notes(D)		1,016,283			
Other		12,670		17,437	
		5,217,013		4,991,335	
Less: Current portion		4,784		6,348	
Total long-term debt	\$	5,212,229	\$	4,984,987	

- (A) All 2010 and 2011 mandatory principal payments due under the Senior Credit Agreement were prepaid during 2009. During the nine months ended September 30, 2010, the Company also prepaid \$156.3 million of the outstanding U.S. Tranche A Term Loans and \$1.14 billion of the outstanding U.S. Tranche B Term Loans, using a portion of the net proceeds of the 2017 Senior Notes, the 2020 Senior Notes and cash on hand.
- (B) At September 30, 2010, the \$558.6 million of debt is net of a \$41.4 million discount. At December 31, 2009, the \$538.7 million debt is net of a \$61.3 million discount. Currently, the effective conversion rate for the Senior Convertible Notes is 42.156 shares of common stock per \$1,000 principal amount of notes, representing a stock price of \$23.72 per share, reflecting the Company s suspension of its cash dividend.
- (C) At September 30, 2010, the \$841.9 million consists of \$450.8 million of debt (\$575.0 million face amount, net of \$124.2 million discount) and the bifurcated conversion feature with a fair value of \$391.1 million recorded as a liability within long-term debt in the Condensed Consolidated Balance Sheet at September 30, 2010. Additionally, the Company has purchased call options, which are recorded as assets at their fair value of \$391.1 million within other assets in the Condensed Consolidated Balance Sheet at September 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 September 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 September 30, 2010 period, was more than 130% of the applicable conversion reference price of \$13.32 at September 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.

(D) At September 30, 2010, the \$1.02 billion of debt includes a \$16.3 million premium.

21

MYLAN INC. AND SUBSIDIARIES

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

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

		Oı	utstanding	September 30, 2010 Basis (In thousands)	Rate
Euro Tranche A Term Loa U.S. Tranche B Term Loa		\$	239,281	EURIBO + 2.75%	3.37%
	December 201(0)(2)	\$	500,000	Fixed	6.03%
	March 201 ⁽²⁾		500,000	Fixed	5.38%
Floating Rate			310,010	LIBOR + 3.25%	3.56%
Total U.S. Tranche B Tern Euro Tranche B Term Loa		\$	1,310,010		
Swapped to Fixed Rate	March 201(1)	\$	273,140	Fixed	5.38%
Floating Rate			415,173	EURIBO + 3.25%	3.87%
Total Euro Tranche B Ter	rm Loans	\$	688,313		
		Oı	utstanding	December 31, 2009 Basis (In thousands)	Rate
U.S. Tranche A Term Loa	ıns	O:	utstanding 156,250	Basis	Rate 3.00%
Euro Tranche A Term Loa	ans			Basis (In thousands)	
Euro Tranche A Term Loa U.S. Tranche B Term Loa	ans ans	\$	156,250 252,299	Basis (In thousands) LIBOR + 2.75% EURIBO + 2.75%	3.00%
Euro Tranche A Term Loa U.S. Tranche B Term Loa Swapped to Fixed Rate	ans	\$ \$	156,250	Basis (In thousands) LIBOR + 2.75%	3.00% 3.19%
Euro Tranche A Term Loa U.S. Tranche B Term Loa Swapped to Fixed Rate Swapped to Fixed Rate	ans ans December 2010 ⁽²⁾	\$ \$	156,250 252,299 500,000	Basis (In thousands) LIBOR + 2.75% EURIBO + 2.75% Fixed	3.00% 3.19% 6.03%
Euro Tranche A Term Loa U.S. Tranche B Term Loa Swapped to Fixed Rate Swapped to Fixed Rate	ans ins December 2010 ⁽²⁾ March 2010 ⁽¹⁾	\$ \$	156,250 252,299 500,000 500,000	Basis (In thousands) LIBOR + 2.75% EURIBO + 2.75% Fixed Fixed	3.00% 3.19% 6.03% 5.44%
Euro Tranche A Term Loa U.S. Tranche B Term Loa Swapped to Fixed Rate Swapped to Fixed Rate Swapped to Fixed Rate	ans ons December 2010)(2) March 2010) December 2010) m Loans	\$ \$	156,250 252,299 500,000 500,000 1,000,000	Basis (In thousands) LIBOR + 2.75% EURIBO + 2.75% Fixed Fixed Fixed Fixed	3.00% 3.19% 6.03% 5.44% 7.37%
Euro Tranche A Term Loa U.S. Tranche B Term Loa Swapped to Fixed Rate Swapped to Fixed Rate Swapped to Fixed Rate Floating Rate Total U.S. Tranche B Term	ans ons December 2010 ⁽²⁾ March 2010 ⁽¹⁾ December 2010 ⁽¹⁾ m Loans ons	\$ \$ \$	156,250 252,299 500,000 500,000 1,000,000 453,760	Basis (In thousands) LIBOR + 2.75% EURIBO + 2.75% Fixed Fixed Fixed Fixed	3.00% 3.19% 6.03% 5.44% 7.37%
Euro Tranche A Term Loa U.S. Tranche B Term Loa Swapped to Fixed Rate Swapped to Fixed Rate Swapped to Fixed Rate Floating Rate Total U.S. Tranche B Tern Euro Tranche B Term Loa	ans ons December 2010 ⁽²⁾ March 2010 ⁽¹⁾ December 2010 ⁽¹⁾ m Loans ons	\$ \$ \$	156,250 252,299 500,000 500,000 1,000,000 453,760 2,453,760	Basis (In thousands) LIBOR + 2.75% EURIBO + 2.75% Fixed Fixed Fixed Fixed LIBOR + 3.25%	3.00% 3.19% 6.03% 5.44% 7.37% 3.50%

⁽¹⁾ This interest rate swap is designated as a cash flow hedge of expected future borrowings under the Senior Credit Agreement.

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

At September 30, 2010 and December 31, 2009, the fair value of the Senior Convertible Notes was approximately \$624.6 million and \$612.8 million. At September 30, 2010 and December 31, 2009, the fair value of the Cash Convertible Notes was approximately \$908.6 million and \$879.8 million.

22

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 convertible notes at September 30, 2010, excluding the discounts, premium and conversion features, are as follows for each of the periods ending December 31:

	Euro Tranche	U.S.	Euro Tranche	Senior	Cash	2017	2020	
	A Term	Tranche B Term	B Term	Convertible	Convertible	Senior	Senior	
	Loans	Loans	Loans Notes		Notes ousands)	Notes	Notes	Total
2010	\$	\$	\$	\$	\$	\$	\$	\$
2011 2012 2013	119,640 119,641	1 210 010	7,170 7,170	600,000				726,810 126,811
2014 2015 Thereafter		1,310,010	673,973		575,000	550,000	1,000,000	1,983,983 575,000 1,550,000
Total	\$ 239,281	\$ 1,310,010	\$ 688,313	\$ 600,000	\$ 575,000	\$ 550,000	\$ 1,000,000	\$ 4,962,604

11. Comprehensive Earnings

Comprehensive earnings consist of the following:

	Three Months Ended September 30,						
	201	2009)09				
		(In tho	usands)				
Net earnings (loss)	9	5 143,539		\$	(4,421)		
Other comprehensive earnings, net of tax, as applicable:							
Foreign currency translation adjustments		424,463			230,791		
Change in unrecognized gains (losses) and prior service cost							
related to post-retirement plans		8			(974)		
Net unrecognized gain (loss) on derivatives		16,965			(5,112)		
Unrealized gains on available-for-sale securities							
Net unrealized gains on available-for-sale securities	\$ 176		\$ 685				
Less: Reclassification for gains included in net earnings	14	190	12		697		
Total other comprehensive earnings, net of tax, as applicable:		441,626			225,402		
Comprehensive earnings		585,165			220,981		

Comprehensive earnings attributable to the noncontrolling interest

(356)

(827)

Comprehensive earnings attributable to Mylan Inc.

\$ 584,809

\$ 220,154

23

MYLAN INC. AND SUBSIDIARIES

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

	Nine Months Ended September 30,				
	201	2	2009		
		(In the	ousands)		
Net earnings	\$	324,743		\$ 200,325	
Other comprehensive earnings, net of tax, as applicable:					
Foreign currency translation adjustments		90,206		334,084	
Change in unrecognized gains (losses) and prior service cost					
related to post-retirement plans		4,452		(754)	
Net unrecognized gain on derivatives		17,143		937	
Unrealized gains on available-for-sale securities					
Net unrealized gains on available-for-sale securities	\$ 489		\$ 1,062		
Less: Reclassification for gains included in net earnings	171	660	173	1,235	
Total other comprehensive earnings, net of tax, as applicable:		112,461		335,502	
Comprehensive less (corrings) attributable to the		437,204		535,827	
Comprehensive loss (earnings) attributable to the noncontrolling interest		525		(6,693)	
Comprehensive earnings attributable to Mylan Inc.	\$	437,729		\$ 529,134	

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

1,535 1,039 (22,138) 143,832	\$	(3,413) (39,281) 53,626
124,268	\$	11,807
	(22,138) 143,832	(22,138) 143,832

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 nine months ended September 30, 2010 and 2009 is as follows:

	Sha	Mylan Inc. areholders Equity	I	controlling interest usands)	Total
December 31, 2009 Net earnings (loss) Other comprehensive earnings Dividends paid on preferred stock Stock option activity Stock compensation expense Purchase of subsidiary shares from noncontrolling	\$	3,131,146 325,268 112,461 (104,276) 37,215 24,156	\$	14,052 (525)	\$ 3,145,198 324,743 112,461 (104,276) 37,215 24,156
interest Tax benefit of stock option plans Other		(4,376) 4,863 3,671		(623) (92)	(4,999) 4,863 3,579
September 30, 2010	\$	3,530,128	\$	12,812	\$ 3,542,940
December 31, 2008 Net earnings Other comprehensive income Dividends paid on preferred stock Stock option activity Stock compensation expense Impact on additional paid-in capital of equity transaction Purchase of subsidiary shares from noncontrolling interest	\$	2,757,733 193,667 335,467 (104,276) 8,803 23,591 (154,033)	\$	29,108 6,658 35	\$ 2,786,841 200,325 335,502 (104,276) 8,803 23,591 (154,033)
Other		(2,117)		(21,020) $(1,118)$	(21,020) $(3,235)$
September 30, 2009	\$	3,058,835	\$	13,057	\$ 3,071,892

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, injectable 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

25

MYLAN INC. AND SUBSIDIARIES

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

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, 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.

Presented in the table below is segment information for the periods identified and a reconciliation of segment information to total consolidated information.

		Generics Segment	Specialty Corporate / Segment Other ⁽¹⁾ (In thousands)		Consolidated			
Three Months Ended September 30, 2010 Total revenues Third party Intersegment	\$	1,213,216 2,392	\$	141,897 13,689	\$	(16,081)	\$	1,355,113
Total Segment profitability	\$ \$	1,215,608 357,393	\$ \$	155,586 49,761	\$ \$	(16,081) (172,836)	\$ \$	1,355,113 234,318
	Generics Segment		Specialty Segment		Corporate / Other ⁽¹⁾		Consolidated	
Nine Months Ended September 30, 2010 Total revenues Third party Intersegment	\$	3,663,733 34,314	\$	352,290 47,419	\$	(81,733)	\$	4,016,023
Total Segment profitability	\$ \$	3,698,047 1,015,980	\$ \$	399,709 104,881	\$ \$	(81,733) (493,451)	\$ \$	4,016,023 627,410
	Generics Segment		Specialty Segment		_		Co	onsolidated

Three Months Ended September 30, 2009

Total revenues Third party Intersegment	\$ 1,113,199 2,608	\$ 150,875 3,776	\$ (6,384)	\$ 1,264,074
Total	\$ 1,115,807	\$ 154,651	\$ (6,384)	\$ 1,264,074
Segment profitability	\$ 295,190	\$ 39,799	\$ (273,711)	\$ 61,278

26

MYLAN INC. AND SUBSIDIARIES

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

	Generics Segment	Specialty Segment				• •		Co	onsolidated
Nine Months Ended September 30, 2009									
Total revenues									
Third party	\$ 3,387,921	\$	353,047	\$		\$	3,740,968		
Intersegment	20,836		15,196		(36,032)				
Total	\$ 3,408,757	\$	368,243	\$	(36,032)	\$	3,740,968		
Segment profitability	\$ 995,207	\$	71,494	\$	(603,369)	\$	463,332		

(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 September 30, 2010 and December 31, 2009 are restructuring reserves totaling \$16.6 million and \$39.3 million. Of these amounts, \$10.9 million and \$27.0 million, as of September 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 nine months ended September 30, 2010, payments of \$16.1 million were made against the reserve, of which \$6.7 million was for severance costs and the remaining \$9.4 million was for other exit costs. The majority of the remaining accrual relates to additional severance and related costs, 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 \$5.8 million remains at September 30, 2010. During the nine months ended September 30, 2010, the Company recorded restructuring charges of approximately \$4.9 million, nearly all of which relates to severance and related costs. Spending during the nine months, primarily related to severance, amounted to approximately \$11.4 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

27

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, with oral argument having been held on October 8, 2010. 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 \$15.0 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, Oklahoma, 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

28

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, and the Massachusetts state action, which settlements are 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 sallegations 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, and Pennsylvania, 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. 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 \$96 million recorded in other liabilities related to the price-related litigation involving Dey. As

29

MYLAN INC. AND SUBSIDIARIES

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

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 \$96 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 or transferred to the Eastern District of Pennsylvania, by a variety of plaintiffs purportedly representing direct and indirect purchasers of the drug modafinil and a third-party payor and one action brought by Apotex, Inc., a manufacturer of generic drugs, seeking approval to market a generic modafinil product. These actions allege violations of federal and state laws in connection with the defendants settlement of patent litigation relating to modafinil. 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. As of October 15, 2010, there are approximately 1,039 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. In September 2010, Actavis entered into a Settlement Agreement with the plaintiffs in a majority of the claims and lawsuits. Mylan and UDL will not contribute monetarily to the settlement, but will be dismissed with prejudice from any settled cases. Any lawsuits in which the plaintiffs choose to opt out of this settlement will continue to be litigated. 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

30

Table of Contents

MYLAN INC. AND SUBSIDIARIES

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

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 responded to these requests. On August 13, 2010, Matrix received an additional request for information. Matrix has responded to this request. Matrix is cooperating with the Commission in this investigation.

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. Additional requests were received on March 18, 2010 and July 29, 2010. Mylan S.A.S. has responded to these requests. 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.

On March 19, 2010, Mylan Inc. and Generics [U.K.] Ltd. received notice that the EU Commission had opened proceedings against Lundbeck with respect to alleged unilateral practices and/or agreements related to citalopram in the European Economic Area. On this same date, Mylan Inc. and Generics [U.K.] Ltd. received requests for information from the EU Commission in connection with any agreements between Lundbeck and Generics [U.K.] Ltd. concerning citalopram. Both companies are cooperating with the EU Commission. Generics [U.K.] Ltd. responded to the request for information on May 10, 2010 and September 30, 2010. No statement of objections has been filed in connection with this 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.

31

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. The interim results of operations for the three and nine months ended September 30, 2010 and the interim cash flows for the nine months ended September 30, 2010 are not necessarily indicative of the results to be expected for the full fiscal year or any other future period.

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 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 our 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, injectable 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 and Loan Repayment

In May 2010, we issued \$550.0 million of 7.625% Senior Notes due 2017 (the 2017 Senior Notes) and \$700.0 million of 7.875% Senior Notes due 2020 (the 2020 Senior 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

32

Table of Contents

Securities Act. During the quarter ended September 30, 2010, we privately placed \$300.0 million aggregate principal amount of senior notes through a reopening of our 2020 Senior Notes. The 2017 Senior Notes and 2020 Senior Notes are Mylan s senior unsecured obligations and are guaranteed on a senior unsecured basis by certain of our domestic subsidiaries.

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

We used approximately \$1.00 billion of the net proceeds of the initial 2017 Senior Notes and 2020 Senior Notes offering to repay a portion of the U.S. Tranche B Term Loans due under the terms of its Senior Credit Agreement. Also, during the quarter ended September 30, 2010, we repaid approximately \$300.0 million of debt under the Senior Credit Agreement, by repaying the remaining balance of the U.S. Tranche A Term Loans and a portion of the U.S. Tranche B Term Loans.

Acquisition of Bioniche Pharma Holdings Limited

On September 7, 2010, we acquired 100% of the outstanding equity in Bioniche Pharma, a privately held, global injectable pharmaceutical company, for a purchase price of \$543.7 million in cash. Mylan did not assume any of Bioniche Pharma s outstanding long-term debt or acquire any of its cash as part of the transaction. We financed this transaction using a combination of cash on hand and long-term borrowings.

Bioniche Pharma manufactures and sells a diverse portfolio of products across several therapeutic areas for the hospital setting, including analgesics/anesthetics, orthopedics, oncology, and urology, and most of its sales are made to customers in the U.S. The results for Bioniche Pharma from the date of the acquisition through September 30, 2010 are included in the Condensed Consolidated Results of Operations and disclosed as part of the North American region of our Generics Segment.

Financial Summary

For the three months ended September 30, 2010, Mylan reported total revenues of \$1.36 billion compared to \$1.26 billion for the three months ended September 30, 2009. This represents an increase in revenues of \$91.0 million, or 7.2%. Consolidated gross profit for the current quarter was \$580.1 million compared to \$505.0 million in the comparable prior year period, an increase of \$75.1 million, or 14.9%. For the current quarter, earnings from operations of \$234.3 million were realized compared to \$61.3 million for the three months ended September 30, 2009.

The net earnings attributable to Mylan Inc. before preferred dividends for the three months ended September 30, 2010 were \$143.2 million and earnings per diluted share were \$0.33. In the same prior year period, the net loss attributable to Mylan Inc. common shareholders was \$40.0 million, which translates into a loss per diluted share of \$0.13. 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 September 30, 2010 and 2009 are the following items of note:

Three months ended September 30, 2010:

Amortization, primarily related to purchased intangible assets associated with acquisitions, of \$74.6 million;

Interest of \$17.6 million, primarily related to the accretion of the discounts on our convertible debt instruments, net of amortization of the premium on our 2020 Senior Notes;

Net unfavorable litigation settlement charges of \$1.5 million;

33

Costs related to the acquisition of Bioniche Pharma of \$10.9 million;

A loss on the sale of certain non-operating assets of \$4.9 million;

Additional costs, primarily restructuring, totaling \$16.0 million; and

A tax effect of \$79.7 million related to the above items and other income tax-related items.

Three months ended September 2009:

Amortization, primarily related to purchased intangible assets associated with acquisitions, of \$71.8 million;

Interest of \$10.8 million relating to the accretion of the discounts on our convertible debt instruments;

Net unfavorable litigation settlement charges of \$114.3 million (pre-tax), primarily related to the settlement of an investigation by the U.S. Department of Justice, concerning calculations of Medicaid drug rebates;

Additional costs, primarily restructuring, related to the integration of acquired entities, and other costs, totaling \$15.8 million; and

A tax effect of \$65.3 million related to the above items and other income tax-related items.

Mylan s financial results for the nine months ended September 30, 2010 include total revenues of \$4.02 billion compared to \$3.74 billion for the nine months ended September 30, 2009, representing an increase of \$275.1 million, or 7.4%. Consolidated gross profit for the nine months ended September 30, 2010 was \$1.64 billion compared to \$1.56 billion in the same prior year period. For the nine months ended September 30, 2010, earnings from operations of \$627.4 million were realized compared to \$463.3 million for the same prior year period.

The net earnings attributable to Mylan Inc. common shareholders for the nine months ended September 30, 2010 were \$221.0 million, which translates into earnings per diluted share of \$0.71. In the same prior year period, net earnings attributable to Mylan Inc. common shareholders were \$89.4 million, which translates into earnings per diluted share of \$0.29. 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 nine months ended September 30, 2010 and 2009 are the following items of note:

Nine months ended September 30, 2010:

Amortization, primarily related to purchased intangible assets associated with acquisitions, of \$217.6 million;

Interest of \$42.0 million, primarily related to the accretion of discounts on our convertible debt instruments, net of amortization of the premium on our 2020 Senior Notes;

Net unfavorable litigation charges of \$14.3 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;

Costs related to the acquisition of Bioniche Pharma of \$12.5 million;

A loss on the sale of certain non-operating assets of \$4.9 million;

Additional costs, primarily restructuring, totaling \$44.9 million; and

A tax effect of \$165.9 million related to the above items and other income tax-related items.

Nine months ended September 30, 2009:

Amortization, primarily related to purchased intangible assets associated with acquisitions, of \$210.9 million;

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

34

Interest of \$31.7 million relating to the accretion of the discounts on our convertible debt instruments;

Net unfavorable litigation settlement charges of \$111.5 million (pre-tax), primarily related to the settlement of an investigation by the U.S. Department of Justice, concerning calculations of Medicaid drug rebates;

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 \$51.0 million; and

A tax effect of \$137.7 million related to the above items and other income tax-related items.

Results of Operations

Three Months Ended September 30, 2010, Compared to Three Months Ended September 30, 2009

Total Revenues and Gross Profit

For the current quarter, Mylan reported total revenues of \$1.36 billion compared to \$1.26 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 \$1.34 billion compared to \$1.26 billion for the same prior year period, representing an increase of \$89.3 million, or 7.1%. Other third party revenues for the current quarter were \$10.1 million compared to \$8.4 million in the same prior year period, an increase of \$1.7 million.

Total revenues were negatively impacted by the effect of foreign currency translation, primarily reflecting a stronger U.S. dollar in comparison to the functional currencies of Mylan s Euro-denominated subsidiaries, partially offset by the strengthening against the U.S. dollar of the currencies of Mylan s subsidiaries in Australia, Japan and India. Translating current year revenues at prior year exchange rates would have resulted in year-over-year growth in total revenues excluding foreign currency of approximately \$109 million, or approximately 9%.

Gross profit for the three months ended September 30, 2010 was \$580.1 million and gross margins were 42.8%. For the three months ended September 30, 2009, gross profit was \$505.0 million, and gross margins were 39.9%. Gross profit for the current quarter is impacted by certain purchase accounting related items recorded during the three months ended September 30, 2010, of approximately \$74.6 million, which consisted primarily of amortization related to purchased intangible assets associated with acquisitions. Excluding such items, gross margins would have been approximately 48.3%. Prior year gross profit is also impacted by similar purchase accounting related items in the amount of \$71.8 million. Excluding such items, gross margins in the prior year would have been approximately 45.6%.

The increase in gross margins, excluding the items noted above, can primarily be attributed to both Generics, mainly the North America region, and Specialty. In North America, favorable gross margins were primarily the result of new product introductions, while Specialty benefitted from favorable pricing, mainly on the EpiPen® Auto-injector.

Generics Segment

For the current quarter, Generics third party net revenues were \$1.20 billion compared to \$1.11 billion in the comparable prior year period, an increase of \$96.1 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 of approximately \$114 million, or 10%. Generics sales are derived 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 \$572.5 million for the current quarter, compared to \$487.9 million for the comparable prior year period, representing an increase of \$84.6 million, or 17.3%. The effect of foreign currency is insignificant within North America. New products launched in the U.S. and Canada

35

Table of Contents

contributed sales of \$106.5 million, which drove the growth in revenue year over year. Partially offsetting the impact of new products was unfavorable pricing on certain other existing products, including divalproex sodium extended-release (divalproex ER) tablets, the generic version of Abbott Laboratories Depart. 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.

Sales volumes for Fentanyl, our AB-rated generic alternative to Duragesic[®], have remained relatively constant primarily due to Mylan s ability to continue to be a stable and reliable source of supply to the market, and as a result fentanyl continues to contribute to both net revenues and gross profit. 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.

During the current quarter, Mylan launched minocycline hydrochloride extended release (minocycline ER) tablets, the generic version of Medicis Pharmaceuticals Corporation s Solody ER. After receiving final approval from the U.S. Food and Drug Administration on July 20, 2010, Mylan commenced immediate shipment of the product. Mylan also reached settlement and license agreements with Medicis Pharmaceuticals Corporation (Medicis) resolving patent litigation relating to minocycline ER, and the Company has ceased additional distribution. Pursuant to the terms of the agreements, Medicis will release Mylan from any liability related to the prior sales of the product, and Mylan will have the right to market minocycline ER in the U.S. beginning in November 2011, or earlier under certain circumstances.

As a result of significant uncertainties surrounding the pricing and market conditions with respect to this product, the Company is not able to reasonably estimate the amount of potential price adjustments, including product returns. Therefore, revenues on shipments of this product are currently being deferred until the resolution of such uncertainties. At the present time, such uncertainties are resolved upon our customers—sale of this product. As a result, the Company is recognizing revenue only upon our customers—sale of this product.

Third party net revenues from EMEA were \$363.5 million for the three-month period ended September 30, 2010, compared to \$413.8 million for the comparable prior year period, a decrease of \$50.3 million, or 12.2%. However, translating current quarter third party net revenues from EMEA at prior year exchange rates would have reduced the year-over-year decrease in third party net revenues excluding the effect of foreign currency to approximately \$14 million, or 3%. This decrease was mainly the result of unfavorable pricing in many of the European markets in which Mylan operates, partially offset by new product launches in several markets totaling approximately \$25.3 million.

Certain markets in which we do business have recently undergone government-imposed price reductions. 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.

In the current quarter, the most significant impact of government-imposed price reductions was felt by our subsidiaries in Portugal and Spain. Spain, however, realized year over year growth in net revenues mainly as a result of new product launches which more than offset the impact of the pricing reform.

New product launches were also the driving force behind year over year local currency growth by Mylan s largest European subsidiary in France. In addition to new products, France realized increased volumes on existing products. Partially offsetting these drivers were pricing pressures resulting from increased competition in the French market.

In Italy, excluding the effect of foreign currency, third party sales increased as a result of successful new product launches and increased market penetration, which resulted in increased volume. In addition, our Italian subsidiary benefitted from certain regulatory changes which resulted in an overall positive pricing effect. In June 2010, additional regulatory changes were introduced which decreased prices on certain products, and which may offset these positive pricing impacts in future periods.

36

Table of Contents

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, in particular, 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 \$267.9 million for the three-month period ended September 30, 2010, compared to \$206.1 million for the comparable prior year period, an increase of \$61.8 million, or 30.0%. Excluding the effect of foreign currency, calculated as described above, the increase was approximately \$44 million, or 22%. This increase is primarily driven by higher third party sales by our Matrix subsidiary in India, with growth in third party sales in Australia and Japan also contributing.

At our Matrix subsidiary, 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 \$46.6 million for the three months ended September 30, 2010, compared to \$21.3 million in the comparable prior year period. These intercompany sales eliminate within, and therefore are not included in, Generics or consolidated net revenues.

As in EMEA, both Japan and Australia have undergone government-imposed price reductions which have had, and could continue to have, a negative impact on sales and gross profit in these markets. In the current quarter, these price reductions offset the positive contribution from new products, mainly those launched in Japan.

Specialty Segment

For the current quarter, Specialty reported third party net revenues of \$141.1 million, a decrease of \$6.8 million, or 4.6%, from the comparable prior year period of \$147.9 million. Intercompany sales by Specialty totaled \$13.7 million in the current quarter compared to \$3.8 million in the same prior year period. The increase is due to the fact that 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 \$7.8 million or 5.9%.

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%. Specialty realized increased sales of the EpiPen Auto-injector, mainly as a result of favorable pricing.

Operating Expenses

Research and development (R&D) expense for the three months ended September 30, 2010 was \$72.0 million, compared to \$69.8 million in the same prior year period, an increase of \$2.2 million. The increase is due primarily to costs associated with higher volumes of internal and external product development.

Selling, general and administrative (SG&A) expense for the current quarter was \$272.3 million, compared to \$259.6 million for the same prior year period, an increase of \$12.7 million, which includes a favorable impact from foreign currency of approximately \$5 million. Excluding the impact of foreign currency, SG&A increased approximately \$18 million compared to the same prior year period. This increase is primarily the result of professional fees, including those incurred in connection with the Bioniche Pharma acquisition, as well as increased payroll and payroll related costs.

37

Table of Contents

Litigation Settlements, net

During the three months ended September 30, 2010, we recorded net unfavorable litigation charges of \$1.5 million, compared to \$114.3 million during the prior year quarter. The prior year amount is made up primarily of a charge for \$121.0 million, pre-tax (approximately \$83.0 million, after-tax), related to the settlement of an investigation by the U.S. Department of Justice concerning calculations of Medicaid drug rebates.

Interest Expense

Interest expense for the three months ended September 2010, totaled \$87.5 million, compared to \$77.0 million for the three months ended September 30, 2009. The increase is primarily due to interest associated with the 2017 and 2020 Senior Notes debt offerings in May 2010 and July 2010, partially offset by lower overall debt balances on the Company s Senior Credit Facility. Included in interest expense for the current quarter and the comparable prior year period are \$17.6 million and \$10.8 million, primarily related to the accretion of the discounts on our convertible debt instruments, net of accretion of the premium on our 2020 Senior Notes.

Other (Expense) Income, net

Other (expense) income, net, was expense of \$15.3 million in the current quarter compared to income of \$0.2 million in the comparable prior year period. Generally included in other (expense) income are interest and dividend income and foreign exchange gains and losses. Additionally, included in the current quarter is a \$4.9 million loss on the sale of certain non-operating assets and certain non-income-based taxes related to our acquisition of Bioniche Pharma.

Income Tax Expense

We recorded an income tax benefit of \$12.0 million in the current quarter compared to a benefit of \$11.1 million in the prior year quarter. In the current quarter, the Company realized a tax benefit on positive earnings as a result of the release of several tax reserves, due to favorable tax rulings received from certain taxing authorities, as well as the expiration of certain statutes of limitations during the three-month period.

Nine Months Ended September 30, 2010, Compared to Nine Months Ended September 30, 2009

Total Revenues and Gross Profit

For the current nine-month period, Mylan reported total revenues of \$4.02 billion compared to \$3.74 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 nine months were \$3.98 billion compared to \$3.68 billion for the same prior year period, representing an increase of \$299.8 million, or 8.1%.

Other revenues from third parties for the nine months ended September 30, 2010, were \$36.4 million compared to \$61.1 million in the same prior year period, a decrease of \$24.7 million, or 40.5%. During the nine months ended September 30, 2009, within Generics, we recognized \$28.5 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.

Total revenues were positively impacted by the effect of foreign currency translation, primarily reflecting a weaker U.S. dollar in comparison to the functional currencies of Mylan s subsidiaries in Australia, Japan and India, partially offset by the impact of a stronger U.S. dollar in comparison to the functional currencies of certain of our subsidiaries in Europe. Translating current year third party total revenues at prior year exchange rates would have resulted in

year-over-year growth excluding foreign currency of approximately \$229 million, or 6%.

Gross profit for the nine months ended September 30, 2010 was \$1.64 billion and gross margins were 40.8%. For the nine months ended September 30, 2009, gross profit was \$1.56 billion, and gross margins were 41.7%. Gross profit for the current year to date period is impacted by certain purchase accounting related items recorded during the nine months ended September 30, 2010, of approximately \$217.6 million, which consisted primarily of amortization related to purchased intangible assets associated with acquisitions. Excluding such items, gross

38

Table of Contents

margins would have been approximately 46.2%. Prior year gross profit is also impacted by similar purchase accounting related items in the amount of \$210.9 million. Excluding such items, gross margins in the prior year would have been approximately 47.3%.

The decrease in gross margins, excluding the items noted above, can generally be attributed to pricing pressure across the EMEA region of Generics and the impact of the timing of significant product launches in the North America region, partially offset by favorable pricing on Specialty s EpiPen Auto-injector. 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 until August 2009, or in periods of limited generic competition.

Generics Segment

For the nine months ended September 30, 2010, Generics reported third party net revenues of \$3.63 billion, compared to \$3.33 billion in the comparable prior year period, an increase of \$300.9 million, or 9.0%. Excluding the effect of foreign currency, calculated as described above, the increase was approximately \$255.0 million, or 7.7%.

Third party net revenues from North America were \$1.71 billion for the nine-month period, compared to \$1.56 billion for the comparable prior year period, representing an increase of \$150.9 million, or 9.7%. Excluding the effect of foreign currency, calculated as described above, the increase was approximately \$139 million, or 9%. This increase was driven by sales contributed from new products in the U.S. and Canada totaling approximately \$255.0 million, and, to a lesser extent, 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, mainly divalproex ER. Additional generic competition on divalproex ER entered the market upon expiration of Mylan s market exclusivity in August 2009. As such, sales of divalproex ER in the current year were significantly lower than in the prior year.

Third party net revenues from EMEA were \$1.15 billion for the nine-month period ended September 30, 2010, compared to \$1.16 billion for the comparable prior year period, a decrease of \$11.3 million, or 1.0%. Translating current year third party net revenues from EMEA at prior year exchange rates would have resulted in year-over-year increase in third party net revenues excluding the effect of foreign currency of approximately \$25 million, or 2%.

The most significant revenue growth was realized in Italy, as a result of higher volumes driven by increased market penetration, and certain regulatory changes which had a positive impact on pricing. In June 2010, new regulatory changes were introduced which decreased prices on certain products, and which may offset the positive pricing impacts in future periods. Italy s strong third party net revenues for the nine months ended September 30, 2010, were also bolstered by sales of new products.

New products were also primarily responsible for a year over year increase in third party net revenues realized in France. This increase was partially offset by unfavorable pricing as a result of increased competition in the French market.

Unfavorable pricing, as a result of government-imposed price reductions, had a significant impact in the current year in certain markets in which Mylan operates, most notably in Portugal and Spain. Spain, however, realized year over year growth in net revenues mainly as a result of new product launches which more than offset the impact of the pricing reform. In total for EMEA, new products contributed net revenues of approximately \$86.4 million during the nine months ended September 30, 2010.

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, and by the loss of sales related to tenders which Mylan did not win. Conversely, sales in the Netherlands were favorably impacted as a result of tenders won by Mylan.

In Asia Pacific, third party net revenues were \$769.1 million for the nine-month period ended September 30, 2010, compared to \$607.9 million for the comparable prior year period, an increase of \$161.2 million, or 26.5%. Excluding the effect of foreign currency, calculated as described above, the increase was approximately \$91 million, or 15%. This increase is primarily driven by higher third party sales from our operations in India and Japan.

39

Table of Contents

At our Matrix subsidiary, 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 \$110.6 million for the nine months ended September 30, 2010, compared to \$41.6 million in the comparable prior year period. These intercompany sales eliminate within, and therefore are not included in, Generics or consolidated net revenues.

In Japan, third party net revenues were favorably impacted by new product launches, as well as a full nine months of revenues from products launched mid-way through 2009. Partially offsetting this new product revenue were unfavorable price variances as a result of government-imposed price reductions.

Third party net revenues in Australia were flat as compared to the prior year to date period as a result of unfavorable pricing due to both government-imposed price reductions and increased competition. Partially offsetting the unfavorable pricing were favorable volume on existing products and revenue from the launch of new products.

Specialty Segment

For the nine months ended September 30, 2010, Specialty reported third party net revenues of \$347.8 million, a decrease of \$1.1 million, or 0.3% over the comparable prior year period of \$348.9 million. Intercompany sales of product by Specialty totaled \$47.4 million in the current nine-month period compared to \$15.2 million in the same prior year period. As in the quarter, the increase is due to the fact that 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 \$44.7 million or 14.8%.

The most significant contributor to Specialty 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%.

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

Operating Expenses

R&D expense for the nine months ended September 30, 2010 was \$200.1 million, compared to \$202.7 million in the same prior year period, a decrease of \$2.6 million, which includes an unfavorable impact from foreign currency of approximately \$3 million. Excluding the impact of foreign currency, R&D decreased approximately \$5 million compared to the same prior year period. Included in R&D for the nine months ended September 30, 2009, was an up-front payment of \$18 million related to our execution of a co-development agreement. Excluding this payment, R&D is higher in the current year mainly as a result of costs associated with higher volumes of internal and external product development.

SG&A expense for the nine months ended September 30, 2010 was \$796.4 million, compared to \$781.0 million for the same prior year period, an increase of \$15.5 million, which includes an unfavorable impact from foreign currency of approximately \$9 million. Excluding the impact of foreign currency, SG&A increased approximately \$7 million compared to the same prior year period. This increase is not considered to be significant.

Litigation Settlements, net

During the nine months ended September 30, 2010, we recorded net unfavorable litigation charges of \$14.3 million related to the potential settlement of certain ongoing matters. During the nine months ended September 30, 2009, we recorded net unfavorable litigation charges of \$111.5 million. The prior year amount

40

Table of Contents

consists primarily of a charge for \$121.0 million, pre-tax (approximately \$83.0 million, after-tax), related to the settlement of an investigation by the U.S. Department of Justice concerning calculations of Medicaid drug rebates.

Interest Expense

Interest expense for the nine months ended September 30, 2010, totaled \$240.0 million, compared to \$240.2 million for the nine months ended September 30, 2009. Incremental interest in the current year associated with the 2017 and 2020 Senior Notes offerings in May 2010 and July 2010, was offset by less interest on our Senior Credit Facility as a result of prepayments made in March 2009 and December 2009. Included in interest expense for the current nine months and the comparable prior year period are \$42.0 million and \$31.7 million, primarily related to the accretion of the discounts on our convertible debt instruments, net of accretion of the premium on our 2020 Senior Notes.

Other (Expense) Income, net

Other (expense) income, net was expense of \$29.4 million in the current nine-month period compared to income of \$29.7 million in the comparable prior year period. Generally included in other (expense) income are interest and dividend income and foreign exchange gains and losses. Additionally, included in the current year is a \$4.9 million loss on the sale of certain non-operating assets, charges associated with the termination of certain interest rate swaps totaling \$7.4 million, the write-off of previously deferred financing fees of \$7.6 million, in conjunction with the debt offering during the current period, and certain non-income-based taxes related to our acquisition of Bioniche Pharma. 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 \$33.2 million in the nine months ended September 30, 2010 compared to \$52.5 million in the comparable prior year period. The decrease in tax expense is driven by a decrease in the effective tax rate. The effective rate for the current year period was 9.3%, versus 20.8% in the comparable prior year period. The decrease in the effective rate was mainly due to the release of certain tax reserves due to favorable tax rulings from taxing authorities and expirations of statutes of limitations.

Liquidity and Capital Resources

Our primary source of liquidity is cash provided by operations, which was \$736.9 million for the nine months ended September 30, 2010. 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 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 nine months ended September 30, 2010, changes in operating assets and liabilities resulted in a net cash inflow of \$31.7 million, primarily due to the receipt of approximately \$98.8 million, representing a tax refund received in the first quarter, and cash collections on accounts receivable, partially offset by an increase in our inventory balances.

Cash used in investing activities for the nine months ended September 30, 2010 was \$620.7 million, consisting primarily of cash paid for acquisitions and capital expenditures. On September 7, 2010, we acquired Bioniche Pharma, a privately held, global injectable pharmaceutical company, for \$543.7 million. 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. In addition, cash of approximately \$10.0 million was paid as part of the purchase consideration for an FDF manufacturing facility in India. Capital expenditures were \$96.3 million, and were made primarily for equipment, including a portion related to our previously announced planned expansions and integration plans. Capital expenditures for the year 2010 are expected to be approximately \$200.0 to \$250.0 million.

41

Table of Contents

Cash provided by financing activities was \$128.3 million for the nine months ended September 30, 2010. During the nine months ended September 30, 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. Through a reopening of the 2020 Senior Notes during the quarter ended September 30, 2010, the Company privately placed \$300.0 million aggregate principal amount of senior notes, which were issued at a price of 105.5%, giving an effective yield to maturity of 7.087%. We used approximately \$1.30 billion of the net proceeds from the private placement to repay a portion of our outstanding term loans. Additionally, we paid cash dividends of \$104.3 million on our 6.5% mandatory convertible preferred stock.

As of September 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 September 30, 2010 period was more than 130% of the applicable conversion reference price of \$13.32 at September 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 September 30, 2010 includes restructuring reserves of \$16.6 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 during 2010 and 2011.

On October 19, 2010, the Company announced that the last quarterly dividend of \$16.25 per share had been declared, based on the annual dividend rate of 6.5% and a liquidation preference of \$1,000 per share, payable on November 15, 2010, to the holders of preferred stock of record as of November 1, 2010. All outstanding shares of preferred stock will also automatically convert to common stock on November 15, 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.

At September 30, 2010 and December 31, 2009, we had \$85.2 million and \$77.5 million, respectively, outstanding under existing letters of credit. Additionally, as of September 30, 2010, we had \$44.6 million available under the \$100.0 million subfacility on our Senior Credit Agreement for the issuance of letters of credit.

42

Table of Contents

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

	Euro Tranche A Term Loans	U.S. Tranche B Term Loans	Euro Tranche B Term Loans	Senior Convertible Notes	Cash Convertible Notes	2017 Senior Notes	2020 Senior	Total
							Notes	
				(In the	ousands)			
2010	\$	\$	\$	\$	\$	\$	\$	\$
2011								
2012	119,640		7,170	600,000				726,810
2013	119,641		7,170					126,811
2014		1,310,010	673,973					1,983,983
2015					575,000			575,000
Thereafter						550,000	1,000,000	1,550,000
Total	\$ 239,281	\$ 1,310,010	\$ 688,313	\$ 600,000	\$ 575,000	\$ 550,000	\$ 1,000,000	\$ 4,962,604

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 nine months ended September 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. Mylan is currently evaluating the impact of adoption on its consolidated financial statements.

In April 2010, the FASB issued revised accounting guidance for the milestone method of revenue recognition. The amended guidance is effective for fiscal years beginning on or after June 15, 2010. It provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research and development transactions. Mylan 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 September 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.

During the quarter ended September 30, 2010, the Company completed its acquisition of Bioniche Pharma. Bioniche Pharma will be excluded for the purposes of managements evaluation of the Company s internal control over financial reporting as of December 31, 2010.

Management has not identified any other 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.

43

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, with oral argument having been held on October 8, 2010. 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 \$15.0 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, Oklahoma, South Carolina, Texas, Utah and Wisconsin and also by the city

44

Table of Contents

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 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, and the Massachusetts state action, which settlements are 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 sallegations 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, and Pennsylvania, 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

45

Table of Contents

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. 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 \$96 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 \$96 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 or transferred to the Eastern District of Pennsylvania, by a variety of plaintiffs purportedly representing direct and indirect purchasers of the drug modafinil and a third-party payor and one action brought by Apotex, Inc., a manufacturer of generic drugs, seeking approval to market a generic modafinil product. These actions allege violations of federal and state laws in connection with the defendants settlement of patent litigation relating to modafinil. 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. As of October 15, 2010, there are approximately 1,039 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. In September 2010, Actavis entered into a Settlement Agreement with the plaintiffs in a majority of the claims and lawsuits. Mylan and UDL will not contribute monetarily to the settlement, but will be dismissed with prejudice from any settled cases. Any lawsuits in which the plaintiffs choose to opt out of this settlement will continue to be litigated. 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.

Table of Contents

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, 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 responded to these requests. On August 13, 2010, Matrix received an additional request for information. Matrix has responded to this request. Matrix is cooperating with the Commission in this investigation.

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. Additional requests were received on March 18, 2010 and July 29, 2010. Mylan S.A.S. has responded to these requests. 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.

On March 19, 2010, Mylan Inc. and Generics [U.K.] Ltd. received notice that the EU Commission had opened proceedings against Lundbeck with respect to alleged unilateral practices and/or agreements related to citalopram in the European Economic Area. On this same date, Mylan Inc. and Generics [U.K.] Ltd. received requests for information from the EU Commission in connection with any agreements between Lundbeck and Generics [U.K.] Ltd. concerning citalopram. Both companies are cooperating with the EU Commission. Generics [U.K.] Ltd. responded to the request for information on May 10, 2010 and September 30, 2010. No statement of objections has been filed in connection with this 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.

47

Table of Contents

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.

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. 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, as well as the recent 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;

48

Table of Contents

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;

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.

49

Table of Contents

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.

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

50

Table of Contents

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 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 EMA or national regulatory agencies may grant marketing authorizations to any number of generics. However, if there are other relevant patents when the core patent expires, for example, new formulations, the owner of the original brand pharmaceutical may be able to obtain preliminary injunctions in certain European jurisdictions preventing launch of the generic product, if the generic company did not commence proceedings in a timely manner to invalidate any relevant patents prior to launch of its generic.

In addition, in 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

51

Table of Contents

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 as new drug applications (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 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.

52

Table of Contents

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 or ineffective, and can be potentially life-threatening. Counterfeit medicines may contain harmful substances, the wrong dose of the active pharmaceutical ingredient (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.

53

Table of Contents

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

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

proprietary processes or delivery systems;

larger research and development and marketing staffs;

larger production capabilities in a particular therapeutic area;

more experience in preclinical testing and human clinical trials;

more products; or

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;

54

Table of Contents

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 an NDA is under regulatory review, some companies have proposed extending the patent term by a full year for each year spent in clinical trials rather than the one-half year that is currently permitted.

If proposals like these in the 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.

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;

55

Table of Contents

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.

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

56

Table of Contents

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 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

57

Table of Contents

respect to the manufacture, labeling, sale, distribution, marketing, advertising, promotion and development of pharmaceutical products. Failure to comply with regulations of the FDA and other regulators can result in fines, disgorgement, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the applicable regulator s review of our submissions, enforcement actions, injunctions and criminal prosecution. Under certain circumstances, the regulators may also have the authority to revoke previously granted drug approvals. Although we have internal regulatory compliance programs and policies and have had a favorable compliance history, there is no guarantee that these programs, as currently designed, will meet regulatory agency standards in the future. Additionally, despite our efforts at compliance, there is no guarantee that we may not be deemed to be deficient in some manner in the future. If we were deemed to be deficient in any significant way, our business, financial position and results of operations could be materially affected and the market value of our common stock could decline.

In Europe we must also comply with regulatory requirements with respect to the manufacture, labeling, sale, distribution, marketing, advertising, promotion and development of pharmaceutical products. Some of these requirements are contained in EU regulations and governed by the EMA. Other requirements are set down in national laws and regulations of the EU Member States. Failure to comply with the regulations can result in a range of fines, penalties, product recalls/suspensions or even criminal liability. Similar laws and regulations exist in most of the markets in which we operate.

In addition to the new drug approval process, government agencies also regulate the facilities and operational procedures that we use to manufacture our products. We must register our facilities with the FDA and other similar regulators. Products manufactured in our facilities must be made in a manner consistent with current good manufacturing practices or 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,

58

Table of Contents

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 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 PAYORS. 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 payors 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 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.

59

Table of Contents

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

Current or future federal, state or foreign laws and regulations may influence the prices of drugs and, therefore, could adversely affect the prices that we receive for our products. For example, programs in existence in certain states in the 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 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.

60

Table of Contents

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 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.

61

Table of Contents

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.

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.

The Education, Jobs and Medicaid Assistance Act was passed on August 5, 2010 and contained several provisions meant to limit the ability of corporations to claim foreign tax credits in reduction of their U.S. tax liability. We do not anticipate that the enactment of these provisions will materially impact our overall effective tax rate and income tax expense. Other proposals to change the U.S. income tax rules were proposed by the Obama administration in their fiscal year 2011 budget. 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;

62

Table of Contents

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.

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

63

Table of Contents

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.

THE TOTAL AMOUNT OF INDEBTEDNESS RELATED TO OUR OUTSTANDING CASH CONVERTIBLE NOTES DUE 2015 (THE 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 1.25% SENIOR CONVERTIBLE NOTES DUE 2012 (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

64

Table of Contents

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.

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

We may continue to seek to expand our product line through complementary or strategic acquisitions of other companies, products or assets, 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 savings, expected to result from any acquisitions, joint ventures or other transactions or investments we may undertake, or be unable to generate additional revenue to offset any unanticipated inability to realize these expected synergies or benefits. Realization of the anticipated benefits of acquisitions or other transactions could take longer than expected, and implementation difficulties, unforeseen 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.

Table of Contents

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

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

WE ARE IN THE PROCESS OF 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.

66

Table of Contents

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. 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.

67

Table of Contents

- 4.1(f) Amendment No. 5 to Rights Agreement dated as of December 19, 2005, between the registrant and American Stock Transfer & Trust Company, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on December 19, 2005, and incorporated herein by reference.
- 4.2(a) Indenture, dated as of July 21, 2005, between the registrant and The Bank of New York, as trustee, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on July 27, 2005, and incorporated herein by reference.
- 4.2(b) Second Supplemental Indenture, dated as of October 1, 2007, among the registrant, the Subsidiaries of the registrant listed on the signature page thereto and The Bank of New York, as trustee, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on October 5, 2007, and incorporated herein by reference.
- 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.
- 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 July 30, 2010, among the registrant, the guarantors named therein and Goldman, Sachs & Co.
- 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

68

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)

October 27, 2010

/s/ John D. Sheehan

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

October 27, 2010

/s/ Daniel C. Rizzo, Jr.

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

October 27, 2010

69

Table of Contents

EXHIBIT INDEX

10.1	Purchase Agreement, dated as of July 30, 2010, among the registrant, the guarantors named therein and Goldman, Sachs & Co.
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

70