MYLAN INC. Form 10-O October 26, 2011 **Table of Contents** 

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

# **Form 10-Q**

#### QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE þ ACT OF 1934

For the quarterly period ended September 30, 2011

OR

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

For the transition period from

**Commission File Number 1-9114** 

# **MYLAN INC.**

(Exact name of registrant as specified in its charter)

Pennsylvania

(State or other jurisdiction

25-1211621 (I.R.S. Employer

Identification No.)

of incorporation or organization) 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

Table of Contents

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 "

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

Accelerated filer

...

Non-accelerated filer" (Do not check if a smaller reporting company)Smaller reporting companyIndicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).Yes " 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

þ

**Common Stock** \$0.50 par value Outstanding at

**October 20, 2011** 426,512,086

#### MYLAN INC. AND SUBSIDIARIES

### INDEX TO FORM 10-Q

#### For the Quarterly Period Ended

September 30, 2011

		Page
	PART I FINANCIAL INFORMATION	
ITEM 1.	Condensed Consolidated Financial Statements (unaudited) Condensed Consolidated Statements of Operations Three and Nine Months Ended September 30, 2011 and 2010	3
	Condensed Consolidated Balance Sheets September 30, 2011 and December 31, 2010	4
	Condensed Consolidated Statements of Cash Flows Nine Months Ended September 30, 2011 and 2010	5
	Notes to Condensed Consolidated Financial Statements	6
ITEM 2.	Management s Discussion and Analysis of Financial Condition and Results of Operations	33
ITEM 3.	Quantitative and Qualitative Disclosures About Market Risk	44
ITEM 4.	Controls and Procedures	45
	PART II OTHER INFORMATION	
ITEM 1.	Legal Proceedings	46
ITEM 1A.	Risk Factors	46
ITEM 2.	Unregistered Sales of Equity Securities and Use of Proceeds	68
ITEM 5.	Other Information	68
ITEM 6.	Exhibits	68
SIGNATURE	<u>S</u>	70

#### MYLAN INC. AND SUBSIDIARIES

#### **Condensed Consolidated Statements of Operations**

	Period Ended September 30, Three Months Nine Months 2011 2010 2011 2010 (Unaudited; in thousands, except per share amounts)					2010		
D	(	Unaudite	d; in tho	usands,	excep	ot per share	amo	unts)
Revenues: Net revenues	\$ 1,57	2 2 4 1	\$ 1,344	1.000	¢ /	,579,215	¢	3,979,648
Other revenues	\$ 1,57	3,415		,999 ),114	φ٩	19,375	<b>ф</b> .	36,375
		,		,		,		,
Total revenues	1,57	5,756	1,355	5,113	4	,598,590	4	4,016,023
Cost of sales	91	7,365	775	5,056	2	,679,825	,	2,377,818
Gross profit	65	58,391	580	),057	1	,918,765		1,638,205
Operating expenses:								
Research and development	7	0,847	71	,992		218,651		200,076
Selling, general and administrative	31	9,389		2,285		913,604		796,420
Litigation settlements, net		2,247	1	,462		28,457		14,299
Total operating expenses	39	2,483	345	5,739	1	,160,712		1,010,795
		5 000						(07.410
Earnings from operations		5,908		4,318		758,053		627,410
Interest expense Other income (expense), net		35,772 2,073		7,536 5,269)		254,836 22,543		239,985 (29,437)
other meonie (expense), net	1	2,075	(1.	,209)		22,343		(29,437)
Earnings before income taxes and noncontrolling interest	19	2,209	131	,513		525,760		357,988
Income tax provision (benefit)	3	4,831	(12	2,026)		116,851		33,245
Net earnings	15	7,378	143	3,539		408,909		324,743
Net (earnings) loss attributable to the noncontrolling interest		(680)		(356)		(1,590)		525
Net earnings attributable to Mylan Inc. before preferred dividends Preferred dividends	15	6,698		3,183 1,759		407,319		325,268 104,276
Net earnings attributable to Mylan Inc. common shareholders	\$ 15	6,698	\$ 108	3,424	\$	407,319	\$	220,992
Earnings not common share attributable to Myden Inc. common share ballore								
Earnings per common share attributable to Mylan Inc. common shareholders: Basic	\$	0.37	\$	0.35	\$	0.94	\$	0.72
Diluted	\$	0.36	\$	0.33	\$	0.92	\$	0.71
Weighted average common shares outstanding:								
Basic	42	26,412	309	9,446		432,265		308,470
Diluted	43	1,587	437	7,921		441,817		313,014

See Notes to Condensed Consolidated Financial Statements

#### MYLAN INC. AND SUBSIDIARIES

### **Condensed Consolidated Balance Sheets**

	•	mber 30, 2011 (Unaudite except share an	d; in thou	
ASSETS		except shure un	a per sna	c uniounts)
Current assets:				
Cash and cash equivalents	\$	512,837	\$	662,052
Restricted cash		9,329		23,972
Marketable securities		30,249		29,085
Accounts receivable, net		1,280,011		1,157,081
Inventories		1,386,541		1,240,271
Deferred income tax benefit		191,858		258,731
Prepaid expenses and other current assets		198,213		188,251
Total current assets		3,609,038		3,559,443
Property, plant and equipment, net		1,238,762		1,209,342
Intangible assets, net		2,226,283		2,501,150
Goodwill		3,558,677		3,599,334
Deferred income tax benefit		75,306		58,284
Other assets		410,052		609,251
Total assets	\$ 1	1,118,118	\$	11,536,804
LIABILITIES AND EQUITY				
Liabilities				
Current liabilities:				
Trade accounts payable	\$	532,921	\$	564,706
Short-term borrowings		175,010		162,451
Income taxes payable		55,492		15,106
Current portion of long-term debt and other long-term obligations		685,331		7,319
Deferred income tax liability		1,368		2,457
Other current liabilities		924,812		1,057,573
Total current liabilities		2,374,934		1,809,612
Long-term debt		4,483,221		5,263,376
Other long-term obligations		337,207		370,321
Deferred income tax liability		428,619		478,094
Total liabilities		7,623,981		7,921,403
Equity				
Mylan Inc. shareholders equity Common stock par value \$0.50 per share				
Shares authorized: 1,500,000,000				
Shares issued: 530,126,658 and 525,817,549 as of September 30, 2011 and December 31,		265.062		262.000
2010 Additional maid in comital		265,063		262,909
Additional paid-in capital		3,783,115		3,849,682
Retained earnings Accumulated other comprehensive earnings		1,291,029 43,871		883,710 171,867
		5,383,078		5,168,168

12,580		13,522
1,901,521		1,566,289
3,494,137		3,615,401
\$ 11,118,118	\$	11,536,804
	1,901,521 3,494,137	1,901,521 3,494,137

See Notes to Condensed Consolidated Financial Statements

#### MYLAN INC. AND SUBSIDIARIES

#### **Condensed Consolidated Statements of Cash Flows**

	Septen 2011	nths Ended nber 30, 2010
Carle flame from anothing activities	(Unaudited;	in thousands)
Cash flows from operating activities:	¢ 408.000	¢ 204.742
Net earnings	\$ 408,909	\$ 324,743
Adjustments to reconcile net earnings to net cash provided by operating activities:	206 451	200.072
Depreciation and amortization	386,451	309,872
Stock-based compensation expense	32,803	24,156
Change in estimated sales allowances	(43,176)	6,096
Deferred income tax expense (benefit)	1,443	(78,450)
Other non-cash items	73,642	104,486
Litigation settlements, net	28,457	14,299
Changes in operating assets and liabilities:		
Accounts receivable	(82,286)	64,721
Inventories	(181,548)	(69,340)
Trade accounts payable	(51,902)	8,365
Income taxes	45,823	80,883
Deferred revenue	(999)	20,602
Other operating assets and liabilities, net	(191,279)	(73,485)
Net cash provided by operating activities	426,338	736,948
Cash flows from investing activities:		
Capital expenditures	(168,474)	(96,270)
Change in restricted cash	15,007	24,856
Cash paid for acquisitions, net		(556,112)
Proceeds from sale of property, plant and equipment	2,400	4,947
Purchase of marketable securities	(3,363)	(7,835)
Proceeds from sale of marketable securities	1,855	4,739
Other items, net	(477)	4,975
Net cash used in investing activities	(153,052)	(620,700)
Cash flows from financing activities:		
Cash dividends paid		(104,276)
Payment of financing fees	(237)	(23,704)
Cash paid for warrant amendment and exchange	(149,947)	
Purchase of common stock	(349,998)	
Change in short-term borrowings, net	22,722	(45,036)
Proceeds from issuance of long-term debt		1,569,300
Payment of long-term debt	(6,152)	(1,305,224)
Proceeds from exercise of stock options	65,035	37,215
Other items, net	6,284	
Net cash (used in) provided by financing activities	(412,293)	128,275
Effect on cash of changes in exchange rates	(10,208)	(14,118)
Net (decrease) increase in cash and cash equivalents	(149,215)	230,405

Cash and cash equivalents	beginning of period	662,052	380,516
Cash and cash equivalents	end of period	\$ 512,837	\$ 610,921

#### See Notes to Condensed Consolidated Financial Statements

#### 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, 2010. The December 31, 2010 Condensed Consolidated Balance Sheet was derived from audited financial statements.

The interim results of operations for the three and nine months ended September 30, 2011 and the interim cash flows for the nine months ended September 30, 2011 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 using an estimated effective tax rate for the full year with consideration of certain discrete tax items which occurred within the interim periods. The estimated annual effective tax rate for 2011 includes an estimate of the full-year effect of foreign tax credits that the Company anticipates it will claim against its 2011 U.S. tax liabilities.

#### 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, 2011. Such allowances were \$695.9 million and \$751.8 million at September 30, 2011 and December 31, 2010. Other current liabilities include \$166.8 million and \$167.0 million at September 30, 2011 and December 31, 2010, for certain sales allowances and other adjustments that are paid to indirect customers.

#### 3. Recent Accounting Pronouncements

In September 2011, the Financial Accounting Standards Board (FASB) issued revised disclosure guidance for employers that participate in multiemployer plans. The amended guidance requires that employers provide additional quantitative and qualitative disclosures for multiemployer plans. The amended guidance is effective for annual periods ending after December 15, 2011. The adoption of the amended guidance in future periods will not materially impact the Company s results of operations, financial position or cash flows.

In June 2011, the FASB issued revised accounting guidance for the presentation of comprehensive income. Under the amendments in this update, an entity has the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. The amended guidance eliminates the option to present the components of other comprehensive income as a part of the statement of changes in stockholders equity. The amended guidance is effective for fiscal years beginning after December 15, 2011, and it must be applied retrospectively. The adoption of the amended guidance in future periods will not materially impact the Company s results of operations, financial position or cash flows.

#### MYLAN INC. AND SUBSIDIARIES

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

#### 4. Acquisitions *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. In accordance with GAAP guidance regarding business combinations, the Company used the purchase method of accounting to account for this transaction. Under the purchase method of accounting, the assets acquired and liabilities assumed in the transaction were recorded at the date of acquisition at their respective fair values.

Bioniche Pharma manufactures and sells a diverse portfolio of injectable 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 purchase price of \$543.7 million has been allocated to the assets acquired and liabilities assumed for the Bioniche Pharma business as of the acquisition date as follows:

(In thousands)	
Current assets (excluding inventories)	\$ 41,680
Inventories	28,500
Property, plant and equipment, net	16,211
Identified intangible assets	186,000
In-process research and development ( IPR&D )	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
וויכו מאפרוא מרקעוורט	\$ 545,750

The amount allocated to acquired IPR&D 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 IPR&D 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 GAAP guidance. A discount rate of 11.0% was utilized to discount net cash inflows to present values.

Three research projects represent approximately 60% of the total fair value of IPR&D, and, combined, these projects had an expected cost to complete of less than \$10 million as of the acquisition date. All projects are in various stages of completion, but are expected to begin producing a benefit to the Company by 2013. There are risks and uncertainties associated with the timely and successful completion of the projects included in IPR&D, and no assurances can be given that the underlying assumptions used to prepare the discounted cash flow analysis will not change or the timely completion of each project to commercial success will occur. Refer to Note 8 *Goodwill and Intangible Assets* for information regarding the Company s annual impairment review of these IPR&D assets.

The identified intangible assets of \$186.0 million are comprised of product rights and licenses that have a weighted average useful life of approximately eight years. The goodwill of \$207.4 million arising from the

#### MYLAN INC. AND SUBSIDIARIES

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

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.

#### 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 presents supplemental unaudited pro forma information as if the acquisition of Bioniche Pharma had occurred on January 1, 2009. This summary of the unaudited pro forma results of operations is not necessarily indicative of what Mylan s results of operations would have been had Bioniche Pharma been acquired on January 1, 2009 and may not be indicative of future performance.

The unaudited pro forma financial information for the period below includes the following charges directly attributable to the accounting for the acquisition: amortization of intangibles of \$6.8 million and \$20.3 million for the three and nine months ended September 30, 2010. In addition, the unaudited pro forma financial information for the period presented includes the effects of certain additional borrowings used to purchase Bioniche Pharma as if they occurred on January 1, 2009.

(Unaudited; in thousands, except per share amounts)	ree Months Ended ptember 30, 2010	 ne Months Ended ptember 30, 2010
Total revenues	\$ 1,386,730	\$ 4,127,302
Net earnings attributable to Mylan Inc. before preferred dividends Preferred dividends	135,602 34,759	307,306 104,276
Net earnings attributable to Mylan Inc. common shareholders	\$ 100,843	\$ 203,030
Earnings per common share attributable to Mylan Inc. common shareholders		
Basic	\$ 0.33	\$ 0.66
Diluted	\$ 0.31	\$ 0.65
Weighted average common shares outstanding:		
Basic	309,446	308,470
Diluted	437,921	313,014

#### 5. Stock-Based Incentive Plan

Mylan s shareholders have approved the 2003 Long-Term Incentive Plan (as amended, the 2003 Plan ). Under the 2003 Plan, 37,500,000 shares of common stock are reserved for issuance to key employees, consultants, independent contractors and non-employee directors of Mylan through a variety of incentive awards, including: stock options, stock appreciation rights, restricted shares and units, performance awards, other stock-based awards and short-term cash awards. Stock option awards are granted at the fair value of the shares underlying the options at the date of the grant, generally become exercisable over periods ranging from three to four years, and generally expire in ten years. Pursuant to 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.

#### MYLAN INC. AND SUBSIDIARIES

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

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:

		eighted verage
	Number of Shares Under Option	 cise Price r Share
Outstanding at December 31, 2010	23,840,049	\$ 15.99
Options granted	4,548,178	22.63
Options exercised	(4,325,376)	15.12
Options forfeited	(472,966)	18.21
Outstanding at September 30, 2011	23,589,885	\$ 17.39
Vested and expected to vest at September 30, 2011	22,491,500	\$ 17.29
Options exercisable at September 30, 2011	15,594,369	\$ 16.03

As of September 30, 2011, options outstanding, options vested and expected to vest, and options exercisable had average remaining contractual terms of 6.10 years, 5.98 years and 4.71 years, respectively. Also at September 30, 2011, options outstanding, options vested and expected to vest and options exercisable had aggregate intrinsic values of \$35.5 million, \$34.3 million and \$29.2 million, respectively.

A summary of the status of the Company s nonvested restricted stock and restricted stock unit awards, including performance based restricted stock, as of September 30, 2011 and the changes during the nine months ended September 30, 2011 are presented below:

	Number of	Weight	ed Average		
	Restricted	Gra	nt-Date		
	Stock Awards	Fair Val	Fair Value per Share		
Nonvested at December 31, 2010	2,339,410	\$	15.36		
Granted	1,147,408		22.70		
Released	(1,120,910)		13.19		
Forfeited	(59,584)		16.64		
Nonvested at September 30, 2011	2,306,324	\$	20.03		

As of September 30, 2011, the Company had \$57.3 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 1.85 years. The total intrinsic value of stock-based awards exercised and restricted stock units converted during the nine months ended September 30, 2011 and September 30, 2010 was \$61.2 million and \$32.6 million.

#### MYLAN INC. AND SUBSIDIARIES

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

#### 6. Balance Sheet Components

Selected balance sheet components consist of the following:

	September 30, 2011	Dece ousands)	ember 31, 2010
Inventories:	(in m	ousunus)	
Raw materials	\$ 375,516	\$	337,087
Work in process	238,670		230,243
Finished goods	772,355		672,941
	\$ 1,386,541	\$	1,240,271
Property, plant and equipment:			
Land and improvements	\$ 73,616	\$	73,267
Buildings and improvements	671.337	Ψ	670,639
Machinery and equipment	1,345,627		1,264,750
Construction in progress	197,814		164,923
	2,288,394		2,173,579
Less accumulated depreciation	1,049,632		964,237
	\$ 1,238,762	\$	1,209,342
Other current liabilities:			
Legal and professional accruals, including litigation reserves	\$ 202,554	\$	246,064
Payroll and employee benefit plan accruals	188,937	Ψ	185,953
Accrued sales allowances	166,833		166,997
Accrued interest	45,492		88,430
Fair value of financial instruments	43,173		33,395
Other	277,823		336,734
	\$ 924,812	\$	1,057,573

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

Basic earnings per common share is computed by dividing net earnings attributable to Mylan Inc. common shareholders by the weighted average number of shares outstanding during the period. Diluted earnings per common share is computed by dividing net earnings attributable to Mylan Inc. common shareholders by the weighted average number of shares outstanding during the period increased by the number of additional shares that would have been outstanding related to potentially dilutive securities or instruments, if the impact is dilutive.

On November 15, 2010, pursuant to its terms, the Company s 6.50% mandatorily convertible preferred stock converted into 125,234,172 shares of Mylan s common stock, and Mylan is no longer obligated to pay dividends. With respect to the Company s convertible preferred stock, for the three and nine months ended September 30, 2010, the Company considered the effect on diluted earnings per share of the preferred stock conversion feature using the if-converted method. The preferred stock was convertible into between 125,234,172 shares and 152,785,775 shares of the Company s common stock. For the three months ended September 30, 2010, the if-converted method was dilutive; therefore, the preferred stock conversion was included in the computation of diluted earnings per share. For the nine months ended September 30, 2010, the if-converted

method was anti-dilutive; therefore, the preferred stock conversion was excluded from the computation of diluted earnings per share.

#### MYLAN INC. AND SUBSIDIARIES

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

On September 15, 2008, concurrent with the sale of \$575.0 million aggregate principal amount of Cash Convertible Notes due 2015 (the Cash Convertible Notes ), Mylan entered into a convertible note hedge and warrant transaction with certain counterparties. Pursuant to the warrant transactions, the Company sold to the counterparties warrants to purchase in the aggregate up to approximately 43.2 million shares of Mylan common stock, subject to anti-dilution adjustments substantially similar to the anti-dilution adjustments for the Cash Convertible Notes, which under most circumstances represents the maximum number of shares that underlie the conversion reference rate for the Cash Convertible Notes. The sold warrants had an exercise price of \$20.00 and will be net share settled, meaning that Mylan will issue a number of shares per warrant corresponding to the difference between its share price at each warrant expiration date and the exercise price. The warrants meet the definition of derivatives under the guidance in FASB Accounting Standards Codification (ASC) 815 *Derivatives and Hedging* (ASC 815); however, because these instruments have been determined to be indexed to the Company s own stock and meet the criteria for equity classification under ASC 815-40 *Contracts in Entity s Own Equity*, the warrants have been recorded in shareholders equity in the Condensed Consolidated Balance Sheets.

In the third quarter of 2011, the Company entered into amendments with the counterparties to exchange the original warrants with an exercise price of \$20.00 (the Old Warrants ) with new warrants with an exercise price of \$30.00 (the New Warrants ). Approximately 41.0 million of the Old Warrants were exchanged in the transaction. All other terms and settlement provisions of the Old Warrants remain unchanged in the New Warrants. As part of the amendments, the Company paid the holders of the Old Warrants approximately \$3.66 per warrant or approximately \$150 million in total. Under the provisions of ASC 815-40, the Company recorded the payment as a reduction of shareholders equity in the Condensed Consolidated Balance Sheets as the Old Warrants were classified in permanent equity. The New Warrants meet the definition of derivatives under the guidance in ASC 815; however, because these instruments have been determined to be indexed to the Company s own stock and meet the criteria for equity classification under ASC 815-40, the New Warrants have also been recorded in shareholders equity in the Condensed Consolidated Balance Sheets.

For the three and nine months ended September 30, 2011, the average market value of the Company s shares exceeded the exercise price of the Old Warrants, and as a result, the Company has included 1.2 million and 4.3 million shares, respectively, in the calculation of the diluted earnings per share, which includes the weighted average impact of the amendments entered into during the third quarter of 2011. The average market value of the Company s shares did not exceed the exercise price of the Old Warrants during the three and nine months ended September 30, 2010. The average market value of the Company s shares did not exceed the exercise price of the exercise price of the New Warrants during the three and nine months ended September 30, 2011.

On May 3, 2011, the Company announced that its Board of Directors had approved the repurchase of up to \$350 million of the Company s common stock and other equity securities, either in the open market or through privately-negotiated transactions. During the second quarter of 2011, the repurchase program was completed with approximately 14.8 million shares of common stock being repurchased for approximately \$350 million.

#### MYLAN INC. AND SUBSIDIARIES

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

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

	Three Months Ended September 30,			nths Ended nber 30,	
	2011	2010	2011	2010	
	(In th	iousands, excep	t per share amo	ounts)	
Basic earnings attributable to Mylan Inc. common shareholders (numerator):					
Net earnings attributable to Mylan Inc. before preferred dividends	\$ 156,698	\$ 143,183	\$407,319	\$ 325,268	
Less: Preferred dividends		34,759		104,276	
Net earnings attributable to Mylan Inc. common shareholders	\$ 156,698	\$ 108,424	\$ 407,319	\$ 220,992	
Shares (denominator):					
Weighted average common shares outstanding	426,412	309,446	432,265	308,470	
Basic earnings per common share attributable to Mylan Inc. common shareholders	\$ 0.37	\$ 0.35	\$ 0.94	\$ 0.72	

	Three Months Ended September 30,			ths Ended iber 30,
	2011 (Jp. th	2010	2011	<b>2010</b>
Diluted earnings attributable to Mylan Inc. common shareholders (numerator):	(III U	iousanus, excep	ot per share amo	Junts)
Net earnings attributable to Mylan Inc. common shareholders	\$ 156,698	\$ 108,424	\$ 407,319	\$ 220,992
Add: Preferred dividends	+,	34,759	+,	+ == 0,5 5 =
Earnings attributable to Mylan Inc. common shareholders and assumed conversions	\$ 156,698	\$ 143,183	\$ 407,319	\$ 220,992
Shares (denominator):				
Weighted average common shares outstanding	426,412	309,446	432,265	308,470
Stock-based awards and warrants	5,175	3,241	9,552	4,544
Preferred stock conversion		125,234		
Total dilutive shares outstanding	431,587	437,921	441,817	313,014
Diluted earnings per common share attributable to Mylan Inc. common shareholders	\$ 0.36	\$ 0.33	\$ 0.92	\$ 0.71

Additional stock options or restricted stock awards were outstanding during the periods ended September 30, 2011 and 2010 but were not included in the computation of diluted earnings per share for each respective period, because the effect would be anti-dilutive. Such anti-dilutive stock options or restricted stock awards represented 7.5 million and 4.9 million shares for the three and nine months ended September 30, 2011, and they represented 8.6 million and 6.8 million shares for the three and nine months ended September 30, 2010.

#### MYLAN INC. AND SUBSIDIARIES

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

#### 8. Goodwill and Intangible Assets

The changes in the carrying amount of goodwill for the nine months ended September 30, 2011 are as follows:

	Generics Segment	-	ialty Segment thousands)	Total
Balance at December 31, 2010				
Goodwill	\$ 3,277,827	\$	706,507	\$ 3,984,334
Accumulated impairment losses			(385,000)	(385,000)
	3,277,827		321,507	3,599,334
Foreign currency translation	(40,657)			(40,657)
	3,237,170		321,507	3,558,677
Balance at September 30, 2011				
Goodwill	3,237,170		706,507	3,943,677
Accumulated impairment losses			(385,000)	(385,000)
	\$ 3,237,170	\$	321,507	\$ 3,558,677

Intangible assets consist of the following components:

	Weighted Average Life (Years)	Original Cost	Accumulated Amortization (In thousands)	Net Book Value
September 30, 2011				
Amortized intangible assets:				
Patents and technologies	20	\$ 116,631	\$ 81,447	\$ 35,184
Product rights and licenses	10	3,343,110	1,347,329	1,995,781
Other <sup>(1)</sup>	8	112,619	45,551	67,068
IPR&D		3,572,360 128,250 \$ 3,700,610	1,474,327 \$ 1,474,327	2,098,033 128,250 \$ 2,226,283
December 31, 2010				
Amortized intangible assets:				
Patents and technologies	20	\$ 122,926	\$ 83,563	\$ 39,363
Product rights and licenses	10	3,323,902	1,099,103	2,224,799
Other <sup>(1)</sup>	8	143,716	55,171	88,545
		3,590,544	1,237,837	2,352,707
IPR&D		148,443	, ,	148,443

#### \$ 3,738,987 \$ 1,237,837 \$ 2,501,150

<sup>(1)</sup> Other intangibles consist principally of customer lists and contracts.

Amortization expense, which is classified primarily within cost of sales on Mylan s Condensed Consolidated Statements of Operations, for the nine months ended September 30, 2011 and 2010 was \$273.0 million and \$209.9 million, respectively, and is expected to be approximately \$80.9 million for the remainder of 2011 and \$322.1 million, \$316.4 million, \$308.8 million and \$286.5 million for the years ended December 31, 2012 through 2015, respectively.

#### MYLAN INC. AND SUBSIDIARIES

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

Indefinite-lived intangibles, such as the Company s IPR&D assets, are tested at least annually for impairment, but may be tested whenever certain impairment indicators are present. Impairment is determined to exist when the fair value is less than the carrying value of the assets being tested.

During the quarter ended September 30, 2011, the Company performed its annual impairment review of its IPR&D assets and recorded an impairment charge in the amount of \$16.2 million, which has been recorded as a component of amortization expense. These IPR&D assets were acquired as part of the Bioniche Pharma acquisition. This impairment charge resulted from the Company s updated estimate of the fair value of these assets, which was based upon updated forecasts, compared with the assigned fair values as of the Bioniche Pharma acquisition date, September 7, 2010. The fair value was determined based upon detailed valuations employing the income approach which utilized Level 3 inputs, as defined in Note 9. These valuations reflect, among other things, the impact of changes to the development programs, the projected development and regulatory timeframes and the current competitive environment. Changes in any of the Company s assumptions may result in a further reduction to the estimated fair value of the IPR&D asset and could result in additional future impairment charges.

During the nine months ended September 30, 2011, approximately \$4.3 million was reclassified from acquired IPR&D to product rights and licenses.

### 9. Financial Instruments and Risk Management

#### Financial Risks

Mylan 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.

The Company has entered into forward contracts to hedge forecasted 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 ( AOCE ), depending on the nature and effectiveness of the offset.

As of September 30, 2011 and December 31, 2010, 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 amounts was \$914.2 million and \$909.3 million at September 30, 2011 and December 31, 2010. 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 fixed and floating-rate debt. The Company s interest rate swaps designated as cash flow hedges fix the interest rate on the Company s variable-rate U.S. Tranche B Term Loans under the terms of its Senior Credit

#### MYLAN INC. AND SUBSIDIARIES

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

Agreement. These derivative instruments 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.

During 2011, the Company entered into interest rate swaps which convert \$500.0 million of the Company s fixed-rate 6.0% Senior Notes due 2018 (the 2018 Senior Notes ) to a variable rate. These interest rate swaps, which are designated as fair value hedges, are measured at fair value and reported as current assets or current liabilities on the Condensed Consolidated Balance Sheets. The change in the fair value of these derivative instruments, as well as the offsetting change in fair value of the portion of the fixed-rate debt being hedged, is included in interest expense.

As of September 30, 2011 and December 31, 2010, the total notional amount of the Company s interest rate swaps on floating-rate debt was \$500 million and \$767.7 million. As of September 30, 2011, the total notional amount of the Company s interest rate swaps on fixed-rate debt was \$500 million.

Certain derivative instrument contracts entered into by the Company are governed by Master Agreements, which contain credit-risk-related contingent features that 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 were in a liability position at September 30, 2011 was \$17.3 million. The Company is not subject to any obligations to post collateral under derivative instrument contracts.

The Company maintains significant credit exposure arising from the convertible note hedge on its Cash Convertible Notes. Holders may convert their Cash Convertible Notes subject to certain conversion provisions determined by a) the market price of the Company s common stock, b) specified distributions to common shareholders, c) a fundamental change, as defined in the purchase agreement, or d) certain time periods specified in the purchase agreement. The conversion feature can only be settled in cash and, therefore, it is bifurcated from the Cash Convertible Notes and treated as a separate derivative instrument. In order to offset the cash flow risk associated with the cash conversion feature, the Company entered into a convertible note hedge with certain counterparties. Both the cash conversion feature and the purchased convertible note hedge are measured at fair value with gains and losses recorded in the Company s Condensed Consolidated Statements of Operations. Also, in conjunction with the issuance of the Cash Convertible Notes, the Company entered into several warrant transactions with certain counterparties. The warrants meet the definition of derivatives; however, because these instruments have been determined to be indexed to the Company s own stock, and have been recorded in shareholders equity in the Company s Condensed Consolidated Balance Sheets, the instruments are exempt from the scope of the FASB s guidance regarding accounting for derivative instruments and hedging activities and are not subject to the fair value provisions set forth therein.

At September 30, 2011, the convertible note hedge had a total fair value of \$294.9 million, which reflects the maximum loss that would be incurred should the parties fail to perform according to the terms of the contract. The counterparties are highly rated diversified financial institutions. 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.

#### MYLAN INC. AND SUBSIDIARIES

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

#### **Fair Values of Derivative Instruments**

#### **Derivatives Designated as Hedging Instruments**

	Asset Derivatives						
	September 30, 2011 Balance Sheet Location	Fair Value	December 31, 2010 Balance Sheet Location	Fai	ir Value		
(In thousands)							
Interest rate swaps	Prepaid expenses and other current assets	\$ 39,780	Prepaid expenses and other current assets	\$			
Foreign currency forward contracts	Prepaid expenses and other current assets		Prepaid expenses and other current assets		8,884		
Total		\$ 39,780		\$	8,884		

	Liability Derivatives					
	September 30, 2011	1	December 31, 201	0		
	Balance Sheet	Fair	<b>Balance Sheet</b>	Fair		
	Location	Value	Location	Value		
(In thousands)						
Interest rate swaps	Other current liabilities	\$ 17,340	Other current liabilities	\$ 25,666		
Foreign currency forward contracts	Other current liabilities	16,975	Other current liabilities			
Foreign currency borrowings	Long-term debt	914,281	Long-term debt	909,255		
Total		\$ 948,596		\$ 934,921		

Fair Values of Derivative Instruments

#### **Derivatives Not Designated as Hedging Instruments**

	Asset Derivatives						
	September 30, 2011		December 31, 2010				
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value			
(In thousands)	Location	value	Location	value			
Foreign currency forward contracts	Prepaid expenses and other current		Prepaid expenses and other current				
	assets	\$ 3,252	assets	\$ 2,668			
Purchased cash convertible note hedge	Other assets	294,900	Other assets	472,400			
Total		\$ 298,152		\$ 475,068			

(In the second c)	September 30, 2011 Balance Sheet Location	Liability I Fair Value	Derivatives December 31, 2010 Balance Sheet Location	Fair Value
(In thousands) Foreign currency forward contracts	Other current liabilities	\$ 8,810	Other current liabilities	\$ 7,375
Cash conversion feature of Cash Convertible Notes	Long-term debt	294,900	Long-term debt	472,400
Total		\$ 303,710		\$ 479,775

#### MYLAN INC. AND SUBSIDIARIES

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

#### The Effect of Derivative Instruments on the Condensed Consolidated Statements of Operations

#### **Derivatives in Fair Value Hedging Relationships**

	Location of Gain or	Amount of Gain or (Loss) Recognized in Earnings on Derivatives				
	(Loss) Recognized in Earnings	Three Month Septembe	r 30,	Nine Months Septembe	r 30,	
(In thousands)	on Derivatives	2011	2010	2011	2010	
Interest Rate Swaps	Interest Expense	\$ 34,985	\$	\$ 39,780	\$	
Total		\$ 34,985	\$	\$ 39,780	\$	

	Location of Gain or	Amount of Gain or (Loss) Recognized in Earnings on Hedged Items				
	(Loss) Recognized in Earnings	Three Month Septembe		Nine Months September		
	on Hedged Items	2011	2010	2011	2010	
(In thousands)						
2018 Senior Notes	Interest Expense	\$ (34,985)	\$	\$ (39,780)	\$	
Total		\$ (34,985)	\$	\$ (39,780)	\$	

#### 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)					
	Three Mon Septem	ths Ended	Nine Mont Septem	hs Ended			
(In thousands)	2011	2010	2011	2010			
Foreign currency forward contracts	\$ (30,105)	\$ 9,293	\$ (28,417)	\$ 6,430			
Interest rate swaps	2,354	7,440	5,243	10,481			
Total	\$ (27,751)	\$ 16,733	\$ (23,174)	\$ 16,911			

	Location of Gain or (Loss) Reclassified from AOCE	Amount of Gain or (Loss) Reclassified from AOCE into Earnings (Effective Portion)				
	into Earnings	Three Months Ended Nine Month September 30, September 2011 2010 2011				
(In thousands)	(Effective Portion)	2011	2010	2011	2010	
Foreign currency forward contracts	Net revenues	\$ (267)	\$ (232)	\$ 2,099	\$ 647	
Interest rate swaps	Interest expense	(466)	(5,843)	(2,655)	(28,201)	
Total		\$ (733)	\$ (6,075)	\$ (556)	\$ (27,554)	

#### MYLAN INC. AND SUBSIDIARIES

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

	Location of Gain or (Loss) Excluded from the Assessment of Hedge Effectiveness	Amount of Gain or (Loss)Excluded from the Assessment of Hedge EffectiveThree Months EndedNine Months EnSeptember 30,September 302011201020112011			nths Ended
(In thousands) Foreign currency forward contracts	Other income (expense), net	\$ 12,158	\$ (4,971)	\$ 17,246	\$ (3,721)
Total		\$ 12,158	\$ (4,971)	\$ 17,246	\$ (3,721)

#### The Effect of Derivative Instruments on the Condensed Consolidated Statements of Operations

#### **Derivatives in Net Investment Hedging Relationships**

	Three Mo	Amount of Gain or (Loss)   Recognized in AOCE (Net of Tax)   on Derivative (Effective Portion)   tree Months Ended   September 30,   September 30,   11 2010		) hs Ended
(In thousands) Foreign currency borrowings	\$ 7,428	\$ (58,079)	\$ (39,868)	\$ 30,979
Total	\$ 7,428	\$ (58,079)	\$ (39,868)	\$ 30,979

There was no gain or loss recognized into earnings on derivatives with net investment hedging relationships during the nine months ended September 30, 2011 or 2010.

#### The Effect of Derivative Instruments on the Condensed Consolidated Statements of Operations

#### **Derivatives Not Designated as Hedging Instruments**

	Location of Gain	Amount of Gain or (Loss) Recognized			d
	or (Loss)	in Earnings on Derivatives			
	Recognizedin Earnings on	Three Months EndedNine Months EndedSeptember 30,September 30,			
(In thousands)	Derivatives	2011	2010	2011	2010
Foreign currency forward contracts	Other income (expense), net	\$ (19,368)	\$ (4,590)	\$ (5,244)	\$ (27,741)
Cash conversion feature of Cash					
Convertible Notes	Other income (expense), net	286,500	(43,200)	177,500	19,500
Purchased cash convertible note hedge	Other income (expense), net	(286,500)	43,200	(177,500)	(19,500)
	•				
Total		\$ (19,368)	\$ (4,590)	\$ (5,244)	\$ (27,741)

#### MYLAN INC. AND SUBSIDIARIES

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

#### 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.

Financial assets and liabilities carried at fair value are classified in the following categories described above:

	Level 1	September 30, 2011 Level 2 (In thousands)	Total
Financial Assets:			
Trading securities:			
Equity securities exchange traded funds	\$ 6,135	\$	\$ 6,135
Total trading securities	6,135		6,135
Available-for-sale fixed income investments:			
U.S. Treasuries		12,899	12,899
Corporate bonds		6,761	6,761
Agency mortgage-backed securities		1,652	1,652
Other		2,646	2,646
Total available-for-sale fixed income investments		23,958	23,958
Available-for-sale equity securities:			
Biosciences industry	156		156
Total available-for-sale equity securities	156		156
Foreign exchange derivative assets		3,252	3,252
Interest rate swap derivative assets		39,780	39,780
Purchased cash convertible note hedge		294,900	294,900

Total assets at fair value <sup>(1) (2)</sup>	\$ 6,291	\$ 361,890	\$ 368,181
Financial Liabilities:			
Foreign exchange derivative liabilities	\$	\$ 25,785	\$ 25,785
Interest rate swap derivative liabilities		17,340	17,340
Cash conversion feature of cash convertible notes		294,900	294,900
Total liabilities at fair value <sup>(1) (2)</sup>	\$	\$ 338,025	\$ 338,025

#### MYLAN INC. AND SUBSIDIARIES

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

Trading securities: Equity securities: Equity securities\$ 3,693\$ 3,693Total trading securities3,6933,693Available-for-sale fixed income investments: U.S. Treasuries12,38712,387Corporate bonds8,1168,116Agency mortgage-backed securities1,9341,934Other2,5732,573Total available-for-sale fixed income investments25,01025,010Available-for-sale equity securities: Biosciences industry382382		Level 1	December 31, 2010 Level 2 (In thousands)	Total
Equity securities $\$$ 3,693 $\$$ $\$$ 3,693Total trading securities $3,693$ $\$$ 3,693Available-for-sale fixed income investments: $12,387$ $12,387$ U.S. Treasuries $12,387$ $12,387$ Corporate bonds $\$,116$ $\$,116$ Agency mortgage-backed securities $1,934$ $1,934$ Other $2,573$ $2,573$ Total available-for-sale fixed income investments $25,010$ $25,010$ Available-for-sale equity securities: $382$ $382$ Biosciences industry $382$ $382$ $382$ Total available-for-sale equity securities $382$ $382$ Foreign exchange derivative assets $19,877$ $19,877$ Purchased cash convertible note hedge $472,400$ $472,400$ Total assets at fair value <sup>(1) (2)</sup> $\$$ 4,075 $\$$ 5,17,287 $\$$ 5,21,362Financial Liabilities: $\$$ 2,5,66625,66625,666Foreign exchange derivative liabilities $\$$ 2,5,66625,666Cash conversion feature of cash convertible notes $472,400$ $472,400$	Financial Assets:			
Total trading securities $3,693$ $3,693$ Available-for-sale fixed income investments: $12,387$ $12,387$ U.S. Treasuries $12,387$ $12,387$ Corporate bonds $8,116$ $8,116$ Agency mortgage-backed securities $1,934$ $1,934$ Other $2,573$ $2,573$ Total available-for-sale fixed income investments $25,010$ $25,010$ Available-for-sale equity securities: $382$ $382$ Biosciences industry $382$ $382$ Total available-for-sale equity securities $382$ $382$ Foreign exchange derivative assets $19,877$ $19,877$ Purchased cash convertible note hedge $472,400$ $472,400$ Total assets at fair value <sup>(1)(2)</sup> $\$4,075$ $\$517,287$ $\$521,362$ Financial Liabilities: $\$5$ $\$7,729$ $\$7,729$ Foreign exchange derivative liabilities $\$25,666$ $25,666$ Event conversion feature of cash convertible notes $472,400$ 472,400 $472,400$ $472,400$	Trading securities:			
Available-for-sale fixed income investments:12,387U.S. Treasuries12,387Corporate bonds8,116Agency mortgage-backed securities1.934Other2,5732,5732,573Total available-for-sale fixed income investments25,010Available-for-sale equity securities:382Biosciences industry382382382Total available-for-sale equity securities:382Biosciences industry382382382Total available-for-sale equity securities382Foreign exchange derivative assets19,877Purchased cash convertible note hedge472,400472,400472,400Total assets at fair value (1) (2)\$ 4,075\$ 517,287\$ 521,362Financial Liabilities:\$ 7,729Foreign exchange derivative liabilities\$ 7,729Foreign exchange derivative liabilities\$ 7,729Cotal assets at fair value of cash convertible notes472,400	Equity securities exchange traded funds	\$ 3,693	\$	\$ 3,693
Available-for-sale fixed income investments:12,387U.S. Treasuries12,387Corporate bonds8,116Agency mortgage-backed securities1.934Other2,5732,5732,573Total available-for-sale fixed income investments25,010Available-for-sale equity securities:382Biosciences industry382382382Total available-for-sale equity securities:382Biosciences industry382382382Total available-for-sale equity securities382Foreign exchange derivative assets19,877Purchased cash convertible note hedge472,400472,400472,400Total assets at fair value (1) (2)\$ 4,075\$ 517,287\$ 521,362Financial Liabilities:\$ 7,729Foreign exchange derivative liabilities\$ 7,729Foreign exchange derivative liabilities\$ 7,729Cotal assets at fair value of cash convertible notes472,400				
U.S. Treasuries12,38712,387Corporate bonds8,1168,116Agency mortgage-backed securities1,9341,934Other2,5732,573Total available-for-sale fixed income investments25,01025,010Available-for-sale equity securities:382382Biosciences industry382382Total available-for-sale equity securities382382Total available-for-sale equity securities382382Foreign exchange derivative assets19,87719,877Purchased cash convertible note hedge472,400472,400Total assets at fair value (1) (2)\$ 4,075\$ 517,287\$ 521,362Financial Liabilities:\$ $$ 7,729$ \$ 7,729\$ 7,729Interest rate swap derivative liabilities25,66625,666Cash conversion feature of cash convertible notes472,400472,400	Total trading securities	3,693		3,693
U.S. Treasuries12,38712,387Corporate bonds8,1168,116Agency mortgage-backed securities1,9341,934Other2,5732,573Total available-for-sale fixed income investments25,01025,010Available-for-sale equity securities:382382Biosciences industry382382Total available-for-sale equity securities382382Total available-for-sale equity securities382382Foreign exchange derivative assets19,87719,877Purchased cash convertible note hedge472,400472,400Total assets at fair value (1) (2)\$ 4,075\$ 517,287\$ 521,362Financial Liabilities:\$ $$ 7,729$ \$ 7,729\$ 7,729Interest rate swap derivative liabilities25,66625,666Cash conversion feature of cash convertible notes472,400472,400				
Corporate bonds8,1168,1168,116Agency mortgage-backed securities1,9341,934Other2,5732,573Total available-for-sale fixed income investments25,01025,010Available-for-sale equity securities:382382Biosciences industry382382Total available-for-sale equity securities382382Foreign exchange derivative assets19,87719,877Purchased cash convertible note hedge472,400472,400Total assets at fair value (1) (2)\$ 4,075\$ 517,287\$ 521,362Financial Liabilities: Foreign exchange derivative liabilities\$ \$ 7,729\$ 7,729\$ 7,729Interest rate swap derivative liabilities\$ \$ \$ 7,729\$ 7,729\$ 7,729Interest rate swap derivative liabilities\$ \$ \$ 7,729\$ 7,729Interest rate swap derivative liabilities\$ \$ \$ 7,2400472,400Attract of cash convertible notes472,400472,400	Available-for-sale fixed income investments:			
Agency mortgage-backed securities $1,934$ $1,934$ $1,934$ Other $2,573$ $2,573$ $2,573$ Total available-for-sale fixed income investments $25,010$ $25,010$ Available-for-sale equity securities: Biosciences industry $382$ $382$ Total available-for-sale equity securities $382$ $382$ Foreign exchange derivative assets $19,877$ $19,877$ Purchased cash convertible note hedge $472,400$ $472,400$ Total assets at fair value $^{(1)(2)}$ $\$4,075$ $\$517,287$ $\$521,362$ Financial Liabilities: Foreign exchange derivative liabilities $\$$ $\$,7.29$ $\$,7.29$ $\$,7.29$ Interest rate swap derivative liabilities $\$25,666$ $25,666$ $25,666$ Cash conversion feature of cash convertible notes $472,400$ $472,400$	U.S. Treasuries		12,387	12,387
Other2,5732,573Total available-for-sale fixed income investments25,01025,010Available-for-sale equity securities: Biosciences industry382382Total available-for-sale equity securities382382Total available-for-sale equity securities382382Foreign exchange derivative assets19,87719,877Purchased cash convertible note hedge472,400472,400Total assets at fair value (1) (2)\$ 4,075\$ 517,287\$ 521,362Financial Liabilities: Foreign exchange derivative liabilities\$ \$ 7,729\$ 7,729\$ 7,729Interest rate swap derivative liabilities Cash convertible notes472,400472,400	Corporate bonds		8,116	8,116
Total available-for-sale fixed income investments25,01025,010Available-for-sale equity securities: Biosciences industry382382Total available-for-sale equity securities382382Total available-for-sale equity securities382382Foreign exchange derivative assets19,87719,877Purchased cash convertible note hedge472,400472,400Total assets at fair value (1) (2)\$ 4,075\$ 517,287\$ 521,362Financial Liabilities: Foreign exchange derivative liabilities\$ 7,729\$ 7,729\$ 7,729Interest rate swap derivative liabilities Cash conversion feature of cash convertible notes472,400472,400	Agency mortgage-backed securities		1,934	1,934
Available-for-sale equity securities:Biosciences industry382382382Total available-for-sale equity securities382Securities382Foreign exchange derivative assets19,877Purchased cash convertible note hedge472,400472,400472,400Total assets at fair value (1) (2)\$ 4,075Financial Liabilities:\$Foreign exchange derivative liabilities\$Foreign exchange derivative liabilities\$Construction feature of cash convertible notes472,400472,400472,400	Other		2,573	2,573
Available-for-sale equity securities:Biosciences industry382382382Total available-for-sale equity securities382Securities382Foreign exchange derivative assets19,877Purchased cash convertible note hedge472,400472,400472,400Total assets at fair value (1) (2)\$ 4,075Financial Liabilities:\$Foreign exchange derivative liabilities\$Foreign exchange derivative liabilities\$Construction feature of cash convertible notes472,400472,400472,400				
Biosciences industry382382Biosciences industry382382Total available-for-sale equity securities382382Foreign exchange derivative assets19,87719,877Purchased cash convertible note hedge472,400472,400Total assets at fair value (1) (2)\$ 4,075\$ 517,287\$ 521,362Financial Liabilities:57,729\$ 7,729Foreign exchange derivative liabilities\$ \$ 7,729\$ 7,729Interest rate swap derivative liabilities25,66625,666Cash conversion feature of cash convertible notes472,400472,400	Total available-for-sale fixed income investments		25,010	25,010
Biosciences industry382382Biosciences industry382382Total available-for-sale equity securities382382Foreign exchange derivative assets19,87719,877Purchased cash convertible note hedge472,400472,400Total assets at fair value (1) (2)\$ 4,075\$ 517,287\$ 521,362Financial Liabilities:57,729\$ 7,729Foreign exchange derivative liabilities\$ \$ 7,729\$ 7,729Interest rate swap derivative liabilities25,66625,666Cash conversion feature of cash convertible notes472,400472,400				
Total available-for-sale equity securities382382Foreign exchange derivative assets19,87719,877Purchased cash convertible note hedge472,400472,400Total assets at fair value (1) (2)\$ 4,075\$ 517,287\$ 521,362Financial Liabilities: Foreign exchange derivative liabilities\$ \$ 7,729\$ 7,729Interest rate swap derivative liabilities25,66625,666Cash conversion feature of cash convertible notes472,400472,400	Available-for-sale equity securities:			
Foreign exchange derivative assets19,87719,877Purchased cash convertible note hedge472,400472,400Total assets at fair value (1) (2)\$ 4,075\$ 517,287\$ 521,362Financial Liabilities: Foreign exchange derivative liabilities\$ 7,729\$ 7,729Interest rate swap derivative liabilities25,66625,666Cash conversion feature of cash convertible notes472,400472,400	Biosciences industry	382		382
Foreign exchange derivative assets19,87719,877Purchased cash convertible note hedge472,400472,400Total assets at fair value (1) (2)\$ 4,075\$ 517,287\$ 521,362Financial Liabilities: Foreign exchange derivative liabilities\$ 7,729\$ 7,729Interest rate swap derivative liabilities25,66625,666Cash conversion feature of cash convertible notes472,400472,400				
Purchased cash convertible note hedge472,400472,400Total assets at fair value (1) (2)\$ 4,075\$ 517,287\$ 521,362Financial Liabilities: Foreign exchange derivative liabilities\$ 7,729\$ 7,729Interest rate swap derivative liabilities\$ 25,66625,666Cash conversion feature of cash convertible notes472,400472,400	Total available-for-sale equity securities	382		382
Purchased cash convertible note hedge472,400472,400Total assets at fair value (1) (2)\$ 4,075\$ 517,287\$ 521,362Financial Liabilities: Foreign exchange derivative liabilities\$ 7,729\$ 7,729Interest rate swap derivative liabilities\$ 25,66625,666Cash conversion feature of cash convertible notes472,400472,400				
Purchased cash convertible note hedge472,400472,400Total assets at fair value (1) (2)\$ 4,075\$ 517,287\$ 521,362Financial Liabilities: Foreign exchange derivative liabilities\$ 7,729\$ 7,729Interest rate swap derivative liabilities\$ 25,66625,666Cash conversion feature of cash convertible notes472,400472,400	Foreign exchange derivative assets		19.877	19.877
Total assets at fair value (1) (2)\$ 4,075\$ 517,287\$ 521,362Financial Liabilities: Foreign exchange derivative liabilities\$ 7,729\$ 7,729Interest rate swap derivative liabilities25,66625,666Cash conversion feature of cash convertible notes472,400472,400			,	,
Financial Liabilities:Foreign exchange derivative liabilities\$ 7,729Interest rate swap derivative liabilities25,666Cash conversion feature of cash convertible notes472,400	e e e e e e e e e e e e e e e e e e e		,	,
Financial Liabilities:Foreign exchange derivative liabilities\$ 7,729Interest rate swap derivative liabilities25,666Cash conversion feature of cash convertible notes472,400	Total ascots at fair value $^{(1)(2)}$	\$ 4.075	\$ 517 207	\$ 501 260
Foreign exchange derivative liabilities\$ 7,729\$ 7,729Interest rate swap derivative liabilities25,66625,666Cash conversion feature of cash convertible notes472,400472,400	Total assets at fair value	\$4,075	\$ 317,287	\$ 521,502
Foreign exchange derivative liabilities\$ 7,729\$ 7,729Interest rate swap derivative liabilities25,66625,666Cash conversion feature of cash convertible notes472,400472,400	Einempiel Liebilities			
Interest rate swap derivative liabilities25,66625,666Cash conversion feature of cash convertible notes472,400472,400		¢	¢ 7.720	\$ 7,720
Cash conversion feature of cash convertible notes472,400472,400		φ	1 . )	
			- ,	- )
Total liabilities at fair value <sup>(1) (2)</sup> \$ 505,795   \$ 505,795	Cash conversion readure of cash convertible notes		472,400	472,400
Total habilities at fair value   \$ 505,795   \$ 505,795	· · · · · · · · · · · · · · · · · · ·			
	Total liabilities at fair value (1/6)	\$	\$ 505,795	\$ 505,795

(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.

<sup>(2)</sup> None of the Company s financial assets and liabilities measured at fair value on a recurring basis are valued using Level 3 inputs as of September 30, 2011 or December 31, 2010.

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 active 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

#### MYLAN INC. AND SUBSIDIARIES

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

experienced any significant downgrades during the nine months ended September 30, 2011 that would reduce the receivable amount owed, if any, to the Company.

*Foreign exchange derivative assets and liabilities* valued using quoted forward foreign exchange prices at the reporting date. Counterparties to these contracts are highly rated financial institutions, none of which experienced any significant downgrades during the nine months ended September 30, 2011 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, 2011 that would reduce the receivable amount owed, if any, to the Company. 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

A summary of long-term debt is as follows:

	September 30, 2011 (In tho	September 30, 2011 December 31 (In thousands)	
Euro Tranche A Term Loans (A)	\$ 235,847	\$	234,550
U.S. Tranche B Term Loans <sup>(A)</sup>	500,000		500,000
Euro Tranche B Term Loans <sup>(A)</sup>	678,434		674,705
Senior Convertible Notes (B)	586,602		565,476
Cash Convertible Notes (C)	766,466		928,344
2017 Senior Notes	550,000		550,000
2018 Senior Notes (D)	828,461		787,728
2020 Senior Notes (E)	1,014,944		1,015,848
Other	4,344		11,534
	5,165,098		5,268,185
Less: Current portion	681,877		4,809
Total long-term debt	\$ 4,483,221	\$	5,263,376

<sup>(A)</sup> All 2011 mandatory principal payments due under the Senior Credit Agreement were prepaid during 2009.

In May 2011, the Senior Credit Agreement was amended to increase the minimum amount of other restricted payments permitted under the Senior Credit Agreement from \$50 million to \$300 million.

(B) At September 30, 2011, the \$586.6 million of debt is net of a \$13.4 million discount. At December 31, 2010, the \$565.5 million of debt is net of a \$34.5 million discount. As of September 30, 2011, the effective conversion rate for the Senior Convertible Notes was 42.156 shares of common stock per \$1,000 principal

#### MYLAN INC. AND SUBSIDIARIES

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

amount of notes, representing a stock price of \$23.72 per share, reflecting the Company s suspension of its cash dividend. On October 3, 2011, the effective conversion rate for the Senior Convertible Notes was adjusted to 41.678 shares of common stock per \$1,000 principal amount of notes, representing a stock price of \$23.99 per share. As these notes are due in March 2012, this amount is now classified as a current portion of long-term debt.

(C) At September 30, 2011, the \$766.5 million consists of \$471.6 million of debt (\$575.0 million face amount, net of \$103.4 million discount) and the bifurcated conversion feature with a fair value of \$294.9 million recorded as a liability within long-term debt in the Condensed Consolidated Balance Sheets at September 30, 2011. The Cash Convertible Notes will mature on September 15, 2015, subject to earlier repurchase or conversion. Holders may convert their notes subject to certain conversion provisions determined by the market price of the company s common stock, specified distributions to common shareholders, a fundamental change, and certain time periods specified in the purchase agreement. Additionally, the Company has purchased call options, which are recorded as assets at their fair value of \$294.9 million within other assets in the Condensed Consolidated Balance Sheets at September 30, 2011. At December 31, 2010, the \$928.3 million consisted of \$455.9 million of debt (\$575.0 million face amount, net of \$119.1 million discount) and the bifurcated conversion feature with a fair value of \$472.4 million recorded as a liability within other long-term obligations in the Condensed Consolidated Balance Sheets. The purchased call options are assets recorded at their fair value of \$472.4 million within other assets in the Condensed Consolidated Balance Sheets at December 31, 2010.

As of September 30, 2011, because the closing price of Mylan s 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, 2011 period, was more than 130% of the applicable conversion reference price of \$13.32 at September 30, 2011, the \$575.0 million of Cash Convertible Notes were 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. Should holders elect to convert, the Company intends to draw on its revolving credit facility to fund any principal payments. 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, 2011, the \$828.5 million of debt is net of a \$11.3 million discount. At December 31, 2010, the \$787.7 million of debt is net of a \$12.3 million discount. In 2011, the Company entered into interest rate swaps which convert \$500.0 million of principal debt to a variable rate. The variable rate is 3.25% at September 30, 2011. The \$828.5 million of debt includes a mark to market adjustment of \$39.8 million associated with these interest rate swaps.
- (E) At September 30, 2011, the \$1.02 billion of debt includes a \$14.9 million premium. At December 31, 2010, the \$1.02 billion of debt includes a \$15.8 million premium.

#### MYLAN INC. AND SUBSIDIARIES

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

Details of the interest rates in effect at September 30, 2011 and December 31, 2010 on the outstanding borrowings under the Term Loans are in the table below:

		September 30, 2011			
	Outstanding (In thousands)	Basis	Rate		
Euro Tranche A Term Loans	\$ 235,847	EURIBO + 2.75%	4.11%		
U.S. Tranche B Term Loans					
Swapped to Fixed Rate December 2012 <sup>11</sup>	\$ 500,000	Fixed	6.60%		
Euro Tranche B Term Loans	\$ 678,434	EURIBO + 3.25%	4.60%		

	December 31, 2010				
	Outstanding (In thousands)	Basis	Rate		
Euro Tranche A Term Loans	\$ 234,550	EURIBO + 2.75%	3.66%		
U.S. Tranche B Term Loans					
Swapped to Fixed Rate December $2012^{(1)}$	\$ 500,000	Fixed	6.60%		
Euro Tranche B Term Loans					
Swapped to Fixed Rate March $201 f^{(1)}$	\$ 267,740	Fixed	5.38%		
Floating Rate	406,965	EURIBO + 3.25%	4.11%		
Total Euro Tranche B Term Loans	\$ 674,705				

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

At September 30, 2011, the fair value of the Senior Notes and Senior Convertible Notes was approximately \$3.01 billion, and at December 31, 2010, the fair value of the Senior Notes and Senior Convertible Notes was approximately \$3.06 billion. At September 30, 2011 and December 31, 2010, the fair value of the Cash Convertible Notes was approximately \$831.4 million and \$996.2 million.

Mandatory minimum repayments remaining on the outstanding borrowings under the term loans and notes at September 30, 2011, at notional amounts, 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 (In thousands)	2017 Senior Notes	2018 Senior Notes	2020 Senior Notes	Total
2011	\$	\$	\$	\$	\$	\$	\$	\$	\$
2012	117,923		7,067	600,000					724,990
2013	117,924		7,067						124,991
2014		500,000	664,300						1,164,300
2015					575,000				575,000
Thereafter						550,000	800,000	1,000,000	2,350,000

Total	\$ 235,847	\$ 500,000	\$ 678,434	\$ 600,000	\$ 575,000	\$ 550,000	\$ 800,000	\$ 1,000,000	\$ 4,939,281
-------	------------	------------	------------	------------	------------	------------	------------	--------------	--------------

#### MYLAN INC. AND SUBSIDIARIES

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

#### 11. Comprehensive Earnings

Comprehensive earnings consist of the following:

	Three Months Ended Sept 2011			nber 30, 2010
		(In thous	ands)	
Net earnings		\$ 157,378		\$ 143,539
Other comprehensive (loss) earnings, net of tax, as applicable:				
Foreign currency translation adjustment		(383,108)		424,463
Change in unrecognized gains and prior service cost related to post-retirement plans, net of tax		155		8
Net unrecognized (loss) gain on derivatives, net of tax		(27,484)		16,965
Unrealized gains on available-for-sale securities				
Net unrealized gains on available-for-sale securities, net of tax	145		176	
Less: Reclassification for (losses) gains included in net earnings	(88)	57	14	190
Total other comprehensive (loss) earnings, net of tax, as applicable:		(410,380)		441,626
Comprehensive (loss) earnings		(253,002)		585,165
Comprehensive earnings attributable to the noncontrolling interest		(680)		(356)
Comprehensive (loss) earnings attributable to Mylan Inc.	:	\$ (253,682)		\$ 584,809

	Nine Months Ended September 30,			,
	2	011 (In thous	ands)	2010
Net earnings		\$ 408,909	and s)	\$ 324,743
Other comprehensive (loss) earnings, net of tax, as applicable:				
Foreign currency translation adjustment		(103,178)		90,206
Change in unrecognized gains and prior service cost related to post-retirement plans, net of tax		482		4,452
Net unrecognized (loss) gain on derivatives, net of tax		(25,273)		17,143
Unrealized (losses) gains on available-for-sale securities				
Net unrealized gains on available-for-sale securities, net of tax	99		489	
Less: Reclassification for (losses) gains included in net earnings	(127)	(28)	171	660
Total other comprehensive (loss) earnings, net of tax, as applicable:		(127,997)		112,461
Comprehensive earnings		280,912		437,204
comprehensive earnings		200,912		+57,204
Comprehensive (earnings) loss attributable to the noncontrolling interest		(1,590)		525
Comprehensive earnings attributable to Mylan Inc.		\$ 279,322		\$ 437,729

#### MYLAN INC. AND SUBSIDIARIES

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

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

	September 30, 2011 (In t	nber 31, 2010	
Accumulated other comprehensive earnings:			
Net unrealized gain on available-for-sale securities, net of tax	\$ 1,019	\$	1,047
Net unrecognized losses and prior service costs related to post retirement			
plans, net of tax	(4,167)		(4,650)
Net unrecognized losses on derivatives, net of tax	(34,867)		(9,594)
Foreign currency translation adjustment	81,886		185,064
	\$ 43,871	\$	171,867

#### 12. Shareholders Equity

A summary of the change in shareholders equity for the nine months ended September 30, 2011 and 2010 is as follows:

	Total Mylan			
			controlling	
	Shareholders Equity		Interest thousands)	Total
December 31, 2010	\$ 3,601,879	\$	13,522	\$ 3,615,401
Net earnings	407,319		1,590	408,909
Other comprehensive earnings	(127,997)			(127,997)
Share repurchase	(349,998)			(349,998)
Warrant amendment and exchange	(149,947)			(149,947)
Stock option activity	65,035			65,035
Stock compensation expense	32,803			32,803
Issuance of restricted stock, net of shares withheld	(6,093)			(6,093)
Purchase of subsidiary shares from noncontrolling interest	(2,607)		(2,385)	(4,992)
Tax benefit of stock option plans	11,163			11,163
Other			(147)	(147)
September 30, 2011	\$ 3,481,557	\$	12,580	\$ 3,494,137
-				
December 31, 2009	\$ 3,131,146	\$	14.052	\$ 3,145,198
Net earnings (loss)	325,268	φ	(525)	324,743
Other comprehensive loss	112,461		(323)	112,461
Dividends paid on preferred stock	(104,276)			(104,276)
Stock option activity	37,215			37,215
Stock opposition activity Stock compensation expense	24,156			24,156
Purchase of subsidiary shares from noncontrolling interest	(4,376)		(623)	(4,999)
Tax benefit of stock option plans	4,863		(023)	4,863
Other	3,671		(92)	3,579
Uliu	5,071		()2)	5,579

September 30, 2010

\$ 3,530,128	\$	12,812	\$ 3,542,940
--------------	----	--------	--------------

#### MYLAN INC. AND SUBSIDIARIES

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

#### 13. Segment Information

Mylan has two segments, Generics and Specialty. 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 development, manufacture and sale of branded specialty nebulized and injectable products.

The Company s chief operating decision maker evaluates the performance of its segments based on total revenues and segment profitability. Segment profitability represents segment gross profit less direct research and development expenses and direct selling, general and administrative expenses. Certain general and administrative and research and development expenses not allocated to the segments, as well as net charges 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. 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, 2010. Intersegment revenues are accounted for at current market values and are eliminated at the consolidated level.

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 Segment (In tho	Corporate / Other <sup>(1)</sup> usands)	Consolidated
Three Months Ended September 30, 2011				
Total revenues				
Third party	\$ 1,361,462	\$ 214,294	\$	\$ 1,575,756
Intersegment	398	17,118	(17,516)	
Total	\$ 1,361,860	\$231,412	\$ (17,516)	\$ 1,575,756
Segment profitability	\$ 393,985	\$ 92,084	\$ (220,161)	\$ 265,908

	Generics Segment	Specialty Segment (In thou	Corporate / Other <sup>(1)</sup> Isands)	Consolidated
Nine Months Ended September 30, 2011				
Total revenues				
Third party	\$ 4,153,365	\$ 445,225	\$	\$ 4,598,590
Intersegment	1,200	51,402	(52,602)	
Total	\$ 4,154,565	\$ 496,627	\$ (52,602)	\$ 4,598,590
Segment profitability	\$ 1,214,524	\$ 169,729	\$ (626,200)	\$ 758,053

# Edgar Filing: MYLAN INC. - Form 10-Q

#### MYLAN INC. AND SUBSIDIARIES

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

	Generics Segment	Specialty Segment (In thou	Corporate / Other <sup>(1)</sup> Isands)	Consolidated
Three Months Ended September 30, 2010				
Total revenues				
Third party	\$ 1,213,216	\$ 141,897	\$	\$ 1,355,113
Intersegment	2,392	13,689	(16,081)	
Total	\$ 1,215,608	\$ 155,586	\$ (16,081)	\$ 1,355,113
Segment profitability	\$ 357,393	\$ 49,761	\$ (172,836)	\$ 234,318

	Generics Segment	Specialty Segment (In thou	Corporate / Other <sup>(1)</sup> usands)	Consolidated
Nine Months Ended September 30, 2010				
Total revenues				
Third party	\$ 3,663,733	\$ 352,290	\$	\$ 4,016,023
Intersegment	34,314	47,419	(81,733)	
Total	\$ 3,698,047	\$ 399,709	\$ (81,733)	\$ 4,016,023
Segment profitability	\$ 1,015,980	\$ 104,881	\$ (493,451)	\$ 627,410

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

#### 14. Contingencies Legal Proceedings

While it is not possible to determine with any degree of certainty the ultimate outcome of the following legal proceedings, the Company believes that it has meritorious defenses with respect to the claims asserted against it and intends to vigorously defend its position. 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, pursuant to the agreement by which Mylan acquired the former Merck Generics business. An adverse outcome in any of the following proceedings, or the inability or denial of Merck KGaA to pay an indemnified claim, could have a material 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

# Edgar Filing: MYLAN INC. - Form 10-Q

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

#### MYLAN INC. AND SUBSIDIARIES

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

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 \$11.0 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 \$58.0 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 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 has contested this ruling along with the liability finding and other damages awards as part of its appeal, which was filed in the Court of Appeals for the D.C. Circuit. On January 18, 2011, the Court of Appeals issued a judgment remanding the case to the District Court for further proceedings based on lack of diversity with respect to certain plaintiffs. On June 13, 2011, Mylan filed a certiorari petition with the U.S. Supreme Court requesting review of the judgment of the D.C. Circuit. On October 3, 2011, the certiorari petition was denied. The case will now proceed before the District Court where several motions are currently pending. In connection with the Company s appeal of the 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 an irrevocable letter of credit for \$24.5 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, Louisiana, 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. Other 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 the cases that remain pending may go to trial in 2012. Mylan and its subsidiaries have denied liability and intend to defend each of these actions vigorously.

In May 2008, an amended complaint was filed in the U.S. District Court for the District of Massachusetts by a 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 alleged violations of the False Claims Act and set forth allegations substantially similar to those alleged in the state AG cases mentioned in the preceding paragraph and purported 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 December 2010,

#### MYLAN INC. AND SUBSIDIARIES

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

the Company completed a settlement of this case (except for the claims related to the California federal share) and the Texas state action mentioned above. This settlement resolved a significant portion of the damages claims asserted against Mylan, MPI and UDL in the various pending pricing litigations. In addition, Mylan reached settlements of the Alabama, Alaska, Hawaii, Iowa, Kansas, Kentucky, Massachusetts, Mississippi, South Carolina, and Utah state actions. The Company has also reached agreements in principle to settle the California, Florida, Idaho, New York state and county and Oklahoma actions, 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 had accrued approximately \$157 million at December 31, 2010. Following settlements of certain of these matters and settlement payments of approximately \$32 million during the nine months ended September 30, 2011, the Company has a remaining accrual of approximately \$125 million at September 30, 2011. 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 reached and/or adverse judgments received, if any, will not exceed the amounts currently provided for. However, the range of possible loss above the amount provided for cannot be reasonably estimated.

Dey is currently a defendant in a lawsuit brought by the state AG of Louisiana and 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. Dey has also reached an agreement in principle to settle the Louisiana action. 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 asserted that Dey was jointly liable with a codefendant and sought recovery of alleged overpayments, together with treble damages, civil penalties and equitable relief. Dey completed a settlement of this action in December 2010. These cases all have generally alleged 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.

Under the terms of the purchase agreement with Merck KGaA, Mylan is fully indemnified for these claims and Merck KGaA is entitled to any income tax benefit the Company realizes for any deductions of amounts paid for such pricing litigation. Under the indemnity, Merck KGaA is responsible for all settlement and legal costs, and, as such, these settlements had no impact on the Company s Condensed Consolidated Statements of Operations. At September 30, 2011, the Company has accrued approximately \$68 million in other current liabilities, which represents its estimate of the remaining amount of anticipated income tax benefits due to Merck KGaA. During the quarter ended September 30, 2011 the Company paid approximately \$60 million related to this matter to Merck KGaA which was previously accrued. Substantially all of Dey s known claims with respect to this pricing litigation have been settled.

#### Modafinil Antitrust Litigation and FTC Inquiry

Beginning in April 2006, Mylan and four other drug manufacturers have been named as defendants 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 in a lawsuit filed 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. The deadline for filing dispositive motions was September 9, 2011, and fact discovery closed on

#### MYLAN INC. AND SUBSIDIARIES

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

February 11, 2011. The Court has deferred briefing on dispositive motions pending issuance of the Court s decision in the patent litigation between Cephalon and Apotex. 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 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<sup>®</sup> 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. Following the recall, approximately 1,000 lawsuits were filed against Mylan, UDL and Actavis. Most of these cases were 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 remaining cases are being litigated in the state courts in which they were filed. Actavis has reached settlements in principle with the plaintiffs in a majority of the claims and lawsuits. Mylan and UDL will not contribute monetarily to the settlements, 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. As of October 6, 2011, approximately 12 plaintiffs had opted out of the settlement. 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, although the range of possible loss cannot be reasonably estimated.

#### EU Commission Proceedings

On or around July 8, 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 Laboratories Servier (Servier) as well as possible infringement of Article 81 EC by the Company s Indian subsidiary, Mylan Laboratories Limited (formerly known as Matrix Laboratories Limited), and four other companies, each of which entered into agreements with Servier relating to the product Perindopril. Mylan Laboratories Limited in connection with the investigation. No statement of objections has been filed against Mylan Laboratories Limited in connection with this matter, and have responded and are cooperating with the Commission in this investigation.

#### MYLAN INC. AND SUBSIDIARIES

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

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 and has responded to other requests for additional information. The Company is cooperating with the Commission in connection with the investigation, and no statement of objections has been filed against the Company in connection with the investigation.

On March 19, 2010, Mylan 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. Mylan and Generics [U.K.] Ltd. have received requests for information from the EU Commission in connection with any agreements between Lundbeck and Generics [U.K.] Ltd. concerning Citalopram. Generics [U.K.] Ltd. has responded and continues to respond to additional requests for information. Both companies are cooperating with the EU Commission. No statement of objections has been filed in connection with this investigation.

#### U.K. Office of Fair Trading

On August 12, 2011 Generics [U.K.] Ltd. received notice that the Office of Fair Trading was initiating an investigation to explore the possible infringement of the Competition Act 1998 with respect to alleged agreements related to Paroxetine. Generics [U.K.] Ltd. has produced documents and information in connection with this inquiry and is continuing to cooperate with the investigation. No statement of objections has been filed in connection with this investigation.

#### **Product Liability**

The Company is involved in a number of product liability lawsuits and claims related to alleged personal injuries arising out of certain products manufactured and/or distributed by the Company, including but not limited to its Fentanyl Transdermal System, Phenytoin and Amnesteem. The Company believes that it has meritorious defenses to these lawsuits and claims and is vigorously defending itself with respect to those matters. From time to time, the Company has agreed to settle or otherwise resolve certain lawsuits and claims on terms and conditions that are in the best interests of the Company. During 2010, the Company accrued \$41.0 million in connection with certain settlements. Following these settlements, the Company has paid approximately \$15.0 million during the nine months ended September 30, 2011.

There are no assurances that settlements reached and/or adverse judgments received, if any, will not exceed the amounts currently provided for. However, the range of possible loss above the amount provided for cannot be reasonably estimated.

#### **Other Litigation**

Beaufour Ipsen Pharma ( Ipsen ) sued Merck Generiques (n/k/a Mylan S.A.S.) for unfair competition on October 11, 2007, following Mylan S.A.S. s receipt of market authorization for Vitalogink earlier in 2007 (prior to Mylan s acquisition of the former Merck Generics business). The Commercial Court of Paris dismissed

#### MYLAN INC. AND SUBSIDIARIES

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

Ipsen s claim in a January 2008 decision. Ipsen filed an appeal of this decision to the Paris Appeals Court in March 2008. On April 28, 2011, the Paris Appeals Court reversed the decision of the Commercial Court of Paris and found that Mylan S.A.S. is liable for unfair competition and further ordered damages against Mylan S.A.S. in the amount of 17 million (approximately \$24 million), which was subsequently paid by Mylan S.A.S. The Company believes the Court erred in its decision and has filed its notice of appeal, believing that it has meritorious defenses to this claim and intends to vigorously defend itself with respect to this matter.

The Company is involved in various other legal proceedings that are considered normal to its business, including but not limited to certain proceedings assumed as a result of the acquisition of the former Merck Generics business. While it is not possible to predict the ultimate outcome of such other proceedings, the ultimate outcome of any such proceeding is not currently expected to be material to the Company s financial position, results of operations or cash flows.

**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, 2010, 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, 2011 and the interim cash flows for the nine months ended September 30, 2011 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 , believe , anticipate , expect , plan , estimate , forecast , potential , intend , continue and var comparable words. Forward-looking statements inherently involve risks and uncertainties. Accordingly, actual results may differ materially from those expressed or implied by these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, the risks described below under Risk Factors in Part II, ITEM 1A. The Company undertakes no obligation to update any forward-looking statements for revisions or changes after the filing date of this Form 10-Q.

#### **Executive** Overview

Mylan ranks among the leading generic and specialty pharmaceutical companies in the world, offering one of the industry s broadest and highest quality product portfolios, a robust pipeline and a global commercial footprint that spans more than 150 countries and territories. With a workforce of more than 18,000 employees and external contractors, Mylan has attained leading positions in key international markets through its wide array of dosage forms and delivery systems, significant manufacturing capacity, global scale and commitment to customer service. Through its Indian subsidiary, Mylan Laboratories Limited (formerly known as Matrix Laboratories Limited), Mylan operates 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 capability makes Mylan one of only two global generics companies with a comprehensive, vertically integrated supply chain.

Mylan has two segments, Generics and Specialty. 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, if any, and other items not directly attributable to the segments.

#### Financial Summary

For the three months ended September 30, 2011, Mylan reported total revenues of \$1.58 billion compared to \$1.36 billion for the three months ended September 30, 2010. This represents an increase in revenues of \$220.6 million, or 16.3%. Consolidated gross profit for the current quarter was \$658.4 million, compared to \$580.1 million in the comparable prior year period, an increase of \$78.3 million, or 13.5%. For the current quarter, earnings from operations were \$265.9 million, compared to \$234.3 million for the three months ended September 30, 2010.

The net earnings attributable to Mylan Inc. common shareholders for the three months ended September 30, 2011 were \$156.7 million, and earnings per diluted share were \$0.36. In the prior year quarter ended September 30, 2010, the net earnings attributable to Mylan Inc. common shareholders were \$143.2 million, or earnings per diluted share of \$0.33. A more detailed discussion of the Company s financial results can be found below in the section titled Results of Operations.

Included in the results for the three months ended September 30, 2011 and 2010 are the following items of note:

Three months ended September 30, 2011:

Amortization expense, primarily related to purchased intangible assets associated with acquisitions, of \$104.1 million, including a \$16.2 million IPR&D asset impairment charge;

Interest of \$12.6 million, primarily related to the amortization of the discounts on our convertible debt instruments and 2018 Senior Notes, net of amortization of the premium on our 2020 Senior Notes;

Net charges related to the settlement of litigation of \$2.2 million;

Additional costs, primarily restructuring related items, totaling \$15.4 million; and

A tax effect of \$53.2 million related to the above items and other income tax-related items. *Three months ended September 30, 2010:* 

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

Interest of \$17.6 million, primarily related to the amortization of the discounts on our convertible debt instruments and 2018 Senior Notes, net of amortization of the premium on our 2020 Senior Notes;

Net charges related to the settlement of litigation of \$1.5 million;

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 integration and restructuring, totaling \$16.0 million; and

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

Mylan s financial results for the nine months ended September 30, 2011 include total revenues of \$4.60 billion compared to \$4.02 billion for the nine months ended September 30, 2010, representing an increase of \$582.6 million, or 14.5%. Consolidated gross profit for the nine months

### Edgar Filing: MYLAN INC. - Form 10-Q

ended September 30, 2011 was \$1.92 billion compared to \$1.64 billion in the same prior year period, representing an increase of \$280.6 million, or 17.1%. For the nine months ended September 30, 2011, earnings from operations of \$758.1 million were realized compared to \$627.4 million for the same prior year period.

The net earnings attributable to Mylan Inc. common shareholders for the nine months ended September 30, 2011 were \$407.3 million, and earnings per diluted share were \$0.92. In the prior year period ended September 30, 2010, the net earnings attributable to Mylan Inc. common shareholders were \$221.0 million, and earnings per diluted share were \$0.71. 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, 2011 and 2010 are the following items of note:

Nine months ended September 30, 2011:

Amortization expense, primarily related to purchased intangible assets associated with acquisitions, of \$278.1 million, including a \$16.2 million IPR&D asset impairment charge;

Interest of \$36.8 million, primarily related to the amortization of the discounts on our convertible debt instruments and 2018 Senior Notes, net of amortization of the premium on our 2020 Senior Notes;

Net charges related to the settlement of litigation of \$28.5 million;

Additional costs, primarily restructuring related items, totaling \$46.0 million; and

A tax effect of \$130.2 million related to the above items and other income tax-related items. *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 amortization of the discounts on our convertible debt instruments, net of amortization of the premium on our 2020 Senior Notes;

Net charges related to the settlement of litigation of \$14.3 million;

Charges, related to refinancing, of \$15.0 million, primarily swap termination fees and the write-off of deferred financing costs included in other income (expense), 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 integration and restructuring, totaling \$44.9 million; and

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

#### Three Months Ended September 30, 2011, Compared to Three Months Ended September 30, 2010

#### Total Revenues and Gross Profit

For the current quarter, Mylan reported total revenues of \$1.58 billion compared to \$1.36 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 \$1.57 billion compared to \$1.34 billion for the same prior year period, representing an increase of \$227.3 million, or 16.9%. Other third party revenues for the current quarter were \$3.4 million compared to \$10.1 million in the same prior year period, a decrease of \$6.7 million.

Mylan s current quarter revenues were impacted by the effect of foreign currency translation, generally reflecting a weaker U.S. dollar as compared to the currencies in other markets in which Mylan operates. Translating third party net revenues for the current quarter at prior year

## Edgar Filing: MYLAN INC. - Form 10-Q

comparative period foreign currency exchange rates would have resulted in year-over-year growth of approximately \$177 million, or 13%.

Gross profit for the three months ended September 30, 2011 was \$658.4 million and gross margins were 41.8%. For the three months ended September 30, 2010, gross profit was \$580.1 million, and gross margins were 42.8%. Gross profit for the current quarter is impacted by certain purchase accounting related items, of approximately \$104.1 million, as noted above. Excluding such items, gross margins would have been approximately 48%. Prior year gross profit is also impacted by similar purchase accounting related items in the amount of \$74.6 million. Excluding such items, gross margins in the prior year would have been approximately 48%.

From time to time, a limited number of our products may represent a significant portion of our net revenues, gross profit and net earnings. Generally, this is due to the timing of new product launches and the amount, if any, of additional competition in the market. Our top ten products in terms of sales, in the aggregate, represented approximately 27% of total revenues in the three months ended September 30, 2011.

#### **Generics** Segment

For the current quarter, Generics third party net revenues were \$1.36 billion compared to \$1.20 billion in the comparable prior year period, an increase of \$154.5 million, or 12.8%. Translating Generics third party net revenues for the current quarter at prior year quarter foreign currency exchange rates would have resulted in year-over-year growth of approximately \$104 million, or 9%. This increase is primarily driven by increased revenue in North America, partially offset by a decrease in Europe, Middle East and Africa (collectively, EMEA) net revenues as discussed below. Generics sales are derived primarily in or from North America, EMEA and India, Australia, Japan, and New Zealand (collectively, Asia Pacific).

Third party net revenues from North America were \$697.0 million for the current quarter, compared to \$572.5 million for the comparable prior year period, representing an increase of \$124.5 million, or 21.7%. The increase in current year net revenues was driven by new product launches, favorable pricing on existing products and incremental revenue from the Bioniche Pharma Holdings Limited (Bioniche Pharma) acquisition in September 2010. Products generally contribute most significantly to revenues and gross margin at the time of their launch, even more so in periods of market exclusivity or in periods of limited generic competition. As such, the timing of new product introductions can have a significant impact on Mylan s financial results. Products launched by the Company subsequent to September 30, 2010 are considered new products. New product revenue in the current quarter included Mylan s 2011 launch of Budesonide (the generic version of AstraZeneca s Entocort EC<sup>®</sup> capsules). The increase in current quarter third party net revenues from new product launches and, to a lesser extent, acquired businesses, totaled approximately \$103.0 million.

Pricing is often affected by factors outside of the Company s control. The entrance into the market of additional competition generally has a negative impact on the volume and pricing of the affected products.

Third party net revenues from EMEA were \$350.8 million for the three-month period ended September 30, 2011, compared to \$363.5 million for the comparable prior year period, a decrease of \$12.7 million, or 3.5%. Translating current quarter third party net revenues from EMEA at comparable prior year period exchange rates would have resulted in a year-over-year decrease in third party net revenues excluding the effect of foreign currency of approximately \$40 million, or 11%. This decrease was the result of competitive market conditions, which resulted in lower pricing in a number of European markets in which Mylan operates, primarily France and Spain. These decreases were partially offset by continued market share gains in Italy, where local currency revenues increased as compared to the prior year comparative period. Lower volumes on existing products, due mainly to competitive market conditions, were offset by revenue from new product launches.

In addition to the impact that competition in EMEA has had on pricing, certain markets in which we do business, primarily Spain and Italy, have recently undergone government-imposed price reductions, and further government-imposed price reductions are expected in the future. 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, pro-generic government initiatives in certain markets could help to offset some of the unfavorable effect of the price reductions by potentially increasing rates of generic substitution.

A number of markets in which we operate have implemented or may implement tender systems for generic pharmaceuticals in an effort to lower prices. Generally speaking, tender systems can have an unfavorable impact on revenue and profitability. Under such tender systems, manufacturers submit bids which establish prices for generic pharmaceutical products. Upon winning the tender, the winning company will receive a preferential reimbursement for a period of time. The tender system often results in companies underbidding one another by proposing low pricing in order to win the tender. Additionally, the loss of a tender by a third party to whom we supply API can also have a negative impact on our sales and profitability. Sales, primarily in Germany, continue to be negatively affected by the impact of tender systems.

In Asia Pacific, third party net revenues were \$310.6 million for the three-month period ended September 30, 2011, compared to \$267.9 million for the comparable prior year period, an increase of

\$42.7 million, or 15.9%. Excluding the favorable effect of foreign currency translation, calculated as described above, the increase was approximately \$23 million, or 8%. This increase is primarily driven by higher third party sales from India, with growth in third party sales in Japan also contributing.

The increase in third party net revenues in India is due to double-digit growth, excluding the effect of foreign currency, in sales of anti-retroviral (ARV) finished dosage form (FDF) generic products, which are used in the treatment of HIV/AIDS. 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 \$48.4 million for the three months ended September 30, 2011, compared to \$46.6 million in the prior year. 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 overall market growth. In Australia, sales were negatively impacted by lower pricing and volume on existing products, offset partially by new product introductions. As in EMEA, both Australia and Japan 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.

#### Specialty Segment

For the current quarter, Specialty reported third party net revenues of \$213.9 million, an increase of \$72.8 million, or 51.6%, from the comparable prior year period of \$141.1 million. The increase was the result of higher sales of the EpiPen<sup>®</sup> Auto-Injector, which is used in the treatment of severe allergic reactions, and Dey s Perforomist Inhalation Solution. The EpiPen Auto-Injector is the number one epinephrine auto-injector for the treatment of severe allergic reactions with more than 95% market share in the U.S. and more than 90% market share worldwide. The increased sales of the EpiPen Auto-Injector were the result of favorable pricing and increased volumes, while the increased sales of the Perforomist Inhalation Solution were the result of increased volume.

#### **Operating Expenses**

Research and development expense ( R&D ) for the three months ended September 30, 2011 was \$70.8 million, compared to \$72.0 million in the same prior year period, a decrease of \$1.2 million. R&D decreased due primarily to the timing of internal and external product development projects, partially offset by an unfavorable impact from foreign currency.

Selling, general and administrative expense (SG&A) for the current quarter was \$319.4 million, compared to \$272.3 million for the same prior year period, an increase of \$47.1 million. SG&A increased as a result of increased payroll and payroll related costs, increased legal costs primarily due to the timing of certain litigation matters, the EpiPen Auto-Injector direct-to-consumer marketing campaign and an unfavorable impact from foreign currency.

#### Litigation Settlements, net

During the three months ended September 30, 2011, the Company recorded \$2.2 million in net charges for litigation settlements.

#### Interest Expense

Interest expense for the three months ended September 30, 2011, totaled \$85.8 million, compared to \$87.5 million for the three months ended September 30, 2010. The decrease is primarily due to a \$5.0 million decrease in non-cash interest expense, primarily related to the amortization of the discounts on our convertible debt instruments and 2018 Senior Notes, net of amortization of the premium on our 2020 Senior Notes. Included

in interest expense for the current quarter and the comparable prior year period are \$12.6 million and \$17.6 million, primarily related to the amortization of the discounts on our convertible debt instruments and 2018 Senior Notes, net of amortization of the premium on our 2020 Senior Notes.

#### Other Income (Expense), net

Other income (expense), net, was income of \$12.1 million in the current quarter compared to expense of \$15.3 million in the comparable prior year period. Other income (expense), net, includes certain foreign exchange transaction gains and losses and interest and dividend income. Additionally, included in the prior year quarter was 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.

#### Nine Months Ended September 30, 2011, Compared to Nine Months Ended September 30, 2010

#### Total Revenues and Gross Profit

For the current nine-month period, Mylan reported total revenues of \$4.60 billion compared to \$4.02 billion in the comparable prior year period. Third party net revenues for the current nine months were \$4.58 billion compared to \$3.98 billion for the same prior year period, representing an increase of \$599.6 million, or 15.1%. Other third party revenues for the nine months ended September 30, 2011 were \$19.4 million compared to \$36.4 million in the same prior year period, a decrease of \$17.0 million. Translating third party net revenues for the current quarter at prior year comparative period foreign exchange rates would have resulted in year-over-year growth of approximately \$459 million, or 12%.

Gross profit for the nine months ended September 30, 2011 was \$1.92 billion, and gross margins were 41.7%. For the nine months ended September 30, 2010, gross profit was \$1.64 billion, and gross margins were 40.8%. Gross profit for the current year-to-date period is impacted by certain purchase accounting related items, of approximately \$278.1 million, as noted above. Excluding such items, gross margins would have been approximately 48%. Prior year gross profit is also impacted by similar purchase accounting related items in the amount of \$217.6 million. Excluding such items, gross margins in the prior year would have been approximately 46%.

The increase in gross margins, excluding the items noted above, can be attributed to both Generics and Specialty. The improvement in the Generics Segment was primarily the result of new product introductions, principally in North America, while gross margins in the Specialty Segment improved as a result of favorable pricing and volume on the EpiPen Auto-Injector.

From time to time, a limited number of our products may represent a significant portion of our net revenues, gross profit and net earnings. Generally, this is due to the timing of new product launches and the amount, if any, of additional competition in the market. Our top ten products in terms of sales, in the aggregate, represented approximately 23% of total revenues in the nine months ended September 30, 2011.

#### **Generics Segment**

For the nine months ended September 30, 2011, Generics third party net revenues were \$4.14 billion compared to \$3.63 billion in the comparable prior year period, an increase of \$504.7 million, or 13.9%. Translating Generics third party net revenues for the current quarter at prior year foreign currency exchange rates would have resulted in year-over-year growth of approximately \$364 million, or 10%.

Third party net revenues from North America were \$2.12 billion for the nine-month period, compared to \$1.71 billion for the comparable prior year period, representing an increase of \$406.5 million, or 23.7%. The increase in current year net revenues was primarily driven by new product launches, incremental revenue from the Bioniche Pharma acquisition in September 2010 and increased sales of certain existing products. The effect of foreign currency translation was insignificant within North America.

The increase in current year third party net revenues from new product launches and, to a lesser extent, acquired businesses, totaled approximately \$357.9 million.

North American third party net revenues from existing products increased year over year as a result of higher volumes, partially offset by a decrease in pricing. The lower pricing in the nine-month period was generally the result of increased competition on existing products. The entrance into the market of additional competition generally has a negative impact on the volume and pricing of the affected products. The effect of foreign currency translation was insignificant within North America.

Third party net revenues from EMEA were \$1.12 billion for the nine-month period ended September 30, 2011, compared to \$1.15 billion for the comparable prior year period, a decrease of \$30.3 million, or 2.6%. Translating current nine-month period third party net revenues from EMEA at comparable prior year period exchange rates would have resulted in a decrease in third party net revenues excluding the effect of foreign currency of approximately \$99 million, or 9%. This decrease was mainly the result of competitive market conditions, which resulted in lower pricing and volume in a number of the European markets in which Mylan operates, primarily France, the United Kingdom and Germany, partially offset by strong performance in Italy and new product revenue.

Local currency revenues from Mylan s business in France decreased as compared to the prior year as a result of the impact of lower pricing and volume due to an increasingly competitive market, partially offset by new product launches. Local currency revenues in Italy increased as a result of successful product launches and increased market penetration, which has favorably affected sales volume, partially offset by lower pricing due to government-imposed price reductions.

In addition to the impact that competition in EMEA has had on pricing, certain markets in which we do business, primarily Spain and Italy, have recently undergone government-imposed price reductions, and further government-imposed price reductions are expected in the future. 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, pro-generic government initiatives in certain markets could help to offset some of the unfavorable effect of the price reductions by potentially increasing rates of generic substitution.

A number of markets in which we operate have implemented or may implement tender systems for generic pharmaceuticals in an effort to lower prices. Generally speaking, tender systems can have an unfavorable impact on revenue and profitability. Under such tender systems, manufacturers submit bids which establish prices for generic pharmaceutical products. Upon winning the tender, the winning company will receive a preferential reimbursement for a period of time. The tender system often results in companies underbidding one another by proposing low pricing in order to win the tender. Additionally, the loss of a tender by a third party to whom we supply API can also have a negative impact on our sales and profitability. Sales, primarily in Germany, continue to be negatively affected by the impact of tender systems.

In Asia Pacific, third party net revenues were \$897.6 million for the nine-month period ended September 30, 2011, compared to \$769.1 million for the comparable prior year period, an increase of \$128.5 million, or 16.7%. Excluding the favorable effect of foreign currency translation, calculated as described above, the increase was approximately \$65 million, or 8%. This increase is primarily driven by higher third party sales in India and Japan.

The increase in third party net revenues in India is due to double-digit growth, excluding the effect of foreign currency, in sales of both ARV 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 \$158.5 million for the nine months ended September 30, 2011, compared to \$110.6 million in the prior year. 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 through new product launches and overall market growth. In Australia, sales were negatively impacted by lower pricing and an unfavorable product mix. 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.

#### Specialty Segment

For the nine months ended September 30, 2011, Specialty reported third party net revenues of \$442.7 million, an increase of \$94.9 million, or 27.3%, from the comparable prior year period of \$347.8 million. The increase was the result of higher sales of the EpiPen Auto-Injector and the Perforomist Inhalation Solution. The increased sales of the EpiPen Auto-Injector were the result of favorable pricing and increased volume, while the increased sales of the Perforomist Inhalation Solution were the result of increased volume.

#### **Operating Expenses**

R&D expense for the nine months ended September 30, 2011 was \$218.7 million, compared to \$200.1 million in the same prior year period, an increase of \$18.6 million. R&D increased due primarily to the timing of internal and external product development projects, including those related to Bioniche Pharma, which was acquired in September 2010 and is part of our Mylan Institutional business, and an unfavorable impact from foreign currency.

SG&A expense for the nine months ended September 30, 2011 was \$913.6 million, compared to \$796.4 million for the same prior year period, an increase of \$117.2 million. SG&A increased as a result of increased payroll and payroll related costs, increased legal costs primarily due to the timing of certain litigation matters and an unfavorable impact from foreign currency.

#### Litigation Settlements, net

During the nine months ended September 30, 2011, we recorded net unfavorable litigation charges of \$28.5 million related to the potential settlement of certain ongoing matters. During the nine months ended September 30, 2010, we recorded net unfavorable litigation charges of \$14.3 million.

#### Interest Expense

Interest expense for the nine months ended September 30, 2011, totaled \$254.8 million, compared to \$240.0 million for the nine months ended September 30, 2010. The increase is primarily due to interest associated with the 2017, 2018 and 2020 Senior Notes debt offerings in 2010, partially offset by lower overall debt balances on the company s Senior Credit Facility and a decrease in non-cash interest. Included in interest expense for the current nine months and the comparable prior year period are \$36.8 million and \$42.0 million, primarily related to the amortization of the discounts on our convertible debt instruments and 2018 Senior Notes, net of amortization of the premium on our 2020 Senior Notes.

#### Other Income (Expense), net

Other income (expense), net, was income of \$22.5 million in the current nine-month period compared to expense of \$29.4 million in the comparable prior year period. Included in other income (expense), net, are certain foreign exchange gains and losses and interest and dividend income. Additionally, included in the prior year are 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 prior period, 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.

#### Liquidity and Capital Resources

Our primary source of liquidity is cash provided by operations. We believe that cash provided by operating activities and available liquidity 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.

Net cash provided by operating activities decreased by \$310.6 million to \$426.3 million for the nine months ended September 30, 2011, as compared to \$736.9 million for the nine months ended September 30, 2010. The net decrease in cash provided by operating activities was principally due to the following:

a net decrease in the amount of cash provided by changes in accounts receivable of \$147.0 million, as a result of higher receivable balances at September 30, 2011 due principally to the increase in sales in the current quarter;

a net increase of \$112.2 million in the amount of cash used by changes in inventory balances. In the current year, inventories increased to support an expected increase in future demand, whereas in the prior year, inventory balances decreased as a result of the timing of shipments;

a net increase in the amount of cash used through changes in accounts payable of \$60.3 million as a result of an increase in purchases to support inventory demand combined with the timing of cash payments;

a net decrease in the amount of cash provided by changes in income taxes of \$35.1 million, driven primarily by the receipt of an income tax refund of approximately \$99 million in 2010 and the timing of income tax payments in 2011;

a payment of \$60.4 million to Merck KGaA related to the income tax benefits on indemnified litigation; and

an increase in payments for the settlement of litigation of approximately \$55 million. These net decreases were partially offset by an increase in net income of \$84.2 million, which includes an increase in non-cash depreciation and amortization expense of \$76.6 million.

Cash used in investing activities was \$153.1 million for the nine months ended September 30, 2011, as compared to \$620.7 million for the nine months ended September 30, 2010, a decrease of \$467.6 million. Cash flows from investing activities for the nine months ended September 30, 2010 included cash paid for acquisitions of \$556.1 million. Excluding these acquisitions, cash flows used in investing activities increased \$88.4 million primarily as a result of an increase in capital expenditures. Capital expenditures, primarily for equipment, were \$168.5 million in the current year. The increase over 2010 is the result of our previously announced planned expansions and integration plans, and includes the timing of expenditures. While there can be no assurance that current expectations will be realized, capital expenditures for the 2011 calendar year are expected to be between \$250 million and \$300 million.

Cash used in financing activities was \$412.3 million for the nine months ended September 30, 2011, as compared to a cash inflow of \$128.3 million for the nine months ended September 30, 2010. Cash used in financing activities in the current year consists primarily of approximately \$350.0 million used to repurchase approximately 14.8 million shares of common stock as part of a repurchase program completed during the second quarter and \$150.0 million used for the amendment and exchange of the warrants outstanding on the Cash Convertible Notes.

In the prior year nine-month period, we generated cash proceeds from the net issuance of long-term debt totaling \$264.1 million. In May 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,

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%. In the prior year nine-month period, payments of long-term debt totaled approximately \$1.30 billion.

We believe that through the foregoing 2010 capital market transactions, Mylan s debt maturity schedule was substantially improved. Mylan has no significant debt maturities in 2011. The Company has \$725 million due in 2012 and \$125 million due in 2013. Our current intention is to repay such amounts at maturity using available liquidity.

As of September 30, 2011, 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, 2011 period was more than 130% of the applicable conversion reference price of \$13.32, the \$575.0 million of Cash Convertible Notes were 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 (75.0751 as of October 1, 2011) 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. Should holders elect to convert, we intend to draw on our revolving credit facility to fund any principal payments. The facility is a secured revolving credit agreement expiring in October 2013, with available capacity of approximately \$705 million at September 30, 2011.

We are involved in various legal proceedings that are considered normal to our business. While it is not feasible 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, including our operating cash flow. We have approximately \$200 million accrued for such legal contingencies. 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 effect on our financial position, results of operations or cash flows.

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, 2011 and December 31, 2010, we had \$79.1 million and \$85.4 million outstanding under existing letters of credit. Additionally, as of September 30, 2011, we had \$54.8 million available under the \$100.0 million subfacility on our Senior Credit Agreement for the issuance of letters of credit.

Mandatory minimum repayments remaining on the outstanding borrowings under the term loans and notes at notional amounts at September 30, 2011 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	2018 Senior Notes	2020 Senior Notes	Total
2011	\$	\$	\$	\$	(In thousands \$	s) \$	\$	\$	\$
2012	117,923	Ψ	7,067	600,000	Ψ	Ψ	Ψ	Ŧ	÷ 724,990
2013	117,924		7,067						124,991
2014		500,000	664,300						1,164,300
2015					575,000				575,000
Thereafter						550,000	800,000	1,000,000	2,350,000
Total	\$ 235,847	\$ 500,000	\$ 678,434	\$ 600,000	\$ 575,000	\$ 550,000	\$ 800,000	\$ 1,000,000	\$ 4,939,281

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. In May 2011, the Senior Credit Agreement was amended to increase the minimum amount of other restricted payments permitted under the Senior Credit Agreement from \$50 million to \$300 million. The Senior Credit Agreement also 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 2011, and expect to remain in compliance for the next twelve months.

In October 2011, the Company announced that it intends to refinance its existing Senior Credit Agreement. The proposed \$2.25 billion facility is expected to be comprised of a \$1 billion revolving credit facility and a \$1.25 billion Term Loan A. The facility is expected to have a five year term and include customary terms and covenants. The facility is expected to close in the fourth quarter of 2011, subject to market and other customary conditions.

#### **Application of Critical Accounting Policies**

There have been no changes to the Critical Accounting Policies disclosed in our Annual Report on Form 10-K for the year ended December 31, 2010. The following discussion supplements our Critical Accounting Policy for Intangible Assets and Goodwill as it relates to our annual Goodwill impairment test.

We test goodwill for possible impairment on an annual basis and at any other time events occur or circumstances indicate that the carrying amount of goodwill may be impaired. Goodwill is allocated among and evaluated for impairment at the reporting unit level, which is defined as an operating segment or one level below an operating segment. Mylan has four reporting units, of which three are included in the Generics segment with the remaining reporting unit consisting of our Specialty segment. As of the date of our most recent annual impairment test, April 1, 2011, approximately 90% of Mylan s total goodwill is allocated to the three reporting units within the Generics segment as follows: North America (\$810 million), EMEA (\$1,229 million) and Asia Pacific (\$1,295 million), with the remainder (\$322 million) allocated to our Specialty segment and reporting unit.

The first step of our annual impairment analysis consisted of a comparison of the estimated fair value of the individual reporting units with their carrying amount, including goodwill. In estimating each reporting unit s fair value, we performed extensive valuation analyses, utilizing both income and market-based approaches, in our

goodwill assessment process. We utilize an average of the two methods in estimating the fair value of the individual reporting units. The following describes the valuation methodologies used to derive the estimated fair value of the reporting units.

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

*Market-Based Approach:* The Company also utilizes a market-based approach to estimate fair value, principally utilizing the guideline company method which focuses on comparing our risk profile and growth prospects to a select group of publicly traded companies with reasonably similar guidelines.

The Company performed its annual impairment test as of April 1, 2011, and the estimated fair value of three of the four reporting units was well in excess of the carrying value of these reporting units. For the Asia Pacific reporting unit, the estimated fair value of this business exceeded its carrying value by approximately 10%. The Asia Pacific reporting unit has been impacted by government pricing reform measures in Australia and Japan and increased levels of competition. As it relates to the income approach for the Asia Pacific unit, we forecasted cash flows for the next nine years. During the forecast period, the revenue compound annual growth rate (CAGR) was approximately 10%. A terminal value year was calculated with a 4% revenue growth rate. The CAGR in EBITDA margins was approximately 1% over the period of estimated cash flows. The discount rate utilized was 11.5%. Under the market-based approach, we utilized an estimated range of market multiples of 7.5 to 9.5 times EBITDA plus a control premium of 10%. The averaging of the two valuation methods did not significantly impact the estimated fair value of the Asia Pacific reporting unit.

The determination of the fair value of the reporting units requires us to make significant estimates and assumptions that affect the reporting unit s expected future cash flows. These estimates and assumptions primarily include, but are not limited to, market multiples, control premiums, the discount rate, terminal growth rates, operating income before depreciation and amortization, and capital expenditures forecasts. Due to the inherent uncertainty involved in making these estimates, actual results could differ from those estimates. In addition, changes in underlying assumptions, especially as it relates to the key assumptions detailed above for the Asia Pacific reporting unit, could have a significant impact on the fair value of the reporting units.

In the event the estimated fair value of a reporting unit is less than the carrying value, additional analysis would be required. The additional analysis would compare the carrying amount of the reporting unit s goodwill with the implied fair value of that goodwill. The implied fair value of goodwill is the excess of the fair value of the reporting unit over the fair value amounts assigned to all of the assets and liabilities of that unit as if the reporting unit was acquired in a business combination and the fair value of the reporting unit represented the purchase price. If the carrying value of goodwill exceeds its implied fair value, an impairment loss equal to such excess would be recognized, which would likely materially impact the Company s reported results of operations.

#### 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, 2011. Based upon that evaluation, the Principal Executive Officer and the Principal Financial Officer concluded that the Company s disclosure controls and procedures were effective.

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

#### PART II OTHER INFORMATION

#### ITEM 1. LEGAL PROCEEDINGS

For information regarding legal proceedings, refer to Note 14, Contingencies, in the accompanying Notes to Condensed Consolidated Financial Statements in this Quarterly Report.

#### ITEM 1A. RISK FACTORS

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

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

Over the past few years, the global economy has undergone a period of unprecedented volatility, and the economic environment may continue to be less favorable than that of past years. In particular the risk of a debt default by certain European countries or deficit reduction programs instituted by the U.S. government could negatively impact the global economy. This has led, and/or could lead, to reduced consumer and customer spending and/or reduced or eliminated third party payor coverage or reimbursement 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, customers reduce spending or purchases, and/or reduced third party payor coverage or reimbursement amounts. In addition, reduced consumer and customer spending and/or reduced third party payor coverage or reimbursement, may drive us and our competitors to decrease prices and may reduce the ability of customers to pay due balances. These conditions may have a material adverse effect on 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 the former Matrix Laboratories Limited, as well as the acquisition of Bioniche Pharma in September 2010. 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., and operating globally exposes us to certain additional risks including, but not limited to:

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

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

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

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

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

supply disruptions, and increases in energy and transportation costs;

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

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. Furthermore, whether due to language, cultural or other differences, statements we make may be misinterpreted, misconstrued or taken out of context. 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.

#### A SIGNIFICANT PART OF OUR BUSINESS IS LOCATED IN INDIA AND 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, Mylan s Indian subsidiary, Mylan Laboratories Limited, 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 and the conduct of our business 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 Mylan Laboratories Limited 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, Mylan Laboratories Limited might not be able to continue its operations. We generally do not have insurance for losses and interruptions caused by terrorist attacks, military conflicts and wars. These risks could cause a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

#### MOVEMENTS IN FOREIGN CURRENCY EXCHANGE RATES COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

A significant portion of our revenues, indebtedness and other liabilities and our costs are denominated in foreign currencies, including the Euro, the Australian Dollar, the British Pound, the Canadian Dollar, 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 exposures 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 anti-bribery laws in other jurisdictions, including new anti-bribery legislation in the U.K. that took effect on July 1, 2011, generally prohibit companies and their intermediaries from making improper payments for the purpose of obtaining or retaining business or other commercial advantage. Our policies mandate compliance with these anti-bribery laws, which often carry substantial penalties. We operate in jurisdictions that have experienced governmental and private sector 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 the supply of product meeting specifications and terms such as license scope or termination rights. The development and commercialization process, particularly with regard to new drugs, also requires substantial time, effort and financial resources. We, or a partner, may not be successful in commercializing any of such products on a timely basis, if at all, which could adversely affect our business, financial position and results of operations and could cause the market value of our common stock to decline.

Before any prescription drug product, including generic drug products, can be marketed, marketing authorization approval is required by the relevant regulatory authorities and/or national regulatory agencies (for example the FDA in the U.S. and the 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. Bioequivalence studies conducted in one country may not be accepted in other 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. However, our ability to obtain 180 days of generic marketing exclusivity may be dependent upon our ability to obtain FDA approval or tentative approval within 30 months of the FDA s acceptance of our ANDA. If we are unable to obtain approval or tentative approval within that time period, we may risk forfeiture of such marketing exclusivity. 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 patents which the brand alleges are relevant, for example, new formulations, the owner of the original brand pharmaceutical may be able to obtain a preliminary injunction in certain European jurisdictions delaying launch of the generic product, depending on local court practices and/or the relevance of the asserted patents.

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

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

Much of our development effort is focused on technically difficult-to-formulate products and/or products that require advanced manufacturing technology. We conduct research and development primarily to enable us to manufacture and market approved pharmaceuticals in accordance with applicable regulations. We also partner with third parties to develop products. Typically, research expenses related to the development of innovative compounds and the filing of marketing authorization applications for innovative compounds (such as 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 change standards and/or request that we conduct additional studies and, as a result, we may incur total research and development costs to develop a particular product in excess of what we anticipated. 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 subject to market withdrawal or recall or 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 product quality, illness or other adverse effects resulting from, or perceived to be resulting from, our products could have

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

#### THE ILLEGAL DISTRIBUTION AND SALE BY THIRD PARTIES OF COUNTERFEIT VERSIONS OF OUR PRODUCTS OR OF STOLEN PRODUCTS COULD HAVE A NEGATIVE IMPACT ON OUR REPUTATION AND A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

The drug supply has been increasingly challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the Internet. The World Health Organization (WHO) 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 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 and may differ in various countries. Any patents we have obtained, or obtain in the future, may be challenged, invalidated or circumvented. Moreover, the U.S. Patent and Trademark Office or any other governmental agency may commence interference proceedings involving our patents or patent applications. Any challenge to, or invalidation or circumvention of, our patents or patent applications would be costly, would require significant time and attention of our management, could cause a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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

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

proprietary processes or delivery systems;

larger research and development and marketing staffs;

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;

# Edgar Filing: MYLAN INC. - Form 10-Q

launching a generic version of their own branded product at the same time generic competition initially enters the market;

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

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

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

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

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

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

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

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

In the U.S., some companies have lobbied Congress for amendments to the Hatch-Waxman legislation that would give them additional advantages over generic competitors. For example, although the term of a company s drug patent can be extended to reflect a portion of the time 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 we use our business judgment and decide to market and sell products, notwithstanding the fact that allegations of patent infringement(s) have not been finally resolved by the courts (i.e., an at-risk launch situation). The risk involved in doing so can be substantial because the remedies available to the owner of a patent for infringement may include, among other things, damages measured by the profits lost by the patent owner and not necessarily by the profits earned by the infringer. In the case of a willful infringement, the definition of which is subjective, such damages may be trebled. Moreover, because of the discount pricing typically involved with bioequivalent products, patented branded products generally realize a substantially higher profit margin than bioequivalent products. An adverse decision in a case such as this or in other similar litigation could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

#### OUR SPECIALTY BUSINESS DEVELOPS, FORMULATES, MANUFACTURES OR IN-LICENSES AND MARKETS BRANDED PRODUCTS THAT ARE SUBJECT TO RISKS. THESE RISKS COULD CAUSE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Our branded products developed, formulated, manufactured (or alternatively, in-licensed) and marketed by our specialty business may be subject to the following risks, among others:

limited patent life, or the loss of patent protection;

competition from generic products;

reductions in reimbursement rates by third-party payors;

importation by consumers;

product liability;

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

unpredictability with regard to establishing a market.

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

# A RELATIVELY SMALL GROUP OF PRODUCTS MAY REPRESENT A SIGNIFICANT PORTION OF OUR 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 revenues, gross profit and net earnings. For the three and nine months ended September 30, 2011, our top ten products in terms of sales, in the aggregate, represented approximately 27% and 23% of our consolidated total revenues. 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 REVENUES ARE DERIVED FROM SALES TO A LIMITED NUMBER OF CUSTOMERS. ANY SIGNIFICANT REDUCTION OF BUSINESS WITH ANY OF THESE CUSTOMERS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS, AND THE MARKET VALUE OF OUR COMMON STOCK COULD DECLINE.

A significant portion of our revenues are 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.

# Edgar Filing: MYLAN INC. - Form 10-Q

#### 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.

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

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

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

We utilize controlled substances in certain of our current products and products in development and therefore must meet the requirements of the Controlled Substances Act of 1970 and the related regulations administered by the 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 AND CERTAIN THIRD PARTY SUPPLIERS 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 and certain third party suppliers. A significant disruption at any one of the facilities within our internal or third party supply chain, even on a short-term basis, whether due to a labor strike, failure to reach acceptable agreement with labor and unions, adverse quality or compliance observation, act of God, civil or political unrest, or other events could impair our ability to produce and ship products to the market on a timely basis and could, among other consequences, subject us to exposure to claims from customers. Any of these events could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

#### BECAUSE THE PHARMACEUTICAL INDUSTRY IS HEAVILY REGULATED, WE FACE SIGNIFICANT COSTS AND UNCERTAINTIES ASSOCIATED WITH OUR EFFORTS TO COMPLY WITH APPLICABLE REGULATIONS. SHOULD WE FAIL TO COMPLY, WE COULD EXPERIENCE MATERIAL ADVERSE EFFECTS ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS, AND THE MARKET VALUE OF OUR COMMON STOCK COULD DECLINE.

The pharmaceutical industry is subject to regulation by various governmental authorities. For instance, we must comply with requirements of the FDA and similar requirements of similar agencies in our other markets with respect to the research, development, manufacture, quality, safety, labeling, sale, distribution, marketing, advertising, promotion and development of pharmaceutical products. Failure to comply with regulations of the FDA and other regulators could result in fines, disgorgement, unanticipated compliance expenditures, rejection or delay in approval of applications, recall or seizure of products, total or partial suspension of production and/or distribution, our inability to sell products, the return by customers of our products, 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, or if any of the noted risks occur, 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 and other regulatory standards at one of our manufacturing facilities could result in an enforcement action brought by the FDA or other regulatory bodies which could include

withholding or withdrawing the approval of our submissions or other product applications of that facility, discontinuation of manufacture, recalls, or other adverse actions. If any regulatory body were to withhold or withdraw approval of an application, or require a recall or other adverse product action, or 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 and those related to climate change. 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 such 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 or other controls, or if we are found to have violated any applicable rules, we may be required to expend significant funds. Such changes could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

#### OUR REPORTING AND PAYMENT OBLIGATIONS UNDER THE MEDICARE AND/OR MEDICAID REBATE PROGRAM AND OTHER GOVERNMENTAL PURCHASING AND REBATE PROGRAMS ARE COMPLEX AND MAY INVOLVE SUBJECTIVE DECISIONS THAT COULD CHANGE AS A RESULT OF NEW BUSINESS CIRCUMSTANCES, NEW REGULATORY GUIDANCE, OR ADVICE OF LEGAL COUNSEL. ANY DETERMINATION OF FAILURE TO COMPLY WITH THOSE OBLIGATIONS COULD SUBJECT US TO PENALTIES AND SANCTIONS WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS, AND THE MARKET VALUE OF OUR COMMON STOCK COULD DECLINE.

The regulations regarding reporting and payment obligations with respect to Medicare and/or Medicaid reimbursement and rebates and other governmental programs are complex. Because our processes for these calculations and the judgments involved in making these calculations involve, and will continue to involve, subjective decisions and complex methodologies, these calculations are subject to the risk of errors. In addition, they are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in material changes. The Patient Protection and Affordable Care Act ( PPACA ) of 2010 included a provision requiring the Centers for Medicare and Medicaid Services ( CMS ) to publish a weighted average Average Manufacturer Price ( AMP ) for all multi-source drugs. The provision was effective October 1, 2010; however, weighted average AMP s have not yet been published by CMS. Although the weighted average AMP would not reveal Mylan s individual AMP, publishing a weighted average AMP available to 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 Mylan relating to the sales, marketing, pricing, quality, or manufacturing of pharmaceutical products could seek to 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 reimbursements or subsidies 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.

# 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. 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 PPACA and The Health Care and Education and Reconciliation Act of 2010 (H.R. 4872), which amends the PPACA (collectively the Health Reform Laws ), were signed into law in March 2010. While the Health Reform Laws may increase the number of patients who have insurance coverage for our products, they also include provisions such as the assessment of a pharmaceutical manufacturer fee and an increase in the amount of rebates that manufacturers pay for coverage of their drugs by Medicaid programs.

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

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

If significant additional reforms are made to the U.S. healthcare system, or to the healthcare systems of other markets in which we operate, those reforms could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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

We are or may be involved in various legal proceedings and certain government inquiries, including, but not limited to, patent infringement, product liability, antitrust matters, breach of contract and claims involving Medicare and/or Medicaid reimbursements, or laws relating to sales and marketing practices, 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, including but not limited to civil or criminal fines and penalties and exclusion from participation in various government healthcare-related programs. 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 a combination of self-insurance (including through our wholly-owned captive insurance subsidiary) and 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 indemnifies and, accordingly, there can be no assurance that we will receive the full benefits of such indemnification, which could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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

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

#### UNANTICIPATED CHANGES IN OUR TAX PROVISIONS OR EXPOSURE TO ADDITIONAL INCOME TAX LIABILITIES COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

We are subject to income taxes in the U.S. and many foreign jurisdictions. Significant judgment is required in determining our worldwide provision for income taxes. In the ordinary course of business, there are many transactions and calculations where the ultimate tax determination is uncertain. The final determination of any tax audits or related litigation could be materially different from our historical income tax provisions and accruals.

Additionally, changes in the effective tax rate as a result of a change in the mix of earnings in countries with differing statutory tax rates, changes in our overall profitability, changes in the valuation of deferred tax assets and liabilities, the results of audits and the examination of previously filed tax returns by taxing authorities and continuing assessments of our tax exposures could impact our tax liabilities and affect our income tax expense, which could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

#### 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.

On September 19, 2011, President Obama submitted to the Joint Select Committee on Deficit Reduction five international tax reform proposals that the Administration stated would reduce the deficit by approximately \$112 billion over 10 years. Those measures would defer deduction of interest expense related to deferred income; determine the foreign tax credit on a pooling basis; tax currently excess returns associated with transfers of intangibles offshore; clarify the definition of intangible property for purposes of Internal Revenue Code sections 367(d) and 482 to prevent inappropriate shifting of income outside the United States; and limit earnings stripping by expatriated entities. We cannot determine whether these proposals will be modified or enacted, whether other proposals unknown at this time will be made or the extent to which the corporate tax rate might be reduced and ameliorate the adverse impact of these proposals. 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 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.

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

Our high level of indebtedness could have important consequences, including but not limited to:

increasing our vulnerability to general adverse economic and industry conditions;

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

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

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

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

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

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

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

restricting us from exploiting business opportunities;

increasing our cost of borrowings; and

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

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 and our bond indentures 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. If global credit markets return to their recent levels of contraction, 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.

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

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 CONVERTIBLE 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 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 potential cash payments required to be made by us upon the cash settlement value (issuance of common stock) upon the conversion of the notes. We have also entered into respective warrant transactions with the counterparties pursuant to which we will have sold to each counterparty warrants for the purchase of shares of our common stock. Together, each of the note hedges and warrant transactions are expected to provide us with some protection against increases in our stock price over the conversion price per share. However, there is no assurance that these transactions will remain in effect at all times. Also, although we believe the counterparties are highly rated financial institutions, there are no assurances that the counterparties will be able to perform their respective obligations under the agreement we have with each of them. Any net exposure related to conversion of the notes or any failure of the counterparties to perform their obligations under the agreements we have with them could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

#### 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. We also may inherit legal, regulatory and other risks that accrued prior to the acquisition, whether known or unknown to us. These factors could impair our growth and ability to compete, require us to focus additional resources on integration of operations rather than other profitable areas, or otherwise cause a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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

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

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

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

#### 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 Mylan to provide reasonable assurance with respect to its financial reports. We are spending a substantial amount of management time and resources to comply with laws, regulations and standards relating to corporate governance and public disclosure. In the U.S., such regulations include the Sarbanes-Oxley Act of 2002, 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 attestation 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 we fail to maintain the adequacy of our internal controls, including any failure to implement required new or improved controls, this could have a material adverse effect on our business, financial position and results of operations, and the market value of our common stock could decline.

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

The Consolidated and Condensed Consolidated Financial Statements included in the periodic reports we file with the SEC are prepared in accordance with GAAP. The preparation of financial statements in accordance with GAAP involves making estimates, judgments and assumptions that affect reported amounts of assets, liabilities,

revenues, expenses and income. Estimates, judgments and assumptions are inherently subject to change in the future and any necessary revisions to prior estimates, judgments or assumptions could lead to a restatement. 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 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Issuer Purchases of Equity Securities:

Period	Total Number of Shares Purchased <sup>(1)(2)</sup>	Average Price Paid per Share <sup>(3)</sup>	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs	
April 1 - April 30, 2011					
May 1 - May 31, 2011	12,341,182	\$ 23.90	12,341,182	\$	55,054,643
June 1 - June 30, 2011	2,431,824	\$ 22.64	2,431,824		
Total	14,773,006	\$ 23.69	14,773,006	\$	

<sup>(1)</sup> On May 3, 2011, the Company announced that its Board of Directors had approved the repurchase of up to \$350 million of the Company s common stock and other securities, either in the open market or through privately-negotiated transactions. The repurchase was completed by June 30, 2011.

<sup>(2)</sup> The number of shares purchased is based on the purchase date and not the settlement date.

#### <sup>(3)</sup> Average price per share includes commissions. **ITEM 5.** *OTHER INFORMATION*

#### Potential Stock Sales in Connection with Expiring Stock Options.

Several directors of the Company, namely Robert J. Coury, Wendy Cameron, Douglas J. Leech, and Randall L. Vanderveen, Ph.D, R.Ph, have stock options that will expire during 2012 if not exercised, some as early as February. These options cover a total of 939,375 shares of our common stock. The directors may exercise these stock options prior to their expiration dates either by paying the exercise price in cash, by selling a sufficient number of shares of Mylan common stock to cover the exercise price and the related tax obligations, or by other methods permitted under the applicable plan and option agreements. The directors also may establish 10b5-1 plans in order to permit sales of common stock, without regard to whether they may be in possession of material, non-public information at the time of sale, for the purpose of funding the exercise price and any tax obligations related to the exercise of these or other stock options.

# 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.

# Edgar Filing: MYLAN INC. - Form 10-Q

- 4.1(c) Amendment No. 2 to Rights Agreement dated as of August 13, 2004, between the registrant and American Stock Transfer & Trust Company, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on August 16, 2004, and incorporated herein by reference.
- 4.1(d) Amendment No. 3 to Rights Agreement dated as of September 8, 2004, between the registrant and American Stock Transfer & Trust Company, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on September 9, 2004, and incorporated herein by reference.

- 4.1(e) Amendment No. 4 to Rights Agreement dated as of December 2, 2004, between the registrant and American Stock Transfer & Trust Company, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on December 3, 2004, and incorporated herein by reference.
- 4.1(f) Amendment No. 5 to Rights Agreement dated as of December 19, 2005, between the registrant and American Stock Transfer & Trust Company, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on December 19, 2005, and incorporated herein by reference.
- 4.2(a) Indenture, dated as of July 21, 2005, between the registrant and The Bank of New York, as trustee, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on July 27, 2005, and incorporated herein by reference.
- 4.2(b) Second Supplemental Indenture, dated as of October 1, 2007, among the registrant, the Subsidiaries of the registrant listed on the signature page thereto and The Bank of New York, as trustee, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on October 5, 2007, and incorporated herein by reference.
- 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.
- 4.6 Indenture, dated as of November 24, 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 November 24, 2010, and incorporated herein by reference.
- 10.1 Amendment, dated September 9, 2011, to the Confirmation of OTC Warrant Transaction, dated September 9, 2008, among the Company, Merrill Lynch International and Merrill Lynch Pierce, Fenner & Smith Incorporated.
- 10.2 Amendment, dated September 13, 2011, to the Confirmation of OTC Warrant Transaction, dated September 9, 2008, between the Company and Goldman, Sachs & Co., as successor to Wells Fargo Bank, National Association.
- 10.3 Amendment, dated September 14, 2011, to the Confirmation of OTC Warrant Transaction, dated September 9, 2008, between the Company and Goldman, Sachs & Co., as successor to Wells Fargo Bank, National Association.
- 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.DEF XBRL Taxonomy Definition Linkbase
- 101.LAB XBRL Taxonomy Extension Label Linkbase
- 101.PRE XBRL Taxonomy Extension Presentation Linkbase

#### 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 26, 2011

October 26, 2011

October 26, 2011

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

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

# EXHIBIT INDEX

- 10.1 Amendment, dated September 9, 2011, to the Confirmation of OTC Warrant Transaction, dated September 9, 2008, among the Company, Merrill Lynch International and Merrill Lynch Pierce, Fenner & Smith Incorporated.
- 10.2 Amendment, dated September 13, 2011, to the Confirmation of OTC Warrant Transaction, dated September 9, 2008, between the Company and Goldman, Sachs & Co., as successor to Wells Fargo Bank, National Association.
- 10.3 Amendment, dated September 14, 2011, to the Confirmation of OTC Warrant Transaction, dated September 9, 2008, between the Company and Goldman, Sachs & Co., as successor to Wells Fargo Bank, National Association.
- 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.DEF XBRL Taxonomy Definition Linkbase
- 101.LAB XBRL Taxonomy Extension Label Linkbase
- 101.PRE XBRL Taxonomy Extension Presentation Linkbase