MEDICINES CO /DE
Form 10-Q
November 09, 2012

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

FORM 10-Q
(Mark One)

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

For the quarterly period ended: September 30, 2012

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 (No Fee Required)

For the transition period from to

Commission file number 000-31191

THE MEDICINES COMPANY
(Exact name of registrant as specified in its charter)

Delaware	04-3324394
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
8 Sylvan Way Parsippany, New Jersey (Address of principal executive offices)	07054 (Zip Code)

Registrant's telephone number, including area code: (973) 290-6000

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 þ No o

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

Yes þ No o

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

Large accelerated filer þ Accelerated filer o Non-accelerated filer o Smaller reporting company o

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes o No þ

As of November 5, 2012 there were 53,804,460 shares of Common Stock, $0.001 par value per share, outstanding (excluding 2,192,982 shares held in the treasury).

THE MEDICINES COMPANY

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Part I. Financial Information

Item 1. Financial Statements

THE MEDICINES COMPANY
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)
(unaudited)

	September 30, 2012	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	$480,389	$315,382
Available for sale securities	64,966	25,130
Accrued interest receivable	414	374
Accounts receivable, net of allowances of approximately $15.1 million and $18.1 million at September 30, 2012 and December 31, 2011, respectively	83,425	74,559
Inventory	62,337	45,145
Deferred tax assets	8,123	9,395
Prepaid expenses and other current assets	12,922	11,738
Total current assets	712,576	481,723
Fixed assets, net	16,540	17,979
Intangible assets, net	120,702	87,329
Goodwill	14,671	14,671
Restricted cash	1,564	4,714
Deferred tax assets, net	72,531	78,441
Other assets	14,950	7,790
Total assets	$953,534	$692,647
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$6,344	$6,587
Accrued expenses	134,398	147,382
Deferred revenue	1,830	666
Total current liabilities	142,572	154,635
Contingent purchase price	22,633	20,431
Convertible senior notes (due 2017)	223,711	—
Other liabilities	6,076	5,939
Total liabilities	394,992	181,005
Stockholders' equity:		
Preferred stock, $1.00 par value per share, 5,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.001 par value per share, 125,000,000 shares authorized; 53,780,319 and 54,313,107 issued and outstanding at September 30, 2012 and December 31, 2011, respectively	56	54
Additional paid-in capital	690,259	623,801
Treasury stock, at cost; 2,192,982 and 0 shares at September 30, 2012 and December 31, 2011, respectively	(50,000)	—
Accumulated deficit	(81,074)	(111,665)
Accumulated other comprehensive loss	(697)	(548)
Total The Medicines Company stockholders' equity	558,544	511,642
Non-controlling interest in joint venture	(2)	—
Total stockholders' equity	558,542	511,642
Total liabilities and stockholders' equity	$953,534	$692,647

See accompanying notes to unaudited condensed consolidated financial statements.

THE MEDICINES COMPANY
CONSOLIDATED STATEMENTS OF INCOME
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Net revenue	$136,786	$120,773	$399,098	$352,501
Operating expenses:				
Cost of revenue	43,767	39,459	125,111	112,859
Research and development	34,536	26,550	100,276	76,878
Selling, general and administrative	43,396	45,353	127,049	124,701
Total operating expenses	121,699	111,362	352,436	314,438
Income from operations	15,087	9,411	46,662	38,063
Legal settlement	—	—	—	17,984
Co-promotion income	3,750	—	6,250	—
Interest expense	(3,605)	—	(4,389)	—
Other income	204	578	963	1,450
Income before income taxes	15,436	9,989	49,486	57,497
(Provision) benefit for income taxes	(6,172)	62,625	(18,897)	50,798
Net income	9,264	72,614	30,589	108,295
Net loss attributable to non-controlling interest	1	—	2	—
Net income attributable to The Medicines Company	$9,265	$72,614	$30,591	$108,295
Basic earnings per common share attributable to The Medicines Company	$0.18	$1.36	$0.57	$2.03
Diluted earnings per common share attributable to The Medicines Company	$0.17	$1.34	$0.55	$2.00
Weighted average number of common shares outstanding:				
Basic	52,896	53,534	53,653	53,414
Diluted	55,145	54,260	55,455	54,242

See accompanying notes to unaudited condensed consolidated financial statements.

THE MEDICINES COMPANY
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(in thousands)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Net income	$9,264	$72,614	$30,589	$108,295
Other comprehensive income (loss):				
Unrealized gain (loss) on available for sale securities	55	(20)	32	—
Foreign currency translation adjustment	453	(817)	(181)	(947)
Other comprehensive income (loss)	508	(837)	(149)	(947)
Comprehensive income	$9,772	$71,777	30,440	107,348

See accompanying notes to unaudited condensed consolidated financial statements.

THE MEDICINES COMPANY
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2012	2011
Cash flows from operating activities:		
Net income	$30,589	$108,295
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	5,401	4,514
Amortization of net premiums and discounts on available for sale securities	513	2,021
Amortization of long term debt financing costs	326	—
Amortization of debt discount	2,908	—
Unrealized foreign currency transaction (gain) losses, net	(498)	596
Non-cash stock compensation expense	11,132	8,376
Loss on disposal of fixed assets	46	310
Deferred tax provision	8,233	(68,385)
Excess tax benefit from share-based compensation arrangements	(1,052)	—
Adjustment to contingent purchase price	2,202	2,817
Changes in operating assets and liabilities:		
Accrued interest receivable	(40)	836
Accounts receivable	(8,852)	(26,011)
Inventory	(17,189)	(4,973)
Prepaid expenses and other current assets	(1,334)	(2,602)
Accounts payable	(38)	1,805
Accrued expenses	(12,955)	32,264
Deferred revenue	1,164	618
Other liabilities	137	128
Net cash provided by operating activities	20,693	60,609
Cash flows from investing activities:		
Purchases of available for sale securities	(65,354)	(33,835)
Proceeds from maturities and sales of available for sale securities	25,036	102,356
Purchases of fixed assets	(695)	(879)
Acquisition of intangible assets	(36,678)	—
Other investments	(500)	—
Decrease in restricted cash	3,148	1,143
Net cash (used in) provided by investing activities	(75,043)	68,785
Cash flows from financing activities:		
Proceeds from issuances of common stock, net	21,606	3,972
Purchase of treasury stock	(50,000)	—
Proceeds from issuance of convertible senior notes	275,000	—
Proceeds from issuance of warrants	38,425	—
Purchase of convertible note hedge	(58,223)	—
Debt issuance costs	(8,774)	—
Excess tax benefit from stock-based compensation arrangements	1,052	—
Net cash provided by financing activities	219,086	3,972
Effect of exchange rate changes on cash	271	(1,695)
Increase in cash and cash equivalents	165,007	131,671
Cash and cash equivalents at beginning of period	315,382	126,364
Cash and cash equivalents at end of period	$480,389	$258,035
Supplemental disclosure of cash flow information:		
Taxes paid	$1,155	$6,783

See accompanying notes to unaudited condensed consolidated financial statements.

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THE MEDICINES COMPANY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

The Medicines Company® name and logo, Angiomax®, Angiox® and Cleviprex® are either registered trademarks or trademarks of The Medicines Company in the United States and/or other countries. All other trademarks, service marks or other tradenames appearing in this quarterly report on Form 10-Q are the property of their respective owners. Except where otherwise indicated, or where the context may otherwise require, references to “Angiomax” in this quarterly report on Form 10-Q mean Angiomax and Angiox collectively. References to “the Company,” “we,” “us” or “our” mean The Medicines Company, a Delaware corporation, and its subsidiaries.

1. Nature of Business

The Medicines Company (the Company) is a global pharmaceutical company focused on advancing the treatment of critical care patients through the delivery of innovative, cost-effective medicines to the worldwide hospital marketplace. The Company has three marketed products, Angiomax® (bivalirudin), Cleviprex® (clevidipine butyrate) injectable emulsion and a ready-to-use formulation of Argatroban. The Company also has a pipeline of acute and intensive care hospital products in development, including three late-stage development product candidates, cangrelor, oritavancin and MDCO-157, and one early stage development product candidate, MDCO-216. The Company believes that its marketed products and products in development possess favorable attributes that competitive products do not provide, can satisfy unmet medical needs in the acute and intensive care hospital product market and offer, or, in the case of its products in development, have the potential to offer, improved performance to hospital businesses. In January 2012, the Company acquired from APP Pharmaceuticals, LLC (APP) non-exclusive rights to market in the United States a portfolio of ten generic drugs, which the Company refers to as its acute care generic products. The Company expects to begin selling certain of those products in the fourth quarter of 2012. In May 2012, as part of the Company's global collaboration agreement with AstraZeneca LP (AstraZeneca), the Company and AstraZeneca commenced a four-year co-promotion arrangement for AstraZeneca's oral antiplatelet medicine BRILINTA® (ticagrelor) tablets in the United States.

2. Significant Accounting Policies

The Company's significant accounting policies are described in note 2 of the notes to the consolidated financial statements included in the Company's annual report on Form 10-K for the year ended December 31, 2011 filed with the Securities and Exchange Commission (SEC).

Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and with the instructions to Form 10-Q. Accordingly, they do not include all the information and footnotes required by GAAP for complete financial statements. In the opinion of management, the accompanying financial statements include all adjustments, consisting of normal recurring accruals, considered necessary for a fair presentation of the Company's financial position, results of operations, and cash flows for the periods presented.

The condensed consolidated financial statements include the accounts of the Company and its wholly owned and majority owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation. The Company records net income (loss) attributable to non-controlling interest, if any, in the Company's consolidated financial statements equal to the percentage of ownership interest retained in the respective

operations by the non-controlling parties. The Company has no unconsolidated subsidiaries or significant investments accounted for under the equity method.

The Company's results of operations for the three and nine months ended September 30, 2012 are not necessarily indicative of the results that may be expected from the Company for the entire fiscal year or the final quarter of the fiscal year ending December 31, 2012. These condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements included in the Company's annual report on Form 10-K for the year ended December 31, 2011, filed with the SEC.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, costs, expenses and accumulated other comprehensive income that are reported in the consolidated financial statements and accompanying disclosures. Actual results may be different. See note 2

of the notes to the consolidated financial statements in the Company's annual report on Form 10-K for the year ended December 31, 2011 for a discussion of the Company's critical accounting policies.

Loss Attributable to Noncontrolling Interest

In 2010, the Company and Windlas Healthcare Private Limited entered into a joint venture in India. Given the Company's majority ownership interest of approximately 99.7% of the joint venture company, the Medicines Company (India) Private Limited, the accounts of the Medicines Company (India) Private Limited have been consolidated with the Company's accounts, and a noncontrolling interest has been recorded for the noncontrolling investors' interests in the equity and operations of the Medicines Company (India) Private Limited. For the three and nine months ended September 30, 2012, the loss attributable to the noncontrolling interest in the Medicines Company (India) Private Limited was approximately $1,000 and $2,000, respectively.

Treasury Stock

Treasury stock is recognized at the cost to reacquire the shares. Shares issued from treasury are recognized utilizing the first-in first-out method.

Contingencies

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company continually assesses litigation to determine if an unfavorable outcome would lead to a probable loss or reasonably possible loss which could be estimated. In accordance with the guidance of the Financial Accounting Standards Board (FASB) on accounting for contingencies, the Company accrues for all contingencies at the earliest date at which the Company deems it probable that a liability has been incurred and the amount of such liability can be reasonably estimated. If the estimate of a probable loss is a range and no amount within the range is more likely than another, the Company accrues the minimum of the range. In the cases where the Company believes that a reasonably possible loss exists, the Company discloses the facts and circumstances of the litigation, including an estimable range, if possible.

Recent Accounting Pronouncements

In June 2011, the FASB issued Accounting Standards Update (ASU) 2011-05, "Presentation of Comprehensive Income" (ASU 2011-05) that requires the presentation 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. ASU 2011-05 also requires presentation of adjustments for items that are reclassified from other comprehensive income to net income in the statement where the components of net income and the components of other comprehensive income are presented. ASU 2011-05 requires retrospective application, and it is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011 and therefore was effective for the Company in its first quarter of 2012. In December 2011, the FASB issued ASU 2011-12, "Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05" to defer the new requirement to present components of reclassifications of other comprehensive income on the face of the financial statements. Companies are still required to adopt the other requirements contained in ASU 2011-05. The Company's adoption of ASU 2011-05 changed the order in which certain financial statements are presented and provides additional detail on those financial statements when applicable, but did not have any other impact on its financial statements. The Company elected to present the total of comprehensive income, the components of net income and the components of other comprehensive income in two separate consecutive statements.

In July 2012, the FASB issued ASU 2012-02, “Testing Indefinite-Lived Intangible Assets for Impairment” (ASU 2012-02). ASU 2012-02 amended the procedures for testing the impairment of indefinite-lived intangible assets by permitting an entity to first assess qualitative factors to determine whether the existence of events and circumstances

indicates that it is more likely than not that the indefinite-lived intangible assets are impaired. An entity's assessment of the totality of events and circumstances and their impact on the entity's indefinite-lived intangible assets will then be used as a basis for determining whether it is necessary to perform the quantitative impairment test as described in Accounting Standard Codification (ASC) 350-30, "Intangibles – Goodwill and Other – General Intangibles Other than Goodwill." ASU 2012-02 will be effective for the Company on January 1, 2013, with early adoption permitted. The adoption of this guidance is not expected to have a significant effect on the Company's consolidated financial statements.

3. Stock-Based Compensation

The Company recorded approximately $3.8 million and $11.1 million of stock-based compensation expense for the three and nine months ended September 30, 2012. The Company recorded approximately $2.9 million and $8.4 million of stock-based compensation expense for the three and nine months ended September 30, 2011. As of September 30, 2012, there was approximately $17.9 million of total unrecognized compensation costs related to non-vested stock-based employee compensation arrangements granted under the Company's equity compensation plans. The Company expects to recognize those costs over a weighted average period of 1.38 years.

During the nine months ended September 30, 2012, the Company issued a total of 1,660,194 shares of its common stock upon the exercise of stock options, pursuant to restricted stock grants and pursuant to purchases under its 2010 employee stock purchase plan (the 2010 ESPP). During the nine months ended September 30, 2011, the Company issued a total of 629,816 shares of its common stock upon the exercise of stock options, pursuant to restricted stock grants and pursuant to purchases under the 2010 ESPP. Cash received from the exercise of stock options and purchases through the 2010 ESPP during the nine months ended September 30, 2012 and September 30, 2011 was approximately $20.1 million and $4.0 million, respectively, and is included within the financing activities section of the consolidated statements of cash flows.

At September 30, 2012, there were an aggregate of 2,760,859 shares of common stock reserved for future issuance under the 2010 ESPP and for future grants under the Company's amended and restated 2004 stock incentive plan.

4. Earnings per Share

The following table sets forth the computation of basic and diluted earnings per share for the three and nine months ended September 30, 2012 and 2011:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
	(in thousands, except per share amounts)			
Basic and diluted				
Net income attributable to The Medicines Company	$9,265	$72,614	$30,591	$108,295
Weighted average common shares outstanding, basic	52,896	53,534	53,653	53,414
Plus: net effect of dilutive stock options and restricted common shares	2,249	726	1,802	828
Weighted average common shares outstanding, diluted	55,145	54,260	55,455	54,242
Earnings per share attributable to The Medicines Company, basic	$0.18	$1.36	$0.57	$2.03
Earnings per share attributable to The Medicines Company, diluted	$0.17	$1.34	$0.55	$2.00

Basic earnings per share is computed using the weighted average number of shares of common stock outstanding during the period, reduced where applicable for outstanding yet unvested shares of restricted common stock. The number of dilutive common stock equivalents was calculated using the treasury stock method. For the three months ended September 30, 2012 and 2011, options to purchase 2,750,027 shares and 7,618,529 shares, respectively, of common stock that could potentially dilute basic earnings per share in the future were excluded from the calculation of diluted earnings per share as their effect would have been anti-dilutive. For the nine months ended September 30, 2012 and 2011, options to purchase 3,156,309 shares and 7,351,738 shares, respectively, of common stock that could potentially dilute basic earnings per share in the future were excluded from the calculation of diluted earnings per

share as their effect would have been anti-dilutive.

For the three and nine months ended September 30, 2012, 7,500 and 100,480 shares, respectively, of unvested restricted stock that could potentially dilute basic earnings per share in the future were excluded from the calculation of diluted earnings per common share as their effect would have been anti-dilutive. No shares of unvested restricted stock were excluded from the calculation of diluted earnings per common share for the three months ended September 30, 2011. For the nine months ended September 30, 2011, 83,297 shares of unvested restricted stock that could potentially dilute basic earnings per share in the future were excluded from the calculation of diluted earnings per common share as their effect would have been anti-dilutive.

In June 2012, the Company issued, at par value, $275.0 million aggregate principal amount of 1.375% convertible senior notes due June 1, 2017 (the Notes) (see note 10 "Convertible Senior Notes”). In connection with the issuance of the Notes, the Company

entered into convertible note hedge transactions with respect to its common stock (the Note Hedges) with several of the initial purchasers of the Notes, their affiliates and other financial institutions (the Hedge Counterparties). The options that are part of the Note Hedges are not considered for purposes of calculating the total shares outstanding under the basic and diluted net income per share, as their effect would be anti-dilutive. The Note Hedges are expected generally to reduce the potential dilution with respect to shares of the Company's common stock upon any conversion of the Notes in the event that the market price per share of the Company's common stock, as measured under the terms of the Note Hedges, is greater than the strike price of the Note Hedges, which initially corresponded to the conversion price of the Notes and is subject to anti-dilution adjustments substantially similar to those applicable to the conversion rate of the Notes. The shares of common stock issuable upon conversion of the Notes are not included for purposes of calculating the total shares outstanding under the basic and diluted net income per share, as the effect would be anti-dilutive.

In addition, in connection with the Note Hedges, the Company entered into warrant transactions with the Hedge Counterparties, pursuant to which the Company sold warrants (the Warrants) to the Hedge Counterparties to purchase, subject to customary anti-dilution adjustments, up to 9.8 million shares of the Company's common stock at a strike price of $34.20 per share. For the three and nine months ended September 30, 2012, the warrants did not have a dilutive effect on earnings per share because the average market price during the periods presented was below the strike price. The Warrants will have a dilutive effect with respect to the Company's common stock to the extent that the market price per share of the Company's common stock, as measured under the terms of the Warrants, exceeds the applicable strike price of the Warrants. However, subject to certain conditions, the Company may elect to settle all of the Warrants in cash.

5. Income Taxes

For the three months ended September 30, 2012 and 2011, the Company recorded a $6.2 million provision for income taxes and a $62.6 million benefit for income taxes, respectively, based upon its estimated federal, state and foreign tax liability for the year. During the third quarter of 2011, the Company concluded that it was more likely than not that substantially all of its deferred tax assets would be realizable in future periods. The Company reduced its valuation allowance against its deferred tax assets by $66.5 million and recorded a corresponding tax benefit. The worldwide effective income tax rates for the Company for the three months ended September 30, 2012 and 2011 were 40.0% and (626.9)%, respectively. Both the 2012 and 2011 effective income tax rates include a non-cash tax expense arising from purchase accounting for in-process R&D acquired in the Company's acquisition of Targanta Therapeutics Corporation (Targanta).

For the nine months ended September 30, 2012 and 2011, the Company recorded an $18.9 million provision for income taxes and a $50.8 million benefit for income taxes, respectively, based upon its estimated federal, state and foreign tax liability for the year. The worldwide effective income tax rates for the Company for the nine months ended September 30, 2012 and 2011 were 38.2% and (88.3)%, respectively. In addition to the $66.5 million reduction in the valuation allowance discussed above, the Company's income benefit for the nine months ended September 30, 2011 includes the effect of a one-time $2.5 million income tax benefit resulting from a prospective change in the New Jersey income tax law enacted in the second quarter 2011 and the tax impact of the settlement from the law firm Wilmer Cutler Pickering Hale and Dorr LLP (WilmerHale), which were both treated as discrete events. Both the 2012 and 2011 effective income tax rates include a non-cash tax expense arising from purchase accounting for in-process R&D acquired in the Company's acquisition of Targanta.

The Company continues to evaluate its ability to realize its deferred tax assets and liabilities on a periodic basis and will adjust such amounts in light of changing facts and circumstances including, but not limited to, future projections of taxable income, tax legislation, rulings by relevant tax authorities, the progress of ongoing tax audits and the

regulatory approval of products currently under development. Any changes to the valuation allowance or deferred tax assets in the future would impact the Company's income taxes.

6. Cash, Cash Equivalents and Available for Sale Securities

The Company considers all highly liquid investments purchased with original maturities at the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents included cash of $479.8 million and $290.2 million at September 30, 2012 and December 31, 2011, respectively. Cash and cash equivalents at September 30, 2012 and December 31, 2011 also included investments of $0.6 million and $25.2 million, respectively, in money market funds and commercial paper with original maturities of less than three months.

At September 30, 2012 and December 31, 2011, the Company held available for sale securities with a fair value totaling $65.0 million and $25.1 million, respectively. These available for sale securities included various U.S. government agency notes, U.S. treasury notes and corporate debt securities. At September 30, 2012, all of the $65.0 million of available for sale securities were

due within one year. At December 31, 2011, all of the $25.1 million of available for sale securities were due within one year. The Company evaluates securities with unrealized losses to determine whether such losses are other than temporary. The Company has determined that there were no other than temporary declines in fair values of its investments as of September 30, 2012.

Available for sale securities, including carrying value and estimated fair values, are summarized as follows:

	As of September 30, 2012				As of December 31, 2011			
	Cost	Fair Value	Carrying Value	Unrealized Gain	Cost	Fair Value	Carrying Value	Unrealized Gain
	(in thousands)							
U.S. government agency notes	$7,150	$7,153	$7,153	$3	$901	$901	$901	$—
U.S. treasury notes	—	—	—	—	3,021	3,022	3,022	1
Corporate debt securities	57,781	57,813	57,813	32	21,204	21,207	21,207	3
Total	$64,931	$64,966	$64,966	$35	$25,126	$25,130	$25,130	$4

Restricted Cash

The Company had restricted cash of $1.6 million and $4.7 million at September 30, 2012 and December 31, 2011, respectively, which is included in restricted cash on the consolidated balance sheets. On October 11, 2007, the Company entered into a lease for new office space in Parsippany, New Jersey. The Company relocated its principal executive offices to the new space in the first quarter of 2009. Restricted cash of $1.0 million and $4.1 million at September 30, 2012 and December 31, 2011, respectively, collateralized outstanding letters of credit associated with this lease. The funds are invested in certificates of deposit. The letter of credit permits draws by the landlord to cure defaults by the Company. In addition, as a result of the acquisition of Targanta in 2009, the Company had restricted cash of $0.3 million at September 30, 2012 and December 31, 2011, respectively, in the form of a guaranteed investment certificate collateralizing an available credit facility. The Company also had restricted cash of $0.3 million at September 30, 2012 and December 31, 2011, respectively, related to certain foreign tender requirements.

7. Fair Value Measurements

FASB ASC 820-10 “Fair Value Measurements and Disclosures” (ASC 820-10) provides a framework for measuring fair value under GAAP and requires expanded disclosures regarding fair value measurements. ASC 820-10 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820-10 also establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

Level 1 Quoted prices in active markets for identical assets or liabilities. The Company's Level 1 assets and liabilities consist of money market investments and U.S. treasury notes.

Level 2 Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. The Company's Level 2 assets and liabilities consist

	of U.S. government agency notes and corporate debt securities. Fair values are determined by utilizing quoted prices for similar assets and liabilities in active markets or other market observable inputs such as interest rates and yield curves.
Level 3	Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. The Company's Level 3 assets and liabilities consist of the contingent purchase price associated with the Company's acquisition of Targanta. The fair value of the contingent purchase price was determined utilizing a probability weighted discounted financial model based on management's assessment of the likelihood of achievement of certain development, regulatory and sales milestones.

The following table sets forth the Company's assets and liabilities that were measured at fair value on a recurring basis at September 30, 2012 and December 31, 2011 by level within the fair value hierarchy. As required by ASC 820-10, assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the asset or liability:

	As of September 30, 2012				As of December 31, 2011			
Assets and Liabilities	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of September 30, 2012	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance at December 31, 2011
	(in thousands)							
Assets:								
Money market	$509	$—	$ —	$ 509	$25,240	$ —	$ —	$ 25,240
U.S. treasury notes	—	—	—	—	3,022	—	—	3,022
U.S. government agency notes	—	7,153	—	7,153	—	901	—	901
Corporate debt securities	—	57,813	—	57,813	—	21,207	—	21,207
Total assets at fair value	$509	$ 64,966	$ —	$ 65,475	$28,262	$ 22,108	$ —	$ 50,370
Liabilities:								
Contingent purchase price	$—	$—	$ 22,633	$ 22,633	$—	$ —	$ 20,431	$ 20,431
Total liabilities at fair value	$—	$—	$ 22,633	$ 22,633	$—	$ —	$ 20,431	$ 20,431

The Company measures the contingent purchase price at fair value based on significant inputs not observable in the market, which causes it to be classified as a Level 3 measurement within the fair value hierarchy. The valuation of contingent purchase price uses assumptions and estimates the Company believes would be made by a market participant in making the same valuation. The Company assesses these assumptions and estimates on an on-going basis as additional data impacting the assumptions and estimates are obtained. Changes in the fair value of contingent purchase price related to updated assumptions and estimates are recognized within the consolidated statements of income.

Contingent purchase price may change significantly as additional data is obtained, impacting the Company’s assumptions regarding probabilities of successful achievement of related milestones used to estimate the fair value of the liability. In evaluating this information, considerable judgment is required to interpret the market data used to develop the assumptions and estimates. The estimates of fair value may not be indicative of the amounts that could be realized in a current market exchange. Accordingly, the use of different market assumptions and/or different valuation techniques may have a material effect on the estimated fair value amounts, and such changes could materially impact the Company’s results of operations in future periods.

Level 3 Disclosures

The following table provides quantitative information associated with the fair value measurement of the Company's Level 3 inputs:

	Fair Value as of September 30, 2012 (in thousands)	Valuation Technique	Unobservable Input	Range (Weighted Average)
Targanta:				
Contingent purchase price	$22,633	Probability-adjusted discounted cash flow	Probabilities of success	20% - 76% (58%)
			Periods in which milestones are expected to be achieved	2013 - 2018
			Discount rate	11%

	Fair Value as of December 31, 2011 (in thousands)	Valuation Technique	Unobservable Input	Range (Weighted Average)
Targanta:				
Contingent purchase price	$20,431	Probability-adjusted discounted cash flow	Probabilities of success	20% - 76% (58%)
			Periods in which milestones are expected to be achieved	2013 - 2018
			Discount rate	12%

The fair value of the contingent purchase price represents the fair value of the Company's liability for all potential payments under the Company's agreement with Targanta. The significant unobservable inputs used in the fair value measurement of the Company's contingent purchase price are the probabilities of successful achievement of development, regulatory and sales milestones, which would trigger payments under the Targanta agreement, probabilities as to the periods in which the milestones are expected to be achieved and a discount rate. Significant changes in any of the probabilities of success would result in a significantly higher or lower fair value measurement, respectively. Significant changes in the probabilities as to the periods in which milestones will be achieved would result in a significantly lower or higher fair value measurement, respectively.

The changes in fair value of the Company's Level 3 contingent purchase price during the three and nine months ended September 30, 2012 and 2011were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
	(in thousands)			
Balance at beginning of period	$21,568	$27,416	$20,431	$25,387
Fair value adjustment to contingent purchase price included in net income	1,065	788	2,202	2,817
Balance at end of period	$22,633	$28,204	$22,633	$28,204

For the three and nine months ended September 30, 2012, the changes in the fair value of the contingent purchase price obligations resulted from the passage of time as development work towards the achievement of the milestones progresses. No other changes in valuation techniques or inputs occurred during the three and nine months ended September 30, 2012. No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the three and nine months ended September 30, 2012.

8. Inventory

The major classes of inventory were as follows:

Inventory	September 30, 2012	December 31, 2011
	(in thousands)	
Raw materials	$29,865	$ 23,234

Work-in-progress	23,745	19,203
Finished goods	8,727	2,708
Total	$62,337	$ 45,145

The Company reviews inventory, including inventory purchase commitments, for slow moving or obsolete amounts based on expected volume. If annual volume is less than expected, the Company may be required to make additional allowances for excess or obsolete inventory in the future.

9. Intangible Assets

The following information details the carrying amounts and accumulated amortization of the Company's intangible assets subject to amortization:

	As of September 30, 2012				As of December 31, 2011		
	Weighted Average Useful Life	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
		(in thousands)					
Identifiable intangible assets							
Customer relationships	8 years	$7,457	$ (3,796)	$3,661	$7,457	$ (2,863)	$4,594
Distribution agreements	5.7 years	9,125	(3,005)	6,120	4,448	(1,708)	2,740
Trademarks	8 years	3,024	(1,539)	1,485	3,024	(1,161)	1,863
Product licenses	9.6 years	39,000	(903)	38,097	7,000	(226)	6,774
Cleviprex milestones	13 years	2,000	(161)	1,839	2,000	(142)	1,858
Total	8.8 years	$60,606	$ (9,404)	$51,202	$23,929	$ (6,100)	$17,829

In January 2012, the Company reacquired its rights to sell Angiomax in Australia and New Zealand from CSL Limited (CSL) and is now marketing and selling Angiomax in those countries with a sales force that as of September 30, 2012 consisted of two engagement partners and two engagement managers. The Company valued the intangible assets related to Angiomax in those countries obtained from CSL at $4.7 million, classified such assets as distribution agreements intangibles and commenced amortization of the assets using a 3.5 year expected useful life.

In January 2012, the Company acquired a non-exclusive license under APP's marketing authorizations and intellectual property to sell ten specified generic products to hospitals and integrated delivery networks in the United States. The Company valued the intangible assets obtained from APP in the United States at $32.0 million, classified such assets as product licenses intangibles and will amortize the assets using a 10 year expected useful life.

The Company expects amortization expense related to its intangible assets to be $2.7 million for the remainder of 2012. The Company expects annual amortization expense related to its intangible assets to be $8.7 million, $9.9 million, $4.5 million, $4.3 million and $4.4 million for the years ending December 31, 2013, 2014, 2015, 2016 and 2017, respectively, with the balance of $16.7 million being amortized thereafter. The Company records amortization of customer relationships, distribution agreements and trademarks in selling, general and administrative expense on the consolidated statements of income. The Company records amortization of Cleviprex milestones and product license in cost of revenue on the consolidated statements of income.

The following information details the carrying amounts of the Company's intangible assets not subject to amortization:

As of September 30, 2012			As of December 31, 2011		
Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
(in thousands)					

Intangible assets not subject to amortization:						
In-process research and development	$69,500	—	$69,500	$69,500	—	$69,500
Total	$69,500	—	$69,500	$69,500	—	$69,500

10. Convertible Senior Notes

In June 2012, the Company issued, at par value, $275.0 million aggregate principal amount of the Notes. The Notes bear cash interest at a rate of 1.375% per year, payable semi-annually on June 1 and December 1 of each year, beginning on December 1,

2012. The Notes will mature on June 1, 2017. The net proceeds to the Company from the offering were $266.2 million after deducting the initial purchasers' discounts and commissions and the offering expenses payable by the Company.

The Notes are governed by an indenture dated as of June 11, 2012 (the Indenture), between the Company, as issuer, and Wells Fargo Bank, National Association, a national banking association, as trustee (the Trustee). The Notes do not contain any financial or operating covenants or any restrictions on the payment of dividends, the incurrence of other indebtedness, or the issuance or repurchase of securities by the Company.

The Notes are senior unsecured obligations of the Company and will rank senior in right of payment to the Company's future indebtedness, if any, that is expressly subordinated in right of payment to the Notes and equal in right of payment to the Company's existing and future unsecured indebtedness that is not so subordinated. The Notes are effectively junior in right of payment to any secured indebtedness of the Company to the extent of the value of the assets securing such indebtedness and are structurally junior to all existing and future indebtedness and other liabilities (including trade payables) incurred by the Company's subsidiaries.

Holders may convert their Notes at their option at any time prior to the close of business on the business day immediately preceding March 1, 2017 only under the following circumstances:

- during any calendar quarter commencing on or after September 1, 2012 (and only during such calendar quarter), if the last reported sale price of the Company's common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price (described below) on each applicable trading day;

- during the five business day period after any five consecutive trading day period (the Measurement Period) in which the trading price (as defined in the Indenture) per $1,000 principal amount of Notes for each trading day of the Measurement Period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such trading day; or

- upon the occurrence of specified corporate events, including a merger or a sale of all or substantially all of the Company's assets.

On or after March 1, 2017, until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their Notes at any time, regardless of the foregoing circumstances. Upon conversion, the Company will pay cash up to the aggregate principal amount of the Notes to be converted and deliver shares of the Company's common stock in respect of the remainder, if any, of the Company's conversion obligation in excess of the aggregate principal amount of the Notes being converted, subject to a daily share cap, as described in the Indenture. Holders of Notes will not receive any additional cash payment or additional shares representing accrued and unpaid interest, if any, upon conversion of a Note, except in limited circumstances. Instead, accrued but unpaid interest will be deemed to be paid by the cash and shares, if any, of the Company's common stock, together with any cash payment for any fractional share, paid or delivered, as the case may be, upon conversion of a Note.

The conversion rate for the Notes was initially, and remains, 35.8038 shares of the Company's common stock per $1,000 principal amount of Notes, which is equivalent to an initial conversion price of $27.93 per share of the Company's common stock. The conversion rate and the conversion price are subject to customary adjustments for certain events, including, but not limited to, the issuance of certain stock dividends on the Company's common stock, the issuance of certain rights or warrants, subdivisions, combinations, distributions of capital stock, indebtedness, or assets, cash dividends and certain issuer tender or exchange offers, as described in the Indenture.

The Company may not redeem the Notes prior to maturity and is not required to redeem or retire the Notes periodically. However, upon the occurrence of a "fundamental change" (as defined in the Indenture), subject to certain conditions, in lieu of converting their Notes, holders may require the Company to repurchase for cash all or part of their Notes at a repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. Following certain corporate transactions that constitute a change of control, the Company will increase the conversion rate for a holder who elects to convert the Notes in connection with such change of control in certain circumstances.

The Indenture contains customary events of default with respect to the Notes, including that upon certain events of default (including the Company's failure to make any payment of principal or interest on the Notes when due and payable) occurring and continuing, the Trustee by notice to the Company, or the holders of at least 25% in principal amount of the outstanding Notes by notice to the Company and the Trustee, may, and the Trustee at the request of such holders (subject to the provisions of the Indenture)

shall, declare 100% of the principal of and accrued and unpaid interest, if any, on all the Notes to be due and payable. In case of an event of default involving certain events of bankruptcy, insolvency or reorganization, involving the Company or a significant subsidiary, 100% of the principal of and accrued and unpaid interest on the Notes will automatically become due and payable. Upon a declaration of acceleration, such principal and accrued and unpaid interest, if any, will be due and payable immediately.

In accounting for the issuance of the Notes, the Company separated the Notes into liability and equity components. The carrying amount of the liability component was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The carrying amount of the equity component representing the conversion option was determined by deducting the fair value of the liability component from the par value of the Notes as a whole. The excess of the principal amount of the liability component over its carrying amount, referred to as the debt discount, is amortized to interest expense over the five-year term of the Notes. The equity component is not re-measured as long as it continues to meet the conditions for equity classification.

In accounting for the transaction costs related to the issuance of the Notes, the Company allocated the total costs incurred to the liability and equity components of the Notes based on their relative values. Transaction costs attributable to the liability component are amortized to interest expense over the five-year term of the Notes, and transaction costs attributable to the equity component are netted with the equity components in stockholders' equity. Additionally, the Company initially recorded a deferred tax asset of $1.5 million in connection with the Notes.

The Notes consisted of the following:

Liability component	September 30, 2012	December 31, 2011
	(in thousands)	
Principal	$275,000	$ —
Less: Debt discount, net[1]	(51,289)	—
Net carrying amount	$223,711	$ —

[1] Included in the condensed consolidated balance sheets within convertible senior notes (due 2017) and amortized to interest expense over the remaining life of the Notes using the effective interest rate method.

The fair value of the Notes was approximately $236.1 million as of September 30, 2012. The Company estimates the fair value of its Notes utilizing market quotations for debt that have quoted prices in active markets. Since the Notes do not trade on a daily basis in an active market, the fair value estimates are based on market observable inputs based on borrowing rates currently available for debt with similar terms and average maturities (Level 2). As of September 30, 2012, the remaining contractual life of the Notes is approximately 4.7 years.

The following table sets forth total interest expense recognized related to the Notes:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
	(in thousands)			
Contractual interest expense	949	—	1,156	—
Amortization of debt issuance costs	268	—	326	—
Amortization of debt discount	2,389	—	2,908	—
	3,606	—	4,390	—
Effective interest rate of the liability component	6.02 %	— %	6.02 %	— %

Note Hedges. In June 2012, the Company paid an aggregate amount of $58.2 million for the Note Hedges, which was recorded as a reduction of additional paid-in-capital in stockholders' equity. The Note Hedges cover approximately 9.8 million shares of the Company's common stock, subject to anti-dilution adjustments substantially similar to those applicable to the Notes, have a strike price that corresponds to the initial conversion price of the Notes and are

exercisable upon conversion of the Notes. The Note Hedges will expire upon the maturity of the Notes. The Note Hedges are expected generally to reduce the potential dilution with respect to shares of the Company's common stock upon conversion of the Notes in the event that the market price per share of the Company’s common stock, as measured under the terms of the Note Hedges, at the time of exercise is greater than the strike price of the Note Hedges. The Note Hedges are separate transactions entered into by the Company with the Hedge Counterparties

and are not part of the terms of the Notes or the Warrants. Holders of the Notes and Warrants will not have any rights with respect to the Note Hedges. As of September 30, 2012, the fair value of the Note Hedges was $68.0 million.

Warrants. The Company received aggregate proceeds of $38.4 million from the sale to the Hedge Counterparties of the Warrants to purchase up to 9.8 million shares of the Company's common stock, subject to customary anti-dilution adjustments, at a strike price of $34.20 per share, which the Company recorded as additional paid-in-capital in stockholders' equity. The Warrants will have a dilutive effect with respect to the Company's common stock to the extent that the market price per share of the Company's common stock, as measured under the terms of the Warrants, exceeds the applicable strike price of the Warrants. However, subject to certain conditions, the Company may elect to settle all of the Warrants in cash. The Warrants were anti-dilutive for the three and nine months ended September 30, 2012. The Warrants are separate transactions entered into by the Company with the Hedge Counterparties and are not part of the terms of the Notes or Note Hedges. Holders of the Notes and Note Hedges will not have any rights with respect to the Warrants. The Warrants also meet the definition of a derivative under current accounting principles. Because the Warrants are indexed to the Company's common stock and are recorded in equity in the Company's consolidated balance sheets, the Warrants are exempt from the scope and fair value provisions of accounting principles related to accounting for derivative instruments.

11. Treasury Stock

On June 5, 2012, the Company's Board of Directors authorized the Company to use a portion of the net proceeds of the Notes offering to repurchase up to an aggregate of $50.0 million of its common stock. The Company repurchased 2,192,982 shares of its common stock in the second quarter of fiscal 2012 for an aggregate cost of $50.0 million.

As of September 30, 2012, there were 2,192,982 shares of the Company's common stock held in treasury.

12. Restructuring Costs and Other, Net

In September 2011, the Company commenced the closure of its drug discovery research and development facility and operations in Leipzig, Germany and terminated ten employees at its Leipzig facility. The Company transferred active pre-clinical projects from Leipzig to its research and development facility in Montreal, Canada and the MDCO-2010 back-up compound to the clinical team in Parsippany, New Jersey. Upon signing release agreements, the terminated employees received severance and other benefits. The Company recorded, in the aggregate, charges of $2.2 million in 2011 associated with the 2011 Leipzig closure. These charges were recorded in research and development expenses in the Company's consolidated statements of income. Of these charges, $0.3 million related to asset write-offs were noncash charges. The Company paid out $0.3 million during 2011 and $0.8 million during the nine months ended September 30, 2012 and expects to pay out $0.8 million during the remainder of 2012. The Company no longer has any research employees or research capabilities in Leipzig. The Company did not record any charges relating to the 2011 Leipzig closure during the nine months ended September 30, 2012.

For the nine months ended September 30, 2011, the Company recorded a $0.1 million favorable adjustment to selling, general and administrative costs associated with two workforce reductions conducted in 2010, due to the charges for employee severance and other employee-related termination costs being slightly lower than originally estimated. See note 14 "Restructuring Costs and Other, Net" of the notes to the consolidated financial statements in the Company's annual report on Form 10-K for the year ended December 31, 2011.

Details of the activities described above and the movement in the accrual during the nine-month period ended September 30, 2012 are as follows:

	Balance as of December 31, 2011	Expenses (Income), Net	Cash	Noncash	Balance as of September 30, 2012
	(in thousands)				
Employee severance and other personnel benefits:					
2011 Leipzig closure	$697	$—	$(697)	—	$—
Other associated costs (Leipzig)	918	—	(110)	—	808
Total	$1,615	$—	$(807)	$—	$808

13. Legal Settlements

WilmerHale Settlement

During the nine months ended September 30, 2011, the Company recorded approximately $18.0 million in legal settlement income in connection with the settlement agreement and release the Company entered into with WilmerHale in February 2011. Pursuant to the settlement agreement, WilmerHale agreed to pay approximately $18.0 million from its professional liability insurance providers to the Company within 60 days after the date of the settlement agreement and delivered such amount in two equal payments in March 2011 and April 2011.

APP Settlement

On January 22, 2012, the Company settled its patent litigation with APP, including the patent infringement suits with respect to U.S. Patent No. 7,582,727 (the '727 patent) and U.S. Patent No. 7,598,343 (the '343 patent) and APP's appeal of the August 2010 federal district court decision holding that the Company's application for Hatch Waxman patent term extension of U.S. Patent No. 5,196,404 (the '404 patent) was timely filed. Under the settlement agreement, APP admitted that the '727 patent and '343 patent are valid and enforceable and that they would be infringed by any generic bivalirudin for injection product that is the subject of APP's ANDAs. In connection with the APP settlement, the Company entered into a license agreement with APP under which it granted APP a non-exclusive license under the '727 patent and '343 patent to sell a generic bivalirudin for injection product under an APP abbreviated new drug application in the United States beginning on May 1, 2019. In certain limited circumstances, the license to APP could become effective prior to May 1, 2019. In addition, in certain limited circumstances, this license to APP could include the right to sell a generic bivalirudin product under the Company's new drug application for Angiomax in the United States beginning on May 1, 2019 or, in certain limited circumstances, on June 30, 2019 or on a date prior to May 1, 2019. Contemporaneously with entering into the settlement agreement and license agreement, the Company entered into a contract manufacturing agreement, a license and supply agreement and an authorized generic supply agreement with APP. On January 24, 2012, the U.S. District Court for the District of Delaware entered a consent judgment and order of permanent injunction concluding the Company's patent infringement suits against APP. On January 24, 2012, the parties filed a joint dismissal of APP's appeal with respect to the extension of the patent term of the '404 patent and the Federal Circuit entered an order dismissing the appeal. On February 1, 2012, the Company and APP submitted the settlement documents to the U.S. Federal Trade Commission and the U.S. Department of Justice. The Company's settlement with APP is described in more detail in Part I, Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations - Overview - APP Settlement, of this quarterly report.

14. Segment and Geographic Information

The Company manages its business and operations as one segment and is focused on advancing the treatment of acute and intensive care patients through the delivery of innovative, cost-effective medicines to the worldwide hospital marketplace. Revenues reported to date are derived primarily from the sales of Angiomax in the United States.

The geographic segment information provided below is classified based on the major geographic regions in which the Company operates.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
	(in thousands)		(in thousands)	
Net revenue:				

United States	$126,829	92.7	%	$111,561	92.4	%	$366,582	91.9	%	$328,849	93.3	%
Europe	7,974	5.8	%	6,060	5.0	%	26,785	6.7	%	18,429	5.2	%
Rest of world	1,983	1.4	%	3,152	2.6	%	5,731	1.4	%	5,223	1.5	%
Total net revenue	$136,786			$120,773			$399,098			$352,501		

	September 30, 2012 (in thousands)			December 31, 2011		
Long-lived assets:						
United States	$165,995	99.5	%	$126,513	99.0	%
Europe	698	0.4	%	1,069	0.8	%
Rest of world	170	0.1	%	187	0.1	%
Total long-lived assets	$166,863			$127,769		

15. Contingencies

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company accrues for loss contingencies at the earliest date at which the Company deems that it is probable that a liability has been incurred and the amount of such loss can be reasonably estimated.

Eagle Pharmaceuticals, Inc. (Eagle) Arbitration. The Company received a Demand for Arbitration filed by Eagle dated October 25, 2011. In the Demand for Arbitration, Eagle claims that the Company failed to meet its obligations under the license and development agreement between the Company, Eagle and certain other parties relating to the development of a new formulation of Angiomax, and to the Company's efforts to seek and obtain regulatory approval, market and sell that new formulation. As a result, Eagle alleges that it has been damaged in an amount it believes exceeds $200.0 million. The Company believes it has valid defenses to Eagle's claims and intends to defend itself vigorously. The Company believes that any potential liability is not estimable at this time.

In addition, the Company is party to the legal proceedings described in Part II, Item I of this quarterly report, which are principally patent litigation matters. The Company has assessed such legal proceedings and does not believe that it is probable that a liability has been incurred or that the amount of any potential liability can be reasonably estimated. As a result, the Company did not record any loss contingencies for any of these matters. While it is not possible to determine the outcome of the matters described in Part II, Item 1, Legal Proceedings, of this quarterly report, the Company believes that, the resolution of all such matters will not have a material adverse effect on its consolidated financial position or liquidity, but could possibly be material to the Company's consolidated results of operations in any one accounting period.

16. Subsequent Events

On October 4, 2012, the Company voluntarily discontinued its Phase 2b dose-ranging study of MDCO-2010, a serine protease inhibitor which was being developed to reduce blood loss during surgery. This action was taken in response to serious unexpected patient safety issues encountered during the trial, which at the time the trial was discontinued, had recruited 44 of a planned 90 patients in the first stage of the study.

While the cause of the safety issues and any potential link to the study drug are still under investigation, the Company decided to end the trial and further development of MDCO-2010 because of the evidence of risk to patients. The Company is conducting an assessment of patient data from the study. Once this assessment is completed and reviewed with experts in the field, the Company plans to publish its findings.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and accompanying notes included elsewhere in this quarterly report. In addition to the historical information, the discussion in this quarterly report contains certain forward-looking statements that involve

risks and uncertainties. Our actual results could differ materially from those anticipated by the forward-looking statements due to our critical accounting estimates discussed below and important factors set forth in this quarterly report, including under “Risk Factors” in Part II, Item 1A of this quarterly report.

Overview

Our Business

We are a global pharmaceutical company focused on advancing the treatment of critical care patients through the delivery of innovative, cost-effective medicines to the worldwide hospital marketplace. We have three marketed products, Angiomax® (bivalirudin), Cleviprex® (clevidipine butyrate) injectable emulsion and our ready-to-use formulation of Argatroban. We also have a pipeline of acute and intensive care hospital products in development, including three late-stage development product candidates, cangrelor, oritavancin and MDCO-157, and one early stage development product candidate, MDCO-216. We believe that our marketed products and products in development possess favorable attributes that competitive products do not provide, can satisfy unmet medical needs in the acute and intensive care hospital product market and offer, or, in the case of our products in development, have the potential to offer, improved performance to hospital businesses. In addition, in January 2012 we acquired from APP Pharmaceuticals, LLC, or APP, non-exclusive rights to market in the United States a portfolio of ten generic drugs, which we refer to as our acute care generic products. We expect to begin selling certain of those products in the fourth quarter of 2012. In May 2012, as part of our global collaboration agreement with AstraZeneca LP, or AstraZeneca, we and AstraZeneca commenced a four-year co-promotion arrangement for AstraZeneca's oral antiplatelet medicine, BRILINTA® (ticagrelor), tablets in the United States.

The following chart identifies each of our marketed products and our products in development, their stage of development, their mechanism of action and the indications for which they have been approved for use or which they are intended to address. The following chart also identifies each of our acute care generic products and the therapeutic areas which they are intended to address. All of our marketed products and products in development are administered intravenously. All of our acute care generic products are injectable products.

Product or Product in Development	Development Stage	Mechanism/Target	Clinical Indication(s)/Therapeutic Areas
Angiomax	Marketed	Direct thrombin inhibitor	U.S. - for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty and for use in patients undergoing percutaneous coronary intervention, or PCI, including patients with or at risk of heparin induced thrombocytopenia and thrombosis syndrome, or HIT/HITTS Europe - for use as an anticoagulant in patients undergoing PCI, adult patients with acute coronary syndrome, or ACS, and for the treatment of patients with ST-segment elevation myocardial infarction, or STEMI, undergoing primary PCI

Cleviprex	Marketed in the United States Approved in the United Kingdom, the Netherlands, Sweden, Switzerland, Australia and New Zealand Marketing Authorization Application, or MAA, submitted in other European Union countries	Calcium channel blocker	U.S. - Blood pressure reduction when oral therapy is not feasible or not desirable Ex-U.S. - with indications for blood pressure control in perioperative settings
Cangrelor	Phase 3	Antiplatelet agent	Prevention of platelet activation and aggregation when oral therapy is not feasible or not desirable
Oritavancin	Phase 3	Antibiotic	Treatment of serious gram-positive bacterial infections, including acute bacterial skin and skin structure infections, or ABSSSI, and including infections that are resistant to conventional treatment

MDCO-157 (IV clopidogrel)	Pre-registration stage	Platelet inhibitor	Platelet inhibition in patients suffering from ACS or patients recently experiencing myocardial infarction, stroke, or peripheral arterial disease when oral therapy is not feasible or not desirable
MDCO-216	Phase 1	Naturally occurring variant of a protein found in high-density lipoprotein, or HDL	Reversal cholesterol transport agent to reduce atherosclerotic plaque burden development and thereby reduce the risk of adverse thrombotic events
Ready-to-Use Argatroban	Marketed in the United States	Direct thrombin inhibitor	Approved for prophylaxis or treatment of thrombosis in adult patients with HIT and for use as an anticoagulant in adult patients with or at risk for HIT undergoing PCI
Acute care generic products: Adenosine, Amiodarone, Esmolol and Milrinone	Approved in the United States	Various	Cardiovascular
Acute care generic products: Azithromycin and Clindamycin	Approved in the United States	Various	Serious infection
Acute care generic products: Haloperidol, Ondansetron, Midazolam and Rocuronium	Approved in the United States	Various	Neurocritical care

Our revenues to date have been generated primarily from sales of Angiomax in the United States. We continue to expand our sales and marketing efforts outside the United States. We believe that by establishing operations outside the United States, we can increase our sales of Angiomax outside of the United States and be positioned to commercialize Cleviprex and our products in development, if and when they are approved outside the United States.

Research and development expenses represent costs incurred for licenses of rights to products, clinical trials, nonclinical and preclinical studies, activities relating to regulatory filings and manufacturing development efforts. We outsource much of our clinical trials, nonclinical and preclinical studies and all of our manufacturing development activities to third parties to maximize efficiency and minimize our internal overhead. We expense our research and development costs as they are incurred. Selling, general and administrative expenses consist primarily of salaries and related expenses, costs associated with general corporate activities and costs associated with marketing and promotional activities. Research and development expense, selling, general and administrative expense and cost of revenue also include stock-based compensation expense, which we allocate based on the responsibilities of the recipients of the stock-based compensation.

As of September 30, 2012, we had an accumulated deficit of approximately $81.1 million. We expect to make substantial expenditures to further develop and commercialize our products and to develop our product candidates,

including costs and expenses associated with clinical trials, nonclinical and preclinical studies, regulatory approvals and commercialization.

Angiomax Patent Litigation

The principal U.S. patents covering Angiomax include U.S. Patent No. 5,196,404, or the '404 patent, U.S. Patent No. 7,582,727, or the '727 patent, and U.S. Patent No. 7,598,343, or the '343 patent.

The '404 patent was set to expire in March 2010, but the term was extended to December 15, 2014 by the U.S. Patent and Trademark Office, or the PTO, under the Hatch-Waxman Act following our litigation against the PTO, the U.S. Food and Drug Administration, or the FDA, and the U.S. Department of Health and Human Services, or HHS. In addition, as a result of our study of Angiomax in the pediatric setting, we are entitled to a six-month period of pediatric exclusivity following expiration of the '404 patent, which extends exclusivity to June 15, 2015.

In the second half of 2009, the PTO issued to us the '727 patent and the '343 patent, covering a more consistent and improved Angiomax drug product and the processes by which it is made. The '727 patent and the '343 patent are set to expire in July 2028. In response to Paragraph IV Certification Notice letters we received with respect to abbreviated new drug applications, or ANDAs, filed by a number of parties with the FDA seeking approval to market generic versions of Angiomax, we have filed lawsuits against the ANDA filers alleging patent infringement of the '727 patent and '343 patent.

On September 30, 2011, we settled our '727 patent and '343 patent infringement litigation with Teva Pharmaceuticals USA, Inc. and its affiliates, which we collectively refer to as Teva. In connection with the Teva settlement, we entered into a license agreement with Teva under which we granted Teva a non-exclusive license under the '727 patent and '343 patent to sell a generic bivalirudin for injection product under a Teva ANDA in the United States beginning June 30, 2019 or earlier under certain conditions.

On January 22, 2012, we settled our patent infringement litigation with APP. In connection with the APP settlement, we entered into a license agreement with APP under which we granted APP a non-exclusive license under the '727 patent and '343 patent to sell a generic bivalirudin for injection product under an APP ANDA in the United States beginning on May 1, 2019. In certain limited circumstances, the license to APP could become effective prior to May 1, 2019. In addition, in certain limited circumstances, this license to APP could include the right to sell a generic bivalirudin product under our NDA for Angiomax in the United States beginning on May 1, 2019 or, in certain limited circumstances, on June 30, 2019 or on a date prior to May 1, 2019. On January 24, 2012, the U.S. District Court for the District of Delaware entered a consent judgment and order of permanent injunction concluding our patent infringement suits against APP. On February 1, 2012, we and APP submitted the settlement documents to the U.S. Federal Trade Commission, or FTC, and the U.S. Department of Justice, or the DOJ.

We remain in patent infringement litigation involving the '727 patent and '343 patent with other ANDA filers, as described in Part II, Item 1, Legal Proceedings of this quarterly report. If we are unable to maintain our market exclusivity for Angiomax in the United States through enforcement of our U.S. patents covering Angiomax, then Angiomax could be subject to generic competition earlier than May 1, 2019.

In February 2011, we entered into a settlement agreement and release with the law firm Wilmer Cutler Pickering Hale and Dorr LLP, or WilmerHale, with respect to all potential claims and causes of action between the parties related to the '404 patent. Under the settlement agreement, WilmerHale agreed to make available to us up to approximately $232 million, consisting of approximately $117 million from the proceeds of professional liability insurance policies and $115 million of payments from WilmerHale itself. WilmerHale agreed to pay approximately $18 million from its professional liability insurance providers to us within 60 days after the date of the settlement agreement and delivered such amount in two equal payments in March 2011 and April 2011. The balance of the approximately $232 million aggregate amount provided in the settlement agreement remains available to pay future expenses incurred by us in continuing to defend the extension of the '404 patent, and any damages that may be suffered by us in the event that a generic version of Angiomax is sold in the United States before June 15, 2015 because the extension of the '404 patent is held invalid on the basis that the application for the extension was not timely filed. Payments by WilmerHale itself would be made only after payments from its insurance policies are exhausted and cannot exceed $2.875 million for any calendar quarter.

APP Settlement

On January 22, 2012, we settled our patent litigation with APP, including, as noted above, our patent infringement litigation with APP and our litigation with respect to the extension of the patent term of the '404 patent which was dismissed on January 24, 2012. In connection with the APP settlement, we entered into a settlement agreement, a license agreement with respect to the '727 patent and '343 patent, a contract manufacturing agreement with APP, under which APP has agreed to manufacture and supply Angiomax finished product to us, a license and supply agreement with APP under which APP has agreed to license and supply to us a portfolio of ten generic products and an AG supply agreement with APP under which we have agreed to supply APP with an authorized generic bivalirudin product, upon specified circumstances set forth in the APP license agreement.

Under the APP license agreement, we granted APP a non-exclusive license under the '727 patent and '343 patent to sell in the United States a generic bivalirudin for injection product under an APP ANDA, or an APP product,

beginning on May 1, 2019 or earlier under specified conditions, and, in certain limited circumstances, to sell a generic bivalirudin for injection product under our NDA for Angiomax, or an APP generic product, in the United States beginning on May 1, 2019 or, in certain limited circumstances, on June 30, 2019 or on a date prior to May 1, 2019. APP's right under the APP license agreement to sell an APP generic product is subject to the payment to us of a royalty on sales of the APP generic product. If APP has the right to sell an APP generic product, such right could extend for a period of as long as 180 days. The license also covers any other present or future patents owned, licensed or controlled by us that cover or would cover an APP product or an APP generic product other than the '404 patent. Under the APP license agreement, we and APP have also agreed to negotiate an agreement under which we would supply APP with bivalirudin bulk drug substance for use by APP in the manufacture of APP product to be sold under the APP license agreement. The APP license agreement will remain in effect until the later of the expiration of all of the patents covered by the APP license agreement, and the date six months after the expiration of the '404 patent.

Under the APP manufacturing agreement, we have agreed to purchase from APP a specified minimum percentage of the Company's requirements for Angiomax finished product for the sale of Angiomax product in the United States. We have agreed to pay APP a fixed price per vial supplied and to reimburse APP for specified development costs and capital expenditures made

by APP. The term of the APP manufacturing agreement ends on May 1, 2019, but may be extended, at our sole option, for an additional term of two years. If a generic form of bivalirudin for injection is marketed by APP or another third party during the term of the APP manufacturing agreement, we have the right to renegotiate the price and minimum quantity terms of the APP manufacturing agreement and, if such terms cannot be agreed to by the parties, we will have the right to terminate the APP manufacturing agreement upon 90 days prior written notice.

Under the APP generic supply and license agreement, APP has granted us a non-exclusive license under APP's marketing authorizations and intellectual property to sell ten specified generic products to hospitals and integrated delivery networks in the United States. We have agreed to purchase our entire requirements for these products from APP for a price equal to APP's cost of goods. We made a one-time, upfront payment of $30 million to APP. The term of the APP generic supply and license agreement ends January 22, 2022.

Under the AG supply agreement, we have agreed to supply APP with an authorized generic bivalirudin product in the event APP has the right to market the product under the APP license agreement. We have agreed to use commercially reasonable efforts to supply the authorized generic bivalirudin product during the period during which APP can market the product, or the supply period. APP shall purchase the authorized generic bivalirudin product from us at a price based on the costs we have paid to third parties in connection with the manufacture of the product. The AG supply agreement terminates upon the earlier of the end of the supply period or December 27, 2019.

Convertible Senior Note Offering

On June 11, 2012, we completed our private offering of $275.0 million aggregate principal amount of our 1.375% convertible senior notes due 2017, or the Notes, and entered into an indenture with Wells Fargo Bank, National Association, a national banking association, as trustee, or the Trustee, governing the Notes, which we refer to as the Indenture. The net proceeds from the offering were $266.2 million, after deducting the initial purchasers' discounts and commissions and our offering expenses.

The Notes will bear cash interest at a rate of 1.375% per year, payable semi-annually on June 1 and December 1 of each year, beginning on December 1, 2012. The Notes will mature on June 1, 2017. The Notes do not contain any financial or operating covenants or any restrictions on the payment of dividends, the incurrence of other indebtedness, or the issuance or repurchase of securities by us.

The Notes are our senior unsecured obligations and will rank senior in right of payment to our future indebtedness, if any, that is expressly subordinated in right of payment to the Notes and equal in right of payment to our existing and future unsecured indebtedness that is not so subordinated. The Notes are effectively junior in right of payment to any of our secured indebtedness to the extent of the value of the assets securing such indebtedness and are structurally junior to all existing and future indebtedness and other liabilities (including trade payables) incurred by our subsidiaries.

Holders may convert their Notes at their option at any time prior to the close of business on the business day immediately preceding March 1, 2017 only under certain specified circumstances which are set forth in the Indenture. On or after March 1, 2017, until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their Notes at any time, regardless of the foregoing circumstances. Upon conversion, we will pay cash up to the aggregate principal amount of the Notes to be converted and deliver shares of our common stock in respect of the remainder, if any, of our conversion obligation in excess of the aggregate principal amount of the Notes being converted, subject to a daily share cap, as described in the Indenture. Holders of Notes will not receive any additional cash payment or additional shares representing accrued and unpaid interest, if any, upon conversion of a note, except in limited circumstances. Instead, accrued but unpaid interest will be deemed to be paid by the cash and shares, in any, of our common stock, together with any cash payment for any fractional share, paid or delivered, as the case may be, upon conversion of a Note.

The conversion rate for the Notes was initially, and remains, 35.8038 shares of our common stock per $1,000 principal amount of Notes, which is equivalent to an initial conversion price of $27.93 per share of our common stock.

The conversion rate and the conversion price are subject to customary adjustments for certain events, including, but not limited to, the issuance of certain stock dividends on our common stock, the issuance of certain rights or warrants, subdivisions, combinations, distributions of capital stock, indebtedness, or assets, cash dividends and certain issuer tender or exchange offers, as described in the Indenture.

We may not redeem the Notes prior to maturity and are not required to redeem or retire the Notes periodically. However, upon the occurrence of a "fundamental change" (as defined in the Indenture), subject to certain conditions, in lieu of converting their Notes, holders may require us to repurchase for cash all or part of their Notes at a repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase

date. Following certain corporate transactions that constitute a change of control, we will increase the conversion rate for a holder who elects to convert the Notes in connection with such change of control in certain circumstances.

The Indenture contains customary events of default with respect to the Notes, including that upon certain events of default (including our failure to make any payment of principal or interest on the Notes when due and payable) occurring and continuing, the Trustee by notice to us, or the holders of at least 25% in principal amount of the outstanding Notes by notice to us and the Trustee, may, and the Trustee at the request of such holders (subject to the provisions of the Indenture) shall, declare 100% of the principal of and accrued and unpaid interest, if any, on all the Notes to be due and payable. In case of an event of default involving certain events of bankruptcy, insolvency or reorganization, involving us or a significant subsidiary of ours, 100% of the principal of and accrued and unpaid interest on the Notes will automatically become due and payable. Upon a declaration of acceleration, such principal and accrued and unpaid interest, if any, will be due and payable immediately.

Convertible Note Hedge and Warrant Transactions

On June 5, 2012, we entered into convertible note hedge transactions and warrant transactions with several of the initial purchasers of the Notes, their respective affiliates and other financial institutions, which we refer to as the Hedge Counterparties. We used approximately $19.8 million of the net proceeds from the offering to pay the cost of the convertible note hedge transactions (after such cost was partially offset by the proceeds to us from the sale of warrants in the warrant transactions).

We expect the convertible note hedge transactions to reduce the potential dilution with respect to shares of our common stock upon any conversion of the Notes in the event that the market price per share of our common stock, as measured under the terms of the convertible note hedge transactions, is greater than the strike price of the convertible note hedge transactions, which initially corresponds to the conversion price of the Notes and is subject to anti-dilution adjustments substantially similar to those applicable to the conversion rate of the Notes. The warrant transactions will have a dilutive effect with respect to our common stock to the extent that the market price per share of our common stock, as measured under the terms of the warrant transactions, exceeds the applicable strike price of the warrants. However, subject to certain conditions, we may elect to settle all of the warrants in cash.

Share Repurchase

We used approximately $50.0 million of the net proceeds of the offering of the Notes to repurchase 2,192,982 shares of our common stock in a privately negotiated transaction with one of the purchasers of the Notes. We repurchased the shares of our common stock in this transaction at a price of $22.80 per share, which was the last reported sale price per share of our common stock on June 5, 2012, the date that we priced the private offering of the Notes.

Cleviprex Resupply, Re-launch and Formulation

In December 2009 and March 2010, we conducted voluntary recalls of manufactured lots of Cleviprex due to the presence of visible particulate matter at the bottom of some vials. As a result, we were not able to supply the market with Cleviprex and sell Cleviprex from the first quarter of 2010 through the first quarter of 2011. We cooperated with the FDA and our contract manufacturer to remedy the problem at the manufacturing site that resulted in the recalls. We began to resupply existing customers with Cleviprex in April 2011. In June 2011, the FDA approved our supplemental New Drug Application, or sNDA, for an improved formulation of Cleviprex. The new formulation triples the maximum allowable infusion time per vial, commonly referred to in hospitals as "hang time", to 12 hours compared to the original 4-hour hang time approved by the FDA in 2008. We re-launched Cleviprex in October 2011 with the new formulation, targeting neurocritical care patients, including intracranial bleeding and acute ischemic stroke patients requiring blood pressure control, and cardiac surgery patients, including patients undergoing coronary artery bypass graft surgery, heart valve replacement or repair, and surgery for the repair of aortic dissection.

Ready-to-Use Argatroban Recall

In December 2011, Eagle Pharmaceuticals, Inc., or Eagle, conducted a voluntary recall of ready-to-use Argatroban due to the presence of particulate matter in some vials. As a result, we were not able to sell ready-to-use Argatroban from December 2011 to April 2012. In April 2012, we re-commenced selling ready-to-use Argatroban to existing and new customers.

Collaboration with AstraZeneca

On April 25, 2012, we entered into a global collaboration agreement with AstraZeneca, LP, or AstraZeneca, pursuant to which we and AstraZeneca have agreed to collaborate globally to develop and commercialize certain acute ischemic heart disease compounds. Under the terms of the collaboration agreement, a joint development and research committee and a joint commercialization committee have been established to prepare and deliver a global development plan and a country-by-country

collaboration and commercialization plan, respectively, related to BRILINTA and Angiomax and cangrelor. Implementation of these plans is subject to agreement between both parties. The first joint activity agreed upon by the parties under the global collaboration is a four-year co-promotion arrangement for BRILINTA in the United States. Pursuant to the agreement, our sales force began supporting promotion activities for BRILINTA in May 2012. Under the terms of the agreement, AstraZeneca paid us $2.5 million for conducting BRILINTA co-promotion activities in the second quarter of 2012. In addition, under the terms of the agreement, AstraZeneca has agreed to pay us $7.5 million in base consideration for conducting BRILINTA co-promotion activities during the period from July 1, 2012 to December 31, 2012, plus up to $2.5 million in additional consideration for the same period, contingent upon the number of new prescriptions written during that period, $15.0 million in base consideration per year from 2013 through 2015 for conducting BRILINTA co-promotion activities, plus up to an additional $5.0 million per year from 2013 to 2015 if certain performance targets with respect to new prescriptions are achieved and $7.5 million in base consideration for conducting BRILINTA co-promotion activities during the period from January 1, 2016 until June 30, 2016, plus up to an additional $2.5 million in additional consideration for the same period if certain performance targets with respect to new prescriptions are achieved. We and AstraZeneca have not agreed as to any development and commercialization activities to be performed with respect to Angiomax and cangrelor or as to any terms under which such activities would be performed.

Biogen Letter Agreement

On August 7, 2012, we and Biogen Idec MA Inc., or Biogen, entered into a letter agreement resolving a disagreement between the parties as to the calculation and amount of the royalties required to be paid to Biogen by us under our license agreement with Biogen. The letter agreement amends the license agreement providing, among other things, that effective solely for the period from January 1, 2013 through and including December 15, 2014, each of the royalty rate percentages payable by us as set forth in the license agreement shall be increased by one percentage point.

MDCO-2010 Clinical Trial Discontinuation

On October 4, 2012, we voluntarily discontinued our Phase 2b dose-ranging study of MDCO-2010, a serine protease inhibitor which was being developed to reduce blood loss during surgery. This action was taken in response to serious unexpected patient safety issues encountered during the trial, which at the time the trial was discontinued, had recruited 44 of a planned 90 patients in the first stage of the study.
While the cause of the safety issues and any potential link to the study drug are still under investigation, we decided to end the trial and further development of MDCO-2010 because of the evidence of risk to patients. We are conducting an assessment of patient data from the study. Once this evaluation is completed and reviewed with experts in the field, we plan to publish our findings.

U.S. Health Care Reform

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, or PPACA, which was amended by the Health Care and Education Reconciliation Act of 2010. The PPACA, as amended, contains numerous provisions that impact the pharmaceutical and healthcare industries that are expected to be implemented over the next several years. We are continually evaluating the impact of the PPACA on our business. As of the date of this quarterly report, we have not identified any provisions that currently materially impact our business or results of operations. However, the potential impact of the PPACA on our business and results of operations is inherently difficult to predict because many of the details regarding the implementation of this legislation have not been determined. In addition, the impact on our business and results of operations may change as and if our business evolves.

On July 9, 2012, President Obama signed the Food and Drug Administration Safety and Innovation Act, or FDASIA. Under the "Generating Antibiotic Incentives Now," or GAIN, provisions of FDASIA, the FDA may designate a product as a qualified infectious disease product, or QIDP. A QIDP is defined as an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by either an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens or a so-called "qualifying pathogen" found on a list of potentially dangerous, drug-resistant organisms to be established and maintained by the FDA under the new law. The GAIN provisions describe several examples of "qualifying pathogens," including methicillin-resistant Staphylococcus aureus, or MRSA, and Clostridium difficile. Upon the designation of a drug by the FDA as a QIDP, any non-patent exclusivity period awarded to the drug will be extended by an additional five years. This extension is in addition to any pediatric exclusivity extension awarded.

We are currently developing oritavancin for the treatment of ABSSSI, including infections caused by MRSA, and are exploring the development of oritavancin for other indications, including for the treatment of Clostridium difficile, anthrax and other Gram-

positive bacterial infections. We believe that oritavancin may qualify as a QIDP and intend to request that oritavancin be designated as a QIDP. If we are successful in having oritavancin designated as a QIDP by the FDA under the GAIN provisions of the new FDASIA legislation, we expect the non-patent exclusivity awarded to oritavancin upon approval of an NDA to be extended by an additional five years.

Results of Operations

Net Revenue:

Net revenue increased 13.3% to $136.8 million for the three months ended September 30, 2012 as compared to $120.8 million for the three months ended September 30, 2011.

Net revenue increased 13.2% to $399.1 million for the nine months ended September 30, 2012 as compared to $352.5 million for the nine months ended September 30, 2011.

The following tables reflect the components of net revenue for the three and nine months ended September 30, 2012 and 2011:

Net Revenue

	Three Months Ended September 30,				
	2012	2011	Change $	Change %	
		(in thousands)			
Angiomax	$133,765	$120,347	$13,418	11.1	%
Cleviprex/Ready-to-Use Argatroban	3,021	425	2,596	610.8	%
Total net revenue	$136,786	$120,772	$16,014	13.3	%

	Nine Months Ended September 30,				
	2012	2011	Change $	Change %	
		(in thousands)			
Angiomax	$392,975	$351,762	$41,213	11.7	%
Cleviprex/Ready-to-Use Argatroban	6,123	739	5,384	728.6	%
Total net revenue	$399,098	$352,501	$46,597	13.2	%

Net revenue increased by $16.0 million, or 13.3%, to $136.8 million in the three months ended September 30, 2012 compared to $120.8 million in the three months ended September 30, 2011, reflecting increases of $15.3 million or 13.7% in the United States, and $0.7 million or 8.1% in international markets. The net revenue increase was comprised of net volume increases of $7.1 million and price increases of $9.2 million, which were offset by the unfavorable impact from foreign exchange of $0.3 million.

Net revenue increased by $46.6 million, or 13.2%, to $399.1 million in the nine months ended September 30, 2012 compared to $352.5 million in the nine months ended September 30, 2011, reflecting increases of $37.7 million or 11.5% in the United States, and $8.9 million or 37.5% in international markets. The net revenue increase was comprised of net volume increases of $21.5 million and price increases of $25.5 million, which were offset by the unfavorable impact from foreign exchange of $0.4 million.

Angiomax. Net revenue from sales of Angiomax increased by $13.4 million, or 11.1%, to $133.8 million in the three months ended September 30, 2012 compared to $120.3 million in the three months ended September 30, 2011, primarily due to a price increase in the United States and increased unit sales globally. Net revenue in the United States in both the three months ended September 30, 2012 and 2011 reflect chargebacks related to the 340B Drug Pricing Program under the Public Health Services Act and rebates related to the PPACA. Under the 340B Drug Pricing Program, we offer qualifying entities a discount off the commercial price of Angiomax for patients undergoing PCI on an outpatient basis. Chargebacks related to the 340B Drug Pricing Program increased by $0.7 million to $11.8 million in the three months ended September 30, 2012 compared to $11.1 million in the three months ended September 30, 2011, primarily due to increased usage by eligible hospital customers. Rebates related to the PPACA increased by $0.1 million to $0.2 million in the three months ended September 30, 2012 compared to $0.1 million in the three months ended September 30, 2011. Net revenue from sales of Angiomax outside the United States increased in the three months

ended September 30, 2012 compared to the three months ended September 30, 2011 due to greater demand by existing hospital customers and the addition of new hospital customers in the United Kingdom, Italy, Denmark, France, the Netherlands, Israel, Australia and Saudi Arabia.

Net revenue from sales of Angiomax increased by $41.2 million, or 11.7%, to $393.0 million in the nine months ended September 30, 2012 compared to $351.8 million in the nine months ended September 30, 2011, primarily due to a price increase in the United States and increased unit sales globally. Net revenue in the United States in both the nine months ended September 30, 2012 and 2011 reflect chargebacks related to the 340B Drug Pricing Program and rebates related to the PPACA. Chargebacks related to 340B Drug Pricing Program increased by $3.6 million to $33.9 million in the nine months ended September 30, 2012 compared to $30.3 million in the nine months ended September 30, 2011, primarily due to increased usage by eligible hospital customers. Rebates related to the PPACA increased by $0.1 million to $0.6 million in the nine months ended September 30, 2012 compared to $0.5 million in the nine months ended September 30, 2011. Net revenue from sales of Angiomax outside the United States increased in the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 due to greater demand by existing hospital customers and the addition of new hospital customers in Russia, the United Kingdom, Italy, Denmark, France, Germany, the Netherlands and Australia.

Cleviprex/Ready-to-Use Argatroban. Net revenue from sales of Cleviprex was $0.8 million in the three months ended September 30, 2012 compared to $0.2 million in the three months ended September 30, 2011. Net revenue from sales of ready-to-use Argatroban was $2.2 million in the three months ended September 30, 2012 compared to $0.2 million in the three months ended September 30, 2011. This formulation of ready-to-use Argatroban was not approved for sale by the FDA until July 2011.

Net revenue from sales of Cleviprex was $1.9 million in the nine months ended September 30, 2012 compared to $0.5 million in the nine months ended September 30, 2011. Due to the recalls, we only began to resupply existing customers with Cleviprex in April 2011 and re-launched Cleviprex in October 2011 with the new 12-hour hang-time formulation. Net revenue from sales of ready-to-use Argatroban was $4.2 million in the nine months ended September 30, 2012 compared to $0.2 million in the nine months ended September 30, 2011. This formulation of ready-to-use Argatroban was not approved for sale by the FDA until July 2011 and not sold from December 2011 to April 2012 due to a voluntary recall by Eagle of the drug.

Cost of Revenue:

Cost of revenue in the three months ended September 30, 2012 was $43.8 million, or 32% of net revenue, compared to $39.5 million, or 33% of net revenue, in the three months ended September 30, 2011.

Cost of revenue in the nine months ended September 30, 2012 was $125.1 million, or 31% of net revenue, compared to $112.9 million, or 32% of net revenue, in the nine months ended September 30, 2011.

Cost of revenue during both periods consisted of expenses in connection with the manufacture of our products sold, royalty expenses under our agreements with Biogen and Health Research Inc., or HRI, related to Angiomax, our agreement with AstraZeneca related to Cleviprex, our agreement with Eagle related to ready-to-use Argatroban, amortization of the costs of license agreements, product rights and other identifiable intangible assets, which result from product and business acquisitions, and logistics costs related to Angiomax, Cleviprex and ready-to-use Argatroban, including distribution, storage, and handling costs.

Cost of Revenue

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2012	% of Total	2011	% of Total	2012	% of Total	2011	% of Total

	(in thousands)			(in thousands)			(in thousands)			(in thousands)		
Manufacturing/Logistics	$12,254	28	%	$11,500	29	%	$35,436	28	%	$33,663	30	%
Royalty	31,287	71	%	27,959	71	%	$88,998	71	%	$79,196	70	%
Amortization of product rights and intangible assets	226	1	%	—	—	%	$677	1	%		—	%
Total cost of revenue	$43,767	100	%	$39,459	100	%	$125,111	100	%	$112,859	100	%

Cost of revenue increased by $4.3 million during the three months ended September 30, 2012 compared to the three months ended September 30, 2011 primarily due to an increase in royalty expense to Biogen due to higher royalty sales under our agreement with Biogen triggered by higher sales of Angiomax.

Cost of revenue increased by $12.2 million during the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 primarily due to an increase in royalty expense to Biogen due to higher royalty sales under our agreement with Biogen triggered by higher sales of Angiomax. The increase in cost of revenue was also related to an increase in manufacturing and logistics expenses due to costs associated with our entry into an agreement with Patheon International A.G., or Patheon, in March 2011 under which Patheon agreed to be an additional supplier of Angiomax drug product.

We expect royalty expense to Biogen to increase beginning in the first quarter of 2013 due to the increase in royalty rates agreed to under the letter agreement we entered into with Biogen on August 7, 2012.

Research and Development Expenses:

Research and development expenses increased by 30% to $34.5 million for the three months ended September 30, 2012, compared to $26.6 million for the three months ended September 30, 2011. The increase primarily reflects additional costs incurred in connection with our ongoing Phase 3 clinical trials of cangrelor and oritavancin, including our acceleration of patient enrollment in our SOLO I Phase 3 trial of oritavancin. The increase also reflects costs related to MDCO-216, including costs incurred in preparation for the filing of an investigational new drug application, or IND, in the fourth quarter of 2012, and for the manufacture of drug product for the anticipated Phase 1 clinical trial that we plan to commence in the fourth quarter of 2012. These increases were offset by a decrease in administrative and headcount expenses related to MDCO-2010 associated with the closure of our drug discovery research and development facility and operations in Leipzig in September 2011.

Research and development expenses increased by 30% to $100.3 million for the nine months ended September 30, 2012, compared to $76.9 million for the nine months ended September 30, 2011. The increase primarily reflects additional costs incurred in connection with our ongoing Phase 3 clinical trials of cangrelor and oritavancin, including our acceleration of patient enrollment in our SOLO I Phase 3 trial of oritavancin. The increase also reflects costs incurred in preparation for the commencement of a Phase 1 clinical trial of MDCO-216, including the manufacturing of drug product for the anticipated Phase 1 trial and costs incurred with the commencement enrollment of healthy volunteers in a pharmacodynamic study of intravenous MDCO-157 comparing it with oral clopidogrel. These increases were offset by a decrease in administrative and headcount expenses related to MDCO-2010 associated with the 2011 Leipzig closure.

We expect to continue to invest in the development of Angiomax, Cleviprex, cangrelor, oritavancin, MDCO-216 and MDCO-157 during the remainder of 2012 and that our research and development expenses will increase in 2012 from their levels in 2011. We expect research and development expenses in 2012 to include costs associated with our ongoing Phase 3 clinical trials of oritavancin and cangrelor, global regulatory activities related to oritavancin and cangrelor, manufacturing development activities for Angiomax, Cleviprex, cangrelor and MDCO-216, our evaluation of data related to our Phase 2 clinical trial program for MDCO-2010, our planned Phase 1 clinical trial of MDCO-216, product lifecycle management activities and the development of MDCO-157.

The following table identifies for each of our major research and development projects our spending for the three and nine months ended September 30, 2012 and 2011. Spending for past periods is not necessarily indicative of spending in future periods.

Research and Development Spending

	Three Months Ended September 30,					
	2012	% of Total R&D		2011	% of Total R&D	
	(In thousands)			(In thousands)		
Angiomax						
Clinical trials	$2,610	7	%	$1,116	4	%
Manufacturing development	14	—	%	34	—	%
Administrative and headcount costs	939	3	%	768	3	%
Total Angiomax	3,563	10	%	1,918	7	%
Cleviprex						
Clinical trials	—	—	%	659	3	%
Manufacturing development	95	—	%	109	—	%
Administrative and headcount costs	518	2	%	450	2	%
Total Cleviprex	613	2	%	1,218	5	%
Cangrelor						
Clinical trials	11,688	34	%	6,622	25	%
Manufacturing development	53	—	%	320	1	%
Administrative and headcount costs	1,861	5	%	1,466	6	%
Total Cangrelor	13,602	39	%	8,408	32	%
Oritavancin						
Clinical trials	6,615	19	%	6,038	23	%
Manufacturing development	1,146	3	%	925	4	%
Administrative and headcount costs	491	2	%	1,153	4	%
Total Oritavancin	8,252	24	%	8,116	31	%
MDCO-157						
Clinical trials	526	2	%	—	—	%
Manufacturing development	58	—	%	—	—	%
Administrative and headcount costs	425	1	%	35	—	%
Acquisition license fee	—	—	%	—	—	%
Total MDCO-157	1,009	3	%	35	—	%
MDCO-2010						
Clinical trials	349	1	%	73	—	%
Manufacturing development	196	1	%	97	—	%
Administrative and headcount costs	446	1	%	2,081	8	%
Government subsidy	—	—	%	—	—	%
Total MDCO-2010	991	3	%	2,251	8	%
MDCO-216						
Clinical trials	388	1	%	102	1	%
Manufacturing development	603	2	%	612	2	%
Administrative and headcount costs	354	1	%	267	1	%
Total MDCO-216	1,345	4	%	981	4	%
Ready-to-Use Argatroban						
Administrative and headcount costs	—	—	%	(147)	(1)	%
Total Ready-to-Use Argatroban	—	—	%	(147)	(1)	%

Other	5,161	15	%	3,770	14	%
Total	$34,536	100	%	$26,550	100	%

	Nine Months Ended September 30,					
	2012	% of Total R&D		2011	% of Total R&D	
	(In thousands)			(In thousands)		
Angiomax						
Clinical trials	$5,090	5	%	$4,763	6	%
Manufacturing development	69	—	%	206	—	%
Administrative and headcount costs	1,984	2	%	2,194	3	%
Total Angiomax	7,143	7	%	7,163	9	%
Cleviprex						
Clinical trials	163	—	%	1,332	2	%
Manufacturing development	781	1	%	300	1	%
Administrative and headcount costs	1,274	1	%	1,095	1	%
Total Cleviprex	2,218	2	%	2,727	4	%
Cangrelor						
Clinical trials	34,767	35	%	17,648	23	%
Manufacturing development	1,233	1	%	868	1	%
Administrative and headcount costs	4,863	5	%	4,741	6	%
Milestone	—	—	%	—	—	%
Total Cangrelor	40,863	41	%	23,257	30	%
Oritavancin						
Clinical trials	22,093	22	%	17,678	23	%
Manufacturing development	3,539	4	%	1,825	2	%
Administrative and headcount costs	2,448	2	%	3,860	5	%
Total Oritavancin	28,080	28	%	23,363	30	%
MDCO-157						
Clinical trials	626	1	%	—	—	%
Manufacturing development	471	—	%	—	—	%
Administrative and headcount costs	1,658	2	%	35	—	%
Acquisition license fee	—	—	%	1,750	2	%
Total MDCO-157	2,755	3	%	1,785	2	%
MDCO-2010						
Clinical trials	767	—	%	531	1	%
Manufacturing development	822	1	%	199	—	%
Administrative and headcount costs	1,865	2	%	3,867	5	%
Government subsidy		—	%	(222)	—	%
Total MDCO-2010	3,454	3	%	4,375	6	%
MDCO-216						
Clinical trials	786	1	%	588	1	%
Manufacturing development	1,684	2	%	2,025	3	%
Administrative and headcount costs	1,005	1	%	749	1	%
Total MDCO-216	3,475	4	%	3,362	5	%
Ready-to-Use Argatroban						
Administrative and headcount costs	—	—	%	544	1	%
Total Ready-to-Use Argatroban	—	—	%	544	1	%
Other	12,288	12	%	10,302	13	%

Total	$100,276	100	%	$76,878	100	%

Angiomax

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Research and development spending related to Angiomax during the three months ended September 30, 2012 increased by approximately $1.6 million compared to the three months ended September 30, 2011. Clinical trial costs increased by $1.5 million, primarily due to increased expenditures in connection with our EUROMAX trial. Research and development spending related to Angiomax during the nine months ended September 30, 2012 was relatively unchanged compared to the nine months ended September 30, 2011. Clinical trial costs increased by $0.3 million, primarily due to increased expenditures in connection with our EUROMAX trial, offset by lower administrative and headcount related expenses.

We are conducting our EUROMAX trial at sites in seven European countries to assess whether the early administration of Angiox in STEMI patients intended for primary PCI presenting either via ambulance or to referral centers where PCI is not performed improves 30-day outcomes when compared to the current standard of care, heparin plus an optional glycoprotein IIb/IIIa receptor inhibitor, or GP IIb/IIIa inhibitor. We commenced enrollment in our EUROMAX clinical trial in March 2010. We expect to enroll approximately 2,200 patients in the EUROMAX trial and to complete enrollment in 2013.

We expect that our total research and development expenses relating to Angiomax will increase in 2012 as compared to 2011 levels in connection with our efforts to further develop Angiomax for use in additional patient populations, including our EUROMAX trial, as well as continued research and development expenses related to our product lifecycle management activities.

Cleviprex

Research and development expenditures for Cleviprex decreased by approximately $0.6 million during the three months ended September 30, 2012 compared to the three months ended September 30, 2011. The decrease in costs in the 2012 was primarily due to lower clinical costs associated with our PRONTO trial.

Research and development expenditures for Cleviprex decreased by approximately $0.5 million during the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011. The decrease in costs during the nine months ended September 30, 2012 was primarily due to lower clinical costs associated with our PRONTO trial. These decreased costs were partially offset by an increase in manufacturing development costs related to product lifecycle activities.

Our PRONTO trial, which we commenced in 2009, evaluated the efficacy and safety of an intravenous infusion of Cleviprex as compared with standard-of-care intravenous antihypertensives for blood pressure lowering in patients with acute heart failure and elevated blood pressure. We are no longer enrolling patients in our PRONTO trial and, in November 2012, data from the trial was presented at the American Heart Association Scientific Sessions 2012.

We expect total research and development expenses relating to Cleviprex will increase in 2012 as compared to 2011 levels. We expect we will incur increased research and development expenses in 2012 in connection with our efforts to obtain marketing approval of Cleviprex outside the United States, the re-commencement of clinical studies that had been suspended due to recalls and an increase in manufacturing development activities.

Cangrelor

Research and development expenditures related to cangrelor increased by approximately $5.2 million in the three months ended September 30, 2012 compared to the three months ended September 30, 2011. The increase primarily reflects increased clinical trial expenses related to our Phase 3 CHAMPION PHOENIX clinical trial.

Research and development expenditures related to cangrelor increased by approximately $17.6 million in the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011. The increase primarily reflects increased clinical trial expenses related to our Phase 3 CHAMPION PHOENIX clinical trial, as well as an increase in manufacturing development expenses.

The CHAMPION PHOENIX clinical trial is a double-blind parallel group randomized study which compares cangrelor to clopidogrel given according to institutional practice. In July 2012 the trial's independent Data Safety Monitoring Board completed a pre-specified interim analysis on effectiveness and the safety data from the first seventy percent of patients enrolled in the trial and recommended that we continue the CHAMPION PHOENIX clinical trial as planned with a sample size of 10,900 patients. We completed patient enrollment in October 2012 and expect to report top-line data regarding the trial in the first quarter of 2013.

We expect total research and development expenses relating to cangrelor will increase in 2012 compared to 2011 levels. We expect we will continue to incur research and development expenses in 2012 in connection with the CHAMPION PHOENIX clinical trial and global regulatory activities.

Oritavancin

Research and development expenditures related to oritavancin increased by approximately $0.1 million in the three months ended September 30, 2012 compared to the three months ended September 30, 2011. The increase primarily reflects increased costs incurred relating to our SOLO I and SOLO II Phase 3 clinical trials.

Research and development expenditures related to oritavancin increased by approximately $4.7 million in the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011. The increase primarily reflects increased costs incurred relating to our SOLO I and SOLO II Phase 3 clinical trials.

The SOLO I and SOLO II clinical trials are designed to assess the efficacy of front-loaded single infusion of oritavancin compared with twice daily infusions of vancomycin for seven to 10 days using a primary efficacy endpoint consisting of a composite of resolution of fever and cessation of spread of visible infection with the use of rescue antibiotics at 48 to 72 hours as measured by cessation of lesion spread, absence of fever, and no rescue antibiotic treatment. Additionally, the trials are designed to meet European Medicines Agency drug approval requirements. In October 2012, we completed enrollment in the SOLO I clinical trial. As of October 24, 2012, we had enrolled 682 of the expected 960 patients in the SOLO II clinical trial. We expect to report top line results from the SOLO I trial in the first quarter of 2013. If the SOLO I clinical trial results are positive, we plan to accelerate enrollment in the SOLO II clinical trial. Under the accelerated timeline, if the results of the trials warrant, we would expect to file an NDA in the middle of 2013.

We expect to incur increased research and development expenses relating to oritavancin in 2012 as compared to 2011 due to the SOLO I and SOLO II clinical trials and global regulatory activities.

MDCO-157

In May 2011, we entered into a licensing agreement with Ligand Pharmaceuticals Incorporated, through its subsidiary CyDex Pharmaceuticals, Inc., under which we acquired an exclusive, worldwide license to patents claiming a Captisol®-enabled intravenous formulation of clopidogrel bisulfate, which we refer to as MDCO-157, and to related know-how. Costs incurred during the three and nine months ended September 30, 2012 were primarily related to increased clinical trial expenses related to our pharmacodynamic study, administrative and headcount related expenses and manufacturing development. Costs incurred during the nine months ended September 30, 2011 were primarily related to the acquisition of the licensing agreement. Under the license agreement, we agreed to spend at least $2.5 million annually on the development of MDCO-157.

We commenced subject enrollment in a dose-response pharmacodynamic study in healthy volunteers of MDCO-157 comparing it with oral clopidogrel during the third quarter of 2012.
We expect total research and development expenses relating to MDCO-157 to increase in 2012 as compared to 2011, as clinical development progresses, including the pharmacodynamic study of MDCO-157.

MDCO-2010

In August 2008, as a result of our acquisition of Curacyte Discovery GmbH, or Curacyte Discovery, we acquired a small molecule serine protease inhibitor that we are developing as an intravenous antifibrinolytic for the reduction of blood loss during surgery, which we refer to as MDCO-2010. Research and development expenditures related to MDCO-2010 decreased by approximately $1.3 million in the three months ended September 30, 2012 compared to the three months ended September 30, 2011. Costs incurred during the three months ended September 30, 2012 primarily related to the Phase 2b dose ranging trial of MDCO-2010 we commenced in the first quarter of 2012 and that we

discontinued in October 2012. Costs incurred during the three months ended September 30, 2011 primarily related to our Phase 2a clinical trial of MDCO-2010. Research and development costs related to MDCO-2010 were partially offset by a German government research and development subsidy paid during the three months ended September 30, 2011.

Research and development expenditures related to MDCO-2010 decreased by approximately $0.9 million in the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011. Costs incurred during the nine months ended September 30, 2012 primarily related to the Phase 2b dose ranging trial of MDCO-2010. Costs incurred during the nine months ended September 30, 2011 primarily related to our Phase 2a clinical trial of MDCO-2010, which we commenced in November 2010 and completed in the third quarter of 2011 and costs associated with the 2011 Leipzig closure. Research and development costs related to MDCO-2010 were partially offset by a German government research and development subsidy paid during the nine months ended September 30, 2011.

We expect that our total research and development expenses relating to MDCO-2010 will decrease in 2012 as compared to 2011, as 2011 expenses reflected the achievement of a €4.0 million clinical milestone earned in the three months ended March 31, 2011 and payable to Curacyte AG and because we discontinued the Phase 2b dose ranging trial and further development of MDCO-2010 in October 2012.

MDCO-216

In December 2009, we licensed from Pfizer Inc. the exclusive worldwide rights to a novel biologic, a naturally occurring variant of a protein found in HDL that has the potential to reverse atherosclerotic plaque development and reduce the risk of coronary events in patients with ACS which we refer to as MDCO-216. Research and development expenditures related to MDCO-216 increased by approximately $0.4 million in the three months ended September 30, 2012 as compared to the three months ended September 30, 2011. Costs incurred during the three months ended September 30, 2012 primarily related to manufacturing development in connection with preparation for the commencement of a Phase 1 study of MDCO-216 that we plan to commence in the fourth quarter of 2012 and administrative and headcount expenses. Costs incurred during the three months ended September 30, 2011 were primarily manufacturing development related to preclinical activities, the costs in preparation of a Phase 1 study of MDCO-216 and administrative and headcount expenses.

Research and development expenditures related to MDCO-216 increased by approximately $0.1 million in the nine months ended September 30, 2012 as compared to the nine months ended September 30, 2011. Costs incurred during the nine months ended September 30, 2012 primarily related to manufacturing development in connection with preparation for the commencement of a Phase 1 study of MDCO-216 and administrative and headcount expenses. Costs incurred during the nine months ended September 30, 2011 were primarily manufacturing development related to preclinical activities and in preparation for a Phase 1 study of MDCO-216 and administrative and headcount expenses.

The Phase 1 study of MDCO-216 will investigate the safety and tolerability of escalating single doses of MDCO-216 in subjects presenting stable angina and angiographic evidence of coronary disease and to characterize the single dose pharmacokinetics of MDCO-216 in subjects presenting stable angina and angiographic evidence of coronary disease.

We expect that our total research and development expenses relating to MDCO-216 will increase in 2012 as compared to 2011, as we plan to submit an IND for MDCO-216 to the FDA and to commence the Phase 1 study of MDCO-216 in the fourth quarter of 2012.

Ready-to-Use Argatroban

We did not have any research and development expenses with respect to ready-to-use Argatroban in either the three months ended September 30, 2012 or the three months ended September 30, 2011.

Research and development expenditures related to ready-to-use Argatroban decreased by $0.5 million in the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 as we did not incur any research and development expenses with respect to ready-to-use Argatroban in the nine months ended September 30, 2012. The costs incurred during the nine months ended September 30, 2011 primarily related to administrative and headcount related expenses.

We expect total research and development expenses relating to ready-to-use Argatroban in 2012 to decrease from 2011 levels.

Other Research and Development Expense

Research and development expenditures in this category includes infrastructure costs in support of our product development efforts, which includes expenses for data management, statistical analysis, analysis of pre-clinical data, analysis of pharmacokinetic-pharmacodynamic data and product safety as well as expenses related to business development activities in connection with our efforts to evaluate early stage and late stage compounds for development and commercialization and other strategic opportunities. Spending in this category increased by approximately $1.4 million during the three months ended September 30, 2012 compared to the three months ended September 30, 2011 and by approximately $2.0 million during the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011, in each case, primarily due to an increase in administrative and headcount expenses.

Our success in further developing Angiomax and obtaining marketing approvals for Angiomax in additional countries and for additional patient populations, developing and obtaining marketing approvals for Cleviprex outside the United States, and developing and obtaining marketing approvals for our products in development, is highly uncertain. We cannot predict expenses

associated with ongoing data analysis or regulatory submissions, if any. In addition, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts necessary to continue the development of Angiomax, Cleviprex and our products in development, the period in which material net cash inflows are expected to commence from further developing Angiomax and Cleviprex, the timing and estimated costs of obtaining marketing approvals for Angiomax in additional countries and additional patient populations, the timing and estimated costs of obtaining marketing approvals for Cleviprex outside the United States, or the timing and estimated costs of developing and obtaining marketing approvals for our products in development, due to the numerous risks and uncertainties associated with developing and commercializing drugs, including the uncertainty of:

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- future clinical trial results;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;
- the cost and timing of establishing and maintaining sales, marketing and distribution capabilities;
- the cost of establishing and maintaining clinical and commercial supplies of our products and product candidates;
- the effect of competing technological and market developments; and
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

Selling, General and Administrative Expenses:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2012	2011	Change $	Change %	2012	2011	Change $	Change %
	(in thousands)				(in thousands)			
Selling, general and administrative expenses	$43,396	$45,353	$(1,957)	(4.3)%	$127,049	$124,701	$2,348	1.9 %

The decrease in selling, general and administrative expenses of approximately $2.0 million in the three months ended September 30, 2012 as compared to the three months ended September 30, 2011 reflects a $6.2 million decrease in general corporate and administrative spending driven by a reduction in legal costs related to the patent term extension of the '404 patent and to our patent litigation with APP, which we settled in January 2012. This decrease was partially offset by a $3.5 million increase in selling, marketing and promotional expense primarily related to Angiomax and higher stock-based compensation costs of $0.7 million.

The increase in selling, general and administrative expenses of $2.3 million in the nine months ended September 30, 2012 as compared to the nine months ended September 30, 2011 reflects a $6.9 million increase in selling, marketing and promotional expense primarily related to Angiomax and higher stock-based compensation costs of $2.5 million. These increases were partially offset by a $7.0 million decrease in general corporate and administrative spending primarily driven by a reduction in legal costs related to the patent term extension of the '404 patent and the settlement of our patent litigation with APP.

Legal Settlement:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2012	2011	Change $	Change %	2012	2011	Change $	Change %
	(in thousands)				(in thousands)			
Legal settlement	$—	$—	$—	100.0 %	$—	$17,984	$(17,984)	100.0 %

During the nine months ended September 30, 2011, we recorded approximately $18.0 million in legal settlement income in connection with the settlement agreement we entered into with WilmerHale in February 2011. Pursuant to the settlement agreement,

WilmerHale agreed to pay approximately $18.0 million from its professional liability insurance providers to us within 60 days after the date of the settlement agreement and delivered such amount in two equal payments in March 2011 and April 2011.

Co-promotion Income:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2012	2011	Change $	Change %	2012	2011	Change $	Change %
	(in thousands)				(in thousands)			
Co-promotion income	$3,750	$—	$3,750	100.0 %	$6,250	$—	$6,250	100.0 %

During the three and nine months ended September 30, 2012, we recorded income of approximately $3.8 million and $6.3 million, respectively, in connection with our collaboration with AstraZeneca for the co-promotion of BRILINTA in the United States. Pursuant to the agreement, our sales force began supporting promotion activities for BRILINTA in May 2012. We did not record any co-promotion income in the three and nine months ended September 30, 2011.

Interest Expense:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2012	2011	Change $	Change %	2012	2011	Change $	Change %
	(in thousands)				(in thousands)			
Interest expense	$(3,605)	$—	$(3,605)	100.0 %	$(4,389)	$—	$(4,389)	100.0 %

During the three and nine months ended September 30, 2012, we recorded approximately $3.6 million and $4.4 million, respectively, in interest expense related to the Notes. We did not record any interest expense in the three and nine months ended September 30, 2011. We issued the Notes on June 11, 2012 and have accrued interest from that date. We expect our interest expense from the Notes to increase in future periods as we record non-cash interest expense as a result of the amortization of the excess of the principal amount of the liability component of the Notes over its carrying amount over the term of the Notes.

Other Income (expense):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2012	2011	Change $	Change %	2012	2011	Change $	Change %
	(in thousands)				(in thousands)			
Other income	$204	$578	$(374)	(64.7)%	$963	$1,450	$(487)	(33.6)%

Other income, which is comprised of interest income and gains and losses on foreign currency transactions, decreased by approximately $0.4 million to $0.2 million for the three months ended September 30, 2012, from $0.6 million for the three months ended September 30, 2011. This decrease was primarily due to higher losses on foreign currency transactions in the three months ended September 30, 2012, and was partially offset by increased interest associated with investment of higher levels of cash.

Other income decreased by $0.5 million to $1.0 million for the nine months ended September 30, 2012, from $1.5 million for the nine months ended September 30, 2011. This decrease was primarily due to higher losses on foreign

currency transactions in the nine months ended September 30, 2012, but was partially offset by increased interest associated with investment of higher levels of cash.

(Provision) Benefit for Income Tax:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2012	2011	Change $	Change %	2012	2011	Change $	Change %
	(in thousands)							
(Provision) benefit for income tax	$(6,172)	$62,625	$(68,797)	(109.9)%	$(18,897)	$50,798	$(69,695)	(137.2)%

We recorded a $6.2 million provision for income taxes and a $62.6 million benefit for income taxes for the three months ended September 30, 2012 and 2011, respectively, based on income before taxes for such periods of $15.4 million and $10.0 million. Our effective income tax rates for the three months ended September 30, 2012 and 2011 were approximately 40.0% and (626.9)%, respectively. The effective tax rate for the three months ended September 30, 2011 reflects the effect of a $66.5 million income tax benefit arising from a reduction in our valuation allowance against its deferred tax assets. Both the 2012 and 2011 effective tax rates include a non-cash tax expense arising from purchase accounting for in-process R&D acquired in our acquisition of Targanta Therapeutics Corporation, or Targanta.

We recorded an $18.9 million provision for income taxes and a $50.8 million provision for income taxes for the nine months ended September 30, 2012 and 2011, respectively, based on income before taxes for such periods of $49.5 million and $57.5 million. Our effective income tax rates for the nine months ended September 30, 2012 and 2011 were approximately 38.2% and (88.3)%, respectively. In addition to the $66.5 million reduction in the valuation allowance discussed above, our income tax benefit for the nine months ended September 30, 2011 includes the effect of a one-time $2.5 million income tax benefit resulting from a prospective change in the New Jersey income tax law enacted in the second quarter 2011 and the tax impact of the settlement from the law firm WilmerHale treated as discrete events. Both the 2012 and 2011 effective tax rates include a non-cash tax expense arising from purchase accounting for in-process R&D acquired in the Targanta acquisition.

It is possible that our full-year effective tax rate could change because of discrete events, our mix of U.S. to foreign earnings, specific transactions, or the receipt of new information affecting our current projections.

At September 30, 2012, we maintained a $4.2 million valuation allowance against $106.5 million of deferred tax assets compared to a $4.2 million valuation allowance against $116.4 million of deferred tax assets at September 30, 2011. A significant portion of this reduction in valuation allowance occurred during the third quarter of 2011 after considering all available positive and negative evidence regarding our future ability to realize our deferred tax assets.

We will continue to evaluate our future ability to realize our deferred tax assets on a periodic basis in light of changing facts and circumstances. These include but are not limited to projections of future taxable income, tax legislation, rulings by relevant tax authorities, the progress of ongoing tax audits, the regulatory approval of products currently under development and the ability to achieve future anticipated revenues.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have financed our operations principally through revenues from sales of Angiomax, the sale of common stock, convertible promissory notes and warrants and interest income. We had $545.4 million in cash, cash equivalents and available for sale securities as of September 30, 2012.

Cash Flows

As of September 30, 2012, we had $480.4 million in cash and cash equivalents, as compared to $315.4 million as of December 31, 2011. The increase in cash and cash equivalents was primarily due to $20.7 million of net cash provided by operating activities and $219.1 million in net cash provided by financing activities, which were partially offset by $75.0 million in net cash used in investing activities.

Net cash provided by operating activities was $20.7 million in the nine months ended September 30, 2012, compared to net cash provided by operating activities of $60.6 million in the nine months ended September 30, 2011. The decrease was primarily due to the timing of changes in working capital. The cash provided by operating activities in the nine months ended September 30, 2012 included net income of $30.6 million and non-cash items of $29.2 million consisting primarily of stock-based compensation expense and depreciation and amortization, which were offset by a $39.1 million decrease resulting from changes in working capital items. The changes in working capital items reflect a decrease in accounts payable and accrued expenses of $13.0 million

primarily due to payments related to inventory of active pharmaceutical ingredient bivalirudin and payment of certain corporate expenses, an increase in accounts receivable of $8.9 million, which was due in part to the timing of receipts and related sales volume, and an increase in inventory of $17.2 million due to purchases under our supply agreement with Teva API, Inc., or Teva API, which was formerly known as Plantex USA Inc., of certain minimum quantities of the active pharmaceutical ingredient bivalirudin for our commercial supply.

Net cash provided by operating activities in the nine months ended September 30, 2011 included net income of $108.3 million offset by non-cash items of $49.8 million consisting primarily of deferred tax benefit of $68.4 million and stock-based compensation expense of $8.4 million, depreciation and amortization of $4.5 million and an adjustment to the contingent purchase price related to the Targanta acquisition of $2.8 million. Cash provided by operating activities in the nine months ended September 30, 2011 also included a decrease of $2.1 million due to changes in working capital items.

During the nine months ended September 30, 2012, $75.0 million in net cash was used in investing activities, which reflected $65.4 million used to purchase available for sale securities and $36.7 million used to acquire intangible assets related to our acute care generic products in connection with our settlement with APP and the reacquisition of our rights to sell Angiomax in Australia and New Zealand from CSL Limited, offset by $25.0 million in proceeds from the maturity and sale of available for sale securities and a $3.1 million decrease in restricted cash resulting from a reduction of our outstanding letter of credit associated with the lease of our principal executive offices.

During the nine months ended September 30, 2011, $68.8 million in net cash was provided by investing activities, which reflected $102.4 million in proceeds from the maturity and sale of available for sale securities and a $1.1 million decrease in restricted cash resulting from a reduction of our outstanding letter of credit associated with the lease of our principal executive offices, offset by $33.8 million used to purchase available for sale securities and $0.9 million used to purchase fixed assets.

Net cash provided by financing activities was $219.1 million in the nine months ended September 30, 2012, which reflected $275.0 million in proceeds from the issuance of the Notes, $38.4 million in proceeds from the issuance of warrants in connection with the issuance of the Notes and $21.6 million of proceeds from option exercises, excess tax benefits and purchases of stock under our employee stock purchase plan. These were partially offset by the $58.2 million purchase of a convertible note hedge, $50.0 million for purchase of treasury shares and $8.8 million in issuance costs in connection with our convertible note offering.

We received $4.0 million in the nine months ended September 30, 2011 in net cash provided by financing activities, which consisted of proceeds to us from option exercises, excess tax benefits and purchases of stock under our employee stock purchase plan.

Funding Requirements

We expect to devote substantial resources to our research and development efforts and to our sales, marketing and manufacturing programs associated with our products and products in development. We also will require cash to pay interest on the Notes and to make principal payments on the Notes at maturity or upon conversion. Our sources of funding to meet these requirements will depend upon many factors, including:

- the extent to which Angiomax is commercially successful globally;

- our ability to maintain market exclusivity for Angiomax in the United States through the enforcement of the '727 patent and the '343 patent during the period following the expiration of the patent term of the '404 patent on December 15, 2014 and the six month pediatric exclusivity on June 15, 2015 through at least May 1, 2019, the date on which we

agreed APP may sell a generic version of Angiomax;

- the extent to which Cleviprex, ready-to-use Argatroban and the acute care generic products for which we acquired the non-exclusive right to sell and distribute from APP are commercially successful in the United States;

- the extent to which our global collaboration with AstraZeneca, including our four-year co-promotion arrangement for BRILINTA in the United States, is successful;

- the extent to which we are successful in our efforts to establish a commercial infrastructure outside the United States;

- the consideration paid by us in connection with acquisitions and licenses of development-stage compounds, clinical-stage product candidates, approved products, or businesses, and in connection with other strategic arrangements;

- the progress, level, timing and cost of our research and development activities related to our clinical trials and non-clinical studies with respect to Angiomax, Cleviprex, as well as cangrelor, oritavancin and MDCO-157 and our other products in development;

- the cost and outcomes of regulatory submissions and reviews for approval of Angiomax in additional countries and for additional indications, of Cleviprex outside the United States, including Australia, the Netherlands, New Zealand, Sweden, Switzerland and the United Kingdom and of our products in development globally;

- the continuation or termination of third-party manufacturing, distribution and sales and marketing arrangements;

- the size, cost and effectiveness of our sales and marketing programs globally;

- the amounts of our payment obligations to third parties as to our products and products in development; and

- our ability to defend and enforce our intellectual property rights.

We believe that our cash on hand and the cash we generate from our operations will be sufficient to meet our ongoing funding requirements, other than for any material acquisition activity. If our existing cash resources, together with revenues that we generate from sales of our products and other sources, are insufficient to satisfy our funding requirements due to slower than anticipated sales of Angiomax, Cleviprex, ready-to-use Argatroban and the acute generic products for which we acquired the non-exclusive right to sell and distribute from APP or higher than anticipated costs globally, we may need to sell additional equity or debt securities or seek additional financing through other arrangements. Any sale of additional equity or debt securities may result in dilution to our stockholders. Debt financing may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures. Moreover, our ability to obtain additional debt financing may be limited by the Notes. We cannot be certain that public or private financing will be available in amounts or on terms acceptable to us, if at all. Further, we may seek additional financing to fund our acquisitions of development stage compounds, clinical stage product candidates and approved products and/or the companies that have such products, and we may not be able to obtain such financing on terms acceptable to us or at all.

If we seek to raise funds through collaboration or licensing arrangements with third parties, we may be required to relinquish rights to products, product candidates or technologies that we would not otherwise relinquish or grant licenses on terms that may not be favorable to us. If we are unable to obtain additional financing, we may be required to delay, reduce the scope of, or eliminate one or more of our planned research, development and commercialization activities, which could harm our financial condition and operating results.

Certain Contingencies:

We may be, from time to time, a party to various disputes and claims arising from normal business activities. We accrue for loss contingencies at the earliest date at which we deem that it is probable that a liability has been incurred and the amount of such loss can be reasonably estimated.

Eagle Pharmaceuticals, Inc. Arbitration. We have received a Demand for Arbitration filed by Eagle Pharmaceuticals, Inc., or Eagle, dated October 25, 2011. In the Demand for Arbitration, Eagle claims that we failed to meet our obligations under the license and development agreement between us, Eagle and certain other parties relating to the development of a new formulation of our product, Angiomax, and to our efforts to seek and obtain regulatory approval, market and sell that new formulation. As a result, Eagle alleges that it has been damaged in an amount it believes exceeds $200 million. We believe we have valid defenses to Eagle's claims and intend to defend ourselves vigorously. We believe that any potential liability is not estimable at this time.

Currently, we are party to the legal proceedings described in Part II, Item I, Legal Proceedings, of this quarterly report, We have assessed such legal proceedings and do not believe that it is probable that a liability has been incurred and the amount of such liability can be reasonably estimated. As a result, we have not recorded a loss contingency related to these legal proceedings.

Contractual Obligations

Our long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business. These include commitments related to purchases of inventory of our products, research and development service agreements, income tax contingencies, operating leases, selling, general and administrative obligations, restricted cash in connection with our lease of our principal office space in Parsippany, New Jersey and royalties, milestone payments and other

contingent payments due under our license and acquisition agreements as of December 31, 2011. During the quarter ended September 30, 2012, there were no material changes outside the ordinary course of business to the specified contractual obligations set forth in the contractual obligations table included in our annual report on Form 10-K for the year ended December 31, 2011, other than the issuance of the Notes in June 2012.

Application of Critical Accounting Estimates

The discussion and analysis of our financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP, for interim financial information and with the instructions to Form 10-Q. Accordingly, they do not include all the information and footnotes required by GAAP for complete financial statements. The preparation of these financial statements requires us to make estimates and judgments that affect our reported assets and liabilities, revenues and expenses, and other financial information. Actual results may differ significantly from these estimates under different assumptions and conditions. In addition, our reported financial condition and results of operations could vary due to a change in the application of a particular accounting standard.

We regard an accounting estimate or assumption underlying our financial statements as a “critical accounting estimate” where:

- the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change; and
- the impact of the estimates and assumptions on financial condition or operating performance is material.

Our significant accounting policies are more fully described in note 2 of our unaudited condensed consolidated financial statements in this quarterly report and note 2 of our consolidated financial statements in our annual report on Form 10-K for the year ended December 31, 2011. Not all of these significant accounting policies, however, require that we make estimates and assumptions that we believe are “critical accounting estimates.” We have discussed our accounting policies with the audit committee of our board of directors, and we believe that our estimates relating to revenue recognition, inventory, income taxes and stock-based compensation described under the caption “Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations - Application of Critical Accounting Estimates” in our annual report on Form 10-K for the year ended December 31, 2011 are “critical accounting estimates.”

Forward-Looking Information

This quarterly report on Form 10-Q includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. For this purpose, any statements contained herein regarding our strategy, future operations, financial position, future revenue, projected costs, prospects, plans and objectives of management, other than statements of historical facts, are forward-looking statements. The words “anticipates,” “believes,” “estimates,” “expects,” “intends,” “may,” “plans,” “projects,” “will,” “would” and similar expressions to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations expressed or implied in our forward-looking statements. There are a number of important factors that could cause actual results, levels of activity, performance or events to differ materially from those expressed or implied in the forward-looking statements we make. These important factors include our “critical accounting estimates” described in Part I, Item 2 of this quarterly report on Form 10-Q and the factors set forth under the caption “Risk Factors” in Part II, Item 1A of this quarterly report on Form 10-Q. Although we may elect to update forward-looking statements in the future, we specifically disclaim

any obligation to do so, even if our estimates change, and readers should not rely on those forward-looking statements as representing our views as of any date subsequent to the date of this quarterly report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Market risk is the risk of change in fair value of a financial instrument due to changes in interest rates, equity prices, creditworthiness, financing, exchange rates or other factors. Our primary market risk exposure relates to changes in interest rates in our cash, cash equivalents and available for sale securities. We place our investments in high-quality financial instruments, primarily money market funds, corporate debt securities, asset backed securities and U.S. government agency notes with maturities of less than two years, which we believe are subject to limited interest rate and credit risk. We currently do not hedge interest rate exposure. At September 30, 2012, we held $545.4 million in cash, cash equivalents and available for sale securities which had an average interest rate of approximately 0.37%. A 10 basis point change in such average interest rate would have had an approximate $0.2 million impact on our interest income. At September 30, 2012, all cash, cash equivalents and available for sale securities were due on demand or within one year.

Most of our transactions are conducted in U.S. dollars. We do have certain agreements with parties located outside the United States. Transactions under certain of these agreements are conducted in U.S. dollars, subject to adjustment based on significant fluctuations in currency exchange rates. Transactions under certain other of these agreements are conducted in the local foreign currency. As of September 30, 2012, we had receivables denominated in currencies other than the U.S. dollar. A 10% change in foreign exchange rates would have had an approximate $1.2 million impact on our other income and cash.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2012. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2012, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended September 30, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Part II. Other Information

Item 1. Legal Proceedings

From time to time we are party to legal proceedings in the course of our business in addition to those described below. We do not, however, expect such other legal proceedings to have a material adverse effect on our business, financial condition or results of operations.

'727 Patent and '343 Patent Litigations

Hospira, Inc.

In July 2010, we were notified that Hospira, Inc., or Hospira, had submitted two ANDAs seeking permission to market its generic version of Angiomax prior to the expiration of the '727 patent and '343 patent. On August 19, 2010, we filed suit against Hospira in the U.S. District Court for the District of Delaware for infringement of the '727 patent and '343 patent. On August 25, 2010, the case was reassigned in lieu of a vacant judgeship to the U.S. District Court for the Eastern District of Pennsylvania. Hospira's answer denied infringement of the '727 patent and '343 patent and raised counterclaims of non-infringement and invalidity of the '727 patent and '343 patent. On September 24, 2010, we filed a reply denying the counterclaims raised by Hospira. The Hospira action was consolidated for discovery purposes with the then pending and now settled cases against Teva and APP. The case was reassigned back to U.S. District Court for the District Court of Delaware. No trial date has been set.

Mylan Pharmaceuticals, Inc.

In January 2011, we were notified that Mylan Pharmaceuticals, Inc. had submitted an ANDA seeking permission to market its generic version of Angiomax prior to the expiration of the '727 patent and '343 patent. On February 23, 2011, we filed suit against Mylan Inc., Mylan Pharmaceuticals Inc. and Bioniche Pharma USA, LLC, which we refer to collectively as Mylan, in the U.S. District Court for the Northern District of Illinois for infringement of the '727 patent and '343 patent. Mylan's answer denied infringement of the '727 patent and '343 patent and raised counterclaims of non-infringement and invalidity of the '727 patent and '343 patent. On April 13, 2011, we filed a reply denying the counterclaims raised by Mylan. On May 4, 2011 the Court set a pretrial schedule. Following a joint request, the Court issued an amended scheduling order on September 22, 2011. On November 29, 2011, Mylan moved to amend its answer to add counterclaims and affirmative defenses of inequitable conduct and unclean hands. Following motion practice, the Court granted Mylan's request to add counterclaims and affirmative defenses of inequitable conduct and to add affirmative defenses of unclean hands. On March 7, 2012, we filed a reply denying these counterclaims. A Markman hearing was held on July 30, 2012. No trial date has been set.

Dr. Reddy's Laboratories, Inc.

In March 2011, we were notified that Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. had submitted an ANDA seeking permission to market its generic version of Angiomax prior to the expiration of the '727 and '343 patents. On April 28, 2011, we filed suit against Dr. Reddy's Laboratories, Ltd., Dr. Reddy's Laboratories, Inc. and Gland Pharma, Inc., which we refer to collectively as Dr. Reddy's, in the U.S. District Court for the District of New Jersey for infringement of the '727 patent and '343 patent. Dr. Reddy's answer denied infringement of the '727 patent and '343 patent and raised counterclaims of non-infringement and invalidity of the '727 patent and '343 patent. An initial case scheduling conference was conducted before the Magistrate Judge on August 25, 2011. Following the conference, a pretrial scheduling order was issued setting dates following the New Jersey Local Patent Rules. On May 11, 2012, Dr. Reddy's filed a motion for summary judgment. On October 2, 2012, the Court held oral argument on Dr.

Reddy's summary judgment motion and conducted a Markman hearing. On October 15, 2012, the Court denied Dr. Reddy's summary judgment motion. A trial date has been set for June 3, 2013.

Sun Pharmaceutical Industries LTD

In October 2011, we were notified that Sun Pharmaceutical Industries LTD had submitted an ANDA seeking permission to market its generic version of Angiomax prior to the expiration of the '727 and '343 patents. On November 21, 2011, we filed suit against Sun Pharma Global FZE, Sun Pharmaceutical Industries LTD., Sun Pharmaceutical Industries Inc., and Caraco Pharmaceutical Laboratories, LTD., which we refer to collectively as Sun, in the U.S. District Court for the District of New Jersey for infringement of the '727 patent and '343 patent. The case has been assigned to the same judge and magistrate judge as the above referenced Dr. Reddy's action. Sun's answer denied infringement of the '727 patent and '343 patent. The Court set an initial case scheduling conference for June 7, 2012. At the conference, the Court set a pretrial schedule. No trial date has been set.

Eagle Pharmaceuticals, Inc. Arbitration

We have received a Demand for Arbitration filed by Eagle Pharmaceuticals, Inc., or Eagle, dated October 25, 2011. In the Demand for Arbitration, Eagle claims that we failed to meet our obligations under the license and development agreement between us, Eagle and certain other parties relating to the development of a new formulation of our product, Angiomax, and to our efforts to seek and obtain regulatory approval, market and sell that new formulation. As a result, Eagle alleges that it has been damaged in an amount it believes exceeds $200 million. We believe we have valid defenses to Eagle's claims and intend to defend ourselves vigorously.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below in addition to the other information included or incorporated by reference in this quarterly report. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer. In that case, the trading price of our common stock could fall. Updated risk factors associated with our business, which include updates regarding Angiomax intellectual property and risk factors with respect to the Notes are set forth below.

Risks Related to Our Financial Results

We have a history of net losses and may not achieve profitability in future periods or maintain profitability on an annual basis

We have incurred net losses in many years and on a cumulative basis since our inception. As of September 30, 2012, we had an accumulated deficit of approximately $81.1 million. We expect to make substantial expenditures to further develop and commercialize our products, including costs and expenses associated with research and development, clinical trials, nonclinical and preclinical studies, regulatory approvals and commercialization. We anticipate needing to generate greater revenue in future periods from our marketed products and from our products in development in order to achieve and maintain profitability in light of our planned expenditures. If we are unable to generate greater revenue, we may not achieve profitability in future periods, and may not be able to maintain any profitability we do achieve. Our ability to generate future revenue will be substantially dependent on our ability to maintain market exclusivity for Angiomax. If we fail to achieve profitability or maintain profitability on a quarterly or annual basis within the time frame expected by investors or securities analysts, the market price of our common stock may decline.

Our business is very dependent on the commercial success of Angiomax. If Angiomax does not generate the revenues we anticipate, our business may be materially harmed

Angiomax has accounted for substantially all of our revenue since we began selling this product in 2001. Until the approval by the FDA of Cleviprex in August 2008 and the ready-to-use formulation of Argatroban in July 2011, Angiomax was our only commercial product. We expect revenue from Angiomax to account for substantially all of our revenue in 2012. The commercial success of Angiomax depends upon:

- our ability to maintain market exclusivity for Angiomax in the United States through the enforcement of the '727 patent and the '343 patent during the period following the expiration of the patent term of the '404 patent on December 15, 2014 and the six month pediatric exclusivity on June 15, 2015 through at least May 1, 2019, the date on which we agreed APP may sell a generic version of Angiomax;

- the continued acceptance by regulators, physicians, patients and other key decision-makers of Angiomax as a safe, therapeutic and cost-effective alternative to heparin and other products used in current practice or currently being

developed;

- our ability to further develop Angiomax and obtain marketing approval of Angiomax for use in additional patient populations and the clinical data we generate to support expansion of the product label;
- the overall number of PCI procedures performed;
- the ability of our third-party supply and manufacturing partners to provide us with sufficient quantities of Angiomax;

- the impact of competition from existing competitive products and from competitive products that may be approved in the future;

- the continued safety and efficacy of Angiomax;

- to what extent and in what amount government and third-party payors cover or reimburse for the costs of Angiomax; and

- our success and the success of our international distributors in selling and marketing Angiomax in Europe and in other countries outside the United States.

We continue to develop Angiomax for use in additional patient populations, including in patients with structural heart disease, patients undergoing peripheral angioplasty, carotid angioplasty and cardiovascular surgery and patients with or at risk of HIT/HITTS. However, even if we are successful in obtaining approval for the use of Angiomax in additional patient populations, our ability to sell Angiomax for use in these additional patient populations may not result in higher revenue or income on a continuing basis.

As of September 30, 2012, our inventory of Angiomax was $61.2 million and we had inventory-related purchase commitments totaling $20.1 million for 2012, $29.9 million for 2013, $26.6 million for 2014 and $7.5 million for 2015 for Angiomax bulk drug substance. If sales of Angiomax were to decline, we could be required to make an allowance for excess or obsolete inventory or increase our accrual for product returns, which could negatively impact our results of operations and our financial condition.

If we are unable to meet our funding requirements, we may need to raise additional capital. If we are unable to obtain such capital on favorable terms or at all, we may not be able to execute on our business plans and our business, financial condition and results of operations may be adversely affected

We expect to devote substantial financial resources to our research and development efforts, clinical trials, nonclinical and preclinical studies and regulatory approvals and to our commercialization and manufacturing programs associated with our products and our products in development. We also will require cash to pay interest on the Notes and to make principal payments on the Notes at maturity or upon conversion. Our sources of funding to meet these requirements will depend upon many factors, including:

- the extent to which Angiomax is commercially successful globally;

- our ability to maintain market exclusivity for Angiomax in the United States through the enforcement of the '727 patent and the '343 patent during the period following the expiration of the patent term of the '404 patent on December 15, 2014 and the six month pediatric exclusivity on June 15, 2015 through at least May 1, 2019, the date on which we agreed APP may sell a generic version of Angiomax;

- the extent to which Cleviprex, ready-to-use Argatroban and the acute care generic products that we acquired the non-exclusive right to sell and distribute from APP are commercially successful in the United States;

- the extent to which our global collaboration with AstraZeneca, including our four-year co-promotion arrangement for BRILINTA in the United States, is successful;

- the extent to which we are successful in our efforts to establish a commercial infrastructure outside the United States;

-

the consideration paid by us in connection with acquisitions and licenses of development-stage compounds, clinical-stage product candidates, approved products, or businesses, and in connection with other strategic arrangements;

- the progress, level, timing and cost of our research and development activities related to our clinical trials and non-clinical studies with respect to Angiomax, Cleviprex, as well as cangrelor, oritavancin and MDCO-157 and our other products in development;

- the cost and outcomes of regulatory submissions and reviews for approval of Angiomax in additional countries and for additional indications, of Cleviprex outside the United States, including Australia, the Netherlands, New Zealand, Sweden, Switzerland and the United Kingdom and of our products in development globally;

- the continuation or termination of third-party manufacturing, distribution and sales and marketing arrangements;

- the size, cost and effectiveness of our sales and marketing programs globally;
- the amounts of our payment obligations to third parties as to our products and products in development; and
- our ability to defend and enforce our intellectual property rights.

If our existing resources, together with revenues that we generate from sales of our products and other sources, are insufficient to satisfy our funding requirements, we may need to sell equity or debt securities or seek additional financing through other arrangements. Public or private financing may not be available in amounts or on terms acceptable to us, if at all. If we seek to raise funds through collaboration or licensing arrangements with third parties, we may be required to relinquish rights to products, products in development or technologies that we would not otherwise relinquish or grant licenses on terms that may not be favorable to us. Moreover, our ability to obtain additional debt financing may be limited by the $275 million in outstanding principal amount of the Notes. If we are unable to obtain additional financing, we may be required to delay, reduce the scope of, or eliminate one or more of our planned research, development and commercialization activities, which could adversely affect our business, financial condition and operating results.

Our revenue in the United States from sales of our products is completely dependent on our sole source distributor, Integrated Commercialization Solutions, or ICS, and our revenue outside the United States is substantially dependent on a limited number of international distributors. If the buying patterns of ICS or these international distributors for our products are not consistent with underlying hospital demand, then our revenue will be subject to fluctuation from quarter to quarter based on these buying patterns and not underlying demand for the products. Any change in these buying patterns could adversely affect our financial results and our stock price.

We distribute Angiomax, Cleviprex and ready-to-use Argatroban in the United States through a sole source distribution model. Under this model, we currently sell Angiomax, Cleviprex and ready-to-use Argatroban to our sole source distributor, ICS. ICS then sells Angiomax, Cleviprex and ready-to-use Argatroban to a limited number of national medical and pharmaceutical wholesalers with distribution centers located throughout the United States and, in certain cases, directly to hospitals. We expect that we will also sell the acute care generic products for which we acquired non-exclusive rights to sell and distribute from APP through the same sole source distribution model. Our revenue from sales of Angiomax in the United States is exclusively from sales to ICS pursuant to our agreement with them. We anticipate that our revenue from sales of Cleviprex, ready-to-use Argatroban and the acute care generic products for which we acquired non-exclusive rights to sell and distribute from APP in the United States will be exclusively from sales to ICS. In connection with a reduction in marketing, sales and distribution fees payable to ICS, we amended our agreement with ICS to extend the ICS payment terms under our distribution agreement with them from 30 days to 45 days, which can be further extended to 49 days if ICS pays by wire transfer. The amendment has caused, and we expect to continue to cause, an increase in accounts receivable. As a result of our relationship with ICS, we expect that our revenue will continue to be subject to fluctuation from quarter to quarter based on the buying patterns of ICS, which may be independent of underlying hospital demand.

In some countries outside the European Union and in a few countries in the European Union, we sell Angiomax to international distributors and these distributors then sell Angiomax to hospitals. Our reliance on a small number of distributors for international sales of Angiomax could cause our revenue to fluctuate from quarter to quarter based on the buying patterns of these distributors, independent of underlying hospital demand.

If inventory levels at ICS or at our international distributors become too high, these distributors may seek to reduce their inventory levels by reducing purchases from us, which could have a material and adverse effect on our revenue in periods in which such purchase reductions occur.

Servicing the Notes will require a significant amount of cash, and we may not have sufficient cash flow from our business to pay the Notes

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance the Notes depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be unfavorable to us or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at the time we seek such refinancing. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

We may not have the ability to raise the funds necessary to settle conversions of the Notes or to repurchase the Notes upon a fundamental change, and our future debt may contain limitations on our ability to pay cash upon conversion or repurchase of the Notes

Holders of the Notes will have the right to require us to repurchase their Notes upon the occurrence of a fundamental change at a repurchase price equal to 100% of their principal amount, plus accrued and unpaid interest, if any, as described in the Indenture. In addition, upon conversion of the Notes, we will be required to make with respect to each $1,000 in principal amount of Notes converted cash payments of at least the lesser of $1,000 and the sum of the daily conversion values as described in the Indenture. However, we may not have enough available cash or be able to obtain financing at the time we are required to repurchase Notes or to pay cash upon conversions of Notes. In addition, our ability to repurchase Notes or to pay cash upon conversions of Notes may be limited by law, by regulatory authority or by agreements governing our future indebtedness. Our failure to repurchase Notes at a time when the repurchase is required by the Indenture or to pay any cash payable on future conversions of the Notes as required by the Indenture would constitute a default under the Indenture. A default under the Indenture or the fundamental change itself could also lead to a default under agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Notes or make cash payments upon conversions thereof.

The conditional conversion feature of the Notes, if triggered, may adversely affect our financial condition and operating results

Holders of the Notes are entitled to convert the Notes at any time during specified periods at their option upon the occurrence of certain conditions, which are set forth in the Indenture. If one or more holders elect to convert their Notes, we would be required to settle any converted principal through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

The accounting method for convertible debt securities that may be settled in cash, such as the Notes, could have a material effect on our reported financial results

In May 2008, the Financial Accounting Standards Board, or FASB, issued FASB Staff Position No. APB 14-1, "Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement)", which has subsequently been codified as Accounting Standards Codification 470-20, "Debt with Conversion and Other Options", which we refer to as ASC 470-20. Under ASC 470-20, an entity must separately account for the liability and equity components of the convertible debt instruments (such as the Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. The effect of ASC 470-20 on the accounting for the Notes is that the equity component is required to be included in the additional paid-in capital section of stockholders' equity on our consolidated balance sheet and the value of the equity component is treated as original issue discount for purposes of accounting for the liability component of the Notes. As a result, we will be required to record non-cash interest expense in current periods presented as a result of the amortization of the excess of the principal amount of the liability component of the Notes over its carrying amount over the term of the Notes. We will report lower net income in our financial results because ASC 470-20 will require interest expense to include the current period's amortization of the debt discount and transaction costs, as well as the Notes' contractual interest, which could adversely affect our reported or future financial results, the market price of our common stock and the trading price of the Notes.

In addition, under certain circumstances, convertible debt instruments (such as the Notes) that may be settled entirely or partly in cash are currently accounted for utilizing the treasury stock method, the effect of which is that the shares issuable upon conversion of the Notes are not included in the calculation of diluted earnings per share except to the extent that the conversion value of the Notes exceeds their principal amount. Under the treasury stock method, for diluted earnings per share purposes, the transaction is accounted for as if the number of shares of common stock that would be necessary to settle such excess, if we elected to settle such excess in shares, are issued. We cannot be sure that the accounting standards in the future will continue to permit the use of the treasury stock method. If we are unable to use the treasury stock method in accounting for the shares issuable upon conversion of the Notes, then our diluted earnings per share would be adversely affected.

If we seek to raise capital to fund acquisitions of development-stage compounds, clinical-stage product candidates, approved products, or businesses or for other reasons by selling equity or debt securities or through other arrangements, our stockholders could be subject to dilution and we may become subject to financial restrictions and covenants, which may limit our activities

If we seek to acquire any development-stage compounds, clinical-stage product candidates, approved products, or businesses or determine that raising additional capital would be in our interest and in the interest of our stockholders, we may seek to sell additional equity or debt securities or seek additional financings through other arrangements. Any sale of additional equity or debt securities may result in dilution to our stockholders. Debt financing may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures. Moreover, our ability to obtain additional debt financing may be limited by the $275 million in outstanding principal amount of the Notes. Our ability to comply with these financial restrictions and covenants could be dependent on our future performance, which is subject to prevailing economic conditions and other factors, including factors that are beyond our control such as foreign exchange rates, interest rates and changes in the level of competition. Failure to comply with the financial restrictions and covenants would adversely affect our business, financial condition and operating results.

Risks Related to Commercialization

Angiomax faces significant competition from all categories of anticoagulant drugs, which may limit the use of Angiomax and adversely affect our revenue

Due to the incidence and severity of cardiovascular diseases, the market for anticoagulant therapies is large and competition is intense. There are a number of anticoagulant drugs currently on the market, awaiting regulatory approval or in development, including orally administered agents. Angiomax competes with, or may compete with in the future, these anticoagulant drugs to the extent Angiomax and any of these anticoagulant drugs are approved for the same or similar indications.

We have positioned Angiomax to compete primarily with heparin, platelet inhibitors such as GP IIb/IIIa inhibitors, and treatment regimens combining heparin and GP IIb/IIIa inhibitors. Because heparin is generic and inexpensive and has been widely used for many years, physicians and medical decision-makers may be hesitant to adopt Angiomax instead of heparin. GP IIb/IIIa inhibitors that Angiomax competes with include ReoPro from Eli Lilly and Johnson & Johnson/Centocor, Inc., Integrilin from Merck & Co., Inc., and Aggrastat from Iroko Pharmaceuticals, LLC and MediCure Inc. GP IIb/IIIa inhibitors are widely used and some physicians believe they offer superior efficacy to Angiomax. Physicians may choose to use heparin combined with GP IIb/IIIa inhibitors due to their years of experience with this combination therapy and reluctance to change existing hospital protocols and pathways. Physician resistance to the use of Angiomax due to either custom or efficacy could adversely affect our revenue.

In some circumstances, Angiomax competes with other anticoagulant drugs for the use of hospital financial resources. For example, many U.S. hospitals receive a fixed reimbursement amount per procedure for the angioplasties and other treatment procedures they perform. As this amount is not based on the actual expenses the hospital incurs, hospitals may choose to use either Angiomax or other anticoagulant drugs or a GP IIb/IIIa inhibitor but not necessarily more than one of these drugs. If hospitals do not choose Angiomax in these instances, our revenue will be adversely affected.

If we are unable to maintain our market exclusivity for Angiomax in the United States as a result of our inability to enforce our U.S. patents covering Angiomax, Angiomax could become subject to generic competition in the United States earlier than we anticipate. We have agreed that APP may sell a generic version of Angiomax beginning May 1, 2019 or earlier under certain conditions, and that Teva may sell a generic version of Angiomax beginning June 30, 2019, or earlier under certain conditions. Competition from generic equivalents that would be sold at a price that is less than the price at which we currently sell Angiomax could have a material adverse impact on our business, financial condition and operating results.

Cleviprex faces significant competition from all categories of intravenous antihypertensive, or IV-AHT, drugs, which may limit the use of Cleviprex and adversely affect our revenue

Because different IV-AHT drugs act in different ways on the factors contributing to elevated blood pressure, physicians have several therapeutic options to reduce acutely elevated blood pressure. We have positioned Cleviprex as an improved alternative drug for selected patient types with acute, severe hypertension. Because all other drug options for this use are available as generics, Cleviprex must demonstrate compelling advantages in delivering value to the hospital. In addition to advancements in efficacy, convenience, tolerability and/or safety, we may need to demonstrate that Cleviprex will save the hospital resources in other areas such as length of stay and other resource utilization in order to become commercially successful. Because generic therapies are inexpensive and have been widely used for many years, physicians and decision-makers for hospital resource allocation may be hesitant to adopt Cleviprex and fail to recognize the value delivered through a newer agent that offers precise blood pressure control. Physician resistance to the use of Cleviprex due to either custom or efficacy would adversely affect our revenue.

In addition, since the re-launch of the new formulation of Cleviprex in October 2011, we have focused our marketing of Cleviprex on neurocritical care and cardiac surgery patients. We have not focused our marketing of Cleviprex in these areas previously and may not be successful in this change in marketing focus.

We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do

Our industry is highly competitive. Competitors in the United States and other countries include major pharmaceutical companies, specialized pharmaceutical companies and biotechnology firms, universities and other research institutions. Many of our competitors have substantially greater research and development capabilities and experience, and greater manufacturing, marketing and financial resources, than we do.

Our competitors may develop, market or license products or other novel technologies that are more effective, safer, more convenient or less costly than any that have been or are being developed or sold by us, or may obtain marketing approval for their products from the FDA or equivalent foreign regulatory bodies more rapidly than we may obtain approval for ours. There are well established products, including generic products, that are approved and marketed for the indications for which Angiomax, Cleviprex, ready-to-use Argatroban and the acute care generic products that we acquired the non-exclusive right to sell and distribute from APP are approved and the indications for which we are developing our products in development. In addition, competitors are developing products for such indications. In the case of the ready-to-use Argatroban, GlaxoSmithKline markets a branded formulation of Argatroban and Sandoz markets a generic formulation of Argatroban that compete with our ready-to-use formulation of Argatroban. In the case of the acute care generic products, such products will compete with their respective brand name reference products and other equivalent generic products that may be sold by APP and other third parties. We compete, in the case of Angiomax, Cleviprex and ready-to-use Argatroban, and expect to compete, in the cases of our products in development, on the basis of product efficacy, safety, ease of administration, price and economic value compared to drugs used in current practice or currently being developed. If we are not successful in demonstrating these attributes, physicians and other key healthcare decision makers may choose other products over our products, switch from our products to new products or choose to use our products only in limited circumstances, which could adversely affect our business, financial condition and results of operations.

If we are unable to successfully identify and acquire or license development stage compounds, clinical stage product candidates or approved products and develop or commercialize those compounds and products, our business, financial condition and results of operations may be adversely affected

Our business strategy is based on us selectively licensing or acquiring and then successfully developing and commercializing development stage compounds, clinical stage product candidates and approved products. Our success will be based in part on our ability to build and actively manage a portfolio of drugs that addresses unmet medical needs and creates value in patient therapy. However, the acquisition and licensing of pharmaceutical products is a competitive area. A number of more established companies, which have acknowledged strategies to license and acquire products, may have competitive advantages over us due to their size, cash flows and institutional experience. In addition, we may compete with emerging companies taking similar or different approaches to product acquisition.

Because of the intense competition for these types of product candidates and approved products, the cost of acquiring, in-licensing or otherwise obtaining rights to such candidates and products has grown dramatically in recent years and are often at levels that we cannot afford or that we believe are not justified by market potential. Any acquisition or license of product candidates or approved products that we pursue may not result in any short or long term benefit to us. We may incorrectly judge the value or worth of an acquired or licensed product candidate or approved product. Even if we succeed in acquiring product candidates, we may not be successful in developing them and obtaining marketing approval for them, manufacturing them economically or commercializing them successfully. We have previously acquired or licensed rights to clinical or development stage compounds and, after having conducted development activities, determined not to devote further resources to those compounds. In addition, our future success would depend in part on our ability to manage any required growth associated with some of these acquisitions and

licenses. Any acquisition might distract resources from the development of our existing product candidates and could otherwise negatively impact sales of our other marketed products. Furthermore, the development or expansion of any licensed or acquired product candidate or approved product may require a substantial capital investment by us, and we may not have these necessary funds to do so.

If we are unable to identify and acquire additional promising candidates or to develop and commercialize successfully those candidates we have, we will not be able to implement our business strategy and our business, operating results and financial condition may be materially and adversely affected.

If we are not able to convince hospitals to include our products on their approved formulary lists, our revenues may not meet expectations and our business, results of operations and financial condition may be adversely affected

Hospitals establish formularies, which are lists of drugs approved for use in the hospital. If a drug is not included on the formulary, the ability of our engagement partners and engagement managers to promote and sell the drug may be limited or denied. For example, in connection with the launch of Cleviprex, we experienced difficulties in getting Cleviprex included on hospitals' formulary lists, in part because hospital formularies may limit the number of IV-AHT drugs in each drug class, and revenues from Cleviprex were adversely affected. If we fail to secure and maintain formulary inclusion for our products on favorable terms or are significantly delayed in doing so, we may have difficulty achieving market acceptance of our products and our business, results of operations and financial condition could be materially adversely affected.

If we are unable to negotiate and maintain satisfactory arrangements with group purchasing organizations with respect to the purchase of our products, our sales, results of operations and financial condition could be adversely affected

Our ability to sell our products to hospitals in the United States depends in part on our relationships with group purchasing organizations, or GPOs. Many existing and potential customers for our products become members of GPOs. GPOs negotiate pricing arrangements and contracts, sometimes on an exclusive basis, with medical supply manufacturers and distributors. These negotiated prices are then made available to a GPO's affiliated hospitals and other members. If we are not one of the providers selected by a GPO, affiliated hospitals and other members may be less likely to purchase our products, and if the GPO has negotiated a strict sole source, market share compliance or bundling contract for another manufacturer's products, we may be precluded from making sales to members of the GPO for the duration of the contractual arrangement. Our failure to renew contracts with GPOs may cause us to lose market share and could have a material adverse effect on our sales, financial condition and results of operations. We cannot assure you that we will be able to renew these contracts at the current or substantially similar terms. If we are unable to keep our relationships and develop new relationships with GPOs, our competitive position may suffer.

If physicians, patients and other key healthcare decision-makers do not accept clinical data from trials of Angiomax and Cleviprex, then sales of Angiomax and Cleviprex may be adversely affected

We believe that the near-term commercial success of Angiomax and Cleviprex will depend in part upon the extent to which physicians, patients and other key healthcare decision-makers accept the results of clinical trials of Angiomax and Cleviprex. For example, following the announcement of the original results of the REPLACE-2 clinical trial of Angiomax in 2002, additional hospitals granted Angiomax formulary approval and hospital demand for the product increased. However, some commentators have challenged various aspects of the trial design of the REPLACE-2 trial of Angiomax, the conduct of the clinical trial and the analysis and interpretation of the results from the clinical trial. Similarly, physicians, patients and other key decision-makers may not accept the results of the ACUITY and HORIZONS AMI clinical trials of Angiomax. The FDA, in denying our sNDA for an additional Angiomax dosing regimen in the treatment of ACS initiated in the emergency department, indicated that the basis of its decision involved the appropriate use and interpretation of non-inferiority trials such as our ACUITY trial. If physicians, patients and other key decision-makers do not accept clinical trial results, adoption and continued use of Angiomax and Cleviprex may suffer, and our business will be materially adversely affected.

If the number of PCI procedures performed decreases, sales of Angiomax may be negatively impacted

The number of PCI procedures performed in the United States declined in 2007 due in part to the reaction to data from a clinical trial that was published in March 2007 in the New England Journal of Medicine entitled “Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation,” or “COURAGE”, and to the controversy regarding the use of drug-eluting stents. Since 2007, PCI procedure volume has remained similar to the 2007 levels and has not returned to the level of PCI procedures performed prior to the 2007 decline. With ongoing economic pressures on our hospital customers, PCI procedure volume might further decline and might not return to its previous levels. Because PCI procedures are the primary procedures during which Angiomax is used, a decline in the number of procedures may

negatively impact sales of Angiomax, possibly materially.

If we are unable to successfully expand our business infrastructure and develop our global operations, our ability to generate future product revenue will be adversely affected and our business, results of operations and financial condition may be adversely affected

To support the global sales and marketing of Angiomax, Cleviprex and our product candidates in development, if and when they are approved for sale and marketed outside the United States, we are developing our business infrastructure globally. Our ability to do this successfully will depend on our ability to expand our internal organization and infrastructure to accommodate additional anticipated growth. To manage the existing and planned future growth and the increasing breadth and complexity of our activities, we will need to continue building our organization and making significant additional investments in personnel, infrastructure, information management systems and other operational resources. If we are unable to expand our global operations successfully and in a timely manner, the growth of our business may be limited. Such expansion may be more difficult, more

expensive or take longer than we anticipate. If we are not able to successfully market and sell our products globally, our business, results of operations and financial condition may be adversely affected.

Future rapid expansion could strain our operational, human and financial resources. For instance, we may be required to allocate additional resources to the expanded business, which we would have otherwise allocated to another part of our business. In order to manage expansion, we must:

- continue to improve operating, administrative, and information systems;
- accurately predict future personnel and resource needs to meet contract commitments;
- track the progress of ongoing projects; and
- attract and retain qualified management, sales, professional, scientific and technical operating personnel.

If we do not take these actions and are not able to manage our global business, then our global operations may be less successful than anticipated.
The success of our global operations may be adversely affected by international risks and uncertainties. If these operations are not successful, our business, results of operations and financial condition could be adversely affected

Our future profitability will depend in part on our ability to grow and ultimately maintain our product sales in foreign markets, particularly in Europe. For the nine months ended September 30, 2012, we had $32.5 million in sales outside of the United States and we have historically encountered difficulty in selling Angiomax outside of the United States. Our foreign operations subject us to additional risks and uncertainties, particularly because we have limited experience in marketing, servicing and distributing our products or otherwise operating our business outside of the United States. These risks and uncertainties include:

- political and economic determinations that adversely impact pricing or reimbursement policies;
- our customers' ability to obtain reimbursement for procedures using our products in foreign markets;
- compliance with complex and changing foreign legal, tax, accounting and regulatory requirements;
- language barriers and other difficulties in providing long-range customer support and service;
- longer accounts receivable collection times;
- significant foreign currency fluctuations, which could result in increased operating expenses and reduced revenues;
- trade restrictions and restrictions on direct investment by foreign entities;
- reduced protection of intellectual property rights in some foreign countries; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Our foreign operations could also be adversely affected by export license requirements, the imposition of governmental controls, political and economic instability, trade restrictions, changes in tariffs and difficulties in staffing and managing foreign operations.

If reimbursement by government payors or other third-party payors is not available or limited for our products, drug pricing is delayed or set at unfavorable levels or access to our products is reduced or terminated by governmental and other third-party payors, our ability to generate revenue would be adversely affected

Acceptable levels of coverage and reimbursement of drug treatments by government payors, such as Medicare and Medicaid programs, private health insurers and other organizations, have a significant effect on our ability to successfully commercialize our products. Reimbursement in the United States, Europe or elsewhere may not be available for any products we may develop or, if already available, may be decreased in the future. We may not get reimbursement or reimbursement may be limited if government payors, private health insurers and other organizations are influenced by the prices of existing drugs in determining whether our products will be reimbursed and at what levels. For example, the availability of numerous generic antibiotics at lower prices than branded antibiotics, such as oritavancin, if it were approved for commercial sale, could substantially affect the likelihood

of reimbursement and the level of reimbursement for oritavancin. If reimbursement is not available or is available only at limited levels, we may not be able to commercialize our products, or may not be able to obtain a satisfactory financial return on our products.

In certain countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals and the level of reimbursement are subject to governmental control. In some countries, pricing and reimbursement are set with limited, if any, participation in the process by the marketing authorization holder. In addition, it can take an extended period of time after the receipt of initial approval of a product to establish and obtain reimbursement or pricing approval. Reimbursement approval also may be required at the individual patient level, which can lead to further delays. In addition, in some countries, it may take an extended period of time to collect payment even after reimbursement has been established. If prices are set at unsatisfactory levels, such prices may negatively impact our revenues from sales in those countries. An increasing number of countries are taking initiatives to attempt to reduce large budget deficits by focusing cost-cutting efforts on pharmaceuticals for their state-run health care systems. These international price control efforts have impacted all regions of the world, but have been most drastic in the European Union. Further, a number of European Union countries use drug prices from other countries of the European Union as “reference prices” to help determine pricing in their own countries. Consequently, a downward trend in drug prices for some countries could contribute to similar occurrences elsewhere. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

Third-party payors, including Medicare and Medicaid increasingly are challenging prices charged for and the cost-effectiveness of medical products and services and they increasingly are limiting both coverage and the level of reimbursement for drugs. Also, the trend toward managed health care in the United States and the changes in health insurance programs may result in lower prices for pharmaceutical products and health care reform. The recently enacted Patient Protection and Affordable Care Act of 2010, or the PPACA, may also have a significant impact on pricing as the legislation contains a number of provisions that are intended to reduce or limit the growth of healthcare costs. The provisions of the PPACA could, among other things, increase pressure on drug pricing and, as a result, the number of procedures that are performed. In addition to federal legislation, state legislatures and foreign governments have also shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. The establishment of limitations on patient access to our drugs, adoption of price controls and cost-containment measures in new jurisdictions or programs, and adoption of more restrictive policies in jurisdictions with existing controls and measures could adversely impact our business and future results. If governmental organizations and third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not reimburse providers or consumers of our products or, if they do, the level of reimbursement may not be sufficient to allow us to sell our products on a profitable basis.

Use or misuse of our products may result in serious injuries or even death to patients and may subject us to significant claims for product liability. If we are unable to obtain insurance at acceptable costs and adequate levels or otherwise protect ourselves against potential product liability claims, we could be exposed to significant liability

Our business exposes us to potential significant product liability risks which are inherent in the testing, manufacturing, marketing and sale of human healthcare products. Product liability claims might be made by patients in clinical trials, consumers, health care providers or pharmaceutical companies or others that sell our products. These claims may be made even with respect to those products that are manufactured in licensed and regulated facilities or otherwise possess regulatory approval for commercial sale or study.

These claims could expose us to significant liabilities that could prevent or interfere with the development or commercialization of our products. Product liability claims could require us to spend significant time and money in litigation or pay significant damages. With respect to our commercial sales and our clinical trials, we are covered by

product liability insurance in the amount of $20.0 million per occurrence and $20.0 million annually in the aggregate on a claims-made basis. This coverage may not be adequate to cover all or any product liability claims that we face

As we continue to commercialize our products, we may wish to increase our product liability insurance. Product liability coverage is expensive. In the future, we may not be able to maintain or obtain such product liability insurance on reasonable terms, at a reasonable cost or in sufficient amounts to protect us against losses due to product liability claims.

An adverse decision in the arbitration between us and Eagle could have a material adverse effect on our financial condition

We have received a Demand for Arbitration filed by Eagle, dated October 25, 2011. In the Demand for Arbitration, Eagle claims that we failed to meet our obligations under the license and development agreement between us, Eagle and certain other parties relating to the development of a new formulation of our product, Angiomax, and to our efforts to seek and obtain regulatory approval, market and sell that new formulation. As a result, Eagle alleges that it has been damaged in an amount Eagle believes

exceeds $200 million. We believe we have valid defenses to Eagle's claims and intend to defend ourselves vigorously. Arbitration, like litigation, is inherently uncertain. An adverse decision in this arbitration could have a material adverse effect on our financial condition.

Risks Related to our Dependence on Third Parties for Manufacturing, Research and Development, and Distribution Activities

We have no manufacturing or supply capabilities and are completely dependent on third parties for the manufacture and supply of our products. We depend on a limited number of suppliers for the production of bulk drug substance for our products and products in development and to carry out fill-finish activities. If any of these suppliers does not or cannot fulfill its manufacturing or supply obligations to us, our ability to meet commercial demands for our products and to conduct clinical trials of our products and products in development could be impaired and our business could be harmed.

We do not manufacture any of our products and do not plan to develop any capacity to manufacture them. We currently rely on a limited number of manufacturers for bulk substance and to carry out fill-finish activities for our products and products in development. We expect to continue this manufacturing arrangement for the foreseeable future.

In the event that any of our third-party manufacturers is unable or unwilling to carry out its respective manufacturing or supply obligations or terminates or refuses to renew its arrangements with us, we may be unable to obtain alternative manufacturing or supply on commercially reasonable terms on a timely basis or at all. In addition, we purchase finished drug product from a number of our third-party manufacturers under purchase orders. In such cases, the third-party manufacturers have made no commitment to supply the drug product to us on a long-term basis and could reject our purchase orders. Only a limited number of manufacturers are capable of manufacturing our products and products in development. Consolidation within the pharmaceutical manufacturing industry could further reduce the number of manufacturers capable of producing our products, or otherwise affect our existing contractual relationships.

If we were required to transfer manufacturing processes to other third-party manufacturers and we were able to identify an alternative manufacturer, we would still need to satisfy various regulatory requirements. Satisfaction of these requirements could cause us to experience significant delays in receiving an adequate supply of our products and products in development and could be costly. Moreover, we may not be able to transfer processes that are proprietary to the manufacturer. Any delays in the manufacturing process may adversely impact our ability to meet commercial demands for our products on a timely basis, which could reduce our revenue, and to supply product for clinical trials of Angiomax, Cleviprex and our products in development, which could affect our ability to complete clinical trials on a timely basis.

If third parties on whom we rely to manufacture and support the development and commercialization of our products do not fulfill their obligations or we are unable to establish or maintain such arrangements, the development and commercialization of our products may be terminated or delayed, and the costs of development and commercialization may increase

Our development and commercialization strategy involves entering into arrangements with corporate and academic collaborators, contract research organizations, distributors, third-party manufacturers, licensors, licensees and others to conduct development work, manage or conduct our clinical trials, manufacture our products and market and sell our products outside of the United States. We do not have the expertise or the resources to conduct many of these activities on our own and, as a result, are particularly dependent on third parties in many areas.

We may not be able to maintain our existing arrangements with respect to the commercialization or manufacture of our products or establish and maintain arrangements to develop, manufacture and commercialize our products in development or any additional product candidates or products we may acquire on terms that are acceptable to us. Any current or future arrangements for development and commercialization may not be successful. If we are not able to establish or maintain agreements relating to our products, our products in development or any additional products or product candidates we may acquire, our results of operations would be materially adversely affected.

Third parties may not perform their obligations as expected. The amount and timing of resources that third parties devote to developing, manufacturing and commercializing our products are not within our control. Our collaborators may develop, manufacture or commercialize, either alone or with others, products and services that are similar to or competitive with the products that are the subject of the collaboration with us. Furthermore, our interests may differ from those of third parties that manufacture or commercialize our products. Our collaborators may reevaluate their priorities from time to time, including following mergers and consolidations, and change the focus of their development, manufacturing or commercialization efforts. Disagreements that may arise with these third parties could delay or lead to the termination of the development or commercialization of our product candidates, or result in litigation or arbitration, which would be time consuming and expensive.

If any third party that manufactures or supports the development or commercialization of our products breaches or terminates its agreement with us, or fails to commit sufficient resources to our collaboration or conduct its activities in a timely manner, or fails to comply with regulatory requirements, such breach, termination or failure could:

- delay or otherwise adversely impact the manufacturing, development or commercialization of our products, our products in development or any additional products or product candidates that we may acquire or develop;
- require us to seek a new collaborator or undertake unforeseen additional responsibilities or devote unforeseen additional resources to the manufacturing, development or commercialization of our products; or
- result in the termination of the development or commercialization of our products.

Our reliance on third-party manufacturers to supply our products and product candidates may increase the risk that we will not have appropriate supplies of our products or our product candidates, which could adversely affect our business, results of operations and financial condition

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured products or products candidates ourselves, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party; and
- the possible termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

For example, in December 2009 and March 2010 we conducted voluntary recalls of manufactured lots of Cleviprex due to the presence of visible particulate matter at the bottom of some vials that were manufactured for us by a third party. As a result, we were not able to supply the market with Cleviprex or sell Cleviprex from the first quarter of 2010 until April 2011. In addition, in December 2011 Eagle, the licensor and sole supplier of ready-to-use Argatroban, conducted a voluntary recall of the product due to the presence of particulate matter in some vials. As a result, we were not able to sell ready-to-use Argatroban from December 2011 to April 2012. In April 2012, we re-commenced selling ready-to-use Argatroban to existing and new customers.

Our products and products in development may compete with products and product candidates of third parties for access to manufacturing facilities. If we are not able to obtain adequate supplies of our products and products in development, it will be more difficult for us to compete effectively, market and sell our approved products and develop our products in development.

Our contract manufacturers are subject to ongoing, periodic, unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to evaluate compliance with the FDA's cGMP, regulations and other governmental regulations and corresponding foreign standards. We cannot be certain that our present or future manufacturers will be able to comply with cGMP regulations and other FDA regulatory requirements or similar regulatory requirements outside the United States. We do not control compliance by our contract manufacturers with these regulations and standards. Failure of our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines and other monetary penalties, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, suspension of clinical trials, license revocation, seizures or recalls of product candidates or

products, interruption of production, warning letters, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and products in development.

If we use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages

We conduct research and development activities that involve the controlled use of potentially hazardous substances, including chemical, biological and radioactive materials and viruses. In addition, our operations produce hazardous waste products. Federal, state and local laws and regulations in the United States and Canada govern the use, manufacture, storage, handling and disposal of hazardous materials. We may incur significant additional costs to comply with applicable laws in the future. Also, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials and we may incur liability as a result of any such contamination or injury. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We have only limited insurance for liabilities arising from hazardous materials. Compliance

with applicable environmental laws and regulations is expensive, and current or future environmental regulations may restrict our research, development and production efforts, which could harm our business, operating results and financial condition.

If we fail to acquire and develop additional development-stage compounds, clinical-stage product candidates or approved products, it will impair our ability to grow our business

We have sold and generated revenue from three products, Angiomax, Cleviprex and ready-to-use Argatroban. In order to generate additional revenue, our business plan is to acquire or license, and then develop and market, additional development-stage compounds, clinical-stage product candidates and approved products. From 2008 through June 2012, for instance, we acquired Curacyte Discovery and Targanta, licensed marketing rights to the ready-to-use formulation of Argatroban, licensed development and commercialization rights to MDCO-216 and MDCO-157 and licensed the non-exclusive rights to sell and distribute ten acute care generic products. The success of this growth strategy depends upon our ability to identify, select and acquire or license pharmaceutical products that meet the criteria we have established. Because we have only the limited internal scientific research capabilities that we acquired in our acquisitions of Curacyte Discovery and Targanta, and we do not anticipate establishing additional scientific research capabilities, we are dependent upon pharmaceutical and biotechnology companies and other researchers to sell or license product candidates to us. In addition, proposing, negotiating and implementing an economically viable acquisition or license is a lengthy and complex process. Other companies, including those with substantially greater financial, marketing and sales resources, may compete with us for the acquisition or license of development-stage compounds, clinical-stage product candidates and approved products. We may not be able to acquire or license the rights to additional product candidates and approved products on terms that we find acceptable, or at all.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on our ability to attract and retain qualified personnel for the acquisition, development and commercialization activities we conduct or sponsor. If we lose one or more of the members of our senior management, including our Chairman and Chief Executive Officer, Clive A. Meanwell, our President and Chief Financial Officer, Glenn P. Sblendorio, or other key employees or consultants, our ability to implement successfully our business strategy could be seriously harmed. Our ability to replace these key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to acquire, develop and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate such additional personnel.

Risks Related to Regulatory Matters

If we do not obtain regulatory approvals for our product candidates in any jurisdiction or for our products in any additional jurisdictions, we will not be able to market our products and product candidates in those jurisdictions and our ability to generate additional revenue could be materially impaired

We must obtain approval from the FDA in order to sell our product candidates in the United States and from foreign regulatory authorities in order to sell our product candidates in other countries. In addition, we must obtain approval from foreign regulatory authorities in order to sell our U.S.-approved products in other countries. Obtaining regulatory approval is uncertain, time-consuming and expensive. Any regulatory approval we ultimately obtain may limit the indicated uses for the product or subject the product to restrictions or post-approval commitments that render the product commercially non-viable. Securing regulatory approval requires the submission of extensive non-clinical and clinical data, information about product manufacturing processes and inspection of facilities and supporting

information to the regulatory authorities for each therapeutic indication to establish the product's safety and efficacy. If we are unable to submit the necessary data and information, for example, because the results of clinical trials are not favorable, or if the applicable regulatory authority delays reviewing or does not approve our applications, we will be unable to obtain regulatory approval. Delays in obtaining or failure to obtain regulatory approvals may:

- delay or prevent the successful commercialization of any of the products or product candidates in the jurisdiction for which approval is sought;
- diminish our competitive advantage; and
- defer or decrease our receipt of revenue.

The regulatory review and approval process to obtain marketing approval takes many years and requires the expenditure of substantial resources. This process can vary substantially based on the type, complexity, novelty and indication of the product involved. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or

may decide that data are insufficient for approval and require additional pre-clinical, clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a product. For example, the FDA issued a complete response letter to Targanta in December 2008 before it was acquired by us with respect to the oritavancin NDA indicating that the FDA could not approve the NDA in its present form and that it would be necessary for Targanta to perform an additional adequate and well-controlled study to demonstrate the safety and efficacy of oritavancin in patients with ABSSSI before the application could be approved. Moreover, recent events, including complications experienced by patients taking FDA-approved drugs, have raised questions about the safety of marketed drugs and may result in new legislation by the U.S. Congress or foreign legislatures and increased caution by the FDA and comparable foreign regulatory authorities in reviewing applications for marketing approval.

In the fourth quarter of 2010, we initiated our SOLO I and SOLO II clinical trials of oritavancin pursuant to a Special Protocol Assessment, or SPA, with the FDA. Many companies which have been granted SPAs have ultimately failed to obtain final approval to market their drugs. Since we are developing oritavancin under an SPA, based on protocol designs negotiated with the FDA, we may be subject to enhanced scrutiny. Additionally, even if the primary endpoints in the SOLO trials are achieved, an SPA does not guarantee approval. An SPA is not binding on the FDA if public health concerns unrecognized at the time the SPA was entered into become evident; the data, assumptions or information underlying the SPA request change or are called into question; other new scientific concerns regarding product safety or efficacy arise; or if we fail to comply with the agreed upon trial protocols. The FDA may raise issues of safety, study conduct, bias, deviation from the protocol, statistical power, patient completion rates, changes in scientific or medical parameters or internal inconsistencies in the data prior to making its final decision. The FDA may also seek the guidance of an outside advisory committee prior to making its final decision.

The procedures to obtain marketing approvals vary among countries and can involve additional clinical trials or other pre-filing requirements. The time required to obtain foreign regulatory approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all the risks associated with obtaining FDA approval, or different or additional risks. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by the regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by the FDA or regulatory authorities in other foreign countries. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products and products in development in any market.

We cannot expand the indications for which we are marketing Angiomax unless we receive regulatory approval for each additional indication. Failure to expand these indications will limit the size of the commercial market for Angiomax

In order to market Angiomax for expanded indications, we will need to conduct appropriate clinical trials, obtain positive results from those trials and obtain regulatory approval for such proposed indications. Obtaining regulatory approval is uncertain, time-consuming and expensive. The regulatory review and approval process to obtain marketing approval for a new indication can take many years and require the expenditure of substantial resources. This process can vary substantially based on the type, complexity, novelty and indication of the product involved. The regulatory authorities have substantial discretion in the approval process and may refuse to accept any application. Alternatively, they may decide that any data submitted is insufficient for approval and require additional pre-clinical, clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a new indication for a product.

For example, in 2006 we received a non-approvable letter from the FDA in connection with our application to market Angiomax for patients with or at risk of HIT/HITTS undergoing cardiac surgery. In addition, in May 2008, we received a non-approvable letter from the FDA with respect to an sNDA that we submitted to the FDA seeking

approval of an additional indication for Angiomax for the treatment of patients with ACS in the emergency department. In its May 2008 letter, the FDA indicated that the basis of their decision involved the appropriate use and interpretation of non-inferiority trials, including the ACUITY trial. If we determine to pursue these indications, the FDA may require that we conduct additional studies of Angiomax, which studies could require the expenditure of substantial resources. Even if we undertook such studies, we might not be successful in obtaining regulatory approval for these indications or any other indications in a timely manner or at all. If we are unsuccessful in expanding the Angiomax product label, the size of the commercial market for Angiomax will be limited.

Clinical trials of product candidates are expensive and time-consuming, and the results of these trials are uncertain. If we are unable to conduct clinical trials that demonstrate the safety and efficacy of our product candidates on a timely basis, then our costs of developing the product candidates may increase and we may not be able to obtain regulatory approval for our product candidates on a timely basis or at all.

Before we can obtain regulatory approvals to market any product for a particular indication, we will be required to complete pre-clinical studies and extensive clinical trials in humans to demonstrate the safety and efficacy of such product for such indication.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in pre-clinical testing or early clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. An unexpected result in one or more of our clinical trials can occur at any stage of testing. For example, in October 2012, we voluntarily discontinued our Phase 2b dose-ranging study of MDCO-2010 in response to serious unexpected patient safety issues encountered during the trial and, in May 2009, we discontinued enrollment in our Phase 3 CHAMPION clinical trial program of cangrelor in patients undergoing PCI after receiving a letter from the clinical program's independent Interim Analysis Review Committee that reported that the efficacy endpoints of the trial program would not be achieved.

We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent us from receiving regulatory approval or commercializing our products, including:

- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials which even if undertaken cannot ensure we will gain approval;
- data obtained from pre-clinical testing and clinical trials may be subject to varying interpretations, which could result in the FDA or other regulatory authorities deciding not to approve a product in a timely fashion, or at all;
- the cost of clinical trials may be greater than we currently anticipate;
- regulators, ethics committees or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we, or the FDA or other regulatory authorities, might suspend or terminate a clinical trial at any time on various grounds, including a finding that participating patients are being exposed to unacceptable health risks. For example, we have in the past voluntarily suspended enrollment in one of our clinical trials to review an interim analysis of safety data from the trial; and
- the effects of our product candidates may not be the desired effects or may include undesirable side effects or the product candidates may have other unexpected characteristics.

The rate of completion of clinical trials depends in part upon the rate of enrollment of patients. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials and the availability of alternative or new treatments. In particular, the patient population targeted by some of our clinical trials may be small. Delays in patient enrollment in any of our current or future clinical trials may result in increased costs and program delays.

If we or our contract manufacturers fail to comply with the extensive regulatory requirements to which we, our contract manufacturers and our products and product candidates are subject, our products could be subject to restrictions or withdrawal from the market, the development of our product candidates could be jeopardized, and we could be subject to penalties

The research, testing, manufacturing, labeling, safety, advertising, promotion, storage, sales, distribution, import, export and marketing, among other things, of our products, both before and after approval, are subject to extensive regulation by governmental authorities in the United States, Europe and elsewhere throughout the world. Both before and after approval of a product, quality control and manufacturing procedures must conform to current good manufacturing practice, or cGMP. Regulatory authorities, including the FDA, periodically inspect manufacturing facilities to assess compliance with cGMP. Our failure or the failure of our contract manufacturers to comply with the laws administered by the FDA, the EMA or other governmental authorities could result in, among other things, any of

the following:

- delay in approving or refusal to approve a product;
- product recall or seizure;
- suspension or withdrawal of an approved product from the market;
- delays in, suspension of or prohibition of commencing, clinical trials of products in development;
- interruption of production;

- operating restrictions;
- untitled or warning letters;
- injunctions;
- fines and other monetary penalties;
- the imposition of civil or criminal penalties;
- disruption of importing and exporting activities; and
- unanticipated expenditures.

We may incur significant liability if it is determined that we are promoting the “off-label” use of any of our products

Physicians may prescribe drug products for uses that are not described in the product's labeling and that differ from those approved by the FDA or other applicable regulatory agencies. Off-label uses are common across medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDA and other regulatory agencies do restrict communications on the subject of off-label use. Companies may not promote drugs for off-label uses. The FDA and other regulatory and enforcement authorities actively enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained. A company that is found to have promoted off-label uses may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific exchange concerning their products. We engage in medical education activities and communicate with investigators and potential investigators regarding our clinical trials. If the FDA or another regulatory or enforcement authority determines that our communications regarding our marketed products are not in compliance with the relevant regulatory requirements and that we have improperly promoted off-label uses, we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

If we do not comply with federal, state and foreign laws and regulations relating to the health care business, we could face substantial penalties

We and our customers are subject to extensive regulation by the federal government, and the governments of the states and foreign countries in which we may conduct our business. In the United States, the laws that directly or indirectly affect our ability to operate our business include the following:

- the Federal Anti-Kickback Law, which prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual or furnishing or arranging for a good or service for which payment may be made under federal health care programs such as Medicare and Medicaid;
- other Medicare laws and regulations that prescribe the requirements for coverage and payment for services performed by our customers, including the amount of such payment;
-

the Federal False Claims Act, which imposes civil and criminal liability on individuals and entities who submit, or cause to be submitted, false or fraudulent claims for payment to the government;

- the Federal False Statements Act, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with delivery of or payment for health care benefits, items or services; and

- various state laws that impose similar requirements and liability with respect to state healthcare reimbursement and other programs.

If our operations are found to be in violation of any of the laws and regulations described above or any other law or governmental regulation to which we or our customers are or will be subject, we may be subject to civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and the curtailment or restructuring of our operations. Similarly, if our

customers are found to be non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on us. Any penalties, damages, fines, curtailment or restructuring of our operations would adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation.

Failure to comply with the U.S. Foreign Corrupt Practices Act, or FCPA, as well as the anti-bribery laws of the nations in which we conduct business, could subject us to penalties and other adverse consequences

We are subject to the FCPA, which generally prohibits U.S. companies from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business and requires companies to maintain accurate books and records and internal controls, including at foreign-controlled subsidiaries. In addition, we are subject to other anti-bribery laws of the nations in which we conduct business that apply similar prohibitions as the FCPA. Our employees or other agents may engage in prohibited conduct without our knowledge under our policies and procedures and the Foreign Corrupt Practices Act and other anti-bribery laws that we may be subject to for which we may be held responsible. If our employees or other agents are found to have engaged in such practices, we could suffer severe penalties and other consequences that may have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Intellectual Property

If we are unable to maintain our market exclusivity for Angiomax in the United States as a result of our inability to enforce our U.S. patents covering Angiomax, Angiomax could be subject to generic competition earlier than we anticipate. Generic competition for Angiomax would have a material adverse effect on our business, financial condition and results of operations

The principal U.S. patents covering Angiomax include the '404 patent, the '727 patent and the '343 patent. The '404 patent was set to expire in March 2010, but the term was extended to December 15, 2014 by the PTO under the Hatch-Waxman Act. As a result of our study of Angiomax in the pediatric setting, we are entitled to a six-month period of pediatric exclusivity following expiration of the '404 patent. In the second half of 2009, the PTO issued to us the '727 patent and the '343 patent, covering a more consistent and improved Angiomax drug product and the processes by which it is made. The '727 patent and the '343 patent are set to expire in July 2028. In response to Paragraph IV Certification Notice letters we received with respect to ANDAs filed by a number of parties with the FDA seeking approval to market generic versions of Angiomax, we have filed lawsuits against the ANDA filers alleging patent infringement of the '727 patent and '343 patent.

On September 30, 2011, we settled our patent infringement litigation with Teva. In connection with the Teva settlement we entered into a license agreement with Teva under which we granted Teva a non-exclusive license under the '727 patent and '343 patent to sell a generic bivalirudin for injection product under a Teva ANDA in the United States beginning June 30, 2019 or earlier under certain conditions.

On January 22, 2012, we settled our patent infringement litigation with APP. In connection with the APP settlement, we entered into a license agreement with APP under which we granted APP a non-exclusive license under the '727 patent and '343 patent to sell a generic bivalirudin for injection product under an APP ANDA in the United States beginning on May 1, 2019. In certain limited circumstances, the license to APP could include the right to sell a generic bivalirudin product under our NDA for Angiomax in the United States beginning on May 1, 2019 or, in certain limited circumstances, on June 30, 2019 or on a date prior to May 1, 2019.

We remain in infringement litigation involving the '727 patent and '343 patent with the other ANDA filers.

If we are unable to maintain our market exclusivity for Angiomax in the United States as a result of our inability to enforce our U.S. patents covering Angiomax, Angiomax could become subject to generic competition in the United States earlier than May 1, 2019. Competition from generic equivalents that would be sold at a price that is less than the price at which we currently sell Angiomax could have a material adverse impact on our business, financial condition and operating results.

Following our settlements with Teva and APP, we submitted the settlement documents for each settlement to the FTC, and the DOJ. The FTC and the DOJ could seek to challenge our settlements with Teva and APP, or a third-party could initiate a private action under antitrust or other laws challenging our settlements with Teva and APP. While we believe our settlements are lawful, we may not prevail in any such challenges or litigation, in which case the other party might obtain injunctive relief, remedial relief, or such other relief as a court may order. In any event, we may incur significant costs in the event of an investigation or in defending any such action and our business and results of operations could be materially impacted if we fail to prevail against any such challenges.

Our patent infringement litigation involving the '727 patent and '343 patent are described in more detail in Part II, Item 1, Legal Proceedings, of this quarterly report.

If we breach any of the agreements under which we license rights to products or technology from others, we could lose license rights that are material to our business or be subject to claims by our licensors

We license rights to products and technology that are important to our business, and we expect to enter into additional licenses in the future. For instance, we have exclusively licensed patents and patent applications relating to each of our products and products in development. Under these agreements, we are subject to a range of commercialization and development, sublicensing, royalty, patent prosecution and maintenance, insurance and other obligations.

Any failure by us to comply with any of these obligations or any other breach by us of our license agreements could give the licensor the right to terminate the license in whole, terminate the exclusive nature of the license or bring a claim against us for damages. Any such termination or claim, particularly relating to our agreements with respect to Angiomax, could have a material adverse effect on our financial condition, results of operations, liquidity or business. Even if we contest any such termination or claim and are ultimately successful, such dispute could lead to delays in the development or commercialization of potential products and result in time-consuming and expensive litigation or arbitration. In addition, on termination we may be required to license to the licensor any related intellectual property that we developed.

If we are unable to obtain or maintain patent protection for the intellectual property relating to our products, the value of our products will be adversely affected

The patent positions of pharmaceutical companies like us are generally uncertain and involve complex legal, scientific and factual issues. We cannot be certain that our patents and patent applications, including our own and those that we have rights through licenses from third parties will adequately protect our intellectual property. Our success protecting our intellectual property depends significantly on our ability to:

- obtain and maintain U.S. and foreign patents, including defending those patents against adverse claims;
- secure patent term extension for the patents covering our approved products;
- protect trade secrets;
- operate without infringing the proprietary rights of others; and
- prevent others from infringing our proprietary rights.

We may not have any additional patents issued from any patent applications that we own or license. If additional patents are granted, the claims allowed may not be sufficiently broad to protect our technology. In addition, issued patents that we own or license may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection we may have for our products, and we may not be able to obtain patent term extension to prolong the terms of the principal patents covering our approved products. Changes in patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the value of patents, once obtained, and with regard to our ability to obtain patents in the future. Depending on decisions by the U.S. Congress, the federal courts, and the PTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that others have not filed or maintained patent applications for technology used by us or covered by our pending patent applications without our being aware of these applications.

We exclusively license patents and patent applications for each of our products and products in development, for which we own the patents and patent applications, and the acute care generic products that we licensed from APP on a non-exclusive basis which are not covered by any patents or patent applications. The patents covering our approved products and our product candidates are currently set to expire at various dates:

Angiomax. The principal U.S. patents covering Angiomax include the '404 patent, the '727 patent and the '343 patent. The '404 patent, was set to expire in March 2010, but the term was extended to December 15, 2014 by the PTO under the Hatch-Waxman Act. As a result of our study of Angiomax in the pediatric setting, we are entitled to a six-month period of pediatric exclusivity following expiration of the '404 patent.

In the second half of 2009, the PTO issued to us the '727 patent and the '343 patent, covering a more consistent and improved Angiomax drug product and the processes by which it is made. The '727 patent and the '343 patent are set to expire in July 2028. In response to Paragraph IV Certification Notice letters we received with respect to abbreviated new drug applications, or ANDAs, filed with the FDA seeking approval to market generic versions of Angiomax, we have filed lawsuits against the ANDA filers alleging patent infringement of the '727 patent and '343 patent. On September 30, 2011, we settled our patent infringement litigation with Teva. In connection with the settlement, we entered into a license agreement with Teva under which we granted Teva a non-exclusive license under the '727 patent and '343 patent to sell a generic bivalirudin for injection product under a Teva ANDA in the United States beginning June 30, 2019 or earlier under certain conditions. On January 22, 2012, we settled our patent infringement litigation with APP. In connection with the settlement, we entered into a license agreement with APP under which we granted APP a non-exclusive license under the '727 patent and '343 patent to sell a generic bivalirudin for injection product under an APP ANDA in the United States beginning on May 1, 2019. In addition, in certain limited circumstances, the license to APP could include the right to sell a generic bivalirudin product under our NDA for Angiomax in the United States beginning on May 1, 2019 or, in certain limited circumstances, on June 30, 2019 or on a date prior to May 1, 2019. We remain in infringement litigation involving the '727 patent and '343 patent with the other ANDA filers. If we are unable to maintain our market exclusivity for Angiomax in the United States through enforcement of our U.S. patents covering Angiomax, Angiomax could be subject to generic competition earlier than May 1, 2019.

Our patent infringement litigation involving the '727 patent and '343 patent are described in more detail in Part II, Item 1, Legal Proceedings, of this quarterly report.

In Europe, the principal patent covering Angiomax expires in 2015.

Cleviprex. The principal U.S. patent for Cleviprex is U.S. Patent No. 5,856,346, or the '346 patent, which was set to expire in January 2016, but the term has been extended to January 2021 by the PTO under the Hatch-Waxman Act. In addition, we have filed and are currently prosecuting a number of patent applications relating to Cleviprex covering compositions of matter and uses in the United States, Europe and other foreign countries. We have filed for patent term extensions, also known as supplementary protection certificates, in European countries where we received regulatory approval and expect to file for supplementary protection certificates in other European countries as we receive approvals. In Europe, the principal patent covering Cleviprex expires in November 2014 if no patent term extension is obtained.

Cangrelor. The principal U.S. and European patents for cangrelor are set to expire in February 2014 if no patent term extension is obtained. In addition, we have issued patents directed to cangrelor pharmaceutical compositions which expire in 2017 and 2018 if no patent term extension is obtained. We have also filed and are currently prosecuting a number of patent applications related to cangrelor.

Oritavancin. The principal patent for oritavancin in both the United States and Europe is set to expire in November 2015 if no patent term extension is obtained. We have issued patents directed to the process of making oritavancin and

these patents expire in 2017. We have also filed and are prosecuting a number of patent applications relating to oritavancin and its uses.

MDCO-157. The principal patent application for MDCO-157 in both the United States and Europe, if issued, would expire in April 2028.

MDCO-216. We are maintaining a number of U.S. patents with respect to MDCO-216, including patents that claim the use of MDCO-216 in certain disease indications. One of these U.S. patents is directed to the use of MDCO-216 for the treatment of ACS and is set to expire in October 2024. We have also filed and are prosecuting a number of patent applications related to the use and production of MDCO-216 in the United States, Europe and other foreign countries. In addition, as a biologic, we expect MDCO-216 to receive 12 years of regulatory exclusivity in the United States and 10 years of regulatory exclusivity in Europe from the date of the initial marketing approval of MDCO-216, if approved.

Ready-to-Use Argatroban. We exclusively licensed from Eagle rights to two U.S. patents covering certain formulations of Argatroban. Our exclusive license is limited to the United States and Canada. The patents are set to expire in September 2027. In February 2012, we were notified that Sandoz had submitted an ANDA seeking permission to market its second generic version of ready-to-use Argatroban prior to the expiration of these patents. On March 29, 2012, Eagle, which is directing and controlling the enforcement of its intellectual property rights with respect to ready-to-use Argatroban, filed suit against Sandoz in the U.S. District Court for the District of New Jersey for infringement of its ready-to-use Argatroban patents.

We plan to file applications for patent term extension for our products in development upon their approval. If we do not receive patent term extensions for the periods requested by us or at all, our patent protection for our products in development could be limited.

We are a party to a number of lawsuits that we brought against pharmaceutical companies that have notified us that they have filed ANDAs seeking approval to market generic versions of Angiomax. We cannot predict the outcome of these lawsuits. Involvement in litigation, regardless of its outcome, is time-consuming and expensive and may divert our management's time and attention. During the period in which these matters are pending, the uncertainty of their outcome may cause our stock price to decline. An adverse result in these matters whether appealable or not, will likely cause our stock price to decline. Any final, unappealable, adverse result in these matters will likely have a material adverse effect on our results of operations and financial conditions and cause our stock price to decline.

If upon expiration of our agreement with Lonza Braine, Lonza Braine breaches our agreement and fails to transfer the technology that was used to develop the Chemilog process, we would be unable to employ the Chemilog process to manufacture Angiomax bulk drug substance, which could cause us to experience delays in the manufacturing process and increase our manufacturing costs in the future.

Our agreement with Lonza Braine for the supply of Angiomax bulk drug substance requires that Lonza Braine transfer the technology that was used to develop the Chemilog process to a secondary supplier of Angiomax bulk drug substance or to us or an alternate supplier at the expiration of the agreement, which is currently scheduled to occur in September 2013, but is subject to automatic renewals of consecutive three-year periods unless either party provides notice of non-renewal at least one year prior to the expiration of the initial term or any renewal term. If Lonza Braine fails or is unable to transfer successfully this technology, we would be unable to employ the Chemilog process to manufacture our Angiomax bulk drug substance, which could cause us to experience delays in the manufacturing process and increase our manufacturing costs in the future.

If we are not able to keep our trade secrets confidential, our technology and information may be used by others to compete against us

We rely significantly upon unpatented proprietary technology, information, processes and know-how. We seek to protect this information by confidentiality agreements and invention assignment agreements with our employees, consultants and other third-party contractors, as well as through other security measures. We may not have adequate remedies for any breach by a party to these confidentiality agreements or invention assignment agreements. In addition, our competitors may learn or independently develop our trade secrets. If our confidential information or trade secrets become publicly known, they may lose their value to us.

If we infringe or are alleged to infringe intellectual property rights of third parties, our business may be adversely affected

Our research, development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents or patent applications under which we do not hold

licenses or other rights. Third parties may own or control these patents and patent applications in the United States and abroad. These third parties could bring claims against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

As a result of patent infringement claims, or in order to avoid potential claims, we or our collaborators may choose or be required to seek a license from the third party and be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference proceedings declared by the PTO and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to our products and technology. Patent litigation and other proceedings may also absorb significant management time. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

Risks Related to Our Common Stock

Fluctuations in our operating results could affect the price of our common stock

Our operating results may vary from period to period based on factors including the amount and timing of sales of and underlying hospital demand for our products, our customers' buying patterns, the timing, expenses and results of clinical trials, announcements regarding clinical trial results and product introductions by us or our competitors, the availability and timing of third-party reimbursement, including in Europe, sales and marketing expenses and the timing of regulatory approvals. If our operating results do not meet the expectations of securities analysts and investors as a result of these or other factors, the trading price of our common stock will likely decrease.

The warrant transactions and the derivative transactions entered into by the Hedge Counterparties in connection with the convertible note hedge and warrant transactions may affect the price of our common stock

In connection with sale of the Notes, we entered into convertible note hedge and warrant transactions with the Hedge Counterparties. Upon settlement, the warrants could have a dilutive effect on our earnings per share and the market price of our common stock to the extent that the market price per share of our common stock exceeds the then applicable strike price of the warrants. However, subject to certain conditions, we may elect to settle all of the warrants in cash.

In connection with establishing their hedges of the convertible note hedge and warrant transactions, the Hedge Counterparties or their affiliates entered into various derivative transactions with respect to our common stock. These parties may modify their hedge positions in the future by entering into or unwinding various derivatives with respect to our common stock and/or purchasing or selling our common stock or other securities of ours in secondary market transactions prior to the maturity of the Notes (and are likely to do so during any observation period related to a conversion of the Notes). These activities could cause a decrease or avoid an increase in the market price of our common stock.

Our stock price has been and may in the future be volatile. This volatility may make it difficult for you to sell common stock when you want or at attractive prices

Our common stock has been and in the future may be subject to substantial price volatility. From January 1, 2010 to November 5, 2012, the last reported sale price of our common stock ranged from a high of $26.68 per share to a low of $7.00 per share. The value of your investment could decline due to the effect upon the market price of our common stock of any of the following factors, many of which are beyond our control:

- achievement or rejection of regulatory approvals of our product candidates and our products;

- regulatory actions by the FDA or a foreign jurisdiction limiting or revoking the use of our products;
- changes in securities analysts' estimates of our financial performance;
- changes in valuations of similar companies;
- variations in our operating results;
- acquisitions and strategic partnerships;

- announcements of technological innovations or new commercial products by us or our competitors or the filing of ANDAs or NDAs for products competitive with ours;
- disclosure of results of clinical testing or regulatory proceedings by us or our competitors;
- the timing, amount and receipt of revenue from sales of our products and margins on sales of our products;
- changes in governmental regulations;
- developments in patent rights or other proprietary rights, particularly with respect to our U.S. Angiomax patents;
- the extent to which Angiomax is commercially successful globally;
- our ability to maintain market exclusivity for Angiomax in the United States through the enforcement of the '727 patent and the '343 patent during the period following the expiration of the patent term of the '404 patent on December 15, 2014 and the six month pediatric exclusivity on June 15, 2015 through at least May 1, 2019, the date on which we agreed APP may sell a generic version of Angiomax;
- significant new litigation;
- developments or issues with our contract manufacturers;
- changes in our management; and
- general market conditions.

We believe that period-to-period comparisons of our financial results will not necessarily be indicative of our future performance. If our revenues in any particular period do not meet expectations, we may not be able to adjust our expenditures in that period, which could cause our operating results to suffer. If our operating results in any future period fall below the expectations of securities analysts or investors, our stock price may fall by a significant amount.

The stock markets in general, and The NASDAQ Global Market and the market for biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations recently. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. These broad market and industry factors may adversely affect the market price of our common stock, regardless of our actual operating performance.

Our corporate governance structure, including provisions in our certificate of incorporation and by-laws and Delaware law, may prevent a change in control or management that security holders may consider desirable

The General Corporation Law of the State of Delaware and our certificate of incorporation and by-laws contain provisions that might enable our management to resist a takeover of our company or discourage a third party from attempting to take over our company. These provisions include

- Section 203 of the Delaware General Corporation Law, which provides that we may not enter into a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in the manner prescribed in Section 203;
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our board of directors has the authority to issue, without a vote or action of stockholders, up to 5,000,000 shares of a new series of preferred stock and to fix the price, rights, preferences and privileges of those shares, each of which could be superior to the rights of holders of our common stock;

- our directors are elected to staggered terms, which prevents our entire board of directors from being replaced in any single year;

- our directors may be removed only for cause and then only by the affirmative vote of the holders of at least 75% of the votes which all stockholders would be entitled to cast in any annual election of directors;

- the size of our board of directors is determined by resolution of the board of directors;

- any vacancy on our board of directors, however occurring, including a vacancy resulting from an enlargement of our board, may only be filled by vote of a majority of our directors then in office, even if less than a quorum;

- only our board of directors, the chairman of the board or our president may call special meetings of stockholders;

- our by-laws may be amended, altered or repealed by (i) the affirmative vote of a majority of our directors, subject to any limitations set forth in the by-laws, or (ii) the affirmative vote of the holders of at least 75% of the votes which all the stockholders would be entitled to cast in any annual election of directors;

- stockholders must provide us with advance notice, and certain information specified in our by-laws, in connection with nominations or proposals by such stockholder for consideration at an annual meeting;

- stockholders may not take any action by written consent in lieu of a meeting; and

- our certificate of incorporation may only be amended or repealed by the affirmative vote of a majority of our directors and the affirmative vote of the holders of at least 75% of the votes which all the stockholders would be entitled to cast in any annual election of directors (and plus any separate class vote that might in the future be required pursuant to the terms of any series of preferred stock that might be outstanding at the time any of these amendments are submitted to stockholders).

These provisions could have the effect of delaying, deferring, or preventing a change in control of us or a change in our management that stockholders may consider favorable or beneficial. These provisions could also discourage proxy contests and make it more difficult for stockholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock or our other securities.

Our business could be negatively affected as a result of the actions of activist shareholders.

Proxy contests have been waged against many companies in the biopharmaceutical industry over the last few years. If faced with a proxy contest, we may not be able to successfully defend against the contest, which would be disruptive to our business. Even if we are successful, our business could be adversely affected by a proxy contest because:

- responding to proxy contests and other actions by activist shareholders may be costly and time-consuming and may disrupt our operations and divert the attention of management and our employees;

- perceived uncertainties as to our future direction may result in our inability to consummate potential acquisitions, collaborations or in-licensing opportunities and may make it more difficult to attract and retain qualified personnel and business partners; and

- if individuals are elected to our board of directors with a specific agenda different from ours, it may adversely affect our ability to effectively and timely implement our strategic plan and create additional value for our stockholders.

Item 6. Exhibits

Exhibits

See the Exhibit Index on the page immediately preceding the exhibits for a list of exhibits filed as part of this quarterly report, which Exhibit Index is incorporated herein by this reference.

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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.

THE MEDICINES COMPANY

Date: November 9, 2012

By: /s/ Glenn P. Sblendorio
Glenn P. Sblendorio
President and Chief Financial Officer (Principal Financial and Accounting Officer)

EXHIBIT INDEX

Exhibit Number	Description
10.1*	Letter Agreement, dated August 7, 2012, by and between the registrant and Biogen Idec MA Inc.
10.2	Consulting Agreement, dated July 6, 2012, by and between the registrant and Strategic Imagery, LLC
31.1	Chairman and Chief Executive Officer Certification pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Chief Financial Officer Certification pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Chairman and Chief Executive Officer Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Chief Financial Officer Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	The following materials from The Medicines Company Quarterly Report on Form 10-Q for the quarter ended September 30, 2012, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Balance Sheet, (ii) the Consolidated Statement of Income, (iii) the Consolidated Statement of Cash Flow, and (iv) Notes to Consolidated Financial Statements.

* Confidential treatment requested as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.