

MEDICINES CO /DE
Form 10-Q
November 09, 2011

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

FORM 10-Q
(Mark One)

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

For the quarterly period ended: September 30, 2011

OR
 TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT
OF 1934 (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
(State or other jurisdiction of
incorporation or organization)

04-3324394
(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 No

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

Yes No

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

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

Edgar Filing: MEDICINES CO /DE - Form 10-Q

(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 No

As of November 7, 2011 there were 54,200,472 shares of Common Stock, \$0.001 par value per share, outstanding.

THE MEDICINES COMPANY

TABLE OF CONTENTS

Part I. Financial Information	
<u>Item 1 - Financial Statements</u>	<u>1</u>
<u>Item 2 - Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>14</u>
<u>Item 3 - Quantitative and Qualitative Disclosures about Market Risk</u>	<u>35</u>
<u>Item 4 - Controls and Procedures</u>	<u>35</u>
Part II. Other Information	<u>36</u>
<u>Item 1 - Legal Proceedings</u>	<u>36</u>
<u>Item 1A - Risk Factors</u>	<u>39</u>
<u>Item 6 - Exhibits</u>	<u>60</u>
<u>Signatures</u>	<u>61</u>
<u>Exhibit Index</u>	<u>62</u>
EX-10.1	
EX-10.2	
EX-10.3	
EX-10.4	
EX-10.5	
EX-10.6	
EX-31.1	
EX-31.2	
EX-32.1	
EX-32.2	

Part I. Financial Information

Item 1. Financial Statements

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

	September 30, 2011 (unaudited)	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	\$258,035	\$126,364
Available for sale securities	49,739	120,280
Accrued interest receivable	443	1,279
Accounts receivable, net of allowances of approximately \$15.8 million and \$15.5 million at September 30, 2011 and December 31, 2010, respectively	72,725	46,551
Inventory	30,426	25,343
Prepaid expenses and other current assets	7,452	4,804
Total current assets	418,820	324,621
Fixed assets, net	18,528	20,662
Intangible assets, net	86,147	82,925
Goodwill	14,671	14,671
Restricted cash	4,626	5,778
Deferred tax assets, net	93,582	25,197
Other assets	289	270
Total assets	\$636,663	\$474,124
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$10,432	\$8,594
Accrued expenses	113,655	76,242
Deferred revenue	1,183	534
Total current liabilities	125,270	85,370
Contingent purchase price	28,204	25,387
Other liabilities	5,896	5,769
Total liabilities	159,370	116,526
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; 54,093,961 and 53,464,145 issued and outstanding at September 30, 2011 and December 31, 2010, respectively	54	53
Additional paid-in capital	609,013	596,667
Accumulated deficit	(131,247)	(239,542)
Accumulated other comprehensive income	(527)	420
Total stockholders' equity	477,293	357,598
Total liabilities and stockholders' equity	\$636,663	\$474,124

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2011	2010	2011	2010
Net revenue	\$120,773	\$105,743	\$352,501	\$317,966
Operating expenses:				
Cost of revenue	39,459	31,568	112,859	93,905
Research and development	26,550	16,676	76,878	54,128
Selling, general and administrative	45,353	35,788	124,701	121,318
Total operating expenses	111,362	84,032	314,438	269,351
Income from operations	9,411	21,711	38,063	48,615
Legal settlement	—	—	17,984	—
Other income	578	483	1,450	55
Income before income taxes	9,989	22,194	57,497	48,670
Benefit (provision) for income taxes	62,625	(989)	50,798	(2,607)
Net income	\$72,614	\$21,205	\$108,295	\$46,063
Basic earnings per common share	\$1.36	\$0.40	\$2.03	\$0.87
Diluted earnings per common share	\$1.34	\$0.40	\$2.00	\$0.87
Weighted average number of common shares outstanding:				
Basic	53,534	52,991	53,414	52,773
Diluted	54,260	53,359	54,242	53,005

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,	
	2011	2010
Cash flows from operating activities:		
Net income	\$ 108,295	\$ 46,063
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	4,514	5,085
Amortization of net premiums and discounts on available for sale securities	2,021	2,432
Unrealized foreign currency transaction losses (gain), net	596	(596)
Non-cash stock compensation expense	8,376	6,855
Loss on disposal of fixed assets	310	6
Deferred tax (benefit) provision	(68,385)	710
Adjustment to contingent purchase price	2,817	2,265
Changes in operating assets and liabilities:		
Accrued interest receivable	836	—
Accounts receivable	(26,011)	(4,214)
Inventory	(4,973)	(3,656)
Prepaid expenses and other current assets	(2,602)	2,450
Accounts payable	1,805	4,275
Accrued expenses	32,264	(12,481)
Deferred revenue	618	(691)
Other liabilities	128	122
Net cash provided by operating activities	60,609	48,625
Cash flows from investing activities:		
Purchases of available for sale securities	(33,835)	(100,830)
Proceeds from maturities and sales of available for sale securities	102,356	80,140
Purchases of fixed assets	(879)	(151)
Adjustment to goodwill	—	263
Decrease in restricted cash	1,143	1,285
Net cash provided by (used in) investing activities	68,785	(19,293)
Cash flows from financing activities:		
Proceeds from issuances of common stock, net	3,972	2,764
Net cash provided by financing activities	3,972	2,764
Effect of exchange rate changes on cash	(1,695)	848
Increase in cash and cash equivalents	131,671	32,944
Cash and cash equivalents at beginning of period	126,364	72,225
Cash and cash equivalents at end of period	\$ 258,035	\$ 105,169
Supplemental disclosure of cash flow information:		
Taxes paid	\$ 6,783	\$ 229

See accompanying notes to unaudited condensed consolidated financial statements.

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, a novel intravenous formulation of clopidogrel bisulfate, and two early stage development product candidates, MDCO-2010 and MDCO-216. The Company believes that its marketed products and its 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 the Company's products in development, have the potential to offer, improved performance to hospital businesses.

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 annual report on Form 10-K for the year ended December 31, 2010 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 subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation. The Company has no unconsolidated subsidiaries or significant investments accounted for under the equity method.

The results of operations for the three months and nine months ended September 30, 2011 are not necessarily indicative of the results that may be expected for the entire fiscal year or any other quarter of the fiscal year ending December 31, 2011. These condensed consolidated financial statements should be read in conjunction with the audited financial statements included in the Company's annual report on Form 10-K for the year ended December 31, 2010, 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, 2010 for a discussion of the Company's critical accounting estimates.

Contingencies

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The

4

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 it is deemed 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 May 2011, the FASB issued Accounting Standards Update (ASU) 2011-04, "Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRS (ASU 2011-04) that clarifies the application of existing guidance and disclosure requirements, changes certain fair value measurement principles and requires additional disclosures about fair value measurements. ASU 2011-04 will be effective for interim and annual periods beginning on or after December 15, 2011 and therefore is effective for the Company in its first quarter of fiscal 2012 and will be applied prospectively. The Company does not expect its adoption of ASU 2011-04 to have a material impact on its financial statements.

In June 2011, the FASB issued 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 will be effective for the Company in its first quarter of fiscal 2012. Early adoption of ASU 2011-05 is permitted; however, the Company does not expect that it will do so. The Company believes the adoption of ASU 2011-05 will change the order in which certain financial statements are presented and provide additional detail on those financial statements when applicable, but will not have any other impact on its financial statements.

In September 2011, the FASB issued ASU 2011-08, "Testing Goodwill for Impairment" (ASU 2011-08) that allows entities to first assess qualitatively whether it is necessary to perform the two-step goodwill impairment test. If an entity believes, as a result of its qualitative assessment, that it is more likely than not that the fair value of an asset in a reporting period is less than its carrying amount, the quantitative two-step goodwill impairment test is required. An entity has the unconditional option to bypass the qualitative assessment and proceed directly to performing the first step of the goodwill impairment test. ASU 2011-08 will be effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011 and therefore will be effective for the Company in its first quarter of 2012. Early adoption of ASU 2011-08 is permitted; however, the Company does not expect that it will do so. The Company anticipates that the adoption of this standard will not have a material impact on its consolidated financial statements and footnote disclosures.

3. Stock-Based Compensation

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, respectively. The Company recorded approximately \$1.8 million and \$6.9 million of stock-based compensation expense for the three and nine months ended September 30, 2010, respectively. As of September 30, 2011, there was approximately \$13.3 million of total unrecognized compensation

costs related to non-vested share-based employee compensation arrangements granted under the Company's equity compensation plans. The Company expects to recognize this cost over a weighted average period of 1.35 years.

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 its 2010 employee stock purchase plan (the 2010 ESPP). During the nine months ended September 30, 2010, the Company issued a total of 543,460 shares of its common stock upon the exercise of stock options, pursuant to restricted stock grants and pursuant to purchases under its 2000 employee stock purchase plan (the 2000 ESPP). Cash received from the exercise of stock options and purchases through the 2010 ESPP during the nine months ended September 30, 2011 and the exercise of stock options and purchases through the 2000 ESPP during the nine months ended September 30, 2010 was approximately \$4.0 million and \$2.8 million, respectively, and is included within the financing activities section of the consolidated statements of cash flows.

At September 30, 2011, there were no shares reserved for future issuance under the 2000 ESPP and 5,171,643 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, 2011 and 2010:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
	(in thousands, except per share amounts)			
Basic and diluted Net income	\$72,614	\$21,205	\$108,295	\$46,063
Weighted average common shares outstanding, basic	53,534	52,991	53,414	52,773
Plus: net effect of dilutive stock options and restricted common shares	726	368	828	232
Weighted average common shares outstanding, diluted	54,260	53,359	54,242	53,005
Earnings per share, basic	\$1.36	\$0.40	\$2.03	\$0.87
Earnings per share, diluted	\$1.34	\$0.40	\$2.00	\$0.87

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, 2011 and 2010, options to purchase 7,618,529 shares and 7,150,519 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, 2011 and 2010, options to purchase 7,351,738 shares and 8,684,283 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 months ended September 30, 2011 and 2010, 0 and 6,750 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. For the nine months ended September 30, 2011 and 2010, 83,297 and 8,500 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.

5. Comprehensive Income

Comprehensive income includes net income, unrealized gain (loss) on available for sale securities and foreign currency translation adjustments. Comprehensive income for the three and nine months ended September 30, 2011 and 2010 is detailed below.

Edgar Filing: MEDICINES CO /DE - Form 10-Q

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2011	2010	2011	2010
	(in thousands)			
Net income	\$72,614	\$21,205	\$108,295	\$46,063
Unrealized gain (loss) on available for sale securities	(20) 80	—	61
Foreign currency translation adjustment	(817) 79	(947) 126
Comprehensive income	\$71,777	\$21,364	\$107,348	\$46,250

6. Income Taxes

6

For the three months ended September 30, 2011 and 2010, the Company recorded a \$62.6 million net benefit and a \$1.0 million provision for income taxes, respectively. During the third quarter of 2011, after considering both the positive and negative evidence, including the enactment of Leahy-Smith America Invents Act (see Part I, Item 2 of this quarterly report under the caption Overview - Angiomax Patent Litigation), the settlement of the Company's patent infringement litigation against Teva Pharmaceuticals USA, Inc. and its affiliates (Teva) (see Part I, Item 2 of this quarterly report under the caption Overview - Legal Settlements), continued U.S. taxable income, the launch of ready-to-use Argatroban and an increased ability to forecast future taxable income due to these legislative, business and legal developments, 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. At September 30, 2011, the remaining valuation allowance is \$4.2 million against \$116.4 million of deferred tax assets. The income tax provision for the 2010 period reflected the utilization of U.S. net operating loss carryforwards against projected taxable income and a liability for alternative minimum tax. Both the 2011 and 2010 periods include a non-cash tax expense arising from purchase accounting for in-process research and development acquired in the Company's acquisition of Targanta Therapeutics Corporation (Targanta).

For the nine months ended September 30, 2011 and 2010, the Company recorded a \$50.8 million benefit and a \$2.6 million provision for income taxes, respectively. In addition to the \$66.5 million reduction in the valuation allowance discussed above, the Company's income tax benefit for the nine months ended September 30, 2011 includes the effects 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 of 2011 and the tax impact of the settlement from the law firm Wilmer Cutler Pickering Hale and Dorr LLP (WilmerHale) (see note 12) as discrete events. The provision for income taxes is based on federal, state and foreign income taxes.

The Company continues to evaluate the realizability of 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, the regulatory approval of products currently under development and the extension of the patent rights relating to Angiomax. Any changes to the valuation allowance or deferred tax assets in the future would impact the Company's income taxes.

7. 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 \$241.5 million and \$114.1 million at September 30, 2011 and December 31, 2010, respectively. Cash and cash equivalents at September 30, 2011 and December 31, 2010 also included investments of \$16.5 million and \$12.2 million, respectively, in money market funds and commercial paper with original maturities of less than three months.

At September 30, 2011 and December 31, 2010, the Company held available for sale securities with a fair value totaling \$49.7 million and \$120.3 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, 2011, all of the \$49.7 million of available for sale securities were due within one year. At December 31, 2010, approximately \$115.2 million of available for sale securities were due within one year. The remaining \$5.1 million were due within two years.

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

As of September 30, 2011			As of December 31, 2010				
Cost	Fair Value	Carrying	Unrealized	Cost	Fair Value	Carrying	Unrealized

Edgar Filing: MEDICINES CO /DE - Form 10-Q

	(in thousands)		Value	Gain			Value	Gain	
U.S. government agency notes	\$ 14,917	\$ 14,919	\$ 14,919	\$ 2		\$ 55,222	\$ 55,222	\$ 55,222	\$—
U.S. treasury notes	3,054	3,056	3,056	2		—	—	—	—
Corporate debt securities	31,765	31,764	31,764	(1)	65,055	65,058	65,058	3
Total	\$ 49,736	\$ 49,739	\$ 49,739	\$ 3		\$ 120,277	\$ 120,280	\$ 120,280	\$ 3

Restricted Cash

7

The Company had restricted cash of \$4.6 million and \$5.8 million at September 30, 2011 and December 31, 2010, 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 \$4.1 million and \$5.5 million at September 30, 2011 and December 31, 2010, 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. The amount of the letter of credit is subject to reduction upon the achievement of certain regulatory and operational milestones relating to the Company's products. However, in no event will the amount of the letter of credit be reduced below approximately \$1.0 million. In addition, as a result of the acquisition of Targanta in 2009, the Company had at September 30, 2011 and December 31, 2010 restricted cash of \$0.2 million and \$0.3 million, respectively, in the form of a guaranteed investment certificate collateralizing an available credit facility. The Company also had at September 30, 2011 restricted cash of \$0.3 million related to certain foreign tender requirements.

8. Fair Value Measurements

FASB Accounting Standards Codification (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.

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 Targanta acquisition. 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 and net 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, 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:

Assets and Liabilities	Quoted Prices In Active Markets for Identical Assets (Level 1) (in thousands)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance at September 30, 2011
Assets:				
Money market	\$16,540	\$—	\$—	\$16,540
U.S. treasury notes	3,056	—	—	3,056
U.S. government agency notes	—	14,919	—	14,919
Corporate debt securities	—	31,764	—	31,764
Total assets at fair value	\$19,596	\$46,683	\$—	\$66,279
Liabilities:				
Contingent purchase price	\$—	\$—	\$28,204	\$28,204
Total liabilities at fair value	\$—	\$—	\$28,204	\$28,204

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

	Level 3 (in thousands)
Balance at December 31, 2010	\$25,387
Fair value adjustment to contingent purchase price included in net income	2,817
Balance at September 30, 2011	\$28,204

For the nine months ended September 30, 2011, the changes in the fair value of the contingent purchase price obligations resulted from an adjustment to the discount rates used in the probability weighted discounted financial model. No changes in valuation techniques or inputs occurred during the nine months ended September 30, 2011. No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the nine months ended September 30, 2011.

9. Inventory

To date, the Company has obtained all of its Angiomax bulk drug substance from Lonza Braine, S.A. (Lonza Braine). On September 30, 2011, the Company entered into a supply agreement with Plantex USA Inc., an affiliate of Teva Pharmaceuticals USA, Inc., under which the Company will obtain Angiomax bulk drug substance. The Company also has separate agreements with Ben Venue Laboratories, Inc. and Patheon Italia S.p.A for the fill-finish of Angiomax drug product. As of September 30, 2011, the Company had inventory-related purchase commitments totaling \$23.9 million during 2011, \$57.2 million during 2012, \$30.1 million during 2013, \$7.5 million during 2014 and \$7.5 million during 2015 for Angiomax and ready-to-use Argatroban bulk drug substance.

The major classes of inventory were as follows:

Inventory	September 30, 2011	December 31, 2010
	(in thousands)	
Raw materials	\$8,079	\$9,801
Work-in-progress	16,217	7,183
Finished goods	6,130	8,359

Total	\$30,426	\$25,343
-------	----------	----------

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.

10. Intangible Assets and Goodwill

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

	Weighted Average Useful Life	As of September 30, 2011			As of December 31, 2010		
		Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
(in thousands)							
Identifiable intangible assets							
Customer relationships ⁽¹⁾	8 years	\$7,457	\$ (2,576)	\$4,881	\$7,457	\$ (1,715)	\$5,742
Distribution agreement ⁽¹⁾	8 years	4,448	(1,536)	2,912	4,448	(1,023)	3,425
Trademarks ⁽¹⁾	8 years	3,024	(1,045)	1,979	3,024	(695)	2,329
Product license ⁽²⁾	5 years	5,000	—	5,000	—	—	—
Cleviprex milestones ⁽³⁾	13 years	2,000	(125)	1,875	2,000	(71)	1,929
Total	9 years	\$21,929	\$ (5,282)	\$16,647	\$16,929	\$ (3,504)	\$13,425

(1) The Company amortizes intangible assets related to Angiox based on the ratio of annual forecasted revenue compared to total forecasted revenue from the sale of Angiox through the end of its patent life.

(2) The Company amortizes intangible assets related to the product license over the life of the agreement.

(3) The Company amortizes intangible assets related to the Cleviprex approval over the remaining life of the patent.

The Company expects amortization expense related to these intangible assets to be \$0.8 million for the remainder of 2011. The Company expects annual amortization expense related to these intangible assets to be \$3.4 million, \$4.0 million, \$4.6 million, \$1.8 million and \$1.0 million for the years ending December 31, 2012, 2013, 2014, 2015 and 2016, respectively, with the balance of \$1.0 million being amortized thereafter. Amortization of customer relationships, distribution agreements and trademarks will be recorded in selling, general and administrative expense on the consolidated statements of operations. Amortization of Cleviprex milestones and product license will be recorded in cost of revenue on the consolidated statements of operations.

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

	As of September 30, 2011			As of December 31, 2010		
	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

The changes in goodwill for the nine months ended September 30, 2011 and for the year ended December 31, 2010 are as follows:

	September 30, 2011	December 31, 2010
	(in thousands)	
Balance at beginning of period	\$ 14,671	\$ 14,934
Adjustment to goodwill	—	(263)
Balance at end of period	\$ 14,671	\$ 14,671

The goodwill is solely attributable to the Targanta acquisition.

11. Restructuring Costs and Other, Net

On September 22, 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, NJ. Upon signing release agreements, the terminated employees received severance and other benefits. The Company recorded, in the aggregate, charges of \$2.1 million in the three and nine months ended September 30, 2011 associated with the 2011 Leipzig closure. These charges were recorded in research and development expenses in the Company's financial statements. Of the \$2.1 million of charges related to the 2011 Leipzig closure, \$0.3 million related to asset write-offs were noncash charges. The Company expects to pay out \$1.0 million during the fourth quarter of 2011 and to pay out \$0.8 million during 2012. The Company no longer has any research employees or research capabilities in Leipzig.

During the nine months ended September 30, 2011, the Company recorded a \$0.1 million favorable adjustment to selling, general and administrative costs due to a reversal of costs associated with the 2010 workforce reductions, primarily due to the charges for employee severance and other employee-related termination costs being slightly lower than originally estimated. The 2010 workforce reductions were effected in two separate actions, which were designed to improve efficiencies and better align the Company's costs and structure for the future. The 2010 workforce reductions reduced office based personnel by 30 and field based personnel by 42. The Company did not record any adjustment to selling, general and administrative costs for the three months ended September 30, 2011.

For the nine months ended September 30, 2010, the Company recorded charges of \$6.9 million associated with the 2010 workforce reductions. See note 13 "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, 2010. The Company recorded a \$0.2 million favorable adjustment to selling, general and administrative costs for the three months ended September 30, 2010 primarily due to the charges for employee severance and other employee-related termination costs being slightly lower than originally estimated.

Details of the activities described above and the movement in the accrual during the nine-month period ended September 30, 2011 are as follows:

	Balance as of January 1, 2011	Expenses (Income), Net	Cash	Noncash	Balance as of September 30, 2011
	(in thousands)				
Employee severance and other personnel benefits:					
2011 Leipzig closure	\$—	\$849	\$—	—	\$849
2010 workforce reductions	134	(119)) (15) —	—
Leases and equipment write-offs	10	304	(10) (304) —
Other associated costs	—	918	—	—	918
Total	\$144	\$1,952	\$(25) \$(304) \$1,767

12. 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. The Company did not record any legal settlement income for the three months ended September 30, 2011.

Teva Settlement

On September 30, 2011, the Company entered into a settlement agreement and a license agreement with Teva with respect to the Company's patent infringement suits against Teva, which includes the Company's suit against Pliva Hrvatska d.o.o., et al. Under the settlement agreement, Teva admitted that U.S. Patent No. 7,582,727 ('727 patent) and U.S. Patent No. 7,598,343 ('343 patent), which cover a more consistent and improved Angiomax drug product and the processes by which it is made, are valid and enforceable and that they would be infringed by the manufacture and sale of Teva's generic bivalirudin for injection products. On October 13, 2011, the district court for the Eastern District of Pennsylvania entered a judgment and order of permanent injunction concluding the Company's patent infringement suits against Teva. Under the settlement agreement, the Company made a one-time payment to Teva in recognition of the savings inuring to the Company in terms of the avoidance of costs and burden associated with prosecuting the patent infringement suits. The settlement agreement terminates upon the earlier of the expiration of the '727 patent and '343 patent and the termination of the license agreement. The '727 patent and the '343 patent are currently due to expire on July 27, 2028. Under the license agreement, the Company 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. Under the license agreement, Teva will be required to pay the Company royalties on gross profits of its sales of its bivalirudin product under certain circumstances. The license agreement also contains a grant by Teva to the Company of an exclusive (except as to Teva) license under Teva's bivalirudin patents and right to enforce Teva's bivalirudin patents, in consideration of which the Company made a one-time payment to Teva. The license to Teva will remain in effect until the expiration of all of the Company's patents covering Angiomax except for the '404 patent. The Company and Teva may terminate the license agreement in the event of a material breach by the other party, unless the material breach is cured within 60 days of a written notice. The Company may terminate the license agreement, effectively immediately, for certain breaches of the license agreement. On October 13, 2011, the Company and Teva submitted the settlement agreement and license agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice. The Company's patent infringement suits with Teva are described in more detail in Part II, Item 1 of this quarterly report.

13. Segment and Geographic Information

The Company 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 and manages its business and operations as one segment. 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, 2011						Nine Months Ended September 30, 2011					
	2011		2010		2011		2010		2011		2010	
	(in thousands)				(in thousands)				(in thousands)			
Net revenue:												
United States	\$ 111,561	92.4	%	\$ 100,234	94.8	%	\$ 328,849	93.3	%	\$ 301,065	94.7	%
Europe	6,060	5.0	%	4,018	3.8	%	18,429	5.2	%	13,613	4.3	%
Rest of world	3,152	2.6	%	1,491	1.4	%	5,223	1.5	%	3,288	1.0	%
Total net revenue	\$ 120,773			\$ 105,743			\$ 352,501			\$ 317,966		

September 30,
2011December 31,
2010

Edgar Filing: MEDICINES CO /DE - Form 10-Q

(in thousands)

Long-lived assets:						
United States	\$ 118,451	99.0	%	\$ 117,095	98.8	%
Europe	1,121	0.9	%	1,213	1.0	%
Rest of world	63	0.1	%	220	0.2	%
Total long-lived assets	\$ 119,635			\$ 118,528		

14. Relocation of Principal Offices

12

On January 12, 2009, the Company moved its principal executive offices to new office space in Parsippany, New Jersey. The lease for the Company's previous office facility expires in January 2013. As a result of vacating the previous facility, the Company triggered a cease-use date on January 12, 2009 and incurred estimated lease termination costs. Estimated lease termination costs include the net present value of future minimum lease payments from the cease-use date to the end of the remaining lease term net of estimated sublease rental income. As of September 30, 2011, the Company has accrued approximately \$1.2 million for its estimate of the net present value of these estimated lease termination costs. Additionally, certain other costs such as leasing commissions and legal fees will be expensed as incurred in conjunction with the sublease of the vacated office space.

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 when information available indicates that it is probable that a liability has been incurred and the amount of such loss can be reasonably estimated.

Currently, 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. While it is not possible to determine the outcome of the matters described in Part II, Item 1 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

Eagle Pharmaceuticals Arbitration

The Company has received a Demand for Arbitration filed by Eagle Pharmaceuticals, Inc. (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 the Company's product, 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 million. The Company believes that 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.

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, a novel intravenous formulation of clopidogrel bisulfate, and two early stage development product candidates, MDCO-2010 and 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.

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 which they have been approved for use or which they are intended to address. Each of our marketed products and products in development is administered intravenously.

Product or Product in Development	Development Stage	Mechanism/Target	Clinical Indication(s)
Angiomax	Marketed	Direct thrombin inhibitor	<p>U.S. - for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty, or PTCA, 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</p> <p>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</p>
Cleviprex	Marketed in the United States; Marketing Authorization Application, or MAA, submitted in European Union countries	Calcium channel blocker	Blood pressure reduction when oral therapy is not feasible or not desirable
Ready-to-Use Argatroban	Marketed in the United States	Direct thrombin inhibitor	<p>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. Prevention of platelet activation and aggregation when oral therapy is not feasible or not desirable</p>
Cangrelor	Phase 3	Antiplatelet agent	Treatment of serious gram-positive bacterial infections, including acute bacterial skin and skin structure infections, or
Oritavancin	Phase 3	Antibiotic	

MDCO-157 (IV clopidogrel)	Pre-registration stage	Platelet inhibitor	ABSSSI and including infections that are resistant to conventional treatment 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-2010	Phase 2	Serine protease inhibitor	Reduction of blood loss during surgery Reversal cholesterol
MDCO-216	Phase 1	Naturally occurring variant of a protein found in high-density lipoprotein, or HDL	transport agent to reduce atherosclerotic plaque burden development and thereby reduce the risk of adverse thrombotic events

Our revenues to date have been generated primarily from sales of Angiomax in the United States, but we continue to expand our sales and marketing efforts outside the United States. We believe that by establishing operations outside the United States for Angiomax, we will be positioned to better market and sell Angiomax where approved, to commercialize our acute and intensive care products and product candidates from our pipeline if and when they are approved outside the United States and to potentially in-license marketed products 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, 2011, we had an accumulated deficit of approximately \$131.2 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. patent covering Angiomax, U.S. patent No. 5,196,404, or the '404 patent, was set to expire in March 2010, but has been extended under the Hatch-Waxman Act following our litigation against the U.S. Patent and Trademark Office, or PTO, the FDA and the U.S. Department of Health and Human Services, or HHS. We had applied, under the Hatch-Waxman Act, for an extension of the term of the '404 patent. However, the PTO rejected our application because in its view the application was not timely filed. As a result, we filed suit against the PTO, the FDA and HHS seeking to set aside the denial of our application to extend the term of the '404 patent. On August 3, 2010, the U.S. Federal District Court for the Eastern District of Virginia granted our motion for summary judgment and ordered the PTO to consider our patent term extension application timely filed. Following the expiration of the government's appeal period, the FDA determined the applicable regulatory review period for Angiomax. Based on the FDA's determination, we believe that the term of the '404 patent should be extended until December 15, 2014.

However, to date the PTO has not yet communicated a final determination concerning the length of any patent term extension for the '404 patent. At this time, we do not know when the PTO will make or communicate such a determination. On July 28, 2011, the PTO granted us a one-year interim extension of the '404 patent until August 13, 2012. 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. If the patent term of the '404 patent is extended to December 15, 2014, we currently believe that this pediatric exclusivity would extend until June 15, 2015.

The period for the government to appeal the court's August 3, 2010 decision expired without government appeal. However, on August 19, 2010, APP Pharmaceuticals, LLC, or APP, filed a motion to intervene for the purpose of appeal in our case against the PTO, the FDA and HHS. On September 13, 2010, the federal district court denied APP's motion. APP has appealed the denial of its motion, as well as the federal district court's August 3, 2010 order (and all related and underlying orders). This appeal is pending in the U.S. Court of Appeals for the Federal Circuit.

On September 16, 2011, President Obama signed into law the Leahy-Smith America Invents Act, or the America Invents Act. Section 37 of the America Invents Act clarifies the filing timeline for patent term extension applications

under the Hatch-Waxman Act. This clarification confirms the interpretation of the Hatch-Waxman Act adopted by the federal district court's August 3, 2010 decision in our suit against the PTO, the FDA and HHS, which ordered the PTO to consider our patent term extension application timely filed. We and APP have filed supplemental briefs concerning the America Invents Act. In its appeal, APP is contending that Section 37 of the America Invents Act does not govern our matter and is challenging the constitutionality of the America Invents Act. In addition, on September 27, 2011, APP filed a Motion for Stay Pending Appeal in order to attempt to prevent the PTO from issuing a final certificate of extension for the '404 patent. The United States has intervened to defend the constitutionality of the America Invents Act. On October 25, 2011 the U.S. Department of Justice, or DOJ, filed a brief with the Federal Circuit taking the position that Section 37 of the America Invents Act applies to our matter and is constitutional. Oral argument before the Federal Circuit on APP's appeal is scheduled for November 15, 2011.

If (1) the pre-America Invents Act interpretation of the Hatch-Waxman Act set forth in the August 3, 2010 court order requiring the PTO to consider our application to extend the term of the '404 patent timely filed is successfully challenged, either by APP in its pending appeal or by APP or a third party in a separate challenge and (2) Section 37 of the America Invents Act is found to be

unconstitutional or not to apply to the '404 patent, Angiomax could be subject to generic competition in the United States earlier than we anticipate. In such event, a court or the FDA could determine that the '404 patent expired in March 2010. In such case, the pediatric exclusivity period for Angiomax would have expired in September 2010. It is also possible that a court or the FDA could determine that the '404 patent expired on a later date, in which case the pediatric exclusivity for Angiomax would run from that later date. In Europe, the principal patent covering Angiox expires in 2015.

In addition, in October 2011, a legislative proposal was filed in the United States Senate to deny the PTO funding to implement Section 37 of the America Invents Act. This proposal was not brought up for a vote by the Senate, but could be brought up in the future. It is difficult to predict whether this proposal or other legislation amending or otherwise preventing the application of Section 37 of the America Invents Act might be proposed and enacted, or, if so enacted, the legal effect of such legislation.

In the second half of 2009, the PTO issued to us U.S. Patent No. 7,582,727, or the '727 patent, and U.S. Patent No. 7,598,343, or 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 Pharmaceuticals USA, Inc. and its affiliates, which we refer collectively as Teva, which is described in more detail below. 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. 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 June 30, 2019.

Our litigation with the PTO, the FDA and HHS, APP's efforts to appeal the August 3, 2010 decision and the patent infringement suits are described in more detail in Part II, Item 1 of this quarterly report.

Legal Settlements

Teva Settlement. On September 30, 2011, we entered into a settlement agreement and a license agreement with Teva, with respect to our patent infringement suits against Teva, which includes our suit against Pliva Hrvatska d.o.o., et al. Under the settlement agreement, Teva admitted that the '727 patent and '343 patent are valid and enforceable and that they would be infringed by the manufacture and sale of Teva's generic bivalirudin for injection products. On October 13, 2011, the district court for the Eastern District of Pennsylvania entered a judgment and order of permanent injunction concluding our patent infringement suits against Teva. Under the settlement agreement, we made a one-time payment to Teva in recognition of the savings inuring to us in terms of the avoidance of costs and burden associated with prosecuting the patent infringement suits. The settlement agreement terminates upon the earlier of the expiration of the '727 patent and '343 patent and the termination of the license agreement. The '727 patent and '343 patent are currently due to expire on July 27, 2028. Under the license agreement, 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. Under the license agreement, Teva will be required to pay us royalties on gross profits of its sales of its bivalirudin product under certain circumstances. The license agreement also contains a grant by Teva to us of an exclusive (except as to Teva) license under Teva's bivalirudin patents and right to enforce Teva's bivalirudin patents, in consideration of which we made a one-time payment to Teva. The license to Teva will remain in effect until the expiration of all of our patents covering

Angiomax except for the '404 patent. We and Teva may terminate the license agreement in the event of a material breach by the other party, unless the material breach is cured within 60 days of a written notice. We may terminate the license agreement, effectively immediately, for certain breaches of the license agreement. On October 13, 2011, we and Teva submitted the settlement agreement and license agreement to the U.S. Federal Trade Commission, or FTC, and the DOJ. Our patent infringement suits with Teva are described in more detail in Part II, Item 1 of this quarterly report.

Supply Agreement with Teva. Contemporaneously with entering into the settlement and license agreements with Teva, we and Plantex USA Inc., or Plantex, a Teva affiliate, entered into a supply agreement under which we agree to purchase from Plantex certain minimum quantities of the active pharmaceutical ingredient bivalirudin for our commercial supply. The initial term of the supply agreement ends December 31, 2015 and will automatically be renewed for up to two successive three-year periods unless terminated by us with at least six-month written notice or by Teva with at least 24-months written notice prior to the expiration of the initial term or either renewal term. We have the right to terminate the supply agreement, effectively immediately, if a generic form of bivalirudin is launched after January 1, 2013. We and Teva may terminate the supply agreement in the event of a material breach by the other party, unless the material breach is cured within 30 days of a written notice, and we may terminate the supply agreement upon breach of the settlement agreement and certain breaches of the license agreement.

WilmerHale Settlement. 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.

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. Our contract manufacturer made manufacturing process improvements, including enhanced filtration and equipment maintenance, to assure product quality. 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 vial 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.

Distribution and Sales

We market and sell Angiomax, Cleviprex and ready-to-use Argatroban in the United States with a sales force that, as of September 30, 2011, consisted of 101 representatives, who we refer to as engagement partners and engagement managers, experienced in selling to hospital customers. We distribute our products 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, Integrated Commercialization Solutions, Inc., or ICS, which then sells the products 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. Our agreement with ICS, which we initially entered into February 2007, provides that ICS will be our exclusive distributor of Angiomax, Cleviprex and ready-to-use Argatroban in the United States. Under the terms of this fee-for-service agreement, ICS places orders with us for sufficient quantities of Angiomax, Cleviprex and ready-to-use Argatroban to maintain an appropriate level of inventory based on our customers' historical purchase volumes. ICS assumes all credit and inventory risks, is subject to our standard return policy and has sole responsibility for determining the prices at which it sells Angiomax, Cleviprex and ready-to-use Argatroban, subject to specified limitations in the agreement. The agreement terminates on September 30, 2013, but will automatically renew for additional one-year periods unless either party gives notice at least 90 days prior to the automatic extension. Either party may terminate the agreement at any time and for any reason upon 180 days prior written notice to the other party. In addition, either party may terminate the agreement

upon an uncured default of a material obligation by the other party and other specified conditions.

In Europe, we market and sell Angiox with a sales force that, as of September 30, 2011, consisted of 44 engagement partners and engagement managers experienced in selling to hospital customers. Our European sales force targets hospitals with cardiac catheterization laboratories that perform approximately 200 or more coronary angioplasties per year. In October 2011, we entered into a local sales support agreement with Daiichi Sankyo, Inc. under which they have agreed to provide supplemental sales force coverage to approximately 480 hospitals in Germany treating ACS patients and call upon most interventional cardiologists in Germany. We also market and sell Angiomax outside the United States through distributors, including Sunovion Pharmaceuticals Inc., which distributes Angiomax in Canada, and affiliates of Grupo Ferrer Internacional, which distribute Angiox in Greece, Portugal and Spain and in a number of countries in Central America and South America. We also have agreements with other third parties for other countries outside of the United States and Europe, including Israel and Australia. We are developing a global commercialization strategy for Cleviprex in anticipation of its further approval outside of the United States.

To support the commercialization and distribution efforts of Angiomax, we have developed, and continue to develop, our

18

business infrastructure outside the United States, including forming subsidiaries, obtaining licenses and authorizations necessary to distribute Angiomax, hiring personnel and entering into arrangements for services from third parties, such as importation, packaging, quality control and distribution. We currently have operations in Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, India, Italy, the Netherlands, New Zealand, Norway, Poland, Spain, Sweden, Switzerland and the United Kingdom and are developing our business infrastructure and capabilities in Brazil, China, Eastern Europe, Russia and Turkey. We believe that by establishing operations outside the United States for Angiomax, we will be positioned to commercialize Cleviprex and our products in development, if and when they are approved outside the United States.

Workforce Reductions

2010 Reductions. On January 7, 2010 and February 9, 2010, we commenced two separate workforce reductions to improve efficiencies and better align our costs and structure for the future. As a result of the first workforce reduction, we reduced our office-based personnel by 30 employees. The second workforce reduction resulted in a reduction of 42 primarily field-based employees. In the year ended December 31, 2010, we recorded, in the aggregate, charges of \$6.8 million associated with these workforce reductions. During the nine months ended September 30, 2011, we recorded a \$0.1 million favorable adjustment to selling, general and administrative costs due to a reversal of costs associated with these workforce reductions, primarily due to the charges for employee severance and other employee-related termination costs being slightly lower than originally estimated. We did not record any adjustment to selling, general and administrative costs for the three months ended September 30, 2011.

Leipzig Reduction. On September 22, 2011, we commenced the closure of our drug discovery research and development facility and operations in Leipzig, Germany and terminated ten employees at our Leipzig facility, which we refer to herein as the 2011 Leipzig closure. We transferred active pre-clinical projects to our research and development facility in Montreal, Canada and the MDCO-2010 back-up compound to the clinical team in Parsippany, NJ. Upon signing release agreements, the terminated employees received severance and other benefits. We recorded, in aggregate, charges of \$2.1 million in the three and nine months ended September 30, 2011 associated with the 2011 Leipzig closure. These charges were recorded in research and development expenses in our financial statements. Of the \$2.1 million of charges related to the 2011 Leipzig closure, \$0.3 million related to asset write-offs were noncash charges. We expect to pay out \$1.0 million during the fourth quarter of 2011 and to pay out \$0.8 million during 2012. We no longer have any research employees or research capabilities in Leipzig.

Licensing Agreement with Ligand Pharmaceuticals Incorporated

In May 2011, we entered into a licensing agreement with Ligand Pharmaceuticals Incorporated, or Ligand, 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. Under the license agreement, we paid Ligand an upfront payment of approximately \$1.8 million in June 2011 and agreed to make additional payments of up to \$22 million upon the achievement of certain clinical, regulatory and commercial milestones. We also agreed to pay to Ligand tiered royalties from high single digits up to low double digits on annual worldwide net sales. The license obligates us to use commercially reasonable efforts to develop a licensed product, and to make \$2.5 million per year in development expenditures until we submit a new drug application, or NDA. The licenses and rights under the agreement remain in force on a country-by-country basis until the expiration of our obligations to pay royalties under the license agreement or the license agreement is otherwise terminated. Either party may terminate the agreement for material breach upon 30 days' prior written notice for breaches involving non-payment of amounts due under the license agreement or 120 days for all other material breaches (which can be extended for up to 90 days if the breaching party submits a reasonable plan to cure the breach), if the breach is not cured within the applicable period. We may terminate the agreement for any reason upon

specified written notice. Ligand may terminate the agreement if we do not meet certain timelines or fulfill certain obligations under the license agreement. Finally, the license agreement will terminate if we terminate the supply agreement (described below) without cause or Ligand terminates it due to our material breach.

Under a separate supply agreement entered in May 2011, Ligand has agreed to supply us with clinical materials of Captisol, an excipient in MDCO-157, for the MDCO-157 development program. If the intravenous formulation is approved for commercialization, we have agreed that Ligand will be the exclusive supplier of Captisol for the product. This agreement will expire or automatically terminate simultaneously with the expiration or termination, respectively, of the licensing agreement, and either party may terminate it for the other's material breach on the same terms as those of the licensing agreement.

We expect to seek an FDA marketing approval for MDCO-157 pursuant to the Section 505(b)(2) NDA process. This process would enable us to rely, in part, on the safety and efficacy data of an existing product, or published literature, in support of an application for marketing approval. In connection with the Section 505(b)(2) NDA process, we plan to conduct a pharmacodynamic equivalence study of MDCO-157.

Europe. The increase in net revenue was a result of a price increase we implemented in January 2011 in the United States, increased demand globally by existing hospital customers and the addition of new hospital customers internationally. Net sales in the United States in both the three months ended September 30, 2011 and September 30, 2010 reflects the chargebacks related to the 340B Drug Pricing Program under the Public Health Services Act. Under this program, we offer qualifying entities a discount off the commercial price of Angiomax for patients undergoing PCI on an outpatient basis. These chargebacks increased by \$1.0 million to \$11.1 million in the three months ended September 30, 2011 compared to \$10.1 million in the three months ended September 30, 2010. In addition, we recognized a reduction in product net sales of approximately \$0.1 million in both the three months ended September 30, 2011 and September 30, 2010 for rebates related to the PPACA. U.S. sales also included net sales of our ready-to-use Argatroban of \$0.2 million and Cleviprex of \$0.2 million in the three months ended September 30, 2011. We recognized

no revenue from sales of ready-to-use Argatroban and Cleviprex in the three months ended September 30, 2010, as our formulation of ready-to-use Argatroban was not approved until July 2011 and we did not sell Cleviprex from the first quarter of 2010 through the first quarter of 2011 as a result of the voluntary recalls of manufactured lots of Cleviprex. We began to resupply existing customers with Cleviprex in April 2011. We re-launched Cleviprex in October 2011 with a 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.

Net revenue during the nine months ended September 30, 2011 increased by \$34.5 million compared to the nine months ended September 30, 2010 primarily due to increases in sales of Angiomax in the United States and Angiox in Europe. The net revenue increase was a result of a price increase we implemented in January 2011 in the United States and increased demand by existing hospital customers and the addition of new hospital customers internationally. Net sales in the United States in both the nine months ended September 30, 2011 and September 30, 2010 reflect the chargebacks related to the 340B Drug Pricing Program under the Public Health Services Act. These chargebacks increased by \$1.8 million to \$30.3 million in the nine months ended September 30, 2011 compared to \$28.5 million in the nine months ended September 30, 2010. In addition, in the nine months ended September 30, 2011, we recognized a reduction in product net sales of approximately \$0.5 million, a \$0.2 million increase when compared to the nine months ended September 30, 2010 for rebates related to the PPACA. U.S. sales included net sales of Cleviprex of \$0.5 million in the nine months ended September 30, 2011 compared to \$0.8 million of revenue from sales of Cleviprex in the nine months ended September 30, 2010. The \$0.8 million in sales of Cleviprex in the nine months ended September 30, 2010 reflects an offset of \$0.7 million due to returns related to the Cleviprex recall. U.S. sales also included net sales of ready-to-use Argatroban of \$0.2 million in the nine months ended September 30, 2011. We recognized no revenue from sales of ready-to-use Argatroban in the nine months ended September 30, 2010.

International net revenue increased by \$3.7 million during the three months ended September 30, 2011 compared to the three months ended September 30, 2010 primarily as a result of increased demand for Angiomax in Canada, Italy, the United Kingdom, Sweden, South America, Denmark, Belgium and the Netherlands.

International net revenue increased by \$6.8 million during the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010 primarily as a result of increased demand for Angiomax in Canada, Italy, the United Kingdom, Sweden, Denmark, Belgium and the Netherlands, which was partially offset by decreased sales of Angiomax in France, Spain, Israel and South America.

If we are unable to maintain our market exclusivity for Angiomax in the United States as a result of an adverse court decision or adverse legislation relating to the '404 patent or our inability to enforce our other U.S. patents covering Angiomax, Angiomax could be subject to generic competition in the United States earlier than we anticipate. Competition from generic equivalents sold at a price that is less than the price at which we currently sell Angiomax would reduce our revenues, possibly materially.

Cost of Revenue:

Cost of revenue in the three months ended September 30, 2011 was \$39.5 million, or 33% of net revenue, compared to \$31.6 million, or 30% of net revenue, in the three months ended September 30, 2010.

Cost of revenue in the nine months ended September 30, 2011 was \$112.9 million, or 32% of net revenue, compared to \$93.9 million, or 30% of net revenue, in the nine months ended September 30, 2010.

Cost of revenue during both periods consisted of expenses in connection with the manufacture of Angiomax, Cleviprex and ready-to-use Argatroban sold, royalty expenses under our agreements with Biogen Idec and Health Research Inc., or HRI, related to Angiomax and our agreement with AstraZeneca AB, or AstraZeneca, related to Cleviprex and the logistics costs related to Angiomax, Cleviprex and ready-to-use Argatroban, including distribution, storage, and handling costs.

Cost of Revenue

21

	Three Months Ended September 30,				Nine Months Ended September 30,				
	2011	% of Total	2010	% of Total	2011	% of Total	2010	% of Total	
	(in thousands)		(in thousands)		(in thousands)		(in thousands)		
Manufacturing	\$6,737	17	% \$7,277	23	% \$22,413	20	% \$21,645	23	%
Royalty	27,958	71	% 21,129	67	% \$79,196	70	% \$63,004	67	%
Logistics	4,764	12	% 3,162	10	% \$11,250	10	% \$9,256	10	%
Total cost of revenue	\$39,459	100	% \$31,568	100	% \$112,859	100	% \$93,905	100	%

Cost of revenue increased by \$7.9 million during the three months ended September 30, 2011 compared to the three months ended September 30, 2010. The increase in cost of revenue was primarily related to an increase in royalty expense to Biogen Idec due to a higher effective royalty rate under our agreement with Biogen Idec as a result of increased net sales of Angiomax as well as a corresponding increase in royalty expense associated with the higher sales of Angiomax. This increase in cost of revenue was also related to an increase in manufacturing expense due to costs associated with obtaining an additional supplier for the fill-finish of Angiomax drug product.

Cost of revenue increased by \$19.0 million during the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010. The increase in cost of revenue was primarily related to an increase in royalty expense to Biogen Idec due to a higher effective royalty rate under our agreement with Biogen Idec as well as a corresponding increase in royalty expense associated with the higher sales of Angiomax. This increase in cost of revenue was also related to an increase in manufacturing expense due to costs associated with obtaining an additional supplier for the manufacture of Angiomax. In addition, this increase in manufacturing expense reflects a \$0.9 million reduction in manufacturing costs in the nine months ended September 30, 2010 related to the reversal in nine months ended September 30, 2010 of certain charges which were originally recorded in the fourth quarter of 2009 in connection with production failures at the third-party manufacturer for Angiomax.

Research and Development Expenses:

Research and development expenses increased by 59% to \$26.6 million for the three months ended September 30, 2011, compared to \$16.7 million for the three months ended September 30, 2010. The increase primarily reflects an increase in costs incurred in connection with our ongoing Phase 3 clinical trials of cangrelor and oritavancin, both of which were commenced in the fourth quarter of 2010. The increase also reflects charges of approximately \$2.1 million associated with the 2011 Leipzig closure in the third quarter of 2011. These increases were offset by a decrease in clinical trial costs related to Angiomax and a decrease in manufacturing development expenses related to product lifecycle management activities of Angiomax.

Research and development expenses increased by 42% to \$76.9 million for the nine months ended September 30, 2011, compared to \$54.1 million for the nine months ended September 30, 2010. The increase primarily reflects an increase in costs incurred in connection with our ongoing Phase 3 clinical trials of cangrelor and oritavancin. The increase also reflects costs incurred in connection with the commencement of a Phase 1 clinical trial of MDCO-216, the manufacturing of product for the Phase 1 trial, the licensing fee paid in connection with obtaining the licensing rights to MDCO-157 and charges of approximately \$2.1 million associated with the 2011 Leipzig closure in the third quarter of 2011. These increases were offset by a decrease in manufacturing development expenses related to product lifecycle management activities of Angiomax, charges recorded in the nine months ended September 30, 2010 associated with a payment made to AstraZeneca in connection with the June 2010 amendment to our cangrelor license agreement with AstraZeneca and by charges recorded in the nine months ended September 30, 2010 of approximately \$1.7 million associated with our workforce reductions in the first quarter of 2010. Under the June 2010 amendment to our cangrelor license agreement with AstraZeneca, we agreed to conduct certain clinical studies of cangrelor, that the

specific development time lines set forth in the license agreement would be eliminated and that certain regulatory assistance obligations of AstraZeneca in the license agreement would be terminated.

We expect to continue to invest in the development of Angiomax, Cleviprex, cangrelor, oritavancin, MDCO-2010, MDCO-216 and MDCO-157 during the fourth quarter of 2011 and that our research and development expenses will increase in 2011 as compared to 2010. We expect research and development expenses in 2011 to be approximately 20% of net revenues in 2011, excluding any transaction costs, and to reflect costs associated with our Phase 3 clinical trials of oritavancin and cangrelor, manufacturing development activities for Angiomax, Cleviprex, cangrelor and MDCO-216, our Phase 2 clinical trial program for MDCO-2010, our Phase 1 clinical trial of MDCO-216, product lifecycle management activities and the development of MDCO-157. We plan to evaluate, and make changes to, our budget allocation for such projects throughout the year based on net revenue amounts actually achieved.

The following tables identify, for each of our major research and development projects, our spending for the three and nine months ended September 30, 2011 and 2010. Spending for past periods is not necessarily indicative of spending in future periods.

23

Research and Development Spending

	Three Months Ended September 30,				
	2011 (In thousands)	% of Total R&D	2010 (In thousands)	% of Total R&D	
Angiomax					
Clinical trials	\$1,116	4	% \$1,781	11	%
Manufacturing development	34	—	% 622	4	%
Administrative and headcount costs	768	3	% 417	2	%
Total Angiomax	1,918	7	% 2,820	17	%
Cleviprex					
Clinical trials	659	2	% 229	1	%
Manufacturing development	109	—	% 488	3	%
Administrative and headcount costs	450	2	% 521	3	%
Total Cleviprex	1,218	4	% 1,238	7	%
Cangrelor					
Clinical trials	6,622	25	% 1,611	10	%
Manufacturing development	320	1	% 763	5	%
Administrative and headcount costs	1,466	6	% 1,082	6	%
Milestone	—	—	% —	—	%
Total Cangrelor	8,408	32	% 3,456	21	%
Oritavancin					
Clinical trials	6,038	23	% 1,186	7	%
Manufacturing development	925	3	% 383	3	%
Administrative and headcount costs	1,153	4	% 2,034	12	%
Total Oritavancin	8,116	30	% 3,603	22	%
MDCO-2010					
Clinical trials	73	—	% 861	5	%
Manufacturing development	97	—	% 575	3	%
Administrative and headcount costs	2,081	8	% 1,077	7	%
Government subsidy	—	—	% (530)	(3))%
Total MDCO-2010	2,251	8	% 1,983	12	%
MDCO-216					
Clinical trials	102	—	% 86	—	%
Manufacturing development	612	2	% 655	4	%
Administrative and headcount costs	267	1	% 121	1	%
Total MDCO-216	981	3	% 862	5	%
Ready-to-Use Argatroban					
Manufacturing development	—	—	% 139	1	%
Administrative and headcount costs	(147)	(1))% —	—	%
Total Ready-to-Use Argatroban	(147)	(1))% 139	1	%
MDCO-157					
Administrative and headcount costs	35	—	% —	—	%
Acquisition license fee	—	—	% —	—	%
Total MDCO-157	35	—	% —	—	%

Edgar Filing: MEDICINES CO /DE - Form 10-Q

Other	3,770	14	%	2,575	15	%
Total	\$26,550	97	%	\$16,676	100	%

24

Edgar Filing: MEDICINES CO /DE - Form 10-Q

	Nine Months Ended September 30,				
	2011 (In thousands)	% of Total R&D	2010 (In thousands)	% of Total R&D	
Angiomax					
Clinical trials	\$4,763	6	% \$5,080	9	%
Manufacturing development	206	—	% 4,596	9	%
Administrative and headcount costs	2,194	3	% 1,824	3	%
Total Angiomax	7,163	9	% 11,500	21	%
Cleviprex					
Clinical trials	1,332	2	% 1,316	3	%
Manufacturing development	300	1	% 1,209	2	%
Administrative and headcount costs	1,095	1	% 1,610	3	%
Total Cleviprex	2,727	4	% 4,135	8	%
Cangrelor					
Clinical trials	17,648	23	% 4,964	9	%
Manufacturing development	868	1	% 1,724	3	%
Administrative and headcount costs	4,741	6	% 3,094	6	%
Milestone	—	—	% 3,000	6	%
Total Cangrelor	23,257	30	% 12,782	24	%
Oritavancin					
Clinical trials	17,678	23	% 2,250	4	%
Manufacturing development	1,825	2	% 2,833	5	%
Administrative and headcount costs	3,860	5	% 5,728	11	%
Total Oritavancin	23,363	30	% 10,811	20	%
MDCO-2010					
Clinical trials	531	1	% 1,516	3	%
Manufacturing development	199	—	% 946	2	%
Administrative and headcount costs	3,867	5	% 3,151	6	%
Government subsidy	(222)) —	% (1,038) (2)%
Total MDCO-2010	4,375	6	% 4,575	9	%
MDCO-216					
Clinical trials	588	1	% 126	—	%
Manufacturing development	2,025	3	% 1,246	2	%
Administrative and headcount costs	749	1	% 430	1	%
Total MDCO-216	3,362	5	% 1,802	3	%
Ready-to-Use Argatroban					
Manufacturing development	—	—	% 616	1	%
Administrative and headcount costs	544	1	% 169	—	%
Total Ready-to-Use Argatroban	544	1	% 785	1	%
MDCO-157					
Administrative and headcount costs	35	—	% —	—	%
Acquisition license fee	1,750	2	% —	—	%
Total MDCO-157	1,785	2	% —	—	%
Other	10,302	13	% 7,738	14	%
Total	\$76,878	100	% \$54,128	100	%

Angiomax

Research and development spending related to Angiomax during the three months ended September 30, 2011 decreased by approximately \$0.9 million compared to the three months ended September 30, 2010, primarily due to decreases of \$0.7 million

25

in clinical trial costs in connection with the reduction of the number of clinical sites for our Phase 4 EUROMAX clinical trial and of \$0.6 million in manufacturing development expenses related to product lifecycle management activities. These decreases were partially offset by an increase of \$0.4 million in administrative and headcount expenses related to our efforts to further develop Angiomax for use in additional patient populations. We are conducting the EUROMAX trial at sites in six 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 GP IIb/IIIa inhibitor. We commenced enrollment in our EUROMAX clinical trial in March 2010. We expect to enroll approximately 3,680 patients in the EUROMAX trial.

Research and development spending related to Angiomax during the nine months ended September 30, 2011 decreased by approximately \$4.3 million compared to the nine months ended September 30, 2010, primarily due to a decrease of \$4.4 million in manufacturing development expenses related to product lifecycle management activities and a decrease of \$0.3 million in clinical trial costs, primarily due to decreased expenditures in connection with our Phase 4 EUROMAX clinical trial. These decreases were partially offset by an increase of \$0.4 million in administrative and headcount expenses related to our efforts to further develop Angiomax for use in additional patient populations.

We expect that our research and development expenses relating to Angiomax will decrease in 2011 as compared to 2010 due to the completion of enrollment of our Phase 4 EUROVISION trial in 2010, which we designed to study utilization patterns of patients receiving Angiox and collect descriptive outcome and safety data of patients, and decreased manufacturing and regulatory expenses. We expect that this decrease will be partially offset by increased expenses in connection with our efforts to further develop Angiomax for use in additional patient populations such as the EUROMAX trial, as well as continued research and development expenses related to our product lifecycle management activities.

Cleviprex

Research and development expenditures for Cleviprex were relatively unchanged during the three months ended September 30, 2011 compared to the three months ended September 30, 2010. Increases in clinical trial costs were offset by decreases in manufacturing development expenses. The increases in clinical trial costs reflect that during the second quarter of 2011, hospitals and third-party researchers restarted clinical studies that we support that were discontinued in late 2009 as a result of the supply issues and we resumed our efforts to obtain marketing approval of Cleviprex outside the United States, which had ceased after the recall of Cleviprex in 2009.

Research and development expenditures for Cleviprex decreased by approximately \$1.4 million during the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010. The decrease was primarily due to the recalls of Cleviprex and the related supply issues and the resulting discontinuation in late 2009 of clinical studies of Cleviprex being conducted by hospitals and third-party researchers that we were supporting.

We expect total research and development expenses relating to Cleviprex in 2011 to remain similar to 2010 levels. We expect we will incur increased research and development expenses in 2011 in connection with our efforts to obtain marketing approval of Cleviprex outside the United States and the clinical studies being conducted by hospitals and third-party researchers. We expect these increased costs to be offset by decreased manufacturing development expenses related to an improved formulation of Cleviprex which provides a longer infusion time that the FDA approved in June 2011.

Cangrelor

Research and development expenditures related to cangrelor increased by approximately \$5.0 million in the three months ended September 30, 2011 compared to the three months ended September 30, 2010. The increase primarily reflects increased clinical trial expenses related to our Phase 3 PHOENIX clinical trial program, which we commenced in October 2010 to evaluate cangrelor in patients undergoing PCI, as well as an increase in the related administrative and headcount expenses. These increases were partially offset by a decrease in drug product manufacturing development expenses.

Research and development expenditures related to cangrelor increased by approximately \$10.5 million in the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010. The increase primarily reflects increased clinical trial expenses related to our Phase 3 PHOENIX clinical trial program, as well as an increase in the related administrative and headcount expenses. The 2010 period also included charges recorded in the nine months ended September 30, 2010, associated with a \$3.0 million payment made to AstraZeneca in connection with the June 2010 amendment to our agreement with AstraZeneca.

We expect to incur increased research and development expenses relating to cangrelor in 2011 as compared to 2010 in connection with the PHOENIX clinical trial. We initially expect to enroll approximately 10,900 patients, and we may enroll additional patients,

in this double-blind parallel group randomized study which compares cangrelor to clopidogrel given according to institutional practice. We currently have enrolled approximately 3,500 patients in the PHOENIX clinical trial.

Oritavancin

Research and development expenditures related to oritavancin increased by approximately \$4.5 million in the three months ended September 30, 2011 compared to the three months ended September 30, 2010. The increase primarily reflects increased costs incurred in the three months ended September 30, 2011 related to our SOLO I and SOLO II Phase 3 clinical trials, which are two identical Phase 3 clinical trials of oritavancin for the treatment of ABSSSI, which we commenced in the fourth quarter of 2010. This increase in expenditures in the third quarter of 2011 was partially offset by decreases in headcount expenses in 2011.

Research and development expenditures related to oritavancin increased by approximately \$12.6 million in the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010. The increase primarily reflects increased costs incurred in the nine months ended September 30, 2011 related to our SOLO I and SOLO II Phase 3 clinical trials. This increase in expenditures in the first nine months of 2011 was partially offset by decreased manufacturing costs as we had manufactured product in 2010 for use in the SOLO I and SOLO II trials and decreased headcount expenses in 2011. Oritavancin research and development costs for the nine months ended September 30, 2010 also included approximately \$1.3 million of severance payments related to the workforce reductions initiated in the first quarter of 2010.

We expect to incur increased research and development expenses relating to oritavancin in 2011 as compared to 2010 due to the SOLO I and SOLO II clinical trials. We plan to enroll a total of approximately 2,000 patients in the SOLO I and SOLO II clinical trials and to test the use of a simplified dosing regimen involving a single dose of oritavancin as compared to multiple doses of vancomycin for the treatment of ABSSSI. We currently have enrolled approximately 400 patients in the SOLO I and SOLO II clinical trials.

MDCO-2010

Research and development expenditures related to MDCO-2010 increased by approximately \$0.3 million in the three months ended September 30, 2011 compared to the three months ended September 30, 2010. Costs incurred during the three months ended September 30, 2011 primarily related to the 2011 Leipzig closure, our ongoing Phase 2 clinical trial program of MDCO-2010. Costs incurred during the three months ended September 30, 2010 primarily related to our Phase 1 clinical trial of MDCO-2010, which we commenced in July 2009 and which we completed in 2010 in healthy volunteers that demonstrated safety and tolerability at low doses. Costs related to our Phase 2 clinical trial program include headcount related costs and manufacturing expenses related to the production of drug product for the trial. Costs related to MDCO-2010 in the three months ended September 30, 2010 were partially offset by a German government research and development subsidy paid during that period. We commenced our Phase 2 clinical trial program in November 2010 with a Phase 2a clinical trial conducted in Switzerland to study the safety, tolerability, pharmacokinetics and pharmacodynamics of MDCO-2010 in patients undergoing elective CABG surgery. We completed this trial in the third quarter of 2011 and presented the data at the American Society of Anesthesiologist conference in October 2011. Based on the Phase 2a results, we plan to commence a Phase 2b clinical trial of MDCO-2010 in the first quarter of 2012. We initially plan to conduct this trial in Germany, Canada and Switzerland, to determine dose response relationship regarding blood loss, pharmacokinetics and pharmacodynamics, and clinical outcomes of MDCO-2010 versus placebo and tranexamic acid in patients undergoing primary CABG surgery or combined primary CABG and aortic valve replacement. We further expect to submit an investigational new drug application, or IND, for MDCO-2010 to the FDA in the first quarter of 2012 and subject to the IND becoming effective, we plan to add the United States as a location for our Phase 2b clinical trial of MDCO-2010.

Research and development expenditures related to MDCO-2010 decreased by \$0.2 million in the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010. Costs incurred during the nine months ended September 30, 2011 primarily related to our ongoing Phase 2 clinical trial program of MDCO-2010 and the 2011 Leipzig closure. Costs incurred during the nine months ended September 30, 2010 primarily related to our Phase 1 clinical trial of MDCO-2010, which we commenced in July 2009. Costs related to our Phase 2 clinical trial program include headcount related costs and manufacturing expenses related to the production of drug product for the trial. Costs related to MDCO-2010 were partially offset by a German government research and development subsidy paid in both the nine months ended September 30, 2011 and September 30, 2010.

We expect that our research and development expenses relating to MDCO-2010 will decrease in 2011 as compared to 2010, as we incurred an expense of \$4.3 million for achieving a clinical milestone in 2010. We expect that these decreased expenses will be partially offset by an increase in the clinical trial expense related to our Phase 2b clinical trial of MDCO-2010.

MDCO-216

Research and development expenditures related to MDCO-216 increased by approximately \$0.1 million in the three months ended September 30, 2011 compared to the three months ended September 30, 2010. Costs incurred during the three months ended September 30, 2011 primarily related to manufacturing development related to preclinical activities and clinical trial costs in connection with preparation for the commencement of a Phase 1 study of MDCO-216. Costs incurred during the three months ended September 30, 2010 primarily related to manufacturing development related to preclinical activities, administrative and headcount expenses and our preparation for a Phase 1 study.

Research and development expenditures related to MDCO-216 increased by approximately \$1.6 million in the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010. Costs incurred during the nine months ended September 30, 2011 primarily related to manufacturing development related to preclinical activities, clinical trial costs 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, 2010 primarily related to manufacturing development, administrative and headcount expenses and clinical trial costs.

We expect to incur increased research and development expenses relating to MDCO-216 in 2011 as compared to 2010 in connection with our planned Phase 1 study of MDCO-216. In 2010, we completed a technology transfer program with Pfizer related to improved manufacturing methodologies developed by Pfizer since the Phase 1/2 trial of MDCO-216 conducted by Pfizer prior to the time that we obtained our license for MDCO-216. Using these new methodologies, we manufactured MDCO-216 on a small scale for use in preclinical studies of MDCO-216 in 2010. We plan to commence a Phase 1 study of MDCO-216 in the first half of 2012 and to use the same new methodologies to produce product for the Phase 1 study.

Ready-to-Use Argatroban

Research and development expenditures related to ready-to-use Argatroban decreased by \$0.3 million in the three months ended September 30, 2011 compared to the three months ended September 30, 2010. Costs incurred during the three months ended September 30, 2011 primarily related to administrative and headcount related expenses and costs incurred during the three months ended September 30, 2010 primarily related to manufacturing development expenses.

Research and development expenditures related to ready-to-use Argatroban decreased by \$0.2 million in the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010. Costs incurred during the nine months ended September 30, 2011 primarily related to administrative and headcount related expenses and costs incurred during the nine months ended September 30, 2010 primarily related to manufacturing development activities and administrative and headcount related expenses.

We expect total research and development expenses relating to ready-to-use Argatroban in 2011 to remain similar to 2010 levels.

MDCO-157

In May 2011, we entered into a licensing agreement with Ligand under which we acquired exclusive, worldwide license rights to MDCO-157, a novel intravenous formulation of clopidogrel bisulfate. Costs incurred during the three months ended September 30, 2011 primarily related to administrative and headcount related expenses. Costs incurred during the nine months ended September 30, 2011 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 and

therefore will be obligated to spend the pro rata amount of approximately \$1.5 million in 2011 on MDCO-157.

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, or PK/PD 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 \$1.2 million during the three months ended September 30, 2011 compared to the three months ended September 30, 2010, primarily due to an increase in administrative and headcount expenses.

Spending in this category increased by approximately \$2.6 million during the nine months ended September 30, 2011 compared

to the nine months ended September 30, 2010, 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. Nor can we 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, or the period in which material net cash inflows are expected to commence from further developing Angiomax and Cleviprex, obtaining marketing approvals for Angiomax in additional countries and additional patient populations and for Cleviprex outside the United States or 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,			
	2011	2010	Change \$	Change %	2011	2010	Change \$	Change %
	(in thousands)				(in thousands)			
Selling, general and administrative expenses	\$45,353	\$35,788	\$9,565	26.7 %	\$124,701	\$121,318	\$3,383	2.8 %

The increase in selling, general and administrative expenses of \$9.6 million in the three months ended September 30, 2011 as compared to the three months ended September 30, 2010 reflects a \$0.5 million increase in selling, marketing and promotional expense primarily from an increase in our efforts to expand global sales and marketing activities in the third quarter of 2011, \$6.9 million of higher general corporate and administrative spending in the third quarter of 2011, largely associated with our efforts with respect to the patent term extension of the '404 patent and settlement of our patent infringement litigation with Teva, increased site costs of \$1.2 million which includes lease termination costs as a result of vacating our previous office facility in New Jersey, and a \$1.0 million increase in stock-based compensation expense in the third quarter of 2011 as compared to the third quarter of 2010.

The increase in selling, general and administrative expenses of \$3.4 million in the nine months ended September 30, 2011 as compared to the nine months ended September 30, 2010 reflects a \$7.5 million increase in general corporate and administrative spending largely in connection with our efforts with respect to the patent term extension of the '404 patent and settlement of our patent infringement litigation with Teva, higher intangible amortization costs of \$1.0 million, increased site costs of \$0.7 million which includes lease termination costs as a result of vacating our previous office facility, and higher stock-based compensation costs of \$1.6 million. These increases were partially offset by \$2.1 million decrease in selling, marketing, and promotional expenses primarily related to Angiomax and \$5.3 million of lower corporate and administrative spending resulting from a reduction in personnel costs due to the first quarter

2010 reduction in force and the closure of our Indianapolis site.

Legal settlement:

29

Edgar Filing: MEDICINES CO /DE - Form 10-Q

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2011	2010	Change \$	Change %	2011	2010	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. We did not record any legal settlement income for the three months ended September 30, 2011.

Other income (expense):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2011	2010	Change \$	Change %	2011	2010	Change \$	Change %
	(in thousands)				(in thousands)			
Other income	\$578	\$483	\$95	19.7 %	\$1,450	\$55	\$1,395	2,536.4 %

Other income, which is comprised of interest income, gains and losses on foreign currency transactions and impairment of investment, increased by \$0.1 million to \$0.6 million of income for the three months ended September 30, 2011, from \$0.5 million for the three months ended September 30, 2010. This increase was primarily due to higher gains on foreign currency transactions in the three months ended September 30, 2011.

Other income increased by \$1.4 million to \$1.5 million of income for the nine months ended September 30, 2011, from \$0.1 million for the nine months ended September 30, 2010. This increase was primarily due to higher gains on foreign currency transactions in the nine months ended September 30, 2011 and increased interest due to higher levels of cash to invest.

Provision for Income Tax:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2011	2010	Change \$	Change %	2011	2010	Change \$	Change %
	(in thousands)				(in thousands)			
Provision for income tax	\$62,625	\$(989)	\$63,614	(6,432.2)%	\$50,798	\$(2,607)	\$53,405	(2,048.5)%

On a periodic basis, we evaluate the realizability of our deferred tax assets net of deferred tax liabilities and adjust such amounts in light of changing facts and circumstances, including but not limited to our level of past and future taxable income, the current and future expected utilization of tax benefit carryforwards, any regulatory or legislative actions by relevant authorities with respect to the Angiomax patents, and the status of litigation with respect to those patents. We consider all available evidence, both positive and negative, to determine whether, based on the weight of

that evidence, a valuation allowance is required to reduce the net deferred tax assets to the amount that is more likely than not to be realized in future periods. During the third quarter of 2011, based on review of the following positive and negative evidence, we reduced our valuation allowance against our deferred tax assets by \$66.5 million and recorded a corresponding tax benefit.

Positive:

on September 16, 2011, President Obama signed the Leahy-Smith America Invents Act, which clarified the filing timeline for patent term extension applications under the Hatch-Waxman Act. This clarification confirmed the interpretation of the Hatch-Waxman Act adopted by the federal district court's August 3, 2010 decision in our suit against the PTO, the

30

FDA and HHS, which ordered the PTO to consider our patent term extension application for the '404 patent timely filed. Based on the FDA's determination of the applicable regulatory review period for Angiomax, we believe that the term of the '404 patent should be extended until December 15, 2014. However, to date the PTO has not yet communicated a final determination concerning the length of any patent term extension for the '404 patent. At this time, we do not know when the PTO will make or communicate such a determination. On July 28, 2011, the PTO granted us a one-year interim extension of the '404 patent until August 13, 2012. 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. If the patent term of the '404 patent is extended to December 15, 2014, we currently believe that this pediatric exclusivity would extend until June 15, 2015;

on September 30, 2011, we entered into a settlement agreement and a license agreement with Teva, with respect to our patent infringement suits against Teva, which includes our suit against Pliva Hrvatska d.o.o., et al. As part of the settlement agreement, Teva admitted that the '727 patent and '343 patent are valid and enforceable and that they would be infringed by the manufacture and sale of Teva's generic bivalirudin for injection products. Under the license agreement, 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. The '727 patent and '343 patent are listed in the Orange Book and expire on July 27, 2028;

for 2010 and the nine months ended September 30, 2011, our reported U.S. income before income taxes totaled approximately \$80.8 million and \$57.9 million, respectively; and

we launched our third product, ready-to-use Argatroban, in the United States in September 2011.

Negative:

APP filed a motion to intervene for the purpose of appeal in our case against the PTO, the FDA and HHS. On September 13, 2010, the federal district court denied APP's motion. APP has appealed the denial of its motion, as well as the federal district court's August 3, 2010 order (and all related and underlying orders). This appeal is pending in the U.S. Court of Appeals for the Federal Circuit. In its appeal, APP is contending that Section 37 of the America Invents Act does not govern our matter and is challenging the constitutionality of the America Invents Act. On September 27, 2011, APP filed for a Motion for Stay Pending Appeal in order to prevent the PTO from issuing a final certificate of extension for the '404 patent.

we were, and currently are, involved in patent infringement litigation with four generic manufacturers with respect to our '343 and '727 patents, the negative outcomes of which may have a material impact on our future operations and profitability.

In the third quarter of 2011, we recorded a \$66.5 million income tax benefit by reducing our valuation allowance to \$4.2 million against \$116.4 million of deferred tax assets compared to a \$104.3 million valuation allowance against all of our deferred tax assets at December 31, 2010. Any changes to the valuation allowance or deferred tax assets in the future would impact our income taxes.

We recorded a \$62.6 million net benefit and a \$1.0 million provision for income taxes for the three months ended September 30, 2011 and 2010, respectively, based on income before taxes for such periods of \$10.0 million and \$22.2 million.

We recorded a \$50.8 million benefit and a \$2.6 million provision for income taxes for the nine months ended September 30, 2011 and 2010, respectively, based on income before taxes of \$57.5 million and \$48.7 million. In addition to the \$66.5 million tax benefit discussed above, our income tax benefit for the nine months ended September 30, 2011 also reflects a one-time \$2.5 million benefit resulting from a prospective change in the New

Jersey income tax law enacted in the second quarter of 2011 and the tax treatment of the entire WilmerHale settlement as cumulative discrete events in this period. The income tax provision for 2010 reflected the utilization of U.S. net operating loss carryforwards against projected taxable income and a liability for alternative minimum tax. Both the 2011 and 2010 periods include a non-cash tax expense arising from purchase accounting for in-process research and development acquired in the Targanta acquisition. It is possible that our full-year effective tax rate used in our income tax expense calculation could change because of discrete events, specific transactions or actual results that differ from our current projections.

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, sales of convertible promissory notes and warrants and interest income. Except for 2004, 2006 and 2010, we have incurred losses on an annual basis since our inception. We had \$307.8 million in cash, cash equivalents and available for sale securities as of September 30, 2011.

Cash Flows

As of September 30, 2011, we had \$258.0 million in cash and cash equivalents, as compared to \$126.4 million as of December 31, 2010. Our primary sources of cash during the nine months ended September 30, 2011 included \$60.6 million of net cash provided by operating activities, which includes the impact of the approximately \$18.0 million received from the legal settlement with WilmerHale in March and April 2011, \$68.8 million in net cash provided by investing activities and \$4.0 million in net cash provided by financing activities.

Net cash provided by operating activities was \$60.6 million in the nine months ended September 30, 2011, compared to net cash provided by operating activities of \$48.6 million in the nine months ended September 30, 2010. The 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, stock-based compensation expense and depreciation and amortization. Cash provided by operating activities in the nine months ended September 30, 2011 also included \$2.1 million due to changes in working capital items. These changes in working capital items reflect an increase in inventory of \$5.0 million due to purchases under our supply agreement with Plantex of certain minimum quantities of the active pharmaceutical ingredient bivalirudin for our commercial supply, an increase in accrued expenses of \$32.3 million primarily due to our efforts with respect to the patent term extension of the '404 patent and settlement of our patent litigation with Teva, and an increase in accounts receivable of \$26.0 million. This increase in accounts receivable is due in part to increased volume of our sales of Angiomax and to an extension of 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. We agreed to this extension in connection with a reduction in marketing, sales and distribution fees payable to ICS. The adjusted payment terms began to be implemented midway through the first quarter of 2011.

The cash provided by operating activities in the nine months ended September 30, 2010 included net income of \$46.1 million. Cash provided by operating activities in the nine months ended September 30, 2010 also included a decrease of \$14.2 million due to changes in working capital items.

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.

During the nine months ended September 30, 2010, \$19.3 million in net cash was used in investing activities, which reflected \$100.8 million used to purchase available for sale securities, offset by \$80.1 million in proceeds from the maturity and sale of available for sale securities and a \$1.3 million decrease in restricted cash resulting from a reduction of our outstanding letter of credit associated with the lease of our principal executive offices.

We received \$4.0 million in the nine months ended September 30, 2011 and \$2.8 million in the nine months ended September 30, 2010 in net cash provided by financing activities, which consisted of proceeds to us from option exercises 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. Our funding requirements to support these efforts and programs 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 at least June 2015, which could be adversely affected as a result of an adverse court decision or adverse legislation relating to the '404 patent;
- our ability to maintain market exclusivity for Angiomax in the United States through June 30, 2019, the date on which we agreed Teva may sell a generic version of Angiomax, through the enforcement of our other U.S. patents covering

Angiomax;

the terms of any settlements with Biogen Idec, HRI or the law firm with which we have not settled our claims with respect to the '404 patent and the PTO's initial denial of our application to extend the term of the patent;

- the extent to which Cleviprex and ready-to-use Argatroban are commercially successful in the United States;
- the extent to which we can successfully 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 and 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, Australia, New Zealand and Switzerland 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 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 and ready-to-use Argatroban, or higher than anticipated costs globally, we may need to sell 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. We cannot be certain that public or private financing will 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, 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 when information available indicates that it is probable that a liability has been incurred and the amount of such loss can be reasonably estimated. We believe that the ultimate resolution of these matters will not have a material adverse effect on our financial condition or liquidity. However, adjustments, if any, to our estimates could be material to operating results for the periods in which adjustments to the liability are recorded.

Currently, we are party to the legal proceedings described in Part II, Item I 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 so no loss contingency was recorded 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 purchase of inventory of our products, research and development service agreements, milestone payments due under our license agreements, income tax contingencies, operating leases, and selling, general and administrative obligations as of December 31, 2010. During the quarter ended September 30, 2011, 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, 2010, other than with respect to inventory

related commitments. Our inventory related commitments increased in connection with our supply agreement with Plantex that we entered into on September 30, 2011. Under the agreement with Plantex, we agreed to purchase certain minimum quantities of the active pharmaceutical ingredient bivalirudin for our commercial supply. These obligations are reflected in the table below.

Contractual Obligations (in thousands)	Total (in thousands)	2011 Q4	2012-2013	2014-2015	After 2015
Inventory related commitments	\$ 126,161	\$ 23,884	\$ 87,277	\$ 15,000	\$—

In addition to the amounts shown in the above table, we are contractually obligated to make potential future success-based development, regulatory and commercial milestone payments and royalty payments in conjunction with collaborative agreements or acquisitions we have entered into with third parties. In June 2011, we entered into a licensing agreement with Ligand under which we acquired an exclusive, worldwide license to MDCO-157. Under the license agreement, we paid Ligand an upfront payment of approximately \$1.8 million in June 2011 and agreed to make additional payments of up to \$22 million upon the achievement of certain clinical, regulatory and commercial milestones. These payments are contingent upon the occurrence of certain future events and, given the nature of these events, it is unclear when, if ever, we may be required to pay such amounts. These contingent payments have not been included in the table above. Further, the timing of any future payment is not reasonably estimable.

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, 2010. 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, 2010 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 are used 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, 2011 we held \$307.8 million in cash, cash equivalents and available for sale securities which had an average interest rate of approximately 0.45%. A 10 basis point change in such average interest rate would have had an approximate \$0.1 million impact on our interest income. At September 30, 2011, 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, 2011, we had receivables denominated in currencies other than the U.S. dollar. A 10% change in foreign exchange rates would have had an approximate \$0.9 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, 2011. 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, 2011, 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, 2011 that has materially affected, or is reasonably

likely to materially affect, our internal control over financial reporting.

35

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

Teva Parenteral Medicines, Inc.

In September 2009, we were notified that Teva Parenteral Medicines, Inc. had submitted an ANDA seeking permission to market its generic version of Angiomax prior to the expiration of the '727 patent. The '727 patent was issued on September 1, 2009 and relates to a more consistent and improved Angiomax drug product. The '727 patent expires on July 27, 2028. On October 8, 2009, we filed suit against Teva Parenteral Medicines, Inc., Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd., which we refer to collectively as Teva Pharmaceuticals, in the U.S. District Court for the District of Delaware for infringement of the '727 patent. On October 29, 2009, Teva Pharmaceuticals filed an answer denying infringement and alleging affirmative defenses of non-infringement and invalidity. On October 21, 2009, the case was reassigned in lieu of a vacant judgeship to the U.S. District Court for the Eastern District of Pennsylvania.

On October 6, 2009, we were issued U.S. Patent No. 7,598,343, or the '343 patent, which relates to a more consistent and improved Angiomax drug product made by processes described in the patent. On January 4, 2010, we filed suit against Teva Pharmaceuticals in the U.S. District Court for the District of Delaware for infringement of the '343 patent. The case was assigned to the same judge in the Eastern District of Pennsylvania as the Teva Pharmaceuticals '727 patent case above.

The judge in the Eastern District of Pennsylvania has consolidated the Teva Pharmaceuticals '727 patent and '343 patent cases with the Pliva '727 patent and '343 patent cases (discussed below), the APP '727 patent and '343 patent cases (discussed below) and the Hospira '727 patent and '343 patent cases (discussed below).

On September 30, 2011, we entered into a settlement agreement and a license agreement with Teva, which included Pliva Hrvatska d.o.o., with respect to the patent infringement suits. Under the settlement agreement, Teva admitted that the '727 patent and '343 patent are valid and enforceable and that they would be infringed by the manufacture and sale of Teva's generic bivalirudin for injection products. Under the license agreement, 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 October 13, 2011, the district court entered a judgment and order of permanent injunction concluding our patent infringement suits against Teva. On October 13, 2011, we and Teva submitted the settlement agreement and license agreement to the FTC and the DOJ.

Pliva Hrvatska d.o.o.

In September 2009, we were notified that Pliva Hrvatska d.o.o. had submitted an ANDA seeking permission to market its generic version of Angiomax prior to the expiration of the '727 patent. On October 8, 2009, we filed suit against Pliva Hrvatska d.o.o., Pliva d.d., Barr Laboratories, Inc., Barr Pharmaceuticals, Inc., Barr Pharmaceuticals, LLC, Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd., which we refer to collectively as Pliva, in the

U.S. District Court for the District of Delaware for infringement of the '727 patent. On October 28, 2009, Pliva filed an answer denying infringement and alleging affirmative defenses of non-infringement and invalidity. On October 21, 2009, the case was reassigned in lieu of a vacant judgeship to the U.S. District Court for the Eastern District of Pennsylvania.

On October 6, 2009, we were issued the '343 patent, which relates to a more consistent and improved Angiomax drug product made by processes described in the patent. On January 4, 2010, we filed suit against Pliva in the U.S. District Court for the District of Delaware for infringement of the '343 patent. The case was assigned to the same judge in the Eastern District of Pennsylvania as the '727 patent case above.

On September 30, 2011, we entered into a settlement agreement and a license agreement with Teva, which included Pliva, with respect to the patent infringement suits, as described above.

APP Pharmaceuticals, LLC

In September 2009, we were notified that APP Pharmaceuticals, LLC had submitted an ANDA seeking permission to market its generic version of Angiomax prior to the expiration of the '727 patent. On October 8, 2009, we filed suit against APP Pharmaceuticals, LLC and APP Pharmaceuticals, Inc., which we refer to collectively as APP, in the U.S. District Court for the District of Delaware for infringement of the '727 patent. On October 21, 2009, the case was reassigned in lieu of a vacant judgeship to the U.S. District Court for the Eastern District of Pennsylvania. An amended complaint was filed on February 5, 2010. APP's answer denied infringement and raised counterclaims of invalidity, non-infringement and a request to delist the '727 patent from the Orange Book. On March 1, 2010, we filed a reply denying the counterclaims raised by APP. The court has set a pre-trial schedule in the case and fact discovery is ongoing. No trial date has been set by the court.

On October 6, 2009, we were issued the '343 patent, which relates to a more consistent and improved Angiomax drug product made by processes described in the patent. In April 2010, we were notified by APP that it is seeking permission to market its generic version of Angiomax prior to the expiration of the '343 patent. On June 1, 2010, we filed suit against APP in the U.S. District Court for the District of Delaware for infringement of the '343 patent. On June 28, 2010, APP filed an answer denying infringement and raised counterclaims of invalidity, non-infringement and a request to delist the '343 patent from the Orange Book. On July 16, 2010, we filed a reply denying the counterclaims raised by APP. The case has been assigned to a judge in the U.S. District Court for the District of Delaware. On October 14, 2010, the case was reassigned to the same judge in the Eastern District of Pennsylvania who was then presiding over the above APP '727 patent case and the Teva Pharmaceuticals '727 patent and '343 patent cases and the Pliva '727 patent and '343 patent cases. On the same day, the APP '343 patent case was consolidated with these other cases.

On February 25, 2011, APP filed a motion to amend its answer and add counterclaims of inequitable conduct and unclean hands. The motion was referred to a special master. Our opposition papers were filed on March 14, 2011 and APP filed a reply on March 24, 2011. The special master heard oral argument on April 13, 2011 and issued a report and recommendations on April 26, 2011. The parties briefed the issues raised to the judge. Following recent federal circuit decisions, the judge sent APP's motion back to the special master for further review. A second report and recommendation was issued on June 23, 2011. The issues were again briefed to the judge and the court issued an order adopting the special master's report and granting APP's motion. APP filed its amended answers and counterclaims on July 25, 2011.

On October 8, 2011, we filed a motion to dismiss, strike or alternatively bifurcate APP's allegations of inequitable conduct and unclean hands. The motion was referred to the special master. APP filed an answering brief on August 19, 2011. We filed a reply on August 24, 2011. On September 22, 2011 the special master issued a report and recommendation. The parties briefed the issues raised to the judge and the court issued an order adopting the special master's report and denying our motion. On October 21, 2011 we filed replies answering APP's counterclaims.

The special master also directed the parties to file supplemental briefing for a pretrial hearing known as a Markman hearing. Opening briefs were filed on October 7, 2011 and responding briefs on October 20, 2011. A Markman hearing date has not been set.

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.

On September 17, 2010, Hospira filed a motion to be consolidated with the Teva Pharmaceuticals, Pliva and APP cases. On October 13, 2010 the Court denied Hospira's motion to consolidate. As part of setting the schedule in this case, the Hospira '727 patent and '343 patent cases were consolidated with the above Teva Pharmaceuticals, Pliva and APP cases. 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. 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. The Court did not set a Markman hearing date or trial date.

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. We are in the process of reviewing this correspondence and determining what further action we may take.

'404 Patent Litigation

PTO, FDA and HHS, et al.

On January 27, 2010, we filed a complaint in the U.S. District Court for the Eastern District of Virginia against the PTO, the FDA, and HHS et al. seeking to set aside the denial of our application pursuant to the Hatch-Waxman Act to extend the term of the '404 patent. In our complaint, we primarily alleged that the PTO and the FDA each misinterpreted the filing deadlines in the Hatch-Waxman Act when they rendered their respective determinations that our application for extension of the term of the '404 patent was not timely filed. We asked the court to grant relief including to vacate and set aside the PTO's and the FDA's determinations regarding the timeliness of our application for patent term extension and to order the PTO to extend the term of the '404 patent for the full period required under the Hatch-Waxman Act. On March 10, 2010, the court conducted a hearing on the parties' cross motions for summary judgment. On March 16, 2010, the court set aside the PTO's denial of our patent term extension application and sent the matter back to the PTO for reconsideration. The court further ordered that the PTO take the actions necessary to ensure that the '404 patent did not expire pending resolution of the court proceedings. On March 18, 2010, the PTO issued an interim extension of the '404 patent to May 23, 2010. On March 19, 2010, the PTO issued a decision again denying our application for patent term extension for the '404 patent.

On March 25, 2010, we filed a complaint in the U.S. District Court for the Eastern District of Virginia against the PTO, the FDA, and HHS, et al. asking the court to set aside the PTO's March 19, 2010 decision, to instruct the PTO to accept our patent term extension application as timely filed and to order the PTO to extend the term of the '404 patent for the full period required under the Hatch-Waxman Act. On May 6, 2010, the court conducted a hearing on the parties' cross motions for summary judgment. On May 21, 2010, the court issued an order instructing the PTO to take the actions necessary to ensure that the '404 patent did not expire until at least 10 days after the court issued an order deciding the case. On August 3, 2010, the court granted our motion for summary judgment and ordered the PTO to

consider our patent term extension application timely filed. The period for the government to appeal the court's August 3, 2010 decision expired on October 4, 2010 without government appeal and the PTO sent our patent term extension application to the FDA for a determination on the length of the extension of the '404 patent. On December 16, 2010, the FDA published its determination of the applicable regulatory review period for Angiomax. The PTO uses the regulatory review period determined by the FDA with several statutory limitations to calculate the length of a patent extension. Based on the FDA's determination, we believe that the term of the '404 patent should be extended until December 15, 2014. However, to date the PTO has not yet communicated a final determination concerning the length of any patent term extension for the '404 patent. At this time we do not know when the PTO will make or communicate such a determination.

On August 19, 2010, APP filed a motion to intervene in the U.S. District Court for the Eastern District of Virginia for purpose of appeal in our case against the PTO, FDA and HHS, et al. On September 13, 2010, the court issued an order denying APP's motion to intervene. On September 1, 2010, as amended on September 17, 2010, APP filed a notice of appeal to the United States Court of Appeals for the Federal Circuit of the district court's August 3, 2010 and September 13, 2010 orders (and all related and

underlying orders). On October 5, 2010, we filed a motion to dismiss APP's appeal. On February 2, 2011, the federal circuit court issued an order denying our motion to dismiss and requesting additional briefings by both parties in connection with APP's appeal. The court expressed no opinion on the merits of APP's appeal. The parties have fully briefed the issues in connection with APP's appeal.

On September 16, 2011, President Obama signed into law the America Invents Act. Section 37 of the America Invents Act clarifies the filing timeline for patent term extension applications under the Hatch-Waxman Act. This clarification confirms the interpretation of the Hatch-Waxman Act adopted in the district court's August 3, 2010 decision in our suit against the PTO, the FDA and HHS, which ordered the PTO to consider our patent term extension application timely filed. We and APP have filed supplemental briefs concerning the America Invents Act. In its appeal, APP is contending that Section 37 of the America Invents Act does not govern our matter and is challenging the constitutionality of the America Invents Act. In addition, on September 27, 2011, APP filed a Motion for Stay Pending Appeal in order to attempt to prevent the PTO from issuing a final certificate of extension for the '404 patent. The United States has intervened to defend the constitutionality of the America Invents Act. On October 25, 2011 the DOJ filed a brief with the Federal Circuit taking the position that Section 37 of the America Invents Act applies to our matter and is constitutional. Oral argument before the Federal Circuit on APP's appeal is scheduled for November 15, 2011.

Eagle Pharmaceuticals 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 carefully consider the risks and uncertainties described below in addition to the other information included or incorporated by reference in this annual 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 a risk factor regarding the Eagle arbitration and updates regarding the Angiomax patent litigation, 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

Except for 2004, 2006, and 2010, we have incurred net losses on an annual basis since our inception. As of September 30, 2011, we had an accumulated deficit of approximately \$131.2 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 existing 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 or at all, 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 of Cleviprex by the FDA 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 2011. The commercial

success of Angiomax depends upon:

- our ability to maintain market exclusivity for Angiomax in the United States through at least June 2015, which could be adversely affected as a result of an adverse court decision or adverse legislation relating to the '404 patent;

- our ability to maintain market exclusivity for Angiomax in the United States through June 30, 2019, the date on which we agreed Teva may sell a generic version of Angiomax, through the enforcement of our other U.S. patents covering 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 and intend to seek market approval of 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. Even if we are successful in obtaining approval of an expanded Angiomax label, the expanded label may not result in higher revenue or income on a continuing basis.

As of September 30, 2011, our inventory of Angiomax was \$29.1 million and we had inventory-related purchase commitments totaling \$23.9 million for 2011, \$57.2 million for 2012 and \$30.1 million for 2013 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.

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 approved products and our products in development. Our funding requirements to support these efforts and programs 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 at least June 2015, which could be adversely affected as a result of an adverse court decision or adverse legislation relating to the '404 patent;

- our ability to maintain market exclusivity for Angiomax in the United States through June 30, 2019, the date on which we agreed Teva may sell a generic version of Angiomax, through the enforcement of our other U.S. patents covering Angiomax;

40

the terms of any settlements with Biogen Idec, HRI or the law firm with which we have not settled our claims with respect to the '404 patent and the PTO's initial denial of our application to extend the term of the patent;

- the extent to which Cleviprex and ready-to-use Argatroban are commercially successful in the United States;
- the extent to which we can successfully 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, Australia, New Zealand and Switzerland 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. 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.

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 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. 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.

Our revenue in the United States is completely dependent on our sole source distributor, 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. 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 and ready-to-use Argatroban 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 extended 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 materially adverse effect on our revenue in periods in which such purchase reductions occur.

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 in high risk patients. 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 therapies 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 an adverse court decision or adverse legislation relating to the '404 patent or our inability to enforce our other U.S. patents covering

Angiomax, Angiomax could become subject to generic competition in the United States earlier than we anticipate. We have agreed 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.

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 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 and ready-to-use Argatroban 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 currently markets and has marketed for a number of years a formulation of Argatroban that competes with our ready-to-use formulation of Argatroban. 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 the drug may be limited or denied. 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. While PCI procedure volume has increased from 2007 levels, it 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.

Because we did not sell Cleviprex from the first quarter of 2010 through the first quarter of 2011, as a result of product recalls and related supply issues, market acceptance of Cleviprex may be adversely affected

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 or sell Cleviprex from the first quarter of 2010 through the first quarter 2011. We began to resupply existing customers with Cleviprex in April 2011. In July 2011, the FDA approved our sNDA, for an improved formulation of Cleviprex. We re-launched Cleviprex in October 2011 with the new formulation, targeting neurocritical care and cardiac surgery patients. However, physicians and decision makers who have used Cleviprex prior to the recalls may be reluctant to resume using Cleviprex and physicians and

decision makers who had not used Cleviprex may be reluctant to begin using Cleviprex because of the recalls and the related supply issues. Physicians and healthcare decision makers who had adopted Cleviprex as their preferred antihypertensive therapy when it was available may also have adopted other antihypertensive therapies during the period when Cleviprex was not available and may be reluctant to change. In addition, in the re-launch of Cleviprex, we are focusing 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.

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, 2011 we had \$23.7 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;

45

• 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 subjects 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.

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.

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

48

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.

In order to satisfy some non-U.S. regulatory authorities, we may need to reformulate the way in which our oritavancin bulk drug substance is created to remove porcine source product, which may delay marketing approval of oritavancin and increase our costs

Oritavancin bulk drug substance is manufactured using porcine-sourced products. Some non-U.S. regulatory authorities have historically objected to the use of animal-sourced products, particularly bovine-sourced products, during the preparation of finished drug product. As a result and in order to better position oritavancin for approval in foreign jurisdictions, under our agreement with Abbott, we and Abbott are seeking to develop a manufacturing process for oritavancin bulk drug substance that does not rely on the use of any animal-sourced products.

If we are unable to develop a manufacturing process for oritavancin bulk drug substance that does not rely on the use of animal-sourced product, we may be unable to receive regulatory approval for oritavancin in some foreign jurisdictions, which would likely have a negative impact on our ability to achieve our business objectives as to oritavancin.

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 two products, Angiomax and Cleviprex. 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 2011, for instance, we acquired Curacyte Discovery and Targanta, licensed marketing rights to the ready-to-use formulation of Argatroban and licensed development and commercialization rights to MDCO-216 and MDCO-157. 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 Executive Vice 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. Except for Angiomax in the United States, Europe, India and other countries, Cleviprex in the United States, Australia, New Zealand and Switzerland and the ready-to-use formulation of Argatroban in the United States, we do not have any other product approved for sale in the United States or any foreign market. 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 pre-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, a 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 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 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 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 improperly 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 an adverse court decision or adverse legislation relating to the '404 patent or our inability to enforce our other 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. patent covering Angiomax, the '404 patent, was set to expire in March 2010, but has been extended under the Hatch-Waxman Act following our litigation against the PTO, the FDA and HHS. We had applied, under the Hatch-Waxman

Act, for an extension of the term of the '404 patent, but the PTO rejected our application because in its view the application was not timely filed. As a result, we filed suit against the PTO, the FDA and HHS seeking to set aside the denial of our application to extend the term of the '404 patent. On August 3, 2010, the federal district court granted our motion for summary judgment and ordered the PTO to consider our patent term extension application timely filed. The period for the government to appeal the federal district court's August 3, 2010 decision expired without government appeal. However, on August 19, 2010, APP filed a motion to intervene for the purpose of appeal in our case against the PTO, the FDA and HHS. On September 13, 2010, the federal district court denied APP's motion. APP has appealed the denial of its motion, as well as the federal district court's August 3, 2010 order (and all related and underlying orders). This appeal is pending in the U.S. Court of Appeals for the Federal Circuit.

On September 16, 2011, President Obama signed into law the America Invents Act. Section 37 of the America Invents Act clarifies the filing timeline for patent term extension applications under the Hatch-Waxman Act. This timeline clarification confirms the interpretation of the Hatch-Waxman Act adopted by the federal district court's August 3, 2010 decision in our suit against the PTO, the FDA and HHS, which ordered the PTO to consider our patent term extension application timely filed. In its appeal, APP is challenging the applicability of the America Invents Act to our matter and the constitutionality of the America Invents Act. We have filed briefs with the Federal Circuit responding to these challenges by APP. In addition, on October 25, 2011, the DOJ filed a brief with the Federal Circuit in opposition to APP's challenges of the applicability of the America Invents Act to our matter and to the constitutionality of the America Invents Act. Oral argument before the Federal Circuit on APP's appeal is scheduled for November 15, 2011. If (1) the pre-America Invents Act interpretation of the Hatch-Waxman Act set forth in the August 3, 2010 court order requiring the PTO to consider our application to extend the term of the '404 patent timely filed is successfully challenged, either by APP in its pending appeal or by APP or a third party in a separate challenge and (2) Section 37 of the America Invents Act is found to be unconstitutional or not to apply to the '404 patent, Angiomax could be subject to generic competition in the United States earlier than we anticipate. 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.

In addition, in October 2011, a legislative proposal was filed in the United States Senate to deny the PTO funding to implement Section 37 of the America Invents Act. This proposal was not brought up for a vote by the Senate, but could be brought up in the future. It is difficult to predict whether this proposal or other legislation amending or otherwise preventing the application of Section 37 of the America Invents Act might be proposed and enacted, or, if so enacted, the legal effect of such legislation.

In the second half of 2009, the PTO issued to us U.S. Patent No. 7,582,727, or the '727 patent, and U.S. Patent No. 7,598,343, or 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 Pharmaceuticals USA, Inc. and its affiliates, which we refer collectively as 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. 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 June 30, 2019.

Our litigation with the PTO, the FDA and HHS, APP's efforts to appeal the August 3, 2010 decision and the patent infringement suits are described in more detail in Part II, Item 1 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 other than MDCO-2010. 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.

We have entered into an agreement with Biogen Idec, one of our licensors of Angiomax, that suspends the statute of limitations relating to any claims, including claims for damages and/or license termination, that Biogen Idec may bring relating to the PTO's initial denial of the application under the Hatch-Waxman Act for an extension of the term of the '404 patent on the grounds that it was filed late. We are also in discussions with Biogen Idec and HRI with respect to the possible resolution of any potential claims among the parties with respect to this matter. We may not reach any agreement with the parties on terms acceptable to us or at all.

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 in protection 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 other than MDCO-2010 for which we own the patents and 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 has been extended under the Hatch-Waxman Act following our litigation against the PTO, the FDA and HHS. Following the expiration of the government's appeal period in the litigation, the FDA determined the applicable regulatory review period for Angiomax. Based on the FDA's determination, we believe that the term of the '404 patent

should be extended until December 15, 2014. However, to date the PTO has not yet communicated a final determination concerning the length of any patent term extension for the '404 patent. At this time, we do not know when the PTO will make or communicate such a determination. On July 28, 2011, the PTO granted us a one-year interim extension of the '404 patent until August 13, 2012. 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. If the patent term of the '404 is extended to December 15, 2014, we currently believe that this pediatric exclusivity would extend until June 15, 2015.

If (1) the pre-America Invents Act interpretation of the Hatch-Waxman Act set forth in the August 3, 2010 court order requiring the PTO to consider our application to extend the term of the '404 patent timely filed is successfully challenged, either by APP in its pending appeal or by APP or a third party in a separate challenge and (2) Section 37 of the America Invents Act is found to be unconstitutional or not to apply to the '404 patent, Angiomax could be subject to generic competition in the United States earlier than we anticipate. In such event, a court or the FDA could determine that the '404 patent expired in March 2010. In such case, the pediatric exclusivity period for Angiomax would have expired in September 2010. It is also possible that a court or the FDA could determine that the '404 patent expired on a later date, in which case the pediatric exclusivity for Angiomax would run from that later date. In Europe, the principal patent covering Angiox expires in 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 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. We remain in infringement litigation involving the '727 patent and '343 patent with the other ANDA filers.

Our litigation with the PTO, the FDA and HHS, APP's efforts to appeal the August 3, 2010 decision in that litigation, our patent infringement suits relating to the '727 patent and '343 patent and the Teva settlement are described in more detail in Part I, Item 2 under the caption Overview - Angiomax Patent Litigation and Part I, Item 2 of this quarterly report.

Cleviprex. The principal U.S. patent for Cleviprex is U.S. Patent No. 5,856,346, or the '346 patent, which is set to expire in January 2016. Following receipt of marketing approval from the FDA, we submitted an application under the Hatch-Waxman Act to extend the term of the '346 patent. This application is currently pending. 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. 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 also filed and are currently prosecuting a number of patent applications related to cangrelor.

Oritavancin. The principal patent for oritavancin is set to expire in November 2015 in both the United States and Europe if no patent term extension is obtained. We have also filed and are prosecuting a number of patent applications relating to oritavancin and its uses.

MDCO-210. The principal patent application for MDCO-210, if issued, would expire in October 2027 in both the United States and Europe.

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 MDCO-216's use and production 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 if MDCO-216 is approved.

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

Ready-to-Use Argatroban. Eagle, the licensor of ready-to-use Argatroban, is prosecuting a patent application in the United States that, if issued, would expire in September 2027.

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 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 Angiomax and Cleviprex, underlying hospital demand for Angiomax and Cleviprex, 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.

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, 2008 to November 7, 2011, the last reported sale price of our common stock ranged from a high of \$27.68 per share to a low of \$6.47 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 at least June 2015, which could be adversely affected as a result of an adverse court decision or adverse legislation relating to the '404 patent;

our ability to maintain market exclusivity for Angiomax in the United States through June 30, 2019, the date on which we agreed Teva may sell a generic version of Angiomax, through the enforcement of our U.S. patents covering Angiomax;

our ability to maintain our market exclusivity for Angiomax in the United States, which would be adversely affected as a result of an adverse court decision or adverse legislation relating to the '404 patent or our inability to enforcement of our other U.S. patents covering Angiomax;

significant new litigation;

58

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;

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.

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, 2011

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

EXHIBIT INDEX

Exhibit Number	Description
10.1*	Manufacturing Services Agreement, dated March 30, 2011, between registrant and Patheon International A.G.
10.2*	Settlement Agreement, dated September 30, 2011, between registrant and Teva Pharmaceuticals USA, Inc.
10.3*	License Agreement, dated September 30, 2011, between registrant and Teva Pharmaceuticals USA, Inc.
10.4*	Supply Agreement, dated September 30, 2011, between registrant and Plantex USA Inc.
10.5*	First Amendment to the Second Amended and Restated Distribution Agreement, dated July 1, 2011, between registrant and Integrated Commercial Solutions, Inc.
10.6*	Second Amendment to the Second Amended and Restated Distribution Agreement, dated July 1, 2011, between registrant and Integrated Commercial Solutions, Inc.
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, 2011, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Balance Sheet, (ii) the Consolidated Statement of Operations, (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.