

MEDICINES CO /DE
Form 10-Q
August 02, 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: June 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 July 29, 2011, there were 54,012,340 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>13</u>
<u>Item 3 - Quantitative and Qualitative Disclosures about Market Risk</u>	<u>30</u>
<u>Item 4 - Controls and Procedures</u>	<u>30</u>
Part II. Other Information	<u>32</u>
<u>Item 1 - Legal Proceedings</u>	<u>32</u>
<u>Item 1A - Risk Factors</u>	<u>34</u>
<u>Item 5 - Other Information</u>	<u>50</u>
<u>Item 6 - Exhibits</u>	<u>51</u>
<u>Signatures</u>	<u>52</u>
<u>Exhibit Index</u>	<u>53</u>
EX-10.1	
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)

	June 30, 2011 (unaudited)	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 195,608	\$ 126,364
Available for sale securities	88,021	120,280
Accrued interest receivable	895	1,279
Accounts receivable, net of allowances of approximately \$16.1 million and \$15.5 million at June 30, 2011 and December 31, 2010, respectively	67,008	46,551
Inventory	29,161	25,343
Prepaid expenses and other current assets	8,908	4,804
Total current assets	389,601	324,621
Fixed assets, net	19,298	20,662
Intangible assets, net	81,740	82,925
Goodwill	14,671	14,671
Restricted cash	5,783	5,778
Deferred tax assets, net	27,286	25,197
Other assets	296	270
Total assets	\$538,675	\$474,124
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 17,269	\$ 8,594
Accrued expenses	86,156	76,242
Deferred revenue	416	534
Total current liabilities	103,841	85,370
Contingent purchase price	27,416	25,387
Other liabilities	5,854	5,769
Total liabilities	137,111	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; 54,003,475 and 53,464,145 issued and outstanding at June 30, 2011 and December 31, 2010, respectively	54	53
Additional paid-in capital	605,061	596,667
Accumulated deficit	(203,861)	(239,542)
Accumulated other comprehensive income	310	420
Total stockholders' equity	401,564	357,598
Total liabilities and stockholders' equity	\$538,675	\$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 June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Net revenue	\$ 119,591	\$ 110,135	\$ 231,728	\$ 212,223
Operating expenses:				
Cost of revenue	37,830	33,568	73,400	62,337
Research and development	26,536	20,575	50,328	37,452
Selling, general and administrative	41,420	39,409	79,348	85,530
Total operating expenses	105,786	93,552	203,076	185,319
Income from operations	13,805	16,583	28,652	26,904
Legal settlement	—	—	17,984	—
Other income (expense)	61	(117)	872	(428)
Income before income taxes	13,866	16,466	47,508	26,476
Provision for income taxes	(2,426)	(1,040)	(11,827)	(1,618)
Net income	\$ 11,440	\$ 15,426	\$ 35,681	\$ 24,858
Basic earnings per common share	\$ 0.21	\$ 0.29	\$ 0.67	\$ 0.47
Diluted earnings per common share	\$ 0.21	\$ 0.29	\$ 0.66	\$ 0.47
Weighted average number of common shares outstanding:				
Basic	53,441	52,819	53,343	52,658
Diluted	54,314	52,924	54,223	52,823

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2011	2010
Cash flows from operating activities:		
Net income	\$35,681	\$24,858
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	2,991	3,725
Amortization of net premiums and discounts on available for sale securities	1,503	1,596
Unrealized foreign currency transaction losses (gain), net	292	(785)
Non-cash stock compensation expense	5,474	5,080
Loss on disposal of fixed assets	—	6
Deferred tax provision	(2,089)	857
Adjustment to contingent purchase price	2,029	1,478
Changes in operating assets and liabilities:		
Accrued interest receivable	384	(335)
Accounts receivable	(19,986)	8,741
Inventory	(3,569)	(2,629)
Prepaid expenses and other current assets	(3,888)	3,654
Accounts payable	8,529	(427)
Accrued expenses	9,024	(4,698)
Deferred revenue	(171)	(577)
Other liabilities	86	78
Net cash provided by operating activities	36,290	40,622
Cash flows from investing activities:		
Purchases of available for sale securities	(33,835)	(65,855)
Proceeds from maturities and sales of available for sale securities	64,611	51,100
Purchases of fixed assets	(359)	(119)
Adjustment to goodwill	—	263
Increase in restricted cash	(6)	—
Net cash provided by (used in) investing activities	30,411	(14,611)
Cash flows from financing activities:		
Proceeds from issuances of common stock, net	2,920	2,510
Net cash provided by financing activities	2,920	2,510
Effect of exchange rate changes on cash	(377)	950
Increase in cash and cash equivalents	69,244	29,471
Cash and cash equivalents at beginning of period	126,364	72,225
Cash and cash equivalents at end of period	\$195,608	\$101,696
Supplemental disclosure of cash flow information:		
Taxes paid	\$6,763	\$200

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 two marketed products, Angiomax® (bivalirudin) and Cleviprex® (clevidipine butyrate) injectable emulsion, and a pipeline of acute and intensive care hospital products in development, including three late-stage development product candidates, cangrelor, oritavancin and a novel intravenous formulation of clopidogrel bisulfate that the Company licensed from Ligand Pharmaceuticals Incorporated in June 2011, and two early stage development product candidates, MDCO-2010 (formerly known as CU2010) and MDCO-216 (formerly known as ApoA-I Milano). In addition, the Company has marketing rights in the United States and Canada to a ready-to-use formulation of Argatroban, which the U.S. Food and Drug Administration (FDA) approved on June 29, 2011 for prophylaxis or treatment of thrombosis in adult patients with heparin-induced thrombocytopenia (HIT) and for use as an anticoagulant in adult patients with or at risk for HIT undergoing percutaneous coronary intervention (PCI). The Company expects to launch the ready-to-use formulation of Argatroban in the second half of 2011. 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 intercompany balances and transactions have been eliminated in consolidation. The Company has no unconsolidated subsidiaries or investments accounted for under the equity method.

The results of operations for the three months and six months ended June 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 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, the Company accrues the minimum of the range. In the cases where the Company believes that a reasonable 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 IFRSs" (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.

3. Stock-Based Compensation

The Company recorded approximately \$3.2 million and \$5.5 million of stock-based compensation expense for the three and six months ended June 30, 2011, respectively. The Company recorded approximately \$2.3 million and \$5.1 million of stock-based compensation expense for the three and six months ended June 30, 2010, respectively. As of June 30, 2011, there was approximately \$15.8 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 1.26 years.

During the six months ended June 30, 2011, the Company issued a total of 539,330 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 six months ended June 30, 2010, the Company issued a total of 594,743 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 six months ended June 30, 2011 and the exercise of stock options and purchases through the 2000 ESPP during the six months ended June 30, 2010 was approximately \$2.9 million and \$2.5 million, respectively, and is included within the financing activities section of the consolidated statements of cash flows.

At June 30, 2011, there were 5,142,350 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

5

The following table sets forth the computation of basic and diluted earnings per share for the three and six months ended June 30, 2011 and 2010:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
	(in thousands, except per share amounts)			
Basic and diluted Net income	\$ 11,440	\$ 15,426	\$ 35,681	\$ 24,858
Weighted average common shares outstanding, basic	53,441	52,819	53,343	52,658
Plus: net effect of dilutive stock options and restricted common shares	873	105	880	165
Weighted average common shares outstanding, diluted	54,314	52,924	54,223	52,823
Earnings per share, basic	\$0.21	\$0.29	\$0.67	\$0.47
Earnings per share, diluted	\$0.21	\$0.29	\$0.66	\$0.47

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 June 30, 2011 and 2010, options to purchase 7,078,216 shares and 9,046,877 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 six months ended June 30, 2011 and 2010, options to purchase 7,218,343 shares and 9,451,165 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 June 30, 2011 and 2010, 47,312 and 18,750 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 six months ended June 30, 2011 and 2010, 124,946 and 9,735 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 six months ended June 30, 2011 and 2010 is detailed below.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
	(in thousands)			
Net income	\$ 11,440	\$ 15,426	\$ 35,681	\$ 24,858
Unrealized gain (loss) on available for sale securities	—	(12)	20	(19)
Foreign currency translation adjustment	273	(10)	(130)	47

Comprehensive income	\$ 11,713	\$ 15,404	\$ 35,571	\$ 24,886
----------------------	-----------	-----------	-----------	-----------

6. Income Taxes

For the three months ended June 30, 2011 and 2010, the Company recorded a \$2.4 million and \$1.0 million provision for income taxes, respectively, based upon its estimated tax liability for the year. The Company's effective tax rate for the three months ended June 30, 2011 and 2010 was approximately 17.5% and 6.3%, respectively. The Company's effective income tax rate of 17.5% for the three months ended June 30, 2011 reflects the effect of a one-time \$2.5 million income tax benefit resulting from a prospective change in the New Jersey income tax law enacted in the second quarter of 2011. For the six months ended June 30, 2011 and 2010, the Company recorded an \$11.8 million and \$1.6 million provision for income taxes, respectively, based upon its estimated tax liability for the year. The Company's effective tax rate for the six months ended June 30, 2011 and 2010 was

approximately 24.9% and 6.1%, respectively. In addition to reflecting the New Jersey law change referred to above, the Company's effective income tax rate of 24.9% for the six months ended June 30, 2011 also reflects the treatment of the entire settlement from the law firm Wilmer Cutler Pickering Hale and Dorr LLP (WilmerHale) (see note 12) as a discrete event in this period. The provision for income taxes is based on federal, state and foreign income taxes.

In the fourth quarter of 2010, the Company reduced its valuation allowance against its deferred tax assets by \$45.2 million and recorded a corresponding tax benefit. 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. If the Company further reduces the valuation allowance on deferred tax assets in future periods, the Company would recognize additional tax benefits.

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 \$187.7 million and \$114.1 million at June 30, 2011 and December 31, 2010, respectively. Cash and cash equivalents at June 30, 2011 and December 31, 2010 also included investments of \$7.9 million and \$12.2 million, respectively, in money market funds and commercial paper with original maturities of less than three months.

At June 30, 2011 and December 31, 2010, the Company held available for sale securities with a fair value totaling \$88.0 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 June 30, 2011, all of the \$88.0 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 June 30, 2011				As of December 31, 2010			
	Cost	Fair Value	Carrying Value	Unrealized Gain	Cost	Fair Value	Carrying Value	Unrealized Gain
	(in thousands)							
U.S. government agency notes	\$21,539	\$21,550	\$21,550	\$11	\$55,222	\$55,222	\$55,222	\$—
U.S. treasury notes	3,086	3,089	3,089	3	—	—	—	—
Corporate debt securities	63,373	63,382	63,382	9	65,055	65,058	65,058	3
Total	\$87,998	\$88,021	\$88,021	\$23	\$120,277	\$120,280	\$120,280	\$3

Restricted Cash

The Company had restricted cash of \$5.8 million at both June 30, 2011 and December 31, 2010, 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 \$5.5 million at both June 30, 2011 and December 31, 2010 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 Therapeutics Corporation (Targanta) in 2009, the Company had at both June 30, 2011 and December 31, 2010 restricted cash of \$0.3 million in the form of a guaranteed investment certificate collateralizing an available credit facility.

8. Fair Value Measurements

7

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 June 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 June 30, 2011
Assets:				
Money market	\$7,884	\$—	\$—	\$7,884
U.S. treasury notes	3,089	—	—	3,089
U.S. government agency notes	—	21,550	—	21,550
Corporate debt securities	—	63,382	—	63,382
Total assets at fair value	\$10,973	\$84,932	\$—	\$95,905
Liabilities:				
Contingent purchase price	\$—	\$—	\$27,416	\$27,416
Total liabilities at fair value	\$—	\$—	\$27,416	\$27,416

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

Balance at December 31, 2010	Level 3 (in thousands) \$25,387
------------------------------	---------------------------------------

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

Fair value adjustment to contingent purchase price included in net income	2,029
Balance at June 30, 2011	\$27,416

For the six months ended June 30, 2011, the changes in the fair value of the contingent purchased price obligations resulted from an adjustment to the discount rates used in the probability weighted discounted financial model. No changes in valuation

8

techniques or inputs occurred during the six months ended June 30, 2011. No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the six months ended June 30, 2011.

9. Inventory

The Company obtains all of its Angiomax bulk drug substance from Lonza Braine, S.A. (Lonza Braine). Under the terms of the Company's agreement with Lonza Braine, the Company provides forecasts of its annual needs for Angiomax bulk substance 18 months in advance. The Company also has a separate agreement with Ben Venue Laboratories, Inc. and Patheon Italia S.p.A for the fill-finish of Angiomax drug product. As of June 30, 2011, the Company had inventory-related purchase commitments totaling \$15.3 million during 2011, \$30.2 million during 2012 and \$15.1 million during 2013 for Angiomax bulk drug substance.

The major classes of inventory were as follows:

Inventory	June 30, 2011	December 31, 2010
	(in thousands)	
Raw materials	\$ 12,860	\$ 9,801
Work-in-progress	9,572	7,183
Finished goods	6,729	8,359
Total	\$ 29,161	\$ 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 June 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	\$ (2,289)	\$ 5,168	\$ 7,457	\$ (1,715)	\$ 5,742
Distribution agreement ⁽¹⁾	8 years	4,448	(1,365)	3,083	4,448	(1,023)	3,425
Trademarks ⁽¹⁾	8 years	3,024	(928)	2,096	3,024	(695)	2,329
Cleviprex milestones ⁽²⁾	13 years	2,000	(107)	1,893	2,000	(71)	1,929
Total	9 years	\$ 16,929	\$ (4,689)	\$ 12,240	\$ 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 Cleviprex approval over the remaining life of the patent.

The Company expects amortization expense related to these intangible assets to be \$1.2 million for the remainder of 2011. The Company expects annual amortization expense related to these intangible assets to be \$2.4 million, \$3.0 million, \$3.6 million, \$0.8 million and \$0.2 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 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 June 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 six months ended June 30, 2011 and for the year ended December 31, 2010 are as follows:

	June 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

During the six months ended June 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 workforce reductions announced and completed in the first quarter of 2010. The 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 workforce reductions reduced office based personnel by 30 and field based personnel by 42, primarily due to the charges for employee severance and other employee-related termination costs being slightly lower than originally estimated. The Company did not record any adjustment to selling, general and administrative costs for the three months ended June 30, 2011.

For the six months ended June 30, 2010, the Company recorded charges of \$7.1 million associated with the workforce reductions announced in 2010. 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 did not record any adjustment to selling, general and administrative costs for the three months ended June 30, 2010.

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

Balance as of January 1,	Expenses (Income),	Cash	Noncash	Balance as of June 30,
--------------------------	--------------------	------	---------	------------------------

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

	2011	Net			2011
	(in thousands)				
Employee severance and other personnel benefits:					
Workforce reductions	\$134	\$(119)) \$(15)) —	\$—
Leases and equipment write-offs	10	—	(10)) —	—
Total	\$144	\$(119)) \$(25)) \$—	\$—

12. Legal Settlement

10

During the six months ended June 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 June 30, 2011.

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 June 30,						Six Months Ended June 30,					
	2011		2010		2011		2011		2010			
	(in thousands)						(in thousands)					
Net revenue:												
United States	\$ 112,298	93.9	%	\$ 104,375	94.8	%	\$ 217,288	93.8	%	\$ 200,831	94.6	%
Europe	6,494	5.4	%	4,727	4.3	%	12,369	5.3	%	9,595	4.5	%
Rest of world	799	0.7	%	1,033	0.9	%	2,071	0.9	%	1,797	0.9	%
Total net revenue	\$ 119,591			\$ 110,135			\$ 231,728			\$ 212,223		

	June 30,			December 31,		
	2011			2010		
	(in thousands)					
Long-lived assets:						
United States	\$ 114,675	98.9	%	\$ 117,095	98.8	%
Europe	1,230	1.1	%	1,213	1.0	%
Rest of world	100	0.1	%	220	0.2	%
Total long-lived assets	\$ 116,005			\$ 118,528		

14. Relocation of Principal Offices

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 June 30, 2011, the Company has accrued approximately \$0.7 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 and the amount of any potential liability can be reasonably estimated so no loss contingencies were recorded related to these litigation matters. 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.

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 two marketed products, Angiomax[®](bivalirudin) and Cleviprex[®] (clevidipine butyrate) injectable emulsion, and a pipeline of acute and intensive care hospital products in development, including three late-stage development product candidates, cangrelor, oritavancin and a novel intravenous formulation of clopidogrel bisulfate that we licensed from Ligand Pharmaceuticals Incorporated, or Ligand, in June 2011, and two early stage development product candidates, MDCO-2010 (formerly known as CU2010) and MDCO-216 (formerly known as ApoA-I Milano). In addition, we have marketing rights in the United States and Canada to a ready-to-use formulation of Argatroban, which the U.S. Food and Drug Administration, or the FDA, approved on June 29, 2011 for prophylaxis or treatment of thrombosis in adult patients with heparin-induced thrombocytopenia, or HIT, and for use as an anticoagulant in adult patients with or at risk for HIT undergoing percutaneous coronary intervention, or PCI. We expect to launch the ready-to-use formulation of Argatroban in the second half of 2011. 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 address or 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	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 PCI, including patients with or at risk of heparin induced thrombocytopenia and thrombosis syndrome, or HIT/HITTS Europe - for use as an anticoagulant in patients undergoing PCI, adult patients with acute coronary syndrome, or ACS, and for the treatment of patients with ST-segment elevation myocardial infarction, or STEMI, undergoing primary PCI
Cleviprex	Marketed in the United States; 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
Cangrelor	Phase 3	Antiplatelet agent	Prevention of platelet activation and aggregation Treatment of serious gram-positive bacterial infections, including acute bacterial skin and skin structure infections, or ABSSSI
Oritavancin	Phase 3	Antibiotic	Reduction of blood loss during surgery
MDCO-2010	Phase 2	Serine protease inhibitor	Reversal of atherosclerotic plaque development and reduction of the risk of coronary events in patients with ACS
MDCO-216	Phase 1	Naturally occurring variant of a protein found in high-density lipoprotein, or HDL	
Ready-to-Use Argatroban	Approved in the United States	Direct thrombin inhibitor	Approved for prophylaxis or treatment of thrombosis in adult patients with HIT

IV Clopidogrel	Phase 3	Platelet inhibitor	and for use as an anticoagulant in adult patients with or at risk for HIT undergoing PCI. Platelet inhibition in patients suffering from acute coronary syndrome or patients recently experiencing myocardial infarction, stroke, or peripheral arterial disease.
----------------	---------	--------------------	---

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 Angiox, we will be positioned to commercialize our pipeline of acute and intensive care product candidates outside the United States, if and when they are approved.

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.

Except for 2004, 2006 and 2010, we have incurred net losses on an annual basis since our inception. As of June 30, 2011, we had an accumulated deficit of approximately \$203.9 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 and Legal Settlement

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 application of the PTO's patent term extension formula would result in the extension of the patent term of the '404 patent to December 15, 2014. However, the PTO has not yet determined the length of any patent term extension. On July 28, 2011, the PTO granted us a one-year interim extension of the '404 patent until August 13, 2012. We expect the PTO to issue a final certificate of extension in the second half of 2011. As a result of our study of Angiomax in the pediatric setting, we are entitled to a six-month period of exclusivity following expiration of the '404 patent.

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. This appeal is pending.

If 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, if we are otherwise unsuccessful in further extending the term of the '404 patent, or if we are unable to maintain our market exclusivity for Angiomax in the United States through enforcement of our other U.S. patents covering Angiomax, Angiomax could be subject to generic competition in the United States earlier than we anticipate. If the federal district court's decision is overturned and the '404 patent is found not to have been validly extended, 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 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.

In the second half of 2009, the PTO issued to us U.S. Patent No. 7,528,727, 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.

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.

Cleviprex Resupply and Re-launch

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 and expect to re-launch fully the product in the second half of 2011 by 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. In July 2011, the FDA approved our supplemental New Drug Application, or sNDA, for an improved formulation of Cleviprex which provides a longer infusion time. We expect to market and sell this improved formulation during the re-launch of Cleviprex.

Distribution and Sales

We market and sell Angiomax and Cleviprex, and plan to market and sell ready-to-use Argatroban, in the United States with a sales force that, as of June 30, 2011, consisted of 110 representatives, who we refer to as engagement partners and engagement managers, experienced in selling to hospital customers. We distribute Angiomax and Cleviprex, and plan to distribute ready-to-use Argatroban, in the United States through a sole source distribution model. Under this model, we currently sell Angiomax and Cleviprex to our sole source distributor, Integrated Commercialization Solutions, Inc., or ICS, which then sells Angiomax and Cleviprex 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 and Cleviprex in the United States. Under the terms of this fee-for-service agreement, ICS places orders with us for sufficient quantities of Angiomax and Cleviprex 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 and Cleviprex, 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 June 30, 2011, consisted of 40 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. 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 preparation for 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 business infrastructure outside the United States, including forming subsidiaries, obtaining licenses and authorizations necessary to distribute Angiomax, hiring personnel and entering into third-party arrangements to provide services, such as importation, packaging, quality control and distribution. We currently have operations in Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Italy, the Netherlands, New Zealand, Norway, Poland, Spain, Sweden, Switzerland and the United Kingdom

and are developing our business infrastructure in Brazil, China, Eastern Europe, India, 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

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 six months ended June 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 June 30, 2011.

Licensing Agreement with Ligand Pharmaceuticals Incorporated

In June 2011, we entered into a licensing agreement with Ligand under which we acquired exclusive, worldwide license rights to a novel intravenous formulation of clopidogrel bisulfate. 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 up to double digit royalties on annual worldwide net sales. Ligand has agreed to supply us with clinical materials of IV clopidogrel for the development program. If the intravenous formulation is approved for commercialization, Ligand will be the exclusive supplier of the product.

U.S. Health Care Reform

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

Results of Operations

Net Revenue:

Net revenue increased 9% to \$119.6 million for the three months ended June 30, 2011 as compared to \$110.1 million for the three months ended June 30, 2010.

Net revenue increased 9% to \$231.7 million for the six months ended June 30, 2011 as compared to \$212.2 million for the six months ended June 30, 2010.

The following tables reflect the components of net revenue for the three and six months ended June 30, 2011 and 2010:

Net Revenue

17

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

	Three Months Ended June 30,				
	2011	2010	Change \$	Change %	
		(in thousands)			
U.S. sales	\$ 112,298	\$ 104,375	\$ 7,923	7.6	%
International net revenue	7,293	5,760	1,533	26.6	%
Total net revenue	\$ 119,591	\$ 110,135	\$ 9,456	8.6	%

	Six Months Ended June 30,				
	2011	2010	Change \$	Change %	
		(in thousands)			
U.S. sales	\$ 217,288	\$ 200,831	\$ 16,457	8.2	%
International net revenue	14,440	11,392	3,048	26.8	%
Total net revenue	\$ 231,728	\$ 212,223	\$ 19,505	9.2	%

Net revenue during the three months ended June 30, 2011 increased by \$9.5 million compared to the three months ended June 30, 2010 primarily due to increases in sales of Angiomax in the United States and Angiox in Europe. The increase in net revenue was a result of a price increase we implemented in January 2011 in the United States, increased demand by existing hospital customers and the addition of new hospital customers internationally. Net sales in the United States in both the three months ended June 30, 2011 and June 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 \$1.4 million to \$10.2 million in the three months ended June 30, 2011 compared to \$8.8 million in the three months ended June 30, 2010. In addition, in the three months ended June 30, 2011, we recognized a reduction in product net sales of approximately \$0.2 million, a \$0.1 million increase when compared to the three months ended June 30, 2010 for rebates related to the PPACA. U.S. sales also include net sales of Cleviprex of \$0.3 million in the three months ended June 30, 2011 compared to \$0.0 million of revenue for sales of Cleviprex in the three months ended June 30, 2010, as 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 and expect to re-launch the product with a focus on neurocritical care, including intracranial bleeding and acute ischemic stroke 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, in the second half of 2011.

Net revenue during the six months ended June 30, 2011 increased by \$19.5 million compared to the six months ended June 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 six months ended June 30, 2011 and June 30, 2010 reflects the chargebacks related to the 340B Drug Pricing Program under the Public Health Services Act. These chargebacks increased by \$0.9 million to \$19.2 million in the six months ended June 30, 2011 compared to \$18.3 million in the six months ended June 30, 2010. In addition, in the six months ended June 30, 2011, we recognized a reduction in product net sales of approximately \$0.4 million, a \$0.2 million increase when compared to the six months ended June 30, 2010 for rebates related to the PPACA. U.S. sales also include net sales of Cleviprex of \$0.3 million in the six months ended June 30, 2011 compared to \$0.8 million of revenue for sales of Cleviprex in the six months ended June 30, 2010. The \$0.8 million in sales of Cleviprex in the six months ended June 30, 2010 reflects an offset of \$0.7 million due to

returns related to the Cleviprex recall.

International net revenue increased by \$1.5 million during the three months ended June 30, 2011 compared to the three months ended June 30, 2010 primarily as a result of increased demand for Angiox in Italy, the United Kingdom, Russia, Denmark, Belgium and Austria, partially offset by decreased sales of Angiox in Canada and France.

International net revenue increased by \$3.0 million during the six months ended June 30, 2011 compared to the six months ended June 30, 2010 primarily as a result of increased demand for Angiox in Italy, the United Kingdom, Sweden, Canada, Denmark and Belgium, partially offset by decreased sales of Angiox in France, Spain, and South America.

If 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 in a separate challenge, if we are otherwise unsuccessful in

further extending the term of the '404 patent, or if we are unable to maintain our market exclusivity for Angiomax in the United States through enforcement of 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 June 30, 2011 was \$37.8 million, or 32% of net revenue, compared to \$33.6 million, or 30% of net revenue, in the three months ended June 30, 2010.

Cost of revenue in the six months ended June 30, 2011 was \$73.4 million, or 32% of net revenue, compared to \$62.3 million, or 29% of net revenue, in the six months ended June 30, 2010.

Cost of revenue during both periods consisted of expenses in connection with the manufacture of Angiomax and Cleviprex 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 and Cleviprex, including distribution, storage, and handling costs.

Cost of Revenue

	Three Months Ended June 30,				Six Months Ended June 30,				% of Total Cost
	2011	% of Total Cost	2010	% of Total Cost	2011	% of Total Cost	2010		
	(in thousands)		(in thousands)		(in thousands)		(in thousands)		(in thousands)
Manufacturing	\$7,931	21 %	\$8,092	24 %	\$15,676	21 %	\$14,368	23 %	
Royalty	25,740	68 %	21,963	65 %	51,238	70 %	41,876	67 %	
Logistics	4,159	11 %	3,513	11 %	6,486	9 %	6,093	10 %	
Total cost of revenue	\$37,830	100 %	\$33,568	100 %	\$73,400	100 %	\$62,337	100 %	

Cost of revenue increased by \$4.3 million during the three months ended June 30, 2011 compared to the three months ended June 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.

Cost of revenue increased by \$11.1 million during the six months ended June 30, 2011 compared to the six months ended June 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 six months ended June 30, 2010 related to the reversal in six months ended June 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 29% to \$26.5 million for the three months ended June 30, 2011, compared to \$20.6 million for the three months ended June 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 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 and the licensing fee paid in connection with obtaining the licensing rights to IV clopidogrel. These increases were offset by a decrease in manufacturing development expenses related to product lifecycle management activities of Angiomax and by charges recorded in the three months ended June 30, 2010, associated with a payment made to AstraZeneca in connection with the June 2010 amendment to our agreement with AstraZeneca.

Research and development expenses increased by 34% to \$50.3 million for the six months ended June 30, 2011, compared to

\$37.5 million for the six months ended June 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 and the licensing fee paid in connection with obtaining the licensing rights to IV clopidogrel. These increases were offset by a decrease in manufacturing development expenses related to product lifecycle management activities of Angiomax, charges recorded in the six months ended June 30, 2010, associated with a payment made to AstraZeneca in connection with the June 2010 amendment to our agreement with AstraZeneca and by charges recorded in the six months ended June 30, 2010, of approximately \$1.7 million associated with our workforce reductions in the first quarter of 2010.

We expect to continue to invest in the development of Angiomax, Cleviprex, cangrelor, oritavancin, MDCO-2010, MDCO-216 and IV clopidogrel during the second half 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, product lifecycle management activities and the development of IV clopidogrel. 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 six months ended June 30, 2011 and 2010. Spending for past periods is not necessarily indicative of spending in future periods.

Research and Development Spending

	Three Months Ended June 30,					
	2011	% of	2010	% of		
	(In	Total R&D	(In	Total R&D		
	thousands)		thousands)			
Angiomax						
Clinical trials	\$1,944	8	% \$1,823	9		%
Manufacturing development	51	—	% 2,718	13		%
Administrative and headcount costs	604	2	% 521	3		%
Total Angiomax	2,599	10	% 5,062	25		%
Cleviprex						
Clinical trials	370	1	% 473	2		%
Manufacturing development	112	1	% 472	2		%
Administrative and headcount costs	325	1	% 560	3		%
Total Cleviprex	807	3	% 1,505	7		%
Cangrelor						
Clinical trials	6,500	25	% 1,535	7		%
Manufacturing development	287	1	% 662	3		%
Administrative and headcount costs	1,588	6	% 855	4		%
Milestone	—	—	% 3,000	15		%
Total Cangrelor	8,375	32	% 6,052	29		%
Oritavancin						
Clinical trials	5,192	19	% 458	2		%
Manufacturing development	718	3	% 848	4		%
Administrative and headcount costs	1,347	5	% 1,434	7		%
Total Oritavancin	7,257	27	% 2,740	13		%
MDCO-2010						
Clinical trials	178	1	% 413	2		%
Manufacturing development	72	—	% 265	1		%
Administrative and headcount costs	946	4	% 1,182	6		%
Government subsidy	(111)) (1)% (265) (1)%	
Total MDCO-2010	1,085	4	% 1,595	8		%
MDCO-216						
Clinical trials	181	1	% —	—		%
Manufacturing development	552	2	% —	—		%
Administrative and headcount costs	125	—	% 587	3		%
Total MDCO-216	858	3	% 587	3		%
Ready-to-Use Argatroban						
Manufacturing development	—	—	% 477	2		%
Administrative and headcount costs	514	2	% —	—		%
Total Ready-to-Use Argatroban	514	2	% 477	2		%
IV Clopidogrel						
Acquisition license fee	1,750	7	% —	—		%
Total IV Clopidogrel	1,750	7	% —	—		%
Other	3,291	12	% 2,557	13		%

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

Total	\$26,536	100	%	\$20,575	100	%
-------	----------	-----	---	----------	-----	---

21

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

	Six Months Ended June 30,					
	2011	% of		2010	% of	
	(In	Total R&D		(In	Total R&D	
	thousands)			thousands)		
Angiomax						
Clinical trials	\$3,647	7	%	\$3,299	9	%
Manufacturing development	172	—	%	3,974	10	%
Administrative and headcount costs	1,426	3	%	1,407	4	%
Total Angiomax	5,245	10	%	8,680	23	%
Cleviprex						
Clinical trials	673	1	%	1,087	3	%
Manufacturing development	191	1	%	721	2	%
Administrative and headcount costs	645	1	%	1,089	3	%
Total Cleviprex	1,509	3	%	2,897	8	%
Cangrelor						
Clinical trials	11,026	22	%	3,353	9	%
Manufacturing development	548	1	%	961	3	%
Administrative and headcount costs	3,275	7	%	2,012	5	%
Milestone	—	—	%	3,000	8	%
Total Cangrelor	14,849	30	%	9,326	25	%
Oritavancin						
Clinical trials	11,640	23	%	1,065	3	%
Manufacturing development	900	2	%	2,450	6	%
Administrative and headcount costs	2,707	5	%	3,694	10	%
Total Oritavancin	15,247	30	%	7,209	19	%
MDCO-2010						
Clinical trials	458	1	%	655	2	%
Manufacturing development	102	—	%	370	1	%
Administrative and headcount costs	1,786	4	%	2,075	5	%
Government subsidy	(222)	(1)	%)	(508)	(1)	%)
Total MDCO-2010	2,124	4	%	2,592	7	%
MDCO-216						
Clinical trials	486	1	%	—	—	%
Manufacturing development	1,413	3	%	—	—	%
Administrative and headcount costs	482	1	%	940	2	%
Total MDCO-216	2,381	5	%	940	2	%
Ready-to-Use Argatroban						
Manufacturing development	—	—	%	477	1	%
Administrative and headcount costs	691	1	%	169	1	%
Total Ready-to-Use Argatroban	691	1	%	646	2	%
IV Clopidogrel						
Acquisition license fee	1,750	4	%	—	—	%
Total IV Clopidogrel	1,750	4	%	—	—	%
Other	6,532	13	%	5,162	14	%
Total	\$50,328	100	%	\$37,452	100	%

Angiomax

Research and development spending related to Angiomax during the three months ended June 30, 2011 decreased by approximately \$2.5 million compared to the three months ended June 30, 2010, primarily due to a decrease of \$2.7 million in manufacturing development expenses related to product lifecycle management activities.

Research and development spending related to Angiomax during the six months ended June 30, 2011 decreased by approximately \$3.4 million compared to the six months ended June 30, 2010, primarily due to a decrease of \$3.8 million in manufacturing development expenses related to product lifecycle management activities. These decreases were partially offset by an increase of \$0.3 million in clinical trial costs, primarily due to increased expenditures in connection with our Phase 4 EUROMAX clinical trial. We are conducting the EUROMAX trial at sites in ten 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, in up to ten European countries.

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, as well as continued research and development expenses related to our product lifecycle management activities.

Cleviprex

Research and development expenditures for Cleviprex decreased by approximately \$0.7 million during the three months ended June 30, 2011 compared to the three months ended June 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. In the three months ended June 30, 2011, we have restarted the studies conducted by hospitals and third-party researchers that were discontinued in late 2009 as a result of the supply issues and 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 six months ended June 30, 2011 compared to the six months ended June 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.

Cangrelor

Research and development expenditures related to cangrelor increased by approximately \$2.3 million in the three months ended June 30, 2011 compared to the three months ended June 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 offset by charges recorded in the three months ended June 30, 2010, associated with a \$3.0 million payment made to AstraZeneca in connection with the June 2010 amendment to our agreement with AstraZeneca.

Research and development expenditures related to cangrelor increased by approximately \$5.5 million in the six months ended June 30, 2011 compared to the six months ended June 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. These increases were offset by charges recorded in the three months ended June 30, 2010, associated with a 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 approximately 15,000 patients, in this double-blind parallel group randomized study which compares cangrelor to clopidogrel given according to institutional practice.

Oritavancin

23

Research and development expenditures related to oritavancin increased by approximately \$4.5 million in the three months ended June 30, 2011 compared to the three months ended June 30, 2010. The increase primarily reflects increased costs incurred in the three months ended June 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. This increase in expenditures in the first quarter of 2011 was partially offset by slight decreases in manufacturing costs and headcount expenses in 2011.

Research and development expenditures related to oritavancin increased by approximately \$8.0 million in the six months ended June 30, 2011 compared to the six months ended June 30, 2010. The increase primarily reflects increased costs incurred in the six months ended June 30, 2011 related to our SOLO I and SOLO II Phase 3 clinical trials. This increase in expenditures in the first half 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 six months ended June 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.

MDCO-2010

Research and development expenditures related to MDCO-2010 decreased by approximately \$0.5 million in the three months ended June 30, 2011 compared to the three months ended June 30, 2010. Costs incurred during the three months ended June 30, 2011 primarily related to our Phase 2 clinical trial of MDCO-2010, which we commenced in November 2010. Costs incurred during the three months ended June 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, conducted in Switzerland to study the safety, tolerability, pharmacokinetics and pharmacodynamics of MDCO-2010 in patients undergoing elective CABG surgery, 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 three months ended June 30, 2011 and June 30, 2010.

Research and development expenditures related to MDCO-2010 decreased by \$0.5 million in the six months ended June 30, 2011 compared to the six months ended June 30, 2010. Costs incurred during the six months ended June 30, 2011 primarily related to our Phase 2 clinical trial of MDCO-2010, which we commenced in November 2010. Costs incurred during the six months ended June 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 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 six months ended June 30, 2011 and June 30, 2010.

We expect that our research and development expenses relating to MDCO-2010 will decrease in 2011 as compared to 2010, reflecting that 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 ongoing Phase 2 clinical trial of MDCO-2010 and the preparation for our Phase 2 clinical trial of MDCO-2010 in the United States in 2012 for patients undergoing high risk cardiothoracic surgery. We expect to submit an investigational new

drug application, or IND, for MDCO-2010 to the FDA in 2011. Subject to the successful completion of our current Phase 2 trial and the IND becoming effective, we plan to commence a Phase 2 clinical trial of MDCO-2010 in the United States in 2012 in patients undergoing high risk cardiothoracic surgery.

MDCO-216

Research and development expenditures related to MDCO-216 increased by approximately \$0.3 million in the three months ended June 30, 2011 compared to the three months ended June 30, 2010. Costs incurred during the three months ended June 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 June 30, 2010 primarily related to administrative and headcount expenses.

Research and development expenditures related to MDCO-216 increased by approximately \$1.4 million in the six months ended June 30, 2011 compared to the six months ended June 30, 2010. Costs incurred during the six months ended June 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 six months ended June 30, 2010 primarily related to administrative and headcount expenses.

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 second half of 2011 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 were relatively unchanged during the three months ended June 30, 2011 compared to the three months ended June 30, 2010. Costs incurred during the three months ended June 30, 2011 primarily related to administrative and headcount related expenses and cost incurred during the three months ended June 30, 2010 primarily related to manufacturing development expenses.

Research and development expenditures related to ready-to-use Argatroban were relatively unchanged during the six months ended June 30, 2011 compared to the six months ended June 30, 2010. Costs incurred during the six months ended June 30, 2011 and the six months ended June 30, 2010 primarily related to administrative and headcount related expenses. We expect to incur increased research and development expenses relating to ready-to-use Argatroban in 2011 as compared to 2010 in connection with our validation work planned for the second half of 2011 required in connection with the approval by the FDA of ready-to-use Argatroban in June 2011.

IV Clopidogrel

In June 2011, we entered into a licensing agreement with Ligand under which we acquired exclusive, worldwide license rights to a novel intravenous formulation of clopidogrel bisulfate. Under the license agreement, we agreed to spend at least \$2.5 million annually on the development of IV clopidogrel and therefore will be obligated to spend the pro rata amount of approximately \$1.5 million in 2011 on IV clopidogrel.

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 \$0.7 million during the three months ended June 30, 2011 compared to the three months ended June 30, 2010, primarily due to an increase in administrative and headcount expenses.

Spending in this category increased by approximately \$1.4 million during the six months ended June 30, 2011 compared to the six months ended June 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 June 30,				Six Months Ended June 30,			
	2011	2010	Change \$	Change %	2011	2010	Change \$	Change %
	(in thousands)				(in thousands)			
Selling, general and administrative expenses	\$41,420	\$39,409	\$2,011	5.1 %	\$79,348	\$85,530	\$(6,182)	(7.2) %

The increase in selling, general and administrative expenses of \$2.0 million in the three months ended June 30, 2011 as compared to the three months ended June 30, 2010 reflects the impact of approximately \$0.9 million of higher general corporate and administrative spending in the second quarter of 2011, associated with a \$0.2 million increase in selling, marketing and promotional expense primarily from an increase in our efforts to expand global sales and marketing activities in the second quarter of 2011 and a \$0.8 million increase in stock-based compensation expense in the second quarter of 2011 as compared to the second quarter of 2010.

The decrease in selling, general and administrative expenses of \$6.2 million in the six months ended June 30, 2011 as compared to the six months ended June 30, 2010 reflects a \$2.5 million decrease in selling, marketing, and promotional expenses primarily related to Angiomax and \$5.5 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. These decreases were partially offset by increases in intangible amortization costs of \$0.8 million, site costs of \$0.5 million, and stock-based compensation costs of \$0.6 million.

Legal settlement:

	Three Months Ended June 30,				Six Months Ended June 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 six months ended June 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 June 30, 2011.

Other income (expense):

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

	Three Months Ended June 30,				Six Months Ended June 30,			
	2011	2010	Change \$	Change %	2011	2010	Change \$	Change %
	(in thousands)				(in thousands)			
Other income (expense)	\$61	\$(117)	\$178	(152.1)%	\$872	\$(428)	\$1,300	(303.7)%

26

Other income (expense), which is comprised of interest income, gains and losses on foreign currency transactions and impairment of investment, increased by \$0.2 million to \$0.1 million of income for the three months ended June 30, 2011, from \$0.1 million of expense for the three months ended June 30, 2010. This increase was primarily due to higher gains on foreign currency transactions in the three months ended June 30, 2011.

Other income (expense) increased by \$1.3 million to \$0.9 million of income for the six months ended June 30, 2011, from \$0.4 million of expense for the six months ended June 30, 2010. This increase was primarily due to higher gains on foreign currency transactions in the six months ended June 30, 2011 and increased interest due to higher levels of cash to invest.

Provision for Income Tax:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2011	2010	Change \$	Change %	2011	2010	Change \$	Change %
	(in thousands)							
Provision for income tax	\$(2,426)	\$(1,040)	\$(1,386)	133.3 %	\$(11,827)	\$(1,618)	\$(10,209)	631.0 %

We recorded a \$2.4 million and a \$1.0 million provision for income taxes for the three months ended June 30, 2011 and 2010, respectively, based on income before taxes for such periods of \$13.9 million and \$16.5 million. Our effective income tax rates for the three months ended June 30, 2011 and June 30, 2010 were approximately 17.5% and 6.3%, respectively. Our effective income tax rate of 17.5% for the three months ended June 30, 2011 reflects the effect of a one-time \$2.5 million income tax benefit resulting from a prospective change in the New Jersey income tax law enacted in the second quarter of 2011. The effective tax rate for the three months ended June 30, 2010 reflected the utilization of U.S. net operating loss carryforwards against projected taxable income and a liability for alternative minimum tax.

We recorded an \$11.8 million and a \$1.6 million provision for income taxes for the six months ended June 30, 2011 and 2010, respectively, based on income before taxes of \$47.5 million and \$26.5 million. Our effective income tax rates for the six months ended June 30, 2011 and June 30, 2010 were approximately 24.9% and 6.1%, respectively. In addition to reflecting the New Jersey law change referred to above, our effective income tax rate of 24.9% for the six months ended June 30, 2011 also reflects the treatment of the entire WilmerHale settlement as a discrete event in this period. Since a significant portion of the settlement is not deemed taxable, the effective tax rate in the first half of 2011 is lower than what should be anticipated for the remaining half of the year. The effective tax rate 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 effective tax rates include a non-cash tax expense arising from purchase accounting for in-process R&D acquired in the Targanta acquisition. It is possible that our full-year effective tax rate could change because of discrete events, specific transactions or the receipt of new information affecting our current projections.

At June 30, 2011, we maintained a \$104.3 million valuation allowance against \$150.1 million of deferred tax assets compared to a full valuation allowance against all of our deferred tax assets at June 30, 2010. We plan to continue to evaluate the future realizability of our deferred tax assets on a periodic basis in light of changing facts and circumstances. These would include but are not limited to projections of future taxable income, tax legislation, rulings by relevant tax authorities, the progress of ongoing tax audits, the regulatory approval of products currently under

development, the extension of the patent rights relating to Angiomax and the ability to achieve future anticipated revenues. If we reduce the valuation allowance on deferred tax assets in a future period, we would recognize additional income tax benefits.

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 \$283.6 million in cash, cash equivalents and available for sale securities as of June 30, 2011.

Cash Flows

As of June 30, 2011, we had \$195.6 million in cash and cash equivalents, as compared to \$126.4 million as of December 31, 2010. Our primary sources of cash during the six months ended June 30, 2011 included \$36.3 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, \$30.4 million in net cash provided by investing activities and \$2.9 million in net cash provided by financing activities.

Net cash provided by operating activities was \$36.3 million in the six months ended June 30, 2011, compared to net cash provided by operating activities of \$40.6 million in the six months ended June 30, 2010. The cash provided by operating activities in the six months ended June 30, 2011 included net income of \$35.7 million and non-cash items of \$10.2 million consisting primarily of stock-based compensation expense of \$5.5 million, depreciation and amortization of \$3.0 million and adjustment to contingent purchase price of \$2.0 million. Cash provided by operating activities in the six months ended June 30, 2011 also included a decrease of \$9.6 million due to changes in working capital items.

The cash provided by operating activities in the six months ended June 30, 2010 included net income of \$24.9 million and non-cash items of \$12.0 million consisting primarily of stock-based compensation expense of \$5.1 million and depreciation and amortization of \$3.7 million. Cash provided by operating activities in the six months ended June 30, 2010 also included an increase of \$3.8 million due to changes in working capital items.

During the six months ended June 30, 2011, \$30.4 million in net cash was provided by investing activities, which reflected \$64.6 million in proceeds from the maturity and sale of available for sale securities, offset by \$33.8 million used to purchase available for sale securities and \$0.4 million used to purchase fixed assets.

During the six months ended June 30, 2010, \$14.6 million in net cash was used in investing activities, which reflected \$65.9 million used to purchase available for sale securities, offset by \$51.1 million in proceeds from the maturity and sale of available for sale securities.

We received \$2.9 million in the six months ended June 30, 2011 and \$2.5 million in the six months ended June 30, 2010, respectively, 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;
- whether the federal district court's 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;
- the outcome of our efforts to otherwise extend the patent term of the '404 patent to 2014 and our ability to maintain market exclusivity for Angiomax in the United States through 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;
- our ability to complete the re-launch Cleviprex on the time frames we expect and the extent to which the product is commercially successful in the United States;

- the extent to which the ready-to-use formulation of Argatroban is 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 products, 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 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 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 Angiomax, Cleviprex and our 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 due to slower than anticipated sales of Angiomax and our sales of Cleviprex not resuming as soon as we anticipate, 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 June 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.

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 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 June 30, 2011 we held \$283.6 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 June 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 June 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 \$1.1 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 June 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

30

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 June 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 June 30, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Part II. Other Information

Item 1. Legal Proceedings

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

'727 Patent and '343 Patent Litigations

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, in the U.S. District Court for the District of Delaware for infringement of the '727 patent. On October 29, 2009, Teva 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. 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 8, 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 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 '727 patent case above.

The judge in the Eastern District of Pennsylvania has consolidated the Teva '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).

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. 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 8, 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.

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 8, 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 is presiding over the above APP '727 patent case and the Teva '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. APP filed its amended answer and counterclaims on July 25, 2011.

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, 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, 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. 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 has been set before the Magistrate Judge for August 25, 2011. No trial date has been set.

'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 5, 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 and the PTO's patent term extension formula, we believe that the '404 patent term will be extended to December 15, 2014.

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.

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 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 June 30, 2011, we had an accumulated deficit of approximately \$203.9 million. We expect to make substantial expenditures to further develop and commercialize our products, including costs and expenses associated with clinical trials, nonclinical and preclinical studies, regulatory approvals and commercialization. We may need to generate greater revenue in future periods to achieve and maintain profitability in light of our planned expenditures. Our ability to generate this revenue will be adversely impacted, possibly materially, if we are unable to maintain market exclusivity for Angiomax. We may not achieve profitability in future periods or at all, and we may not be able to maintain profitability for any substantial period of time. 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. From the first quarter of 2010 through the first quarter of 2011, when we were not supplying the market with Cleviprex, our only revenues were from the sales of Angiomax. We expect revenues from Angiomax to account for substantially all of our revenues in 2011. The commercial success of Angiomax depends upon:

- whether the federal district court's order's 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;
- the outcome of our efforts to otherwise extend the patent term of the '404 patent to 2014 and our ability to maintain market exclusivity for Angiomax in the United States through 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 impact of competition from competitive products;
- 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 June 30, 2011, our inventory of Angiomax was \$26.0 million and we had inventory-related purchase commitments totaling \$15.3 million for 2011, \$30.2 million for 2012 and \$15.1 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.

Our revenue has been substantially dependent on our sole source distributor, ICS, and international distributors involved in the sale of our products, and such revenue may fluctuate from quarter to quarter based on the buying patterns of ICS and our international distributors

We distribute Angiomax and Cleviprex, and plan to distribute ready-to-use Argatroban, in the United States through a sole source distribution model. Under this model, we currently sell Angiomax and Cleviprex to our sole source distributor, ICS. ICS then sells Angiomax and Cleviprex 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. We anticipate that our revenue from sales of Cleviprex in the United States will be exclusively from sales to ICS. As a result, 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.

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, our business, financial condition or results of operations may be adversely affected

We expect to devote substantial resources to our research and development efforts and to our sales, marketing 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;
- whether the federal district court's 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;
- the outcome of our efforts to otherwise extend the patent term of the '404 patent to 2014 and our ability to maintain market exclusivity for Angiomax in the United States through 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;
- our ability to complete the re-launch of Cleviprex on the time frames we expect and the extent to which the product is commercially successful in the United States;
- the extent to which the ready-to-use formulation of Argatroban is 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 products, 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 and oritavancin 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 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 Angiomax, Cleviprex and our 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 or product candidates 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 product candidates 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.

Risks Related to Commercialization

Angiomax competes with 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 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.

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 the federal district court's 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 in a separate challenge, if we are otherwise unsuccessful in further extending the term of the '404 patent, or if we are unable to maintain our market exclusivity for Angiomax in the United States through enforcement of our other U.S. patents covering Angiomax, Angiomax could become 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.

Cleviprex competes with 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.

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. Hospital formularies may also limit the number of IV-AHT drugs in each drug class. If we fail to secure and maintain formulary inclusion for Cleviprex on favorable terms or are significantly delayed in doing so, we will have difficulty achieving market acceptance of Cleviprex and our business could be materially adversely affected.

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 business strategy is based on us selectively licensing or acquiring and then

developing clinical compound candidates or products approved for marketing. 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, and a number of more established companies, which have acknowledged strategies to license and acquire products, may have competitive advantages, as may emerging companies taking similar or different approaches to product acquisition. Established companies pursuing this strategy also may have a competitive advantage over us due to their size, cash flows and institutional experience.

In addition, our competitors may develop, market or license products or other novel technologies that are more effective, safer 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. We compete, in the case of Angiomax and Cleviprex, and expect to compete, in the cases of ready-to-use Argatroban and 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, our business, financial condition and results of operations may be adversely affected.

If physicians, patients and other key 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 decision-makers accept the results of clinical trials of Angiomax and Cleviprex. For example, following the announcement of the original results of REPLACE-2 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 REPLACE-2, the conduct of the study and the analysis and interpretation of the results from the study. Similarly, physicians, patients and other key decision-makers may not accept the results of the ACUITY and HORIZONS AMI trials. The FDA, in denying our sNDA for an additional 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 further 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, our ability to successfully resume selling 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 and expect to re-launch the product in the second half of 2011 with a focus on neurocritical care, including intracranial bleeding and acute ischemic stroke 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. 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 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 plan to focus 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, operating results and financial condition may be harmed

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. 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, operating results and financial condition may be harmed.

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 position 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. In addition, with our acquisitions of Curacyte Discovery GmbH, or Curacyte Discovery, and Targanta, we are conducting research and development activities in Germany and Canada. These 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:

- our customers' ability to obtain reimbursement for procedures using our products in foreign markets;
- the burden of complying 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;
- 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.

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. We can make no assurance that our employees or other agents will not engage in prohibited conduct 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 might 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.

Our ability to generate product revenue is affected by reimbursement and drug pricing and whether access to our products is reduced or terminated by governmental and other third-party payors

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, 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 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 increasingly are challenging prices charged for medical products and services. 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.

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 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.

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 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 any product liability claims.

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.

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 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 be limited or subject 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 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 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.

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. 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

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, 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; and
unanticipated expenditures.

43

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

We depend on single source suppliers for the production of bulk drug substance for our products and products in development and a limited number of suppliers 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.

We do not manufacture any of our products and do not plan to develop any capacity to manufacture them. We currently obtain all bulk drug substance for our products and products in development from single source suppliers, and rely on a limited number of manufacturers to carry out fill-finish activities for our products and products in development.

We do not currently have alternative sources for production of bulk drug substance. 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.

Use of third-party manufacturers may increase the risk that we will not have appropriate supplies of our products or our product candidates

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates or products 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. 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 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 regulatory authorities, we may need to reformulate the way in which our oritavancin bulk drug substance is created to remove animal source product, which may delay marketing approval of our products and increase our costs

Oritavancin bulk drug substance is manufactured using animal-sourced products, namely 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

As a result of our acquisitions of Curacyte Discovery and Targanta, we now 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 each of the United

States, Canada and Germany 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.

Risks Related to Our Intellectual Property

If the federal district court's order requiring the PTO to consider our application to extend the term of the '404 patent timely filed is successfully challenged, if we are otherwise unsuccessful in further extending the term of the '404 patent, or if we are unable to maintain our market exclusivity for Angiomax in the United States through enforcement of 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. This appeal is pending.

In September and October 2009, we were granted two U.S. patents covering Angiomax. We listed both patents in the Orange Book for Angiomax. 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 filed lawsuits against the ANDA filers alleging patent infringement of the two patents. We cannot predict the outcome of these lawsuits.

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 the August 3, 2010 federal district court's 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, if we are otherwise unsuccessful in further extending the term of the '404 patent, or if we are unable to maintain our market exclusivity for Angiomax in the United States through enforcement of 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 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.

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 acceptable terms 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. Our success 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.

On June 23, 2011, the U.S. House of Representatives passed a bill that, if enacted into law, would clarify the deadline for filing an application for patent term extension under the Hatch-Waxman Act and would confirm the federal district court's August 3, 2010 decision in our suit against the PTO, the FDA and HHS. It is not known whether the bill passed by the U.S. House of representatives will be enacted into law.

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 licensed patents and patent applications for each of our products and products in development other than MDCO-2010. The U.S. patents licensed by us are currently set to expire at various dates. We plan to file

applications for U.S. patent term extension for our products in development upon their approval by the FDA. 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.

We may be unable to utilize the Chemilog process if Lonza Braine breaches our agreement

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 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. 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 Growth and Employees

If we fail to acquire and develop additional 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 product candidates or 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 IV clopidogrel. 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 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 successful in developing and commercializing product candidates or approved products we acquire

We need to integrate any acquired products into our existing operations. Integrating any newly acquired business or product could be expensive and time-consuming. We may not be able to integrate any acquired business or product successfully or operate any acquired business profitably. In addition, managing the development of a new product entails numerous financial and operational risks, including difficulties in attracting qualified employees to develop the product.

Any product candidate we acquire or license will require additional research and development efforts prior to commercial sale, including extensive pre-clinical and/or clinical testing and approval by the FDA and corresponding foreign regulatory authorities.

All product candidates are prone to the risks of failure inherent in pharmaceutical product development, including the possibility that the product candidate will not be safe and effective or approved by regulatory authorities. In addition, any approved products that we acquire may not be:

- manufactured or produced economically;
- successfully commercialized; or
- widely accepted in the marketplace.

We have previously acquired or licensed rights to products and, after having conducted development activities, determined not to devote further resources to those products. Any additional products that we acquire or license may not be successfully developed.

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 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 July 29, 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 of any of the following factors upon the market price of our common stock:

- 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;
- 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;
- governmental regulation and approvals;
- 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;
- whether the federal district 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;
- 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;
- developments or issues with our contract manufacturers;
- changes in our management; and
- general market conditions.

In addition, the stock market has experienced significant price and volume fluctuations, and the market prices of specialty pharmaceutical companies have been highly volatile. Moreover, broad market and industry fluctuations that are not within our control may adversely affect the trading price of our common stock. You must be willing to bear the risk of fluctuations in the price of our common stock and the risk that the value of your investment in our securities could decline.

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

Section 203 of 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 the inability of stockholders to act by written consent or to call special meetings, a classified board of directors and the ability of our board of directors to designate the terms of and issue new series of preferred stock without stockholder approval.

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.

Item 5. Other Information

In a Current Report on Form 8-K filed on June 2, 2011, we disclosed that at our 2011 Annual Meeting of Stockholders held on May 26, 2011, a majority of our stockholders indicated their preference for the advisory vote on the compensation of our named executive officers to be held annually.

After consideration of the results of the advisory vote taken at our annual meeting on the frequency with which to hold future advisory votes on the compensation of our named executive officers and other factors, our Board of Directors has determined

that we will hold an advisory vote on the compensation of our named executive officers on an annual basis until the next required vote on the frequency of such advisory votes, or until the Board of Directors otherwise determines that a different frequency for such votes is in the best interests of 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.

51

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: August 2, 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	Fourth Amendment to Lease, dated June 30, 2011, between registrant and Sylvan/Campus Realty L.L.C.
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