

MEDICINES CO /DE  
Form 10-Q  
November 09, 2010

**Table of Contents**

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
FORM 10-Q**

**(Mark One)**

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

**For the quarterly period ended: September 30, 2010**

**OR**

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

**For the transition period from**

**to**

**Commission file number 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

(Do not check if a smaller  
reporting company)

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

Yes  No

As of November 5, 2010, there were 53,386,166 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>	3
<u>Item 2 - Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	16
<u>Item 3 - Quantitative and Qualitative Disclosures about Market Risk</u>	33
<u>Item 4 - Controls and Procedures</u>	34
Part II. Other Information	35
<u>Item 1 - Legal Proceedings</u>	35
<u>Item 1A - Risk Factors</u>	37
<u>Item 6 - Exhibits</u>	54
<u>Signatures</u>	55
<u>Exhibit Index</u>	
<u>EX-10.1</u>	
<u>EX-10.2</u>	
<u>EX-31.1</u>	
<u>EX-31.2</u>	
<u>EX-32.1</u>	
<u>EX-32.2</u>	
<u>EX-101 INSTANCE DOCUMENT</u>	
<u>EX-101 SCHEMA DOCUMENT</u>	
<u>EX-101 CALCULATION LINKBASE DOCUMENT</u>	
<u>EX-101 LABELS LINKBASE DOCUMENT</u>	
<u>EX-101 PRESENTATION LINKBASE DOCUMENT</u>	

**Table of Contents****Item 1. Financial Statements**

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

	<b>September 30, 2010 (Unaudited)</b>	<b>December 31, 2009</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 105,169	\$ 72,225
Available for sale securities	122,284	103,966
Accrued interest receivable	922	922
Accounts receivable, net of allowances of approximately \$21.4 million and \$6.4 million at September 30, 2010 and December 31, 2009, respectively	34,070	29,789
Inventory	29,624	25,836
Prepaid expenses and other current assets	7,367	9,984
Total current assets	299,436	242,722
Fixed assets, net	21,387	25,072
Intangible assets, net	83,363	84,678
Goodwill	14,671	14,934
Restricted cash	5,764	7,049
Other assets	269	321
Total assets	\$ 424,890	\$ 374,776
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 12,788	\$ 8,431
Accrued expenses	64,545	77,088
Deferred revenue	434	1,100
Total current liabilities	77,767	86,619
Contingent purchase price	25,932	23,667
Deferred tax liabilities	19,105	18,395
Other liabilities	5,829	5,706
Total liabilities	128,633	134,387
Stockholders' equity:		
Preferred stock, \$1.00 par value per share, 5,000,000 shares authorized; no shares issued and outstanding		
Common stock, \$0.001 par value per share, 125,000,000 shares authorized; 53,373,836 and 52,830,376 issued and outstanding at September 30, 2010 and December 31, 2009, respectively	53	53
Additional paid-in capital	594,296	584,678
Accumulated deficit	(298,114)	(344,177)
Accumulated other comprehensive income (loss)	22	(165)

Total stockholders' equity	296,257	240,389
Total liabilities and stockholders' equity	\$ 424,890	\$ 374,776

See accompanying notes to unaudited condensed consolidated financial statements.

**Table of Contents**

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

	<b>Three Months Ended</b>		<b>Nine months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>
Net revenue	\$ 105,743	\$ 98,789	\$ 317,966	\$ 302,181
Operating expenses:				
Cost of revenue	31,568	28,308	93,905	86,958
Research and development	16,676	22,464	54,128	68,685
Selling, general and administrative	35,788	47,358	121,318	146,863
Total operating expenses	84,032	98,130	269,351	302,506
Income (loss) from operations	21,711	659	48,615	(325)
Other income	483	151	55	2,055
Income before income taxes	22,194	810	48,670	1,730
Provision for income taxes	(989)	(4,007)	(2,607)	(4,465)
Net income (loss)	\$ 21,205	\$ (3,197)	\$ 46,063	\$ (2,735)
Basic earnings (loss) per common share	\$ 0.40	\$ (0.06)	\$ 0.87	\$ (0.05)
Diluted earnings (loss) per common share	\$ 0.40	\$ (0.06)	\$ 0.87	\$ (0.05)
Weighted average number of common shares outstanding:				
Basic	52,991	52,298	52,773	52,225
Diluted	53,359	52,298	53,005	52,225

See accompanying notes to unaudited condensed consolidated financial statements.

**Table of Contents**

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

	<b>Nine months Ended</b>	
	<b>September 30,</b>	
	<b>2010</b>	<b>2009</b>
Cash flows from operating activities:		
Net income (loss)	\$ 46,063	\$ (2,735)
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	5,085	4,331
Amortization of net premiums and discounts on available for sale securities	2,432	1,460
Unrealized foreign currency transaction (gains) losses, net	(596)	559
Non-cash stock compensation expense	6,855	15,328
Loss on disposal of fixed assets	6	11
Deferred tax provision	710	4,900
Tax effect of option exercises		(928)
Adjustment to contingent purchase price	2,265	(442)
Changes in operating assets and liabilities:		
Accrued interest receivable		468
Accounts receivable	(4,214)	(10,547)
Inventory	(3,656)	8,944
Prepaid expenses and other current assets	2,450	1,283
Accounts payable	4,275	(10,725)
Accrued expenses	(12,481)	(8,988)
Deferred revenue	(691)	(6,319)
Other liabilities	122	(104)
Net cash provided by (used in) operating activities	48,625	(3,504)
Cash flows from investing activities:		
Purchases of available for sale securities	(100,830)	(108,883)
Proceeds from maturities and sales of available for sale securities	80,140	121,510
Purchases of fixed assets	(151)	(287)
Adjustment to goodwill	263	
Acquisition of business, net of cash acquired		(37,229)
Decrease (increase) in restricted cash	1,285	(1,709)
Net cash used in investing activities	(19,293)	(26,598)
Cash flows from financing activities:		
Proceeds from issuances of common stock, net	2,764	1,803
Net cash provided by financing activities	2,764	1,803
Effect of exchange rate changes on cash	848	(794)
Increase (decrease) in cash and cash equivalents	32,944	(29,093)
Cash and cash equivalents at beginning of period	72,225	81,018
Cash and cash equivalents at end of period	\$ 105,169	\$ 51,925



Supplemental disclosure of cash flow information:

Taxes paid	\$	229	\$	354
------------	----	-----	----	-----

5

---

**Table of Contents****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 intensive and 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 critical care hospital products in development, including two late-stage development product candidates, cangrelor and oritavancin, two early stage development product candidates, MDCO-2010 (formerly known as CU2010) and MDCO-216 (formerly known as ApoA-I Milano), and marketing rights in the United States and Canada to a ready-to-use formulation of Argatroban for which a new drug application (NDA) has been submitted to the U.S. Food and Drug Administration (FDA). The Company believes that Angiomax, Cleviprex and its products in development possess favorable attributes that competitive products do not provide, can satisfy unmet medical needs in the critical 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 patients and 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, 2009 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 nine months ended September 30, 2010 are not necessarily indicative of the results that may be expected for the entire fiscal year or the fourth quarter of the fiscal year ending December 31, 2010. 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, 2009, 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/(loss) that are reported in the consolidated financial statements and accompanying disclosures. Actual results may be different. See note 2 of the

**Table of Contents**

notes to the consolidated financial statements in the Company's Annual Report on Form 10-K for the year ended December 31, 2009 for a discussion of the Company's critical accounting estimates.

**Reclassifications**

Certain prior year amounts have been reclassified to conform to the current year presentation.

**Recent Accounting Pronouncements**

In June 2009, the FASB issued SFAS No. 167, Amendments to FASB Interpretation No. 46(R), which was later superseded by the FASB Codification and included in ASC topic 810-10 (ASC 810-10), which modifies how a company determines when an entity that is insufficiently capitalized or is not controlled through voting (or similar rights) should be consolidated. ASC 810-10 clarifies that the determination of whether a company is required to consolidate an entity is based on, among other things, an entity's purpose and design and a company's ability to direct the activities of the entity that most significantly impact the entity's economic performance. ASC 810-10 requires an ongoing reassessment of whether a company is the primary beneficiary of a variable interest entity. ASC 810-10 also requires additional disclosures about a company's involvement in variable interest entities and any significant changes in risk exposure due to that involvement. This guidance is effective for fiscal years beginning after November 15, 2009 and was effective for the Company on January 1, 2010. The Company adopted this accounting pronouncement as of January 1, 2010 and it did not have a material impact on its consolidated financial statements.

**3. Stock-Based Compensation**

The Company recorded approximately \$1.8 million and \$6.9 million of stock-based compensation expense for the three and nine months ended September 30, 2010, respectively. For the three and nine months ended September 30, 2009, the Company recorded approximately \$4.4 million and \$15.3 million of stock-based compensation expense, respectively. As of September 30, 2010, there was approximately \$8.4 million of total unrecognized compensation costs related to non-vested share-based employee compensation arrangements granted under the Company's equity compensation plans. This cost is expected to be recognized over a weighted average period of 1.24 years.

During the nine months ended September 30, 2010, the Company issued a total of 543,460 shares of its common stock upon the exercise of stock options, pursuant to restricted stock grants and pursuant to purchases under employee stock purchase plans (the ESPP). During the nine months ended September 30, 2009, the Company issued a total of 596,818 shares of its common stock upon the exercise of stock options, pursuant to restricted stock grants and pursuant to purchases under the ESPP. Cash received from exercise of stock options and purchases through the ESPP during the nine months ended September 30, 2010 and 2009 was approximately \$2.8 million and \$1.8 million, respectively, and is included within the financing activities section of the consolidated statements of cash flows.

At September 30, 2010, there were a total of 6,726,585 shares of common stock reserved for future issuance under the ESPP and for future grants under the Company's amended and restated 2004 stock incentive plan.

**4. Earnings per Share**

The following table sets forth the computation of basic and diluted earnings per share for the three and nine months ended September 30, 2010 and 2009:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>
	<b>(in thousands, except per share amounts)</b>			
<b>Basic and diluted</b>				
Net income (loss)	\$ 21,205	\$ (3,197)	\$ 46,063	\$ (2,735)
Weighted average common shares outstanding, basic	52,991	52,298	52,773	52,225
Plus: net effect of dilutive stock options and restricted common shares	368		232	
Weighted average common shares outstanding, diluted	53,359	52,298	53,005	52,225

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

Earnings (loss) per share, basic	\$ 0.40	\$ (0.06)	\$ 0.87	\$ (0.05)
Earnings (loss) per share, diluted	\$ 0.40	\$ (0.06)	\$ 0.87	\$ (0.05)

7

---

**Table of Contents**

Basic earnings per share is computed using the weighted average number of shares of common stock outstanding during the period, reduced where applicable for outstanding yet unvested shares of restricted common stock. The number of dilutive common stock equivalents was calculated using the treasury stock method. For the three months ended September 30, 2010 and 2009, options to purchase 7,150,519 shares and 10,887,737 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 because their exercise price was in excess of the average closing price of the common stock during the period. For the nine months ended September 30, 2010 and 2009, options to purchase 8,684,283 shares and 11,032,956 shares, respectively, of common stock that could potentially dilute basic earnings per share in the future were excluded from the calculation of diluted earnings per share as their effect would have been anti-dilutive.

For the three months ended September 30, 2010 and 2009, 6,750 and 0 shares, respectively, of unvested restricted stock that could potentially dilute basic earnings per share in the future were excluded from the calculation of diluted earnings per common share as their effect would have been anti-dilutive. For the nine months ended September 30, 2010 and 2009, 8,500 and 116,870 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 (Loss)**

Comprehensive income (loss) includes net income (loss), unrealized gain (loss) on available for sale securities and currency translation adjustments. Comprehensive income (loss) for the three and nine months ended September 30, 2010 and September 30, 2009 is detailed below.

Comprehensive Income (Loss) (in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Net income (loss)	\$ 21,205	\$ (3,197)	\$ 46,063	\$ (2,735)
Unrealized gain (loss) on available for sale securities	80	(244)	61	(1,004)
Foreign currency translation adjustment	79	132	126	(168)
Comprehensive income (loss)	\$ 21,364	\$ (3,309)	\$ 46,250	\$ (3,907)

**6. Income Taxes**

For the three months ended September 30, 2010 and 2009, the Company recorded a provision for income taxes of \$1.0 million and \$4.0 million, respectively, based upon its estimated tax liability for the year. The Company's effective tax rate for the three months ended September 30, 2010 and 2009 was approximately 4% and 495%, respectively. For the nine months ended September 30, 2010 and 2009, the Company recorded a provision for income taxes of \$2.6 million and \$4.5 million, respectively, based upon its estimated tax liability for the year. The Company's effective tax rate for the nine months ended September 30, 2010 and 2009 was approximately 5% and 258%, respectively. The provision for income taxes is based on federal, state and foreign income taxes.

In the fourth quarter of 2009, the Company established a full valuation allowance against its deferred tax assets. It continues to evaluate their future realizability on a periodic basis in light of changing facts and circumstances, including but 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, extension of the patent rights relating to Angiomax and the ability to achieve future anticipated revenues. If the Company reduces the valuation allowance on deferred tax assets in future periods, the Company would recognize an income tax benefit.

**Table of Contents****7. Acquisition***Targanta Therapeutics Corporation*

In February 2009, the Company acquired Targanta Therapeutics Corporation (Targanta), a biopharmaceutical company focused on developing and commercializing innovative antibiotics to treat serious infections in the hospital and other institutional settings.

Under the terms of the Company's agreement with Targanta, it paid Targanta shareholders an aggregate of approximately \$42.0 million at closing, and agreed to pay contingent cash payments up to an additional \$90.4 million in the aggregate, as described below:

Upon approval from the European Medicines Agency (EMA) for a Marketing Authorization Application (MAA) for oritavancin for the treatment of serious gram-positive bacterial infections, including acute bacterial skin and skin structure infections (ABSSSI) (which were formerly referred to as complicated skin and skin structure infections, or cSSSI) on or before December 31, 2013, approximately \$10.5 million if such approval is granted between July 1, 2010 and December 31, 2013. As of September 30, 2010, the Company has not filed an application with the EMA for oritavancin for the treatment of ABSSSI.

Upon final approval from the FDA for a new drug application, or NDA, for oritavancin for the treatment of ABSSSI (1) within 40 months after the date the first patient is enrolled in a Phase 3 clinical trial of ABSSSI that is initiated by the Company and (2) on or before December 31, 2013, approximately \$10.5 million in the aggregate.

Upon final FDA approval for an NDA for the use of oritavancin for the treatment of ABSSSI administered by a single dose intravenous infusion (1) within 40 months after the date the first patient is enrolled in a Phase 3 clinical trial of ABSSSI that is initiated by the Company and (2) on or before December 31, 2013, approximately \$14.7 million in the aggregate. This payment may become payable simultaneously with the payment described in the previous bullet above.

If aggregate net sales of oritavancin in four consecutive calendar quarters ending on or before December 31, 2021 reach or exceed \$400.0 million, approximately \$49.4 million in the aggregate.

The Company expensed transaction costs as incurred, capitalized as an indefinite lived intangible asset the value of acquired in-process research and development and recorded contingent payments at their estimated fair value. The results of Targanta's operations have been included in the Company's consolidated financial statements since the acquisition date. The purchase price of approximately \$64 million, which includes \$42 million of cash paid upon acquisition and \$23 million that represents the fair market value of the contingent purchase price on the date of acquisition, was allocated to the net tangible and intangible assets of Targanta based on their estimated fair values. Below is a summary which details the assets and liabilities acquired as a result of the acquisition:

	(in thousands)
Acquired Assets:	
Cash and cash equivalents	\$ 4,815
Available for sale securities	397
Prepaid expenses & other current assets	2,440
Fixed assets, net	1,960
In-process research and development	69,500
Goodwill	14,671
Other assets	70
Total assets	93,853
Liabilities Assumed:	
Accounts payable	3,280

Accrued expenses	6,976
Contingent purchase price	23,181
Deferred tax liability	17,877
Other liabilities	556
Total liabilities	51,870
Total cash purchase price paid upon acquisition	\$ 41,983

**Table of Contents**

The purchase price was allocated to the estimated fair value of assets acquired and liabilities assumed based on a valuation and management estimates. The Company recorded a deferred tax liability for the difference in basis of the identifiable intangible assets.

In determining the fair value of all of the Company's in-process research and development projects related to oritavancin, the Company used the income approach, specifically a probability weighting to the estimated future net cash flows that are derived from projected sales revenues and estimated costs. These projections are based on factors such as relevant market size, patent protection, historical pricing of similar products and expected industry trends. This method requires a forecast of cash inflows, cash outflows, and pro forma charges for economic returns of and on tangible assets employed, including working capital, fixed assets and assembled workforce. Cash outflows include direct and indirect expenses for clinical trials, manufacturing, sales, marketing, general and administrative expenses and taxes. For purposes of these forecasts, the Company assumed that cash outflows for research and development, general administrative and marketing expenses from February 2009 and continuing through 2012 would not exceed \$165 million. All internal and external research and development expenses are expensed as incurred.

The Company expects its oritavancin development efforts to have a material impact on its research and development expenses.

The Company defines an in-process research and development project by specific therapeutic treatment indication. At this time, the Company is pursuing four therapeutic treatment indications for oritavancin. After applying a risk adjusted discount rate of 13% to each project's expected cash flow stream, the Company determined a preliminary value for each project as set forth below. In determining these values, the Company assumed that it would generate cash inflows from oritavancin for ABSSSI in 2012 and from the other projects thereafter.

Project	(in thousands)
ABSSSI	\$ 54,000
Bacteremia	5,900
Anthrax	6,400
<i>Clostridium difficile</i> infections	3,200
Total	\$ 69,500

The Company's success in developing and obtaining marketing approval for oritavancin for ABSSSI and for any of the other indications is highly uncertain. Subject to the completion of ongoing discussions with the FDA, the Company expects to commence such a Phase 3 study of oritavancin in the fourth quarter of 2010. The Company cannot know or predict the nature, timing and estimated costs of the efforts necessary to complete the development of, or the period in which material net cash inflows are expected to commence from, oritavancin due to the numerous risks and uncertainties associated with developing and commercializing drugs. These risks and uncertainties, including their impact on the timing of completing clinical trial and development work and obtaining regulatory approval, would have a material impact on each project's value.

If the acquisition of Targanta had occurred as of January 1, 2009, the Company's pro forma results for the three and nine months ended September 30, 2010 and 2009 would have been as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
	(in thousands, except per share amounts)			
Net revenue	\$ 105,743	\$ 98,789	\$ 317,966	\$ 302,181
Income (loss) from operations	21,711	659	48,615	(10,995)
Net income (loss)	21,205	(3,197)	46,063	(13,851)
Basic and diluted loss per share:				
Basic earnings (loss) per share	\$ 0.40	\$ (0.06)	\$ 0.87	\$ (0.27)



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

Diluted earnings (loss) per share	\$ 0.40	\$ (0.06)	\$ 0.87	\$ (0.27)
Weighted average number of common shares outstanding:				
Basic	52,991	52,298	52,773	52,225
Diluted	53,359	52,298	53,005	52,225

The above pro forma information was determined based on historical GAAP results adjusted for the elimination of interest foregone on net cash and cash equivalents used to pay the closing consideration and transaction related costs. Such amount was offset by the elimination of interest expense on third party debt that is assumed to be repaid in full prior to the completion of the acquisition.

**Table of Contents****8. 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 at September 30, 2010 and December 31, 2009 included investments of \$10.6 million and \$47.5 million, respectively, in money market funds and commercial paper with original maturities of less than three months. These investments are carried at cost, which approximates fair value.

At September 30, 2010 and December 31, 2009, the Company held available for sale securities with a fair value totaling \$122.3 million and \$104.0 million, respectively. These available for sale securities included various U.S. government agency notes and corporate debt securities. At September 30, 2010, approximately \$117.1 million of available for sale securities were due on demand or within one year and the remaining \$5.2 million were due within two years. At December 31, 2009, approximately \$100.3 million of available for sale securities were due on demand or within one year and the remaining \$3.7 million were due within two years.

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

	As of September 30, 2010				As of December 31, 2009			
	Cost	Fair Value	Carrying Value	Unrealized Gain	Cost	Fair Value	Carrying Value	Unrealized Gain
U.S. government agency notes	\$ 65,729	\$ 65,768	\$ 65,768	\$ 39	\$ 103,936	\$ 103,965	\$ 103,965	\$ 29
Corporate debt securities	\$ 56,464	\$ 56,516	\$ 56,516	\$ 52	\$	\$	\$	\$
Total	\$ 122,193	\$ 122,284	\$ 122,284	\$ 91	\$ 103,936	\$ 103,966	\$ 103,966	\$ 29

**Restricted Cash**

The Company had restricted cash of \$5.8 million at September 30, 2010 and \$7.0 million at December 31, 2009, which is included in restricted cash on the consolidated balance sheets. On October 11, 2007, the Company entered into a new lease for 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 and \$6.8 million at September 30, 2010 and December 31, 2009, respectively, collateralizes outstanding letters of credit associated with such 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 Targanta acquisition in 2009, the Company has restricted cash of \$0.3 million in the form of a guaranteed investment certificate collateralizing an available credit facility.

**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. for the fill-finish of Angiomax drug product. As of September 30, 2010, the Company had inventory-related purchase commitments totaling \$2.8 million during 2010, \$25.3 million during 2011 and \$14.7 million during 2012 for Angiomax bulk drug substance. The Company obtains all of its Cleviprex bulk drug substance from Johnson Matthey Pharma Services and also has a separate agreement with Hospira, Inc. for the fill-finish of Cleviprex drug product.

The major classes of inventory were as follows:

<b>Inventory</b>	<b>September 30, 2010</b>	<b>December 31, 2009</b>
	<b>(in thousands)</b>	
Raw materials	\$ 11,496	\$ 13,609
Work-in-progress	11,482	8,646
Finished goods	6,646	3,581
<b>Total</b>	<b>\$ 29,624</b>	<b>\$ 25,836</b>

**Table of Contents**

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

**10. Intangible Assets and Goodwill**

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

	Weighted Average Useful Life	As of September 30, 2010			As of December 31, 2009		
		Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount (in thousands)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Identifiable intangible assets							
Customer relationships(1)	8 years	\$ 7,457	\$ (1,501)	\$ 5,956	\$ 7,457	\$ (861)	\$ 6,596
Distribution agreements(1)	8 years	4,448	(896)	3,552	4,448	(514)	3,934
Trademarks(1)	8 years	3,024	(609)	2,415	3,024	(349)	2,675
Cleviprex milestones(2)	13 years	2,000	(60)	1,940	2,000	(27)	1,973
Total	9 years	\$ 16,929	\$ (3,066)	\$ 13,863	\$ 16,929	\$ (1,751)	\$ 15,178

(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 \$0.4 million for the remainder of 2010. The Company expects annual amortization expense related to these intangible assets to be \$2.4 million, \$2.4 million, \$3.0 million, \$3.6 million and \$0.8 for the years ending December 31, 2011, 2012, 2013, 2014 and 2015, respectively, with the balance of \$1.2 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 September 30, 2010			As of December 31, 2009		
	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
<b>Total</b>	\$ 69,500	\$	\$ 69,500	\$ 69,500	\$	\$ 69,500

The changes in goodwill for the nine months ended September 30, 2010 and for the year ended December 31, 2009 are as follows:

	<b>September 30, 2010</b>	<b>December 31, 2009</b>
	(in thousands)	
Balance at beginning of period	\$ 14,934	\$
Goodwill acquired during the year(1)		14,934
Adjustment to goodwill	(263)	
Balance at end of period	\$ 14,671	\$ 14,934

(1) The goodwill acquired during 2009 is solely attributable to the Targanta acquisition (note 7).

**Table of Contents****11. Fair Value Measurements**

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.

**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 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 (note 7). The fair value of the contingent purchase price was determined utilizing a probability weighted discounted financial model.

The following table sets forth the Company's assets and liabilities that were measured at fair value on a recurring basis at September 30, 2010 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)	Significant		Balance at September 30, 2010
		Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
(in thousands)				
Assets:				
Money market	\$ 10,593	\$	\$	\$ 10,593
U.S. government agency	\$	\$ 72,053	\$	\$ 72,053
Corporate debt securities	\$	\$ 50,231	\$	\$ 50,231
Total assets at fair value	\$ 10,593	\$ 122,284	\$	\$ 132,877
Liabilities:				
Contingent purchase price	\$	\$	\$ 25,932	\$ 25,932
Total liabilities at fair value	\$	\$	\$ 25,932	\$ 25,932

The changes in fair value of the Company's Level 3 contingent purchase price during the nine months ended September 30, 2010 were as follows:

	<b>Level 3 (in thousands)</b>
Balance at December 31, 2009	\$ 23,667
Contingent purchase price related to acquisition of Targanta	
Fair value adjustment to contingent purchase price included in net income	2,265
Balance at September 30, 2010	\$ 25,932

No changes in valuation techniques or inputs occurred during the nine months ended September 30, 2010. No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the nine months ended September 30, 2010.

**Table of Contents****12. Restructuring Costs and Other, Net**

On January 7, 2010 and February 9, 2010, the Company commenced two separate workforce reductions to improve efficiencies and better align its costs and structure for the future. As a result of the first workforce reduction, the Company reduced its office-based personnel by 30 employees. The second workforce reduction resulted in a reduction of 42 primarily field-based employees. Upon signing release agreements, affected employees received reduction payments, earned 2009 bonuses, fully paid health care coverage for six months and outplacement services. The Company completed these workforce reductions in February 2010.

The Company recorded, in the aggregate, charges of \$6.9 million associated with the workforce reductions. These charges were recorded in research and development and selling, general and administrative costs in the Company's financial statements.

Of the approximately \$6.9 million of charges related to the workforce reductions, \$1.0 million were noncash charges, \$5.7 million was paid during the nine months ended September 30, 2010 and approximately \$0.2 million are expected to be paid out during the remainder of 2010.

Details of the activities described above during the nine-month period ended September 30, 2010 are as follows:

	<b>Balance as of January 1, 2009</b>	<b>Expenses, Net</b>	<b>Cash      Noncash (in thousands)</b>		<b>Balance as of September 30, 2010</b>
Employee severance and other personnel benefits:					
Workforce reductions	\$	\$ 5,703	\$ 5,536	\$	\$ 167
Leases and equipment write-offs		1,164	150	945	69
<b>Total</b>	<b>\$</b>	<b>\$ 6,867</b>	<b>\$ 5,686</b>	<b>\$ 945</b>	<b>\$ 236</b>

**13. Segment and Geographic Information**

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

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

	<b>Three Months Ended September 30,</b>				<b>Nine months Ended September 30,</b>			
	<b>2010</b>		<b>2009</b>		<b>2010</b>		<b>2009</b>	
	<b>(in thousands)</b>							
Net revenue:								
United States	\$ 100,234	94.8%	\$ 93,317	94.5%	\$ 301,065	94.7%	\$ 289,044	95.6%
Europe	4,018	3.8%	2,915	2.9%	13,613	4.3%	8,692	2.9%
Other	1,491	1.4%	2,557	2.6%	3,288	1.0%	4,445	1.5%
Total net revenue	105,743		98,789		317,966		302,181	



	<b>September 30, 2010</b>		<b>December 31, 2009</b>	
		<b>(in thousands)</b>		
Long-lived assets:				
United States	\$ 118,123	98.7%	\$ 122,968	98.4%
Europe	1,352	1.1%	1,684	1.3%
Other	215	0.2%	353	0.3%
 Total long-lived assets	 \$ 119,690		 \$ 125,005	

**Table of Contents****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 September 30, 2010, the Company has accrued approximately \$1.1 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 were 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. The Company believes that the ultimate resolution of these matters will not have a material adverse effect on the Company's financial condition or liquidity. However, adjustments, if any, to the Company's estimates could be material to operating results for the periods in which adjustments to the liability are recorded.

The U.S. Patent and Trademark Office (PTO) rejected the Company's application under the Hatch-Waxman Act for an extension of the term of U.S. Patent No. 5,196,404 (404 patent), the principal U.S. patent that covers Angiomax (the patent term extension application filing), because in the PTO's view the application was not timely filed. The Company filed suit against the PTO, the FDA and U.S. Department of Health and Human Services (HHS) seeking to set aside the denial of the patent term extension application filing. On August 3, 2010, the court granted the Company's motion for summary judgment and ordered the PTO to consider the patent term extension application timely filed. On August 5, 2010, the PTO granted an interim extension of the term of the 404 patent until August 13, 2011. The period for the government to appeal the court's August 3, 2010 decision expired on October 5, 2010 without government appeal. The PTO has sent the patent term extension application to the FDA for a determination on the length of the extension of the 404 patent.

On August 19, 2010, APP Pharmaceuticals, LLC (APP) filed a motion to intervene for the purpose of appeal in the Company's case against the PTO, the FDA and HHS. 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, the Company filed a motion to dismiss APP's appeal and the Company is awaiting a decision by the court.

The Company has entered into agreements with the law firms involved in the patent term extension application filing that suspend the statute of limitations on any claims against them for failing to make a timely filing. The Company has entered into a similar agreement with Biogen Idec, one of its licensors for Angiomax, relating to any claims, including claims for damages and/or license termination, that Biogen Idec may bring relating to the patent term extension application filing. Such claims by Biogen Idec could have a material adverse effect on the Company's financial condition, results of operations, liquidity or business. The Company is currently in discussions with the law firms involved in the patent term extension application filing and with Biogen Idec and Health Research Inc. with respect to the possible resolution of potential claims among the parties.

**Table of Contents**

**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 intensive and critical care patients through the delivery of innovative, cost-effective medicines to the worldwide hospital marketplace. We have two marketed products, Angiomax<sup>®</sup> (bivalirudin) and Cleviprex<sup>®</sup> (clevidipine butyrate) injectable emulsion, and a pipeline of critical care hospital products in development, including two late-stage development product candidates, cangrelor and oritavancin, two early stage development product candidates, MDCO-2010 (formerly known as CU2010) and MDCO-216 (formerly known as ApoA-I Milano) and marketing rights in the United States and Canada to a ready-to-use formulation of Argatroban for which a new drug application, or NDA, has been submitted to the U.S. Food and Drug Administration, or FDA. We believe that Angiomax, Cleviprex and our products in development possess favorable attributes that competitive products do not provide, can satisfy unmet medical needs in the critical care hospital product market and offer, or, in the case of our products in development, have the potential to offer, improved performance to patients and hospital businesses. During the three months ended September 30, 2010, we did not sell Cleviprex due to a lack of supply as a result of product recalls and manufacturing issues.

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. All of our marketed products and products in development are administered intravenously.

**Table of Contents**

<b>Product or Product in Development</b>	<b>Development Stage</b>	<b>Mechanism/Target</b>	<b>Clinical Indication(s)</b>
Angiomax	Marketed	Direct thrombin inhibitor	U.S. for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing percutaneous coronary intervention, or PCI, with or at risk of heparin induced thrombocytopenia and thrombosis syndrome, or HIT/HITTS  EU for use as an anticoagulant in patients with acute coronary syndrome, or ACS, or ST-segment elevation myocardial infarction, or STEMI, undergoing primary PCI
Cleviprex	Marketed in the U.S.; Marketing Authorization Application, or MAA, submitted in the European Union	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
Oritavancin	Phase 3	Antibiotic	Treatment of serious gram-positive bacterial infections, including acute bacterial skin and skin structure infections, or ABSSSI (which were formerly referred to as complicated skin and skin structure infections, or cSSSI)
MDCO-2010	Phase 1	Serine protease inhibitor	Reduction of blood loss during surgery
MDCO-216	Phase 1	Naturally occurring variant of a protein found in human high-density lipoprotein (HDL)	Reversal of atherosclerotic plaque development and reduction of the risk of coronary events in patients with ACS
Ready-to-Use Argatroban	Phase 3; NDA filed	Direct thrombin inhibitor	Anticoagulant for prophylaxis or treatment of thrombosis in patients with or at risk for HIT and for patients with or at risk for HIT undergoing PCI

We market and sell Angiomax and Cleviprex in the United States with a sales force that, as of September 30, 2010, consisted of 106 representatives, which we refer to as engagement partners and managers, experienced in selling to hospital customers. In Europe, we market and sell Angiox with a sales force that, as of September 30, 2010, consisted of 44 engagement partners and managers experienced in selling to hospital customers. 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 in Europe. We believe that by establishing operations in Europe for Angiox, we will be positioned to

commercialize our pipeline of critical care product candidates in Europe, if and when they are approved.

Research and development expenses represent costs incurred for company acquisitions and license 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, 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 and 2006, we have incurred net losses on an annual basis since our inception. As of September 30, 2010, we had an accumulated deficit of approximately \$298.1 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

**Table of Contents**

approvals and commercialization. Although we achieved profitability in 2004 and 2006 and expect to be profitable in 2010, we have not been profitable on an annual basis since 2006. We will likely need to generate significantly greater revenue in future periods to achieve and maintain profitability in light of our planned expenditures.

*Angiomax Patent Term*

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 in connection with 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 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. In response to court orders, the PTO first extended the term of the patent to May 2010 and then to the date 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. On August 5, 2010, the PTO granted an interim extension of the term of the 404 patent until August 13, 2011. On October 5, 2010, the period for the government to appeal the court's August 3, 2010 summary judgment decision expired without government appeal. The PTO has sent our application to the FDA for a determination on the length of the extension of the 404 patent.

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 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 and we are awaiting a decision by the court.

We also continue to pursue legislative action to address the matter. In addition, we will have a six-month period of market exclusivity for Angiomax in the United States due to our study of Angiomax in the pediatric setting following the expiration of the U.S. patents covering Angiomax.

The PTO has recently issued two patents to us covering a more consistent and improved Angiomax drug product and the processes by which it is made. In October 2009, January 2010 and June 2010, we filed suit against pharmaceutical companies which have filed abbreviated new drug applications, or ANDAs, with the FDA for generic versions of Angiomax, alleging infringement of the two recently issued patents.

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 following the expiration of the six-month period of market exclusivity resulting from our pediatric study of Angiomax. In Europe, the principal patent covering Angiox expires in 2015.

*Cleviprex Resupply*

In December 2009 and March 2010, we conducted voluntary recalls of manufactured lots of Cleviprex due to the presence of visible particulate matter that was deposited at the bottom of some vials. As a result, since the first quarter of 2010 we have not been able to supply the market with Cleviprex with existing inventory or to use the current manufacturing method to manufacture Cleviprex. We are cooperating with the FDA and our contract manufacturer to remedy the problem at the manufacturing site that resulted in the recalls. We expect to be able to resupply the market with drug product and to resume selling Cleviprex in the third quarter of 2011.

*Distribution and Sales*

We distribute Angiomax and Cleviprex in the United States through a sole source distribution model. Under this model, we sell Angiomax and Cleviprex to our sole source distributor, Integrated Commercialization Solutions, Inc., or ICS, which then sells

**Table of Contents**

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 February 28, 2012, but will automatically renew for additional one-year periods unless either party gives notice at least 120 days prior to the automatic extension. We may also terminate the agreement at any time and for any reason upon prior written notice to ICS and payment of a termination fee of between \$100,000 and \$250,000.

In Europe, we market and sell Angiox with a sales force that, as of September 30, 2010, consisted of 44 engagement partners and managers. 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 strategy for Cleviprex in preparation for its potential approval outside of the United States but do not expect to launch Cleviprex in other countries until the manufacturing issues regarding the product have been resolved.

To support the marketing, sales and distribution efforts of Angiomax, we are continuing to develop our business infrastructure outside the United States. We currently have subsidiaries in the Australia, Austria, Belgium, Brazil, Canada, Denmark, Finland, France, Germany, Italy, the Netherlands, Norway, Poland, Spain, Sweden, Switzerland and the United Kingdom, in connection with the development of a business infrastructure to conduct the international sales and marketing of Angiomax. We also obtained licenses and authorizations necessary to distribute Angiomax in the various countries outside the United States, hired personnel and entered into third-party arrangements to provide services, such as importation, packaging, quality control and distribution. We believe that by establishing operations outside the United States for Angiomax, we will be positioned to commercialize our products in development, if and when they are approved.

*Business Development Activity*

Our core strategy is to acquire, develop and commercialize products that we believe help hospitals treat patients more efficiently by improving the effectiveness and safety of treatment while reducing cost. Since the beginning of 2009, we have acquired or licensed a portfolio of critical care products that we are developing.

*Targanta Acquisition.* In February 2009, we acquired Targanta, a biopharmaceutical company focused on developing and commercializing innovative antibiotics to treat serious infections in the hospital and other institutional settings. Targanta's product pipeline included an intravenous version of oritavancin and a program to develop an oral version of oritavancin for the possible treatment of *Clostridium difficile* infections, or *C. difficile*.

Under the terms of our agreement with Targanta, we paid Targanta shareholders an aggregate of approximately \$42.0 million at closing, and agreed to pay contingent cash payments up to an additional \$90.4 million in the aggregate, as described below:

Upon approval from the European Medicines Agency, or EMA, for a MAA for oritavancin for the treatment of ABSSSI on or before December 31, 2013, approximately \$10.5 million if such approval is granted between July 1, 2010 and December 31, 2013. As of September 30, 2010, we had not filed an application with the EMA for oritavancin for the treatment of ABSSSI.

Upon final approval from the FDA for a new drug application, or NDA, for oritavancin for the treatment of ABSSSI (1) within 40 months after the date the first patient is enrolled in a Phase 3 clinical trial of ABSSSI that is initiated by us and (2) on or before December 31, 2013, approximately \$10.5 million in the aggregate.

Upon final FDA approval for an NDA for the use of oritavancin for the treatment of ABSSSI administered by a single dose intravenous infusion (1) within 40 months after the date the first patient is enrolled in a Phase 3 clinical trial of ABSSSI that is initiated by us and (2) on or before December 31, 2013, approximately \$14.7 million in the aggregate. This payment may become payable simultaneously with the payment described in the previous bullet above.



**Table of Contents**

If aggregate net sales of oritavancin in four consecutive calendar quarters ending on or before December 31, 2021 reach or exceed \$400 million, approximately \$49.4 million in the aggregate.

We expensed the transaction costs as incurred and capitalized the value of acquired in-process research and development as an indefinite lived intangible asset. We recorded contingent payments at their estimated fair value. We included the results of Targanta's operations in our consolidated financial statements since the acquisition. The purchase price of approximately \$64 million, which includes \$42 million of cash paid upon acquisition and \$23 million that represents the fair market value of the contingent purchase price on the date of acquisition, was allocated to the net tangible and intangible assets of Targanta based on their estimated fair values.

As a result of our acquisition of Targanta, we are a party to an asset purchase agreement that Targanta entered into with InterMune, Inc., or InterMune, in connection with Targanta's December 2005 acquisition of the worldwide rights to oritavancin from InterMune. Under the agreement, we are obligated to use commercially reasonable efforts to develop oritavancin and to make a \$5.0 million cash payment to InterMune if and when we receive from the FDA all approvals necessary for the commercial launch of oritavancin. We have no other milestone or royalty obligations to InterMune.

*Licensing Arrangement with Eagle.* In September 2009, we licensed marketing rights in the United States and Canada to a ready-to-use formulation of Argatroban developed by Eagle Pharmaceuticals, Inc., or Eagle, for which Eagle submitted an NDA to the FDA in 2008. We and Eagle are currently in discussions with the FDA regarding the NDA. Under the license agreement with Eagle, we paid Eagle a \$5.0 million technology license fee. We also agreed to pay additional approval and commercialization milestones up to a total of \$15.0 million and royalties. Eagle has agreed to supply us with the ready-to-use product under a supply agreement we entered into with it in September 2009.

*Licensing Arrangement with Pfizer.* In December 2009, we licensed exclusive worldwide rights to MDCO-216 (formerly known as ApoA-I Milano) from Pfizer Inc., or Pfizer. Under the terms of the agreement, we paid Pfizer an up-front payment of \$10.0 million and agreed to make additional payments upon the achievement of clinical, regulatory and sales milestones up to a total of \$410 million. We also agreed to pay Pfizer single-digit royalty payments on worldwide net sales of MDCO-216. We also paid \$7.5 million to third parties in connection with the license and agreed to make additional payments to them of up to \$12.0 million in the aggregate upon the achievement of specified development milestones and continuing payments based on sales of MDCO-216.

***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 nine months ended September 30, 2010, we recorded, in the aggregate, charges of \$6.9 million associated with these workforce reductions. Of the approximately \$6.9 million of charges related to the workforce reductions, \$1.0 million were noncash charges, \$5.7 million was paid during the nine months ended September 30, 2010 and approximately \$0.2 million is expected to be paid out during the remainder of 2010. We expect to realize estimated annualized cost savings from the workforce reductions in the range of \$14.5 to \$16.5 million.

**Results of Operations*****Three Months Ended September 30, 2010 and 2009******Net Revenue:***

Net revenue increased 7% to \$105.7 million for the three months ended September 30, 2010 as compared to \$98.8 million for the three months ended September 30, 2009. The following table reflects the components of net revenue for the three months ended September 30, 2010 and 2009:

**Table of Contents****Net Revenue****Three Months Ended September 30,**

	<b>2010</b>	<b>2009</b>	<b>Change</b>	<b>Change</b>
	<b>(in</b>	<b>(in</b>	<b>\$</b>	<b>%</b>
	<b>thousands)</b>	<b>thousands)</b>	<b>(in</b>	
			<b>thousands)</b>	
<b>Net Revenue</b>				
U.S. sales	\$ 100,234	\$ 93,317	\$ 6,917	7.4%
International net revenue	5,509	5,472	37	0.7%
<b>Total net revenue</b>	\$ 105,743	\$ 98,789	\$ 6,954	7.0%

Net revenue during the three months ended September 30, 2010 increased \$7.0 million compared to the three months ended September 30, 2009 primarily due to an increase in sales of Angiomax in the United States and an increase in sales of Angiox in Europe. Increased Angiomax net sales in the United States were offset by higher chargebacks related to the 340B Drug Pricing Program under the Public Health Service Act, pursuant to which we offer qualifying entities a discount off the commercial price of Angiomax for patients undergoing PCI on an outpatient basis. U.S. sales for the three months ended September 30, 2010 do not include any sales of Cleviprex, reflecting our lack of supply of Cleviprex due to manufacturing problems, compared to \$1.1 million from sales of Cleviprex in the three months ended September 30, 2009.

International net revenue was relatively unchanged during the three months ended September 30, 2010 compared to the three months ended September 30, 2009 since decreased sales of Angiomax in Canada offset the increased sales of Angiomax in Europe.

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 successful 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 following the expiration of the six-month period of market exclusivity resulting from our pediatric study of Angiomax. Competition from generic equivalents sold at a price that is less than the price at which we currently sell Angiomax could reduce our revenues, possibly materially.

Since the first quarter of 2010, we have not been able to supply the market with Cleviprex with existing inventory or to use the current manufacturing method to manufacture Cleviprex related to the December 2009 and March 2010 recalls of the drug product. We expect to be able to resupply the market with drug product and to resume selling Cleviprex in the third quarter of 2011.

*Cost of Revenue:*

Cost of revenue in the three months ended September 30, 2010 was \$31.6 million, or 30% of net revenue, compared to \$28.3 million, or 29% of net revenue, in the three months ended September 30, 2009. Cost of revenue 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 with AstraZeneca AB, or AstraZeneca, related to Cleviprex and the logistics costs related to Angiomax and Cleviprex, including distribution, storage and handling costs.

**Table of Contents****Cost of Revenue**

	<b>Three Months Ended September 30,</b>			
	<b>2010</b>	<b>% of</b>	<b>2009</b>	<b>% of</b>
	<b>(in</b>	<b>Total</b>	<b>(in</b>	<b>Total</b>
	<b>thousands)</b>	<b>Cost</b>	<b>thousands)</b>	<b>Cost</b>
<b>Cost of Revenue</b>				
Manufacturing	\$ 7,277	23%	\$ 6,830	24%
Royalty	21,129	67%	18,755	66%
Logistics	3,162	10%	2,723	10%
<b>Total cost of revenue</b>	<b>\$ 31,568</b>	<b>100%</b>	<b>\$ 28,308</b>	<b>100%</b>

Cost of revenue increased \$3.3 million during the three months ended September 30, 2010 compared to the three months ended September 30, 2009. The increase in cost of revenue is primarily related to the higher volume of goods sold and an increase in royalty expense due to a higher effective royalty rate to Biogen Idec and was partially offset by a \$0.5 million decrease related to manufacturing costs of Angiomax reflecting higher manufacturing costs in the third quarter of 2009 due to production failures at the third-party manufacturer for Angiomax that occurred in the third quarter of 2009.

*Research and Development Expenses:*

Research and development expenses decreased by 26% to \$16.7 million for the three months ended September 30, 2010, compared to \$22.5 million for the three months ended September 30, 2009. The decrease primarily reflects reduced clinical activity for cangrelor as the CHAMPION clinical trial program for cangrelor was ongoing until we discontinued enrollment in May 2009. The decrease also reflects reduced regulatory and clinical activity for Cleviprex as we suspend our clinical trials as a result of the recalls and lack of supply. These decreases were offset by an increase in manufacturing development cost for Angiomax, costs incurred in preparation for Phase 3 trials of cangrelor and oritavancin and costs associated with the development of MDCO-2010 and MDCO-216.

We expect to continue to invest in the development of Angiomax, Cleviprex, cangrelor, oritavancin, MDCO-2010 and MDCO-216 during 2010. We expect research and development expenses in the fourth quarter of 2010 to reflect costs associated with our anticipated Phase 3 clinical trials of oritavancin and the Phase 3 clinical trials of cangrelor we began in October 2010, manufacturing development activities for Angiomax, Cleviprex, cangrelor and MDCO-216, our Phase 1 clinical trial program for MDCO-2010 and product lifecycle management activities.

The following table identifies, for each of our major research and development projects, our spending for the three months ended September 30, 2010 and 2009. Spending for past periods is not necessarily indicative of spending in future periods.

**Research and Development Spending**

	<b>Three Months Ended September 30,</b>			
	<b>2010</b>	<b>% of</b>	<b>2009</b>	<b>% of</b>
	<b>(in</b>	<b>Total</b>	<b>(in</b>	<b>Total</b>
	<b>thousands)</b>	<b>R&amp;D</b>	<b>thousands)</b>	<b>R&amp;D</b>
<b>Research and Development</b>				
<b>Angiomax</b>				
Clinical trials	\$ 1,781	11%	\$ 1,008	5%
Manufacturing development	622	4%	2,896	13%

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

Administrative and headcount costs	417	2%	926	4%
<b>Total Angiomax</b>	<b>2,820</b>	<b>17%</b>	<b>4,830</b>	<b>22%</b>
<i>Cleviprex</i>				
Clinical trials	229	1%	563	3%
Manufacturing development	488	3%	744	3%
Administrative and headcount costs	521	3%	1,158	5%
<b>Total Cleviprex</b>	<b>1,238</b>	<b>7%</b>	<b>2,465</b>	<b>11%</b>
<i>Cangrelor</i>				
Clinical trials	1,611	10%	2,796	12%
Manufacturing development	763	5%	512	2%
Administrative and headcount costs	1,082	6%	1,036	5%
<b>Total Cangrelor</b>	<b>3,456</b>	<b>21%</b>	<b>4,344</b>	<b>19%</b>
	22			

---

**Table of Contents**

	<b>Three Months Ended September 30,</b>			
	<b>2010</b>	<b>% of</b>	<b>2009</b>	<b>% of</b>
	<b>(in</b>	<b>Total</b>	<b>(in</b>	<b>Total</b>
	<b>thousands)</b>	<b>R&amp;D</b>	<b>thousands)</b>	<b>R&amp;D</b>
<b><i>Oritavancin</i></b>				
Clinical trials	1,186	7%		0%
Manufacturing development	383	3%		0%
Administrative and headcount	2,034	12%	2,542	11%
<b>Total Oritavancin</b>	<b>3,603</b>	<b>22%</b>	<b>2,542</b>	<b>11%</b>
<b><i>MDCO-2010</i></b>				
Clinical trials	861	5%	833	4%
Manufacturing development	575	3%		0%
Administrative and headcount	1,077	7%	742	3%
Government subsidy	(530)	(3)%	(1,024)	(4)%
<b>Total MDCO-2010</b>	<b>1,983</b>	<b>12%</b>	<b>551</b>	<b>3%</b>
<b><i>MDCO-216</i></b>				
Clinical trials	86	0%		0%
Manufacturing development	655	4%		0%
Administrative and headcount	121	1%		0%
<b>Total MDCO-216</b>	<b>862</b>	<b>5%</b>		<b>0%</b>
<b><i>Ready-to-Use Argatroban</i></b>				
Manufacturing development	139	1%		0%
Acquisition license fee		0%	5,000	22%
<b>Total Ready-to-Use Argatroban</b>	<b>139</b>	<b>1%</b>	<b>5,000</b>	<b>22%</b>
<b><i>Other</i></b>	<b>2,575</b>	<b>15%</b>	<b>2,732</b>	<b>12%</b>
<b>Total</b>	<b>\$ 16,676</b>	<b>100%</b>	<b>\$ 22,464</b>	<b>100%</b>

***Angiomax***

Research and development spending related to Angiomax during the three months ended September 30, 2010 decreased by approximately \$2.0 million compared to the three months ended September 30, 2009, primarily due to a decrease in manufacturing development expenses of \$2.3 million related to product lifecycle management activities and a decrease in administrative costs in the third quarter of 2010 of \$0.5 million primarily reflecting the increased costs incurred in the three months ended September 30, 2009 in connection with the regulatory filing related to a clinical study report for the pediatric extension filed with the FDA in the second quarter of 2009. These decreases were partially offset by an increase in clinical trial costs of approximately \$0.8 million primarily due to increased expenditures in connection with our ongoing Phase 4 EUROMAX and EUROVISION clinical trials. We are conducting the Phase 4 EUROMAX clinical trial to assess whether the early administration of Angiox in ST-segment elevation myocardial infarction, or 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 expect to enroll approximately 3,680 patients in the EUROMAX trial, in up to ten European countries. We commenced enrollment in the trial in March 2010. We are conducting the

EUROVISION study to assess Angiox dosing practices in Europe. We commenced enrollment in this study in May 2009 and in October 2010 we completed enrollment, with 2,022 patients at 70 sites in six European countries.

We plan to incur increased research and development expenses relating to Angiomax in connection with our efforts to further develop Angiomax for use in additional patient populations, as well as to continue to incur research and development expenses related to our product lifecycle management activities.

*Cleviprex*

Research and development expenditures for Cleviprex decreased approximately \$1.2 million during the three months ended September 30, 2010 compared to the three months ended September 30, 2009. The decrease in research and development expenditures is primarily due to the recalls and lack of supply of Cleviprex and the discontinuation in late 2009 of our Phase 4 clinical trials and the observational studies conducted by hospitals and third-party researchers until such time that we are able to resupply the market with Cleviprex.

*Cangrelor*

Research and development expenditures related to cangrelor decreased by approximately \$0.9 million in the three months ended September 30, 2010 compared to the three months ended September 30, 2009. The decrease in research and development expenditures primarily reflects lower clinical trial expenses related to our Phase 3 CHAMPION clinical trial program. In May 2009, we discontinued enrollment in our Phase 3 CHAMPION clinical trial program for cangrelor but continued to have administrative and

**Table of Contents**

headcount costs related to the trial in the third quarter of 2009. In October 2010, we commenced a Phase 3 clinical trial of cangrelor, which we refer to as the PHOENIX clinical trial. We initially expect to enroll approximately 10,900 patients, and may enroll up to 15,000 patients in this double-blind parallel group randomized study which compares cangrelor to clopidogrel given according to institutional practice.

*Oritavancin*

Research and development expenditures related to oritavancin increased by approximately \$1.1 million in the three months ended September 30, 2010 compared to the three months ended September 30, 2009. The increase in research and development expenditures for oritavancin primarily relates to manufacturing costs, headcount expenses and our preparation for our SOLO I and SOLO II Phase 3 clinical trials incurred during the third quarter of 2010. With our acquisition of Targanta in February 2009, we acquired a worldwide exclusive license to oritavancin. Subject to the completion of ongoing discussions with the FDA regarding finalizing a special protocol assessment, we expect to commence two identical Phase 3 clinical trials of oritavancin for the treatment of ABSSSI in the fourth quarter of 2010, SOLO I and SOLO II. The SOLO I and SOLO II clinical trials are expected to each enroll approximately 2,000 patients and will test the use of a simplified dosing regimen involving a single dose of oritavancin. In August 2009, we withdrew the European MAA for oritavancin.

*MDCO-2010*

Research and development expenditures related to MDCO-2010 increased by approximately \$1.4 million in the three months ended September 30, 2010 compared to the three months ended September 30, 2009 due primarily to increased manufacturing expenses related to the production of drug product in preparation for our Phase 1b trial for MDCO-2010. Costs incurred during the third quarter of 2010 primarily relate to our Phase 1a clinical trial of MDCO-2010, which we commenced in July 2009, and headcount related costs. Our costs were partially offset by a \$0.5 million German government research and development subsidy.

*MDCO-216*

Research and development expenditures related to MDCO-216 increased by approximately \$0.9 million in the three months ended September 30, 2010 compared to the three months ended September 30, 2009. In December 2009, we acquired exclusive worldwide rights to MDCO-216 from Pfizer. Costs incurred during the third quarter of 2010 primarily relate to manufacturing development related to preclinical activities, administrative and headcount expenses and our preparation for clinical trials.

*Ready-to-Use Argatroban*

Research and development expenditures related to ready-to-use Argatroban decreased by approximately \$4.9 million in the three months ended September 30, 2010 compared to the three months ended September 30, 2009, reflecting the \$5.0 million technology license fee paid to Eagle in September 2009 in connection with the acquisition of marketing rights for a ready-to-use formulation of Argatroban in the United States and Canada. Costs incurred during the third quarter of 2010 were primarily related to manufacturing development activities.

*Other*

Spending 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 (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 decreased by approximately \$0.2 million during the third quarter of 2010 compared to the third quarter of 2009, primarily due to a reduction of business development expenses.

Our success in further developing Angiomax and Cleviprex, obtaining marketing approvals for Angiomax in additional countries and for Cleviprex outside the United States, and developing and obtaining marketing approval 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

**Table of Contents**

and Cleviprex, or the period in which material net cash inflows are expected to commence from the further development of Angiomax and Cleviprex, obtaining marketing approvals for Angiomax in additional countries and Cleviprex outside the United States, or 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:*

	<b>Three Months Ended September 30,</b>			
	<b>2010</b>	<b>2009</b>	<b>Change</b>	<b>Change</b>
			<b>\$</b>	<b>%</b>
	<b>(in thousands)</b>			
Selling, general and administrative expenses	\$ 35,788	\$ 47,358	\$ (11,570)	(24.4)%

The decrease in selling, general and administrative expenses of \$11.6 million includes a reduction of \$8.3 million in selling, marketing and promotional spending, a \$3.6 million decrease in general administrative expenses, and a \$2.0 million decrease in stock-based compensation expense. Selling, general and administrative expenses decreased due to a reduction in personnel costs caused by our first quarter 2010 reductions in force and a reduction in Cleviprex promotional activities as a result of the recalls. These decreases were offset in part by higher expenses associated with ongoing Angiomax patent restoration efforts.

*Other Income:*

	<b>Three Months Ended September 30,</b>			
	<b>2010</b>	<b>2009</b>	<b>Change</b>	<b>Change</b>
			<b>\$</b>	<b>%</b>
	<b>(in thousands)</b>			
Other income	\$ 483	\$ 151	\$ 332	219.9%

Other income, which is comprised of interest income and gains and losses on foreign currency transactions, increased by \$0.3 million to \$0.5 million for the three months ended September 30, 2010, from \$0.2 million of income for the three months ended September 30, 2009. This increase was primarily due to gains on foreign currency transactions and partially offset by lower rates of return on our available for sale securities in the three months ended September 30, 2010.

*Provision for Income Tax:*

	<b>Three Months Ended September 30,</b>	
	<b>Change</b>	<b>Change</b>



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

	<b>2010</b>	<b>2009</b>	<b>\$</b>	<b>%</b>
			<b>(in thousands)</b>	
Provision for income tax	\$ 989	\$ 4,007	\$ (3,018)	(75.3)%

---

**Table of Contents**

We recorded a \$1.0 million provision for income taxes for the three months ended September 30, 2010 based on income before taxes of \$22.2 million. We recorded a \$4.0 million provision for the three months ended September 30, 2009 based on income before taxes of \$0.8 million. Our effective income tax rate for the three months ended September 30, 2010 and 2009 was approximately 4% and 495%, respectively. The effective tax rate for 2010 currently assumes utilization of U.S. net operating loss carryforwards against projected taxable income and a liability for alternative minimum tax. It also includes a non-cash tax expense arising from purchase accounting for in-process research and development acquired in the Targanta acquisition. It is possible that our full-year effective tax rate could change because of discrete events, specific transactions or receipt of new information affecting our current projections.

In 2009, we established a full valuation allowance against our deferred tax assets and continue to evaluate their future realizability 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 an income tax benefit.

**Nine months Ended September 30, 2010 and 2009***Net Revenue:*

Net revenue increased 5% to \$318.0 million for the nine months ended September 30, 2010, as compared to \$302.2 million for the nine months ended September 30, 2009. The following table reflects the components of net revenue for the nine months ended September 30, 2010 and 2009:

**Net Revenue**

	Nine Months Ended September 30,			
	2010 (in thousands)	2009 (in thousands)	Change \$ (in thousands)	Change %
<b>Net Revenue</b>				
U.S. sales	\$ 301,065	\$ 289,044	\$ 12,021	4.2%
International net revenue	16,901	13,137	3,764	28.7%
<b>Total net revenue</b>	<b>\$ 317,966</b>	<b>\$ 302,181</b>	<b>\$ 15,785</b>	<b>5.2%</b>

Net revenue during the nine months ended September 30, 2010 increased \$15.8 million compared to the nine months ended September 30, 2009 primarily due to an increase in sales of Angiox in Europe and an increase in sales of Angiomax in the United States. Increased Angiomax net sales in the United States were offset by higher chargebacks related to the 340B Drug Pricing Program under the Public Health Services Act. U.S. sales also include net revenue of \$0.8 million from sales of Cleviprex in the nine months ended September 30, 2010 compared to \$2.5 million in the nine months ended September 30, 2009, as a result of the recalls. The \$0.8 million in sales of Cleviprex in the nine months ended September 30, 2010 reflects an offset of \$0.7 million due to returns related to the Cleviprex recall.

International net revenue increased by \$3.8 million during the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009 primarily as a result of increased demand in France, Italy, Sweden and the United Kingdom, partially offset by decreased sales of Angiomax in Canada.

*Cost of Revenue:*

Cost of revenue in the nine months ended September 30, 2010 was \$94.0 million, or 30% of net revenue, compared to \$87.0 million, or 29% of net revenue, in the nine months ended September 30, 2009. Cost of revenue consisted of expenses in connection with the manufacture of Angiomax and Cleviprex sold, royalty expenses under our agreements with Biogen Idec and HRI related to Angiomax and with AstraZeneca related to Cleviprex and the logistics costs of

selling Angiomax and Cleviprex, such as distribution, storage, and handling.

**Table of Contents****Cost of Revenue**

	<b>Nine Months Ended September 30,</b>			
	<b>2010</b>	<b>% of</b>		<b>% of</b>
	<b>(in</b>	<b>Total</b>	<b>2009</b>	<b>Total</b>
	<b>thousands)</b>	<b>Cost</b>	<b>(in</b>	<b>Cost</b>
			<b>thousands)</b>	
<b>Cost of Revenue</b>				
Manufacturing	\$ 21,645	23%	\$ 19,675	23%
Royalty	63,004	67%	58,375	67%
Logistics	9,256	10%	8,908	10%
<b>Total cost of revenue</b>	<b>\$ 93,905</b>	<b>100%</b>	<b>\$ 86,958</b>	<b>100%</b>

Cost of revenue increased \$6.9 million during the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009. The increase in cost of revenue is primarily related to the higher volume of goods sold, an increase in royalty expense due to a higher effective royalty rate to Biogen Idec, and \$0.5 million related to inventory write offs associated with the Cleviprex recall. These increases were partially offset by \$0.9 million related to a reversal of certain charges 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 decreased by 21% to \$54.1 million for the nine months ended September 30, 2010, compared to \$68.7 million for the nine months ended September 30, 2009. The decrease primarily reflects reduced clinical activity for cangrelor as the CHAMPION clinical trial program for cangrelor was ongoing until we discontinued enrollment in May 2009. The decrease also reflects reduced regulatory and clinical activity for Cleviprex. These decreases were offset by an increase in costs incurred in preparation for Phase 3 trials of cangrelor and oritavancin, costs associated with the development of MDCO-2010 and MDCO-216 and charges of approximately \$1.7 million associated with our workforce reductions in the first quarter of 2010.

The following table identifies, for each of our major research and development projects, our spending for the nine months ended September 30, 2010 and 2009. Spending for past periods is not necessarily indicative of spending in future periods.

**Research and Development Spending**

	<b>Nine Months Ended September 30,</b>			
	<b>2010</b>	<b>% of</b>		<b>% of</b>
	<b>(in</b>	<b>Total</b>	<b>2009</b>	<b>Total</b>
	<b>thousands)</b>	<b>R&amp;D</b>	<b>(in</b>	<b>R&amp;D</b>
			<b>thousands)</b>	
<b>Research and Development</b>				
<b>Angiomax</b>				
Clinical trials	\$ 5,080	9%	\$ 2,722	4%
Manufacturing development	4,596	9%	6,530	10%
Administrative and headcount costs	1,824	3%	3,536	5%
<b>Total Angiomax</b>	<b>11,500</b>	<b>21%</b>	<b>12,788</b>	<b>19%</b>
<b>Cleviprex</b>				
Clinical trials	1,316	3%	4,116	6%

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

Manufacturing development	1,209	2%	1,360	2%
Administrative and headcount costs	1,610	3%	4,059	6%
<b>Total Cleviprex</b>	<b>4,135</b>	<b>8%</b>	<b>9,535</b>	<b>14%</b>
<b><i>Cangrelor</i></b>				
Clinical trials	4,964	9%	19,730	29%
Manufacturing development	1,724	3%	2,500	3%
Administrative and headcount costs	3,094	6%	3,388	5%
Milestone	3,000	6%		0%
<b>Total Cangrelor</b>	<b>12,782</b>	<b>24%</b>	<b>25,618</b>	<b>37%</b>
<b><i>Oritavancin</i></b>				
Clinical trials	2,250	4%		0%
Manufacturing development	2,833	5%		0%
Administrative and headcount	5,728	11%	4,461	6%
<b>Total Oritavancin</b>	<b>10,811</b>	<b>20%</b>	<b>4,461</b>	<b>6%</b>
	27			

---

**Table of Contents**

	<b>Nine Months Ended September 30,</b>			
	<b>2010</b>	<b>% of</b>	<b>2009</b>	<b>% of</b>
	<b>(in</b>	<b>Total</b>	<b>(in</b>	<b>Total</b>
	<b>thousands)</b>	<b>R&amp;D</b>	<b>thousands)</b>	<b>R&amp;D</b>
<b><i>MDCO-2010</i></b>				
Clinical trials	1,516	3%	833	1%
Manufacturing development	946	2%		0%
Administrative and headcount	3,151	6%	2,621	4%
Government subsidy	(1,038)	(2)%	(1,024)	(1)%
<b>Total MDCO-2010</b>	<b>4,575</b>	<b>9%</b>	<b>2,430</b>	<b>4%</b>
<b><i>MDCO-216</i></b>				
Clinical trials	126	0%		0%
Manufacturing development	1246	2%		0%
Administrative and headcount	430	1%		0%
<b>Total MDCO-216</b>	<b>1,802</b>	<b>3%</b>		<b>0%</b>
<b><i>Ready-to-Use Argatroban</i></b>				
Manufacturing development	616	1%		0%
Administrative and headcount	169	0%		0%
Acquisition license fee		0%	5,000	7%
<b>Total Ready-to-Use Argatroban</b>	<b>785</b>	<b>1%</b>		<b>7%</b>
<b><i>Other</i></b>	<b>7,738</b>	<b>14%</b>	<b>8,853</b>	<b>13%</b>
<b>Total</b>	<b>\$ 54,128</b>	<b>100%</b>	<b>\$ 68,685</b>	<b>100%</b>

***Angiomax***

Research and development spending related to Angiomax during the nine months ended September 30, 2010 decreased by approximately \$1.3 million compared to the nine months ended September 30, 2009, primarily due to a decrease of \$1.9 million in manufacturing development expenses related to product lifecycle management activities. Administrative costs in the nine months ended September 30, 2010 decreased \$1.7 million primarily reflecting the increased costs incurred in the nine months ended September 30, 2009 in connection with the regulatory filing related to a clinical study report for the pediatric extension filed with the FDA in the second quarter of 2009. These decreases were partially offset by an increase of \$2.3 million in clinical trial costs primarily due to increased expenditures in connection with our Phase 4 EUROMAX and EUROVISION clinical trials. We commenced enrollment in our Phase 4 EUROMAX clinical trial in March 2010 and in our EUROVISION trial in May 2009.

We plan to incur increased research and development expenses relating to Angiomax 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 approximately \$5.4 million during the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009. The decrease in research and development expenditures is primarily due to the recalls and lack of supply of Cleviprex and the discontinuation in late 2009 of our Phase 4 clinical trials and the observational studies conducted by hospitals and third-party researchers until such time that we are able to resupply the market with Cleviprex.

*Cangrelor*

Research and development expenditures related to cangrelor decreased by approximately \$12.8 million in the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009. The decrease in research and development expenditures primarily reflects lower clinical trial expenses related to our Phase 3 CHAMPION clinical trial program. In May 2009, we discontinued enrollment in our Phase 3 CHAMPION clinical trial program for cangrelor. This decrease was partially offset by a payment made to AstraZeneca in the second quarter of 2010 in connection with the June 2010 amendment to our agreement with AstraZeneca.

*Oritavancin*

Research and development expenditures related to oritavancin increased by approximately \$6.4 million in the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009. The increase in research and development expenditures for oritavancin primarily relates to manufacturing costs, headcount expenses and our preparation for our SOLO I and SOLO II Phase 3

**Table of Contents**

clinical trials incurred during the third quarter of 2010. Research and development costs for oritavancin incurred during the nine months ended September 30, 2010 primarily relate to manufacturing costs, headcount and our preparation for Phase 3 clinical trials of oritavancin. Research and development costs also include approximately \$1.3 million of severance payments related to the workforce reductions initiated in the first quarter of 2010. The results of Targanta's operations are included in our consolidated financial statements as of the February 9, 2009 acquisition date.

*MDCO-2010*

Research and development expenditures related to MDCO-2010 increased by approximately \$2.1 million in the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009 due primarily to increased manufacturing expenses related to the production of drug product in preparation for our Phase 1b trial for MDCO-2010. Research and development costs for MDCO-2010 incurred during the nine months ended September 30, 2010 primarily relate to our Phase 1a clinical trial of MDCO-2010, which we commenced in July 2009, and headcount related costs. This increase was partially offset by a \$1.0 million German government research and development subsidy.

*MDCO-216*

Research and development expenditures related to MDCO-216 increased by approximately \$1.8 million in the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009. In December 2009, we acquired exclusive worldwide rights to MDCO-216 from Pfizer. Costs incurred during the nine months ended September 30, 2010 primarily relate to administrative and headcount expenses, clinical trials and manufacturing development related to preclinical activities.

*Ready-to-Use Argatroban*

Research and development expenditures related to ready-to-use Argatroban decreased by approximately \$4.2 million in the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009, reflecting the \$5.0 million technology license fee paid to Eagle in September 2009 in connection with the acquisition of marketing rights for a ready-to-use formulation of Argatroban in the United States and Canada. Costs incurred during the nine months ended September 30, 2010 primarily relate to manufacturing development activities and administrative and headcount related expenses.

*Other*

Spending 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 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 decreased by approximately \$6.1 million during the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009, primarily due to a reduction of business development expenses.

*Selling, General and Administrative Expenses:*

	<b>Nine Months Ended September 30,</b>			
	<b>2010</b>	<b>2009</b>	<b>Change</b>	<b>Change</b>
			<b>\$</b>	<b>%</b>
	<b>(in thousands)</b>			
Selling, general and administrative expenses	\$121,318	\$146,863	\$(25,545)	(17.4)%

The decrease in selling, general and administrative expenses of \$25.5 million reflects the \$6.6 million in costs we incurred in the nine months ended September 30, 2009 in connection with the acquisition of Targanta and our U.S. headquarters relocation, a \$21.5 million decrease related to lower selling, marketing and promotional activity principally related to Angiomax and Cleviprex, approximately \$4.0 million of lower general corporate and administrative spending, and a \$6.8 million decrease in stock-based compensation expense. These decreases were partially offset by costs associated with the Company's ongoing patent restoration efforts and approximately \$5.2 million associated with our reduction in force announced in the first quarter of 2010, including expenses related to



employee severance arrangements and the closure and consolidation of our Indianapolis site which was completed in February 2010.

**Table of Contents***Other Income:*

	<b>Nine Months Ended September 30,</b>			
	<b>2010</b>	<b>2009</b>	<b>Change \$</b>	<b>Change %</b>
	<b>(in thousands)</b>			
Other income	\$55	\$2,055	\$(2,000)	(97.3)%

Other income, which is comprised of interest income and gains and losses on foreign currency transactions, decreased by \$2.0 million to \$0.1 million for the nine months ended September 30, 2010, from \$2.1 million for the nine months ended September 30, 2009. This decrease was primarily due to losses on foreign currency transactions and to lower rates of return on our available for sale securities in the nine months ended September 30, 2010.

*Provision for Income Tax:*

	<b>Nine Months Ended September 30,</b>			
	<b>2010</b>	<b>2009</b>	<b>Change \$</b>	<b>Change %</b>
	<b>(in thousands)</b>			
Provision for income tax	\$2,607	\$4,465	\$(1,858)	(41.6)%

We recorded a \$2.6 million provision for income taxes for the nine months ended September 30, 2010 based on income before taxes of \$48.7 million. We recorded a \$4.5 million provision for the nine months ended September 30, 2009 based on income before taxes of \$1.7 million. Our effective income tax rate for the nine months ended September 30, 2010 and 2009 was approximately 5% and 258%, respectively. The effective tax rate for 2010 currently assumes utilization of U.S. net operating loss carryforwards against projected taxable income and a liability for alternative minimum tax. It also includes a non-cash tax expense arising from purchase accounting for in-process research and development acquired in the Targanta acquisition. It is possible that our full-year effective tax rate could change because of discrete events, specific transactions or receipt of new information affecting our current projections.

In 2009, we established a full valuation allowance against our deferred tax assets and continue to evaluate their future realizability 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 an income tax benefit.

**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 2006 and 2004, we have incurred losses on an annual basis since our inception. We had \$227.5 million in cash, cash equivalents and available for sale securities as of September 30, 2010.

*Cash Flows*

As of September 30, 2010, we had \$105.2 million in cash and cash equivalents, as compared to \$72.2 million as of December 31, 2009. Our primary sources of cash during the nine months ended September 30, 2010 included \$48.6 million of net cash provided by operating activities and \$2.8 million in net cash provided by financing activities. These amounts were partially offset by the \$19.3 million in net cash that we used in investing activities.

Net cash provided by operating activities was \$48.6 million in the nine months ended September 30, 2010, compared to net cash used in operating activities of \$3.5 million in the nine months ended September 30, 2009. The cash provided by operating activities in the nine months ended September 30, 2010 included net income of \$46.1 million and non-cash items of \$16.7 million consisting



**Table of Contents**

primarily of stock-based compensation expense of \$6.8 million and depreciation and amortization of \$5.1 million. Cash provided by operating activities in the nine months ended September 30, 2010 also includes a decrease of \$14.2 million due to changes in working capital items.

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

For the nine months ended September 30, 2010, we received \$2.8 million 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 Angiomax, Cleviprex 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 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;

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 two law firms with respect to the 404 patent and the PTO's denial of our application to extend the term of the patent;

our ability to resupply the market with Cleviprex and the extent to which Cleviprex is commercially successful in the United States;

the extent to which we can successfully establish a commercial infrastructure outside the United States;

the cost of acquisitions or licensing of development-stage products, approved products, or businesses and strategic or licensing arrangements with companies that fit within our growth strategy;

the progress, level, timing and cost of our research and development activities related to our clinical trials and non-clinical studies with respect to Angiomax, Cleviprex and our products in development;

the cost and outcomes of regulatory submissions and reviews for approval of Cleviprex outside the United States 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.



**Table of Contents**

If our existing resources are insufficient to satisfy our liquidity 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, if we acquire additional product candidates or businesses, or if we determine that raising additional capital would be in our interest and the interests of our stockholders, we may 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, and 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:*

As we have previously disclosed, the PTO, rejected the application under the Hatch-Waxman Act for an extension of the term of the 404 patent beyond March 23, 2010 because in its view the application was not timely filed. We refer to such application herein as the patent term extension application filing. We filed suit against the PTO, the FDA and HHS seeking to set aside the denial of our patent term extension application filing. 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. On August 5, 2010, the PTO granted an interim extension of the term of the 404 patent until August 13, 2011. The PTO has sent our application to the FDA for a determination on the length of the extension of the 404 patent.

On August 19, 2010, APP filed a motion to intervene for the purpose of appeal in our case against the PTO, FDA and HHS. 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 and we are awaiting a decision by the court.

We have entered into agreements with the law firms involved in the patent term extension application filing that suspend the statute of limitations on any claims against them for failing to make a timely filing. We have entered into a similar agreement with Biogen Idec, one of our licensors for Angiomax, relating to any claims, including claims for damages and/or license termination, that Biogen Idec may bring relating to the patent term extension application filing. Such claims by Biogen Idec could have a material adverse effect on our financial condition, results of operations, liquidity or business. In the third quarter of 2009, we initiated discussions, which are still ongoing, with the law firms involved in the patent term extension application filing and are currently in related discussions with Biogen Idec and HRI with respect to the possible resolution of potential claims among the parties.

**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 the 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. A summary of these aggregate contractual obligations was included in our Annual Report on Form 10-K for the year ended December 31, 2009. As of September 30, 2010, we have inventory-related purchase commitments totaling \$2.8 million during 2010, \$25.3 million during 2011 and \$14.7 million for 2012 for Angiomax bulk drug substance.

**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 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

## **Table of Contents**

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, 2009. 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, 2009 are critical accounting estimates.

### **Off-Balance Sheet Transactions**

We do not maintain any off-balance sheet transactions, arrangements, obligations or other relationships with unconsolidated entities or others that are reasonably likely to have a material current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

### **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. For this purpose, any statements contained herein regarding our strategy, future operations, financial position, future revenue, projected costs, prospects, plans and objectives of management, other than statements of historical facts, are forward-looking statements. The words anticipates, believes, estimates, expects, intends, may, plans, projects, will, would and similar expressions are in forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the results, plans, intentions or expectations expressed or implied in our forward-looking statements. There are a number of important factors that could cause actual results, levels of activity, performance or events to differ materially from those expressed or implied in the forward-looking statements we make. These important factors include our critical accounting estimates described in Part I, Item 2 of this quarterly report on Form 10-Q and the factors set forth under the caption Risk Factors in Part II, Item 1A of this quarterly report on Form 10-Q. Although we may elect to update forward-looking statements in the future, we specifically disclaim any obligation to do so, even if our estimates change, and readers should not rely on those forward-looking statements as representing our views as of any date subsequent to the date of this quarterly report on Form 10-Q.

### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

Market risk is the risk of change in fair value of a financial instrument due to changes in interest rates, equity prices, creditworthiness, financing, exchange rates or other factors. Our primary market risk exposure relates to changes in interest rates in our cash, cash equivalents and available for sale securities. We place our investments in high-quality financial instruments, primarily money market funds, corporate debt securities, asset backed securities and U.S. government agency notes with maturities of less than two years, which we believe are subject to limited interest rate and credit risk. We currently do not hedge interest rate exposure. At September 30, 2010 we held \$227.5 million in cash, cash equivalents and available for sale securities which had an average interest rate of approximately 0.5% and a 10 basis point change in such average interest rate would have had an approximate \$0.2 million impact on our interest income. Of the \$227.5 million, approximately \$222.2 million of cash, cash equivalents and available for sale securities were due on demand or within one year and had an average interest rate of approximately 0.5%. The remaining \$5.3 million were due within two years and had an average interest rate of



approximately 0.4%.

**Table of Contents**

Most of our transactions are conducted in U.S. dollars. We do have certain agreements with parties located outside the United States. Transactions under certain of these agreements are conducted in U.S. dollars, subject to adjustment based on significant fluctuations in currency exchange rates. Transactions under certain other of these agreements are conducted in the local foreign currency. As of September 30, 2010, we had receivables denominated in currencies other than the U.S. dollar. A 10% change in foreign exchange rates would have had an approximate \$0.6 million impact on our other income and cash.

**Item 4. Controls and Procedures**

*Disclosure Controls and Procedures*

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2010. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2010, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

*Changes in Internal Control over Financial Reporting*

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended September 30, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Table of Contents****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. Other than the proceedings discussed 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 U.S. Patent No. 7,528,727, or 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 Parenteral Medicines, Inc. and its related parent entities 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 case above.

On March 23, 2010, the judge in the Eastern District of Pennsylvania consolidated the Teva 727 and 343 patent cases with the Pliva 727 and 343 patent cases (discussed below) and the APP 727 patent case (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 Hrvatska d.o.o. and its related parent entities 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 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

**Table of Contents**

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 and 343 patent cases and the Pliva 727 and 343 patent cases. On the same day, the APP 343 patent case was consolidated with these other cases.

*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 and 343 patents. 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 and 343 patents. 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 and 343 patents and raised counterclaims of non-infringement and invalidity of the 727 and 343 patents. 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. The Court has yet to set a pre-trial schedule and no trial date has been set by the Court.

***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, 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 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 404 patent does 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, 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 404 patent does not expire until at least 10 days after the court issues 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 has sent our patent term extension application to the FDA for a determination on the length of the extension of the 404 patent.



**Table of Contents**

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 and we are awaiting a decision by the court.

**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 quarterly report. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer. In that case, the trading price of our common stock could fall.*

*An updated description of the risk factors associated with our business is set forth below. These risk factors have been updated from those included in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2010, to, among other things, update the risk factors related to our need to achieve our revenue targets or raise additional funds in the future; Angiomax's competition with all categories of anticoagulant drugs; our use of third-party manufacturers; and whether the court order requiring the PTO to consider our application to extend the term of the 404 patent timely filed is successfully challenged or our ability to maintain market exclusivity for Angiomax in the United States through the enforcement of our other U.S. patents covering Angiomax.*

**Risks Related to Our Financial Results*****We have a history of net losses and may not maintain profitability on an annual basis***

Except for 2004 and 2006, we have incurred net losses on an annual basis since our inception. As of September 30, 2010, we had an accumulated deficit of approximately \$298.1 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. Although we achieved profitability in 2004 and in 2006, we have not been profitable in any year since 2006. We will likely need to generate significantly 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***

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, Angiomax was our only commercial product and in the three months ended September 30, 2010 our only revenues were from sales of Angiomax. We expect revenues from Angiomax to continue to account for substantially all of our revenues in 2010. The commercial success of Angiomax depends upon:

whether the 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;

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;

**Table of Contents**

our ability to further develop 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;

our success in selling and marketing Angiox in Europe;

the impact of competition from competitive products and generic versions of Angiomax and those competitive products; and

the extent to which we and our international distributors are successful in marketing Angiomax.

We intend to continue to develop Angiomax for use in additional patient populations. Even if we are successful in expanding the Angiomax label, the expanded label may not result in higher revenue or income on a continuing basis.

As of September 30, 2010, our inventory of Angiomax was \$28.6 million and we had inventory-related purchase commitments to Lonza Braine totaling \$2.8 million for 2010, \$25.3 million for 2011 and \$14.7 million for 2012 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 a limited number of domestic wholesalers 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 such distributor, wholesalers and distribution partners***

We distribute Angiomax and Cleviprex in the United States through a sole source distribution model. Under this model, we sell Angiomax and Cleviprex to our sole source distributor, 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 revenue from sales of Angiomax in the United States is now 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.

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, regardless 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.

***Failure to achieve our revenue targets or raise additional funds in the future may require us to delay, reduce the scope of, or eliminate one or more of our planned activities***

We expect to devote substantial resources to our research and development efforts and to our sales, marketing and manufacturing programs associated with Angiomax, Cleviprex 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 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;

**Table of Contents**

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 two law firms with respect to the 404 patent and the PTO's denial of our application to extend the term of the patent;

our ability to resupply the market with Cleviprex and the extent to which Cleviprex is commercially successful in the United States;

the extent to which we can successfully establish a commercial infrastructure outside the United States;

the cost of acquisitions and licenses of development-stage products, approved products, or businesses and strategic or licensing arrangements with companies that fit within our growth strategy;

the progress, level, timing and cost of our research and development activities related to our clinical trials and non-clinical studies with respect to Angiomax, Cleviprex and our products in development;

the cost and outcomes of regulatory submissions and reviews for approval of Angiomax in additional countries and Cleviprex outside the United States, Australia and New Zealand 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, or if we determine that raising additional capital would be in our interest and the interests of our stockholders, we may sell equity or debt securities or seek additional financing through other arrangements. Any sale of equity or debt securities may result in dilution to our stockholders. Any debt financing may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures. 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 harm our 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 and in development, including orally administered agents, which we compete with or may compete with in the future. Angiomax competes with 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,

**Table of Contents**

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 in high risk patients. Physicians may chose to use heparin combined with GP IIb/IIIa inhibitors due their years of experience with this combination therapy and reluctance to change existing hospital protocols and pathways.

Angiomax may compete 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 but not necessarily several of the drugs together.

If the court order requiring the PTO to consider our application to extend the term of the 404 patent timely filed is successful 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 following the expiration of the six-month period of market exclusivity resulting from our pediatric study of Angiomax. 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 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 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. Our success will depend on our ability to acquire or license, and then develop, products and apply technology, as well as our ability to establish and maintain markets for our products. 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. Accordingly, our competitors may develop or license products or other novel technologies that are more effective, safer, more convenient or less costly than existing products or technologies or products or technologies that are being developed by us or may obtain regulatory approvals for products more rapidly than we are able. Technological developments by others may render our products or products in development noncompetitive. We may not be successful in establishing or maintaining technological competitiveness.

**Table of Contents*****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, since the original results of REPLACE-2 were announced in 2002, additional hospitals have granted Angiomax formulary approval and hospital demand for the product has increased. These trends, however, may not continue. 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***

We believe that as a result of 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 the controversy regarding the use of drug-eluting stents, the number of PCI procedures performed in the United States declined in 2007. PCI procedure volume increased in 2008 from 2007 levels, but has not returned to the level of PCI procedures performed prior to the 2007 decline and declined again in 2009 from 2008 levels. We believe that the 2009 decline was due, in part, to economic pressures on our hospital customers in 2009. The decline in the number of PCI procedures has had a direct impact on our net revenues. 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.

***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***

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, with European operations being our initial focus. If we are unable to expand our global operations successfully and in a timely manner, the growth of our business may be limited and our business, operating results and financial condition may be harmed. Such expansion may be more difficult, more expensive or take longer than we anticipate, and we may not be able to successfully market and sell our products globally.

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

***The success of our global operations may be adversely affected by international risks and uncertainties. If these operations are not successful, our 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 and Targanta, we are conducting research and



**Table of Contents**

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 currency fluctuations;

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. In addition, we are subject to the Foreign Corrupt Practices Act, any violation of which could create a substantial liability for us and also cause a loss of reputation in the market.

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

Acceptable levels of coverage and reimbursement of drug treatments by government payers such as Medicare and Medicaid programs, private health insurers and other organizations will have a significant effect on our ability to successfully commercialize our product candidates. 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 payers, 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 to 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 to establish and obtain reimbursement, and reimbursement approval 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.

Third-party payers 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. Additionally, the newly enacted Health Care Reform Act has provided sweeping health care reform, which may impact the prices of drugs and the number of procedures that are performed. In addition to the newly enacted 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, including the impact of the Health Care Reform Act, could adversely impact our business and future results. If these 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.

**Table of Contents**

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, and these negotiated prices are 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.



**Table of Contents**

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, we will not be able to market our product candidates 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. Except for Angiomax in the United States, Europe and other countries and Cleviprex in the United States, Australia and New Zealand, 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 our product candidates;

diminish our competitive advantage; and

defer or decrease our receipt of revenue.

The regulatory review and approval process to obtain marketing approval for a new drug or indication 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 candidate involved. The regulatory authorities globally 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 candidate. 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.

***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***

The FDA has approved Angiomax for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing PCI and patients undergoing PCI with or at risk of HIT/HITTS. Angiox is approved for patients undergoing PCI, for adult patients with ACS and for the treatment of STEMI patients undergoing primary PCI in the European Union. One of our key objectives is to expand the indications for which Angiomax is approved. 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 candidate involved. The regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that any data submitted is insufficient for approval and require additional pre-clinical, clinical or other studies. In addition, varying interpretations

**Table of Contents**

of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a new indication product candidate.

For example, in 2006 we received a non-approvable letter from the FDA in connection with our application to market Angiomax in patients with or at risk of HIT/HITTS undergoing cardiac surgery. While we have indicated to the FDA that we are evaluating potential next steps, the FDA may require additional studies which may require the expenditure of substantial resources. Even if any such studies are undertaken, we might not be successful in obtaining regulatory approval for this indication in a timely manner or at all. 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 letter, the FDA indicated that the basis of their decision involved the appropriate use and interpretation of non-inferiority trials, including the ACUITY trial. We disagree with the FDA on these issues and continue to evaluate how to respond to the FDA's views on the ACUITY trial. 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 stated that the CHAMPION-PLATFORM trial would not meet the goal of demonstrating persuasive evidence of clinical effectiveness that could form the basis for regulatory approval.

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

**Table of Contents**

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 are subject, our products could be subject to restrictions or withdrawal from the market 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;

interruption of production;

operating restrictions;

untitled or warning letters;

injunctions;

finest and other monetary penalties;

the imposition of civil or criminal penalties; and

unanticipated expenditures.

**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 Angiomax, Cleviprex and our other products in development and a limited number of suppliers to carry out all fill-finish activities***

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 each of Angiomax, Cleviprex and our products in development from single source suppliers, and rely on a limited number of manufacturers to carry out all fill-finish activities for each of Angiomax, Cleviprex and our products in development.

We do not currently have alternative sources for production of bulk drug substance or to carry out fill finish activities. 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, or obtain such manufacturing or supply on commercially reasonable terms or on a timely basis. 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 a new purchase order. Only a limited number of manufacturers are capable of manufacturing Angiomax, Cleviprex and our products in development. Moreover, consolidation within the pharmaceutical manufacturing industry could further reduce the number of manufacturers capable of producing our products, or



**Table of Contents**

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, which could cause us to experience significant delays in receiving an adequate supply of Angiomax, Cleviprex and our products in development. 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 Angiomax or Cleviprex on a timely basis, which could reduce our revenue, and 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 or at all.

***If third parties on whom we rely to manufacture and support the development and commercialization of our products do not fulfill their obligations, 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 Angiomax and Cleviprex 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 Angiomax, Cleviprex, our products in development or any additional products 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 Angiomax, Cleviprex, our products in development or any additional products 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;

**Table of Contents**

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.

Angiomax and Cleviprex and our 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 Angiomax, Cleviprex and our 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, 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 Angiomax, Cleviprex and our products in development.

On December 16, 2009, we conducted a voluntary recall of 11 lots of Cleviprex due to the presence of visible particulate matter that was deposited at the bottom of some vials and was observed in such vials during a routine annual inspection. On March 17, 2010, we extended our voluntary recall to include four additional manufactured lots of Cleviprex that also showed visible particulate matter that was deposited at the bottom of some vials. As a result of the recalls and the manufacturing issues that resulted in the recalls, we are not able to supply the market at this time with existing inventory or using the current manufacturing method. We are cooperating with the FDA and our contract manufacturer on these recalls and to remedy the problem at the manufacturing site. We expect to resupply the market with drug product and resume selling Cleviprex in the third quarter of 2011. Any delay in resupplying the market with Cleviprex would reduce our revenue.

***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

**Table of Contents**

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 court 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. Generic competition for Angiomax would have a material adverse effect on the 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 in connection with our litigation against the PTO, the FDA and HHS. We 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. On August 3, 2010, the court granted our motion for summary judgment and ordered the PTO to consider our patent term extension application for the 404 patent 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 has sent our patent term extension application to the FDA for a determination on the length of the extension of the 404 patent.

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. 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 and we are awaiting a decision by the court.

We also continue to pursue legislative action to address the term of the 404 patent; however, a bill may not be introduced or enacted. We plan to continue to explore alternatives to extend the term of the 404 patent, but we may not be successful in doing so.

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 October 2009, January 2010, June 2010 and August 2010, 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 in the U.S. District Court for the District of Delaware. We cannot predict the outcome of these lawsuits.

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 successful challenged either by APP in its pending appeal or in a separate challenge of the term of the 404 patent, 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 following the expiration of the six-month period of market exclusivity resulting from our pediatric study of Angiomax. 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.

**Table of Contents**

***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 Angiomax, Cleviprex and each of our 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, our stock price could suffer. 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 for 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 rejection of the application under the Hatch-Waxman Act for an extension of the term of the 404 patent on the grounds that, in its view, it was not timely filed. We have also entered into agreements with the law firms involved in the patent extension filing that suspend the statute of limitations on our claims against them for the filing. In the third quarter of 2009, we initiated discussions with the two law firms involved in the patent extension filing of the application under the Hatch-Waxman Act and are currently in related discussions with Biogen Idec and HRI with respect to the possible resolution of the potential claims among the parties. We may not reach an 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.

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.

**Table of Contents**

We exclusively licensed patents and patent applications for Angiomax, Cleviprex and each of our other 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.

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. During the period in which these matters are pending, the uncertainty of their outcome may cause our stock price to decline. In addition, 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. In addition, involvement in litigation can be expensive.

***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, it will adversely affect our business***

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. 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

**Table of Contents**

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*

We sell and generate 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. In 2008 and 2009, 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. 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. 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 licenses 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 develop or 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. 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 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.





**Table of Contents**

**Risks Related to Our Common Stock**

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

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

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

Our common stock has been and in the future may be subject to substantial price volatility. From January 1, 2008 to November 5, 2010, 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 the our U.S. Angiomax patents;
- the outcome of any challenge of the August 3, 2010 court order requiring the PTO to consider our application to extend the term of the 404 patent timely filed, either by APP in its pending appeal or in a separate challenge;
- the terms of any settlement with Biogen Idec, HRI or the two law firms with respect to the principal U.S. patent covering Angiomax and the PTO's 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.

**Table of Contents**

***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 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.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

THE MEDICINES COMPANY

Date: November 9, 2010

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

55

---

**Table of Contents**

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
10.1	First Amendment to lease for 400 Fifth Avenue, Waltham, MA, dated as of June 30, 2010 by and between ATC Realty Sixteen Inc. and the registrant
10.2	Form of restricted stock agreement under the registrant's Amended and Restated 2004 Stock Incentive Plan
31.1	Chairman and Chief Executive Officer Certification pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Chief Financial Officer Certification pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Chairman and Chief Executive Officer Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Chief Financial Officer Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	The following materials from The Medicines Company Quarterly Report on Form 10-Q for the quarter ended September 30, 2010, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Balance Sheet, (ii) the Consolidated Statement of Operations, (iii) the Consolidated Statement of Cash Flow, and (iv) Notes to Consolidated Financial Statements, tagged as blocks of text.