

MEDICINES CO /DE  
Form 10-Q  
November 10, 2008  
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, 2008**

**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 Campus Drive**

**Parsippany, New Jersey**

(Address of principal executive offices)

**07054**

(Zip Code)

Registrant's telephone number, including area code: **(973) 656-1616**

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 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   
(Do not check if a smaller reporting company)

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: As of November 6, 2008, there were 52,280,006 shares of Common Stock, \$0.001 par value per share, outstanding.



Table of Contents

**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>	18
<u>Item 3 - Quantitative and Qualitative Disclosures about Market Risk</u>	31
<u>Item 4 - Controls and Procedures</u>	31
<u>Part II. Other Information</u>	31
<u>Item 1A - Risk Factors</u>	31
<u>Item 6 - Exhibits</u>	46
<u>Signatures</u>	47
<u>Exhibit Index</u>	48

---

Table of Contents

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.

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 intended to identify 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.

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

**THE MEDICINES COMPANY**  
**CONSOLIDATED BALANCE SHEETS**

(in thousands, except share and per share amounts)

(unaudited)

	September 30, 2008	December 31, 2007
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 78,357	\$ 88,127
Available for sale securities	127,338	133,986
Accrued interest receivable	1,338	1,598
Accounts receivable, net of allowances of \$2,228 and \$1,157 at September 30, 2008 and December 31, 2007	42,906	25,584
Inventory	25,498	35,468
Prepaid expenses and other current assets	13,352	7,425
Total current assets	288,789	292,188
Fixed assets, net	6,448	3,245
Intangible assets, net	16,495	14,929
Deferred tax assets	45,264	46,018
Other assets	10,239	5,136
Total assets	\$ 367,235	\$ 361,516
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 7,044	\$ 9,793
Accrued expenses	54,338	73,827
Deferred revenue	10,005	
Total current liabilities	71,387	83,620
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$1.00 par value per share, 5,000,000 shares authorized; no shares issued and outstanding		
Common stock, \$.001 par value per share, 125,000,000 shares authorized; 52,279,084 and 51,866,398 issued and outstanding at September 30, 2008 and December 31, 2007, respectively	52	52
Additional paid-in capital	560,119	537,027
Accumulated deficit	(263,751)	(259,444)
Accumulated other comprehensive (loss) income	(572)	261
Total stockholders' equity	295,848	277,896
Total liabilities and stockholders' equity	\$ 367,235	\$ 361,516

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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Net revenue	\$ 88,126	\$ 62,191	\$ 254,285	\$ 185,237
Operating expenses:				
Cost of revenue	22,089	16,157	63,121	49,031
Research and development	44,075	18,741	82,518	53,948
Selling, general and administrative	42,865	55,499	117,004	109,457
Total operating expenses	109,029	90,397	262,643	212,436
Loss from operations	(20,903)	(28,206)	(8,358)	(27,199)
Other income	1,070	2,664	5,256	7,965
Loss before income taxes	(19,833)	(25,542)	(3,102)	(19,234)
Benefit from (provision for) income taxes	6,616	1,899	(1,205)	(545)
Net loss	\$ (13,217)	\$ (23,643)	\$ (4,307)	\$ (19,779)
Basic loss per common share	\$ (0.25)	\$ (0.46)	\$ (0.08)	\$ (0.38)
Shares used in computing basic loss per common share	51,941	51,672	51,842	51,596
Diluted loss per common share	\$ (0.25)	\$ (0.46)	\$ (0.08)	\$ (0.38)
Shares used in computing diluted loss per common share	51,941	51,672	51,842	51,596

See accompanying notes to unaudited condensed consolidated financial statements.



Table of Contents

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

	Nine Months Ended September 30,	
	2008	2007
Cash flows from operating activities:		
Net loss	\$ (4,307)	\$ (19,779)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	1,916	1,180
Acquired in-process research and development	21,373	
Amortization of net premiums and discounts on available for sale securities	(254)	(851)
Non-cash foreign currency loss	127	
Non-cash stock compensation expense	17,375	11,285
Loss on sales disposal of fixed assets		1
(Gain) loss on sales of available for sale securities	(48)	2
Deferred tax provision	754	
Tax benefit from option exercises	193	
Changes in operating assets and liabilities:		
Accrued interest receivable	260	(410)
Accounts receivable	(15,686)	(9,073)
Inventory	9,930	12,512
Prepaid expenses and other current assets	(5,976)	1,216
Accounts payable	(2,698)	(4,401)
Accrued expenses	(20,318)	29,838
Deferred revenue	10,005	(2,814)
Net cash provided by operating activities	12,646	18,706
Cash flows from investing activities:		
Purchases of available for sale securities	(118,228)	(108,990)
Maturities and sales of available for sale securities	124,352	94,060
Purchases of fixed assets	(3,624)	(733)
Acquisition of intangible assets	(2,000)	(14,929)
Investment in pharmaceutical company	(5,000)	
Acquisition of business, net of cash acquired	(23,534)	
Net cash used in investing activities	(28,034)	(30,592)
Cash flows from financing activities:		
Proceeds from issuances of common stock, net	5,525	9,307
Net cash provided by financing activities	5,525	9,307
Effect of exchange rate changes on cash	93	21
Decrease in cash and cash equivalents	(9,770)	(2,558)
Cash and cash equivalents at beginning of period	88,127	75,530
Cash and cash equivalents at end of period	\$ 78,357	\$ 72,972
Supplemental disclosure of cash flow information:		
Interest paid	\$	\$
Taxes paid	\$ 2,435	\$ 424
Supplemental disclosure of non-cash investing activities:		
Fixed asset additions included in current liabilities	\$ 201	\$

See accompanying notes to unaudited condensed consolidated financial statements.



**Table of Contents**



**THE MEDICINES COMPANY**



**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**





**1. Nature of Business**

The Medicines Company (the Company) was incorporated in Delaware on July 31, 1996. The Company is a global pharmaceutical company focused on advancing the treatment of critical care patients through the delivery of innovative, cost-effective medicines to the worldwide hospital marketplace. In December 2000, the U.S. Food and Drug Administration (the FDA) approved the Company's product, Angiomax® (bivalirudin), a direct thrombin inhibitor, for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty (PTCA). In June 2005, the FDA approved new prescribing information for Angiomax to also include patients undergoing percutaneous coronary intervention (PCI), in addition to those undergoing PTCA. In November 2005, the FDA approved the expansion of the label to include PCI patients with or at risk of heparin-induced thrombocytopenia and thrombosis syndrome, a complication of heparin administration known as HIT/HITTS that can result in limb amputation, multi-organ failure and death. In September 2004, the Company received authorization from the European Commission to market Angiomax as Angiox® (bivalirudin) in the member states of the European Union for use as an anticoagulant in combination with aspirin in patients undergoing PCI. In January 2008, the European Agency for the Evaluation of Medical Products (EMA) authorized the use of Angiox in adult patients with acute coronary syndrome (ACS), specifically patients with unstable angina or non-ST segment elevation myocardial infarction planned for urgent or early intervention, when used with aspirin and clopidogrel.

On August 1, 2008, the FDA approved the Company's product, Cleviprex (clevidipine butyrate) injectable emulsion, a dihydropyridine calcium channel blocker, for the reduction of blood pressure when oral therapy is not feasible or not desirable. The Company began selling Cleviprex in the United States in September 2008.

In addition to Angiomax and Cleviprex, the Company is currently developing two other pharmaceutical products, cangrelor and CU-2010, as potential acute care hospital products. Cangrelor is an intravenous antiplatelet agent that prevents platelet activation and aggregation, which the Company believes has potential advantages in the treatment of vascular disease. In August 2008, the Company acquired Curacyte Discovery GmbH (Curacyte Discovery) and its lead compound, CU-2010. CU-2010 is a small molecule serine protease inhibitor being developed for the prevention of blood loss during surgery. The Company expects to initiate Phase I clinical trials of CU-2010 in the first half of 2009. The Company has invested, and plans to continue investing, in the development of cangrelor and CU-2010, as well as to continue investing in development programs to expand the indications for which Angiomax and Cleviprex are approved.

Prior to July 1, 2007, the Company concentrated its commercial sales and marketing resources on the United States hospital market, relying on third-party distributors to market and distribute the product outside the United States, and revenues to date have been generated principally from sales of Angiomax in the United States. On July 1, 2007, the Company entered into a series of agreements with Nycomed Danmark ApS (Nycomed) pursuant to which the Company terminated its distribution agreement with Nycomed and reacquired all rights held by Nycomed with respect to the distribution and marketing of the Company's product Angiox in the European Union (excluding Spain, Portugal and Greece) and the former Soviet republics (collectively, the Territory). Under these arrangements, the Company assumed control of the marketing of Angiox immediately and Nycomed agreed to provide, on a transitional basis, sales operations services, which ended December 31, 2007, and product distribution services through 2008. The Company assumed the control of the distribution of Angiox in the majority of the countries in the Territory during the third quarter of 2008 and expects to assume control of the distribution of Angiox in the remaining countries in the Territory by December 31, 2008. To support the marketing, sale and distribution of Angiox in the countries formerly served by Nycomed, the Company is taking the necessary steps to develop its business infrastructure outside the United States.

**2. Significant Accounting Policies**

*Basis of Presentation*

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

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.

Table of Contents

The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation. The Company has no unconsolidated subsidiaries or investments accounted for under the equity method.

The results of operations for the three and nine months ended September 30, 2008 are not necessarily indicative of the results that may be expected for the entire fiscal year or any other quarter of the fiscal year ending December 31, 2008. 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, 2007, filed with the Securities and Exchange Commission (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 and liabilities and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

*Cash, Cash Equivalents and Available for Sale Securities*

The Company considers all highly liquid investments purchased with original maturities at the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents included cash of \$39.1 million and \$20.0 million at September 30, 2008 and December 31, 2007, respectively. Cash and cash equivalents at September 30, 2008 and December 31, 2007 included investments of \$39.3 million and \$68.1 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. The Company measures all original maturities from the date the investment was originally purchased by the Company.

The Company considers securities with original maturities at the date of purchase of greater than three months to be available for sale securities. Securities under this classification are recorded at fair market value and unrealized gains and losses are recorded as a separate component of stockholders' equity. The estimated fair value of the available for sale securities is determined based on quoted market prices or rates for similar instruments. In addition, the cost of debt securities in this category is adjusted for amortization of premium and accretion of discount to maturity. The Company evaluates securities with unrealized losses to determine whether such losses are other than temporary.

At September 30, 2008 and December 31, 2007, the Company held available for sale securities with a fair value totaling \$127.3 million and \$134.0 million, respectively. These available for sale securities included various United States government agency notes, corporate debt securities and asset backed securities. At September 30, 2008, \$123.3 million of the Company's available for sale securities had maturities within one year and \$4.0 million had maturities which were more than one year but less than two years. At December 31, 2007, all of the Company's available for sale securities had maturities within one year.

*Fair Value Measurements*

On January 1, 2008, the Company adopted the provisions of Statement of Financial Accounting Standards (SFAS) No. 157, Fair Value Measurement (SFAS No. 157) for financial assets and liabilities. As permitted by Financial Accounting Standards Board (FASB) Staff Position 157-2 (FSP 157-2), the Company elected to defer until January 1, 2009 the adoption of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis. SFAS No. 157 provides a framework for measuring fair value under GAAP and requires expanded disclosures regarding fair value measurements. SFAS No. 157 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. SFAS No. 157 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 include investments in available for sale securities.

**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. At September 30, 2008, the Company did not have any Level 2 assets or liabilities.

Table of Contents

**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. At September 30, 2008, the Company did not have any Level 3 assets or liabilities.

The following table sets forth the Company's financial assets that were measured at fair value on a recurring basis at September 30, 2008 by level within the fair value hierarchy. The Company did not have any nonfinancial assets or liabilities that were measured or disclosed at fair value on a recurring basis at September 30, 2008. As required by SFAS No. 157, 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	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance at September 30, 2008
	(in thousands)			
Available for sale securities	\$ 127,338	\$	\$	\$ 127,338

**Investments**

The Company accounts for its investment in a minority interest of a company over which it does not exercise significant influence on the cost method in accordance with Accounting Principles Board (APB) No. 18, The Equity Method of Accounting for Investments in Common Stock. Under the cost method, an investment is carried at cost until it is sold or there is evidence that changes in the business environment or other facts and circumstances suggest it may be other than temporarily impaired based on criteria outlined in FAS Staff Position Nos. FAS 115-1 and FAS 124-1 and on Emerging Issues Task Force Issue No. 03-1, The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments. These non-marketable securities have been classified as investments and included in other assets on the consolidated balance sheets.

**Restricted Cash**

On October 11, 2007, the Company entered into a new lease for office space in Parsippany, New Jersey. The Company plans to move its principal executive offices to the new space in the fourth quarter of 2008. Restricted cash of \$5.0 million at September 30, 2008 and December 31, 2007, which is included in other assets on the consolidated balance sheets, collateralizes outstanding letters of credit associated with such lease. The funds are invested in certificates of deposit. Under the lease, the Company agreed to increase the amount of the letter of credit on the Phase I Estimated Commencement Date, as defined in the lease, by an additional \$3.0 million for a total letter of credit of \$8.0 million. The Company anticipates the Phase I Estimated Commencement Date will occur in the fourth quarter of 2008. 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 further reduction upon the achievement of certain regulatory and operational milestones relating to the Company's products and by approximately \$1.3 million on August 1, 2009 and annually for each of the following six years; provided, however, in no event will the amount of the letter of credit be reduced below approximately \$1.0 million.

***Revenue Recognition***

*Product Sales.* In March 2007, the Company entered into an agreement with a third party to distribute Angiomax in the United States through a sole source distribution model. Cleviprex, which was launched in the United States in September 2008, is distributed under the same sole source distribution model with the same third party. Under this model, the Company sells Angiomax and Cleviprex to its sole source distributor, 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. Prior to adopting this sole source distribution model, the Company sold Angiomax to these wholesalers directly and these wholesalers then sold Angiomax to hospitals. Outside of the United States, the Company sells Angiomax either directly to hospitals or to wholesalers or international distributors, which then sell Angiomax to hospitals.

The Company does not recognize revenue from product sales until there is persuasive evidence of an arrangement, delivery has occurred, the price is fixed and determinable, the buyer is obligated to pay the Company, the obligation to pay is not contingent on resale of the product, the buyer has economic substance apart from the Company, the Company has no obligation to bring about sale of the product, the amount of returns can be reasonably estimated and collectibility is reasonably assured.

Table of Contents

Initial gross wholesaler orders of Cleviprex in the United States in the third quarter of 2008 totaled \$10.0 million and were recorded as deferred revenue as the Company could not estimate certain adjustments to gross revenue, including returns. Under this deferred revenue model, the Company does not recognize revenue upon product shipment to its sole source distributor. Instead, upon product shipment, the Company invoices its sole source distributor, records deferred revenue at gross invoice sales price, classifies the cost basis of the product held by the sole source distributor as finished goods inventory held by others and includes such cost basis amount within prepaid expenses and other current assets on its consolidated balance sheets. The Company expects to recognize revenue associated with Cleviprex when hospitals purchase product from the sole source distributor or wholesaler. The Company expects to recognize Cleviprex revenue upon shipment to its sole source distributor in the same manner as it recognizes Angiomax revenue when it has sufficient information to develop reasonable estimates of expected returns and other adjustments to gross revenue.

The Company records allowances for chargebacks and other discounts or accruals for product returns, rebates and fee-for-service charges at the time of sale, and reports revenue net of such amounts. In determining the amounts of certain allowances and accruals, the Company must make significant judgments and estimates. For example, in determining these amounts, the Company estimates hospital demand, buying patterns by hospitals and group purchasing organizations from wholesalers and the levels of inventory held by wholesalers and by its sole source distributor. Making these determinations involves estimating whether trends in past wholesaler and hospital buying patterns will predict future product sales. The Company receives data periodically from its sole source distributor and wholesalers on inventory levels and levels of hospital purchases and the Company considers this data in determining the amounts of these allowances and accruals.

The nature of the Company's allowances and accruals requiring critical estimates, and the specific considerations it uses in estimating their amounts are as follows:

- *Product returns.* The Company's customers have the right to return any unopened product during the 18-month period beginning six months prior to the labeled expiration date and ending 12 months after the labeled expiration date. As a result, in calculating the accrual for product returns, the Company must estimate the likelihood that product sold might not be used within six months of expiration and analyze the likelihood that such product will be returned within 12 months after expiration.

In estimating the likelihood of product being returned, the Company relies on information from the sole source distributor and wholesalers regarding inventory levels, measured hospital demand as reported by third-party sources and internal sales data. The Company also considers the past buying patterns of the sole source distributor and wholesalers, the estimated remaining shelf life of product previously shipped and the expiration dates of product currently being shipped.

At September 30, 2008 and December 31, 2007, the Company's accrual for Angiomax product returns was \$1.8 million and \$3.1 million, respectively. Included within the accrual at September 30, 2008 and December 31, 2007 is a reserve of \$1.7 million and \$3.0 million, respectively, that the Company established for existing inventory at Nycomed that Nycomed has the right to return. A 10% change in the Company's accrual for Angiomax product returns would have had an approximate \$0.2 million effect on the Company's reported net revenue for the three and nine months ended September 30, 2008.

- *Chargebacks and rebates.* Although the Company primarily sells Angiomax and Cleviprex to a sole source distributor in the United States, the Company typically enters into agreements with hospitals, either

directly or through group purchasing organizations acting on behalf of their hospital members, in connection with the hospitals' purchases of Angiomax and Cleviprex. Based on these agreements, most of the Company's hospital customers have the right to receive a discounted price for Angiomax and Cleviprex and volume-based rebates for Angiomax on product purchases. In the case of discounted pricing, the Company typically provides a credit to the sole source distributor, or a chargeback, representing the difference between the sole source distributor's acquisition list price and the discounted price. In the case of the volume-based rebates, the Company typically pays the rebate directly to the hospitals.

As a result of these agreements, at the time of product shipment, the Company estimates the likelihood that Angiomax sold to the sole source distributor might be ultimately sold to a contracting hospital or group purchasing organization. The Company also estimates the contracting hospital's or group purchasing organization's volume of purchases.



Table of Contents

The Company bases its estimates on certain industry data, hospital purchases and the historic chargeback data it receives from its sole source distributor, most of which the sole source distributor receives from wholesalers, which detail historic buying patterns and sales mix for particular hospitals and group purchasing organizations, and the applicable customer chargeback rates and rebate thresholds.

The Company's allowance for Angiomax chargebacks was \$1.2 million at September 30, 2008 and \$0.6 million at December 31, 2007. A 10% change in the Company's allowance for Angiomax chargebacks would have had an approximate \$0.1 million effect on the Company's reported net revenue for the three and nine months ended September 30, 2008. The Company's accrual for Angiomax rebates was \$0.9 million at September 30, 2008 and \$1.7 million at December 31, 2007. A 10% change in the Company's accrual for Angiomax rebates would have had an approximate \$0.1 million effect on the Company's reported net revenue for the three and nine months ended September 30, 2008.

- *Fees-for-service.* The Company offers discounts to certain wholesalers and its sole source distributor based on contractually determined rates for certain services. The Company estimates its fee-for-service accruals and allowances based on historical sales, wholesaler and distributor inventory levels and the applicable discount rate. The Company's discounts are accrued at the time of the sale and are typically settled with the wholesalers or sole source distributor within 60 days after the end of each respective quarter. At September 30, 2008 and December 31, 2007, the Company's Angiomax fee-for-service accruals and allowances were \$2.1 million and \$1.7 million, respectively. A 10% change in the Company's Angiomax fee-for-service accruals and allowances would have had an approximate \$0.2 million effect on the Company's reported net revenue for the three and nine months ended September 30, 2008.

The Company has adjusted its allowances for chargebacks and accruals for product returns, rebates and fees-for-service in the past based on actual sales experience, and the Company will likely be required to make adjustments to these allowances and accruals in the future. The Company continually monitors its allowances and accruals and makes adjustments when the Company believes actual experience may differ from its estimates.

***International Distributors***

Under the Company's agreements with its primary international distributors, including Nycomed under the distribution agreement that was terminated in July 2007, the Company sells its product to these distributors at a fixed transfer price. The established transfer price is typically determined once per year, prior to the first shipment of Angiomax to the distributor each year. The minimum selling price used in determining the transfer price is 50% of the average net unit selling price.

Revenue from the sale of distribution rights during 2007 includes the amortization of milestone payments. These milestone payments are recorded as deferred revenue until contractual performance obligations have been satisfied, and they are typically recognized ratably over the term of these agreements. When the period of deferral cannot be specifically identified from the contract, the Company must estimate the period based upon other critical factors contained within the contract. The Company reviews these estimates at least annually, which could result in a change in the deferral period. In connection with the Nycomed transaction (described in note 8 of these condensed consolidated financial statements), the Company wrote-off approximately \$2.7 million of deferred revenue during the third quarter of 2007, which amount represented the unamortized portion of deferred revenue related to milestone payments received from Nycomed in 2004 and 2002.

*Revenue from Collaborations*

Under the terms of the transitional distribution agreement with Nycomed, the Company is entitled to receive a specified percentage of Nycomed's net sales of Angiox to third parties. In the event the Angiox sold was purchased by Nycomed from the Company prior to July 1, 2007, the amount the Company is entitled to receive in connection with such sale is reduced by the amount previously paid by Nycomed to the Company for such product. Accordingly, revenue related to the transitional distribution agreement with Nycomed is not recognized until the product is sold by Nycomed to a hospital customer. For the three months ended September 30, 2008, the Company recorded \$0.6 million of net revenue from sales made by Nycomed of approximately \$1.4 million under the transitional distribution agreement. For the nine months ended September 30, 2008, the Company recorded \$3.3 million of net revenue from sales made by Nycomed of approximately \$7.3 million under the transitional distribution agreement. Such amounts were recorded as revenue from collaborations and are included in net revenue on the Company's consolidated statements of operations.

Table of Contents***Inventory***

Inventory is recorded upon the transfer of title from the Company's vendors. Inventory is stated at the lower of cost or market value and valued using first-in, first-out methodology. Angiomax and Cleviprex bulk substance is classified as raw materials and its costs are determined using acquisition costs from the Company's contract manufacturers. Work-in-progress costs of filling, finishing and packaging are recorded against specific product batches. The Company obtains all of its Angiomax bulk drug substance from Lonza Braine, S.A. 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, 2008, the Company had inventory-related purchase commitments for Angiomax bulk drug substance totaling \$8.7 million during 2008 and \$19.4 million during 2009. 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, 2008</b>	<b>December 31, 2007</b>
	<b>(in thousands)</b>	
Raw materials	\$ 9,864	\$ 18,573
Work-in-progress	8,348	11,130
Finished goods	7,286	5,765
<b>Total</b>	<b>\$ 25,498</b>	<b>\$ 35,468</b>

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 allowances for excess or obsolete inventory in the future.

***Fixed Assets***



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

Fixed assets are stated at cost. Depreciation is provided using the straight-line method based on estimated useful lives or, in the case of leasehold improvements, over the lesser of the useful lives or the lease terms.

### *Impairment of Long-Lived Assets*



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

The Company evaluates the recoverability of its long-lived assets, including amortizable intangible assets, if circumstances indicate an impairment may have occurred pursuant to SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. This analysis is performed by comparing the respective carrying values of the assets to the current and expected future cash flows, on an undiscounted basis, to be generated from such assets. If such analysis indicates that the carrying value of these assets is not recoverable, the carrying value of such assets is reduced to fair value through a charge to the consolidated statements of income.

### *Research and Development*





Research and development costs are expensed as incurred.

***Stock-Based Compensation***

Effective January 1, 2006, the Company adopted the fair value recognition provisions of FASB Statement No. 123 (revised 2004) Share-Based Payment (SFAS No. 123(R)), and is recognizing expense using the accelerated expense attribution method specified in FASB Interpretation No. (FIN) 28, Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans. SFAS No. 123(R) requires companies to recognize compensation expense in an amount equal to the fair value of all share-based awards granted to employees.

In accordance with SFAS No. 123(R), the Company recorded approximately \$6.0 million and \$17.4 million of stock-based compensation expense for the three and nine months ended September 30, 2008, respectively. For the three and nine months ended September 30, 2007, the Company recorded approximately \$4.1 million and \$11.3 million of stock-based compensation expense, respectively. As of September 30, 2008, the Company had approximately \$24.5 million of total unrecognized compensation costs related to share-based employee compensation arrangements granted under the Company's equity compensation plans. The Company expects to recognize this cost over a weighted average period of 1.48 years.

Table of Contents

During the nine months ended September 30, 2008, the Company issued 412,686 shares of its common stock in connection with the exercise of stock options, grants of restricted stock and purchases under its Employee Stock Purchase Plan (the ESPP). During the nine months ended September 30, 2007, the Company issued 613,660 shares of its common stock in connection with the exercise of stock options, grants of restricted stock and purchases under its ESPP. Cash received from exercise of stock options and purchases through the ESPP during the nine months ended September 30, 2008 and 2007 was approximately \$5.5 million and \$9.3 million, respectively, and is included within the financing activities section of the consolidated statements of cash flows.

At September 30, 2008, there were 2,922,194 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.

***Recent Accounting Pronouncements***

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations* (SFAS No. 141(R)), to replace SFAS No. 141, *Business Combinations*. SFAS No. 141(R) requires use of the acquisition method of accounting, defines the acquirer, establishes the acquisition date and broadens the scope to all transactions and other events in which one entity obtains control over one or more other businesses. This statement is effective for financial statements issued for fiscal years beginning on or after December 15, 2008 with earlier adoption prohibited. While there will be no impact to the Company's financial statements on the accounting for acquisitions completed prior to December 31, 2008, the adoption of SFAS No. 141(R) on January 1, 2009 could materially change the accounting for business combinations consummated after that date.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements* an amendment of ARB No. 51 (SFAS No. 160). SFAS No. 160 establishes accounting and reporting standards for the noncontrolling interest in a subsidiary and for the retained interest and gain or loss when a subsidiary is deconsolidated. This statement is effective for financial statements issued for fiscal years beginning on or after December 15, 2008 with earlier adoption prohibited. The Company does not expect the adoption of SFAS No. 160 to have a material impact on its financial statements as the Company currently does not have any noncontrolling interests. However, the adoption of SFAS No. 160 could materially change the accounting for such interests outstanding as of, or subsequent to, the date of adoption.

***Income Taxes***

The Company provides for income taxes in accordance with SFAS No. 109, *Accounting for Income Taxes* (SFAS No. 109) and FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* an interpretation of FASB Statement No. 109 (FIN 48).

On January 1, 2007, the Company adopted FIN 48, which requires the use of a two-step approach for recognizing and measuring tax benefits taken or expected to be taken in a tax return and disclosures regarding uncertainties in income tax positions. The first step is recognition: the Company determines whether it is more likely than not that a tax position will be sustained upon examination, including resolution of any related appeals or litigation processes, based on the technical merits of the position. In evaluating whether a tax position has met the more-likely-than-not recognition threshold, the Company presumes that the position will be examined by the appropriate taxing authority that has full knowledge of all relevant information. The second step is measurement: a tax position that meets the more-likely-than-not recognition threshold is measured to determine the amount of benefit to recognize in the financial statements. The tax position is measured at the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement. The adoption of FIN 48 by the Company did not

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

have a material impact on the Company's financial condition or results of operation and resulted in no cumulative effect of accounting change being recorded as of January 1, 2007. On January 1, 2007, the Company reduced its deferred tax asset attributable to certain tax credits by approximately \$1.2 million to appropriately measure the amount of such deferred tax asset in accordance with FIN 48. This adjustment did not affect the net deferred tax asset because such asset was subject to a valuation allowance. The recognition of this tax benefit may impact the effective income tax rate if such tax benefit is more likely than not to be realized when such benefit is recognized. The Company does not anticipate a significant change in its unrecognized tax benefits in the next twelve months. The Company is no longer subject to federal, state or foreign income tax audits for tax years prior to 2003, however such taxing authorities can review any net operating losses utilized by the Company in years subsequent to 2003.

In accordance with SFAS No. 109, deferred tax assets and liabilities are determined based on differences between financial reporting and income tax bases of assets and liabilities, as well as net operating loss carryforwards, and are measured using the enacted tax rates and laws in effect when the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance to reflect the uncertainty associated with ultimate realization.

Table of Contents

The Company recognizes potential interest and penalties relating to income tax positions as a component of the provision for income taxes.

### 3. Net Loss per Share

The following table sets forth the computation of basic and diluted net loss per share for the three and nine months ended September 30, 2008 and 2007:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
	(in thousands, except per share amounts)			
<b>Basic and diluted</b>				
Net loss	\$ (13,217)	\$ (23,643)	\$ (4,307)	\$ (19,779)
Weighted average common shares outstanding, basic	52,136	51,808	52,027	51,703
Less: weighted average unvested restricted common shares outstanding	195	136	185	107
Net weighted average common shares outstanding, basic	51,941	51,672	51,842	51,596
Plus: net effect of dilutive stock options and restricted common shares				
Weighted average common shares outstanding, diluted	51,941	51,672	51,842	51,596
Loss per share, basic	\$ (0.25)	\$ (0.46)	\$ (0.08)	\$ (0.38)
Loss per share, diluted	\$ (0.25)	\$ (0.46)	\$ (0.08)	\$ (0.38)

Basic loss 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 table below provides details of the outstanding options and restricted stock for the three and nine months ended September 30, 2008 and 2007. The number of dilutive common stock equivalents was calculated using the treasury stock method.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
	(in thousands)			
Weighted average options outstanding	10,611	7,519	9,924	7,289
Weighted average options included in computation of diluted loss per share	10,611	7,519	9,924	7,289

Weighted average options considered anti-dilutive and excluded from the computation of diluted loss per share				
Weighted average restricted shares outstanding	195	136	185	107
Weighted average restricted shares included in computation of diluted loss per share				
Weighted average unvested restricted common shares considered anti-dilutive and excluded from the computation of diluted loss per share	195	136	185	107

**4. Comprehensive Loss**

The Company reports comprehensive loss and its components in accordance with the provisions of SFAS No. 130, Reporting Comprehensive Income. Comprehensive loss includes net loss, unrealized gain (loss) on available for sale securities and currency translation adjustments. Comprehensive loss for the three and nine months ended September 30, 2008 and September 30, 2007 is detailed below.

Table of Contents

Comprehensive Loss	Three Months ended September 30,		Nine Months ended September 30,	
	2008	2007	2008	2007
	(in thousands)			
Net loss	\$ (13,217)	\$ (23,643)	\$ (4,307)	\$ (19,779)
Unrealized (loss) gain on available for sale securities	(680)	209	(824)	176
Foreign currency translation adjustment	30	6	(9)	23
Comprehensive loss	\$ (13,867)	\$ (23,428)	\$ (5,140)	\$ (19,580)

**5. Income Taxes**

During the three months ended September 30, 2008, the Company recorded a benefit from income taxes of \$6.6 million based on a loss before taxes during this period of \$19.8 million. This resulted in an effective tax rate of approximately 33% for the three months ended September 30, 2008. The benefit recorded during the third quarter of 2008 is attributable to the decrease in the Company's U.S. income since June 30, 2008. The benefit recorded was not in excess of the provision that was recorded during the first six months of 2008. The Company continues to believe that the realization of its U.S. deferred tax assets as of September 30, 2008 is more likely than not. The Company did not record a benefit from income taxes on losses incurred from international operations as it is not more likely than not that the Company will recognize a benefit from the international deferred tax assets. During the three months ended September 30, 2007 the Company recorded a \$1.9 million tax benefit based on a loss before income taxes of \$25.5 million. This tax benefit equaled the amount of the deferred tax provision that was recorded during the first six months of 2007.

For the nine months ended September 30, 2008, the Company recorded a \$1.2 million provision for income taxes based on a loss before taxes of \$3.1 million. The provision for income taxes was recorded based upon U.S. taxable income and the Company did not record a benefit from income taxes on the Company's losses incurred from its international operations as it is not more likely than not that the Company will recognize a benefit from the international deferred tax assets. During the nine months ended September 30, 2007, the Company recorded a provision for income tax of \$0.5 million based upon a loss before income taxes during this period of \$19.2 million. The Company did not record a deferred tax benefit for the losses incurred in the nine months ended September 30, 2007, as the Company believed that the realization of the deferred tax assets associated with those losses was not more likely than not.

During the three months ended December 31, 2006, the Company reduced a portion of the valuation allowances that had been recorded in prior years since the realization of these future benefits was determined to be more likely than not. The amount of the deferred tax asset considered realizable is subject to change based on estimates of future taxable income during the carryforward period. If the Company is profitable, these deferred tax assets are available to offset future income taxes. Factors that could significantly impact the Company's valuation allowance include but are not limited to future projections of taxable income, tax legislation, rulings by relevant tax authorities, the progress of ongoing tax audits, the regulatory approval of products currently under development, extension of the patent rights relating to Angiomax, failure to achieve future anticipated revenues or the implementation of tax planning strategies in connection with the Company's European expansion. The Company will continue to evaluate the realizability of its deferred tax assets and liabilities and will adjust such amounts in light of changing facts and circumstances. Should the Company further reduce or increase the valuation allowance on deferred tax assets, a current year tax benefit or expense would be recognized and future periods would then include income taxes at a higher or lower rate than the effective rate in the period that the adjustment is made.

At December 31, 2007, net operating losses available to offset future taxable income for federal income tax purposes were approximately \$197.0 million. If not utilized, federal net operating loss carryforwards will expire at various dates beginning in 2019 and ending in 2026. In 1998 and 2002, the Company experienced a change in ownership as defined in Section 382 of the Internal Revenue Code. Section 382 can

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

potentially limit a company's ability to use net operating losses, tax credits and other tax attributes in periods subsequent to a change in ownership. Of the \$197.0 million of the Company's federal net operating losses, \$61.3 million is subject to limitations through 2010. However, based on the market value of the Company at such dates, the Company believes that these ownership changes will not significantly impact its ability to use net operating losses or tax credits in the future to offset taxable income.

Table of Contents**6. Investment**

On July 2, 2008, the Company made a short term convertible loan of \$5.0 million to a specialty pharmaceutical company with expertise in drug development. This loan converted into 2.7 million shares of convertible preferred stock in the third quarter of 2008. The \$5.0 million has been classified as investments and is included in other assets on the Company's consolidated balance sheets. The Company holds less than 20% of the issued and outstanding shares of the specialty pharmaceutical company and does not have significant influence over the company. Accordingly, the Company has accounted for the investment under the cost method and included it in other assets on the Company's consolidated balance sheets.

**7. Curacyte Discovery Acquisition**

In August 2008, the Company acquired Curacyte Discovery, a wholly owned subsidiary of Curacyte AG. Curacyte Discovery, a German limited liability company, is primarily engaged in the discovery and development of small molecule serine protease inhibitors. Its lead compound, CU-2010, is being developed for the prevention of blood loss during surgery. In connection with the acquisition, the Company paid Curacyte AG an upfront payment of \$14.5 million (approximately \$22.9 million) and agreed to pay a contingent milestone payment of \$10.5 million if the Company elects to continue to proceed with clinical development of CU-2010 and possible future sales royalty payments and a commercial milestone payment.

The total cost of the acquisition was approximately \$23.7 million which included a purchase price of approximately \$22.9 million and direct acquisition costs of \$0.8 million. The results of Curacyte Discovery's operations since the acquisition date have been included in the Company's consolidated financial statements. Below is a summary which details the assets and liabilities acquired as a result of the acquisition:

	(in thousands)	
<i>Acquired Assets:</i>		
Total current assets	\$	1,970
Fixed assets		1,273
Other assets		51
In-process research and development		21,373
Total acquired assets		24,667
<i>Acquired Liabilities:</i>		
Total current liabilities		(1,004)
Total purchase price	\$	23,663

The purchase price was allocated to the estimated fair value of assets acquired and liabilities assumed based on a preliminary valuation and management estimates. Approximately \$21.4 million of the purchase price was allocated to in-process research and development and was expensed upon completion of the acquisition. This amount was recorded as research and development in the consolidated statements of operations. The Company expects to finalize the purchase price allocation within one year from the date of the acquisition, pending final valuation.



**8. Nycomed Agreements**

On July 1, 2007, the Company entered into a series of agreements with Nycomed (collectively, the Agreements) pursuant to which the Company terminated its prior distribution agreement with Nycomed and reacquired all rights to develop, distribute and market the Company's product Angiox in the Territory. Prior to entering into the Agreements, Nycomed served as the exclusive distributor of Angiox in the Territory pursuant to a sales, marketing and distribution agreement, dated March 25, 2002, as amended. The Territory does not include Spain, Greece and Portugal, which are covered by another third-party distributor.

Pursuant to the Agreements, the Company and Nycomed agreed to transition to the Company the Angiox rights held by Nycomed. Under these arrangements, the Company assumed control of the marketing of Angiox immediately and Nycomed agreed to provide, on a transitional basis, sales operations services, which ended December 31, 2007, and product distribution services through 2008. The Company assumed control of the distribution of Angiox in the majority of countries in the Territory during the third quarter of 2008 and anticipates taking control of the distribution in the remaining countries in the Territory by the end of 2008.

Table of Contents

Under the terms of the transitional distribution agreement with Nycomed, upon the sale by Nycomed to third parties of vials of Angiox purchased by Nycomed from the Company prior to July 1, 2007 (the existing inventory), Nycomed is required to pay the Company a specified percentage of Nycomed's net sales of Angiox, less the amount previously paid by Nycomed to the Company for the existing inventory. Under the transitional distribution agreement, Nycomed had the right to return any existing inventory as of June 30, 2008 for the price paid by Nycomed to the Company for such inventory. Included within the Company's accrual for product return is a reserve of \$1.7 million and \$3.0 million, at September 30, 2008 and December 31, 2007, respectively. During the third quarter of 2008, the Company reduced the reserve by \$1.3 million as Nycomed sold a portion of its existing inventory during the third quarter of 2008.

Under the transitional services agreement the Company had entered into with Nycomed, Nycomed agreed to perform detailing and other selling, sales management, product/marketing management, medical advisor, international marketing and certain pharmacovigilance services in accordance with an agreed upon marketing plan through December 31, 2007. The Company agreed to pay Nycomed's personnel costs, plus an agreed upon markup, for the performance of the services, in accordance with a budget detailed by country and function. In addition, the Company agreed to pay Nycomed's costs, in accordance with a specified budget, for performing specified promotional activities during the term of the services agreement. These amounts were included in selling, general and administrative expense on the condensed consolidated statements of operations as the Company received an identifiable benefit from these services and could reasonably estimate their fair value. This agreement terminated on December 31, 2007.

The Company has incurred total costs of \$45.7 million in connection with the reacquisition of the rights to develop, distribute and market Angiox in the Territory. This amount includes payments of \$20.0 million, \$15.0 million and \$5.0 million paid to Nycomed on July 2, 2007, January 15, 2008 and July 8, 2008, respectively, as well as the \$5.0 million payment made on July 8, 2008 related to the Company obtaining European Commission approval to market Angiox for ACS, which occurred in January 2008.

In the third quarter of 2007, the Company recorded approximately \$30.8 million as expense attributable to the termination of the prior distribution agreement with Nycomed. The \$30.8 million expense was offset in part by the write-off of approximately \$2.7 million of deferred revenue, which amount represented the unamortized portion of deferred revenue related to milestone payments received from Nycomed in 2004 and 2002. Such amounts were included in selling, general and administrative expense on the consolidated statements of operations for the year ended December 31, 2007. The Company allocated approximately \$14.9 million of the costs associated with the reacquisition of the rights to develop, distribute and market Angiox in the European Union to intangible assets. These intangible assets are being amortized over the remaining patent life of Angiox, which expires in 2015. The period in which amortization expense will be recorded reflects the pattern in which the economic benefits of the intangible assets are expected to be consumed.

## 9. Intangible Assets

The following information details the carrying amounts and accumulated amortization of our intangible assets:

	As of September 30, 2008			As of December 31, 2007		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Identifiable intangible assets						
Customer relationships	\$ 7,457	\$ 216	\$ 7,241	\$ 7,457	\$	\$ 7,457

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

Distribution agreement	4,448	128	4,320	4,448	4,448
Trademarks	3,024	87	2,937	3,024	3,024
Cleviprex milestones	2,000	3	1,997		
<b>Total</b>	\$ 16,929	\$ 434	\$ 16,495	\$ 14,929	\$ 14,929

The Company recorded \$2.0 million of intangible assets during the third quarter of 2008 in connection with payments required to be made upon the FDA's approval on August 1, 2008 of Cleviprex for the reduction of blood pressure when oral therapy is not feasible or not desirable. As a result of such approval, the Company paid a \$1.5 million milestone payment to AstraZeneca under the terms of the Company's patent license agreement with AstraZeneca and a \$0.5 million payment to Hospira for development work under the Company's manufacturing agreement with Hospira.

Amortization expense was approximately \$0.1 million and \$0.4 million for the three and nine months ended September 30, 2008, respectively. The Company expects amortization expense related to these intangible assets to be \$0.1

Table of Contents

million for the remainder of 2008. The Company expects annual amortization expense related to these intangible assets to be \$1.2 million, \$1.8 million, \$2.4 million, \$2.4 million and \$3.0 million for the years ending December 31, 2009, 2010, 2011, 2012 and 2013, respectively, with the balance of \$5.6 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.

**10. Contingencies**

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. In accordance with SFAS No. 5, Accounting for Contingencies, 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.

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**



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

We are a global pharmaceutical company focused on advancing the treatment of critical care patients through the delivery of innovative, cost-effective medicines to the worldwide hospital marketplace. We have two marketed products, Angiomax® (bivalirudin) and Cleviprex (clevidipine butyrate) injectable emulsion, one product in late-stage development, cangrelor, and one compound, CU-2010, scheduled to enter clinical development in the first half of 2009. We market Angiomax to interventional cardiology customers for its approved uses in patients undergoing percutaneous coronary intervention, or PCI, including in patients with or at risk of heparin-induced thrombocytopenia and thrombosis syndrome, a complication of heparin administration known as HIT/HITTS that can result in limb amputation, multi organ failure and death. In Europe, we also market Angiomax for use in adult patients with acute coronary syndrome, or ACS. We market Cleviprex to anesthesiology/surgery, critical care and emergency department practitioners in the United States for its approved use for the reduction of blood pressure when oral therapy is not feasible or not desirable. We are also developing Angiomax and Cleviprex for additional indications.

We market and sell Angiomax and Cleviprex in the United States with a joint sales force that, as of September 30, 2008, consisted of 190 representatives and managers experienced in selling to hospital customers. In Europe, we market and sell Angiox® (bivalirudin), the name under which we sell Angiomax in Europe, with a sales force that we are currently building and expects to total approximately 70 sales representatives and managers by the end of the first quarter of 2009. Cleviprex is not approved for sale outside the United States. Our revenues to date have been generated principally from sales of Angiomax in the United States. We are increasing our sales force worldwide in connection with the expansion of our sales and marketing efforts in Europe, approval of the label expansion for the use of Angiox for ACS in Europe, and the approval by the U.S. Food and Drug Administration, or FDA, of Cleviprex for the reduction of blood pressure when oral therapy is not feasible or not desirable.

Research and development expenses represent costs incurred for product acquisition, clinical trials, activities relating to regulatory filings and manufacturing development efforts. We outsource much of our clinical trials 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, 2008, we had an accumulated deficit of approximately \$263.8 million. We expect to make substantial expenditures to further develop and commercialize our products, including costs and expenses associated with clinical trials, regulatory approvals and commercialization. Although we achieved profitability in 2004 and in 2006, we do not expect to be profitable in 2008 primarily as a result of the costs incurred in connection with our acquisition of Curacyte Discovery GmbH, or Curacyte Discovery, in August 2008. We were also not profitable in 2007, primarily as a result of the costs incurred in connection with the Nycomed transaction, which is described below. We will likely need to generate significantly greater revenue in future periods to achieve and maintain profitability in light of our planned expenditures.

In March 2007, we entered into an agreement with a third party to distribute Angiomax in the United States through a sole source distribution model. Cleviprex, which was launched in the United States in September 2008, is distributed under the same sole source distribution model with the same third party. Under this model, we sell Angiomax and Cleviprex to our sole source distributor, 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. Prior to adopting this sole source distribution model, we sold Angiomax to these wholesalers directly and these wholesalers then sold Angiomax to hospitals. We began selling Angiomax under this revised distribution system during the quarter ended March 31, 2007. Outside the United States, we sell Angiomax either directly to hospitals or to wholesalers or international distributors, which then sell Angiomax to hospitals.

Table of Contents

On July 1, 2007, we entered into a series of agreements with Nycomed pursuant to which we terminated our prior distribution agreement with Nycomed and reacquired all development, commercial and distribution rights for Angiox in the European Union (excluding Spain, Portugal and Greece) and the former Soviet republics, or collectively, the Nycomed territory. Prior to entering into the Nycomed agreements, Nycomed served as the exclusive distributor of Angiox in the Nycomed territory pursuant to a sales, marketing and distribution agreement, dated March 25, 2002, as amended. Pursuant to the Nycomed agreements, we and Nycomed agreed to transition the Angiox rights held by Nycomed to us. Under these arrangements, we assumed control of the marketing of Angiox immediately and Nycomed agreed to provide, on a transitional basis, sales operations services, which ended December 31, 2007, and product distribution services through 2008. We assumed control of the distribution of Angiox in the majority of countries in the Nycomed territory during the third quarter of 2008 and anticipate assuming control of the distribution in the remaining countries by the end of 2008.

Under the terms of the transitional distribution agreement with Nycomed, upon the sale by Nycomed to third parties of vials of Angiox purchased by Nycomed from us prior to July 1, 2007, which we refer to as existing inventory, Nycomed agreed to pay us a specified percentage of Nycomed's net sales of Angiox, less the amount previously paid by Nycomed for the existing inventory. Under the transitional distribution agreement, Nycomed had the right to return to us any existing inventory as of June 30, 2008 for the price paid by Nycomed to us for such inventory. We recorded a reserve of \$3.0 million in the fourth quarter of 2007 for the existing inventory at Nycomed which we did not believe would be sold by Nycomed prior to June 30, 2008 and would be subject to return in accordance with such agreement. During the third quarter of 2008, we reduced the reserve by \$1.3 million as Nycomed sold a portion of its existing inventory during the third quarter of 2008.

Under the transitional services agreement we had entered into with Nycomed, Nycomed performed detailing and other selling, sales management, product/marketing management, medical advisor, international marketing and certain pharmacovigilance services in accordance with an agreed upon marketing plan which ended December 31, 2007. Nycomed remains responsible for safety reporting for as long as it sells Angiox in the Nycomed territory. Pursuant to the agreement, we agreed to pay Nycomed's personnel costs, plus an agreed upon markup, for the performance of the services, in accordance with a budget detailed by country and function. In addition, we agreed to pay Nycomed's costs, in accordance with a specified budget, for performing specified promotional activities during the term of the services agreement. This services agreement terminated on December 31, 2007.

We have incurred total costs of \$45.7 million in connection with the reacquisition of the rights to develop, distribute and market Angiox in the Nycomed territory. This amount includes the milestone payments of \$20.0 million paid to Nycomed on June 2, 2007, \$15.0 million paid to Nycomed on January 15, 2008 and \$5.0 million paid to Nycomed on July 8, 2008, as well as an additional \$5.0 million paid to Nycomed on July 8, 2008 for our obtaining European Commission approval to market Angiox for ACS in January 2008.

During the third quarter of 2007, we allocated \$30.8 million of these costs as expense attributable to the termination of the prior distribution agreement with Nycomed and \$14.9 million to intangible assets. The \$30.8 million expense was offset in part by the write-off of approximately \$2.7 million of deferred revenue, which amount represented the unamortized portion of deferred revenue related to milestone payments received from Nycomed in 2004 and 2002. Such amounts were included in selling, general and administrative expense on the consolidated statements of operations for the year ended December 31, 2007. We allocated approximately \$14.9 million of the costs associated with the reacquisition of the rights to develop, distribute and market Angiox in the European Union to intangible assets. These intangible assets are being amortized over the remaining patent life of Angiox, which expires in 2015. The period in which amortization expense will be recorded reflects the pattern in which the economic benefits of the intangible assets are expected to be consumed.

To support the marketing, sales and distribution efforts of Angiox, we are taking the necessary steps to develop our business infrastructure outside the United States. We have conducted market research to examine the number of PCI procedures performed globally and to identify key opinion leaders on a global basis. We are enhancing our worldwide development, sales and marketing capabilities, with European operations being our initial focus. We believe that by establishing operations in Europe for Angiox, we will be positioned to commercialize our pipeline of



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

acute care product candidates upon their approval, including Cleviprex, cangrelor and CU-2010, in Europe.

In August 2008, we acquired Curacyte Discovery, a wholly owned subsidiary of Curacyte AG. Curacyte Discovery, a German limited liability company, is primarily engaged in the discovery and development of small molecule serine protease inhibitors. Its lead compound, CU-2010, is being developed for the prevention of blood loss during surgery. We expect to initiate Phase I clinical trials of CU-2010 during the first half of 2009. In connection with the acquisition, we paid Curacyte AG an upfront payment of 14.5 million (approximately \$22.9 million) and agreed to pay a contingent milestone payment of 10.5 million if the Company elects to continue to proceed with clinical development of CU-2010 and possible future sales royalty

Table of Contents

payments and a commercial milestone payment.

The total cost of the acquisition was approximately \$23.7 million which included a purchase price of approximately \$22.9 million and direct acquisition costs of \$0.8 million. Since the acquisition date, results of Curacyte Discovery's operations have been included in our consolidated financial statements. The purchase price was allocated to the estimated fair value of assets acquired and liabilities assumed based on a preliminary valuation and management estimates. Approximately \$21.4 million of the purchase price was allocated to in-process research and development and was expensed upon completion of the acquisition. This amount was recorded as research and development in the consolidated statements of operations. The remaining portion of the purchase price was allocated to net tangible assets. We expect to complete the purchase price allocation within one year from the date of the acquisition.

We have accrued for U.S. and state income taxes, for state taxes based on net worth and for a certain amount of income tax in international jurisdictions in our financial statements to the extent these taxes apply. At December 31, 2007, net operating losses available to offset future taxable income for federal income tax purposes were approximately \$197.0 million. If not utilized, federal net operating loss carryforwards will expire at various dates beginning in 2019 and ending in 2026. During 2006, we reduced a portion of our valuation allowance associated with the deferred tax assets because at that time we considered the realization of these assets to be more likely than not. The future utilization of net operating losses and credits may be subject to limitation based upon changes in ownership under the rules of the Internal Revenue Code, or IRC. We experienced changes in ownership as defined by Section 382 of the IRC during the years ended December 31, 1998 and 2002. Based on the market value of our common stock at the time of those changes, we believe there will be no impact on our ability to utilize our net operating losses and credits. Of the \$197.0 million of our federal net operating losses, \$61.3 million is subject to limitations through 2010.

**Application of Critical Accounting Estimates**



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

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

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

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

Our significant accounting policies are more fully described in note 2 of the Unaudited Condensed Consolidated Financial Statements section of this quarterly report on Form 10-Q and note 2 of the Consolidated Financial Statements in our annual report on Form 10-K for the year ended December 31, 2007. 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, stock-based compensation and income taxes 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, 2007 are critical accounting estimates. There have been no significant changes to our critical accounting estimates since December 31, 2007, except with respect to the revenue recognition policy for Cleviprex and our investment in a specialty pharmaceutical company.

In March 2007, we entered into an agreement with a third party to distribute Angiomax in the United States through a sole source distribution model. Cleviprex, which was launched in the United States in September 2008, is distributed under the same sole source distribution model with the same third party. Under this model, we sell Angiomax and Cleviprex to our sole source distributor, 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. Prior to adopting this sole source distribution model, we sold Angiomax to these wholesalers directly and these wholesalers then sold

Table of Contents

Angiomax to hospitals. Outside of the United States, we sell Angiomax either directly to hospitals or to wholesalers or international distributors which then sell Angiomax to hospitals.

We do not recognize revenue from product sales until there is persuasive evidence of an arrangement, delivery has occurred, the price is fixed and determinable, the buyer is obligated to pay us, the obligation to pay is not contingent on resale of the product, the buyer has economic substance apart from us, we have no obligation to bring about sale of the product, the amount of returns can be reasonably estimated and collectibility is reasonably assured.

Initial gross wholesaler orders of Cleviprex in the United States in the third quarter of 2008 totaled \$10.0 million and were recorded as deferred revenue as we could not estimate certain adjustments to gross revenue, including returns. Under this deferred revenue model, we do not recognize revenue upon product shipment. Instead, upon product shipment, we invoice our sole source distributor, record deferred revenue at gross invoice sales price, classify the cost basis of the product held by the sole source distributor as finished goods inventory held by others and include such amount within prepaid expenses and other current assets on our consolidated balance sheets. We expect to recognize the deferred revenue as revenue in the fourth quarter of 2008 when hospitals purchase product from the sole source distributor or wholesaler to which the sole source distributor sells Cleviprex at which time returns are unlikely. We expect to recognize Cleviprex revenue upon shipment to our sole source distributor in the same manner as we recognize Angiomax revenue when we have sufficient information to develop reasonable estimates of expected returns and other adjustments to gross revenue.

On July 2, 2008, we made a short term convertible loan of \$5.0 million to a specialty pharmaceutical company with expertise in drug development. This loan converted into 2.7 million shares of convertible preferred stock in the third quarter of 2008. The \$5.0 million has been classified as investments and is included in other assets on our consolidated balance sheets. We hold less than 20% of the issued and outstanding shares of the specialty pharmaceutical company and do not have significant influence over the company. Accordingly, we have accounted for the investment under the cost method and included it in other assets on our consolidated balance sheets. Under the cost method, an investment is carried at cost until it is sold or there is evidence that changes in the business environment or other facts and circumstances suggest it may be other than temporarily impaired based on criteria outlined in FAS Staff Position Nos. FAS 115-1 and FAS 124-1 and on Emerging Issues Task Force Issue No. 03-1, The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments.

**Table of Contents**

**Results of Operations**





*Three Months Ended September 30, 2008 and 2007*



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

*Net Revenue.* Net revenue increased 42% to \$88.1 million for the three months ended September 30, 2008 as compared to \$62.2 million for the three months ended September 30, 2007. The following table reflects the components of net revenue for the three months ended September 30, 2008 and 2007:

**Net Revenue**

Net Revenue	Three Months Ended September 30,			
	2008 (in thousands)	% of Total Revenue	2007 (in thousands)	% of Total Revenue
<b>Angiomax</b>				
United States sales	\$ 84,979	96%	\$ 60,730	98%
International net revenue	2,556	3%	305	0%
<i>Revenue from collaborations, net</i>	591	1%	1,156	2%
<b>Total net revenue</b>	<b>\$ 88,126</b>	<b>100%</b>	<b>\$ 62,191</b>	<b>100%</b>

Net revenue for the three months ended September 30, 2008 increased compared to the three months ended September 30, 2007, primarily due to the increase in U.S. sales of Angiomax. Sales of Angiomax in the United States increased \$24.2 million, or 40%, due to increased demand by existing hospital customers, the addition of new hospital customers and the price increases we implemented in August 2007 and January 2008. Of the 40% increase in United States sales in the third quarter of 2008 compared to the same quarter in 2007, approximately 24% was related to hospital demand by existing and new customers and approximately 16% was attributable to the price increases.

International net revenue increased \$2.3 million during the three months ended September 30, 2008 compared to the three months ended September 30, 2007. During the fourth quarter of 2007, we recorded a \$3.0 million reserve for existing inventory at Nycomed, which we did not believe would be sold by Nycomed prior to June 30, 2008 and would be subject to return in accordance with our transitional distribution agreement with Nycomed. During the third quarter of 2008, Nycomed sold approximately \$1.3 million of its existing inventory, which resulted in an increase of \$1.3 million to international net revenue and a decrease of the reserve for existing inventory. The existing inventory at September 30, 2008 was \$1.7 million, which represents the amount of inventory subject to return by Nycomed. Approximately \$0.4 million of the increase in international net revenue reflects the direct sales we made after assuming control of the distribution of Angiox in the majority of countries in the Nycomed territory during the third quarter of 2008. We anticipate assuming control of the distribution of Angiox in the remaining countries in the Nycomed territory by the end of 2008. The remaining increase in international net revenue is primarily related to increased orders from our Canadian distributor.

During the three months ended September 30, 2008, we recognized as revenue from collaborations approximately \$0.6 million of net revenue from sales made by Nycomed of approximately \$1.4 million of Angiox under our transitional distribution agreement with Nycomed. For the three months ended September 30, 2007, we recognized as revenue from collaborations approximately \$1.2 million of net revenue from sales made by Nycomed of approximately \$2.7 million under the transitional distribution agreement. Under the terms of this transitional distribution agreement, upon the sale by Nycomed to third parties of vials of Angiox, Nycomed pays us a specified percentage of Nycomed's net sales of Angiox, less the amount previously paid by Nycomed to us for the existing inventory. The decrease in revenue from collaborations is primarily a result of us assuming control of the distribution of Angiox in the majority of countries in the Nycomed territory during the third quarter and such amounts being included in international net revenue.

*Cost of Revenue.* Cost of revenue during the three months ended September 30, 2008 was \$22.1 million, or 25% of net revenue, compared to \$16.2 million, or 26% of net revenue, for the three months ended September 30, 2007. The decrease in cost of revenues as a percentage of net revenue is primarily attributable to an increase in revenue due to the above mentioned price increases we implemented in August 2007 and January 2008. Cost of revenue consisted of expenses in connection with the manufacture of Angiomax sold, royalty expenses under our agreements with Biogen

Idec and Health Research Inc. and the logistics costs of selling Angiomax, such as distribution, storage and handling. Cost of revenue increased \$5.9 million during the three months ended September 30, 2008 compared to the three months ended September 30, 2007. Approximately \$4.2 million of the total cost of revenue increase related to an increase in royalty expense due to higher Angiomax sales and approximately \$1.7 million of the increase related to an increase in logistics costs primarily related to higher Angiomax sales and our costs associated with establishing our European distribution network.

Table of Contents

**Cost of Revenue**

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

Cost of Revenue	Three Months Ended September 30,				% of Total Cost
	2008 (in thousands)	% of Total Cost	2007 (in thousands)	% of Total Cost	
Manufacturing	\$ 5,269	24%	\$ 5,230	33%	
Royalty	13,747	62%	9,583	59%	
Logistics	3,073	14%	1,344	8%	
<b>Total Cost of Revenue</b>	<b>\$ 22,089</b>	<b>100%</b>	<b>\$ 16,157</b>	<b>100%</b>	

*Research and Development Expenses.* Research and development expenses increased \$25.4 million to \$44.1 million for the three months ended September 30, 2008, from \$18.7 million for the three months ended September 30, 2007. The increase primarily reflects the acquisition of Curacyte Discovery in August 2008, which resulted in the inclusion in research and development expense of \$21.4 million of acquisition related in-process research and development. The remaining increase in research and development expenses resulted primarily from an increase in expenditures in connection with expenses associated with the development of Angiomax for additional indications and product lifecycle management activities, increased expenses associated with our cangrelor clinical trials and increased business development expenses. The increase in research and development expenses was partially offset by decreased research and development expenditures in connection with Cleviprex.

The following table identifies, for each of our major research and development projects, our spending for the three months ended September 30, 2008 and 2007. Spending for past periods is not necessarily indicative of spending in future periods.

**Research and Development Spending**

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

Research and Development	Three Months Ended September 30,		% of Total R&D	Three Months Ended September 30,		% of Total R&D
	2008 (in thousands)			2007 (in thousands)		
<b>Angiomax</b>						
Clinical trials	\$ 1,253	3%	\$ 865	5%		
Manufacturing development	968	2%	219	1%		
Administrative and headcount costs	1,035	2%	1,251	7%		
<b>Total Angiomax</b>	<b>3,256</b>	<b>7%</b>	<b>2,335</b>	<b>13%</b>		
<b>Cleviprex</b>						
Clinical trials	925	2%	835	4%		
Manufacturing development	322	1%	558	3%		
Administrative and headcount costs	1,301	3%	3,411	18%		
<b>Total Cleviprex</b>	<b>2,548</b>	<b>6%</b>	<b>4,804</b>	<b>25%</b>		
<b>Cangrelor</b>						
Clinical trials	10,907	25%	7,585	40%		
Manufacturing development	623	1%	1,252	7%		
Administrative and headcount costs	1,192	3%	949	5%		
<b>Total Cangrelor</b>	<b>12,722</b>	<b>29%</b>	<b>9,786</b>	<b>52%</b>		
<b>CU-2010</b>						
Clinical trials		0%		0%		
Manufacturing development		0%		0%		
Administrative and headcount costs	386	1%		0%		
Acquisition related in-process research and development	21,373	48%		0%		
<b>Total CU-2010</b>	<b>21,759</b>	<b>49%</b>		<b>0%</b>		
<b>Other</b>	<b>3,790</b>	<b>9%</b>	<b>1,816</b>	<b>10%</b>		
<b>Total</b>	<b>\$ 44,075</b>	<b>100%</b>	<b>\$ 18,7411</b>	<b>100%</b>		

Angiomax

*Research and development spending related to Angiomax in the three months ended September 30, 2008 increased by approximately \$0.9 million compared to in the three months ended September 30, 2007. Approximately \$0.4*



Table of Contents

*million of the increase relates to an increase in clinical trial expenses. Clinical trial expenses in the three months ended September 30, 2008 and 2007 included research and development expenses that we incurred in connection with a study of Angiomax in the pediatric setting that we began in the first half of 2007 in connection with a written request for such a study that we received from the FDA. The study consists of a single trial to clarify the pediatric dose that provides a pharmacodynamic response equivalent to that observed in the adult population at the approved adult dose. We completed the enrollment of 110 patients during the third quarter of 2008 and expect to file a clinical study report for the pediatric extension with the FDA in the fourth quarter of 2008. Costs incurred in connection with the pediatric study were comparable in the three month periods ended September 30, 2008 and 2007. The three months ended September 30, 2007 also included clinical trial expenses for our 13,819 patient Phase III ACUITY trial, primarily related to data analysis.*

During the three months ended September 30, 2008, Angiomax manufacturing development expenses increased \$0.7 million compared to the three months ended September 30, 2007, primarily due to costs incurred in connection with product lifecycle management activities. Although we plan to continue to incur research and development expenses relating to Angiomax in connection with our efforts to expand the indications for which Angiomax is currently approved and to increase our product lifecycle management activities, we expect spending for Angiomax in the remainder of 2008 continues to decrease as a percentage of our research and development expense.

*Cleviprex*



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

*Research and development expenditures for Cleviprex decreased approximately \$2.3 million during the three months ended September 30, 2008 compared to the same period in 2007. The decrease in research and development expenditures in 2008 primarily reflects increased spending during 2007 in preparation for filing our NDA with the FDA, which we submitted in July 2007. On August 1, 2008, the FDA approved Cleviprex for the reduction of blood pressure when oral therapy is not feasible or not desirable and we launched the product in September 2008.*

*Cangrelor*



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

We are developing cangrelor for potential use as an antiplatelet agent in the acute care settings of the cardiac catheterization laboratory, the operating room and/or the emergency department. Research and development expenditures related to cangrelor increased approximately \$2.9 million in the three months ended September 30, 2008 compared to the same period in 2007 as a result of the two pivotal Phase III clinical trials that we continue to conduct for the evaluation of cangrelor's effectiveness and safety in preventing ischemic events in patients who require PCI. In March 2006, we commenced enrollment of our CHAMPION-PCI trial, one of the two pivotal trials in our Phase III program which we designed to evaluate whether use of intravenous cangrelor is superior to use of clopidogrel tablets in patients undergoing PCI. We commenced enrollment in October 2006 of a second trial, called CHAMPION-PLATFORM, which compares cangrelor plus usual care to placebo plus usual care in patients who require PCI. We currently expect to enroll approximately 9,000 patients in the CHAMPION-PCI trial and 6,400 patients in the CHAMPION-PLATFORM trial.

As of September 30, 2008, we had enrolled approximately 7,300 patients in our CHAMPION-PCI trial and approximately 3,400 patients in our CHAMPION-PLATFORM trial. We plan to complete patient enrollment in both trials in the first half of 2009.

*CU-2010*



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

In August 2008, we acquired Curacyte Discovery and its lead compound CU-2010, which is being developed for the prevention of blood loss during surgery. As a result of the acquisition, we allocated approximately \$21.4 million of the purchase price to in-process research and development and expensed it during the third quarter of 2008. We expect to initiate Phase I clinical trials of CU-2010 in the first half of 2009.

### *Other*

Spending in this category consists of 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. We incur business development expenses in connection with our efforts to evaluate early stage and late stage compounds for development and commercialization and other strategic opportunities. In the three months ended September 30, 2008, spending in this category increased by \$2.0 million compared to the same

Table of Contents

period in 2007, primarily related to an increase in business development activities and increased headcount in our business development department.

In order to support the continued development of Angiomax, Cleviprex and cangrelor, and due to the acquisition of Curacyte Discovery, we expect our annual research and development expenses to increase in 2008 from 2007 levels to between \$104.0 million and \$109.0 million in 2008. We expect this increase in research and development expenses to reflect costs associated with the acquisition of Curacyte Discovery, costs of enrollment of our ongoing Phase III CHAMPION-PCI trial and CHAMPION-PLATFORM trial for cangrelor, our anticipated Phase IIIb trials for Cleviprex and additional manufacturing development costs for Cleviprex and cangrelor. We also anticipate that stock-based compensation expense included in research and development expenses will increase in 2008 as a result of increased stock option grants to new and current employees.

Our success in expanding the approved indications for Angiomax, obtaining marketing approval for Cleviprex globally, or developing and obtaining marketing approval for cangrelor and CU-2010, 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 complete the development of, or the period in which material net cash inflows are expected to commence from, Cleviprex outside the United States, cangrelor or CU-2010 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 sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our 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.* Selling, general and administrative expenses decreased by 23% to \$42.9 million for the three months ended September 30, 2008, from \$55.5 million for the same period in 2007. The decrease in selling, general and administrative expenses of \$12.6 million primarily reflects the \$28.1 million of expenses incurred during the third quarter of 2007 related to the termination of the prior distribution agreement with Nycomed and our reacquisition of all the rights to develop, distribute and market Angiox in the Nycomed territory. The decrease in selling, general and administrative expenses was offset by a \$5.9 million increase in expenses incurred in preparation for the launch of Cleviprex in the United States that occurred in September 2008, a \$7.5 million increase related to headcount expansion, including the expansion of medical science, sales management and global operations teams and a \$1.6 million increase in stock based compensation expense.

We expect selling, general and administrative expenses to increase in the remainder of 2008 from 2007 levels primarily due to increased headcount, increased stock-based compensation expense, expenses to support the launch of Cleviprex and expenses related to our European expansion.

*Other Income.* Other income, which is comprised of interest income and gains and losses on foreign currency transactions, decreased \$1.6 million to \$1.1 million for the three months ended September 30, 2008, from \$2.7 million for the comparable period in 2007. Approximately \$1.2 million of the decrease in other income related to a decrease in interest income due to lower rates of return on our available for sale securities in 2008 and the remaining decrease in other income related to losses on foreign currency transactions.

*Benefit from Income Tax.* During the three months ended September 30, 2008, we recorded a benefit from income taxes of \$6.6 million based on a loss before taxes during this period of \$19.8 million during such period. This resulted in an effective tax rate of approximately 33% for the three months ended September 30, 2008. We recorded a benefit from income taxes on losses incurred in the U.S. The benefit recorded during the third quarter of 2008 is attributable to the decrease in our U.S. income since June 30, 2008 and was not in excess of the provision that was recorded during the first six months of 2008. We continue to believe that the recognition of our U.S. deferred tax assets as of September 30, 2008 is more likely than not.

Table of Contents

We did not record a benefit from income taxes on losses incurred from international operations as it is not more likely than not that we will recognize a benefit from the international deferred tax assets. During the three months ended September 30, 2007, we recorded a \$1.9 million benefit from income taxes based on a loss before income taxes of \$25.5 million during such period. This tax benefit equaled the amount of the deferred tax provision that was recorded during the first six months of 2007.

We will continue to evaluate the realizability of our deferred tax assets and liabilities on a periodic basis, and will adjust such amounts in light of changing facts and circumstances, including but not limited to future projections of taxable income, tax legislation, rulings by relevant tax authorities, the progress of ongoing tax audits, the regulatory approval of products currently under development, extension of the patent rights relating to Angiomax, failure to achieve future anticipated revenues or the implementation of tax planning strategies in connection with our global expansion. If we further reduce or increase the valuation allowance of deferred tax assets in future years, we would recognize a tax benefit or expense.

*Nine Months Ended September 30, 2008 and 2007*



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

*Net Revenue.* Net revenue increased 37% to \$254.3 million for the nine months ended September 30, 2008, as compared to \$185.2 million for the nine months ended September 30, 2007. The following table reflects the components of net revenue for the nine months ended September 30, 2008 and 2007:

**Net Revenue**

Net Revenue	Nine Months Ended September 30,		% of Total Revenue
	2008 (in thousands)	2007 (in thousands)	
<b>Angiomax</b>			
United States sales	\$ 246,317	\$ 182,210	98%
International net revenue	4,644	1,871	1%
<i>Revenue from collaborations, net</i>	3,324	1,156	1%
<b>Total net revenue</b>	<b>\$ 254,285</b>	<b>\$ 185,237</b>	<b>100%</b>

U.S. sales of Angiomax for the nine months ended September 30, 2008 increased compared to the nine months ended September 30, 2007 due to increased sales as a result of increased demand by existing hospital customers, the addition of new hospital customers and the price increases we implemented in August 2007 and January 2008. The increase in sales of Angiomax in the United States also reflects a \$1.4 million credit from our domestic wholesalers in connection with our price increase announced January 2008. Of the 35% increase in United States sales in the nine months ended September 30, 2008 compared to the same period in 2007, approximately 19% was attributable to price increases, 14% was related to hospital demand and 2% was related to the \$1.4 million credit from our domestic wholesalers.

International net revenue increased \$2.8 million during the nine months ended September 30, 2008 compared to the nine months ended September 30, 2007. During the fourth quarter of 2007, we recorded a \$3.0 million reserve for existing inventory at Nycomed, which we did not believe would be sold by Nycomed prior to June 30, 2008 and would be subject to return in accordance with our transitional distribution agreement with Nycomed. During the third quarter of 2008, Nycomed sold approximately \$1.3 million of its existing inventory, which resulted in an increase of \$1.3 million to international net revenue and a decrease of the reserve for existing inventory. The existing inventory at September 30, 2008 was \$1.7 million, which represents the amount of inventory subject to return by Nycomed. Approximately \$0.4 million of the increase in international net revenue reflects the direct sales we made after assuming control of the distribution of Angiox in the majority of countries in the Nycomed territory during the third quarter of 2008. We anticipate assuming control of the distribution of Angiox in the remaining countries in the Nycomed territory by the end of 2008. The remaining increase in international net revenue is primarily related to increased orders from our Canadian distributor.

During the nine months ended September 30, 2008, we recognized as revenue from collaborations approximately \$3.3 million of net revenue from sales made by Nycomed of approximately \$7.3 million under our transitional distribution agreement with Nycomed. Under the terms of this transitional distribution agreement, upon the sale by Nycomed to third parties of vials of Angiox, Nycomed pays us a specified percentage of Nycomed's net sales of Angiox, less the amount previously paid by Nycomed to us for the existing inventory. For the nine months ended September 30, 2007, we recognized as revenue from collaborations approximately \$1.2 million of net revenue from sales made by Nycomed of approximately \$2.7 million under the transitional distribution agreement.

*Cost of Revenue.* Cost of revenue during the nine months ended September 30, 2008 was \$63.1 million, or 25% of net revenue, compared to \$49.0 million, or 26% of net revenue, for the nine months ended September 30, 2007. The decrease



Table of Contents

in cost of revenues as a percentage of net revenue is attributable to an increase in revenue from collaborations, net, and an increase in U.S. sales of Angiomax. Cost of revenue during these periods consisted of expenses in connection with the manufacture of Angiomax sold, royalty expenses under our agreements with Biogen Idec and Health Research Inc. and the logistics costs of selling Angiomax, such as distribution, storage and handling.

Cost of revenue increased \$14.1 million during the nine months ended September 30, 2008 compared to the nine months ended September 30, 2007. Approximately \$9.7 million of the total cost of revenue increase related to an increase in royalty expense due to higher Angiomax sales and approximately \$4.0 million of the increase related to an increase in logistics costs primarily related to higher sales of Angiomax and our costs associated with establishing our European distribution network.

**Cost of Revenue**

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

Cost of Revenue	Nine Months Ended September 30,				% of Total Cost
	2008 (in thousands)	% of Total Cost	2007 (in thousands)	% of Total Cost	
Manufacturing	\$ 15,391	24%	\$ 14,939	30%	
Royalty	39,438	63%	29,780	61%	
Logistics	8,292	13%	4,312	9%	
<b>Total Cost of Revenue</b>	<b>\$ 63,121</b>	<b>100%</b>	<b>\$ 49,031</b>	<b>100%</b>	

*Research and Development Expenses.* Research and development expenses increased by 53% to \$82.5 million for the nine months ended September 30, 2008, from \$53.9 million for the nine months ended September 30, 2007. The increase primarily reflects the acquisition of Curacyte Discovery in August 2008, which resulted in the inclusion in research and development expense of \$21.4 million of acquisition related in-process research and development. The remaining increase in research and development expenses resulted primarily from an increase in expenditures in connection with the development of Angiomax for additional indications and product lifecycle management activities, increased expenses associated with our cangrelor clinical trials and increased business development expenses. The increase in research and development expenses was partially offset by decreased research and development expenditures in connection with Cleviprex.

The following table identifies, for each of our major research and development projects, our spending for the nine months ended September 30, 2008 and 2007. Spending for past periods is not necessarily indicative of spending in future periods.

**Research and Development Spending**

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

Research and Development	Nine Months Ended September 30,			
	2008 (in thousands)	% of Total R&D	2007 (in thousands)	% of Total R&D
<b>Angiomax</b>				
Clinical trials	\$ 4,030	5%	\$ 3,354	6%
Manufacturing development	2,853	3%	384	1%
Administrative and headcount costs	2,436	3%	3,556	7%
<b>Total Angiomax</b>	<b>9,319</b>	<b>11%</b>	<b>7,294</b>	<b>14%</b>
<b>Cleviprex</b>				
Clinical trials	1,815	2%	2,023	4%
Manufacturing development	1,811	2%	2,675	5%
Administrative and headcount costs	3,822	5%	7,883	14%
<b>Total Cleviprex</b>	<b>7,448</b>	<b>9%</b>	<b>12,581</b>	<b>23%</b>
<b>Cangrelor</b>				
Clinical trials	28,551	35%	22,223	41%
Manufacturing development	1,773	2%	3,282	6%
Administrative and headcount costs	3,694	4%	2,819	5%
<b>Total Cangrelor</b>	<b>34,018</b>	<b>41%</b>	<b>28,324</b>	<b>52%</b>
<b>CU-2010</b>				
Clinical trials		0%		0%
Manufacturing development		0%		0%
Administrative and headcount costs	386	1%		0%
Acquisition related in-process research and development	21,373	26%		0%
<b>Total CU-2010</b>	<b>21,759</b>	<b>27%</b>		<b>0%</b>
<b>Other</b>	<b>9,974</b>	<b>12%</b>	<b>5,749</b>	<b>11%</b>
<b>Total</b>	<b>\$ 82,518</b>	<b>100%</b>	<b>\$ 53,948</b>	<b>100%</b>



Table of Contents

*Angiomax*



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

*Research and development spending related to Angiomax in the nine months ended September 30, 2008 increased approximately \$2.0 million compared to the nine months ended September 30, 2007. Angiomax clinical trial costs increased approximately \$0.7 million primarily due to the final milestone payment of \$1.5 million we incurred in connection with the investigator initiated trial called HORIZONS to study Angiomax use in adult acute myocardial infarction patients that we supported. This milestone payment was offset by decreased expenditures in connection with our Phase III ACUITY trial. Angiomax manufacturing and development increased \$2.5 million compared to the nine months ended September 30, 2007, primarily due to product lifecycle management activities. These increases were offset by a decrease in administrative and headcount costs primarily related to our efforts to seek approval from the FDA of an additional indication for Angiomax for the treatment of patients with ACS based on results of our Phase III ACUITY trial.*

*Cleviprex*



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

*Research and development expenditures for Cleviprex decreased approximately \$5.1 million during the nine months ended September 30, 2008 compared to the same period in 2007. The decrease in research and development expenditures primarily reflected spending during 2007 in preparation for filing our NDA with the FDA, which we submitted in July 2007.*

*Cangrelor*



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

Research and development expenditures related to cangrelor increased approximately \$5.7 million in the nine months ended September 30, 2008 compared to the same period in 2007 as a result of our CHAMPION-PCI trial and our CHAMPION-PLATFORM trial that we continue to conduct for the evaluation of cangrelor's effectiveness and safety in preventing ischemic events in patients who require PCI.

*CU-2010*





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

In August 2008, we acquired Curacyte Discovery and its lead compound CU-2010, which is being developed for the prevention of blood loss during surgery. As a result of the acquisition, we allocated approximately \$21.4 million of the purchase price to in-process research and development and expensed it during the third quarter of 2008. We expect to initiate Phase I clinical trials of CU-2010 in the first half of 2009.

### *Other*

Expense in this category consists of 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 the nine months ended September 30, 2008, expense in this category increased by \$4.2 million compared to the same period in 2007 primarily related to an increase in business development activities and increased headcount in our business development department.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses increased by 7% to \$117.0 million for the nine months ended September 30, 2008, from \$109.5 million for the same period in 2007. The increase in selling, general and administrative expense of \$7.5 million includes \$12.0 million of expenses in preparation for the launch of Cleviprex, a \$4.4 million increase in expenses relating to marketing of Angiomax, \$4.9 million in fees related to the building of a business infrastructure in Europe, a \$9.8 million increase related to headcount expansion, including the expansion of medical science, sales management and global operations teams and a \$5.3 million increase in stock-based compensation expense. The increase in selling, general and administrative expenses was partially offset by the \$28.1 million of expenses incurred during the third quarter of 2007 related to the termination of the prior distribution agreement with Nycomed and our reacquisition of all the rights to develop, distribute and market Angiox in the European Union (excluding Spain, Portugal and Greece) and the former Soviet republics.

Table of Contents

*Other Income.* Other income, which is comprised of interest income and gains and losses on foreign currency transactions, decreased \$2.7 million to \$5.3 million for the nine months ended September 30, 2008, from \$8.0 million for the comparable period in 2007. Approximately \$2.4 of the decrease in other income related to a decrease in interest income due to lower rates of return on our available for sale securities in 2008 and the remaining decrease in other income related to losses on foreign currency transactions.

*Provision for Income Tax.* During the nine months ended September 30, 2008 we recorded a \$1.2 million provision for income taxes based on a loss before taxes of \$3.1 million during the period. The provision for income taxes was recorded based upon U.S. taxable income and a benefit from income taxes was not recorded on our losses incurred from international operations as it is not more likely than not that we will recognize a benefit from the international deferred tax assets. During the nine months ended September 30, 2007, we recorded a provision for income tax of \$0.5 million based upon loss before income taxes of \$19.2 million. We did not record a deferred tax benefit for the losses incurred in the nine months ended September 30, 2007, as we believed that the realization of the deferred tax assets associated with those losses was not more likely than not.

**Liquidity and Capital Resources**



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

*Sources of Liquidity.* Since our inception, we have financed our operations principally through the sale of common and preferred stock, sales of convertible promissory notes and warrants, interest income and revenues from sales of Angiomax. Except for 2006 and 2004, we have incurred losses on an annual basis since our inception. We had \$205.7 million in cash, cash equivalents and available for sale securities as of September 30, 2008.

*Cash Flows.* As of September 30, 2008, we had \$78.4 million in cash and cash equivalents, as compared to \$88.1 million as of December 31, 2007. Our decrease in cash and cash equivalents during the nine months ended September 30, 2008 included \$28.0 million in cash used in investing activities, which was partially offset by \$12.6 million in net cash provided by operating activities and \$5.5 million in net cash provided by financing activities.

Net cash provided by operating activities was \$12.6 million for the nine months ended September 30, 2008, compared to net cash provided by operating activities of \$18.7 million for the nine months ended September 30, 2007. The net cash provided by operating activities during the nine months ended September 30, 2008 includes a decrease in cash flow from operations reflecting a net loss of \$4.3 million, offset by non-cash items included in net loss totaling \$41.4 million mainly attributable to the in-process research and development charge of \$21.4 million in connection with the Curacyte Discovery acquisition, stock-based compensation expense of \$17.4 million and deferred tax provision of \$0.8 million. Cash provided by operating activities also reflected a \$24.5 million reduction in cash provided by operating activities associated with changes in working capital items. Included within the changes in working capital items was a \$20.3 million decrease in accrued expenses primarily due to payments made to Nycomed under our transitional distribution agreement. We paid Nycomed \$15.0 million on January 15, 2008 and \$5.0 million on July 8, 2008, as well as an additional \$5.0 million on July 8, 2008 for our obtaining European Commission approval to market Angiox for ACS in January 2008.

For the nine months ended September 30, 2008, \$28.0 million in net cash was used in investing activities, which included the purchase of \$118.0 million of available for sale securities, and purchases of \$3.6 million of fixed assets, offset by \$124.4 million in proceeds from the maturity and sale of available for sale securities. Net cash used in investing activities also included \$2.0 million of milestone payments due upon the approval of Cleviprex, a \$5.0 million investment in a specialty pharmaceutical company and a net cash expenditure of \$23.5 million in connection with the Curacyte Discovery acquisition.

For the nine months ended September 30, 2008, we received \$5.5 million in cash provided by financing activities, which consisted of net proceeds to us from purchases of our stock pursuant to option exercises and 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 the commercialization of our products. Our funding requirements will depend on numerous factors including:

- the extent to which Angiomax is commercially successful globally;
- 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;



Table of Contents

- the expansion of our sales force in connection with the expansion of our sales and marketing efforts in Europe and the launch of Cleviprex in the United States;
- our plan to continue to evaluate possible acquisitions of development-stage products, approved products, or businesses and possible additional strategic or licensing arrangements with companies that fit within our growth strategy;
- the progress, level and timing of our research and development activities related to our clinical trials with respect to Angiomax, Cleviprex, cangrelor and CU-2010;
- the cost and outcomes of regulatory submissions and reviews, including our efforts to obtain approval of the expansion of the Angiomax product label in the United States to include an additional dosing regimen in the treatment of ACS initiated in the emergency room in the United States and approval of Cleviprex in Europe;
- the continuation or termination of third-party manufacturing or sales and marketing arrangements;
- the size, cost and effectiveness of our sales and marketing programs in the United States and outside the United States;
- the status of competitive products; and
- our ability to defend and enforce our intellectual property rights.

If our existing resources are insufficient to satisfy our liquidity requirements due to slower than anticipated revenues from Angiomax and Cleviprex, or higher than anticipated costs in Europe, if we acquire additional product candidates, or if we otherwise believe that raising additional capital would be in our interests and the interests of our stockholders, we may sell equity or debt securities or seek 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.

**Contractual Obligations**

Our long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business. These include commitments related to purchase of inventory of our products, research and development service agreements, 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, 2007. During the nine months ended September 30, 2008, we incurred additional commitments related to the purchase of inventory; as of September 30, 2008, we have inventory-related purchase commitments totaling \$8.7 million during 2008 and \$19.4 million during 2009 for Angiomax bulk drug substance. In addition, in connection with the Curacyte Discovery acquisition in August 2008, we agreed to pay a contingent milestone payment of 10.5 million if we elect to continue to proceed with clinical development of CU-2010 and possible future sales royalty payments and a commercial milestone payment.

Table of Contents

**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, 2008 we held \$205.7 million in cash, cash equivalents and available for sale securities which had an average interest rate of approximately 2.7% and a 10% change in such average interest rate would have had an approximate \$0.2 million impact on our interest income. At September 30, 2008, \$201.7 million of our cash, cash equivalents and available for sale securities were due on demand or within one year and \$4.0 million had maturities which were more than one year but less than two years.

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, 2008, we held cash denominated in currencies other than the U.S. dollar. If the applicable currency exchange rate undergoes a change of 10.0%, we would have had an approximate \$1.0 million impact on our other income and cash.

**Item 4. Controls and Procedures**





*Disclosure Controls and Procedures*



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

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, 2008. 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, 2008, 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*



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

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, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

### Part II. Other Information

#### 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 Annual Report on Form 10-K, to, among other things, include an additional risk factors related to the commercialization of Cleviprex, as well as update the risk factor regarding our revenue being substantially dependent on our sole source distributor and a limited number of domestic wholesalers and international distributors.*

Table of Contents

**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, 2008, we had an accumulated deficit of approximately \$263.8 million. We expect to make substantial expenditures to further develop and commercialize our products, including costs and expenses associated with clinical trials, regulatory approvals and commercialization. Although we achieved profitability in 2004 and in 2006, we do not expect to be profitable in 2008 primarily as a result of the costs incurred in connection with our acquisition of Curacyte Discovery in August 2008. We were also not profitable in 2007, primarily as a result of the costs incurred in connection with the Nycomed transaction. We will likely need to generate significantly greater revenue in future periods to achieve and maintain profitability in light of our planned expenditures. 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 Angiomax in 2001 and, until the approval of Cleviprex by the FDA for the reduction of blood pressure when oral therapy is not feasible or not desirable on August 1, 2008, Angiomax was our only commercial product. The commercial success of Angiomax depends upon:

- its continued acceptance by regulators, physicians, patients and other key decision-makers as a safe, therapeutic and cost-effective alternative to heparin and other products used in current practice or currently being developed;
- our ability to expand the indications for which we can market Angiomax and the clinical data we generate to support expansion of the product label, including our ability to obtain FDA approval of the expansion of the product label for Angiomax in the United States to include an additional dosing regimen in the treatment of ACS initiated in the emergency department and the expansion of the use of Angiomax in the pediatric setting;
- the overall number of PCI procedures performed;
- our ability to develop our European sales and marketing infrastructure and to successfully transition from Nycomed the European sales and marketing of Angiox; and

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

We plan to continue to seek to expand the indications for which we may market Angiomax. Even if we are successful in expanding the Angiomax label, we cannot assure you that the expanded label will result in higher revenue or income on a continuing basis.

As of September 30, 2008, our inventory was \$25.5 million. In addition, we have inventory-related purchase commitments to Lonza Braine totaling \$8.7 million for 2008 and \$19.4 million for 2009 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 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***

In March 2007, we entered into an agreement with a third party to distribute Angiomax in the United States through a sole source distribution model. We have been distributing Cleviprex under this arrangement since we began selling Cleviprex in September 2008. Under this model, we sell Angiomax and Cleviprex to our sole source distributor, 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. Prior to adopting this sole source distribution model, we sold Angiomax to these wholesalers directly and these wholesalers then sold Angiomax to hospitals. We began selling Angiomax and Cleviprex under this distribution model during the quarter ended March 31, 2007 and in September 2008, respectively. For the quarter ended September 30, 2008, the sales to our sole source distributor accounted



Table of Contents

for all of our U.S sales. As our revenue from sales of Angiomax and Cleviprex in the United States is now exclusively from sales to the sole source distributor, we expect that our revenue will continue to be subject to fluctuation from quarter to quarter based on the buying pattern of this sole source distributor.

In August 2008, we assumed control of the distribution of Angiomax in the majority of the countries in which Nycomed distributed Angiomax. We plan to assume control of the distribution in the remaining countries of the Nycomed territory by the end of 2008. In these remaining countries and in other countries globally, we sell Angiomax to international distributors and these distributors then sell Angiomax to hospitals. Our reliance on a small number of distributors 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 our sole source distributor 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 will need to generate significantly greater revenue to achieve and maintain profitability on an annual basis. The development of Angiomax for additional indications, the commercialization of Cleviprex and the development of cangrelor, including clinical trials, manufacturing development and regulatory approvals, and the acquisition and development of additional product candidates by us, such as CU-2010, will require a commitment of substantial funds. Our future funding requirements, which may be significantly greater than we expect, will depend upon many factors, including:

- the extent to which Angiomax is commercially successful globally;
- 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 expansion of our sales force in connection with the expansion of our sales and marketing efforts in Europe and the launch of Cleviprex in the United States;

- our plan to continue to seek possible acquisitions of development-stage products, approved products, or businesses and possible additional strategic or licensing arrangements with companies that fit within our growth strategy;
- the progress, level and timing of our research and development activities related to our clinical trials with respect to Angiomax, Cleviprex, cangrelor and CU-2010;
- the cost and outcomes of regulatory submissions and reviews, including our efforts to obtain approval of the expansion of the Angiomax product label in the United States to include an additional dosing regimen in the treatment of ACS initiated in the emergency room in the United States and approval of Cleviprex internationally;
- the continuation or termination of third-party manufacturing or sales and marketing arrangements;
- the size, cost and effectiveness of our sales and marketing programs in the United States and internationally;
- the status of competitive products; and
- our ability to defend and enforce our intellectual property rights.

If our existing resources are insufficient to satisfy our liquidity requirements due to slower than anticipated sales of Angiomax and Cleviprex, or higher than anticipated costs in Europe, 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

Table of Contents

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.

**Risks Related to Commercialization**

*Angiomax competes with all categories of anticoagulant drugs, which may limit the use of Angiomax*

Because different anticoagulant drugs act on different components of the clotting process, we believe that continued clinical work will be necessary to determine the best combination of drugs for clinical use. We recognize that Angiomax competes with other anticoagulant drugs to the extent Angiomax and any of these anticoagulant drugs are approved for the same or similar indications.

In addition, other anticoagulant drugs may compete with Angiomax for 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. Because 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.

*Because the market for thrombin inhibitors is competitive, our product may not obtain widespread use*

We have positioned Angiomax as a replacement for heparin, which is a widely used, inexpensive, generic drug used in patients with arterial thrombosis. Because heparin is inexpensive and has been widely used for many years, physicians and medical decision-makers may be hesitant to adopt Angiomax. In addition, due to the high incidence and severity of cardiovascular diseases, competition in the market for thrombin inhibitors is intense and growing. We cannot assure you that the rate of Angiomax sales growth will not slow or decline in future years. There are a number of direct and indirect thrombin inhibitors currently on the market, awaiting regulatory approval and in development, including orally administered agents. The thrombin inhibitors on the market include products for use in the treatment of patients with HIT/HITTS, patients with unstable angina and patients with deep vein thrombosis.

*Cleviprex competes with all categories of IV antihypertensive, or IV-AHT, drugs, which may limit the use of Cleviprex*

Because different IV-AHT drugs act in different ways on the factors contributing to elevated blood pressure, physicians have several therapeutic options at their disposal to reduce acutely elevated blood pressure and related conditions. We believe that continued clinical work will be necessary to determine the best combination of drugs for the various patient types and clinical settings. We recognize that Cleviprex competes with other IV-AHT drugs to the extent Cleviprex and any of these IV-AHT drugs are approved for the same or similar indications.

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

In addition, other IV-AHT drugs may compete with Cleviprex for hospital financial resources. For example, many U.S. hospitals receive a fixed reimbursement amount per procedure for the procedures and emergency treatments they perform. Because this amount is not based on the actual expenses the hospital incurs, hospitals may choose to use either Cleviprex or other IV-AHT drugs, but not necessarily several of the drugs together.

*Because many of the IV-AHT drugs with which we expect Cleviprex to compete have been widely used in patient care for many years and are generic, our product may not obtain widespread use*

We have positioned Cleviprex as an alternative to multiple older products, all but one of which are inexpensive generics used widely in patients with acute hypertension or requiring acute blood pressure management. Because these 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. We cannot assure you of the rate of Cleviprex sales growth immediately post launch and the longer-term outlook for future years. While we are not aware of any IV-AHT drugs currently awaiting regulatory approval or in development, this remains a possible scenario, the impact of which on Cleviprex sales we cannot estimate.

Table of Contents

***The market for Cleviprex will depend significantly on access to hospital formularies***

Many hospitals establish formularies, which are lists of drugs approved for use in the hospital. If we fail to secure and maintain formulary coverage 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 cannot estimate the extent and uptake rate of which Cleviprex will be accepted on hospital formularies.

***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 and develop products and apply technology, and our ability to establish and maintain markets for our products. Potential competitors in the United States and other countries include major pharmaceutical and chemical 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 product candidates noncompetitive. We may not be successful in establishing or maintaining technological competitiveness.

***Near-term growth in our sales of Angiomax is dependent on acceptance by physicians, patients and other key decision-makers of Angiomax clinical data, as well as other clinical trial data***

We believe that the near-term commercial success of Angiomax will depend upon the extent to which physicians, patients and other key decision-makers accept the results of the Angiomax clinical trials. 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. We cannot be certain, however, that these trends will 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, we cannot be certain of the extent to which physicians, patients and other key decision-makers will accept the results of the ACUITY and HORIZONS 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 their 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 the REPLACE-2, ACUITY or HORIZONS trial results, adoption of Angiomax may suffer, and our business will be materially adversely affected.

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. The decline in the number of procedures has had a direct impact on our net revenues. PCI procedure volume might decline further and might not return to its previous level over time or at all. In the event that the number of procedures further declines, sales of Angiomax may be impacted negatively.

*Our ability to generate future revenue from products will be affected by our ability to develop our global operations*

To support the international sales and marketing of Angiomax and of Cleviprex, cangrelor and CU-2010, if and when they are approved for sale outside the United States, we are taking the necessary steps to develop our business infrastructure globally, with European operations being our initial focus. If we are unable to expand our international 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, be more expensive or take longer than we anticipate, and we may not be able to successfully market and sell our products internationally. 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 client contract commitments;
- track the progress of ongoing client projects; and
- attract and retain qualified management, sales, professional, scientific and technical operating personnel.

Table of Contents

If we do not take these actions and are not able to manage our global business, then our international 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.

***Our future growth depends, in part, on our ability to penetrate foreign markets, particularly in Europe. However, we have limited experience marketing, servicing and distributing our products and otherwise conducting our business outside the United States, where we are subject to additional regulatory burdens and other risks***

Our future profitability will depend in part on our ability to grow and ultimately maintain our product sales in foreign markets, particularly in Europe. However, we have limited experience in marketing, servicing and distributing our products outside of the U.S. In addition, we recently acquired Curacyte Discovery and are conducting research and development activities through this German subsidiary. These foreign operations subject us to additional risks and uncertainties, including:

- 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 sales of our products 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 revenue from products will be affected by reimbursement and drug pricing***

Acceptable levels of reimbursement of drug treatments by government authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize, and attract collaborative partners to invest in the development of, product candidates. We cannot be sure that reimbursement in the United States, Europe or elsewhere will be available for any products we may develop or, if already available, will not be decreased in the future. 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, as well as legislative proposals, may result in lower prices for pharmaceutical products, including any products that may be offered by us. Cost-cutting measures that health care providers are instituting, and the effect of any health care reform, could materially adversely affect our ability to sell any products that are successfully developed by us and approved by regulators. Moreover, we are unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation or regulation would have on our business.



Table of Contents

*We must comply with federal, state and foreign laws and regulations relating to the health care business, and, if we do not fully comply with such laws and regulations, 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; and
- 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.

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.

*We could be exposed to significant liability if we are unable to obtain insurance at acceptable costs and adequate levels or otherwise protect ourselves against potential product liability claims*

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

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

These claims could expose us to significant liabilities that could prevent or interfere with the development or commercialization of our products. Product liability claims could require us to spend significant time and money in litigation or pay significant damages. With respect to our commercial sales and our clinical trials, we are covered by product liability insurance in the amount of \$20.0 million per occurrence and \$20.0 million annually in the aggregate on a claims-made basis. This coverage may not be adequate to cover any product liability claims.

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

### **Risks Related to Regulatory Matters**

*If we do not obtain regulatory approvals for our product candidates we will not be able to market our product candidates and our ability to generate additional revenue could be materially impaired*

Except for Angiomax and Cleviprex, we do not have any other product approved for sale in the United States or any foreign market. Angiomax has been approved for sale in the United States 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/HITS, for sale in the European Union for indications similar to those approved by the FDA and for adult patients with ACS and for sale in other countries for indications similar to those approved by the FDA. Cleviprex was approved for sale in the United States on August 1, 2008 for the reduction of blood pressure when oral therapy is not feasible or not desirable. We must obtain

Table of Contents

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. 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 in the United States and internationally 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.

***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 and for adult patients with ACS in the European Union. One of our key objectives is to expand the indications for which Angiomax is approved for marketing by the FDA, including for ACS in the United States and for use in the pediatric setting. 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 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 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 have initiated discussions to address them. 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.

Table of Contents

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

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

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

***If we or our contract manufacturers fail to comply with the extensive regulatory requirements to which we, our contract manufacturers and our products 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 European Medicines Agency 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;
- warning letters;
- injunctions;
- fines and other monetary penalties;

Table of Contents

- criminal prosecutions; and
- unanticipated expenditures.

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

*We depend on single suppliers for the production of Angiomax, Cleviprex and cangrelor bulk drug substance 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 of our Angiomax bulk drug substance from one manufacturer, Lonza Braine, and rely on another manufacturer, Ben Venue Laboratories, to carry out all fill-finish activities for Angiomax, which includes final formulation and transfer of the drug into vials where it is then freeze-dried and sealed. The terms of our agreement with Lonza Braine require us to purchase from Lonza Braine a substantial portion of our Angiomax bulk drug product manufactured using the Chemilog process, a chemical synthesis process that we developed with UCB Bioproducts S.A., the predecessor to Lonza Braine.

We currently obtain all of our Cleviprex bulk drug substance from one manufacturer, Johnson Matthey Pharma Services. We rely on a different single supplier, Hospira, Inc., and its proprietary formulation technology, for the manufacture of all finished Cleviprex product, as well as for release testing and commercial packaging.

We have transferred the manufacturing process for all of our cangrelor bulk drug substance from AstraZeneca to Johnson Matthey Pharma Services for scale up and manufacture for Phase III clinical trials and commercial supplies. We also plan to rely on different suppliers, Baxter Pharmaceutical Solutions LLC and Ben Venue Laboratories, Inc., for the manufacture of all finished cangrelor drug product for all Phase III clinical trials and to carry out release testing.

A limited number of manufacturers are capable of manufacturing Angiomax, Cleviprex and cangrelor. We do not currently have alternative sources for production of bulk drug substance or to carry out fill-finish activities. Consolidation within the pharmaceutical manufacturing industry could further reduce the number of manufacturers capable of producing our products, or otherwise affect our existing contractual relationships.

In the event that any of Lonza Braine, Johnson Matthey, Hospira, Ben Venue or Baxter is unable or unwilling to carry out its respective manufacturing obligations or terminates or refuses to renew its arrangements with us, we may be unable to obtain alternative manufacturing, or obtain such manufacturing on commercially reasonable terms or on a timely basis. If we were required to transfer manufacturing processes to other third-party manufacturers, we would need to satisfy various regulatory requirements, which could cause us to experience significant delays in receiving an adequate supply of Angiomax, Cleviprex or cangrelor. 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 on a

timely basis and supply product for clinical trials of Angiomax, Cleviprex or cangrelor.

***The development and commercialization of our products may be terminated or delayed, and the costs of development and commercialization may increase, if third parties on whom we rely to manufacture and support the development and commercialization of our products do not fulfill their obligations***

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 such activities on our own and, as a result, are particularly dependent on third parties in most 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 cangrelor, CU-2010 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, cangrelor, CU-2010 or any additional products we may acquire on terms that we deem favorable, our results of operations would be materially adversely affected.



Table of Contents

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, cangrelor, CU-2010 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 product candidates*

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

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

Angiomax and Cleviprex and our other product candidates 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, cangrelor and CU-2010, it will be more difficult for us to compete effectively and develop our product candidates.

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, cangrelor, CU-2010 and our other product candidates.

### **Risks Related to Our Intellectual Property**

*A breach of any of the agreements under which we license commercialization rights to products or technology from others could cause us to lose license rights that are important to our business or subject us 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 from Biogen Idec and Health Research Inc. and relating to Cleviprex and cangrelor from AstraZeneca. Under

Table of Contents

these agreements, we are subject to commercialization and development, sublicensing, royalty, patent prosecution and maintenance, insurance and other obligations. For instance, we were required under our license of Cleviprex to file an NDA for Cleviprex by September 30, 2007, which we submitted in July 2007, and to satisfy additional milestones under such agreement. We are similarly required under our license of cangrelor to file an NDA for cangrelor by December 31, 2009. 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 business. We have entered into an agreement with Biogen Idec that suspends the statute of limitations relating to any claims for damages and/or license termination that they may bring in the event that a dispute arises between us and Biogen Idec relating to the late filing of our application under the Hatch-Waxman Act for an extension of the term of the principal patent that covers Angiomax. Even if we contest any such termination or claim and are ultimately successful, our stock price could suffer. In addition, upon any termination of a license agreement, we may be required to license to the licensor any related intellectual property that we developed.

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

The patent positions of pharmaceutical companies like us are generally uncertain and involve complex legal, scientific and factual issues. Our success depends significantly on our ability to:

- obtain and maintain U.S. and foreign patents, including defending those patents against adverse claims;
- 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. 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.

We exclusively license U.S. patents, patent applications and patent rights and corresponding foreign patents, patent applications and patent rights relating to Angiomax, Cleviprex and cangrelor. We exclusively license six issued U.S. patents relating to Angiomax, three issued U.S. patents relating to Cleviprex and the rights relating to cangrelor under six issued U.S. patents. We have filed several independent patent applications. In addition, we obtained a portfolio of patents and patent applications in connection with our acquisition of Curacyte Discovery.

The principal U.S. patent that covers Angiomax expires in 2010. The U.S. Patent and Trademark Office, or PTO, rejected our application under the Hatch-Waxman Act for an extension of the term of the patent beyond 2010 because the application was not filed on time by our counsel. In October 2002, we filed a request with the PTO for reconsideration of the denial of the application. On April 26, 2007, we received a decision from the PTO denying our application for patent term extension. We continue to explore alternatives to extend the term of the patent but we can provide no assurance that we will be successful in doing so.

On June 23, 2008, the United States House of Representatives passed a bill that, if enacted, would provide the PTO with discretion to consider patent extension applications filed late unintentionally under the Hatch-Waxman Act. This legislation remains subject to the approval of the United States Senate and the President of the United States. Even if this legislation is enacted, the PTO might not consider our application and we might not be successful in extending the term of the patent.

Table of Contents

We have entered into agreements with the counsel involved in the late filing that suspend the statute of limitations on our claims against them for failing to make a timely filing. We have entered into a similar agreement with Biogen Idec relating to any claims for damages and/or license termination they may bring in the event that a dispute arises between us and Biogen Idec relating to the late filing. These agreements may be terminated by either party upon 30 days notice. We cannot assure you that Biogen Idec will not terminate this agreement.

***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 2010, but is subject to automatic renewals of consecutive three-year periods unless either party provides notice of non-renewal within 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.

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

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 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.

Table of Contents

**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, which was launched in September 2008 in the United States. In order to generate additional revenue, we intend to acquire and develop additional product candidates or approved products. For example, in August 2008, we acquired Curacyte Discovery, which is developing CU-2010 for the prevention of blood loss during surgery. The success of this growth strategy depends upon our ability to identify, select and acquire pharmaceutical products that meet the criteria we have established. Because we have only the limited internal scientific research capabilities that we acquired in our acquisition of Curacyte Discovery 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 will be required to integrate any acquired products into our existing operations. 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 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, we cannot assure you that any approved products that we develop or acquire will be:

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

We have previously acquired rights to products and, after having conducted development activities, determined not to devote further resources to those products. We cannot assure you that any additional products that we acquire will be successfully developed. In addition, proposing, negotiating and implementing an economically viable acquisition 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 of product candidates and approved products. We may not be able to acquire the rights to additional product candidates and approved products on terms that we find acceptable, or at all.

*We may undertake strategic acquisitions in the future and any difficulties from integrating such acquisitions could damage our ability to attain or maintain profitability*

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

We may acquire additional businesses and products that complement or augment our existing business. 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. Moreover, we may need to raise additional funds through public or private debt or equity financing to acquire any businesses or products, which may result in dilution for stockholders or the incurrence of indebtedness.

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

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

### **Risks Related to Our Common Stock**

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

Our operating results may vary from period to period based on factors including the amount and timing of sales of Angiomax, underlying hospital demand for Angiomax, our customers' buying patterns, the timing, expenses and results of



Table of Contents

clinical trials, announcements regarding clinical trial results and product introductions by us or our competitors, the availability and timing of third-party reimbursement, including in Europe, sales and marketing expenses and the timing of regulatory approvals. If our operating results do not meet the expectations of securities analysts and investors as a result of these or other factors, the trading price of our common stock will likely decrease.

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

Our common stock has been and in the future may be subject to substantial price volatility. From January 1, 2008 to November 7, 2008, the last reported sale price of our common stock ranged from a high of \$27.68 per share to a low of \$14.31 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;
- changes in our management; and
- general market conditions.

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

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

Section 203 of the General Corporation Law of the State of Delaware and our certificate of incorporation and by-laws contain provisions that might enable our management to resist a takeover of our company or discourage a third party from attempting to take over our company. These provisions include the inability of stockholders to act by written consent or to call special meetings, a classified board of directors and the ability of our board of directors to designate the terms of and issue new series of preferred stock without stockholder approval.

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

Table of Contents

**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**



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

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 10, 2008

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

Table of Contents

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
2.1	Sale and Purchase Agreement, dated August 4, 2008, between the Company and Curacyte AG (incorporated by reference to Exhibit 2.1 of the Current Report on Form 8-K/A, filed on November 10, 2008).
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

---

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