

MEDICINES CO /DE  
Form 10-Q  
November 08, 2006

**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, 2006

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, NJ**  
(Address of Principal Executive Offices)

**07054**  
(Zip Code)

**(973) 656-1616**

(Registrant's telephone number, including area code)

**N/A**

(Former name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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

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

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

Large accelerated filer  Accelerated filer  Non-accelerated filer

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 7, 2006, there were 50,764,975 shares of Common Stock, \$0.001 par value per share, outstanding.

---

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

The Medicines Company® name and logo, Angiomax® and Angiox® 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.

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.

---

THE MEDICINES COMPANY

TABLE OF CONTENTS

**Part I. Financial Information**

<b><u>Item 1 - Unaudited Condensed Consolidated Financial Statements</u></b>	<b>1</b>
<b><u>Item 2 - Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>	<b>13</b>
<b><u>Item 3 - Quantitative and Qualitative Disclosures About Market Risk</u></b>	<b>22</b>
<b><u>Item 4 - Controls and Procedures</u></b>	<b>22</b>
<b><u>Part II. Other Information</u></b>	<b>23</b>
<b><u>Item 1A Risk Factors</u></b>	<b>23</b>
<b><u>Item 6 - Exhibits</u></b>	<b>34</b>
<b><u>Signatures</u></b>	<b>35</b>
<b><u>Exhibit Index</u></b>	<b>36</b>

---

## THE MEDICINES COMPANY

## CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2006 (unaudited)	December 31, 2005
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 100,816,613	\$ 25,705,561
Available for sale securities	75,721,038	114,383,667
Accrued interest receivable	1,262,387	921,704
Accounts receivable, net of allowances of approximately \$0.77 million and \$0.85 million at September 30, 2006 and December 31, 2005, respectively	25,085,613	14,611,137
Inventory	35,233,878	47,985,440
Prepaid expenses and other current assets	2,697,384	970,251
Total current assets	240,816,913	204,577,760
Fixed assets, net	3,346,615	3,990,147
Other assets	139,134	139,134
Total assets	\$ 244,302,662	\$ 208,707,041
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 5,569,764	\$ 5,988,549
Accrued expenses	35,973,663	28,677,480
Total current liabilities	41,543,427	34,666,029
Commitments and contingencies		
Deferred revenue	2,896,281	3,142,192
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 at September 30, 2006 and December 31, 2005; 50,658,992 and 49,723,756 shares issued and outstanding at September 30, 2006 and December 31, 2005, respectively	50,659	49,724
Additional paid-in capital	495,209,376	476,012,428
Accumulated deficit	(295,425,963)	(304,898,644)
Accumulated other comprehensive income/(loss)	28,882	(264,688)
Total stockholders' equity	199,862,954	170,898,820
Total liabilities and stockholders' equity	\$ 244,302,662	\$ 208,707,041

See accompanying notes to unaudited condensed consolidated financial statements.

## THE MEDICINES COMPANY

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Net revenue	\$ 59,579,742	\$ 31,919,597	\$ 153,594,560	\$ 118,086,281
Operating expenses:				
Cost of revenue	14,342,226	6,106,441	38,290,501	27,701,047
Research and development	15,866,971	17,819,639	44,392,931	51,428,247
Selling, general and administrative	20,311,872	15,438,026	65,965,260	44,526,220
Total operating expenses	50,521,069	39,364,106	148,648,692	123,655,514
Income/(loss) from operations	9,058,673	(7,444,509 )	4,945,868	(5,569,233 )
Other income	2,045,805	1,144,930	4,907,396	3,029,722
Income/(loss) before income taxes	11,104,478	(6,299,579 )	9,853,264	(2,539,511 )
Provision for income taxes	(432,089 )	67,674	(380,583 )	(103,745 )
Net income/(loss)	\$ 10,672,389	\$ (6,231,905 )	\$ 9,472,681	\$ (2,643,256 )
Basic earnings/(loss) per common share	\$ 0.21	\$ (0.13 )	\$ 0.19	\$ (0.05 )
Shares used in computing basic earnings/(loss) per common share	50,477,714	49,611,918	50,116,387	49,349,230
Diluted earnings/(loss) per common share	\$ 0.21	\$ (0.13 )	\$ 0.19	\$ (0.05 )
Shares used in computing diluted earnings/(loss) per common share	51,113,942	49,611,918	50,779,433	49,349,230

See accompanying notes to unaudited condensed consolidated financial statements.

## THE MEDICINES COMPANY

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	Nine Months Ended September 30,	
	2006	2005
<b>Cash flows from operating activities:</b>		
Net income/(loss)	\$ 9,472,681	\$ (2,643,256 )
Adjustments to reconcile net income/(loss) to net cash provided by/(used in) operating activities:		
Depreciation	1,086,940	668,952
Amortization of net premiums and discounts on available for sale securities	(885,387 )	137,859
Non-cash stock compensation expense	6,135,673	
Loss on disposals of fixed assets	240,901	15
Changes in operating assets and liabilities:		
Accrued interest receivable	(340,683 )	176,080
Accounts receivable	(10,474,476 )	(20,421,453 )
Inventory	12,751,562	(15,293,531 )
Prepaid expenses and other current assets	(1,725,443 )	(278,607 )
Other assets		21,481
Accounts payable	(422,198 )	(6,410,419 )
Accrued expenses	7,293,777	6,576,421
Deferred revenue	(245,911 )	9,539,428
Net cash provided by/(used in) operating activities	22,887,436	(27,927,030 )
<b>Cash flows from investing activities:</b>		
Purchases of available for sale securities	(70,960,153 )	(77,163,035 )
Maturities and sales of available for sale securities	110,777,000	113,331,000
Purchase of fixed assets	(683,072 )	(2,874,397 )
Net cash provided by investing activities	39,133,775	33,293,568
<b>Cash flows from financing activities:</b>		
Proceeds from issuances of common stock, net	13,062,210	6,730,638
Net cash provided by financing activities	13,062,210	6,730,638
Effect of exchange rate changes on cash	27,631	(25,173 )
Increase in cash and cash equivalents	75,111,052	12,072,003
Cash and cash equivalents at beginning of period	25,705,561	36,504,962
Cash and cash equivalents at end of period	\$ 100,816,613	\$ 48,576,965

See accompanying notes to unaudited condensed consolidated financial statements.

**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 pharmaceutical company that specializes in acute care hospital products and is engaged in the acquisition, development and commercialization of late-stage development drugs. In December 2000, the U.S. Food and Drug Administration (the FDA) approved the Company's initial 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, or PTCA. In 2005, the Company received approvals from the FDA for new prescribing information for Angiomax. In June 2005, the FDA approved new prescribing information for Angiomax to also include patients undergoing percutaneous coronary intervention, or PCI, in addition to those undergoing PTCA. The expanded label also includes a new Angiomax dosing recommendation, which is the same dose as was used in the Company's REPLACE-2 clinical trial. 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. The combination of these conditions, known as HIT/HITTS, is a complication of heparin administration that can result in limb amputation, renal failure and death. The Company is currently developing Angiomax for use in additional patient populations. The Company has concentrated its commercial sales and marketing resources on the United States hospital market and revenue to date has been generated principally from sales of Angiomax in the United States. 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 addition to Angiomax, the Company is currently developing two other Phase III pharmaceutical products as potential acute care hospital products, both of which are currently in Phase III clinical trials. The first of these, clevidipine, is an intravenous drug intended for control of blood pressure in patients who require rapid and precise control of blood pressure in an acute care setting. The second potential product, cangrelor, is an intravenous antiplatelet agent that prevents platelet activation and inhibits platelet aggregation, which the Company believes has potential advantages in the treatment of vascular disease.

**2. Summary of Significant Accounting Policies**

*Basis of Presentation*

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

The results of operations for the three-month and nine-month periods ended September 30, 2006 are not necessarily indicative of the results that may be expected for the entire fiscal year ending December 31, 2006. 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, 2005, filed with the Securities and Exchange Commission.

*Use of Estimates*

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of revenue 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 an original maturity at the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents at September 30, 2006 included





investments of \$100.8 million in demand deposits and money market funds. Cash and cash equivalents at December 31, 2005 included investments of \$23.7 million in demand deposits and money market funds and \$2.0 million of corporate bonds 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 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 in accumulated other comprehensive income/(loss), a separate component of stockholders' equity. The estimated fair market value of the available for sale securities is determined based on quoted market prices or rates for similar instruments. 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, 2006, the Company held available for sale securities with fair market value totaling \$75.7 million. These available for sale securities included various corporate debt securities and United States government agency notes, of which \$69.8 million had maturities within one year and \$5.9 million had maturities of longer than one year and less than two years. At December 31, 2005, the Company held available for sale securities with fair market value totaling \$114.4 million. These available for sale securities included various corporate debt securities and United States government agency notes, all of which had maturities within one year.

#### *Revenue Recognition*

*Product Sales.* The Company sells its products to domestic wholesalers and international distributors, who, in turn, sell 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.

*Domestic Sales.* The Company records allowances for chargebacks and other discounts and accruals for product returns, rebates and fee-for-service charges at the time of sale, and reports revenue net of such amounts. In determining allowances and accruals, the Company must make critical 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. Making these determinations involves estimating whether trends in past wholesaler and hospital buying patterns will predict future product sales. In 2005, the Company agreed with its largest wholesalers to enter into fee-for-service arrangements under which these wholesalers have agreed to provide the Company with more frequent data on wholesaler inventory levels and hospital purchases. The Company believes that this data has assisted and will continue to assist it in determining its 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 to wholesalers might remain in their inventory to within six months prior to expiration and analyze the likelihood that such product will be returned within 12 months after expiration.

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

In estimating the likelihood of product returns, the Company relies primarily on historic patterns of returns and estimated remaining shelf life of product previously shipped.



- *Chargebacks and Rebates.* Although the Company sells Angiomax to wholesalers and distributors, 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 from the Company's wholesalers. Based on the terms of these agreements, most of the Company's hospital customers have the right to receive a discounted price and volume-based rebate on product purchases. The Company provides a credit to the wholesaler, or a chargeback, representing the difference between the wholesaler's acquisition list price and the discounted price available to the hospital customer.

As a result of these contracts, at the time of product shipment, the Company must estimate the likelihood that Angiomax sold to wholesalers might be ultimately sold to a contracting hospital or group purchasing organization. The Company must also estimate the contracting hospital's or group purchasing organization's volume of purchases.

The Company bases its estimates on the historic chargeback data it 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 has adjusted its allowances for chargebacks and accruals for product returns and rebates 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.

At September 30, 2006 and December 31, 2005, the Company's allowance for chargebacks was \$0.3 million and \$0.5 million, respectively, its accrual for rebates was \$1.0 million and \$1.5 million, respectively, and its accrual for product returns was \$0.5 million and \$0.2 million, respectively.

*International Distributors.* Under the Company's agreements with international distributors, the Company sells its product to these distributors at a percentage of the distributor's established net selling price. The established net selling price is typically determined in the quarter in which the Company sells its products to these distributors, based on the distributor's net selling price. In those situations, usually prior to product launch, where product is sold prior to the establishment of the distributor's selling price, the Company records revenue at minimum prices specified in these agreements and subsequently adjusts its selling price once the distributor's established net selling price is determined. In accordance with the terms of these agreements, under no circumstances would the subsequent adjustment result in the net selling price being less than the minimum price.

Revenue from the sale of distribution rights includes the amortization of milestone payments. These payments are recorded as deferred revenue until contractual performance obligations have been satisfied, and they are 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.

*Reimbursement Revenue.* In collaboration with a third party, the Company pays fees for services rendered by a research organization and other out-of-pocket costs for which the Company is reimbursed at cost, without mark-up or profit. The reimbursements received are reported as part of net revenue in the consolidated statements of operations and the fees for the services rendered and the out-of-pocket costs are included in research and development expenses.

#### *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 bulk drug product is classified as raw materials and its costs are determined using acquisition costs from the Company's contract manufacturer. Work-in-progress costs of filling, finishing and packaging are recorded against specific product batches. The Company obtains all of its Angiomax bulk substance from the manufacturing division of UCB Bioproducts S.A., which was recently acquired by Lonza Ltd. and is now known as Lonza Braine, S.A. Under the terms of the Company's agreement with Lonza Braine, the Company provides forecasts of Angiomax bulk substance requirements eighteen months in advance of the year of delivery. The Company also has a separate agreement with Ben Venue Laboratories, Inc. for the fill-finish of Angiomax drug product.



The major classes of inventory are as follows:

Inventory	September 30, 2006	December 31, 2005
Raw materials	\$ 16,465,059	\$ 21,047,747
Work-in-progress	12,735,860	23,630,430
Finished goods	6,032,959	3,307,263
<b>Total inventory</b>	<b>\$ 35,233,878</b>	<b>\$ 47,985,440</b>

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

#### *Fixed Assets*

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

#### *Research and Development*

Research and development costs are expensed as incurred.

#### *Recent Accounting Pronouncements*

In June 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. (FIN) 48 Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109 (FIN 48). FIN 48 prescribes a threshold for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Only tax positions meeting the more-likely-than-not recognition threshold at the effective date may be recognized or continue to be recognized upon adoption of this interpretation. FIN 48 also provides guidance on accounting for derecognition, interest and penalties, and classification and disclosure of matters related to uncertainty in income taxes. FIN 48 will be effective for the Company beginning January 1, 2007. Management is currently evaluating the effect that adoption of this interpretation will have on the Company's consolidated financial position and results of operations.

In September 2006, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 157 Fair Value Measurements, (SFAS 157) which defines fair value, establishes a framework for consistently measuring fair value under GAAP, and expands disclosures about fair value measurements. SFAS No. 157 is effective for the Company beginning January 1, 2008, and the provisions of SFAS No. 157 will be applied prospectively as of that date. Management is currently evaluating the effect that adoption of this statement will have on the Company's consolidated financial position and results of operations when it becomes effective in 2008.

### **3. Stock-Based Compensation**

Prior to January 1, 2006, the Company elected to account for stock-based compensation using the intrinsic value method prescribed in Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees as permitted by SFAS 123, Accounting for Stock-Based Compensation .

Effective January 1, 2006, the Company adopted the fair value recognition provisions of SFAS 123(R), Share-Based Payment (SFAS 123(R)), using the accelerated expense attribution method specified in FIN 28, Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans (FIN 28). SFAS 123(R) requires companies to recognize compensation expense in an amount equal to the fair value of all share-based awards granted to employees. The Company has elected the modified prospective transition method and, therefore, adjustments to prior periods are not required as a result of adopting SFAS 123(R). Under this method, the provisions of SFAS 123(R) apply to all awards granted after January 1, 2006, the date of adoption, and to any unrecognized expense of awards unvested at the date of adoption based on the grant date fair value.

In accordance with SFAS 123(R), the Company recorded approximately \$6.1 million of stock-based



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

compensation expense for the nine months ended September 30, 2006, including \$2.6 million of stock-based compensation expense in the third quarter of 2006. As of September 30, 2006, there was approximately \$11.0 million of total unrecognized compensation costs related to non-vested share-based employee compensation arrangements granted under the Company's equity compensation plans. This cost is expected to be recognized over a weighted average period of 2.77 years.

The following table illustrates the pro forma effect on net income and earnings per share if the Company had applied the fair value recognition and share-based compensation cost provisions of SFAS 123(R) to stock-based employee compensation for the three and nine months ended September 30, 2005:

	Three Months Ended September 30, 2005	Nine Months Ended September 30, 2005
Net income - As reported	\$ (6,231,905 )	\$ (2,643,256 )
Deduct: Total stock-based employee compensation costs determined under fair value-based method for all stock option awards and the 2000 Employee Stock Purchase Plan discounts, net of tax	(5,214,151 )	(14,784,134 )
Net loss - Pro forma	\$ (11,446,056 )	\$ (17,427,390 )
Net loss per share, basic and diluted - As reported	\$ (0.13 )	\$ (0.05 )
Net loss per share, basic and diluted - Pro forma	\$ (0.23 )	\$ (0.35 )

For purposes of applying SFAS 123(R) to the quarter and nine months ended September 30, 2006 and for the purposes of the table above, the Company estimated the fair value of each option on the date of grant using the Black-Scholes closed-form option-pricing model applying the weighted average assumptions in the following table. The Company allocated this fair value to compensation expense using the accelerated expense attribution method specified in FIN 28. Expected volatilities are based on historic volatilities for the Company's common stock as well as peer companies in the life science industry over a range of periods from 12 to 60 months and other factors. The Company uses historical data to estimate expected option term and forfeiture rate. For purposes of performing the valuation, employees were separated into two groups according to patterns of historical exercise behavior; the assumptions given below result from the two groups of employees exhibiting different behavior and have been disclosed separately for both groups. The risk-free interest rate for periods within the contractual life of the option is based on the U.S. Treasury yield in effect at the time of grant.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Expected dividend yield	0	%	0	%
Expected stock price volatility	44%, 47	%	% 44%, 47	%
Risk-free interest rate	4.71%, 4.72	%	% 4.80%, 4.82	%
Expected option term (years)	3.14%, 3.62		3.13, 3.47	2.73

The Company has adopted the following stock incentive plans, each of which has been approved by its stockholders:

- the 2004 Stock Incentive Plan (the 2004 Plan),
- the 1998 Stock Incentive Plan (the 1998 Plan), and
- the 2000 Outside Director Stock Option Plan (the 2000 Director Plan).

Each of these plans provides for the grant of stock options and other stock-based awards to employees, officers, directors, consultants and advisors of the Company and its subsidiaries. The Company ceased making grants under the 2000





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

Director Plan following adoption of the 2004 Plan. The Company ceased making grants under the 1998 Plan following adoption of an amendment to the 2004 Plan at its annual stockholders meeting on May 25, 2006. Unexercised options under the 2000 Director Plan and 1998 Plan remain outstanding.

Stock option grants have an exercise price equal to the fair market value of the Company's common stock on the date of grant and generally have a 10-year term. The fair value of stock option grants is recognized, net of an estimated annual forfeiture rate as of September 30, 2006 of 4.26%, using an accelerated method over the vesting period of the options, which is generally four years.

The following tables present a summary of option activity and data under the Company's option plans for the nine months ended and as of September 30, 2006:

	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding, December 31, 2005	7,679,136	\$ 20.85		
Granted	1,317,275	19.81		
Exercised	(847,284)	14.12		
Forfeited and expired	(927,683)	24.57		
Outstanding, September 30, 2006	7,221,444	\$ 20.97	7.95	\$ 22,946,000
Exercisable, September 30, 2006	5,221,977	\$ 21.64	7.42	\$ 16,255,975

Aggregate intrinsic value is the sum of the amounts by which the quoted market price of the Company's common stock exceeded the exercise price of the options at September 30, 2006, for those options for which the quoted market price was in excess of the exercise price. The weighted-average grant date fair value of options granted during the third quarter of 2006 and 2005 was \$8.22 and \$9.18, respectively. The weighted-average grant date fair value of options granted during the nine months ended September 30, 2006 and 2005 was \$7.35 and \$9.95, respectively. The total intrinsic value of options exercised during the third quarter of 2006 and 2005 was \$0.9 million and \$1.9 million, respectively. The total intrinsic value of options exercised during the nine months ended September 30, 2006 and 2005 was \$4.8 million and \$6.6 million, respectively.

The following table summarizes information regarding options outstanding as of September 30, 2006:

Range of Exercise Prices Per Share	Options Outstanding		Weighted Average Contractual Life (Years)	Weighted Average Exercise Price Per Share	Options Vested Number Outstanding at 9/30/06	Weighted Average Exercise Price Per Share
	Number Outstanding at 9/30/06	Weighted Average Remaining Contractual Life				
\$1.23- \$9.13	461,557	4.06	\$ 5.62	461,557	\$ 5.62	
\$9.39- \$15.38	237,762	5.32	11.64	237,554	11.64	
\$15.50- \$17.38	481,771	6.69	16.30	380,858	16.16	
\$17.45- \$19.09	1,892,987	9.21	18.43	657,739	18.29	
\$19.11- \$22.51	1,203,611	8.90	21.15	646,513	21.63	
\$22.56- \$24.60	925,310	7.83	23.37	819,310	23.45	
\$24.92- \$27.81	951,363	7.65	26.35	951,363	26.35	
\$27.87- \$30.27	789,583	7.92	28.16	789,583	28.16	
\$30.69- \$34.95	277,500	7.63	32.33	277,500	32.33	
	7,221,444	7.95	\$ 20.97	5,221,977	\$ 21.64	

The following table presents a summary of the Company's non-vested shares of restricted stock granted as of September 30, 2006:

	Number of Shares	Weighted Average Grant-Date Fair

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

			Value
Non-vested, December 31, 2005			
Awarded	25,000	\$	20.11
Vested			
Forfeited			
Non-vested, September 30, 2006	25,000	\$	20.11

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

The Company granted a restricted stock award under the 2004 stock incentive plan during the first quarter of 2006. The restricted stock grant vests in equal increments of 25% per year on an annual basis commencing twelve months after grant date. Expense of approximately \$66,000 and \$139,000 was recognized in the quarter ended September 30, 2006 and the nine months ended September 30, 2006, respectively. The remaining expense of approximately \$0.3 million will be recognized over a period of 3.42 years.

*2000 Employee Stock Purchase Plan.* As of September 30, 2006, the Company had issued 240,442 shares over the life of the Company's 2000 Employee Stock Purchase Plan (ESPP). The Company issued 62,952 shares and 52,206 shares under the ESPP during the first nine months of 2006 and 2005, respectively. The Company currently has 265,058 shares in reserve for future issuance under the ESPP. The Company recorded approximately \$0.3 million in ESPP compensation expense in the nine months ended September 30, 2006, including approximately \$0.1 million in the third quarter of 2006.

The fair value of each option element of the ESPP is estimated on the date of grant using the Black-Scholes closed-form option valuation model that applies the assumptions noted in the following table. Expected volatilities are based on historical volatility of the Company's common stock and other factors. Expected term represents the six-month offering period for the ESPP. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant.

	Nine Months Ended September 30,	
	2006	2005
Expected dividend yield		
Expected stock price volatility	31 %	31 %
Risk-free interest rate	4.63-5.06 %	3.57 %
Expected option term (years)	0.5	0.5

During the three months and nine months ended September 30, 2006, the Company issued 255,612 and 935,236 shares of its common stock, respectively, upon the exercise of stock options, restricted stock grants and purchases under the ESPP. During the three and nine months ended September 30, 2005, the Company issued 180,880 and 1,056,974 shares of its common stock, respectively, upon the exercise of stock options, purchases under the ESPP and the exercise of common stock warrants.

Cash received from exercise of stock options and ESPP purchases during the nine months ended September 30, 2006 and 2005 was approximately \$13.1 million and \$6.7 million, respectively, and is included within the financing activities section of the consolidated statements of cash flows.

*Common Stock Reserved for Future Issuance* At September 30, 2006, there were 4,548,595 shares of common stock reserved for future issuance under the ESPP and for future grants made under the 2004 Plan.

#### 4. Net Income/(Loss) per Share

The following table sets forth the computation of basic and diluted net income/(loss) per share for the three and nine months ended September 30, 2006 and 2005:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
<b>Basic and diluted</b>				
Net income/(loss)	\$ 10,672,389	\$ (6,231,905 )	\$ 9,472,681	\$ (2,643,256 )
Weighted average common shares outstanding, basic	50,502,714	49,611,918	50,135,709	49,349,230
Less: unvested restricted common shares outstanding	25,000		19,322	
Net weighted average common shares outstanding, basic	50,477,714	49,611,918	50,116,387	49,349,230
	636,228		663,046	

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

Plus: net effect of dilutive stock options,  
restricted common shares and warrants

Weighted average common shares outstanding, diluted	51,113,942	49,611,918	50,779,433	49,349,230
Earnings/(loss) per share, basic	\$ 0.21	\$ (0.13 )	\$ 0.19	\$ (0.05 )
Earnings/(loss) per share, diluted	\$ 0.21	\$ (0.13 )	\$ 0.19	\$ (0.05 )

10

---

Basic earnings/(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 restricted common shares. As of September 30, 2006, there were options to purchase 7,221,444 shares of common stock outstanding. The options that are at or above the exercise price and the restricted common shares have been included in the computation of diluted earnings per share for the three and nine months ended September 30, 2006. The number of dilutive common stock equivalents was calculated using the treasury stock method. As of September 30, 2005, there were outstanding options to purchase 6,371,732 shares of common stock. These options were not included in the computation of diluted net loss per share for the three and nine months ended September 30, 2005, as their effects would have been antidilutive.

## 5. Comprehensive Income/(Loss)

Comprehensive income/(loss) is primarily comprised of net income/(loss), unrealized gain/(loss) on available for sale securities and currency translation adjustments. Comprehensive income/(loss) for the three and nine months ended September 30, 2006 and September 30, 2005 is detailed below.

Comprehensive Income/(loss)	Three Months ended September 30,		Nine Months ended September 30,	
	2006	2005	2006	2005
Net income/(loss)	\$ 10,672,389	\$ (6,231,905 )	\$ 9,472,681	\$ (2,643,256 )
Unrealized gain on available for sale securities, net of tax	129,481	22,793	268,831	67,279
Foreign currency translation adjustment, net of tax	1,278	(3,508 )	24,739	(15,367 )
Comprehensive income/(loss)	\$ 10,803,148	\$ (6,212,620 )	\$ 9,766,251	\$ (2,591,344 )

## 6. Income Taxes

For the nine months ended September 30, 2006, the Company provided for taxes based upon its estimated tax liability for the year. This provision includes state taxes based on the greater of net income or net worth and some income taxes in international jurisdictions. At December 31, 2005, net operating losses available to offset future taxable income for federal income tax purposes were approximately \$242.6 million. If not utilized, federal net operating loss carryforwards will expire at various dates beginning in 2012 and ending in 2025. The Company has not recognized the potential tax benefit of its net operating losses in its balance sheets or statements of operations. The future utilization of the Company's net operating loss carryforwards may be limited based upon changes in ownership pursuant to Section 382 of the Internal Revenue Code of 1986, as amended.

**7. 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, 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. At September 30, 2006, the Company has accrued \$1.2 million in connection with such contingencies that have arisen in the ordinary course of business. The amounts recorded by the Company rely on assumptions that are based on currently known facts and strategy. The Company's actual liabilities could be significantly higher or lower than those recorded if actual outcomes of these matters vary significantly from assumptions used. 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.

12

---

## 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 on Form 10-Q. In addition to the historical information, the discussion in this quarterly report on Form 10-Q 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 on Form 10-Q, including under Risk Factors in Part II, Item 1A of this quarterly report on Form 10-Q.*

### Overview

We are a pharmaceutical company that specializes in acute care hospital products. To date, we have generated substantially all of our revenue from sales of our first product, Angiomax® (bivalirudin). Angiomax is a direct thrombin inhibitor that was approved by the FDA in December 2000 for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty, or PTCA. In 2005, we received approvals from the FDA for new prescribing information for Angiomax. In June 2005, the FDA approved new prescribing information for Angiomax to also include patients undergoing percutaneous coronary intervention, or PCI, in addition to those undergoing PTCA. The expanded label also includes a new Angiomax dosing recommendation, which is the same dose used in our REPLACE-2 clinical trial. 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. The combination of these conditions, known as HIT/HITTS, is a complication of heparin administration that can result in limb amputation, renal failure and death. We are currently developing Angiomax for use in additional patient populations. Since we began selling Angiomax in 2001, revenue has been generated principally from sales of Angiomax in the United States. In September 2004, we 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, and our international distributors have sold Angiox in countries in Europe since that time. Angiomax is also approved for sale in Australia, Canada and countries in Central America, South America and the Middle East for indications similar to those approved by the FDA.

In evaluating our operating performance in the United States, we focus on use of Angiomax by existing hospital customers and penetration into new hospitals, both of which are critical elements of our ability to increase revenue. In 2005, we expanded our sales force and increased our marketing capabilities. We believe that our increased sales and marketing capabilities, and the expansion of our product label, will allow us to more effectively serve our existing customers and penetrate new hospitals.

Except for 2004, we have incurred losses on an annual basis since our inception.

We outsource much of our clinical trial activities and all of our manufacturing development activities to third parties to maximize efficiency and minimize our internal overhead. Cost of revenue consists of expenses incurred in connection with the manufacture of Angiomax sold, royalty expenses under our agreement with Biogen Idec and the logistics costs of selling Angiomax, such as distribution, storage and handling. Research and development expenses represent costs incurred for product acquisition, clinical trials, activities relating to regulatory filings and manufacturing development efforts. 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.

In 2005, we agreed with our largest wholesalers to enter into fee-for-service arrangements. We believe that these arrangements have resulted in reductions in wholesaler inventories, improved margins, more predictable buying patterns and more frequent data on wholesaler inventory levels and hospital demand. We estimate that during the last two quarters of 2005 and the first quarter of 2006 combined, our three largest wholesalers reduced their aggregate Angiomax inventory levels by approximately \$39.0 million. As a result, we estimate that our three largest wholesalers have held an aggregate average of four to six weeks of inventory since the end of the first quarter of 2006.

We expect to continue to spend significant amounts on the development of our products. In the remainder of 2006, we plan to continue to invest in clinical studies to develop clevidipine and cangrelor and to expand the approved indications for Angiomax. We also plan to continue our sales and marketing programs to promote





Angiomax, and to support programs to educate and inform physicians, nurses, pharmacists and other medical decision-makers about the benefits of Angiomax. In light of these activities, our expanded sales force, and our plan to continue to evaluate possible acquisitions of late-stage development drugs, approved products, or businesses that fit within our growth strategy, we will likely need to generate greater revenue to achieve and maintain profitability.

**Application of Critical Accounting Estimates**

The discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect our reported assets and liabilities, revenue and expenses, and other financial information. Actual results may differ significantly from these estimates.

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 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 the notes 2 and 3 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, 2005. 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 and inventory 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, 2005 are critical accounting estimates.

**Results of Operations**

*Three Months Ended September 30, 2006 and 2005*

*Net Revenue.* Net revenue for the three months ended September 30, 2006 increased 87% to \$59.6 million as compared to \$31.9 million for the three months ended September 30, 2005. The following table reflects the components of net revenue for the three months ended September 30, 2006 and 2005:

(dollars in thousands)	Net Revenue					
	Three Months Ended September 30,				% of	
	2006	% of Net Revenue	2005		Net Revenue	
<b>Angiomax</b>						
United States	\$ 55,650	93 %	\$ 29,385	92 %		
International	3,444	6 %	2,535	8 %		
Reimbursement	486	1 %	0	0 %		
<b>Total Net Revenue</b>	<b>\$ 59,580</b>	<b>100 %</b>	<b>\$ 31,920</b>	<b>100 %</b>		

Net revenue for the three months ended September 30, 2006 increased compared to the three months ended September 30, 2005 primarily due to increased sales of Angiomax to our wholesalers in the United States as a result of increased demand by hospitals including increased use by existing hospital customers, the addition of new



hospital customers, and the beginning of a three quarter wholesaler inventory reduction which commenced in the third quarter of 2005 in conjunction with the entrance into fee-for-service agreements with our three largest wholesalers. We estimate that our wholesalers reduced their aggregate inventories of Angiomax during the three months ended September 30, 2005 by approximately \$13.0 million in implementing the planned inventory reduction.

The increase of \$0.9 million in international sales in the three months ended September 30, 2006 compared to the three months ended September 30, 2005 is primarily due to increased sales to our Canadian distributor Oryx Pharmaceuticals Inc.

In the three months ended September 30, 2006, we had reimbursement revenue of \$0.5 million. We generated this revenue in connection with the performance of services in collaboration with a third party under a contract research agreement.

*Cost of Revenue.* Cost of revenue for the three months ended September 30, 2006 increased 134% to \$14.3 million, or 24% of net revenue, compared to \$6.1 million, or 19% of net revenue, for the three months ended September 30, 2005. The following table reflects the components of cost of revenue for the three months ended September 30, 2006 and 2005:

(dollars in thousands)	Cost of Revenue			
	Three Months Ended September 30,		% of Cost	
	2006	Of Revenue	2005	Of Revenue
Manufacturing	\$ 5,102	35 %	\$ 3,369	55 %
Royalty	7,719	54 %	1,847	30 %
Logistics	1,521	11 %	890	15 %
<b>Total Cost of Revenue</b>	<b>\$ 14,342</b>	<b>100 %</b>	<b>\$ 6,106</b>	<b>100 %</b>

The increase in cost of revenue for the three months ended September 30, 2006 compared to the three months ended September 30, 2005 resulted from an increase in manufacturing costs, logistics costs and royalty expenses due to higher sales volume, and \$0.1 million of stock-based compensation. Royalty expense increased as a percentage of total cost of revenue due to a higher effective royalty rate under our agreement with Biogen Idec.

*Research and Development Expenses.* Research and development expenses for the three months ended September 30, 2006 decreased 11% to \$15.9 million from \$17.8 million for the three months ended September 30, 2005. The decrease in research and development expenses resulted primarily from the completion of patient enrollment in December 2005 and associated expenditures related to the ACUITY trial, our study of Angiomax in patients presenting in the emergency department with acute coronary syndromes. This decrease was partially offset by increased investment in our clevidipine and cangrelor development programs, stock-based compensation expense of \$0.4 million and an accrual of \$1.0 million related to disputed research and development commitments.

The following table identifies for each of our products and product candidates the major research and development spending for the three months ended September 30, 2006 and 2005. Spending for past periods is not necessarily indicative of spending in future periods.

## Research and Development Expenses

(dollars in thousands)	Three Months Ended September 30,					
	2006	% of Total R&D		2005	% of Total R&D	
<i>Angiomax</i>	4,690	30	%	11,783	66	%
<i>Clevidipine</i>	4,209	26	%	1,807	10	%
<i>Cangrelor</i>	4,801	30	%	748	4	%
<i>Other</i>	2,167	14	%	3,482	20	%
<b><i>Total Research &amp; Development</i></b>	<b>\$ 15,867</b>	<b>100</b>	<b>%</b>	<b>\$ 17,820</b>	<b>100</b>	<b>%</b>

As we expect to spend approximately \$63 million to \$65 million in the aggregate on research and development in 2006, excluding stock-based compensation, we plan to increase research and development spending in the three months ending December 31, 2006 compared to the third quarter of 2006. We currently anticipate that approximately 70% of the research and development spending in the three months ending December 31, 2006 will be on cangrelor and clevidipine and we also anticipate that research and development expenses relating to cangrelor, clevidipine and non-Angiomax research and development activities will account for greater than 50% of the annual total spending on research and development. We also expect that in future quarters Angiomax research and development spending will be lower than the combined research and development spending in our other development programs.

The following provides additional information regarding our research and development spending:

*Angiomax.* We expect to continue our research and development spending on Angiomax as we seek to expand the indications for which we are marketing Angiomax.

In 2005, we completed enrollment in the ACUITY trial. In March 2006, the principal investigators of the ACUITY trial announced the results of this trial based on 30-day patient results. We continue to review the 30-day patient results in preparation for the anticipated publication of these results, and we continue to collect one-year patient results. If the one-year results are favorable, we currently anticipate filing an application in 2007 with the FDA with the one-year results to seek approval to market Angiomax in patients presenting in the emergency department with acute coronary syndromes. We have been informed by the principal investigators of the ACUITY trial that the primary results of the ACUITY trial have been accepted for publication in a major peer review journal.

In October 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 heparin-induced thrombocytopenia and thrombosis syndrome, or HIT/HITTS undergoing cardiac surgery. In the letter, the FDA stated that it does not consider the data adequate to support approval for this indication because it did not consider the evidence used to qualify patients for inclusion in the trials as a persuasive indicator for the risk of HIT/HITTS. We plan to discuss this letter with the FDA and evaluate potential next steps following that discussion.

We are continuing to support an investigator-initiated trial called HORIZONS, which is studying Angiomax use in acute myocardial infarction patients.

*Clevidipine.* In July 2006, we completed enrollment of patients in a program of three Phase III 500-patient clinical trials known as the ECLIPSE trials to evaluate the safety of clevidipine in comparison to sodium nitroprusside, nicardipine and nitroglycerine during and following cardiac surgery. We expect to review the completed ECLIPSE data in the fourth quarter of 2006. We voluntarily suspended enrollment in these three trials in March 2005 after a planned interim analysis of approximately half of the study population showed more frequent atrial fibrillation among patients randomized to clevidipine than patients randomized to comparator drugs. After completing our interim review of the results of the safety studies, we found no significant differences in interim safety results between the clevidipine and the comparator arms. We resumed enrolling patients in December 2005.

We recently met with the FDA at our request to discuss the clinical data requirements to expand the proposed label from using clevidipine to control blood pressure in patients undergoing cardiac surgery to using clevidipine to control blood pressure in patients receiving an intravenous hypertensive in the acute care setting. As a result of this meeting, we are conducting an additional study of clevidipine in 100 patients with severe hypertension known as the VELOCITY trial. In September 2006, we commenced enrollment in this study and expect to complete enrollment



by the end of 2006 or early 2007. We believe that this study will cost less than \$2.0 million. If we complete the VELOCITY trial on a timely basis and the results of the VELOCITY trial and the ECLIPSE trials are favorable, we currently anticipate filing an application with the FDA in the first half of 2007 for approval to market clevidipine in patients receiving an intravenous hypertensive in the acute care setting.

Cangrelor. 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. In March 2006, we commenced enrollment in the CHAMPION-PCI trial, one of the two pivotal trials in our Phase III program evaluating cangrelor's effectiveness and safety in preventing ischemic events in patients who require PCI. We plan to enroll approximately 9,000 patients in the CHAMPION-PCI trial, which is designed to evaluate whether use of intravenous cangrelor is superior to use of eight clopidogrel tablets in patients undergoing PCI. In October 2006, we commenced enrollment in the second pivotal trial of this Phase III program, CHAMPION-PLATFORM, which is designed to evaluate whether cangrelor plus usual care is superior to placebo plus usual care in patients who require PCI. We believe that we will have between 1,200 and 2,000 patients enrolled in both trials combined by the end of 2006, and we believe that patient enrollment in both trials will be completed in 2008.

Other. Spending in this category consists of clinical trial infrastructure costs including data management, statistical analysis, product safety related costs and expenses related to business development activities. In the three months ended September 30, 2006, spending in this category also included \$0.5 million of expenses that we incurred in collaboration with a third-party vendor under a contract research agreement with such third-party.

Our success in expanding the approved indications for Angiomax, or developing our product candidates, is uncertain. We cannot 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, any of our product candidates due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and costs 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 for the three months ended September 30, 2006 increased 32% to \$20.3 million from \$15.4 million for the three months ended September 30, 2005. This increase is primarily due to an increase in Angiomax promotional spending, clevidipine market assessment expenses, and increased infrastructure costs, including \$2.1 million of stock-based compensation.

Other Income. Other income, which is almost completely comprised of interest income, increased to \$2.0 million for the three months ended September 30, 2006 from \$1.1 million for the three months ended September 30, 2005. This increase was primarily due to higher rates of return on cash, cash equivalents and available for sale securities.





Nine Months Ended September 30, 2006 and 2005

*Net Revenue.* Net revenue for the nine months ended September 30, 2006 increased 30% to \$153.6 million as compared to \$118.1 million for the nine months ended September 30, 2005. The following table reflects the components of net revenue for the nine months ended September 30, 2006 and 2005:

(dollars in thousands)	Net Revenue					
	Nine Months Ended September 30,				% of	
	2006	% of Net Revenue	2005	% of Net Revenue		
<b>Angiomax</b>						
United States	\$ 141,732	92 %	\$ 109,389	93 %		
International	10,078	7 %	8,697	7 %		
Reimbursement	1,785	1 %		0 %		
<b>Total Net Revenue</b>	<b>\$ 153,595</b>	<b>100 %</b>	<b>\$ 118,086</b>	<b>100 %</b>		

Net revenue for the nine months ended September 30, 2006 increased compared to the nine months ended September 30, 2005 primarily due to increased sales of Angiomax to our wholesalers in the United States as a result of increased demand by hospitals including increased use by existing hospital customers, the addition of new hospital customers, and the beginning of a three-quarter wholesaler inventory reduction which commenced in the third quarter of 2005 in conjunction with the entrance into fee-for-service agreements with our three largest wholesalers.

The increase of \$1.4 million in international sales in the nine months ended September 30, 2006 compared to the nine months ended September 30, 2005 primarily resulted from increased orders from our Canadian distributor, Oryx Pharmaceuticals.

In the nine months ended September 30, 2006, we had reimbursement revenue of \$1.8 million. We generated this revenue in connection with the performance of services in collaboration with a third party under a contract research agreement.

*Cost of Revenue.* Cost of revenue for the nine months ended September 30, 2006 increased 38% to \$38.3 million, or 25% of net revenue, compared to \$27.7 million, or 23% of net revenue, for the nine months ended September 30, 2005. The following table reflects the components of cost of revenue for the nine months ended September 30, 2006 and 2005:

(dollars in thousands)	Cost of Revenue					
	Nine Months Ended September 30,				% of	
	2006	% of Cost of Revenue	2005	% of Cost of Revenue		
Manufacturing	\$ 13,738	36 %	\$ 11,563	42 %		
Royalty	19,995	52 %	12,665	46 %		
Logistics	4,558	12 %	3,473	12 %		
<b>Total Cost of Revenue</b>	<b>\$ 38,291</b>	<b>100 %</b>	<b>\$ 27,701</b>	<b>100 %</b>		

The increase in cost of revenue for the nine months ended September 30, 2006 compared to the nine months ended September 30, 2005 resulted from an increase in manufacturing costs, logistics costs and royalty expenses due to higher sales volume, a higher effective royalty rate under our agreement with Biogen Idec, and \$0.2 million of stock-based compensation.

*Research and Development Expenses.* Research and development expenses for the nine months ended



September 30, 2006 decreased 14% to \$44.4 million from \$51.4 million for the nine months ended September 30, 2005. The decrease in research and development expenses resulted primarily from the completion of patient enrollment in 2005 and the resulting decrease in expenditures related to the ACUITY trial. This decrease was partially offset by increased investment in our clevidipine and cangrelor development programs, increased investment in other research and development expenses, including \$1.8 million of expenses that we incurred in collaboration with a third-party vendor under a contract research agreement, increased investment in statistics and data management for the analysis of the ACUITY trial data, stock-based compensation expense of \$1.0 million and an accrual of \$1.0 million related to disputed research and development commitments.

The following table identifies for each of our products and product candidates the major research and development spending for the nine months ended September 30, 2006 and 2005. Spending for past periods is not necessarily indicative of spending in future periods.

#### Research and Development Expenses

(dollars in thousands)	Nine Months Ended September 30,		2005	% of Total	
	2006	% of Total R&D		% of Total R&D	
<b>Angiomax</b>	14,782	33 %	34,479	67	%
<b>Clevidipine</b>	10,697	24 %	7,974	15	%
<b>Cangrelor</b>	11,590	26 %	3,047	6	%
<b>Other</b>	7,324	17 %	5,928	12	%
<b>Total Research &amp; Development</b>	\$ 44,393	100 %	51,428	100	%

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses for the nine months ended September 30, 2006 increased 48% to \$66.0 million from \$44.5 million for the nine months ended September 30, 2005. This increase is primarily due to an increase in Angiomax selling and promotional expenses driven largely by the July 2005 expansion of the sales force, clevidipine market preparation expenses, and increased infrastructure costs including \$4.9 million of stock-based compensation.

*Other Income.* Other income, which is almost completely comprised of interest income, increased to \$4.9 million for the nine months ended September 30, 2006 from \$3.0 million for the nine months ended September 30, 2005. This increase was primarily due to higher rates of return on cash, cash equivalents and available for sale securities.

#### Liquidity and Capital Resources

*Sources of Liquidity.* Since our inception, we have financed our operations through the sale of common and preferred stock, sales of convertible promissory notes and warrants, interest income and revenue from sales of Angiomax. With the exception of the quarterly periods beginning with the fourth quarter of 2003 through the second quarter of 2005 and the second and third quarters of 2006, we have not been profitable. We had \$176.5 million in cash, cash equivalents and available for sale securities at September 30, 2006.

*Cash Flows.* As of September 30, 2006, we had \$100.8 million in cash and cash equivalents, as compared to \$48.6 million as of September 30, 2005. Our major sources of cash during the nine months ended September 30, 2006 included net cash provided by operating activities of \$22.9 million, net cash of \$39.1 million received in investing activities and \$13.1 million received from employee stock option exercises.

Net cash provided by operating activities was \$22.9 million for the nine-month period ended September 30, 2006, compared to net cash used in operating activities of \$27.9 million for the nine-month period ended September 30, 2005. The operating cash flow increase for the first nine months of 2006 consisted primarily of a decrease in inventory of \$12.8 million attributable to increased sales combined with no new Angiomax bulk substance production, net income of \$9.5 million and an increase in accrued expenses of \$7.3 million driven largely by higher royalties. These items were partially offset by an increase in accounts receivable of \$10.5 million due to higher sales and timing of cash receipts from our customers, and an increase in prepaid expenses and other current assets of \$1.7 million due to timing of payments.

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

During the nine months ended September 30, 2006, we received \$39.1 million in cash from net investing

19

---

activities, which consisted principally of the maturity and sale of available for sale securities, partially offset by purchases of available for sale securities and purchases of fixed assets relating to leasehold improvements and computer equipment.

*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 in the United States;
- the extent to which our international distributors, including Nycomed, are commercially successful;
- the progress, level and timing of our research and development activities related to our clinical trials with respect to Angiomax, clevidipine and cangrelor;
- the cost and outcomes of regulatory submissions and reviews;
- the continuation or termination of third-party manufacturing or sales and marketing arrangements;
- the cost and effectiveness of our sales and marketing programs;
- the status of competitive products;
- our ability to defend and enforce our intellectual property rights; and
- the establishment of additional strategic or licensing arrangements with other companies, or acquisitions.

We believe, based on our operating plan as of the date of this quarterly report, which includes anticipated revenue from Angiomax and interest income, that our current cash, cash equivalents and available for sale securities will be sufficient to fund our operations at least through the next twelve months, without requiring us to obtain external financing. We expect, however, to periodically assess our financing alternatives and access the capital markets if we feel it is appropriate and beneficial for us to do so. If our existing resources are insufficient to satisfy our liquidity requirements due to slower than anticipated revenue from Angiomax or otherwise, if we acquire additional product candidates or businesses, or if we otherwise believe that raising additional capital would be in our interests and the interests of our stockholders, we may sell additional equity or debt securities or seek additional financing through other arrangements. Any sale of additional equity or debt securities may result in dilution to our stockholders, 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 purchases of inventory of our products, research and development service agreements, operating leases and consulting, employment and professional services agreements associated with selling, general and administrative activities.

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

Our estimated contractual obligations as of September 30, 2006 are:

Contractual Obligations	2006(1)	2007	2008	2009	2010	Later Years	Total
Inventory-related commitments	\$ 11,315,228	\$ 15,636,600	\$ 4,343,500	\$	\$	\$	\$ 31,295,328
Research and development commitments	7,830,715	13,632,596	3,099,115	286,161			24,848,587
Operating leases	450,830	1,833,895	1,830,732	1,652,611	1,619,947	3,392,465	10,780,480
Selling, general and administrative	2,968,445	650,233	272,569				3,891,247
Total obligations and commitments	\$ 22,565,218	\$ 31,753,324	\$ 9,545,916	\$ 1,938,772	\$ 1,619,947	\$ 3,392,465	\$ 70,815,642

(1) Represents estimated contractual obligations remaining in 2006

Included above in inventory-related commitments are non-cancellable payments due to Lonza Braine totaling \$10.4 million during the remaining three months of 2006, \$15.6 million during 2007, and \$4.3 million during 2008 for Angiomax bulk drug substance to be produced and \$0.9 million in remaining Angiomax-related filling, finishing and packaging non-cancellable commitments through 2006. We have \$24.8 million of total estimated contractual obligations for research and development activities, of which \$4.0 million is non-cancellable. We also have \$3.9 million of estimated contractual obligations for consulting, employment and professional services agreements associated with selling, general and administrative activities, of which \$1.4 million is non-cancellable.

In addition to the contractual obligations above, we have agreed to make payments upon the achievement of sales and regulatory milestones, and agreed to pay royalties, to Biogen Idec under our product license agreement for Angiomax and to AstraZeneca under our product license agreements for clevidipine and cangrelor.

**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 affecting our cash, cash equivalents and available for sale securities. We place our investments in high-quality financial instruments, primarily money market funds, corporate debt and U.S. government agency securities with maturities or auction dates of less than two years, which we believe are subject to limited interest rate and credit risk. We do not hedge interest rate exposure. At September 30, 2006, we held \$176.5 million in cash, cash equivalents and available for sale securities which had an average interest rate of approximately 5.15%. At September 30, 2006, approximately 88% of the balance of cash, cash equivalents and available for sale securities was due on demand or within one year and had an average interest rate of approximately 5.21%. The remaining 12% was due within two years and had an average interest rate of approximately 4.71%.

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. If the applicable exchange rate undergoes a change of 10.0%, we do not believe that it would have a material impact on our results of operations or cash flows.

**Item 4. Controls and Procedures**

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2006. 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 a company in the reports that it files or submits 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, 2006, 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.

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 fiscal quarter ended September 30, 2006 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

#### Factors that May Affect Future Results

*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 on Form 10-Q. 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.*

#### Risks Related to Our Financial Results

*We have a history of net losses and may not maintain profitability on an annual basis*

Except for the year ended December 31, 2004, we have incurred net losses on an annual basis since our inception. As of September 30, 2006, we had an accumulated deficit of approximately \$295.4 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 the quarters ended June 30, 2006 and September 30, 2006, we were not profitable in 2005 or the quarter ended March 31, 2006 and 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 when we expect to, 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 is our only commercial product and, we expect, will account for almost all of our revenue for the foreseeable future. The commercial success of Angiomax will depend 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 extent to which we and our international distributors are successful in marketing Angiomax.

The rate of Angiomax sales growth was slower than we expected in 2005, and we cannot assure you that our increased sales and marketing efforts or expanded label will result in higher revenue or income on a continuing basis. If Angiomax is not commercially successful, we will have to find additional sources of funding or curtail or cease operations. In addition, our inventory of Angiomax increased from \$27.3 million at December 31, 2004 to \$48.0 million at December 31, 2005. As of September 30, 2006, our inventory was \$35.2 million and we had inventory-related purchase commitments to Lonza Braine totaling \$10.4 million during the remainder of 2006, \$15.6 million during 2007, and \$4.3 million during 2008 for Angiomax bulk drug substance and \$0.9 million in remaining Angiomax-related filling, finishing and packaging commitments through 2006. 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 is substantially dependent on a limited number of domestic wholesalers and international distributors to which we sell Angiomax, and such revenue may fluctuate from quarter to quarter based on the buying patterns of these wholesalers and distribution partners and the levels of inventory they maintain*

We sell Angiomax to a limited number of domestic medical and pharmaceutical wholesalers with distribution centers located throughout the United States and several international distributors. During the quarter ended September 30, 2006, revenue from the sale of Angiomax to our three largest U.S. wholesalers totaled approximately 89% of our net revenue and sales to one of our international distributors totaled



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

approximately 4% of our net revenue. Our reliance on a small number of wholesalers and distributors could cause our revenue to fluctuate from quarter to quarter based on the buying patterns of these wholesalers and distributors, regardless of

23

---

underlying hospital demand. For instance, because an order from Nycomed, one of our European distributors, was not recognized in the quarter ended March 31, 2006 due to a delay in Nycomed's acceptance of the order, our revenue for the first quarter of 2006 was reduced. In addition, if inventory levels at wholesalers and distributors are too high, they may seek to reduce their inventory levels by reducing purchases from us. In 2005, we agreed with our largest wholesalers to enter into fee-for-service arrangements. As a result of these restructured arrangements, we estimate that our three largest wholesalers reduced aggregate Angiomax inventory levels to an average of four to six weeks as of the end of the first quarter of 2006. In implementing the inventory reduction, we estimate that our three largest wholesalers reduced their aggregate inventories of Angiomax by approximately \$39.0 million over the last two quarters of 2005 and the first quarter of 2006 combined, which had an adverse effect on our revenue. Our arrangements with wholesalers may be terminated on short notice, generally 30 days. In addition, if any of these wholesalers or distributors fails to pay us on a timely basis or at all, our financial position and results of operations could be materially adversely affected.

***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 development of clevidipine and cangrelor, including clinical trials, manufacturing development and regulatory approvals, and the acquisition and development of additional product candidates by us 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 in the United States;
- the extent to which our international distributors, including Nycomed, are commercially successful;
- the progress, level and timing of our research and development activities related to our clinical trials with respect to Angiomax, clevidipine and cangrelor;
- the cost and outcomes of regulatory submissions and reviews;
- the continuation or termination of third party manufacturing or sales and marketing arrangements;
- the cost and effectiveness of our sales and marketing programs;
- the status of competitive products;
- our ability to defend and enforce our intellectual property rights; and
- the establishment of additional strategic or licensing arrangements with other companies, or acquisitions.

As of the date of this quarterly report on Form 10-Q, we believe, based on our current operating plan, which includes anticipated revenue from Angiomax and interest income, that our current cash, cash equivalents and available for sale securities are sufficient to fund our operations through at least the next twelve months without requiring us to obtain external financing. However, if our existing resources are insufficient to satisfy our liquidity requirements due to slower than anticipated sales of Angiomax or otherwise, or if we acquire additional product candidates or businesses, 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 additional financing through other arrangements. Any sale of additional equity or debt securities may result in dilution to our stockholders, and debt financing may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures. We cannot be certain that public or private financing will be available in amounts or on terms acceptable to us, if at all. If we seek to raise funds through collaboration or licensing arrangements with third parties, we may be required to relinquish rights to products, product candidates or technologies that we would not otherwise relinquish or grant licenses on terms that may not be favorable to us. If we are unable to obtain additional financing, we may be required to delay, reduce the scope of, or eliminate one or more of our planned research, development and commercialization activities, which could harm our financial condition and operating results.



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

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

Our common stock has been and in the future may be subject to substantial price volatility. From January 1, 2004 to September 30, 2006, the closing price of our common stock ranged from a high of \$35.11 per share to a low of \$15.92 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.

**Risks Related to Commercialization**

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

Because each category of anticoagulant drug acts on different components of the clotting process, we believe that there will be continued clinical work to determine the best combination of drugs for clinical use. We recognize that Angiomax may compete 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

25

---

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. The rate of Angiomax sales growth was slower than we expected in 2005, and we cannot assure you that our increased sales and marketing efforts or expanded label will result in higher revenue or income on a continuing basis. 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.

***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 development 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 continued physician acceptance of Angiomax clinical data***

In the fall of 2002, we completed a 6,002 patient post-marketing Phase 3b/4 clinical trial of Angiomax in coronary angioplasty called REPLACE-2. In November 2002, the principal investigators of the REPLACE-2 trial announced that, based on 30-day patient follow-up results, Angiomax met all of the primary and secondary objectives of the trial. In March 2003, we released the results of the detailed cost analysis study to examine per-patient total hospital resource consumption at U.S. clinical trial sites. In September 2003, the principal investigators of the clinical trial announced that, based on six-month patient follow-up results, Angiomax again met all of the primary and secondary objectives of the trial. In November 2003, the principal investigators presented one-year follow-up mortality data from the trial, which confirmed the 30-day and six-month mortality results. In December 2005, we completed enrollment in a 13,819 patient Phase III clinical trial studying Angiomax use in patients presenting to the emergency department with acute coronary syndromes called the ACUITY trial. In March 2006, the principal investigators of the ACUITY trial announced that ACUITY had met its objectives in favor of Angiomax based on 30-day patient results.

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, 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, including how we define bleeding and the clinical relevance of types of ischemic events. The FDA has noted that in its view, statistical non-inferiority was not demonstrated for the 30-day ischemic endpoint in the REPLACE-2 trial. Similarly, we cannot be certain of the extent to which physicians, patients and other key decision-makers will accept the results of the ACUITY trial. If physicians, patients and other key decision-makers do not accept the REPLACE-2 and ACUITY trial results, adoption of Angiomax may suffer, and our business will be materially adversely affected.

***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 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.

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.

***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***

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 products 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 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 Approval of Our Product Candidates**

***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, which has been approved for sale in the United States for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing percutaneous coronary interventions, and which has been approved for sale in the European Union and in other countries for indications similar to those approved by the FDA, we do not have a product approved for sale in the United States or any foreign market. We must obtain approval from the FDA in order to sell our product candidates in the United States and from foreign regulatory authorities in order to sell our product candidates in other countries. 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. We must successfully complete our clinical trials and demonstrate manufacturing capability before we can file for approval to sell our products. 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 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. Changes in the regulatory approval policy during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. The regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that data is insufficient for approval and require additional pre-clinical, clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. For example, we recently 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 plan to discuss this letter with the FDA, the FDA may require additional studies which may require the expenditure of substantial resources. Therefore, we can provide no assurance that we will be successful in obtaining regulatory approval for this indication.

***We cannot expand the indications for which we are marketing Angiomax unless we receive FDA 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. One of our key objectives is to expand the indications for which Angiomax is approved for marketing by the FDA. In order to market Angiomax for expanded indications, we will need to conduct appropriate clinical trials, obtain positive results from those trials and obtain FDA approval for such proposed indications. For example, if the one-year results of the ACUITY trial are favorable, we currently anticipate filing an application with the FDA in 2007 for approval to market Angiomax in patients presenting in the emergency department with acute coronary syndromes. If the one-year results are not favorable, however, we may not obtain FDA approval to expand the indication to market Angiomax in patients presenting in the emergency department with acute coronary syndromes or we may not seek approval for the additional indication. If we are unsuccessful in expanding the approved indications for the use of Angiomax, the size of the commercial market for Angiomax will be limited.

***Clinical trials of product candidates are expensive and time-consuming, and the results of these trials are uncertain***

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

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in pre-clinical testing or early clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. An unexpected result in one or more of our clinical trials can occur at any stage of testing. 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;
- 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;
- any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the product commercially non-viable;
- 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, 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; 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 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, advertising, promotion, 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. 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 any of the following:

- delay in approving or refusal to approve a product;
- product recall or seizure;
- interruption of production;
- operating restrictions;
- warning letters;
- injunctions;
- criminal prosecutions; and
- unanticipated expenditures.

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. Accordingly, we and our contract manufacturers will need to continue to expend time, monies, and effort in the area of production and quality control to maintain cGMP compliance.

#### **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, clevidipine and cangrelor bulk drug substance and different single 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. As of the date of this quarterly report on Form 10-Q, we obtain all of our Angiomax bulk drug substance from one manufacturer, Lonza Braine, S.A., 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.

As of the date of this quarterly report on Form 10-Q, we obtain all of our clevidipine 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 clevidipine product, as well as for release testing and clinical 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 will also rely on a different single supplier, Baxter Pharmaceutical Solutions LLC, for the manufacture of all finished cangrelor drug product for all Phase III clinical trials and to carry out release testing.

There are a limited number of manufacturers capable of manufacturing Angiomax, clevidipine and cangrelor. As of the date of this quarterly report on Form 10-Q, we do not 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. For example, in January 2006, Lonza Ltd. announced that it acquired the bioproducts manufacturing division of UCB Bioproducts S.A., our sole source of Angiomax bulk drug product as of the date of this quarterly report. Following the acquisition, we rely on Lonza Braine, S.A., as the entity formerly known as UCB Bioproducts S.A. is now known, for a commercial supply of Angiomax. In July 2004, we had entered into a development and supply agreement with Lonza Ltd. for the development of an alternative method of manufacture and commercial supply of Angiomax. We recently terminated the purchase orders under our development and supply agreement with Lonza Ltd. on the basis of Lonza Ltd.'s failure to develop a product conforming to the specifications set forth in the agreement. In the event that Lonza Braine, Johnson Matthey, Hospira, Ben Venue or Baxter is unable to carry out their respective manufacturing obligations, 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 be required to satisfy various regulatory requirements, which could cause us to experience significant delays in receiving an adequate supply of Angiomax, clevidipine or cangrelor. 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, clevidipine 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 entails 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 or establish and maintain arrangements to develop and commercialize clevidipine, cangrelor 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, clevidipine, cangrelor or any additional products we may acquire on terms that we deem favorable, our results of operations would be materially adversely affected.

Third parties may not perform their obligations as expected. The amount and timing of resources that third parties devote to developing, manufacturing and commercializing our products are not within our control. Our collaborators may develop, manufacture or commercialize, either alone or with others, products and services that are similar to or competitive with the products that are the subject of the collaboration with us. Furthermore, our interests may differ from those of third parties that manufacture or commercialize our products. Our collaborators may re-evaluate 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, clevidipine, cangrelor 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 our 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, clevidipine and cangrelor, 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 ensure strict 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, 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, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of Angiomax and our 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 clevidipine and cangrelor from AstraZeneca. Under these agreements, we are subject to commercialization and development, sublicensing, royalty, patent prosecution and maintenance, insurance and other obligations. Any failure by us to comply with any of these obligations or any other breach by us of these 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 Biogen Idec and Health Research Inc., could have a material adverse effect on our business. 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 and patent applications and corresponding foreign patents and patent applications relating to Angiomax, clevidipine and cangrelor. As of the date of this quarterly report on Form 10-Q, we exclusively license six issued U.S. patents relating to Angiomax, three issued U.S. patents relating to clevidipine and four issued U.S. patents relating to cangrelor. We have not yet filed any independent patent applications. The principal U.S. patent that covers Angiomax expires in 2010. The U.S. Patent and Trademark Office, or PTO, has 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. We are exploring alternatives to extend the term of the patent, but we can provide no assurance that we will be successful. A bill has been introduced in the United States Congress that, if enacted, would provide the PTO with discretion to consider Hatch Waxman applications filed late unintentionally. We can provide no assurance that the bill will be enacted or that, if it is enacted, the PTO will consider our application or that we will be successful in extending the term of the patent. 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.

***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. If Lonza Braine fails or is unable to transfer successfully this technology, we would be unable to employ the Chemilog process to manufacture our Angiomax bulk drug substance, which could cause us to experience delays in the manufacturing process and increase our manufacturing costs in the future.

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

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

***If we infringe or are alleged to infringe intellectual property rights of third parties, it will adversely affect our business***

Our research, development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents or patent applications under which we do not hold licenses or other rights. Third parties may own or control these patents and patent applications in the United States and abroad. These third parties could bring claims against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

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

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

### **Risks Related to Growth and Employees**

#### ***If we fail to acquire and develop additional product candidates or approved products it will impair our ability to grow***

We have a single product approved for marketing. In order to generate additional revenue, we intend to acquire and develop additional product candidates or approved products. 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 neither have, nor intend to establish, internal 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***

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, or our President and Chief Operating Officer, John P. Kelley, 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.

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

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

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

**Item 6. Exhibits**

(a) Exhibits

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

**SIGNATURES**

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

**THE MEDICINES COMPANY**

Date: November 8, 2006

By:

/s/ Glenn P. Sblendorio  
Glenn P. Sblendorio  
Executive Vice President and Chief Financial  
Officer

35

---

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
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