

MEDICINES CO /DE
Form 10-Q
August 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 June 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)

8 Campus Drive, Parsippany, NJ
(Address of Principal Executive Offices)

04-3324394

(I.R.S. Employer
Identification No.)

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

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

to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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 August 4, 2006, there were 50,439,357 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

Item 1	Unaudited Condensed Consolidated Financial Statements	1
Item 2	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	14
Item 3	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	22
Item 4	<u>Controls and Procedures</u>	22

Part II. Other Information

Item 1A	<u>Risk Factors</u>	23
Item 4	<u>Submission of Matters to a Vote of Security Holders</u>	34
Item 6	<u>Exhibits</u>	35

Signatures

Exhibit Index

THE MEDICINES COMPANY
CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2006 (unaudited)	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	\$77,623,074	\$25,705,561
Available for sale securities	72,208,215	114,383,667
Accrued interest receivable	685,625	921,704
Accounts receivable, net of allowances of approximately \$0.75 million and \$0.85 million at June 30, 2006 and December 31, 2005, respectively	24,827,664	14,611,137
Inventory	40,282,729	47,985,440
Prepaid expenses and other current assets	1,753,701	970,251
Total current assets	217,381,008	204,577,760
Fixed assets, net	3,381,111	3,990,147
Other assets	142,684	139,134
Total assets	\$220,904,803	\$208,707,041
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$3,066,007	\$5,988,549
Accrued expenses	32,958,075	28,677,480
Total current liabilities	36,024,082	34,666,029
Commitments and contingencies		
Deferred revenue	2,978,252	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 June 30, 2006 and December 31, 2005; 50,403,380 and 49,723,756 shares issued and outstanding at June 30, 2006 and December 31, 2005, respectively	50,403	49,724
Additional paid-in capital	488,052,295	476,012,428
Accumulated deficit	(306,098,352)	(304,898,644)
Accumulated other comprehensive loss	(101,877)	(264,688)
Total stockholders' equity	181,902,469	170,898,820
Total liabilities and stockholders' equity	\$220,904,803	\$208,707,041

See accompanying notes to unaudited condensed consolidated financial statements.

THE MEDICINES COMPANY
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2006	2005	2006	2005
Net revenue	\$ 59,372,477	\$ 42,594,675	\$ 94,014,818	\$ 86,166,684
Operating expenses:				
Cost of revenue	15,449,730	10,997,087	23,948,275	21,594,606
Research and development	13,977,868	16,036,818	28,525,960	33,608,608
Selling, general and administrative	20,618,521	15,237,292	45,653,388	29,088,194
Total operating expenses	50,046,119	42,271,197	98,127,623	84,291,408
Income/(loss) from operations	9,326,358	323,478	(4,112,805)	1,875,276
Other income	1,510,278	1,015,211	2,861,590	1,884,792
Income/(loss) before income taxes	10,836,636	1,338,689	(1,251,215)	3,760,068
Provision for income taxes	77,624	(87,728)	51,507	(171,419)
Net income/(loss)	\$ 10,914,260	\$ 1,250,961	\$ (1,199,708)	\$ 3,588,649
Basic earnings/(loss) per common share				
Basic earnings/(loss) per common share	\$ 0.22	\$ 0.03	\$ (0.02)	\$ 0.07
Shares used in computing basic earnings/(loss) per common share	49,950,818	49,425,961	49,932,737	49,215,685
Diluted earnings/(loss) per common share				
Diluted earnings/(loss) per common share	\$ 0.22	\$ 0.02	\$ (0.02)	\$ 0.07
Shares used in computing diluted earnings/(loss) per common share	50,546,196	50,149,932	49,932,737	50,192,052

See accompanying notes to unaudited condensed consolidated financial statements.

THE MEDICINES COMPANY
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)

	Six Months Ended June 30,	
	2006	2005
Cash flows from operating activities:		
Net (loss)/income	\$ (1,199,708)	\$ 3,588,649
Adjustments to reconcile net (loss)/income to net cash used in operating activities:		
Depreciation	719,284	358,800
Amortization of net premiums and discounts on available for sale securities	(691,905)	205,061
Non-cash stock compensation expense	3,525,480	
Loss on disposals of fixed assets	240,916	11
Tax benefit from option exercises		88,409
Changes in operating assets and liabilities:		
Accrued interest receivable	236,079	(40,936)
Accounts receivable	(10,216,527)	(16,880,769)
Inventory	7,702,711	(12,896,562)
Prepaid expenses and other current assets	(782,468)	31,807
Other assets	(3,550)	21,480
Accounts payable	(2,924,878)	(4,840,620)
Accrued expenses	4,279,591	13,431,838
Deferred revenue	(163,940)	(116,810)
Net cash provided by/(used in) operating activities	721,085	(17,049,642)
Cash flows from investing activities:		
Purchases of available for sale securities	(23,435,293)	(59,301,927)
Maturities and sales of available for sale securities	66,442,000	70,690,000
Purchase of fixed assets	(350,370)	(2,577,139)
Net cash provided by investing activities	42,656,337	8,810,934
Cash flows from financing activities:		
Proceeds from issuances of common stock, net	8,515,066	4,622,802
Net cash provided by financing activities	8,515,066	4,622,802
Effect of exchange rate changes on cash	25,025	(19,529)
Increase/(decrease) in cash and cash equivalents	51,917,513	(3,635,435)
Cash and cash equivalents at beginning of period	25,705,561	36,504,962
Cash and cash equivalents at end of period	\$ 77,623,074	\$ 32,869,527

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 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. 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 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 percutaneous coronary interventions. In addition to Angiomax, the Company is currently developing two other pharmaceutical products as potential acute care hospital products. 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- and six-month periods ended June 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 equivalents at June 30, 2006 included investments of \$37.7 million in money market funds, \$24.1 million in United States government agency notes and \$3.0 million of corporate bonds and commercial paper, all with original maturities of less than three months. Cash equivalents at December 31, 2005 included investments of \$12.6 million in 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 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 June 30, 2006, the Company held available for sale securities with fair market value totaling \$72.2 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. 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 further 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 June 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 \$0.6 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, we pay fees for services rendered by a research organization and other out-of-pocket costs for which we are 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 needs 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	June 30, 2006	December 31, 2005
Raw materials	\$ 16,473,746	\$ 21,047,747
Work-in-progress	12,742,482	23,630,430
Finished goods	11,066,501	3,307,263
Total inventory	\$ 40,282,729	\$ 47,985,440

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.

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 Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* (Statement 123).

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 FASB Interpretation No. (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.

As a result of adopting SFAS 123(R), the Company recorded approximately \$3.5 million of stock-based compensation expense for the six months ended June 30, 2006, including \$2.0 million of stock-based compensation expense in the second quarter of 2006. As of June 30, 2006, there was approximately \$10.1 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 2.85 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 six months ending June 30, 2005:

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

	Three Months Ended June 30, 2005	Six Months Ended June 30, 2005
Net income - As reported	\$ 1,250,961	\$ 3,588,649
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	(4,296,277)	(9,352,602)
Add: Amortization of deferred stock compensation		
Net loss - Pro forma	\$ (3,045,316)	\$ (5,763,953)
Earnings per share, basic - As reported	\$ 0.03	\$ 0.07
Net loss per share, basic - Pro forma	\$ (0.06)	\$ (0.12)
Earnings per share, diluted - As reported	\$ 0.02	\$ 0.07
Net loss per share, diluted - Pro forma	\$ (0.06)	\$ (0.12)

For purposes of applying SFAS 123(R) to the quarter and six months ended June 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 ranges given below result from the two groups of employees exhibiting different behavior. 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 June 30,		Six Months Ended June 30,	
	2006	2005	2006	2005
Expected dividend yield	0	0	% 0	0
Expected stock price volatility	44-47	65	% 44-47	66
Risk-free interest rate	4.89-5.02	4	% 4.78-4.88	4
Expected option term (years)	2.84-3.72	2.60	2.95-3.71	2.70

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 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.

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

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 of 7.9%, 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 under the Company's option plans for the six months ended June 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	1,024,775	19.23		
Exercised	(625,550)	12.81		
Forfeited and expired	(762,324)	24.37		
Outstanding, June 30, 2006	7,316,037	\$ 20.95	8.13	\$ 12,641,469
Exercisable, June 30, 2006	5,446,265	\$ 21.72	7.68	\$ 10,797,620

Range of Exercise Prices Per Share	Options Outstanding			Options Vested		
	Number Outstanding at 6/30/06	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price Per Share	Number Outstanding at 6/30/06	Weighted Average Exercise Price Per Share	
\$1.23- \$9.13	484,753	4.38	\$5.74	484,441	\$5.74	
\$9.39- \$13.80	235,705	5.69	11.18	232,872	11.18	
\$15.32- \$17.38	527,549	6.81	16.23	392,796	16.08	
\$17.45- \$19.09	1,952,879	9.44	18.42	624,088	18.28	
\$19.11- \$22.51	1,157,895	8.99	21.14	754,812	21.66	
\$22.57- \$24.60	843,810	7.84	23.45	843,810	23.45	
\$24.92- \$27.81	990,613	7.91	26.41	990,613	26.41	
\$27.87- \$30.27	826,333	8.18	28.16	826,333	28.16	
\$30.69- \$34.95	296,500	7.86	32.36	296,500	32.36	
	7,316,037	8.13	\$20.95	5,446,265	\$21.72	

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 June 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 second quarter of 2006 and 2005 was \$6.80 and \$9.26, respectively. The weighted-average grant date fair value of options granted during the six months ended June 30, 2006 and 2005 was \$7.08 and \$10.14, respectively. The total intrinsic value of options exercised during the second quarter of 2006 and 2005 was \$3.6 million and \$1.8 million, respectively. The total intrinsic value of options exercised during the six months ended June 30, 2006 and 2005 was \$3.9 million and \$4.8 million, respectively.

Cash received from exercise of options and purchases of common stock under the Company's 2000 Employee Stock Purchase Plan during the three months and six months ended June 30, 2006 was approximately \$8.5 million and \$4.6 million, respectively, and is included within the financing activities section of the consolidated statements of cash flows.

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

	Number of Shares	Weighted Average Grant-Date Fair Value
Non-vested, December 31, 2005		
Awarded	25,000	\$ 20.11
Vested		
Forfeited		
Non-vested, June 30, 2006	25,000	\$ 20.11

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 \$56,000 and \$73,000 was recognized in the quarter ended June 30, 2006 and the six months ended June 30, 2006, respectively. The remaining expense of approximately \$0.3 million will be recognized over a period of 3.68 years.

2000 Employee Stock Purchase Plan. As of June 30, 2006, the Company had issued 206,564 shares over the life of the Company's 2000 Employee Stock Purchase Plan (ESPP). The Company issued 29,074 shares and 27,380 shares during the first six months of 2006 and 2005, respectively. The Company currently has 298,936 shares in reserve for future issuance under the plan. The Company recorded approximately \$0.2 million in ESPP compensation expense in the six months ended June 30, 2006, including approximately \$0.1 million in the second 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 curve in effect at the time of grant.

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

	Six Months Ended June 30,	
	2006	2005
Expected dividend yield	—	—
Expected stock price volatility	31 %	35 %
Risk-free interest rate	3.57-4.63 %	2.86 %
Expected option term (years)	0.5	0.5

During the three months and six months ended June 30, 2006, the Company issued 581,855 and 679,624 shares of its common stock respectively, which shares were issued upon the exercise of stock options, restricted stock grants and purchases under the ESPP. During the three and six months ended June 30, 2005, the Company issued 138,241 and 876,094 shares of its common stock respectively, which shares were issued upon the exercise of stock options, purchases under the ESPP and the exercise of common stock warrants.

Common Stock Reserved for Future Issuance At June 30, 2006, there were 4,790,582 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 six months ended June 30, 2006 and 2005:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2006	2005	2006	2005
Basic and diluted				
Net income/(loss)	\$ 10,914,260	\$ 1,250,961	\$ (1,199,708)	\$ 3,588,649
Weighted average common shares outstanding, basic	49,975,818	49,425,961	49,949,173	49,215,685
Less: unvested restricted common shares outstanding	25,000		16,436	
Net weighted average common shares outstanding, basic	49,950,818	49,425,961	49,932,737	49,215,685
Plus: net effect of dilutive stock options, restricted common shares and warrants	595,378	723,971		976,367
Weighted average common shares outstanding, diluted	50,546,196	50,149,932	49,932,737	50,192,052
Earnings/(loss) per share, basic	\$ 0.22	\$ 0.03	\$ (0.02)	\$ 0.07
Earnings/(loss) per share, diluted	\$ 0.22	\$ 0.02	\$ (0.02)	\$ 0.07

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 June 30, 2006, there were options to purchase 7,316,037 shares of common stock outstanding. The options that are at or above the exercise price have been included in the computation of diluted earnings per share for the three months ended June 30, 2006. These options were not included in the computation of diluted net loss per share for the six months ended June 30, 2006, as their effects would have been antidilutive. As of June 30, 2005, there were outstanding options to purchase 6,473,463 shares of common stock. The options that are at or above the exercise price have been included in the computation of diluted earnings per share for the three and six months ended June 30, 2005. The number of dilutive common stock equivalents was calculated using the treasury stock method.

5. Comprehensive Income/(Loss)

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

Comprehensive income/(loss) is primarily comprised of net income/(loss), unrealized gain/(loss) on available for sale securities and currency translation adjustments. Comprehensive income for the three and six

11

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

months ended June 30, 2006 and June 30, 2005 is detailed below.

Comprehensive Income	Three Months ended June 30,		Six Months ended June 30,	
	2006	2005	2006	2005
Net income/(loss)	\$ 10,914,260	\$ 1,250,961	\$ (1,199,708)	\$ 3,588,649
Unrealized gain on available for sale securities	93,033	179,285	139,350	44,486
Foreign currency translation adjustment	8,237	(8,392)	23,461	(11,859)
Comprehensive income/(loss)	\$ 11,015,530	\$ 1,421,854	\$ (1,036,897)	\$ 3,621,276

6. Income Taxes

For the six months ended June 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. Commitments

Contractual Obligations

The Company's 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 the Company's products, research and development service agreements, operating leases and consulting, employment and professional services agreements associated with selling, general and administrative activities.

The Company's estimated contractual obligations as of June 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	15,127,826	11,499,204	2,346,370	208,750			29,182,150
Operating leases	901,129	1,830,547	1,827,768	1,650,801	1,618,137	3,391,409	11,219,791
Selling, general and administrative	4,286,287	310,846	30,545				4,627,678
Total obligations and commitments	\$ 31,630,470	\$ 29,277,197	\$ 8,548,183	\$ 1,859,551	\$ 1,618,137	\$ 3,391,409	\$ 76,324,947

(1) Represents estimated contractual obligations remaining in 2006

Included above in inventory-related commitments are non-cancellable payments to Lonza Braine totaling

\$10.4 million during the remaining six 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. The Company has \$29.2 million of total estimated contractual obligations for research and development activities, of which \$3.5 million is non-cancellable. The Company also has \$4.6 million of estimated contractual obligations for consulting, employment and professional services agreements associated with selling, general and administrative activities, of which \$0.8 million is non-cancellable.

In addition to the contractual obligations above, the Company has agreed to make payments upon the achievement of sales and regulatory milestones, and agreed to pay royalties, to Biogen Idec Inc. under its product license agreement for Angiomax and to AstraZeneca under the Company's product license agreements for clevidipine and cangrelor.

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 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 Angiox has been sold in countries in Europe since that time.

In evaluating our operating performance, 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 incurred a net loss of \$1.2 million for the six months ended June 30, 2006, as our research and development expenses together with our selling, general and administrative expenses and cost of revenue exceeded our net revenue. Research and development expenses represent costs incurred for product acquisition, clinical trials, activities relating to regulatory filings and manufacturing development efforts. We outsource much of our clinical trial activities and all of our manufacturing development activities to third parties to maximize efficiency and minimize our internal overhead. We expense our research and development costs as they are incurred. Selling, general and administrative expenses consist primarily of salaries and related expenses, general corporate activities and costs associated with marketing and promotional activities.

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, resulting in estimated aggregate wholesaler inventories of an average of four to six weeks of demand as of March 31, 2006. We also estimate that our three largest wholesalers had an aggregate average of four to six weeks of inventory as of June 30, 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 development-stage products, 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 under different assumptions and conditions.

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 June 30, 2006 and 2005

Net Revenue. As shown in the table below, net revenue for the three months ended June 30, 2006 increased 39% to \$59.4 million as compared to \$42.6 million for the three months ended June 30, 2005.

Net Revenue

(dollars in thousands)	Three Months Ended June 30,				% of Total Revenue	
	2006	% of Total Revenue	2005	% of Total Revenue		
Angiomax						
United States	\$ 53,276	90 %	\$ 39,716	93 %		
International	5,795	10 %	2,879	7 %		
Reimbursement	301	0 %	0	0 %		
Total Net Revenue	\$ 59,372	100 %	\$ 42,595	100 %		

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

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

The increase of \$2.9 million in international sales in the three months ended June 30, 2006 compared to the three months ended June 30, 2005 reflects our recognition of the sale of two shipments to one of our European distributors, Nycomed Danmark A/S, in the second quarter of 2006 as compared to one shipment in the second quarter of 2005. The recognition of two shipments to Nycomed in the three months ended June 30, 2006 resulted from the delay in acceptance of an order by Nycomed at the end of the first quarter of 2006.

In the three months ended June 30, 2006, we had reimbursement revenue of \$0.3 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. As shown in the table below, cost of revenue for the three months ended June 30, 2006 increased 41% to \$15.5 million, or 26% of net revenue, compared to \$11.0 million, or 26% of net revenue, for the three months ended June 30, 2005. 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.

Cost of Revenue

(dollars in thousands)	Three Months Ended June 30,					
	2006	% of Total Cost		2005	% of Total Cost	
Manufacturing	\$ 5,693	37	%	\$ 4,434	40	%
Royalty	8,100	52	%	5,351	49	%
Logistics	1,657	11	%	1,212	11	%
Total Cost of Revenue	\$ 15,450	100	%	\$ 10,997	100	%

The increase in cost of revenue for the three months ended June 30, 2006 compared to the three months ended June 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 increased royalties under our agreement with Biogen Idec as a result of higher international sales in the second quarter of 2006.

Research and Development Expenses. Research and development expenses for the three months ended June 30, 2006 decreased 13% to \$14.0 million from \$16.0 million for the three months ended June 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, partially offset by increased investment in our clevidipine and cangrelor development programs and stock-based compensation expense of \$0.3 million.

The following table identifies for each of our major research and development projects our spending for the three months ended June 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 June 30,					
	2006	% of Total R&D		2005	% of Total R&D	
Angiomax	3,580	26	%	11,833	74	%
Clevidipine	3,982	28	%	2,146	13	%

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

<i>Cangrelor</i>	4,397	32	%	877	6	%
<i>Other</i>	2,019	14	%	1,181	7	%
	\$ 13,978	100	%	\$ 16,037	100	%

16

We currently plan to spend approximately \$63 million to \$65 million on research and development in 2006, and anticipate that research and development expenses relating to cangrelor, clevidipine and non-Angiomax research and development activities will account for greater than 50% of that total. 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.

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 with the FDA in 2007 for approval to market Angiomax in patients presenting in the emergency department with acute coronary syndromes in 2007 with the one-year results.

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 500-patient clinical trials to evaluate the safety of clevidipine in comparison to sodium nitroprusside, nicardipine and nitroglycerine during and following cardiac surgery. 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 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 preparing to conduct an additional study of clevidipine in 100 patients with severe hypertension. We anticipate that we will begin enrolling patients in this study in the third quarter of 2006 and expect that we will complete the study by the end of 2006. We believe that this study will cost less than \$2.0 million. If we complete the study on a timely basis and the results 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 also 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 and we expect to commence enrollment in the second pivotal trial of this Phase III program, CHAMPION-PLATFORM, in the second half of 2006. We believe that we will have between 1,000 and 2,000 patients enrolled in both trials combined by the end of 2006.

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 June 30, 2006, spending in this category also included \$0.3 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 highly 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 June 30, 2006 increased 36% to \$20.6 million from \$15.2 million for the three months ended June 30, 2005. This increase is primarily due to an increase of \$1.3 million in continuing medical education grants, \$2.0 million of additional costs related to the Angiomax sales force expansion that occurred in 2005, and \$1.6 million of stock-based compensation.

Other Income. Other income, which is almost completely comprised of interest income, increased to \$1.5 million for the three months ended June 30, 2006 from \$1.0 million for the three months ended June 30, 2005. This increase was primarily due to higher rates of return on cash, cash equivalents and available for sale securities.

Six Months Ended June 30, 2006 and 2005

Net Revenue. As shown in the table below, net revenue for the six months ended June 30, 2006 increased 9% to \$94.0 million as compared to \$86.2 million for the six months ended June 30, 2005.

Net Revenue

(dollars in thousands)	Six Months Ended June 30,			
	2006	% of Total Revenue	2005	% of Total Revenue
Angiomax				
United States	\$ 86,083	92 %	\$ 80,004	93 %
International	6,634	7 %	6,163	7 %
Reimbursement	1,298	1 %		0 %
Total Net Revenue	\$ 94,015	100 %	\$ 86,167	100 %

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

The increase of \$0.5 million in international sales in the six months ended June 30, 2006 compared to the six months ended June 30, 2005 primarily resulted from increased orders from our Canadian distributor, Oryx Pharmaceuticals.

In the six months ended June 30, 2006, we had reimbursement revenue of \$1.3 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. As shown in the table below, cost of revenue for the six months ended June 30, 2006

18

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

increased 11% to \$23.9 million, or 25% of net revenue, compared to \$21.6 million, or 25% of net revenue, for the six months ended June 30, 2005. Cost of revenue consists of expenses 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.

Cost of Revenue

(dollars in thousands)	Six Months Ended June 30,			Six Months Ended June 30,	
	2006	% of Total Cost		2005	% of Total Cost
Manufacturing	\$ 8,636	36 %	\$ 8,193	38 %	
Royalty	12,275	51 %	10,818	50 %	
Logistics	3,037	13 %	2,584	12 %	
Total Cost of Revenue	\$ 23,948	100 %	\$ 21,595	100 %	

The increase in cost of revenue for the six months ended June 30, 2006 compared to the six months ended June 30, 2005 resulted from an increase in manufacturing costs, logistics costs and royalty expenses due to higher sales volume, and \$0.2 million of stock-based compensation.

Research and Development Expenses. Research and development expenses for the six months ended June 30, 2006 decreased 15% to \$28.5 million from \$33.6 million for the six months ended June 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, partially offset by increased investment in our clevidipine and cangrelor development programs, increased investment in other research and development expenses, including \$1.3 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, and stock-based compensation expense of \$0.5 million.

The following table identifies for each of our major research and development projects our spending for the six months ended June 30, 2006 and 2005. Spending for past periods is not necessarily indicative of spending in future periods.

Research and Development Expenses

(dollars in thousands)	Six Months Ended June 30,			Six Months Ended June 30,	
	2006	% of Total R&D		2005	% of Total R&D
<i>Angiomax</i>	10,093	35 %	22,697	68 %	
<i>Clevidipine</i>	6,488	23 %	6,167	18 %	
<i>Cangrelor</i>	6,789	24 %	2,299	7 %	
<i>Other</i>	5,156	18 %	2,446	7 %	
	\$ 28,526	100 %	\$ 33,609	100 %	

Selling, General and Administrative Expenses. Selling, general and administrative expenses for the six months ended June 30, 2006 increased 57% to \$45.7 million from \$29.1 million for the six months ended June 30, 2005. This increase is primarily due to an increase of \$6.3 million in continuing medical education grants, \$4.6 million of additional costs related to the Angiomax sales force expansion, \$1.3 million of one-time costs, including \$0.8 million in connection with a re-evaluation of certain employee benefit programs and \$2.6 million of stock-based compensation.

Other Income. Other income, which is almost completely comprised of interest income, increased to \$2.9 million for the six months ended June 30, 2006 from \$1.9 million for the six months ended June 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 third quarter of 2003 through the second quarter of 2005 and the second quarter of 2006, we have not been profitable. We had \$149.8 million in cash, cash equivalents and available for sale securities at June 30, 2006.

Cash Flows. As of June 30, 2006, we had \$77.6 million in cash and cash equivalents, as compared to \$32.9 million as of June 30, 2005. Our major sources of cash during the six months ended June 30, 2006 included net cash provided by operating activities of \$0.7 million, net cash of \$42.7 million received in investing activities and \$8.5 million received from employee stock option exercises.

Net cash provided by operating activities was \$0.7 million for the six-month period ended June 30, 2006, compared to net cash used in operating activities of \$17.0 million for the six-month period ended June 30, 2005. The operating cash flow increase for the first six months of 2006 consisted primarily of an increase in accrued expenses of \$4.3 million driven largely by higher royalties, a decrease in inventory of \$7.7 million attributable to increased sales combined with no new Angiomax bulk substance production, and non-cash stock compensation expense of \$3.5 million, partially offset by an increase in accounts receivable of \$10.2 million due to higher sales and timing of cash receipts from our customers, and a decrease in accounts payable of \$2.9 million due to timing of payments.

During the six months ended June 30, 2006, we received \$42.7 million in cash from net investing 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;
- packaging approval for Angiox from the European authorities, and pricing reimbursement approvals in individual European countries, on a timely basis or at all;
- 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.

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

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

20

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.

Our estimated contractual obligations as of June 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	15,127,826	11,499,204	2,346,370	208,750			29,182,150
Operating leases	901,129	1,830,547	1,827,768	1,650,801	1,618,137	3,391,409	11,219,791
Selling, general and administrative	4,286,287	310,846	30,545				4,627,678
Total obligations and commitments	\$ 31,630,470	\$ 29,277,197	\$ 8,548,183	\$ 1,859,551	\$ 1,618,137	\$ 3,391,409	\$ 76,324,947

(1) Represents estimated contractual obligations remaining in 2006

Included above in inventory-related commitments are non-cancellable payments to Lonza Braine totaling \$10.4 million during the remaining six 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 \$29.2 million of total estimated contractual obligations for research and development activities, of which \$3.5 million is non-cancellable. We also have \$4.6 million of estimated contractual obligations for consulting, employment and professional services agreements associated with selling, general and administrative activities, of which \$0.8 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 June 30, 2006, we held \$149.8 million in cash, cash equivalents and available for sale securities which had an average interest rate of approximately 4.86%. At June 30, 2006, approximately 80% 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 5.03%. The remaining 20% was due within two years and had an average interest rate of approximately 4.20%.

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 June 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 June 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 June 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 June 30, 2006, we had an accumulated deficit of approximately \$306.1 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, we were not profitable in 2005 or the first half of 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 June 30, 2006, our inventory was \$40.3 million and we had inventory-related 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 June 30, 2006, revenue from the sale of Angiomax to our three largest U.S. wholesalers totaled approximately 84% of our net revenue and sales to one of our international distributors totaled approximately

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

8% 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 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, 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 restructured 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;
- packaging approval for Angiox from the European authorities, and pricing reimbursement approvals in individual European countries, on a timely basis or at all;
- 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, including in connection with our restructured wholesaler arrangements, 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 June 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 quarterly 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 biotechnology 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 indication.

25

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

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

We have positioned Angiomax as a replacement for heparin, which is a widely used, inexpensive, generic drug used in patients with arterial thrombosis. Because heparin is inexpensive and has been widely used for many years, physicians and medical decision-makers may be hesitant to adopt Angiomax. In addition, due to the high incidence and severity of cardiovascular diseases, competition in the market for thrombin inhibitors is intense and growing. 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 March 2006, the principal investigators of the ACUITY trial announced the results of this trial 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 claims 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.

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 with the one-year results. 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.

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

As of the date of this quarterly report on Form 10-Q, we obtain all of our clevidipine bulk drug substance

29

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. 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. Following the acquisition, we rely on Lonza Braine, S.A., as the entity formerly known as UCB Bioproducts is now known, for a commercial supply of Angiomax and Lonza Ltd. for development of the alternative method of manufacture. 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.

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. Angiomax and our product candidates may compete with product candidates and products of third parties for access to manufacturing facilities.

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 4. Submission of Matters to a Vote of Security Holders

On May 25, 2006, the following proposals were voted on at our 2006 annual meeting of stockholders:

Proposal	For	Against/Withheld	Abstentions	Broker Non-Votes
To elect Armin M. Kessler to serve as class 3 director until the 2009 annual meeting of stockholders	39,356,983	2,855,397	N/A	N/A
To elect Robert G. Savage to serve as class 3 director until the 2009 annual meeting of stockholders	38,567,076	3,645,304	N/A	N/A
To elect Melvin K. Spigelman to serve as class 3 director until the 2009 annual meeting of stockholders	41,450,275	762,105	N/A	N/A
To ratify the appointment of Ernst & Young LLP as our independent public accountants for the current fiscal year	41,719,720	483,341	9,318	N/A
To approve an amendment to our 2004 stock incentive plan in order to increase the number of shares of common stock authorized for issuance under the plan from 4,400,000 to	26,628,494	7,534,992	3,234	8,045,660

8,800,000

To approve an amendment to our 2000 employee stock purchase plan in order to increase the number of shares of common stock authorized for issuance under the plan from 255,500 to 505,500

29,966,496

4,161,418

38,806

8,045,660

34

In addition to the three directors listed above who were elected at the meeting, the terms of the following directors continued after the meeting: William W. Crouse, T. Scott Johnson, John Kelley, Robert J. Hugin, Clive A. Meanwell and Elizabeth H.S. Wyatt.

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.

35

SIGNATURES

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

THE MEDICINES COMPANY

Date: August 8, 2006

By:

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

EXHIBIT INDEX

Exhibit Number	Description
10.1	Amendment No. 1 to License Agreement dated as of April 25, 2006 by and between AstraZeneca AB and the Registrant
10.2	2004 Stock Incentive Plan, as amended
10.3	2000 Employee Stock Purchase Plan, as amended
31.1	Chairman and Chief Executive Officer Certification pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Chief Financial Officer Certification pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Chairman and Chief Executive Officer Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Chief Financial Officer Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Confidential treatment has been requested for certain portions of this Exhibit pursuant to Rule 24b-2 promulgated under the Securities Exchange Act of 1934, as amended
