

MEDICINES CO /DE
Form 10-Q
November 08, 2005

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

☒

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

For the quarterly period ended September 30, 2005

OR

☐

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

For the transition period from to

Commission File Number 000-31191

The Medicines Company

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

04-3324394
(I.R.S. Employer Identification No.)

8 Campus Drive, Parsippany, NJ

07054

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(Address of Principal Executive Offices)

(Zip Code)

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

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

Yes ☐ No ☒

Indicate the number of shares outstanding of each of the issuer's classes of Common Stock, as of the latest practicable date: As of November 4, 2005, there were 49,721,388 shares of Common Stock, \$0.001 par value per share, outstanding.

THE MEDICINES COMPANY

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THE MEDICINES COMPANY
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2005 (unaudited)	December 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 48,576,965	\$ 36,504,962
Available for sale securities	87,568,808	123,807,353
Accrued interest receivable	735,727	911,807
Accounts receivable, net of allowances of approximately \$1.55 million and \$3.57 million at September 30, 2005 and December 31, 2004, respectively	38,809,049	18,387,596
Inventory	42,635,386	27,341,855
Prepaid expenses and other current assets	1,529,629	1,252,211
Total current assets	219,855,564	208,205,784
Fixed assets, net	3,880,514	1,677,464
Other assets	139,133	160,614
Total assets	\$ 223,875,211	\$ 210,043,862
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 5,105,773	\$ 11,517,326
Accrued expenses	29,903,291	23,339,111
Deferred revenue	9,752,144	
Total current liabilities	44,761,208	34,856,437
Commitments and contingencies		
Deferred revenue	3,303,807	3,516,523
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 and 75,000,000 shares authorized at September 30, 2005 and December 31, 2004, respectively; 49,701,788 and 48,644,814 shares issued and outstanding at September 30, 2005 and December 31, 2004, respectively	49,702	48,645
Additional paid-in capital	475,830,332	469,100,751
Accumulated deficit	(299,788,597)	(297,145,341)
Accumulated other comprehensive loss	(281,241)	(333,153)
Total stockholders' equity	175,810,196	171,670,902
Total liabilities and stockholders' equity	\$ 223,875,211	\$ 210,043,862

See accompanying notes to unaudited condensed consolidated financial statements.

THE MEDICINES COMPANY

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Net revenue	\$ 31,919,597	\$ 37,714,796	\$ 118,086,281	\$ 103,385,854
Operating expenses:				
Cost of revenue	6,106,441	9,147,602	27,701,047	20,328,546
Research and development	17,819,639	12,331,830	51,428,247	34,182,908
Selling, general and administrative	15,438,026	11,353,209	44,526,220	37,599,126
Total operating expenses	39,364,106	32,832,641	123,655,514	92,110,580
Income/(loss) from operations	(7,444,509)	4,882,155	(5,569,233)	11,275,274
Other income	1,144,930	516,011	3,029,722	1,475,145
Income/(loss) before income taxes	(6,299,579)	5,398,166	(2,539,511)	12,750,419
Provision for income taxes	67,674	(136,742)	(103,745)	(418,497)
Net income/(loss)	\$ (6,231,905)	\$ 5,261,424	\$ (2,643,256)	\$ 12,331,922
Basic earnings/(loss) per common share	\$ (0.13)	\$ 0.11	\$ (0.05)	\$ 0.26
Shares used in computing basic earnings/(loss) per common share	49,611,918	47,885,113	49,349,230	47,715,405
Diluted earnings/(loss) per common share	\$ (0.13)	\$ 0.11	\$ (0.05)	\$ 0.25
Shares used in computing diluted earnings/(loss) per common share	49,611,918	49,665,656	49,349,230	49,696,782

See accompanying notes to unaudited condensed consolidated financial statements.

THE MEDICINES COMPANY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	Nine Months Ended September 30,	
	2005	2004
Cash flows from operating activities:		
Net income/(loss)	\$ (2,643,256)	\$ 12,331,922
Adjustments to reconcile net income/(loss) to net cash used in operating activities:		
Depreciation	668,952	372,211
Amortization of premiums on available for sale securities	137,859	1,137,139
Non-cash stock compensation expense		868,008
Loss on disposals of fixed assets	15	44,838
Changes in operating assets and liabilities:		
Accrued interest receivable	176,080	318,198
Accounts receivable	(20,421,453)	(13,408,143)
Inventory	(15,293,531)	(8,896,304)
Prepaid expenses and other current assets	(278,607)	(562,870)
Other assets	21,481	39,651
Accounts payable	(6,410,419)	(4,855,555)
Accrued expenses	6,576,421	6,899,851
Deferred revenue	9,539,428	2,341,595
Net cash used in operating activities	(27,927,030)	(3,369,459)
Cash flows from investing activities:		
Purchases of available for sale securities	(77,163,035)	(60,293,914)
Maturities and sales of available for sale securities	113,331,000	39,736,000
Purchase of fixed assets	(2,874,397)	(442,536)
Net cash provided by (used in) investing activities	33,293,568	(21,000,450)
Cash flows from financing activities:		
Proceeds from issuances of common stock, net	6,730,638	6,427,067
Net cash provided by financing activities	6,730,638	6,427,067
Effect of exchange rate changes on cash	(25,173)	1,242
Increase/(decrease) in cash and cash equivalents	12,072,003	(17,941,600)
Cash and cash equivalents at beginning of period	36,504,962	43,401,610
Cash and cash equivalents at end of period	\$ 48,576,965	\$ 25,460,010

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 (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 June 2005, the FDA approved new prescribing information for Angiomax to also include patients undergoing percutaneous coronary intervention. The Company is also currently developing Angiomax for other indications. The Company has concentrated its commercial sales and marketing resources on the United States hospital market, and revenues to date have 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 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 the short-term control of blood pressure in surgical patients, including patients undergoing cardiac surgery. The second potential product, cangrelor, is an agent that suppresses 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 nine-month periods ended September 30, 2005 are not necessarily indicative of the results that may be expected for the entire fiscal year ending December 31, 2005. 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, 2004, filed with the Securities and Exchange Commission.

Use of Estimates

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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 revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash, Cash Equivalents and Available for Sale Securities

The Company considers all highly liquid investments purchased with an original maturity at the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents at September 30, 2005 consisted of \$27.1 million in demand deposits and money market funds and \$21.5 million of corporate bonds and United States government agency notes with original maturities of less than three months. Cash and cash equivalents at December 31, 2004 consisted of \$34.5 million in demand deposits and money market funds and \$2.0 million of corporate bonds with original maturities of less than three months. These investments are carried at cost, which

approximates fair value. The Company measures all original maturities from the date the investment was originally purchased by the Company.

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

At September 30, 2005, the Company held available for sale securities with fair value totaling \$87.6 million. These available for sale securities included various corporate debt securities and United States government agency notes, \$33.0 million of which had original maturities of more than three months and up to one year and \$54.6 million of which had original maturities of more than one year and up to two years. At December 31, 2004, the Company held available for sale securities with fair value totaling \$123.8 million. These available for sale securities included various corporate debt securities and United States government agency notes, \$49.1 million of which had original maturities of more than three months and up to one year and \$74.7 million of which had original maturities of more than one year and up to two years.

Revenue Recognition

Product Sales. The Company sells its products primarily to domestic wholesalers and international distribution partners, 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. Revenue from product sales that do not meet all of these requirements is recorded under current deferred revenue.

Domestic Sales. The Company records allowances for chargebacks and other discounts and accruals for product returns and rebates at the time of sale, and reports revenue net of such amounts. In determining allowances and accruals, the Company must make significant judgments and estimates. For example, in determining these amounts, the Company estimates hospital demand, buying patterns by hospitals and group purchasing organizations from wholesalers and the levels of inventory held by wholesalers. Making these determinations involves estimating whether trends in past wholesaler and hospital buying patterns will predict future product sales. The Company recently 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. As these arrangements are implemented, the Company expects to apply this data in determining 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 allowance for product returns, the Company must estimate the likelihood that product sold to wholesalers might remain in their inventory to within six months of expiration and

analyze the likelihood that such product will be returned within 12 months after expiration.

In estimating the likelihood of product remaining in wholesalers' inventory, the Company relies on information from wholesalers regarding their inventory levels and measured hospital demand as reported by the Company's largest wholesalers, other third party sources and internal sales data. The Company believes that the information from its wholesalers and third party sources is directionally reliable, but the Company is unable to verify the accuracy of such data independently. 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 primarily 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.

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 in the future. The Company continually monitors its allowances and makes adjustments when the Company believes actual experience may differ from its estimates.

At September 30, 2005 and December 31, 2004, the Company's allowance for chargebacks was \$0.9 million and \$3.1 million, respectively, its accrual for rebates was \$1.7 million and \$1.6 million, respectively, and its accrual for product returns was \$0.4 million and \$0.6 million, respectively.

International Distribution Partners. Under the Company's agreements with international distribution partners, the Company sells its product to these distribution partners at a percentage of the distribution partner'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 distribution partners, based on the distribution partner's net selling price to its customers. In those situations, usually prior to product launch, where product is sold prior to the establishment of the distribution partner's selling price, the Company records revenue at minimum prices specified in these agreements and subsequently adjusts its selling price once the 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 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.

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. Angiomax bulk drug product is classified as raw materials and its costs are determined using acquisition costs from contract manufacturers. Work-in-progress costs of filling, finishing and packaging are recorded against specific product batches. Prior to FDA approval of Angiomax and its original manufacturing process in December 2000, the Company expensed all of these costs as research and development. The Company recorded as inventory any Angiomax bulk drug product manufactured using the original manufacturing process to which the Company took title after FDA approval.

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Together with its contract-manufacturing partner, UCB Bioproducts S.A., the Company developed a second-generation chemical synthesis process, the Chemilog process, for the manufacture of Angiomax bulk drug substance. In May 2003, the Company received FDA approval of this process. All Angiomax bulk drug product that was manufactured using the Chemilog process to which title had transferred to the Company prior to FDA approval was expensed as research and development at the time of transfer of title, and all bulk drug product manufactured after FDA approval of the Chemilog process has been and will be recorded as inventory upon transfer of title from

the Company's vendors.

The major classes of inventory are as follows:

Inventory	September 30, 2005		December 31, 2004	
Raw materials	\$	13,734,087	\$	7,071,522
Work-in-progress		25,129,741		13,155,988
Finished goods		3,771,558		7,114,345
Total inventory	\$	42,635,386	\$	27,341,855

During the nine months ended September 30, 2005, in order to mitigate the risk of relying on its single suppliers, the Company increased the production of inventory to ensure an adequate supply of Angiomax to meet the anticipated commercial demands for Angiomax. The Company obtains all of its Angiomax bulk drug substance from one manufacturer and relies on a separate third party to carry out all fill-finish activities for Angiomax. The Company reviews inventory for slow-moving or obsolete amounts based on expected product sales.

Research and Development

Research and development costs are expensed as incurred.

Stock-Based Compensation

Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation (Statement 123) encourages, but does not require, companies to record compensation costs for stock-based employee compensation plans at fair value. The Company has 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 (APB Opinion No. 25).

The following table illustrates the pro forma effect on net income/(loss) and earnings/(loss) per share if the Company had applied the fair value recognition and share-based compensation cost provisions of Statement 123 to stock-based employee compensation:

	Three Months Ended September 30, 2005		September 30, 2004		Nine Months Ended September 30, 2005		September 30, 2004	
Net income/(loss) - As reported	\$	(6,231,905)	\$	5,261,424	\$	(2,643,256)	\$	12,331,922
		(5,214,151)		(4,359,712)		(14,784,134)		(10,930,650)

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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 for the periods in 2004

Add: Amortization of deferred stock compensation

5,542

725,184

Net income/(loss) - Pro forma

\$ (11,446,056) \$ 907,254 \$ (17,427,390) \$ 2,126,456

Earnings/(loss) per share, basic As reported

\$ (0.13) \$ 0.11 \$ (0.05) \$ 0.26

Earnings/(loss) per share, basic - Pro forma

\$ (0.23) \$ 0.02 \$ (0.35) \$ 0.04

Earnings/(loss) per share, diluted - As reported

\$ (0.13) \$ 0.11 \$ (0.05) \$ 0.25

Earnings/(loss) per share, diluted - Pro forma

\$ (0.23) \$ 0.02 \$ (0.35) \$ 0.04

For purposes of the table above, the Company estimated the fair value of each option on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Expected dividend yield	0%	0%	0%	0%
Expected stock price volatility	62%	79%	65%	80%
Risk-free interest rate	4%	3%	4%	3%
Expected option term (years)	2.84	2.89	2.73	2.84

During the nine months ended September 30, 2005, the Company issued 1,056,974 shares of its common stock (Common Stock), of which 556,795 shares were issued upon the exercise of stock options and purchases under the 2000 Employee Stock Purchase Plan. The remaining 500,179 shares were issued upon the exercise of common stock purchase warrants. During the nine months ended September 30, 2004, the Company issued 546,476 shares of its Common Stock, of which 511,342 shares were issued upon the exercise of stock options and purchases under the 2000 Employee Stock Purchase Plan. The remaining 35,134 shares were issued upon the exercise of common stock purchase warrants.

3. Recent Accounting Pronouncement

On December 16, 2004, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 123 (revised 2004), Share-Based Payment (Statement 123(R)), which is a revision to Statement 123. Statement 123(R) supersedes APB Opinion No. 25, and amends FASB Statement No. 95, Statement of Cash Flows. Generally, the approach in Statement 123(R), is similar to the approach described in Statement 123. However, Statement 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Statement 123(R) must be adopted no later than January 1, 2006. Thereafter, pro forma disclosure is no longer an alternative.

As permitted by Statement 123, the Company currently accounts for share-based payments to employees using APB Opinion No. 25's intrinsic value method and, as such, generally recognizes no compensation cost for employee stock options or shares purchased by employees under the 2000 Employee Stock Purchase Plan. Accordingly, the adoption of Statement 123(R)'s fair value method will have a significant impact on the Company's results of operations. The specific impact of adoption of Statement 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future and the transition method the Company adopts. The Company has not assessed the impact of Statement 123(R) but the impact of Statement 123(R) would likely be material. Statement 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature.

4. Net Income/(Loss) per Share

The following table sets forth the computation of basic and diluted net income/(loss) per share for the three and nine months ended September 30, 2005 and 2004:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
<i>Basic and diluted</i>				

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Net income/(loss)	\$	(6,231,905)	\$	5,261,424	\$	(2,643,256)	\$	12,331,922
Weighted average common shares outstanding, basic		49,611,918		47,885,113		49,349,230		47,715,670
Less: unvested restricted common shares outstanding								(265)
Net Weighted average common shares outstanding, basic		49,611,918		47,885,113		49,349,230		47,715,405
Plus: net effect of dilutive stock options and warrants				1,780,543				1,981,377
Weighted average common shares outstanding, diluted		49,611,918		49,665,656		49,349,230		49,696,782
Earnings/(loss) per share, basic	\$	(0.13)	\$	0.11	\$	(0.05)	\$	0.26
Earnings/(loss) per share, diluted	\$	(0.13)	\$	0.11	\$	(0.05)	\$	0.25

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 shares. As of September 30, 2005, there were options to purchase 6,371,732 shares of Common Stock outstanding. These options were not included in the computation of diluted net loss per share for the three and nine months ended September 30, 2005, as their effects would have been antidilutive. As of September 30, 2004, there were outstanding options to purchase 5,575,951 shares of Common Stock and outstanding warrants to purchase 754,517 shares of Common Stock. These options and warrants have been included in the computation of diluted earnings per share for the three and nine months ended September 30, 2004. The number of dilutive Common Stock equivalents was calculated using the treasury stock method.

5. Comprehensive Income/(Loss)

Comprehensive income/(loss) is primarily comprised of net income/(loss), unrealized gain/(loss) on available for sale securities and currency translation adjustments. Comprehensive income/(loss) for the three and nine months ended September 30, 2005 and September 30, 2004 is detailed below.

Comprehensive Income/(Loss)	Three Months ended September 30,		Nine Months ended September 30,	
	2005	2004	2005	2004
Net income/(loss)	\$ (6,231,905)	\$ 5,261,424	\$ (2,643,256)	\$ 12,331,922
Unrealized gain/(loss) on available for sale securities	22,793	108,991	67,279	(414,873)
Foreign currency translation adjustment	(3,508)	(5,256)	(15,367)	1,779
Comprehensive income/(loss)	\$ (6,212,620)	\$ 5,365,159	\$ (2,591,344)	\$ 11,918,828

6. Income Taxes

For the nine months ended September 30, 2005, the Company provided for taxes based upon its estimated tax liability for the year. This provision includes state taxes based on net worth and some income taxes in international jurisdictions. At December 31, 2004, net operating losses available to offset future taxable income for federal income tax purposes were approximately \$233.1 million. If not utilized, federal net operating loss carryforwards will expire at various dates beginning in 2011 and ending in 2023. 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 regulations promulgated under the Internal Revenue Code of 1986, as amended.

7. Commitments

Contractual Obligations

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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 and general administrative activities.

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The Company's estimated contractual obligations as of September 30, 2005 are:

Contractual Obligations	2005(1)	2006	2007	2008	2009	Later Years	Total
Inventory-related commitments	\$ 7,094,041	\$ 9,739,200	\$ 14,608,800	\$	\$	\$	\$ 31,442,041
Research and development commitments	4,042,547	11,346,849	18,517,471	1,525,322			35,432,189
Operating leases	408,951	1,757,847	1,818,002	1,812,247	1,639,671	4,995,633	12,432,351
Selling, general and administrative	2,562,829	1,693,983					4,256,812
Total obligations and commitments	\$ 14,108,368	\$ 24,537,879	\$ 34,944,273	\$ 3,337,569	\$ 1,639,671	\$ 4,995,633	\$ 83,563,393

(1) Represents estimated contractual obligations remaining in 2005

Included above are inventory-related non-cancellable commitments to make payments to UCB Bioproducts of a total of \$5.7 million during the fourth quarter of 2005, \$9.7 million during 2006 and \$14.6 million during 2007 for Angiomax bulk drug substance to be produced using the Chemilog process and \$1.4 million in remaining Angiomax-related filling, finishing and packaging non-cancellable commitments through 2005. The Company has \$35.4 million of total estimated contractual obligations for research and development activities, of which \$2.3 million is non-cancellable. The Company also has \$4.3 million of estimated contractual obligations for consulting, employment and professional services agreements associated with selling, general and administrative activities, of which \$1.7 million is non-cancellable.

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 policies and factors set forth under Factors That May Affect Future Results below and elsewhere in this quarterly report on Form 10-Q. 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.

Overview

We are a pharmaceutical company that specializes in acute care hospital products. To date, we have generated substantially all of our revenues 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. In June 2005, the FDA approved new prescribing information for Angiomax to also include patients undergoing percutaneous coronary intervention. The expanded label also includes a new Angiomax dosing recommendation, which is the same dose used in our REPLACE-2 clinical trial. We are also currently developing Angiomax for other indications. Since we began selling Angiomax in 2001, revenues to date have 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 patients undergoing percutaneous coronary interventions.

In evaluating our operating performance, we focus on use of Angiomax by existing hospital customers, as well as penetration to new hospitals, which are critical elements of our ability to increase revenues. Since the announcement of the results of our REPLACE-2 clinical trial in November 2002, the number of hospitals that have granted Angiomax formulary approval and hospital demand for the product have increased. Although these trends continued in the three months ended September 30, 2005, each grew more slowly than we had forecast. We recently expanded our sales force and increased our marketing capabilities and we believe that our improved 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 our most recently completed year, we have incurred losses on an annual basis since our inception. We incurred a net loss this quarter, as our research and development expenses together with our general and administrative expenses, 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 trials and all of our manufacturing development activities to third parties to maximize efficiency and minimize our internal overhead. We expense our research and development costs as they are incurred. Selling, general and administrative expenses consist primarily of salaries and related expenses, general corporate activities and costs associated with marketing and promotional activities.

We expect to continue to spend significant amounts on the development of our products. In the remainder of 2005, we plan to continue to invest in clinical studies to expand the approved indications for Angiomax and to continue to develop clevidipine and cangrelor. 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 revenues to achieve and maintain profitability.

Recent Developments

We recently agreed with our largest wholesalers to enter into fee-for-service arrangements. We expect that these arrangements will result in reductions in wholesaler inventories, improved margins, more predictable buying patterns and more frequent data on wholesaler inventory levels and hospital demand. We expect our three largest wholesalers to reduce their

Angiomax inventory levels to an average of four to six weeks by the end of the first quarter of 2006. As a result, we believe that the reported net sales for Angiomax over the next two quarters will be negatively affected. We estimate that our wholesalers reduced their aggregate inventories of Angiomax by approximately \$13.0 million in the three months ended September 30, 2005. We expect these wholesalers to also reduce their aggregate inventories of Angiomax by approximately \$13.0 million in each of the fourth quarter of 2005 and the first quarter of 2006.

In October 2005, we also announced that we would resume our Phase III clinical safety trials of clevidipine, our intravenous, short-acting antihypertensive agent. We voluntarily suspended enrollment in the safety trials in March 2005 after preliminary data from 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. We recently completed our review of the interim results of the safety studies, which included more patients as well as a more detailed assessment of atrial fibrillation risk factors, incidence, treatment and outcomes than was available at the time of the suspension of enrollment. As a result of this more detailed review, we found no significant differences in the incidence of atrial fibrillation between the clevidipine and the comparator arms. Specifically, the incidence of atrial fibrillation was found to be similar among the randomized groups and in line with published data from other studies. The independent drug safety monitoring board of the trials reviewed the completed data for the interim analysis and supported the resumption of patient enrollment. We plan to resume enrolling patients in January 2006 and anticipate completing enrollment in the safety studies by the end of 2006.

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, revenues and expenses, and other financial information. Actual results may differ significantly from these estimates under different assumptions and conditions. In addition, our reported financial condition and results of operations could vary due to a change in the application of a particular accounting standard.

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

the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for 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 to 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, 2004. 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 Policies in our annual report on Form 10-K for the year ended December 31, 2004, are critical accounting estimates.

Results of Operations

Three Months Ended September 30, 2005 and 2004

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Net Revenue. As shown in the table below, net revenue for the three months ended September 30, 2005 decreased 15% to \$31.9 million as compared to \$37.7 million for the three months ended September 30, 2004.

Net Revenue

(dollars in thousands)	2005	Three Months Ended September 30,		2004	% of Total Revenue	
		% of Total Revenue				
Angiomax						
United States	\$	29,385	92%	\$	34,431	91%
International		2,535	8%		3,284	9%
Total Net Revenue	\$	31,920	100%	\$	37,715	100%

Net revenue for the three months ended September 30, 2005 decreased compared to the three months ended September 30, 2004 primarily as a result of the impact of reduced purchases by wholesalers in connection with our restructured wholesaler arrangements. We estimate that our wholesalers reduced their aggregate inventories of Angiomax during the three months ended September 30, 2005 by approximately \$13.0 million in implementing the planned inventory reduction. This decrease in sales in the 2005 period was offset in part by higher revenues associated with the effect of a 9.6% price increase to wholesalers in December 2004 and an increase in underlying hospital demand for Angiomax.

We expect our revenues in the next two quarters to continue to be affected by lower product sales related to our restructured wholesaler arrangements, as our wholesalers reduce inventory levels to an average of four to six weeks. We expect these wholesalers to reduce their aggregate inventories of Angiomax by approximately \$13.0 million in each of the fourth quarter of 2005 and the first quarter of 2006. The timing of the inventory reduction, and the reduction in product sales in any quarter, may vary depending on the end-user demand for the product and the actions of our wholesalers.

We believe that the decrease in international sales in the three months ended September 30, 2005 compared to the three months ended September 30, 2004 reflects a high initial level of sales in the 2004 period in preparation for the launch of Angiox in the European Union in the fourth quarter of 2004.

Cost of Revenue. As shown in the table below, cost of revenue for the three months ended September 30, 2005 decreased 33% to \$6.1 million, or 19% of net revenue, compared to \$9.1 million, or 24% of net revenue, for the three months ended September 30, 2004. Cost of revenue consists of expenses in connection with the manufacture of Angiomax sold, royalty expenses under our agreement with Biogen Idec, Inc. and the logistics costs of selling Angiomax, such as distribution, storage and handling.

Cost of Revenue

(dollars in thousands)	2005	Three Months Ended September 30,		2004	% of Total Cost	
		% of Total Cost	% of Total Cost			
Manufacturing	\$	3,369	55%	\$	5,113	56%
Royalty		1,847	30%		2,787	30%
Logistics		890	15%		1,248	14%
Total Cost of Revenue	\$	6,106	100%	\$	9,148	100%

The decrease in cost of revenue for the three months ended September 30, 2005 compared to the three months ended September 30, 2004 resulted from a decrease in manufacturing costs and royalty expenses due to lower sales volume. The decrease in royalty expenses in the 2005 period resulted from the decrease in Angiomax sales during the period and an adjustment to the royalty rate used to calculate payments to Biogen due to our reduced sales forecast for Angiomax. As a result of our lower annual forecast, we expect an effective royalty rate for the year ending December 31, 2005 to be lower than the royalty rate we had applied in the first two quarters of 2005. In the three months ended September 30, 2005, we applied a royalty rate that was less than the expected full-year royalty rate in order to bring our effective royalty rate in line with our expected full-year royalty rate.

Research and Development Expenses. Research and development expenses for the three months ended September 30, 2005 increased 45% to \$17.8 million from \$12.3 million for the three months ended September 30,

2004. The increase in research and development expenses resulted primarily from an increase in patient enrollment and associated expenditures related to the ACUITY trial, our study of Angiomax in patients presenting in the emergency department with acute coronary syndromes, which is further described below, as well as expenses related to increased business development activities. The increases were offset in part by lower expenses relating to clevidipine as a result of the voluntary suspension of Phase III safety trials in March 2005.

The following table identifies for each of our major research and development projects, our spending for the three months ended September 30, 2005 and 2004. Spending for past periods is not necessarily indicative of spending in future periods.

Research and Development Expenses

(dollars in thousands)	Three Months Ended September 30,			
	2005	% of Total R&D	2004	% of Total R&D
Angiomax				
Clinical Trials	\$ 10,126		\$ 5,408	
Manufacturing Development	456		682	
Administrative and Headcount Costs	1,201		1,828	
Total Angiomax	11,783	66%	7,918	64%
Clevidipine	1,807	10%	2,339	19%
Cangrelor	748	4%	1,157	9%
Other	3,482	20%	918	8%
	\$ 17,820	100%	\$ 12,332	100%

We currently plan to spend approximately \$10 million to \$13 million on research and development in the fourth quarter of 2005, of which approximately 78% is expected to be spent for Angiomax. This anticipated research and development spending in the fourth quarter of 2005 primarily reflects expected patient enrollment and associated expenditures relating to the ACUITY trial and clinical trial costs for clevidipine and cangrelor.

Angiomax. As of the date of this quarterly report, we are conducting a randomized 13,800-patient Phase III trial called ACUITY to study the use of Angiomax in patients presenting to the emergency department with acute coronary syndromes who may be medically managed or ultimately treated in the catheterization laboratory or operating room. We expect to complete patient enrollment in ACUITY in the fourth quarter of 2005. We recently completed a Phase III trial program studying the use of Angiomax as an anticoagulant in patients undergoing coronary artery bypass graft surgery, or CABG, with and without the use of a bypass pump, and in treatment of patients with a clinical condition known as heparin-induced thrombocytopenia and thrombosis syndrome, or HIT/HITTS, who are undergoing CABG, with and without the use of a bypass pump. We expect to submit an application to the FDA for approval to market Angiomax in patients undergoing CABG in the fourth quarter of 2005.

Clevidipine. We completed two 100-patient pivotal Phase III efficacy studies of clevidipine in cardiac surgery in 2004. We also plan to resume three 500-patient safety trials. We voluntarily suspended enrollment in the safety 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. We recently completed our interim review of the results of the safety studies and we found no

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significant differences in interim safety results between the clevidipine and the comparator arms. We plan to resume enrolling patients beginning in January 2006 and anticipate completing enrollment in the safety studies by the end of 2006.

Cangrelor. We have completed enrollment in a clinical trial of cangrelor in 40 healthy volunteers to identify a dosing strategy for use of cangrelor in the cardiac catheterization laboratory and expect results later this year.

We expect to begin negotiating site agreements with potential sites for a Phase III clinical testing of cangrelor in the fourth quarter of 2005.

Other. Spending in this category consists of clinical trial infrastructure costs including data management, statistical analysis, product safety related costs and expenses related to business development activities. In the three months ended September 30, 2005, we incurred business development expenses in connection with an agreement that we entered into with a third party to evaluate early stage compounds as well as expenses in connection with our evaluation of strategic opportunities for the development and commercialization of cangrelor.

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;

the financial contributions of our third-party distributors to the costs of our clinical trials;

future clinical trial results;

the terms and timing of any collaborative, licensing and other arrangements that we may establish;

the cost and timing of regulatory approvals;

the cost and timing of establishing sales, marketing and distribution capabilities;

the cost of establishing clinical and commercial supplies of our product candidates;

the effect of competing technological and market developments; and

the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

Selling, General and Administrative Expenses. Selling, general and administrative expenses for the three months ended September 30, 2005 increased 35% to \$15.4 million from \$11.4 million for the three months ended September 30, 2004. This increase was primarily due to the

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Angiomax sales force expansion.

Other Income. Other income, which is almost completely comprised of interest income, increased to \$1.1 million for the three months ended September 30, 2005 from \$0.5 million for the three months ended September 30, 2004. This increase was primarily due to higher rates of return.

Nine Months Ended September 30, 2005 and 2004

Net Revenue. As shown on the table below, net revenue for the nine months ended September 30, 2005 increased 14% to \$118.1 million as compared to \$103.4 million for the nine months ended September 30, 2004.

Net Revenue

(dollars in thousands)		Nine Months Ended September 30,			
		% of Total Revenue		% of Total Revenue	
2005		2004			
Angiomax					
United States	\$	109,389	93%	\$	99,413
International		8,697	7%		3,973
Total Net Revenue	\$	118,086	100%	\$	103,386

We believe that the increase in net revenue for the nine months ended September 30, 2005 compared to the nine months ended September 30, 2004 is due primarily to increased use of Angiomax by existing hospital customers, adoption of Angiomax by new hospital customers and effects of higher prices, including a 9.6% price increase to our wholesalers in December 2004 and a 3% price increase to our wholesalers in June 2004. These factors were offset in part by the impact of reduced purchases by wholesalers in connection with our restructured wholesaler arrangements. International sales in the nine months ended September 30, 2005 increased over the comparable period in 2004 because the 2005 period included a full nine months of selling activity in the European Union.

Cost of Revenue. As shown in the table below, cost of revenue for the nine months ended September 30, 2005 increased 36% to \$27.7 million, or 23% of net revenue, compared to \$20.3 million, or 20% of net revenue, for the nine months ended September 30, 2004. Cost of revenue consists of expenses in connection with the manufacture of Angiomax sold, royalty expenses under our agreement with Biogen and the logistics costs of selling Angiomax, such as distribution, storage and handling.

Cost of Revenue

(dollars in thousands)	2005	Nine Months Ended September 30,		2004	% of Total Cost
		% of Total Cost	% of Total Cost		
Manufacturing	\$ 11,563	42%	\$ 9,549	47%	
Royalty	12,665	46%	7,249	36%	
Logistics	3,473	12%	3,531	17%	
Total Cost of Revenue	\$ 27,701	100%	\$ 20,329	100%	

Cost of revenue increased primarily as a result of an increase in the cost of manufacturing and royalty expenses. Cost of manufacturing increased in part due to increased sales volume in the 2005 period. In addition, in the first quarter of 2004, we sold mostly Angiomax manufactured using the Chemilog process prior to the FDA approval of that process in May 2003. All costs of manufacturing this Angiomax had been expensed as research and development costs and therefore were not reflected in cost of revenue. Our cost of manufacturing as a percentage of net revenue increased in the first nine months of 2005, compared to the first nine months of 2004 because all of the Angiomax we sold in 2005 was manufactured using the Chemilog process after FDA approval of the process. All costs of manufacturing this Angiomax had been recorded as inventory, which is reflected in cost of revenue when sold, rather than as research and development expense. Since the second quarter of 2004, and for the foreseeable future, we expect to sell Angiomax manufactured using the Chemilog process that has not been previously expensed. Our royalty expenses increased by \$5.4 million for the 2005 period under our agreement with Biogen reflecting a higher effective royalty rate and increased sales volume compared to the comparable 2004 period.

Research and Development Expenses. Research and development expenses for the nine months ended September 30, 2005 increased 50% to \$51.4 million from \$34.2 million for the nine months ended September 30, 2004. The increase in research and development expenses reflects an increase in patient enrollment and associated expenditures related to the ACUITY trial, enrollment and data analysis in the clevidipine trials, and manufacturing development costs and clinical trial costs for cangrelor.

The following table identifies for each of our major research and development projects, our spending for the nine months ended September 30, 2005 and 2004. Spending for past periods is not necessarily indicative of spending in future periods.

Research and Development Expenses

(dollars in thousands)	2005	Nine Months Ended September 30, % of Total R&D	2004	% of Total R&D
Angiomax				
Clinical Trials	\$ 28,918		\$ 17,839	
Manufacturing Development	820		1,444	
Administrative and Headcount Costs	4,741		5,263	
Total Angiomax	34,479	67%	24,546	72%
Clevidipine	7,974	15%	6,364	19%
Cangrelor	3,047	6%	1,328	4%
Other	5,928	12%	1,945	5%
	\$ 51,428	100%	\$ 34,183	100%

Selling, General and Administrative Expenses. Selling, general and administrative expenses for the nine months ended September 30, 2005 increased 18% to \$44.5 million from \$37.6 million for the nine months ended September 30, 2004. This increase was primarily due to the Angiomax sales force expansion.

Other Income. Other income for the nine months ended September 30, 2005, which is almost completely comprised of interest income, increased 100% to \$3.0 million from \$1.5 million for the nine months ended September 30, 2004. This increase was primarily due to higher rates of return.

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 revenues from sales of Angiomax. With the exception of the quarterly periods beginning with the third quarter of 2003 through the second quarter of 2005, we have not been profitable. We had \$136.1 million in cash, cash equivalents and available for sale securities at September 30, 2005.

Cash Flows. As of September 30, 2005, we had \$48.6 million in cash and cash equivalents, as compared to \$36.5 million as of December 31, 2004. Our major uses of cash during the nine months ended September 30, 2005 included net cash used in operating activities of \$27.9 million, which was offset by net cash of \$33.3 million received in investing activities and \$6.7 million received from employee stock option exercises.

During the period, we used cash in operating activities to fund:

increase in accounts receivable of \$20.4 million, attributable to the timing of cash receipts from our customers;

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planned growth in inventory of \$15.3 million, relating to purchases of Angiomax bulk drug product and filling, finishing and packaging costs from our contract manufacturers to meet anticipated product demand growth; and

a decrease in accounts payable of \$6.4 million due to timing of payments.

These cash uses were partly offset by cash provided by operations, which consisted of an increase of \$9.5 million in deferred revenue and an increase of \$6.6 million in accrued expenses. The increase in deferred revenue represents a product shipment in the quarter ended September 30, 2005 for which all of the revenue recognition requirements were not met.

During the nine months ended September 30, 2005, we received \$33.3 million in cash in 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 distribution partners, 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.

We believe, based on our operating plan as of the date of this quarterly report, which includes anticipated revenues from Angiomax and interest income, that our current cash, cash equivalents and available for sale securities will be sufficient to fund our operations through 2006 and beyond, without requiring us to obtain external financing. We expect, however, to periodically assess our financing alternatives and access the capital markets opportunistically. If our existing resources are insufficient to satisfy our liquidity requirements due to slower than anticipated revenues from 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 interest and the interests of our stockholders, we may sell additional equity or debt securities or seek additional financing through other arrangements. Any sale of additional equity or debt securities may result in dilution to our stockholders, and debt financing may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures. We cannot be certain that public or private financing will be available in amounts or on terms acceptable to us, if at all. If we seek to raise funds through collaboration or licensing arrangements with third parties, we may be required to relinquish rights to products, product candidates or technologies that we would not otherwise relinquish or grant licenses on terms that may not be favorable to us. If we are unable to obtain additional financing, we may be required to delay, reduce the scope of, or eliminate one or more of our planned research, development and commercialization activities, which could harm our financial condition and operating results.

Contractual Obligations

Our long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business. These include commitments related to purchases of inventory of our products, research and development service agreements, operating leases and consulting, employment and professional services agreements associated with selling and general administrative activities.

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Our estimated contractual obligations as of September 30, 2005 are:

Contractual Obligations	2005(1)	2006	2007	2008	2009	Later Years	Total
Inventory-related commitments	\$ 7,094,041	\$ 9,739,200	\$ 14,608,800	\$	\$	\$	\$ 31,442,041
Research and development commitments	4,042,547	11,346,849	18,517,471	1,525,322			35,432,189
Operating leases	408,951	1,757,847	1,818,002	1,812,247	1,639,671	4,995,633	12,432,351
Selling, general and administrative	2,562,829	1,693,983					4,256,812
Total obligations and commitments	\$ 14,108,368	\$ 24,537,879	\$ 34,944,273	\$ 3,337,569	\$ 1,639,671	\$ 4,995,633	\$ 83,563,393

(1) Represents estimated contractual obligations remaining in 2005

Included above are inventory-related non-cancellable commitments to make payments to UCB Bioproducts of a total of \$5.7 million during the fourth quarter of 2005, \$9.7 million during 2006 and \$14.6 million during 2007 for Angiomax bulk drug substance to be produced using the Chemilog process and \$1.4 million in remaining Angiomax-related filling, finishing and packaging non-cancellable commitments through 2005. We have \$35.4 million of total estimated contractual obligations for research and development activities, of which \$2.3 million is non-cancellable. We also have \$4.3 million of estimated contractual obligations for consulting, employment and professional services agreements associated with selling, general and administrative activities, of which \$1.7 million is non-cancellable.

Forward-Looking Statements

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 revenues, anticipated effects of our restructured wholesaler arrangements, 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 and the risk factors set forth below. 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.

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 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 our most recently completed year, we have incurred net losses on an annual basis since our inception. We incurred a net loss for the quarter ended September 30, 2005. As of September 30, 2005, we had an accumulated deficit of approximately \$299.8 million. We expect to make substantial expenditures to further develop and commercialize our products, including costs and expenses associated with clinical trials, regulatory approvals and commercialization. Although we achieved profitability in 2004, we will likely need to generate significantly greater revenues in future periods to achieve and maintain profitability in light of our planned expenditures. We remain unsure as to when we will achieve profitability again, if at all, or whether we will maintain profitability for any substantial period of time. If we fail to achieve profitability or maintain profitability on a quarterly or annual basis, 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 revenues 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 distribution partners are successful in marketing Angiomax.

The rate of Angiomax sales growth was slower than expected in the third quarter of 2005, and we cannot assure you that our increased sales and marketing efforts or expanded label will result in higher revenues or income. If Angiomax is not commercially successful, we will have to find additional sources of funding or curtail or cease operations.

Our revenues are substantially dependent on a limited number of wholesalers and international distribution partners to which we sell Angiomax, and such revenues 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 primarily to a limited number of national medical and pharmaceutical distributors and wholesalers with distribution centers located throughout the United States and several international distribution partners. During the quarter ended September 30, 2005, revenues from the sale of Angiomax to our three largest U.S. wholesalers totaled 92% of our net revenues and sales to one of our international partners totaled nearly 7% of our net revenue. Our reliance on a small number of wholesalers and distribution partners could cause our revenues to fluctuate from quarter to quarter based on the buying patterns of these wholesalers and distribution partners, regardless of underlying hospital demand. For instance, if inventory levels at wholesalers and distributors are too high, they may seek to reduce their inventory levels by reducing purchases from us.

In the quarter ended September 30, 2005, we agreed with our largest wholesalers to enter into fee-for-service arrangements. Based on these arrangements, we expect our three largest wholesalers to reduce their Angiomax inventory levels to an average of four to six weeks by the end of the first quarter of 2006. As a result, we believe that our reported net sales for Angiomax over the next two quarters will be negatively affected. We estimate that our wholesalers will reduce their aggregate inventories of Angiomax by approximately \$13 million in each of the fourth quarter of 2005 and the first quarter of 2006. Our restructured arrangements with wholesalers may be terminated on short notice, generally 30 days, and we cannot assure you that our planned inventory reduction will be gradual or successful. In addition, if any of these wholesalers or international partners 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 revenues to achieve and maintain profitability on an annual basis. The product development, including clinical trials, manufacturing development and regulatory approvals, of Angiomax for additional indications, clevidipine and cangrelor, 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, depend upon many factors, including:

- the extent to which Angiomax is commercially successful in the United States;
- the extent to which our international distribution partners, 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 revenues from Angiomax and interest income, that our current cash, cash equivalents and available for sale securities are sufficient to fund our operations through 2006 and beyond 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 October 31, 2005, 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.

In addition, other anticoagulant drugs may compete with Angiomax for the use of hospital financial resources. For example, many U.S. hospitals receive a fixed reimbursement amount per procedure for the angioplasties and other treatment therapies they perform. 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

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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 the third quarter of 2005, and we cannot assure you that our increased sales and marketing efforts or expanded label will result in higher revenues or income. 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 a clinical condition known as 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.

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 REPLACE-2 trial. Since the original results 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 trial. If physicians, patients and other key decision-makers do not accept the trial results, as a result of these commentators, 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. As of the date of this quarterly report on Form 10-Q, we are covered, with respect to our commercial sales and our clinical trials, 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 revenues 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 revenues.

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 percutaneous coronary interventions. 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 these expanded indications, we will need to conduct appropriate clinical trials, obtain positive results from those trials and obtain FDA approval for such proposed indications. 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. For example, we anticipate that we will complete enrollment of our ACUTY trial in the fourth quarter of 2005 and we expect to announce results in March 2006. If the ACUTY trial is not successful, we will not be able to seek to expand the indication for Angiomax for use in acute coronary syndromes.

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. As of the date of this quarterly report on Form 10-Q, we are evaluating Angiomax for use in the emergency department in medical conditions that require urgent treatment, such as ACS.

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 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. Failure 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 regulations, or GMP. Regulatory authorities, including the FDA, periodically inspect manufacturing facilities to assess compliance with GMP. 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 GMP 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, UCB Bioproducts, 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 UCB Bioproducts require us to purchase from UCB Bioproducts a substantial portion of our Angiomax bulk drug product manufactured using the Chemilog process.

As of the date of this quarterly report on Form 10-Q, we obtain all of our clevidipine bulk drug substance from one manufacturer, Johnson Matthey Pharma Services. We rely on a different single supplier, Hospira, Inc., and its proprietary formulation technology, for the manufacture of all finished clevidipine product, as well as for release testing and clinical packaging.

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

There are a limited number of manufacturers capable of manufacturing Angiomax, clevidipine and cangrelor. As of the date of this quarterly report on Form 10-Q, we do not have alternative sources for production of bulk drug substance or to carry out fill-finish activities. In the event that UCB Bioproducts, 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

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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 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 and 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 and 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 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 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.

We have inventory commitments to UCB Bioproducts into 2007 which are intended to mitigate the risk of inadequate supply. If sales of Angiomax were to decline, we could be required to make an allowance for excess or obsolete inventory.

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 GMP 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 GMP 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 has rejected our application 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. We have entered into agreements with the counsel involved in the 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 UCB Bioproducts breaches our agreement

Our agreement with UCB Bioproducts for the supply of Angiomax bulk drug substance requires that UCB Bioproducts 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 UCB Bioproducts 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 U.S. Patent and Trademark Office 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 revenues, 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 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 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 currently do not hedge interest rate exposure. At September 30, 2005, we held \$136.1 million in cash, cash equivalents and available for sale securities which had an average interest rate of approximately 3.26%, all of which were due on demand or within one year.

Most of our transactions are conducted in U.S. dollars. We do have certain agreements with parties located outside the United States. Transactions under certain of these agreements are conducted in U.S. dollars, subject to adjustment based on significant fluctuations in currency exchange rates. Transactions under certain other of these agreements are conducted in the local foreign currency. If the applicable exchange rate undergoes a change of 10.0%, we do not believe that it would have a material impact on our results of operations or cash flows.

Item 4. Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2005. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2005, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended September 30, 2005 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Part II. Other Information

Item 6. Exhibits

(a) Exhibits

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

SIGNATURES

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

THE MEDICINES COMPANY

Date: November 8, 2005

By:

/s/ Steven H. Koehler
Steven H. Koehler
Senior Vice President and Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description
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.
