

MEDICINES CO /DE  
Form 10-Q  
November 09, 2009

Table of Contents

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

(Mark One)

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

For the quarterly period ended: September 30, 2009

OR

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

For the transition period from to

Commission file number 000-31191

**THE MEDICINES COMPANY**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**04-3324394**

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

**8 Sylvan Way**

**Parsippany, New Jersey**

(Address of principal executive offices)

**07054**

(Zip Code)

Registrant's telephone number, including area code: **(973) 290-6000**

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

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes ☐ No ☐

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

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐  
(Do not check if a smaller reporting company)

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

Yes ☐ No ☒

As of November 5, 2009, there were 52,871,195 shares of Common Stock, \$0.001 par value per share, outstanding.



**THE MEDICINES COMPANY**  
**TABLE OF CONTENTS**

Part I. Financial Information	
<u>Item 1 - Financial Statements</u>	1
<u>Item 2 - Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	17
<u>Item 3 - Quantitative and Qualitative Disclosures about Market Risk</u>	33
<u>Item 4 - Controls and Procedures</u>	34
Part II. Other Information	
<u>Item 1 - Legal Proceedings</u>	34
<u>Item 1A - Risk Factors</u>	34
<u>Item 5 - Other Information</u>	35
<u>Item 6 - Exhibits</u>	52
<u>Signatures</u>	52
<u>Exhibit Index</u>	53
<u>EX-10.1</u>	
<u>EX-10.2</u>	
<u>EX-31.1</u>	
<u>EX-31.2</u>	
<u>EX-32.1</u>	
<u>EX-32.2</u>	

---

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

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

	<b>September 30, 2009 (Unaudited)</b>	<b>December 31, 2008</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 51,925	\$ 81,018
Available for sale securities	120,095	135,188
Accrued interest receivable	868	1,336
Accounts receivable, net of allowances of approximately \$4.9 million and \$1.9 million at September 30, 2009 and December 31, 2008, respectively	44,717	33,657
Inventory	19,440	28,229
Prepaid expenses and other current assets	15,712	16,402
Total current assets	252,757	295,830
Fixed assets, net	26,210	27,331
Intangible assets, net	15,471	16,349
In-process research and development	69,500	
Goodwill	26,035	
Restricted cash	7,169	5,000
Deferred tax assets	4,958	37,657
Other assets	7,325	5,237
Total assets	\$ 409,425	\$ 387,404
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 5,576	\$ 12,968
Accrued expenses	61,798	61,028
Deferred revenue	3,323	9,612
Total current liabilities	70,697	83,608
Contingent purchase price	22,741	
Other liabilities	5,667	5,771
Total liabilities	99,105	89,379
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$1.00 par value per share, 5,000,000 shares authorized; no shares issued and outstanding		
Common stock, \$0.001 par value per share, 125,000,000 shares authorized; 52,876,824 and 52,280,006 issued and outstanding at September 30, 2009 and December 31, 2008, respectively	53	52
Additional paid-in capital	581,286	565,083

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

Accumulated deficit	(270,684)	(267,948)
Accumulated other comprehensive (loss) income	(335)	838
Total stockholders' equity	310,320	298,025
Total liabilities and stockholders' equity	\$ 409,425	\$ 387,404

See accompanying notes to unaudited condensed consolidated financial statements.

1

---

Table of Contents

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
Net revenue	\$ 98,789	\$ 88,126	\$ 302,181	\$ 254,285
Operating expenses:				
Cost of revenue	28,308	22,089	86,958	63,121
Research and development	22,464	44,075	68,685	82,518
Selling, general and administrative	47,358	42,865	146,863	117,004
Total operating expenses	98,130	109,029	302,506	262,643
Income (loss) from operations	659	(20,903)	(325)	(8,358)
Other income	151	1,070	2,055	5,256
Income (loss) before income taxes	810	(19,833)	1,730	(3,102)
(Provision for) benefit from income taxes	(4,007)	6,616	(4,465)	(1,205)
Net loss	\$ (3,197)	\$ (13,217)	\$ (2,735)	\$ (4,307)
Basic earnings per common share	\$ (0.06)	\$ (0.25)	\$ (0.05)	\$ (0.08)
Diluted earnings per common share	\$ (0.06)	\$ (0.25)	\$ (0.05)	\$ (0.08)
Weighted average number of common shares outstanding:				
Basic	52,298	51,941	52,225	51,842
Diluted	52,298	51,941	52,225	51,842

See accompanying notes to unaudited condensed consolidated financial statements.

**Table of Contents**

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

	<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>
Cash flows from operating activities:		
Net loss	\$ (2,735)	\$ (4,307)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	4,331	1,916
Acquired in-process research and development		21,373
Amortization of net premiums and discounts on available for sale securities	1,460	(254)
Unrealized foreign currency transaction losses, net	559	127
Non-cash stock compensation expense	15,328	17,375
Loss on disposal of fixed assets	11	
Gain on sales of available for sale securities		(48)
Deferred tax provision	4,900	754
Tax effect of option exercises	(928)	193
Adjustment to contingent purchase price (see note 8)	(442)	
Changes in operating assets and liabilities:		
Accrued interest receivable	468	260
Accounts receivable	(10,547)	(15,686)
Inventory	8,944	9,930
Prepaid expenses and other current assets	1,283	(5,976)
Other assets		
Accounts payable	(10,725)	(2,698)
Accrued expenses	(8,988)	(20,318)
Deferred revenue	(6,319)	10,005
Other liabilities	(104)	
Net cash (used in) provided by operating activities	(3,504)	12,646
Cash flows from investing activities:		
Purchases of available for sale securities	(108,883)	(118,228)
Maturities and sales of available for sale securities	121,510	124,352
Purchases of fixed assets	(287)	(3,624)
Acquisition of intangible assets		(2,000)
Investment in pharmaceutical company		(5,000)
Acquisition of business, net of cash acquired	(37,229)	(23,534)
Decrease in restricted cash	(1,709)	
Net cash used in investing activities	(26,598)	(28,034)
Cash flows from financing activities:		
Proceeds from issuances of common stock, net	1,803	5,525
Net cash provided by financing activities	1,803	5,525
Effect of exchange rate changes on cash	(794)	93



Decrease in cash and cash equivalents	(29,093)	(9,770)
Cash and cash equivalents at beginning of period	81,018	88,127
Cash and cash equivalents at end of period	\$ 51,925	\$ 78,357
Supplemental disclosure of cash flow information:		
Interest paid	\$	\$
Taxes paid	\$ 354	\$ 2,435
Supplemental disclosure of non-cash investing activities:		
Fixed asset additions included in current liabilities	\$	\$ 201

See accompanying notes to unaudited condensed consolidated financial statements.

**Table of Contents**

**THE MEDICINES COMPANY**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

The Medicines Company® name and logo, Angiomax®, Angiox® and Cleviprex® are either registered trademarks or trademarks of The Medicines Company in the United States and/or other countries. All other trademarks, service marks or other tradenames appearing in this quarterly report on Form 10-Q are the property of their respective owners. Except where otherwise indicated, or where the context may otherwise require, references to Angiomax in this quarterly report on Form 10-Q mean Angiomax and Angiox collectively. References to the Company, we, us, or our mean The Medicines Company, a Delaware corporation, and its subsidiaries.

**1. Nature of Business**

The Medicines Company (the Company) was incorporated in Delaware on July 31, 1996. The Company is a global pharmaceutical company focused on advancing the treatment of critical care patients through the delivery of innovative, cost-effective medicines to the worldwide hospital marketplace. The Company has two marketed products, Angiomax® (bivalirudin) and Cleviprex® (clevidipine butyrate) injectable emulsion, two products in late-stage development, cangrelor and oritavancin, and one compound, CU2010, which entered into a Phase Ia clinical trial in July 2009. The Company believes that Angiomax, Cleviprex and its three product candidates share common features valued by hospital practitioners, including a high level of pharmacological specificity, potency and predictability. The Company believes that Angiomax, Cleviprex and its three product candidates possess favorable attributes that competitive products do not provide, can satisfy unmet medical needs in the critical care hospital product market and offer improved performance to hospital businesses. The Company recently licensed marketing rights in the United States and Canada to a ready-to-use formulation of Argatroban developed by Eagle Pharmaceuticals, Inc. (Eagle), a specialty pharmaceutical company with expertise in drug development. Argatroban, currently marketed in a concentrated formulation, is approved as an anticoagulant for prophylaxis or treatment of thrombosis in patients with or at risk for heparin induced thrombocytopenia (HIT) and for patients with or at risk for HIT undergoing percutaneous coronary intervention. Eagle submitted a NDA for the ready-to-use formulation of Argatroban to the U.S. Food and Drug Administration (FDA) in 2008.

**2. Significant Accounting Policies**

The Company's significant accounting policies are described in note 2 of the notes to the consolidated financial statements included in the Annual Report on Form 10-K for the year ended December 31, 2008 filed with the Securities and Exchange Commission (SEC).

***Basis of Presentation***

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

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

The results of operations for the three months ended September 30, 2009 are not necessarily indicative of the results that may be expected for the entire fiscal year or any other quarter of the fiscal year ending December 31, 2009. 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, 2008, filed with the SEC.

## **Table of Contents**

### ***Use of Estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, costs, expenses and accumulated other comprehensive income/(loss) that are reported in the consolidated financial statements and accompanying disclosures. Actual results may be different. See note 2 of the notes to the consolidated financial statements in the Company's Annual Report on Form 10-K for the year ended December 31, 2008 for a discussion of the Company's critical accounting estimates.

### ***Revenue Recognition***

**Product Sales.** The Company distributes Angiomax and Cleviprex in the United States through a sole source distribution model. Under this model, the Company sells Angiomax and Cleviprex to its sole source distributor, Integrated Commercialization Solutions, Inc. (ICS), which then sells Angiomax and Cleviprex to a limited number of national medical and pharmaceutical wholesalers with distribution centers located throughout the United States and in certain cases, directly to hospitals. The Company's agreement with ICS, which it initially entered into February 2007, provides that ICS will be the Company's exclusive distributor of Angiomax and Cleviprex in the United States. Under the terms of this fee-for-service agreement, ICS assumes all credit and inventory risks, is subject to the Company's standard return policy, places orders with the Company for sufficient quantities of Angiomax and Cleviprex to maintain an appropriate level of inventory based on its customers' historical purchase volumes and has sole responsibility for determining the prices at which it sells Angiomax and Cleviprex, subject to specified limitations in the agreement. The agreement terminates on February 28, 2010, but will automatically renew for additional one-year periods unless either party gives notice at least 120 days prior to the automatic extension. The Company may also terminate the agreement at any time and for any reason upon prior written notice to ICS and payment of a termination fee.

Outside of the United States, the Company sells Angiomax either directly to hospitals or to wholesalers or international distributors, which then sell Angiomax to hospitals. At September 30, 2009 and December 31, 2008, the Company had deferred revenue of \$0.8 million and \$0.4 million, respectively, associated with sales of Angiomax to wholesalers outside of the United States. The Company recognizes revenue from such sales when hospitals purchase the product.

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 the sale of the product, the amount of returns can be reasonably estimated and collectability is reasonably assured.

The Company began selling Cleviprex in the United States in September 2008. Initial gross wholesaler orders of Cleviprex in the United States in the third quarter of 2008 totaled \$10.0 million. The Company recorded this amount as deferred revenue as the Company could not estimate certain adjustments to gross revenue, including returns. Under this deferred revenue model, the Company does not recognize revenue upon product shipment to ICS. Instead, upon product shipment, the Company invoices ICS, records deferred revenue at gross invoice sales price, classifies the cost basis of the product held by ICS as finished goods inventory held by others and includes such cost basis amount within prepaid expenses and other current assets on its consolidated balance sheets. The Company currently recognizes the deferred revenue when hospitals purchase product and will do so until such time that it has sufficient information to develop reasonable estimates of expected returns and other adjustments to gross revenue. When such estimates are developed, the Company expects to recognize Cleviprex revenue upon shipment to ICS in the same manner as it recognizes Angiomax revenue. The Company recognized \$1.1 million of revenue associated with Cleviprex during the third quarter of 2009 related to purchases by hospitals.

The Company records allowances for chargebacks and other discounts or accruals for product returns, rebates and fee-for-service charges at the time of sale, and reports revenue net of such amounts. In determining the amounts of certain allowances and accruals, the Company must make significant judgments and estimates. For example, in determining these amounts, the Company estimates hospital demand, buying patterns by hospitals and group purchasing organizations from wholesalers and the levels of inventory held by wholesalers and by ICS. Making these

determinations involves estimating whether trends in past wholesaler and hospital buying patterns will predict future product sales. The Company receives data periodically from ICS and wholesalers on inventory levels and levels of hospital purchases and the Company considers this data in determining the amounts of these allowances and accruals.

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

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

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

At September 30, 2009 and December 31, 2008, the Company's accrual for product returns was \$0.2 million and \$1.0 million, respectively. Included within the accrual at December 31, 2008 was a reserve of \$0.8 million that the Company established for existing inventory at Nycomed that Nycomed had the right to return at any time. In July 2009, the Company reimbursed Nycomed \$0.8 million for the final amount of inventory held by Nycomed at December 31, 2008. A 10% change in the Company's accrual for product returns would have had less than a \$0.1 million effect on the Company's reported net revenue for the nine months ended September 30, 2009.

*Chargebacks and rebates.* Although the Company primarily sells products to ICS in the United States, the Company typically enters into agreements with hospitals, either directly or through group purchasing organizations acting on behalf of their hospital members, in connection with the hospitals' purchases of products.

Based on these agreements, most of the Company's hospital customers have the right to receive a discounted price for products and volume-based rebates on product purchases. In the case of discounted pricing, the Company typically provides a credit to ICS, or a chargeback, representing the difference between ICS's acquisition list price and the discounted price. In the case of the volume-based rebates, the Company typically pays the rebate directly to the hospitals.

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

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

The Company's allowance for chargebacks was \$2.8 million and \$1.2 million at September 30, 2009 and December 31, 2008, respectively. A 10% change in the Company's allowance for chargebacks would have had an approximate \$0.3 million effect on the Company's reported net revenue for the nine months ended September 30, 2009. The Company's accrual for rebates was nil and \$0.4 million at September 30, 2009 and December 31, 2008, respectively.

*Fees-for-service.* The Company offers discounts to certain wholesalers and ICS based on contractually determined rates for certain services. The Company estimates its fee-for-service accruals and allowances based on historical sales, wholesaler and distributor inventory levels and the applicable discount rate. The Company's discounts are accrued at the time of the sale and are typically settled with the wholesalers or ICS within 60 days after the end of each respective quarter. The Company's fee-for-service accruals and allowances were \$3.2 million and \$2.0 million at September 30, 2009 and December 31, 2008, respectively. A 10% change in the Company's fee-for-service accruals and allowances would have had an approximate \$0.3 million effect on the Company's reported net revenue for the nine months ended September 30, 2009.

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

*International Distributors.* Under the Company's agreements with its primary international distributors, the Company sells Angiomax to these distributors at a fixed transfer price. The established transfer price is typically determined once per year, prior to the first shipment of Angiomax to the distributor each year. The minimum selling price used in determining the transfer price is 50% of the average net unit selling price.

*Revenue from Collaborations.* Under the terms of the transitional distribution agreement with Nycomed, the Company was entitled to receive a specified percentage of Nycomed's net sales of Angiox to third parties. In the event the Angiox sold was purchased by Nycomed from the Company prior to July 1, 2007, the amount the Company was entitled to receive in connection with such sale was reduced by the amount previously paid by Nycomed to the Company for such product. Accordingly, revenue related to the transitional distribution agreement with Nycomed entered into in 2007, under which Nycomed provided product distribution services through the second half of 2008, was not recognized until the product was sold by Nycomed to a hospital customer. For the three months ended September 30, 2008, the Company recorded \$0.6 million of net revenue from sales made by Nycomed of approximately \$1.4 million under the transitional distribution agreement. Such amount was recorded as revenue from collaborations and is included in net revenue on the Company's consolidated statements of operations. Because the Company assumed control of the distribution of Angiox in all countries in the Nycomed territory by December 31, 2008, the Company did not have any revenue from collaborations during the nine months ended September 30, 2009.

#### ***Subsequent Events***

The Company has evaluated subsequent events occurring through November 9, 2009, which is the date of filing the Company's Quarterly Report on Form 10-Q.

#### ***Recent Accounting Pronouncements***

In April 2009, the Financial Accounting Standards Board (FASB) issued FASB Staff Position No. FAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments*, which was later superseded by the FASB Accounting Standards Codification (ASC), also known collectively as the FASB Codification, and included in ASC topic 825 (ASC 825-10-65) which requires disclosures about fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. This guidance is effective for interim reporting periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. The Company adopted this accounting pronouncement as of and for the period ended June 30, 2009 and this adoption did not have a material impact on its financial statements.

In April 2009, the FASB issued FASB Staff Position No. FAS 115-2 and FAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments*, which was later superseded by the FASB Codification and included in ASC topic 320 (ASC 320-10-65), which amends the other-than-temporary impairment guidance in GAAP for debt securities to make the guidance more operational and to improve the presentation and disclosure of other-than-temporary impairments on debt and equity securities in the financial statements. This guidance is effective for interim and annual reporting periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. The Company adopted this accounting pronouncement as of and for the period ended June 30, 2009 and it did not have a material impact on its financial statements.

In May 2009, the FASB issued Statement of Financial Accounting Standard (SFAS) No. 165, *Subsequent Events*, which was later superseded by the FASB Codification and included in ASC topic 855-10 (ASC 855-10). ASC 855-10 is intended to establish general standards of accounting for, and disclosure of, events that occur after the balance sheet

date but before financial statements are issued or are available to be issued. ASC 855-10 requires the disclosure of the date through which an entity has evaluated subsequent events and the basis for selecting that date, including whether that date represents the date the financial statements were issued or were available to be issued. ASC 855-10 is effective for interim or annual financial periods ending after June 15, 2009. The Company adopted this accounting pronouncement as of and for the period ended June 30, 2009 and it did not have a material impact on its financial statements.

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

In June 2009, the FASB issued SFAS No. 168, The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles, a replacement of FASB Statement No. 162. This statement modifies the GAAP hierarchy by establishing only two levels of GAAP, authoritative and nonauthoritative accounting literature. Effective July 2009, the FASB

**Table of Contents**

Codification is considered the single source of authoritative U.S. accounting and reporting standards, except for additional authoritative rules and interpretive releases issued by the SEC. Nonauthoritative guidance and literature would include, among other things, FASB Concepts Statements, American Institute of Certified Public Accountants Issue Papers and Technical Practice Aids and accounting textbooks. The FASB Codification was developed to organize GAAP pronouncements by topic so that users can more easily access authoritative accounting guidance. It is organized by topic, subtopic, section, and paragraph, each of which is identified by a numerical designation. This statement applied beginning in third quarter 2009. All accounting references have been updated, and therefore SFAS references have been replaced with ASC references.

In August 2009, the FASB issued the FASB Codification update No. 2009-05 Fair Value Measurements and Disclosures (ASU 2009-05). The update is to subtopic ASC 820-10, Fair Value Measurements and Disclosures-Overall, for the fair value measurement of liabilities. The purpose of this update is to reduce ambiguity in financial reporting when measuring fair value of liabilities. The guidance in the update was effective for the Company during the three months ending September 30, 2009 and did not have a material impact on its financial statements.

**3. Stock-Based Compensation**

The Company recorded approximately \$4.4 million and \$15.3 million of stock-based compensation expense for the three and nine months ended September 30, 2009, respectively. As of September 30, 2009, there was approximately \$16.8 million of total unrecognized compensation costs related to non-vested share-based employee compensation arrangements granted under the Company's equity compensation plans. This cost is expected to be recognized over a weighted average period of 1.30 years.

During the nine months ended September 30, 2009, the Company issued a total of 596,818 shares of its common stock upon the exercise of stock options, pursuant to restricted stock grants and purchases under its employee stock purchase plan (the ESPP). During the nine months ended September 30, 2008, the Company issued a total of 412,686 shares of its common stock upon the exercise of stock options, pursuant to restricted stock grants and pursuant to purchases under the ESPP. Cash received from exercise of stock options and purchases through the ESPP during the nine months ended September 30, 2009 and 2008 was approximately \$1.8 million and \$5.5 million, respectively, and is included within the financing activities section of the consolidated statements of cash flows.

At September 30, 2009, there were 3,254,722 shares of common stock reserved for future issuance under the ESPP and for future grants under the Company's amended and restated 2004 stock incentive plan and 2009 equity inducement plan.

**4. Earnings (Loss) per Share**

The following table sets forth the computation of basic and diluted earnings per share for the three and nine months ended September 30, 2009 and 2008:

	Three Months Ended September 30, 20092008		Nine Months Ended September 30, 20092008	
	(in thousands, except per share amounts)			
<i>Basic and diluted</i>				
Net loss	\$ (3,197)	\$ (13,217)	\$ (2,735)	\$ (4,307)
Weighted average common shares outstanding, basic	52,789	52,136	52,671	52,027
Less: unvested restricted common shares outstanding	491	195	446	185
Net weighted average common shares outstanding, basic	52,298	51,941	52,225	51,842
Plus: net effect of dilutive stock options and restricted common shares				

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

Weighted average common shares outstanding, diluted	52,298	51,941	52,225	51,842
Loss per share, basic	\$ (0.06)	\$ (0.25)	\$ (0.05)	\$ (0.08)
Loss per share, diluted	\$ (0.06)	\$ (0.25)	\$ (0.05)	\$ (0.08)

Basic earnings per share is computed using the weighted average number of shares of common stock outstanding during the period, reduced where applicable for outstanding yet unvested shares of restricted common stock. The number of dilutive common stock equivalents was calculated using the treasury stock method. The table below provides details of the weighted average number of



**Table of Contents**

outstanding options and restricted stock that were excluded in the calculation of diluted earnings per share for the three and nine months ended September 30, 2009 and 2008 as their effect would have been anti-dilutive.

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
	<b>(in thousands)</b>			
Weighted average options outstanding	11,392	10,611	11,339	9,924
Weighted average options included in computation of diluted earnings per share				
Weighted average options considered anti-dilutive and excluded from the computation of diluted earnings per share	11,392	10,611	11,339	9,924
Weighted average restricted shares outstanding	491	195	446	185
Weighted average restricted shares included in computation of diluted earnings per share				
Weighted average restricted shares considered anti-dilutive and excluded from the computation of earnings per share	491	195	446	185

**5. Comprehensive (Loss) Income**

Comprehensive (loss) income includes net (loss) income, unrealized gain (loss) on available for sale securities and currency translation adjustments. Comprehensive loss for the three and nine months ended September 30, 2009 and September 30, 2008 is detailed below.

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
<b>Comprehensive Loss (in thousands)</b>				
Net loss	\$ (3,197)	\$ (13,217)	\$ (2,735)	\$ (4,307)
Unrealized loss on available for sale securities	(244)	(680)	(1,004)	(824)
Foreign currency translation adjustment	132	30	(168)	(9)
Comprehensive loss	\$ (3,309)	\$ (13,867)	\$ (3,907)	\$ (5,140)

**6. Income Taxes**

For the three months ended September 30, 2009 and 2008, the Company recorded a \$4.0 million provision for and \$6.6 million benefit from income taxes, respectively, based upon its estimated tax liability for the year. The Company's effective tax rate for the three months ended September 30, 2009 and 2008 was approximately 495% and 33%, respectively. For the nine months ended September 30, 2009 and 2008, the Company recorded a \$4.5 million and \$1.2 million provision for income taxes, respectively, based upon its estimated tax liability for the year. The Company's effective tax rate for the nine months ended September 30, 2009 and 2008 was approximately 258% and 39%, respectively. The provision for income taxes is based on federal, state and foreign income taxes.

The Company will continue to evaluate the realizability of its deferred tax assets and liabilities on a periodic basis and will adjust such amounts in light of changing facts and circumstances, including but not limited to future projections of taxable income, tax legislation, rulings by relevant tax authorities, the progress of ongoing tax audits,

the regulatory approval of products currently under development and extension of the patent rights relating to Angiomax. If the Company further reduces or increases the valuation allowance for deferred tax assets in future years, the Company would recognize a tax benefit or expense.

## **Table of Contents**

### **7. Investment**

On July 2, 2008, the Company made a short term convertible loan of \$5.0 million to Eagle Pharmaceuticals, Inc. (Eagle). This loan converted into 2.7 million shares of convertible preferred stock in the third quarter of 2008. In September 2009, pursuant to the license agreement that the Company entered into with Eagle, the Company agreed to make an additional \$2.0 million investment in shares of convertible preferred stock of Eagle in the fourth quarter of 2009 and a \$5.0 million technology license fee which the Company recorded as research and development expense. The \$7.0 million has been classified as investments and is included in other assets on the Company's consolidated balance sheets. The Company holds less than 20% of the issued and outstanding shares of the specialty pharmaceutical company and does not have significant influence over the company. Accordingly, the Company has accounted for the investment under the cost method.

### **8. Acquisitions**

#### *Targanta Therapeutics Corporation*

In February 2009, the Company acquired Targanta, a biopharmaceutical company focused on developing and commercializing innovative antibiotics to treat serious infections in the hospital and other institutional settings. Targanta's product pipeline included an intravenous version of oritavancin and a program to develop an oral version of oritavancin for the possible treatment of *Clostridium difficile*-related infection (C Difficile). Oritavancin is a novel semi-synthetic lipoglycopeptide antibiotic that the Company is developing for the treatment of serious gram-positive infections. The FDA has issued a complete response letter with respect to the NDA that Targanta filed for oritavancin in February 2007 indicating that the FDA could not approve the NDA in its present form and requiring an additional adequate and well-controlled Phase III study to demonstrate oritavancin's safety and efficacy in patients with complicated skin and skin structure infections (cSSSI) before the application could be approved. The Company is in discussions with the FDA with a view to initiating a confirmatory Phase III program in early 2010 for oritavancin for the treatment of cSSSI. In August 2009, the Company withdrew the European marketing authorization application (MAA) for oritavancin.

Under the terms of the Company's agreement with Targanta, it paid Targanta shareholders \$2.00 in cash at closing for each common share of Targanta common stock tendered, or approximately \$42.0 million in aggregate, and agreed to pay contingent cash payments up to an additional \$4.55 per share as described below:

If the Company or a MDCO Affiliated Party (meaning an affiliate of the Company, a successor or assigns of the Company, or a licensee or collaborator of the Company) obtains approval from the European Agency for the Evaluation of Medical Products (EMA) for a MAA for oritavancin for the treatment of cSSSI on or before December 31, 2013, then former Targanta shareholders will be entitled to receive a cash payment equal to (1) \$1.00 per share if such approval is granted on or before December 31, 2009, (2) \$0.75 per share if such approval is granted between January 1, 2010 and June 30, 2010, or (3) \$0.50 per share if such approval is granted between July 1, 2010 and December 31, 2013, a payment of approximately \$21.0 million in the aggregate, approximately \$15.8 million in the aggregate, or approximately \$10.5 million in the aggregate, respectively.

If the Company or a MDCO Affiliated Party obtains final approval from the FDA for a new drug application (NDA), for oritavancin for the treatment of cSSSI (1) within 40 months after the date the first patient is enrolled in a Phase III clinical trial of cSSSI that is initiated by the Company or a MDCO Affiliate Party after the date of the Company's merger agreement with Targanta and (2) on or before December 31, 2013, then former Targanta shareholders will be entitled to receive a cash payment equal to \$0.50 per share, or approximately \$10.5 million in the aggregate.

If the Company obtains final FDA approval for an NDA for the use of oritavancin for the treatment of cSSSI administered by a single dose intravenous infusion (1) within 40 months after the date the first patient is enrolled in a Phase III clinical trial of cSSSI that is initiated by the Company or a MDCO Affiliated Party after the date of the Company's merger agreement with Targanta and (2) on or before December 31, 2013, then former Targanta shareholders will be entitled to receive a cash payment equal to \$0.70 per share, or

approximately \$14.7 million in the aggregate. This payment may become payable simultaneously with the payment described in the previous bullet above.

**Table of Contents**

If aggregate net sales of oritavancin in four consecutive calendar quarters ending on or before December 31, 2021 reach or exceed \$400 million, each former Targanta shareholder will be entitled to receive a cash payment equal to \$2.35 per share, or approximately \$49.4 million in the aggregate.

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

	(in thousands)
Acquired assets:	
Cash and cash equivalents	\$ 4,815
Available for sale securities	397
Prepaid expenses & other current assets	999
Fixed assets, net	1,960
In-process research and development	69,500
Goodwill	26,035
Other assets	71
Total assets	103,777
Liabilities assumed:	
Accounts payable	3,280
Accrued expenses	6,976
Contingent purchase price	23,183
Deferred tax liability	27,799
Other liabilities	556
Total liabilities	61,794
Total cash purchase price paid upon acquisition	\$ 41,983

The purchase price was allocated to the estimated fair value of assets acquired and liabilities assumed based on a preliminary valuation and management estimates. The Company recorded a deferred tax liability for the difference in basis of the identifiable intangible assets. The Company is currently evaluating its tax planning strategy. If the Company elects a different tax planning strategy prior to the completion of the final purchase price allocation, the actual deferred tax liabilities recorded at the date of the acquisition could be significantly different.

In determining the fair value of all of the Company's in-process research and development projects related to oritavancin, the Company used the income approach, specifically a probability weighting to the estimated future net cash flows that are derived from projected sales revenues and estimated costs. These projections are based on factors such as relevant market size, patent protection, historical pricing of similar products and expected industry trends. This method requires a forecast of cash inflows, cash outflows, and pro forma charges for economic returns of and on tangible assets employed, including working capital, fixed assets and assembled workforce. Cash outflows include direct and indirect expenses for clinical trials, manufacturing, sales, marketing, general and administrative expenses and taxes. For purposes of these forecasts, the Company assumed that cash outflows for research and development, general administrative and marketing expenses from the period beginning immediately after closing and continuing through 2012 would not exceed \$160 million. All internal and external research and development expenses are

expensed as incurred.

The Company expects the oritavancin development efforts to be material to its research and development expenses.

The Company defines an in-process research and development project by specific therapeutic treatment indication. At this time, the Company is pursuing four therapeutic treatment indications for oritavancin. After applying a risk adjusted discount rate of 13% to each project's expected cash flow stream, the Company determined a preliminary value for each project as set forth below. In

**Table of Contents**

determining these values, the Company assumed that it would generate cash inflows from oritavancin for cSSSI in 2012 and from the other projects thereafter.

Project	(in thousands)
cSSSI	\$ 54,000
Bacteremia	5,900
Anthrax	6,400
C Difficile	3,200
Total	\$ 69,500

The Company's success in developing and obtaining marketing approval for oritavancin for cSSSI and for any of the other indications is highly uncertain. The Company has not finalized the design or the timing of the Phase III study of oritavancin required by the FDA. The Company cannot know or predict the nature, timing and estimated costs of the efforts necessary to complete the development of, or the period in which material net cash inflows are expected to commence from, oritavancin due to the numerous risks and uncertainties associated with developing and commercializing drugs. These risks and uncertainties, including their impact on the timing of completing clinical trial and development work and obtaining regulatory approval, would have a material impact on each project's value.

If the acquisition of Targanta had occurred as of January 1, 2008, the Company's pro forma results for the three and nine months ended September 30, 2009 and 2008 would have been as follows:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
	<b>(in thousands, except per share amounts)</b>			
Net revenue	\$98,789	\$ 88,126	\$302,181	\$254,285
Income (loss) from operations	659	(33,275)	(10,995)	(55,675)
Net income (loss)	(3,197)	(25,685)	(13,851)	(50,635)
Basic and diluted loss per share:				
Basic earnings (loss) per share	\$ (0.06)	\$ (0.49)	\$ (0.27)	\$ (0.98)
Diluted earnings (loss) per share	\$ (0.06)	\$ (0.49)	\$ (0.27)	\$ (0.98)
Weighted average number of common shares outstanding:				
Basic	52,298	51,941	52,225	51,842
Diluted	52,298	51,941	52,225	51,842

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

***Curacyte Discovery GmbH***

In August 2008, the Company acquired Curacyte Discovery, a wholly owned subsidiary of Curacyte AG. Curacyte Discovery, a German limited liability company, was primarily engaged in the discovery and development of small molecule serine protease inhibitors. Its lead compound, CU2010, is being developed for the prevention of blood loss during surgery. In connection with the acquisition, the Company paid Curacyte AG an upfront payment of 14.5 million (approximately \$22.9 million) and agreed to pay a contingent milestone payment of 10.5 million if the Company proceeds with clinical development of CU2010 and possible future sales royalty payments and a commercial milestone payment.

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

a summary that details the assets and liabilities acquired as a result of the acquisition:

10

---



**Table of Contents**

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

The purchase price was allocated to the estimated fair value of assets acquired and liabilities assumed based on a third-party valuation and management estimates. Approximately \$21.4 million of the purchase price was allocated to in-process research and development and was expensed upon completion of the acquisition. The Company recorded this amount as research and development expenses in its consolidated statements of operations during the three months ended September 30, 2008. The Company allocated the remaining portion of the purchase price to net tangible assets.

**9. Nycomed Agreements**

On July 1, 2007, the Company entered into a series of agreements with Nycomed (collectively, the Agreements) pursuant to which the Company terminated its prior distribution agreement with Nycomed and reacquired all rights to develop, distribute and market the Company's product Angiox in the European Union (excluding Spain, Portugal and Greece, which territories are covered by another third-party distributor) and the former Soviet republics (the Nycomed Territory). Prior to entering into the Agreements, Nycomed served as the exclusive distributor of Angiox in the Nycomed Territory pursuant to a sales, marketing and distribution agreement, dated March 25, 2002, as amended.

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

Under the terms of the transitional distribution agreement with Nycomed, upon the sale by Nycomed to third parties of vials of Angiox purchased by Nycomed from the Company prior to July 1, 2007 (the existing inventory), Nycomed was required to pay the Company a specified percentage of Nycomed's net sales of Angiox, less the amount previously paid by Nycomed to the Company for the existing inventory. In addition, under the transitional distribution agreement, Nycomed had the right to return any existing inventory for the price paid by Nycomed to the Company for such inventory. In July 2009, the Company reimbursed Nycomed \$0.8 million for the final amount of inventory held by Nycomed at December 31, 2008. The transitional distribution agreement terminated on December 31, 2008.

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

from these services and could reasonably estimate their fair value. This agreement terminated on December 31, 2007.

The Company incurred total costs of \$45.7 million in connection with the reacquisition of the rights to develop, distribute and market Angiox in the Nycomed Territory. This total costs amount includes transaction fees of approximately \$0.7 million and agreed

**Table of Contents**

upon milestone payments of \$20.0 million paid to Nycomed on July 2, 2007, \$15.0 million paid to Nycomed on January 15, 2008 and \$5.0 million paid to Nycomed on July 8, 2008, as well as an additional \$5.0 million paid to Nycomed on July 8, 2008 in connection with the Company's obtaining European Commission approval to market Angiox for ACS in January 2008.

In the third quarter of 2007, the Company recorded approximately \$30.8 million as expense attributable to the termination of the prior distribution agreement with Nycomed. The \$30.8 million expense was offset in part by the write-off of approximately \$2.7 million of deferred revenue, which amount represented the unamortized portion of deferred revenue related to milestone payments received from Nycomed in 2004 and 2002. The Company allocated to intangible assets approximately \$14.9 million of the costs associated with the reacquisition of the rights to develop, distribute and market Angiox in the European Union. The Company is amortizing these intangible assets over the remaining patent life of Angiox, which expires in 2015. The period in which amortization expense will be recorded reflects the pattern in which the Company expects the economic benefits of the intangible assets to be consumed.

**10. Cash, Cash Equivalents and Available for Sale Securities**

The Company considers all highly liquid investments purchased with original maturities at the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents at September 30, 2009 and December 31, 2008 included investments of \$31.4 million and \$34.1 million, respectively, in money market funds and commercial paper with original maturities of less than three months. These investments are carried at cost, which approximates fair value.

At each of September 30, 2009 and December 31, 2008, the Company held available for sale securities with a fair value totaling \$120.1 million and \$135.2 million, respectively. These available for sale securities included various U.S. government agency notes and corporate debt securities. At September 30, 2009 and December 31, 2008, all of the Company's available for sale securities had maturities within one year.

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

	As of September 30, 2009				As of December 31, 2008			
	Cost	Fair Value	Carrying Value	Unrealized Gain	Cost	Fair Value	Carrying Value	Unrealized Gain
				(in thousands)				
U.S. government agency notes	\$ 107,557	\$ 107,697	\$ 107,697	\$ 140	\$ 107,513	\$ 108,491	\$ 108,491	\$ 978
Corporate debt securities	\$ 12,356	\$ 12,398	\$ 12,398	\$ 42	\$ 26,487	\$ 26,697	\$ 26,697	\$ 210
Total	\$ 119,913	\$ 120,095	\$ 120,095	\$ 182	\$ 134,000	\$ 135,188	\$ 135,188	\$ 1,188

**Restricted Cash**

On October 11, 2007, the Company entered into a new lease for office space in Parsippany, New Jersey. The Company relocated its principal executive offices to the new space in the first quarter of 2009. Restricted cash of \$6.7 million and \$5.0 million at September 30, 2009 and December 31, 2008, respectively, collateralizes outstanding letters of credit associated with such lease. The funds are invested in certificates of deposit. Under the lease, the Company agreed to increase the amount of the letter of credit on the Phase I Estimated Commencement Date, as defined in the lease, by an additional \$3.0 million for a total letter of credit of \$8.0 million. The Phase I Commencement Date occurred during the fourth quarter of 2008 and the Company increased the letter of credit to \$8.0 million in the first quarter of 2009. The letter of credit permits draws by the landlord to cure defaults by the Company. The amount of the letter of credit is subject to reduction upon the achievement of certain regulatory and operational milestones relating to the Company's products. However, in no event will the amount of the letter of credit be reduced below approximately \$1.0 million. In addition, as a result of the Targanta acquisition, the Company's

restricted cash increased \$0.5 million in the form of a guaranteed investment certificate collateralizing an available credit facility.

**Table of Contents****11. Inventory**

The Company obtains all of its Angiomax bulk drug substance from Lonza Braine, S.A. (Lonza Braine). Under the terms of the Company's agreement with Lonza Braine, the Company provides forecasts of its annual needs for Angiomax bulk substance 18 months in advance. The Company also has a separate agreement with Ben Venue Laboratories, Inc. for the fill-finish of Angiomax drug product. As of September 30, 2009, the Company had inventory-related purchase commitments totaling \$15.4 million during 2009, \$26.1 million during 2010 and \$19.1 million during 2011 for Angiomax bulk drug substance. The Company obtains all of its Cleviprex bulk drug substance from Johnson Matthey Pharma Services and also has a separate agreement with Hospira, Inc. for the fill-finish of Cleviprex drug product.

The major classes of inventory were as follows:

	<b>September 30, 2009</b>	<b>December 31, 2008</b>
	<b>(in thousands)</b>	
Raw materials	\$ 4,444	\$ 10,003
Work-in-progress	7,150	10,334
Finished goods	7,846	7,892
Total	\$ 19,440	\$ 28,229

As of September 30, 2009 and December 31, 2008, the Company had an inventory obsolescence reserve of \$0.5 million. If the Company's estimates or assumptions change, the Company may be required to make additional allowances for excess or obsolete inventory.

**12. Intangible Assets and Goodwill**

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

		<b>As of September 30, 2009</b>			<b>As of December 31, 2008</b>		
		<b>Gross</b>		<b>Net</b>	<b>Gross</b>		<b>Net</b>
	<b>Weighted Average Useful Life</b>	<b>Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Carrying Amount</b>	<b>Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Carrying Amount</b>
<b>(in thousands)</b>							
Identifiable intangible assets							
Customer relationships <sup>(1)</sup>	8 years	\$ 7,457	\$ 718	\$ 6,739	\$ 7,457	\$ 288	\$ 7,169
Distribution agreements <sup>(1)</sup>	8 years	4,448	428	4,020	4,448	171	4,277
Trademarks <sup>(1)</sup>	8 years	3,024	291	2,733	3,024	116	2,908
Cleviprex milestones <sup>(2)</sup>	13 years	2,000	21	1,979	2,000	5	1,995
	9 years						
Total	9 years	\$ 16,929	\$ 1,458	\$ 15,471	\$ 16,929	\$ 580	\$ 16,349

(1) The Company amortizes intangible assets related to Angiox based on the ratio of annual forecasted revenue compared to total forecasted revenue from the sale of Angiox through the end of its patent life.

(2) The Company amortizes intangible assets related to the Cleviprex approval over the remaining life of the patent.

The Company expects amortization expense related to these intangible assets to be \$0.3 million for the remainder of 2009. The Company expects annual amortization expense related to these intangible assets to be \$1.8 million, \$2.4 million, \$2.4 million, \$3.0

**Table of Contents**

million and \$3.6 million for the years ending December 31, 2010, 2011, 2012, 2013 and 2014, respectively, with the balance of \$2.0 million being amortized thereafter. Amortization of customer relationships, distribution agreements and trademarks will be recorded in selling, general and administrative expense on the consolidated statements of operations. Amortization of Cleviprex milestones will be recorded in cost of revenue on the consolidated statements of operations.

The following information details the carrying amounts of the Company's intangible assets not subject to amortization:

	As of September 30, 2009			As of December 31, 2008		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
	(in thousands)					
Intangible assets not subject to amortization:						
In-process research and development	\$ 69,500	\$	\$ 69,500	\$	\$	\$
<b>Total</b>	<b>\$ 69,500</b>	<b>\$</b>	<b>\$ 69,500</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>

The changes in goodwill for the nine months ended September 30, 2009 and for the year ended December 31, 2008 are as follows:

	September 30, 2009	December 31, 2008
	(in thousands)	
Balance at beginning of period	\$	\$
Goodwill acquired during the year	26,035	
Balance at end of period	\$ 26,035	\$

The goodwill acquired during the year is solely attributable to the Targanta acquisition (note 8).

**13. Fair Value Measurements**

On January 1, 2008, the Company adopted the provisions of ASC 820-10, Fair Value Measurements and Disclosures (ASC 820-10) for financial assets and liabilities. As permitted by ASC 820-10, the Company elected to defer until January 1, 2009 the adoption of ASC 820-10 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis. ASC 820-10 provides a framework for measuring fair value under GAAP and requires expanded disclosures regarding fair value measurements. ASC 820-10 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820-10 also establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

**Level 1** Quoted prices in active markets for identical assets or liabilities. The Company's Level 1 assets and liabilities consist of money market investments.

**Level 2**

Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. The Company's Level 2 assets and liabilities consist of U.S. government agency and corporate debt securities.

**Level 3** Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. The Company's Level 3 assets and liabilities consist of the contingent purchase price associated with the Targanta acquisition (note 8). The fair value of the contingent purchase price was determined utilizing a probability weighted discounted financial model.



**Table of Contents**

The following table sets forth the Company's assets and liabilities that were measured at fair value on a recurring basis at September 30, 2009 by level within the fair value hierarchy. As required by ASC 820-10, assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the asset or liability:

Assets and Liabilities	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant		Balance at September 30, 2009
		Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3) (in thousands)	
Assets:				
Money market	\$ 31,364	\$	\$	\$ 31,364
U.S. government agency		107,697		107,697
Corporate debt securities		12,398		12,398
Total assets at fair value	\$ 31,364	\$ 120,095	\$	\$ 151,459
Liabilities:				
Contingent purchase price	\$	\$	\$ 22,741	\$ 22,741
Total liabilities at fair value	\$	\$	\$ 22,741	\$ 22,741

The changes in fair value of the Company's Level 3 contingent purchase price during the nine months ended September 30, 2009 were as follows:

	Level 3 (in thousands)
Balance at December 31, 2008	\$
Contingent purchase price related to acquisition of Targanta	23,183
Fair value adjustment to contingent purchase price included in net loss	(442)
Balance at September 30, 2009	\$ 22,741

**14. Segment and Geographic Information**

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

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

Three Months Ended September 30,		Nine Months Ended September 30,	
2009	2008	2009	2008

(in thousands)								
Net revenue:								
United States	\$ 93,317	94.5%	\$ 84,979	96.4%	\$ 289,044	95.6%	\$ 246,317	96.9%
Europe	2,915	2.9%	2,247	2.6%	8,692	2.9%	4,981	1.9%
Other	2,557	2.6%	900	1.0%	4,445	1.5%	2,987	1.2%
Total net revenue	98,789		88,126		302,181		254,285	

	September 30, 2009		December 31, 2008	
		(in thousands)		
Long-lived assets:				
United States	\$ 142,399	98.5%	\$ 47,308	96.7%
Europe	1,750	1.2%	1,609	3.3%
Other	392	0.3%		%
Total long-lived assets	\$ 144,541		\$ 48,917	

**Table of Contents**

**15. Relocation of Principal Offices**

On January 12, 2009, the Company moved its principal executive offices to new office space in Parsippany, New Jersey. The lease for the Company's previous office facility expires in January 2013. As a result of vacating the previous facility, the Company triggered a cease-use date on January 12, 2009 and incurred estimated lease termination costs. Estimated lease termination costs include the net present value of future minimum lease payments from the cease-use date to the end of the remaining lease term net of estimated sublease rental income. As of September 30, 2009, the Company has accrued approximately \$2.2 million for its estimate of the net present value of these estimated lease termination costs. Additionally, certain other costs such as leasing commissions and legal fees will be expensed as incurred in conjunction with the sublease of the vacated office space.

**16. Contingencies**

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company accrues for loss contingencies when information available indicates that it is probable that a liability has been incurred and the amount of such loss can be reasonably estimated. The Company believes that the ultimate resolution of these matters will not have a material adverse effect on the Company's financial condition or liquidity. However, adjustments, if any, to the Company's estimates could be material to operating results for the periods in which adjustments to the liability are recorded.

The U.S. Patent and Trademark Office rejected the Company's application under the Hatch-Waxman Act for an extension of the term of U.S. Patent No. 5,196,404, the principal U.S. patent that covers Angiomax, beyond March 2010 because the PTO rejected the application on the grounds that it was not timely filed by counsel (the late filing). The Company has entered into agreements with the counsel involved in the late filing that suspend the statute of limitations on any claims against them for failing to make a timely filing. The Company has entered into a similar agreement with Biogen Idec relating to any claims, including claims for damages and/or license termination, that they may bring relating to the late filing. Any such claims by Biogen Idec could have a material adverse effect on the Company's financial condition, results of operations, liquidity or business. In the third quarter of 2009, the Company initiated discussions, which are still ongoing, with the law firms involved in the late filing of the application and are currently in related discussions with Biogen Idec with respect to the possible resolution of any potential claims among the parties.

**17. Subsequent Events**

On October 8, 2009, the Company filed three lawsuits alleging patent infringement by Teva Parenteral Medicines, Inc., Pliva Hrvatska d.o.o., APP Pharmaceuticals, LLC, and their related parent entities in the U.S. District Court for the District of Delaware. Teva Parenteral Medicines, Inc., Pliva Hrvatska d.o.o., and APP Pharmaceuticals, LLC had each submitted an Abbreviated New Drug Application seeking permission to market their respective generic versions of Angiomax prior to the expiration of U.S. Patent No. 7,582,727 (the '727 patent). On October 21, 2009, the three cases were reassigned in lieu of a vacant judgeship to the U.S. District Court for the Eastern District of Pennsylvania. The '727 patent was issued on September 1, 2009 and relates to a more consistent and improved Angiomax drug product. The '727 patent is listed in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations, which is commonly known as the Orange Book, for Angiomax and expires on July 27, 2028.

**Table of Contents****Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and accompanying notes included elsewhere in this quarterly report. In addition to the historical information, the discussion in this quarterly report contains certain forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated by the forward-looking statements due to our critical accounting estimates discussed below and important factors set forth in this quarterly report, including under Risk Factors in Part II, Item 1A of this quarterly report.*

**Overview***Our Business*

We are a global pharmaceutical company focused on advancing the treatment of critical care patients through the delivery of innovative, cost-effective medicines to the worldwide hospital marketplace. We have two marketed products, Angiomax® (bivalirudin) and Cleviprex® (clevidipine butyrate) injectable emulsion, two products in late-stage development, cangrelor, and oritavancin, and one compound, CU2010, which has entered into a Phase Ia clinical trial in Switzerland in July 2009. We also recently licensed marketing rights in the United States and Canada to a ready-to-use formulation of Argatroban developed by Eagle Pharmaceuticals, Inc., or Eagle, a specialty pharmaceutical company with expertise in drug development. Argatroban, currently marketed in a concentrated formulation, is approved as an anticoagulant for prophylaxis or treatment of thrombosis in patients with or at risk for heparin induced thrombocytopenia, or HIT, and for patients with or at risk for HIT undergoing percutaneous coronary intervention, or PCI. Eagle submitted a NDA for the ready-to-use formulation of Argatroban to the U.S. Food and Drug Administration, or FDA, in 2008.

We market Angiomax primarily in the United States and Europe (where we market Angiomax under the name Angiox® (bivalirudin)) to interventional cardiologists and other key decision makers in cardiac catheterization laboratories for its approved uses in patients undergoing PCI, including in patients with or at risk of heparin induced thrombocytopenia and thrombosis syndrome, or HIT/HITTS, that can result in limb amputation, multi-organ failure and death. In Europe, we also market Angiox for use in adult patients with acute coronary syndrome, or ACS. In October 2009, we received a positive opinion from the Committee for Medicinal Products for Human, or CHMP, on our regulatory filing to extend the indications for Angiox in the European Union to include treatment of STEMI patients undergoing PCI. We expect the European Agency for the Evaluation of Medical Products, or EMEA, to grant final approval in the fourth quarter of 2009. We market Cleviprex to anesthesiology/surgery, critical care and emergency department practitioners in the United States for its approved use for the reduction of blood pressure when oral therapy is not feasible or not desirable. In July 2009, Cleviprex was approved for sale in New Zealand for indications similar to those approved by the FDA. Other than in New Zealand, Cleviprex is not approved for sale outside the United States. During the first quarter of 2009, we submitted via the Decentralized Procedure marketing authorization applications, or MAAs, for Cleviprex in the European Union for the reduction of blood pressure when rapid and predictable control is required. We intend to continue to develop Angiomax and Cleviprex for use in additional patient populations.

We market and sell Angiomax and Cleviprex in the United States with a joint sales force that, as of September 30, 2009, consisted of 176 representatives and managers experienced in selling to hospital customers. In Europe, we market and sell Angiox with a sales force that, as of September 30, 2009, consisted of 51 representatives and managers experienced in selling to hospital customers. Our revenues to date have been generated primarily from sales of Angiomax in the United States. We continue to increase our sales force in Europe in connection with the expansion of our sales and marketing efforts in Europe and the approval of the label expansion for Angiox for ACS in Europe that occurred in January 2008.

Research and development expenses represent costs incurred for product acquisition, clinical trials, activities relating to regulatory filings and manufacturing development efforts. We outsource much of our clinical trials and all of our manufacturing development activities to third parties to maximize efficiency and minimize our internal overhead. We expense our research and development costs as they are incurred. Selling, general and administrative expenses consist primarily of salaries and related expenses, general corporate activities and costs associated with marketing and promotional activities. Research and development expense, selling, general and administrative expense

and cost of revenue also include stock-based compensation expense, which we allocate based on the responsibilities of the recipients of the stock-based compensation.

## **Table of Contents**

Except for 2004 and 2006, we have incurred net losses on an annual basis since our inception. As of September 30, 2009, we had an accumulated deficit of approximately \$270.7 million. We expect to make substantial expenditures to further develop and commercialize our products, including costs and expenses associated with clinical trials, regulatory approvals and commercialization. Although we achieved profitability in 2004 and in 2006 and expect to be profitable in 2009, we were not profitable in 2008 primarily as a result of the costs incurred in connection with our acquisition of Curacyte Discovery in August 2008 and were not profitable in 2007, primarily as a result of the costs incurred in connection with the Nycomed transaction. We will likely need to generate significantly greater revenue in future periods to achieve and maintain profitability in light of our planned expenditures.

### *Distribution and Sales*

We distribute Angiomax and Cleviprex in the United States through a sole source distribution model. Under this model, we sell Angiomax and Cleviprex to our sole source distributor, Integrated Commercialization Solutions, Inc., or ICS, which then sells Angiomax and Cleviprex to a limited number of national medical and pharmaceutical wholesalers with distribution centers located throughout the United States and, in certain cases, directly to hospitals. Our agreement with ICS, which we initially entered into in February 2007, provides that ICS will be our exclusive distributor of Angiomax and Cleviprex in the United States. Under the terms of this fee for service agreement, ICS assumes all credit and inventory risks, is subject to our standard returns policy, places order with us for sufficient quantities of Angiomax and Cleviprex to maintain an appropriate level of inventory based on its customers' historical purchase volumes and has sole responsibility for determining the prices at which it sells Angiomax and Cleviprex, subject to specified limitations in the agreement. The agreement terminates on February 28, 2010, but will automatically renew for additional one-year periods unless either party gives notice at least 120 days prior to the automatic extension. We may also terminate the agreement at any time and for any reason upon prior written notice to ICS and payment of a termination fee of between \$100,000 and \$250,000. Outside the United States, we sell Angiomax either directly to hospitals or to wholesalers or international distributors, which then sell Angiomax to hospitals.

The reacquisition of all development, commercial and distribution rights for Angiox from Nycomed in 2007 was our first step directly into international markets and gives us a direct presence in European markets. In July 2007, we entered into a series of agreements with Nycomed pursuant to which we terminated the prior distribution agreement with Nycomed and re-acquired all development, commercial and distribution rights for Angiox in the European Union (excluding Spain, Portugal and Greece, which territories are served by a different third-party distributor) and the former Soviet republics, which we refer to as the Nycomed territory. Prior to entering into the 2007 Nycomed agreements, Nycomed served as the exclusive distributor of Angiox in the Nycomed territory pursuant to a sales, marketing and distribution agreement, dated March 25, 2002, as amended. Pursuant to the 2007 Nycomed agreements, we and Nycomed agreed to transition the Angiox rights held by Nycomed to us. Under these arrangements, including a transitional distribution agreement, we assumed control of the marketing of Angiox immediately and Nycomed provided, on a transitional basis, sales operations services, until December 31, 2007 and product distribution services until the second half of 2008. We assumed control of the distribution of Angiox in the Nycomed territory during the second half of 2008.

Under the terms of the transitional distribution agreement with Nycomed, upon the sale by Nycomed to third parties of vials of Angiox purchased by Nycomed from us prior to July 1, 2007, which we refer to as existing inventory, Nycomed agreed to pay us a specified percentage of Nycomed's net sales of Angiox, less the amount previously paid by Nycomed to us for the existing inventory. Under the transitional distribution agreement, upon the termination of the agreement, Nycomed had the right to return any existing inventory for the price paid by Nycomed to us for such inventory. We recorded a reserve of \$3.0 million in the fourth quarter of 2007 for the existing inventory at Nycomed which we did not believe would be sold prior to the termination of the transitional distribution agreement and would be subject to purchase in accordance with the agreement. During 2008, we reduced the reserve by \$2.2 million as Nycomed sold a portion of its existing inventory during the year. Included within our accrual for product return is a reserve of \$0.8 million at December 31, 2008 for existing inventory at Nycomed that Nycomed has the right to return at any time. In July 2009, we reimbursed Nycomed \$0.8 million for the final amount of inventory held by Nycomed at December 31, 2008. The transitional distribution agreement terminated on December 31, 2008.

We incurred total costs of \$45.7 million in connection with the reacquisition of the rights to develop, distribute and market Angiox in the Nycomed territory. This total costs amount includes transaction fees of approximately \$0.7 million and agreed upon milestone payments of \$20.0 million paid to Nycomed on July 2, 2007, \$15.0 million paid to Nycomed on January 15, 2008 and \$5.0 million paid to Nycomed on July 8, 2008, as well as an additional \$5.0 million paid to Nycomed on July 8, 2008 in connection with our obtaining European Commission approval to market Angiox for ACS in January 2008.

## **Table of Contents**

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

To support the marketing, sales and distribution efforts of Angiomax, we are continuing to develop our business infrastructure outside the United States. We initiated research to understand the PCI market, as well as the hypertension market, on a global basis, including profiling hospitals and identifying key opinion leaders. Since reacquiring these rights from Nycomed, we have formed subsidiaries in the Netherlands, Switzerland, Germany, France, Italy, Sweden, Poland, Denmark, Austria and Belgium, in addition to our pre-existing subsidiary in the United Kingdom, in connection with the development of a business infrastructure to conduct the international sales and marketing of Angiox. We also obtained all the licenses and authorizations necessary to distribute the product in the various countries in Europe, hired new personnel and entered into third-party arrangements to provide services, such as importation, packaging, quality control and distribution. We believe that by establishing operations in Europe for Angiox, we will be positioned to commercialize our pipeline of critical care product candidates, including Cleviprex, cangrelor, oritavancin and CU2010, if and when they are approved.

### *Targanta Acquisition*

In February 2009, we acquired Targanta Therapeutics Corporation, or Targanta. Under the terms of our agreement with Targanta, we paid Targanta shareholders \$2.00 in cash at closing for each common share of Targanta common stock tendered, or approximately \$42.0 million in aggregate, and agreed to pay contingent cash payments up to an additional \$4.55 per share as described below:

If we or a MDCO Affiliated Party (meaning an affiliate of ours, a successor or assigns of ours, or a licensee or collaborator of ours) obtain approval from the EMEA for a MAA for oritavancin for the treatment of cSSSI on or before December 31, 2013, then former Targanta shareholders will be entitled to receive a cash payment equal to (1) \$1.00 per share if such approval is granted on or before December 31, 2009, (2) \$0.75 per share if such approval is granted between January 1, 2010 and June 30, 2010, or (3) \$0.50 per share if such approval is granted between July 1, 2010 and December 31, 2013, a payment of approximately \$21.0 million in the aggregate, approximately \$15.8 million in the aggregate, or approximately \$10.5 million in the aggregate, respectively.

If we or a MDCO Affiliated Party obtain final approval from the FDA for a NDA for oritavancin for the treatment of cSSSI (1) within 40 months after the date the first patient is enrolled in a Phase III clinical trial of cSSSI that is initiated by us or a MDCO Affiliated Party after the date of our merger agreement with Targanta and (2) on or before December 31, 2013, then former Targanta shareholders will be entitled to receive a cash payment equal to \$0.50 per share, or approximately \$10.5 million in the aggregate.

If we obtain final FDA approval for an NDA for the use of oritavancin for the treatment of cSSSI administered by a single dose intravenous infusion (1) within 40 months after the date the first patient is enrolled in a Phase III clinical trial of cSSSI that is initiated by us or a MDCO Affiliated Party after the date of our merger agreement with Targanta and (2) on or before December 31, 2013, then former Targanta shareholders will be entitled to receive a cash payment equal to \$0.70 per share, or approximately \$14.7 million in the aggregate. This payment may become payable simultaneously with the payment described in the previous bullet above.



If aggregate net sales of oritavancin in four consecutive calendar quarters ending on or before December 31, 2021 reach or exceed \$400 million, then former Targanta shareholders will be entitled to receive a cash payment equal to \$2.35 per share, or approximately \$49.4 million in the aggregate.

We expect to complete the allocation of the purchase price within one year from the date of the acquisition.

**Table of Contents**

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

*Curacyte Discovery Acquisition*

In August 2008, we acquired Curacyte Discovery GmbH, or Curacyte Discovery, a wholly owned subsidiary of Curacyte AG. Curacyte Discovery was primarily engaged in the discovery and development of small molecule serine protease inhibitors including CU2010. In connection with the acquisition, we paid Curacyte AG an initial payment of 14.5 million (approximately \$22.9 million) and agreed to pay a contingent milestone payment of 10.5 million if we proceed with clinical development of CU2010. In addition, our agreement with Curacyte AG provides for possible future sales royalty payments and a commercial milestone payment.

The total cost of the acquisition was approximately \$23.7 million, which consisted of a purchase price of approximately \$22.9 million and direct acquisition costs of \$0.8 million. Since the acquisition date, we have included results of Curacyte Discovery's operations in our consolidated financial statements. We allocated the purchase price to the estimated fair value of assets acquired and liabilities assumed based on a third-party valuation and management estimates. We allocated approximately \$21.4 million of the purchase price to in-process research and development, which we expensed upon completion of the acquisition. We recorded this amount as research and development expenses in our consolidated statements of operations for the three months ended September 30, 2008. We allocated the remaining portion of the purchase price to net tangible assets.

*Licensing Arrangement with Eagle*

In September 2009, we entered into a license agreement with Eagle pursuant to which we acquired marketing rights in the United States and Canada to a ready-to-use formulation of Argatroban. Eagle filed a NDA for this formulation in 2008, which is currently under review by the FDA. Under the license agreement with Eagle, we paid a \$5.0 million technology license fee and agreed to purchase \$2.0 million of convertible preferred stock of Eagle in the fourth quarter of 2009. Under the license agreement, we also agreed to pay certain additional approval and commercialization milestones and royalties. Eagle has agreed to supply us with the ready-to-use product under a supply agreement we entered into with it in September 2009.

**Results of Operations*****Three Months Ended September 30, 2009 and 2008****Net Revenue:*

Net revenue increased 12% to \$98.8 million for the three months ended September 30, 2009 as compared to \$88.1 million for the three months ended September 30, 2008. The following table reflects the components of net revenue for the three months ended September 30, 2009 and 2008:

**Net Revenue**

	<b>Three Months Ended September 30,</b>			
	<b>2009</b>	<b>2008</b>	<b>Change</b>	<b>Change</b>
	<b>(in</b>	<b>(in</b>	<b>\$</b>	<b>%</b>
	<b>thousands)</b>	<b>thousands)</b>	<b>(in</b>	
			<b>thousands)</b>	
<b>Net Revenue</b>				
<b><i>Angiomax and Cleviprex</i></b>				
U.S net revenue	\$ 93,317	\$ 84,979	\$ 8,338	9.8%
<b><i>Angiomax</i></b>				
International net revenue	5,472	2,556	2,916	114.1%
<b><i>Revenue from collaborations, net</i></b>		591	(591)	(100)%
<b><i>Total net revenue</i></b>	<b>\$ 98,789</b>	<b>\$ 88,126</b>	<b>\$ 10,663</b>	<b>12.1%</b>



**Table of Contents**

Net revenue for the three months ended September 30, 2009 increased compared to the three months ended September 30, 2008 primarily due to an increase in U.S. sales of Angiomax and an increase in European sales of Angiox. Sales of Angiomax in the United States increased \$7.2 million, or 8.5%, primarily due to increased demand by existing hospital customers, the addition of new hospital customers and the price increase we implemented in May 2009. Of the 8.5% increase in the U.S. sales in the three months ended September 30, 2009 compared to the three months ended September 30, 2008, approximately 2.4% was related to hospital demand by existing and new customers and approximately 6.2% was attributable to the price increase. The increase in U.S. sales in the three months ended September 30, 2009 also included \$1.1 million of net revenue from Cleviprex sales.

International net revenue increased \$2.9 million, or 114%, during the three months ended September 30, 2009 compared to the three months ended September 30, 2008 primarily as a result of the direct sales we made after assuming control of the distribution of Angiox in the majority of the countries in the Nycomed territory during the third quarter of 2008.

During the three months ended September 30, 2008, we recognized as revenue from collaborations approximately \$0.6 million of net revenue from sales made by Nycomed of approximately \$1.4 million under our transitional distribution agreement with Nycomed. Under the terms of this transitional distribution agreement, upon the sale by Nycomed to third parties of vials of Angiox, Nycomed paid us a specified percentage of Nycomed's net sales of Angiox, less the amount previously paid by Nycomed to us for the existing inventory. The transitional distribution agreement terminated on December 31, 2008 and there are no remaining obligations under such agreement for either party.

*Cost of Revenue:*

As shown in the table below, cost of revenue during the three months ended September 30, 2009 was \$28.3 million, or 29% of net revenue, compared to \$22.1 million, or 25% of net revenue, for the three months ended September 30, 2008. The increase in cost of revenues as a percentage of net revenue was driven by a higher projected effective royalty rate for sales of Angiomax under our license agreement with Biogen Idec. Cost of revenue consisted of expenses in connection with the manufacture of Angiomax and Cleviprex sold, royalty expenses under our agreements with Biogen Idec, Health Research Inc. and AstraZeneca and the logistics costs of selling Angiomax and Cleviprex, such as distribution, storage, and handling. Cost of revenue increased \$6.2 million during the three months ended September 30, 2009 compared to the three months ended September 30, 2008, primarily related to higher Angiomax sales and an increase in royalty expense due to a higher projected effective royalty rate for sales of Angiomax under our agreement with Biogen Idec.

**Cost of Revenue**

	<b>Three Months Ended September 30,</b>			
	<b>2009</b>	<b>% of</b>	<b>2008</b>	<b>% of</b>
	<b>(in</b>	<b>Total</b>	<b>(in</b>	<b>Total</b>
	<b>thousands)</b>	<b>Cost</b>	<b>thousands)</b>	<b>Cost</b>
<b>Cost of Revenue</b>				
Manufacturing	\$ 6,830	24%	\$ 5,269	24%
Royalty	18,755	66%	13,747	62%
Logistics	2,723	10%	3,073	14%
<b>Total Cost of Revenue</b>	<b>\$ 28,308</b>	<b>100%</b>	<b>\$ 22,089</b>	<b>100%</b>

*Research and Development Expenses:*

Research and development expenses decreased by 49% to \$22.5 million for the three months ended September 30, 2009, from \$44.1 million for the three months ended September 30, 2008. The decrease in research and development expenses primarily reflects the inclusion in research and development expense in the third quarter of 2008 of

\$21.4 million of acquisition related in-process research and development in 2008 in connection with our acquisition of Curacyte in August 2008, partially offset by a \$5.0 million technology license fee paid to Eagle in connection with the acquisition of the rights to a ready-to-use formulation of Argatroban which was recorded in research and development expense in the third quarter of 2009 and increased expenditures in the third quarter of 2009 in connection with the continued development efforts for Cleviprex and the products acquired in the Curacyte Discovery and Targanta

**Table of Contents**

acquisitions in August 2008 and February 2009, respectively. The results of operations of Curacyte Discovery and Targanta are included within our consolidated financial statements as of the dates of acquisition.

The following table identifies, for each of our major research and development projects, our spending for the three months ended September 30, 2009 and 2008. Spending for past periods is not necessarily indicative of spending in future periods.

**Research and Development Spending**

	<b>Three Months Ended September 30,</b>			
	<b>2009</b>	<b>% of</b>	<b>2008</b>	<b>% of</b>
	<b>(in</b>	<b>Total</b>	<b>(in</b>	<b>Total</b>
	<b>thousands)</b>	<b>R&amp;D</b>	<b>thousands)</b>	<b>R&amp;D</b>
<b>Research and Development</b>				
<b>Angiomax</b>				
Clinical trials	\$ 1,008	5%	\$ 1,253	3%
Manufacturing development	2,896	13%	968	2%
Administrative and headcount costs	926	4%	1,035	2%
<b>Total Angiomax</b>	<b>4,830</b>	<b>22%</b>	<b>3,256</b>	<b>7%</b>
<b>Cleviprex</b>				
Clinical trials	563	3%	925	2%
Manufacturing development	744	3%	322	1%
Administrative and headcount costs	1,158	5%	1,301	3%
<b>Total Cleviprex</b>	<b>2,465</b>	<b>11%</b>	<b>2,548</b>	<b>6%</b>
<b>Cangrelor</b>				
Clinical trials	2,796	12%	10,907	25%
Manufacturing development	512	2%	623	1%
Administrative and headcount costs	1,036	5%	1,192	3%
<b>Total Cangrelor</b>	<b>4,344</b>	<b>19%</b>	<b>12,722</b>	<b>29%</b>
<b>CU2010</b>				
Clinical trials	833	4%		0%
Manufacturing development		0%		0%
Administrative and headcount	742	3%	386	1%
Acquisition related in-process research and development		0%	21,373	48%
Government subsidy	(1,024)	(4)%		0%
<b>Total CU2010</b>	<b>551</b>	<b>3%</b>	<b>21,759</b>	<b>49%</b>
<b>Oritavancin</b>				
Clinical trials		0%		0%
Manufacturing development		0%		0%
Administrative and headcount	2,542	11%		0%
<b>Total Oritavancin</b>	<b>2,542</b>	<b>11%</b>		<b>0%</b>
<b>Other</b>	<b>7,732</b>	<b>34%</b>	<b>3,790</b>	<b>9%</b>

<b>Total</b>	\$ 22,464	100%	\$ 44,075	100%
<i>Angiomax</i>				

Research and development spending in the three months ended September 30, 2009 related to Angiomax increased approximately \$1.6 million primarily due to an increase in Angiomax manufacturing development costs of approximately \$1.9 million. The increased manufacturing development expenses are associated with product lifecycle management activities in which we are engaged. This increase was partially offset by a decrease in Angiomax clinical trial costs of approximately \$0.2 million primarily due to decreased administrative costs incurred in connection with the regulatory filing related to a study of Angiomax in the pediatric setting that we began in the first half of 2007 in connection with a written request by the FDA. The study consisted of a single trial to clarify the pediatric dose that provides a pharmacodynamic response equivalent to that observed in the adult population at the approved adult dose. We filed the clinical study report for the pediatric extension with the FDA in the second quarter of 2009 and in June 2009, based on the study report, the FDA granted us an additional six months of market exclusivity for Angiomax.

**Table of Contents**

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

*Cleviprex*

Research and development expenditures for Cleviprex decreased by approximately \$0.1 million during the three months ended September 30, 2009 compared to the same period in 2008. The decrease in research and development expenditures was primarily related to decreased clinical trial expenses for our MERCURY, ACCELERATE and SPRINT Phase IV trials. The decrease in clinical trial expense was partially offset by increased manufacturing development expenses associated with product lifecycle management activities.

We are conducting Phase IV trials of Cleviprex in neurology and cardiology, along with health economics analyses, and supporting observational studies conducted by hospitals and third-party researchers which include the assessment of acute severe hypertension treatment practices. Our ACCELERATE Phase IV trials evaluate the efficacy and safety of intravenous infusion of Cleviprex for the treatment of acute hypertension in patients with intracerebral hemorrhage (ICH). We are currently enrolling patients in this study in sites across the United States and Germany. Our PRONTO study is a Phase IV trial designed to evaluate the efficacy and safety of an intravenous infusion of Cleviprex as compared with standard-of-care intravenous antihypertensives for blood pressure lowering in patients with acute heart failure and elevated blood pressure. We are currently enrolling patients in this study in sites in the United States and Europe. Our SPRINT study is a Phase IV trial designed to evaluate the pharmacokinetics and pharmacodynamics of a bolus dosing regimen of Cleviprex for the management of blood pressure in cardiac surgery patients. In the third quarter of 2009, we completed enrollment in this study. Our MERCURY Phase IV trial is a retrospective observational study of the use and impact of Cleviprex therapy initiated in the emergency department in the management of patients with acute blood pressure elevations, assessed through the end of the initial hospitalization. We are currently enrolling patients in this study in sites in the United States.

*Cangrelor*

In May 2009, we discontinued enrollment in our Phase III CHAMPION clinical trial program of cangrelor. As a result, research and development expenditures related to cangrelor decreased in the three months ended September 30, 2009 compared to the same period in 2008 as clinical trial and administrative and headcount costs decreased.

We are evaluating development plans for cangrelor after discontinuing enrollment in these clinical trials, including focusing on short-term use of cangrelor in settings where oral drugs cannot be used or when a short half-life is highly desirable. We began studying cangrelor in such settings with our BRIDGE study which was initiated in the fourth quarter of 2008. The BRIDGE study aims to establish the dosage of cangrelor that achieves greater than or equal to 60% inhibition of platelet aggregation for up to five days. We are in a process of collecting one year follow up data from the CHAMPION program. The 48-hour and 30-day CHAMPION data has been analyzed and will be presented as two late-breaking trials in November 2009 at the American Heart Association annual meeting.

*CU2010*

We acquired CU2010 in August 2008 in connection with our acquisition of Curacyte Discovery. CU2010 is a small molecule serine protease inhibitor that we are developing for the prevention of blood loss during surgery. In preclinical studies, the compound has demonstrated a favorable pharmacokinetic profile for the surgical setting with a rapid onset and offset of effect, due to its short half life. The molecule was designed and is being developed to address a significant unmet medical need that has intensified for clinicians since the recent withdrawal of aprotinin from the market. The acquisition of Curacyte Discovery resulted in the inclusion in research and development expense of \$21.4 million of acquisition related in-process research and development in the three months ended September 30, 2008. Costs incurred during the three months ended September 30, 2009 primarily relate to our Phase Ia clinical trial of CU2010 which commenced in July 2009 and headcount. Such research and develop expense is partially offset by a credit of \$1.0 million due to a German government subsidy which we recorded in research and development.

*Oritavancin*

With our acquisition of Targanta in February 2009, we acquired a worldwide exclusive license to oritavancin, which we believe has the potential to provide significant clinical advantages, including superior dosing over current IV antibiotics that treat serious





**Table of Contents**

infections in the hospital setting. We expect that oritavancin will initially be used in critical care settings within the hospital including the ICU, surgical suite and the emergency department, where our sales representatives promote our current products. We are in discussions with the FDA with a view to initiating a confirmatory Phase III program for oritavancin in early 2010 for the treatment of cSSSI. In August 2009, we withdrew the European MAA for oritavancin. Costs incurred during the three months ended September 30, 2009 primarily relate to headcount. The results of Targanta's operations are included in our consolidated financial statements as of the acquisition date.

***Other***

Spending in this category consists of a \$5.0 million technology license fee paid to Eagle in connection with the acquisition of the rights to a ready-to-use formulation of Argatroban and infrastructure costs in support of our product development efforts, which includes expenses for data management, statistical analysis, analysis of pre-clinical data, analysis of pharmacokinetic-pharmacodynamic (PK/PD) data and product safety as well as expenses related to business development activities. We also incur business development expenses in connection with our efforts to evaluate early stage and late stage compounds for development and commercialization and other strategic opportunities. Spending in this category increased by approximately \$3.9 million during the three months ended September 30, 2009 compared to the same period in 2008, primarily due the technology license fee paid to Eagle, which was partially offset by an overall reduction of business development expense.

We expect to continue to invest in the development of Angiomax, Cleviprex, cangrelor, CU2010 and oritavancin during the remainder of 2009. We expect research and development expenses to reflect costs associated with our Phase IV trials for Cleviprex, additional manufacturing development costs for Cleviprex and cangrelor, costs of our Phase I clinical trial program for CU2010 and anticipated Phase III clinical trial of oritavancin and product lifecycle management activities.

Our success in further developing Angiomax, obtaining marketing approvals for Cleviprex outside the United States, or developing and obtaining marketing approval for cangrelor, oritavancin and CU2010, is highly uncertain. We cannot predict expenses associated with ongoing data analysis or regulatory submissions, if any. Nor can we reasonably estimate or know the nature, timing and estimated costs of the efforts necessary to complete the development of, or the period in which material net cash inflows are expected to commence from, Cleviprex outside the United States, cangrelor, oritavancin or CU2010 due to the numerous risks and uncertainties associated with developing and commercializing drugs, including the uncertainty of:

the scope, rate of progress and cost of our clinical trials and other research and development activities;

future clinical trial results;

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

the cost and timing of regulatory approvals;

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

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

the effect of competing technological and market developments; and

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

*Selling, General and Administrative Expenses:*

<b>Three Months Ended September 30,</b>			
<b>2009</b>	<b>2008</b>	<b>Change</b>	<b>Change</b>
		<b>\$</b>	<b>%</b>
<b>(in thousands)</b>			

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

Selling, general and administrative expenses	\$47,358 24	\$42,865	\$4,493	10.5%
--	----------------	----------	---------	-------

---

**Table of Contents**

Selling, general and administrative expenses increased by 10.5% to \$47.4 million for the three months ended September 30, 2009, from \$42.9 million for the same period in 2008. The increase in selling, general and administrative expenses of \$4.5 million was due to \$3.8 million of expansion cost related to our new facility, \$1.4 million of cost related to our acquisitions of Targanta and Curacyte Discovery and \$3.2 million increase in costs related to headcount expansion, including the expansion of global medical science, sales management and operations teams. These increases were offset primarily by decreases of \$3.3 million in marketing and promotional cost as a result of lower spending activity in promotional, market research and medical education activities, and a \$1.2 million decrease in stock-based compensation expense.

*Other Income:*

	<b>Three Months Ended September 30,</b>			
	<b>2009</b>	<b>2008</b>	<b>Change</b>	<b>Change</b>
			<b>\$</b>	<b>%</b>
	<b>(in thousands)</b>			
Other income	\$151	\$1,070	\$(919)	(85.9)%

Other income, which is primarily comprised of interest income, decreased to \$0.2 million for the three months ended September 30, 2009, from \$1.1 million for the comparable period in 2008. This decrease in other income of \$0.9 million was primarily due to lower levels of cash to invest combined with lower rates of return on our available for sale securities in 2009.

*(Provision for) benefit from Income Tax:*

	<b>Three Months Ended September 30,</b>			
	<b>2009</b>	<b>2008</b>	<b>Change</b>	<b>Change</b>
			<b>\$</b>	<b>%</b>
	<b>(in thousands)</b>			
(Provision for ) benefit from income tax	\$(4,007)	\$6,616	\$10,623	160.6%

We recorded a provision for income taxes of \$4.0 million for the three months ended September 30, 2009 based on a profit before taxes in such period of \$0.8 million compared to a \$6.6 million benefit for the three months ended September 30, 2008 based on a loss before taxes of \$19.8 million. This resulted in an effective tax rate of 495% for the three months ended September 30, 2009 compared to 33% for the three months ended September 30, 2008. The significant increase in our effective tax rate is attributable to the higher proportion of non-deductible expenses to reported taxable income. The statutory rates in the geographic areas where we operate remained constant.

***Nine Months Ended September 30, 2009 and 2008****Net Revenue:*

Net revenue increased 19% to \$302.2 million for the nine months ended September 30, 2009, as compared to \$254.3 million for the nine months ended September 30, 2008. The following table reflects the components of net revenue for the nine months ended September 30, 2009 and 2008:

Table of Contents**Net Revenue**

Net Revenue	Nine Months Ended September 30,			
	2009	2008	Change \$	Change %
		(in thousands)		
<b><i>Angiomax and Cleviprex</i></b>				
U.S. sales	\$ 289,044	\$ 246,317	\$ 42,727	17.3%
<b><i>Angiomax</i></b>				
International net revenue	13,137	4,644	8,493	182.9%
<b><i>Revenue from collaborations, net</i></b>		3,324	(3,324)	(100)%
<b><i>Total net revenue</i></b>	<b>\$ 302,181</b>	<b>\$ 254,285</b>	<b>\$ 47,896</b>	<b>18.8%</b>

Net revenue for the nine months ended September 30, 2009 increased compared to the nine months ended September 30, 2008 primarily due to an increase in U.S. sales of Angiomax and an increase in European sales of Angiox. U.S. sales of Angiomax for the nine months ended September 30, 2009 increased compared to the nine months ended September 30, 2008 as a result of increased demand by existing hospital customers, the addition of new hospital customers and the price increase we implemented in May 2009. Of the approximate 16.3% increase in U.S. sales in the nine months ended September 30, 2009 compared to the same period in 2008, approximately 12.8% was related to hospital demand and 3.5% was attributable to the price increase. The increase in U.S. sales in the nine months ended September 30, 2009 also included \$2.5 million of net revenue from sales of Cleviprex, which we launched in September 2008.

The increase of \$8.5 million in international sales in the nine months ended September 30, 2009 compared to the nine months ended September 30, 2008 primarily was a result of direct sales we made after assuming control of the distribution of Angiox in the majority of the countries in the Nycomed territory during the third quarter of 2008, as well as increased orders from our international distributors.

During the nine months ended September 30, 2008, we recognized as revenue from collaborations approximately \$3.3 million of net revenue from sales made by Nycomed of approximately \$7.3 million under our transitional distribution agreement with Nycomed. Under the terms of this transitional distribution agreement, upon the sale by Nycomed to third parties of vials of Angiox, Nycomed pays us a specified percentage of Nycomed's net sales of Angiox, less the amount previously paid by Nycomed to us for the existing inventory. In July 2009, we reimbursed Nycomed \$0.8 million for the final amount of inventory held by Nycomed at December 31, 2008.

***Cost of Revenue:***

Cost of revenue during the nine months ended September 30, 2009 was \$87.0 million, or 29% of net revenue, compared to \$63.1 million, or 25% of net revenue, for the nine months ended September 30, 2008. The increase in cost of revenues as a percentage of net revenue was driven by a higher projected effective royalty rate for sales of Angiomax under our agreement with Biogen Idec. Cost of revenue during these periods consisted of expenses in connection with the manufacture of Angiomax and Cleviprex sold, royalty expenses under our agreements with Biogen Idec and Health Research Inc. and AstraZereca and the logistics costs of selling Angiomax and Cleviprex, such as distribution, storage and handling.

Cost of revenue increased \$23.8 million during the nine months ended September 30, 2009 compared to the nine months ended September 30, 2008. Approximately \$18.9 million of the total cost of revenue increase related to an increase in royalty expense due to a higher projected effective royalty rate to Biogen Idec, \$4.3 million related to an increase in manufacturing costs of Angiomax and \$0.6 million related to an increase in logistics costs primarily related to our costs associated with establishing our European distribution network.

**Cost of Revenue****Nine Months Ended September 30,**

<b>Cost of Revenue</b>	<b>2009 (in thousands)</b>	<b>% of Total Cost</b>	<b>2008 (in thousands)</b>	<b>% of Total Cost</b>
Manufacturing	\$ 19,675	23%	\$ 15,391	24%
Royalty	58,375	67%	39,438	63%
Logistics	8,908	10%	8,292	13%
<b><i>Total Cost of Revenue</i></b>	<b>\$ 86,958</b>	<b>100%</b>	<b>\$ 63,121</b>	<b>100%</b>

**Table of Contents***Research and Development Expenses:*

Research and development expenses decreased by 17% to \$68.7 million for the nine months ended September 30, 2009, from \$82.5 million for the nine months ended September 30, 2008. The decrease in research and development expenses primarily reflects the inclusion in research and development expense in the nine months ended September 30, 2008 of \$21.4 million of acquisition related in-process research and development in 2008 in connection with our acquisition of Curacyte in August 2008, partially offset by a \$5.0 million technology license fee paid to Eagle in connection with the acquisition of the rights to a ready-to-use formulation of Argatroban which we recorded as research and development expense in the third quarter of 2009, an increase in expenditures in the nine months ended September 30, 2009 in connection with product lifecycle management activities and the development of Angiomax for additional indications, the continued development efforts of Cleviprex and the products acquired in the Curacyte Discovery and Targanta acquisitions in August 2008 and February 2009, respectively. The results of operations of Curacyte Discovery and Targanta are included within our consolidated financial statements as of the dates of acquisition.

The following table identifies, for each of our major research and development projects, our spending for the nine months ended September 30, 2009 and 2008. Spending for past periods is not necessarily indicative of spending in future periods.

**Research and Development Spending**

Research and Development	Nine Months Ended September 30,			
	2009 (in thousands)	% of Total R&D	2008 (in thousands)	% of Total R&D
<b>Angiomax</b>				
Clinical trials	\$ 2,722	4%	\$ 4,030	5%
Manufacturing development	6,530	10%	2,853	3%
Administrative and headcount costs	3,536	5%	2,436	3%
<b>Total Angiomax</b>	12,788	19%	9,319	11%
<b>Cleviprex</b>				
Clinical trials	4,116	6%	1,815	2%
Manufacturing development	1,360	2%	1,811	2%
Administrative and headcount costs	4,059	6%	3,822	5%
<b>Total Cleviprex</b>	9,535	14%	7,448	9%
<b>Cangrelor</b>				
Clinical trials	19,730	29%	28,551	35%
Manufacturing development	2,500	3%	1,773	2%
Administrative and headcount costs	3,388	5%	3,694	4%
<b>Total Cangrelor</b>	25,618	37%	34,018	41%
<b>CU2010</b>				
Clinical trials	833	1%		0%
Manufacturing development		0%		0%
Administrative and headcount costs	2,621	4%	386	1%
Acquisition related in-process research and development		0%	21,373	26%
Government subsidy	(1,024)	(1)%		0%

<b>Total CU2010</b>	2,430	4%	21,759	27%
<b><i>Oritavancin</i></b>				
Clinical trials		0%		0%
Manufacturing development		0%		0%
Administrative and headcount	4,461	6%		0%
<b>Total Oritavancin</b>	4,461	6%		0%
<b><i>Other</i></b>	13,853	20%	9,974	12%
<b><i>Total</i></b>	\$ 68,685	100%	\$ 82,518	100%



## **Table of Contents**

### *Angiomax*

Research and development spending in the nine months ended September 30, 2009 related to Angiomax increased approximately \$3.5 million compared to the nine months ended September 30, 2008, primarily due to an increase in manufacturing development expenses driven by product lifecycle management activities. Administrative cost increased \$1.1 million mainly in connection with costs incurred in connection with the regulatory filing related to a clinical study report for the pediatric extension filed with the FDA in the second quarter of 2009. These increases were offset by a decrease in Angiomax clinical trial costs of approximately \$1.3 million primarily due to decreased expenditures in connection with the investigator initiated trial called HORIZONS AMI to study Angiomax use in adult acute myocardial infarction, or AMI, patients that we supported. During the second quarter of 2008, we incurred \$1.5 million in costs related to the final milestone payment in connection with HORIZONS AMI.

### *Cleviprex*

Research and development expenditures for Cleviprex increased approximately \$2.1 million during the nine months ended September 30, 2009 compared to the same period in 2008. The increase in research and development expenditures primarily related to increased clinical trial expenses due to our PRONTO, MERCURY, ACCELERATE and SPRINT Phase IV trials and an increase in administrative and headcount costs primarily due to our MAA for Cleviprex in the European Union, which we submitted during the first quarter of 2009.

### *Cangrelor*

Research and development expenditures related to cangrelor for the nine months ended September 30, 2009 decreased approximately \$8.4 million compared to the nine months ended September 30, 2008. In May 2009, we discontinued enrollment in our Phase III CHAMPION clinical trial program of cangrelor. As a result, research and development expenditures related to cangrelor decreased as clinical trial and administrative and headcount costs decreased. This decrease in research and development related to cangrelor was partially offset by increased manufacturing cost related to cangrelor bulk drug substance development.

### *CU2010*

We acquired CU2010 in August 2008 in connection with our acquisition of Curacyte Discovery. CU2010 is a small molecule serine protease inhibitor that we are developing for the prevention of blood loss during surgery. The acquisition of Curacyte Discovery resulted in the inclusion in research and development expense of \$21.4 million of acquisition related in-process research and development in the nine months ended September 30, 2008. Costs incurred during the nine months ended September 30, 2009 primarily relate to our Phase Ia clinical trial of CU2010 which commenced in July 2009 and headcount. Such research and develop expense is partially offset by a credit of \$1.0 million due to a German government subsidy which we recorded in research and development.

### *Oritavancin*

With our acquisition of Targanta in February 2009, we acquired a worldwide exclusive license to oritavancin, which we believe has the potential to provide significant clinical advantages, including superior dosing over current IV antibiotics that treat serious infections in the hospital setting. We expect that oritavancin will initially be used in critical care settings within the hospital including the ICU, surgical suite and the emergency department, where our sales representatives promote our current products. We are in discussions with the FDA with a view to initiating a confirmatory Phase III program in early 2010 for oritavancin for the treatment of cSSSI. Costs incurred during the nine months ended September 30, 2009 primarily relate to headcount. In August 2009, we withdrew the European MAA for oritavancin. The results of Targanta's operations are included in our consolidated financial statements as of the acquisition date.

### *Other*

Expense in this category primarily consists of the \$5.0 million technology license fee paid to Eagle in September 2009 in connection with the acquisition of the rights to a ready-to-use formulation of Argatroban and infrastructure costs in support of our product development efforts, which includes expenses for data management, statistical analysis, analysis of pre-clinical data, analysis

**Table of Contents**

of pharmacokinetic-pharmacodynamic (PK/PD) data and product safety as well as expenses related to business development activities. In the nine months ended September 30, 2009, expense increased by \$3.9 million compared to the same period in 2008, primarily due the technology license fee paid to Eagle, which was partially offset by an overall reduction of business development expense.

*Selling, General and Administrative Expenses:*

	<b>Nine Months Ended September 30,</b>			
	<b>2009</b>	<b>2008</b>	<b>Change</b>	<b>Change</b>
			<b>\$</b>	<b>%</b>
	<b>(in thousands)</b>			
Selling, general and administrative expenses	\$146,863	\$117,004	\$29,859	25.5%

Selling, general and administrative expenses increased by 25.5% to \$146.9 million for the nine months ended September 30, 2009, from \$117.0 million for the same period in 2008. The increase in selling, general and administrative expenses of \$29.9 million includes an increase in expenses of \$10.9 million related to the sales force expansion in the United States in connection with the Cleviprex launch and in Europe in connection with Angiox, \$8.7 million related to the new office space, which included \$3.0 million of lease termination cost and \$1.9 million of information technology related expenses, and \$2.5 million related to the building of our business infrastructure in Europe. In addition, we incurred in the 2009 period a total of \$8.2 million of cost related to our acquisitions of Targanta and Curacyte Discovery, of which \$4.3 million was one time transaction cost related to Targanta.

*Other Income:*

	<b>Nine Months Ended September 30,</b>			
	<b>2009</b>	<b>2008</b>	<b>Change</b>	<b>Change</b>
			<b>\$</b>	<b>%</b>
	<b>(in thousands)</b>			
Other income	\$2,055	\$5,256	\$(3,201)	(60.9)%

Other income, which is primarily comprised of interest income, decreased approximately 61% to \$2.1 million for the nine months ended September 30, 2009, from \$5.3 million for the comparable period in 2008. The decrease in other income of \$3.2 million was primarily due to lower cash balances to invest combined with lower rates of return on our available for sale securities in 2009.

*Provision for Income Tax:*

	<b>Nine Months Ended September 30,</b>			
	<b>2009</b>	<b>2008</b>	<b>Change</b>	<b>Change</b>
			<b>\$</b>	<b>%</b>
	<b>(in thousands)</b>			
Provision for income tax	\$4,465	\$1,205	\$3,260	270.5%

The provision for income taxes increased to \$4.5 million based on income before taxes of \$1.7 million for the nine months ended September 30, 2009, compared to \$1.2 million based on a loss before taxes of \$3.1 million for the nine months ended September 30, 2008. Our effective income tax rate for the nine months ended September 30, 2009 was 258% compared to 39% for the nine months ended September 30, 2008. The significant increase in our effective tax rate is attributable to the higher proportion of non-deductible expenses to reported taxable income. The statutory rates in the geographic areas where we operate remained constant.

## **Table of Contents**

### **Liquidity and Capital Resources**

#### *Sources of Liquidity:*

Since our inception, we have financed our operations principally through the sale of common and preferred stock, sales of convertible promissory notes and warrants, interest income and revenues from sales of Angiomax. Except for 2006 and 2004, we have incurred losses on an annual basis since our inception. We had \$172.0 million in cash, cash equivalents and available for sale securities as of September 30, 2009.

#### *Cash Flows:*

As of September 30, 2009, we had \$51.9 million in cash and cash equivalents, as compared to \$81.0 million as of December 31, 2008. Our decrease in cash and cash equivalents during the nine months ended September 30, 2009 included \$3.5 million net cash used in operating activities and \$26.6 million in net cash used in investing activities, which was partially offset by \$1.8 million in net cash provided by financing.

Net cash used in operating activities was \$3.5 million for the nine months ended September 30, 2009 compared to net cash provided by operating activities of \$12.6 million for the nine months ended September 30, 2008. The decrease in cash flow from operations includes a net loss of \$2.7 million and non-cash items included in net income totaling \$25.2 million. These non-cash items were mainly attributable to stock-based compensation expense of \$15.3 million and depreciation and amortization expense of \$4.3 million. Cash provided by operating activities also reflects a \$26.0 million reduction in cash provided by operating activities associated with changes in working capital items.

For the nine months ended September 30, 2009, \$26.6 million in net cash was used in investing activities. Net cash used in investing activities included the Targanta acquisition for \$37.2 million, net, the purchase of \$108.9 million of available for sale securities, and an increase of restricted cash of \$1.7 million. Such purchases were offset by \$121.5 million in proceeds from the maturity and sale of available for sale securities.

For the nine months ended September 30, 2009, we received \$1.8 million in cash provided by financing activities, which consisted of net proceeds to us related to purchases of our stock pursuant to option exercises and our employee stock purchase plan.

#### *Funding Requirements:*

We expect to devote substantial resources to our research and development efforts and to our sales, marketing and manufacturing programs associated with the commercialization of our products. Our funding requirements will depend on numerous factors including:

- the extent to which Angiomax is commercially successful globally;

- the extent to which Cleviprex is commercially successful in the United States;

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

- the expansion of our sales force in connection with the expansion of our sales and marketing efforts in Europe and the sale of Cleviprex in the United States;

- our plan to continue to evaluate possible acquisitions of development-stage products, approved products, or businesses and possible additional strategic or licensing arrangements with companies that fit within our growth strategy, such as our acquisitions of Curacyte Discovery and Targanta;

- the progress, level and timing of our research and development activities related to our clinical trials with respect to Angiomax, Cleviprex, cangrelor, oritavancin, CU2010 and a ready-to-use formulation of Argatroban;

- the cost and outcomes of regulatory submissions and reviews, including our efforts to obtain approval of Cleviprex outside the United States and New Zealand and approval of our product candidates globally;



## **Table of Contents**

the continuation or termination of third-party manufacturing or sales and marketing arrangements;

the size, cost and effectiveness of our sales and marketing programs globally;

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

the success of obtaining regulatory approval of oritavancin and the extent of the commercial success of oritavancin, if and when it is approved, which could result in cash payments to former Targanta shareholders; and

our ability to defend and enforce our intellectual property rights.

If our existing resources are insufficient to satisfy our liquidity requirements due to slower than anticipated revenues from Angiomax and Cleviprex, or higher than anticipated costs in Europe, if we acquire additional product candidates or businesses, or if we determine that raising additional capital would be in our interests and the interests of our stockholders, we may sell equity or debt securities or seek financing through other arrangements. Any sale of additional equity or debt securities may result in dilution to our stockholders, and debt financing may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures. We cannot be certain that public or private financing will be available in amounts or on terms acceptable to us, if at all. If we seek to raise funds through collaboration or licensing arrangements with third parties, we may be required to relinquish rights to products, product candidates or technologies that we would not otherwise relinquish or grant licenses on terms that may not be favorable to us. If we are unable to obtain additional financing, we may be required to delay, reduce the scope of, or eliminate one or more of our planned research, development and commercialization activities, which could harm our financial condition and operating results.

### *Certain Contingencies*

As we have previously disclosed, the U.S. Patent and Trademark Office, or PTO, rejected the application under the Hatch-Waxman Act for an extension of the term of U.S. Patent No. 5,196,404, or the 404 patent, the principal U.S. patent that covers Angiomax, beyond March 2010 because the PTO rejected the application on the grounds that it was not timely filed by counsel. We refer to such application herein as the late filing. We have entered into agreements with the law firms involved in the late filing that suspend the statute of limitations on any claims against them for failing to make a timely filing. We have entered into a similar agreement with Biogen Idec relating to any claims, including claims for damages and/or license termination, that they may bring relating to the late filing. Such claims by Biogen Idec could have a material adverse effect on our financial condition, results of operations, liquidity or business. In the third quarter of 2009, we initiated discussions, which are still ongoing, with the law firms involved in the late filing of the application and are currently in related discussions with Biogen Idec with respect to the possible resolution of potential claims among the parties.

### **Contractual Obligations**

Our long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business. These include commitments related to purchase of inventory of our products, research and development service agreements, milestone payments due under our license agreements, income tax contingencies, operating leases, and selling, general and administrative obligations. A summary of these aggregate contractual obligations was included in our Annual Report on Form 10-K for the year ended December 31, 2008. During the quarter ended September 30, 2009, we incurred additional commitments related to the purchase of inventory consistent with our normal course of business. As of September 30, 2009, we have inventory-related purchase commitments totaling \$15.4 million during 2009, \$26.1 million during 2010 and \$19.1 million during 2011 for Angiomax bulk drug substance. In addition, in the quarter ended September 30, 2009 we entered into a license agreement with Eagle for a ready-to-use formulation of Argatroban. The license agreement provides for certain milestone payments of up to \$10.0 million and royalty payments that we would owe Eagle if the ready-to-use formulation of Argatroban achieves certain approval and commercialization milestones.



## **Table of Contents**

### **Application of Critical Accounting Estimates**

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

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

- the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change; and

- the impact of the estimates and assumptions on financial condition or operating performance is material.

Our significant accounting policies are more fully described in note 2 of our unaudited condensed consolidated financial statements in this Quarterly Report and note 2 of our consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2008. Not all of these significant accounting policies, however, require that we make estimates and assumptions that we believe are critical accounting estimates. We have discussed our accounting policies with the audit committee of our board of directors, and we believe that our estimates relating to revenue recognition, inventory, income taxes and stock-based compensation described under the caption Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations Application of Critical Accounting Estimates in our Annual Report on Form 10-K for the year ended December 31, 2008 are critical accounting estimates.

#### *Income Taxes*

At December 31, 2008, we had \$112.8 million of gross deferred tax assets before valuation allowance, which included the tax effect of net operating loss carryforwards of \$56.0 million, research and development credits of \$16.6 million and other items of \$40.2 million. We consider all available evidence, both positive and negative, to determine whether, based on the weight of that evidence, a valuation allowance is needed to reduce the deferred tax assets to the amount that is more likely than not to be realized. At December 31, 2008, we recorded a valuation allowance of \$64.5 million. The balance of the deferred tax assets is entirely associated with U.S. deferred tax assets, and includes a complete valuation allowance on all foreign deferred tax assets. In determining the valuation allowance and the amount of the deferred tax assets that is more likely than not to be realized, we evaluated and considered such positive and negative evidence as:

- our deferred tax assets primarily relate to net operating losses incurred by us, the oldest of which will not expire until 2018;

- we were in a cumulative U.S. income position for the year ended December 31, 2008;

- our most recent projections of pre-tax income support the carrying value of the existing deferred tax assets;

- after adjusting for specific non-recurring business development transactions such as the Nycomed and Curacyte acquisitions, which we believe are not indicative of future operating results, our adjusted cumulative income for the year ended December 31, 2008 would have been significant and would have approximated its planned net income for those periods;

- during the third quarter of 2008, our second product, Cleviprex, was approved for sale in the United States and we expect Cleviprex to generate revenue well past the expiration of the principal patent covering Angiomax;

while unsettled, if legislative actions in Congress provide the U.S. Patent and Trademark Office with discretion to consider patent extension applications filed late unintentionally under the Hatch-Waxman Act, we expect future operations and profit levels during the period of Angiomax exclusivity to be positively impacted;



## **Table of Contents**

we have a limited history of sustained profitability in part as a result of the Targanta and Curacyte acquisitions;

Angiomax market exclusivity ends in September 2010;

the commercial success of our product candidates is not assured; and

if legislative actions in Congress do not provide the U.S. Patent and Trademark Office with discretion to consider patent extension applications filed late unintentionally under the Hatch-Waxman Act, we expect future operations and profit levels during the period of Angiomax exclusivity to be negatively impacted.

Based on this evaluation and consideration of positive and negative evidence, we determined that the weight of the evidence required a \$64.5 million valuation allowance to reduce the deferred tax assets to the amount that is more likely than not to be realized. The ultimate realization of the deferred tax asset is dependent upon the generation of future taxable income during the period in which the related temporary differences become deductible or the net operating losses and credit carryforwards can be utilized.

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

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

### **Effect of Recent Accounting Pronouncements**

See discussion of recent accounting pronouncements in note 2, Significant Accounting Policies to the unaudited condensed consolidated financial statements of this Quarterly Report on Form 10-Q.

### **Forward-Looking Information**

This Quarterly Report on Form 10-Q includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. For this purpose, any statements contained herein regarding our strategy, future operations, financial position, future revenue, projected costs, prospects, plans and objectives of management, other than statements of historical facts, are forward-looking statements. The words anticipates, believes, estimates, expects, intends, may, plans, projects, will, would and similar expressions are in forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the results, plans, intentions or expectations expressed or implied in our forward-looking statements. There are a number of important factors that could cause actual results, levels of activity, performance or events to differ materially from those expressed or implied in the forward-looking statements we make. These important factors include our critical accounting estimates referenced in Part I, Item 2 of this Quarterly Report on Form 10-Q and the factors set forth under the caption Risk Factors in Part II, Item 1A of this Quarterly Report on Form 10-Q. Although we may elect to update forward-looking statements in the future, we specifically disclaim any obligation to do so, even if our estimates change, and readers should not rely on those forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q.

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

Market risk is the risk of change in fair value of a financial instrument due to changes in interest rates, equity prices, creditworthiness, financing, exchange rates or other factors. Our primary market risk exposure relates to changes in interest rates in our cash, cash equivalents and available for sale securities. We place our investments in high-quality financial instruments, primarily money market funds, corporate debt securities, asset backed securities and U.S. government agency notes with maturities of less than two years, which we believe are subject to limited interest rate and credit risk. We currently do not hedge interest rate exposure. At September 30, 2009 we held \$172.0 million in cash, cash equivalents and available for sale securities which had an average interest rate of approximately 0.9% and a 10% change in such average interest rate would have had an approximate \$0.2 million impact on our



## **Table of Contents**

interest income. At September 30, 2009, all of the cash, cash equivalents and available for sale securities were due on demand 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. As of September 30, 2009, we had receivables denominated in currencies other than the U.S. dollar. A 10% change would have had an approximate \$0.5 million impact on our other income and cash.

### **Item 4. Controls and Procedures**

#### *Disclosure Controls and Procedures*

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2009. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2009, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

#### *Changes in Internal Control over Financial Reporting*

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended September 30, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **Part II. Other Information**

### **Item 1. Legal Proceedings**

From time to time we are party to legal proceedings in the course of our business in addition to those described below. We do not, however, expect such other legal proceedings to have a material adverse effect on our business, financial condition or results of operations.

#### *Teva Parenteral Medicines, Inc.*

In September 2009, we were notified that Teva Parenteral Medicines, Inc. had submitted an Abbreviated New Drug Application, or ANDA, seeking permission to market its generic version of Angiomax prior to the expiration of the '727 patent. The '727 patent was issued on September 1, 2009 and relates to a more consistent and improved Angiomax drug product. The '727 patent expires on July 27, 2028. On October 8, 2009, we filed suit against Teva Parenteral Medicines, Inc., Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd., which we refer to collectively as Teva, in the U.S. District Court for the District of Delaware for infringement of the '727 patent. On October 29, 2009, Teva filed an answer denying infringement and alleging affirmative defenses of non-infringement and invalidity.

On October 21, 2009, the case was reassigned in lieu of a vacant judgeship to the U.S. District Court for the Eastern District of Pennsylvania. The court has yet to set a schedule in the case.

## **Table of Contents**

### *Pliva Hrvatska d.o.o.*

In September 2009, we were notified that Pliva Hrvatska d.o.o. had submitted an ANDA seeking permission to market its generic version of Angiomax prior to the expiration of the 727 patent. On October 8, 2009, we filed suit against Pliva Hrvatska d.o.o., Pliva d.d., Barr Laboratories, Inc., Barr Pharmaceuticals, Inc., Barr Pharmaceuticals, LLC, Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd., which we refer to collectively as Pliva, in the U.S. District Court for the District of Delaware for infringement of the 727 patent. On October 28, 2009, Pliva filed an answer denying infringement and alleging affirmative defenses of non-infringement and invalidity.

On October 21, 2009, the case was reassigned in lieu of a vacant judgeship to the U.S. District Court for the Eastern District of Pennsylvania. The court has yet to set a schedule in the case.

### *APP Pharmaceuticals, LLC*

In September 2009, we were notified that APP Pharmaceuticals, LLC had submitted an ANDA seeking permission to market its generic version of Angiomax prior to the expiration of the 727 patent. On October 8, 2009, we filed suit against APP Pharmaceuticals, LLC and APP Pharmaceuticals, Inc., which we refer to collectively as APP, in the U.S. District Court for the District of Delaware for infringement of the 727 patent. APP requested and a Stipulation has been filed extending APP's time to answer until December 9, 2009.

On October 21, 2009, the case was reassigned in lieu of a vacant judgeship to the U.S. District Court for the Eastern District of Pennsylvania. The court has yet to set a schedule in the case.

## **Item 1A. Risk Factors**

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below in addition to the other information included or incorporated by reference in this quarterly report. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer. In that case, the trading price of our common stock could fall.*

*An updated description of the risk factors associated with our business is set forth below. These risk factors have been updated from those included in our Annual Report on Form 10-K, to, among other things, update the risk factor regarding the dependency of near-term growth in Angiomax sales on acceptance of clinical data, the risk factor related to our ability to obtain and maintain patent protection for the intellectual property relating to our products, and the risk factor regarding our ability to acquire and develop additional product candidates or approved product.*

### **Risks Related to Our Financial Results**

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

Except for 2004 and 2006, we have incurred net losses on an annual basis since our inception. As of September 30, 2009, we had an accumulated deficit of approximately \$270.7 million. We expect to make substantial expenditures to further develop and commercialize our products, including costs and expenses associated with clinical trials, regulatory approvals and commercialization. Although we achieved profitability in 2004 and in 2006, we were not profitable in 2008 primarily as a result of the costs incurred in connection with our acquisition of Curacyte Discovery in August 2008 and were not profitable in 2007, primarily as a result of the costs incurred in connection with the Nycomed transaction. We will likely need to generate significantly greater revenue in future periods to achieve and maintain profitability in light of our planned expenditures. We may not achieve profitability in future periods or at all, and we may not be able to maintain profitability for any substantial period of time. If we fail to achieve profitability or maintain profitability on a quarterly or annual basis within the time frame expected by investors or securities analysts, the market price of our common stock may decline.

**Table of Contents**

***Our business is very dependent on the commercial success of Angiomax***

Angiomax has accounted for substantially all of our revenue since we began selling Angiomax in 2000 and, until the approval of Cleviprex by the FDA for the reduction of blood pressure when oral therapy is not feasible or not desirable in August 2008, Angiomax was our only commercial product. We expect revenues from Angiomax to continue to account for substantially all of our revenues in 2009. The commercial success of Angiomax depends upon:

its continued acceptance by regulators, physicians, patients and other key decision-makers as a safe, therapeutic and cost-effective alternative to heparin and other products used in current practice or currently being developed;

our ability to further develop Angiomax for use in additional patient populations and the clinical data we generate to support expansion of the product label, including our ability to obtain EMEA approval of Angiox for the treatment of STEMI patients undergoing PCI;

the overall number of PCI procedures performed;

our ability to sell and market Angiox in Europe;

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

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

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

As of September 30, 2009, our inventory of Angiomax was \$15.3 million and we have inventory-related purchase commitments to Lonza Braine totaling \$15.4 million for 2009, \$26.1 million for 2010 and \$19.1 million for 2011 for Angiomax bulk drug substance. If sales of Angiomax were to decline, we could be required to make an allowance for excess or obsolete inventory or increase our accrual for product returns.

***Our revenue has been substantially dependent on our sole source distributor, ICS, and a limited number of domestic wholesalers and international distributors involved in the sale of our products, and such revenue may fluctuate from quarter to quarter based on the buying patterns of such distributor, wholesalers and distribution partners***

We distribute Angiomax and Cleviprex in the United States through a sole source distribution model. Under this model, we sell Angiomax and Cleviprex to our sole source distributor, ICS, which then sells Angiomax and Cleviprex to a limited number of national medical and pharmaceutical wholesalers with distribution centers located throughout the United States and, in certain cases, directly to hospitals. As our revenue from sales of Angiomax in the United States is now exclusively from sales to ICS, and we anticipate that our revenue from sales of Cleviprex in the United States will be exclusively from sales to ICS, we expect that our revenue will continue to be subject to fluctuation from quarter to quarter based on the buying pattern of ICS.

In 2008, we assumed control of the distribution of Angiox in the countries in which Nycomed distributed Angiox. In other countries, we continue to sell Angiomax to international distributors and these distributors then sell Angiomax to hospitals. Our reliance on a small number of distributors for international sales of Angiomax could cause our revenue to fluctuate from quarter to quarter based on the buying patterns of these distributors, regardless of underlying hospital demand.

If inventory levels at ICS or at our international distributors become too high, these distributors may seek to reduce their inventory levels by reducing purchases from us, which could have a materially adverse effect on our revenue in periods in which such purchase reductions occur.

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

We will need to generate significantly greater revenue to achieve and maintain profitability on an annual basis. The further development of Angiomax and Cleviprex for use in additional patient populations, the commercialization of Cleviprex and the

**Table of Contents**

development of cangrelor, oritavancin and CU2010, including clinical trials, manufacturing development and regulatory approvals, potential milestone payments to our third-party licensors, potential obligations to make cash payments to former Targanta shareholders in connection with our acquisition of Targanta, and the acquisition and development of additional product candidates by us, such as oritavancin in 2009 and CU2010 in 2008, or the acquisition of rights to commercialize products, such as the ready-to-use formulation of Argatroban in 2009, will require a commitment of substantial funds. Our future funding requirements, which may be significantly greater than we expect, will depend upon many factors, including:

- the extent to which Angiomax is commercially successful globally;

- the extent to which Cleviprex is commercially successful in the United States;

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

- the expansion of our sales force in connection with the expansion of our sales and marketing efforts in Europe and the sale of Cleviprex in the United States;

- our plan to continue to seek possible acquisitions of development-stage products, approved products, or businesses and possible additional strategic or licensing arrangements with companies that fit within our growth strategy, such as our acquisitions of Curacyte Discovery and Targanta and our licensing arrangement for the rights to a ready-to-use formulation of Argatroban;

- the progress, level and timing of our research and development activities related to our clinical trials with respect to Angiomax, Cleviprex, cangrelor, oritavancin and CU2010;

- the cost and outcomes of regulatory submissions and reviews, approval of Cleviprex outside the United States and New Zealand and approval of our product candidates globally;

- the continuation or termination of third-party manufacturing or sales and marketing arrangements;

- the size, cost and effectiveness of our sales and marketing programs globally;

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

- the success of obtaining regulatory approval of oritavancin and the extent of the commercial success of oritavancin, if and when it is approved, which could result in the cash payment to former Targanta shareholders; and

- our ability to defend and enforce our intellectual property rights.

If our existing resources are insufficient to satisfy our liquidity requirements due to slower than anticipated sales of Angiomax and Cleviprex, or higher than anticipated costs globally, if we acquire additional product candidates or businesses, or if we determine that raising additional capital would be in our interest and the interests of our stockholders, we may sell equity or debt securities or seek additional financing through other arrangements. Any sale of additional equity or debt securities may result in dilution to our stockholders, and debt financing may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures. We cannot be certain that public or private financing will be available in amounts or on terms acceptable to us, if at all. If we seek to raise funds through collaboration or licensing arrangements with third parties, we may be required to relinquish rights to products, product candidates or technologies that we would not otherwise relinquish or grant licenses on terms that may not be favorable to us. If we are unable to obtain additional financing, we may be

required to delay, reduce the scope of, or eliminate one or more of our planned research, development and commercialization activities, which could harm our financial condition and operating results.



## **Table of Contents**

### **Risks Related to Commercialization**

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

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

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

#### ***Because the market for thrombin inhibitors is competitive, Angiomax may not obtain widespread use***

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

In addition, if we are unable to secure patent term restoration for Angiomax or to enforce our Angiomax patent rights, specifically with respect to the 727 patent which is the subject of litigation we have commenced alleging patent infringement by several parties, we expect the entry of generic competition into the market potentially as early as the third quarter of 2010. Competition from generic equivalents could have a material adverse impact on our financial condition and operating results.

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

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

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

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

We have positioned Cleviprex as an alternative to multiple older products, almost all of which are inexpensive generics used widely in patients with acute hypertension or requiring acute blood pressure management. Any medicine that competes with generic market-leading medicines must demonstrate compelling advantages in efficacy, convenience, tolerability and/or safety in order to overcome price competition and be commercially successful. Because generic therapies are inexpensive and have been widely used for many years, physicians and decision-makers for hospital resource allocation may be hesitant to adopt Cleviprex. We cannot assure you of the rate of Cleviprex sales growth and the long-term outlook for future years. While we are not aware of any IV-AHT drugs currently awaiting regulatory approval or in development, this remains a possible scenario, the impact of which on Cleviprex sales we cannot estimate.

#### ***The market for Cleviprex will depend significantly on its inclusion on hospital formularies***

Many hospitals establish formularies, which are lists of drugs approved for use in the hospital. In those hospitals, if a drug is not included on the formulary, then the ability of our sales representatives to sell the drug in such hospital is limited or denied. If we fail to secure and maintain formulary coverage for Cleviprex on favorable terms or are significantly delayed in doing so, we will have

## **Table of Contents**

difficultly achieving market acceptance of Cleviprex and our business could be materially adversely affected. We cannot guarantee the extent and uptake rate at which Cleviprex will be accepted on hospital formularies.

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

We believe that the near-term commercial success of Angiomax and Cleviprex will depend upon the extent to which physicians, patients and other key decision-makers accept the results of the clinical trials. For example, since the original results of REPLACE-2 were announced in 2002, additional hospitals have granted Angiomax formulary approval and hospital demand for the product has increased. We cannot be certain, however, that these trends will continue. Some commentators have challenged various aspects of the trial design of REPLACE-2, the conduct of the study and the analysis and interpretation of the results from the study. Similarly, we cannot be certain of the extent to which physicians, patients and other key decision-makers will accept the results of the ACUITY and HORIZONS AMI trials. The FDA, in denying our sNDA for an additional dosing regimen in the treatment of ACS initiated in the emergency department, indicated that the basis of their decision involved the appropriate use and interpretation of non-inferiority trials such as our ACUITY trial. If physicians, patients and other key decision-makers do not accept clinical trial results, adoption of Angiomax and Cleviprex may suffer, and our business will be materially adversely affected.

We believe that as a result of data from a clinical trial that was published in March 2007 in the New England Journal of Medicine entitled "Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation, or COURAGE", and the controversy regarding the use of drug-eluting stents, the number of PCI procedures performed in the United States declined in 2007. The decline in the number of procedures has had a direct impact on our net revenues. PCI procedure volume increased in 2008 from 2007 levels, but has not returned to the level of PCI procedures performed prior to the 2007 decline and has declined in the first nine months of 2009. PCI procedure volume might further decline and might not return to its previous level. In the event that the number of procedures declines, sales of Angiomax may be impacted negatively.

***We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do***

Our industry is highly competitive. Our success will depend on our ability to acquire and develop products and apply technology, and our ability to establish and maintain markets for our products. Potential competitors in the United States and other countries include major pharmaceutical and chemical companies, specialized pharmaceutical companies and biotechnology firms, universities and other research institutions. Many of our competitors have substantially greater research and development capabilities and experience, and greater manufacturing, marketing and financial resources, than we do. Accordingly, our competitors may develop or license products or other novel technologies that are more effective, safer, more convenient or less costly than existing products or technologies or products or technologies that are being developed by us or may obtain regulatory approvals for products more rapidly than we are able. Technological developments by others may render our products or product candidates noncompetitive. We may not be successful in establishing or maintaining technological competitiveness.

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

To support the global sales and marketing of Angiomax, and Cleviprex, cangrelor, oritavancin and CU2010 if and when they are approved for sale and marketed outside the United States, we are developing our business infrastructure internationally, with European operations being our initial focus. If we are unable to expand our global operations successfully and in a timely manner, the growth of our business may be limited and our business, operating results and financial condition may be harmed. Such expansion may be more difficult, be more expensive or take longer than we anticipate, and we may not be able to successfully market and sell our products globally. Future rapid expansion could strain our operational, human and financial resources. In order to manage expansion, we must:

continue to improve operating, administrative, and information systems;

accurately predict future personnel and resource needs to meet contract commitments;

track the progress of ongoing projects; and

attract and retain qualified management, sales, professional, scientific and technical operating personnel.

39

---

## **Table of Contents**

If we do not take these actions and are not able to manage our global business, then our global operations may be less successful than anticipated, and we may be required to allocate additional resources to the expanded business, which we would have otherwise allocated to another part of our business.

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

Our future profitability will depend in part on our ability to grow and ultimately maintain our product sales in foreign markets, particularly in Europe. However, we have limited experience in marketing, servicing and distributing our products outside of the United States. In addition, with our acquisitions of Curacyte Discovery and Targanta, we are conducting research and development activities in Germany and Canada. These foreign operations subject us to additional risks and uncertainties, including:

our customers' ability to obtain reimbursement for procedures using our products in foreign markets;

the burden of complying with complex and changing foreign legal, tax, accounting and regulatory requirements;

language barriers and other difficulties in providing long-range customer support and service;

longer accounts receivable collection times;

significant currency fluctuations;

reduced protection of intellectual property rights in some foreign countries; and

the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Our foreign sales of our products could also be adversely affected by export license requirements, the imposition of governmental controls, political and economic instability, trade restrictions, changes in tariffs and difficulties in staffing and managing foreign operations. In addition, we are subject to the Foreign Corrupt Practices Act, any violation of which could create a substantial liability for us and also cause a loss of reputation in the market.

***Our ability to generate future revenue from products will be affected by reimbursement and drug pricing***

Acceptable levels of reimbursement of drug treatments by government authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize, and attract collaborative partners to invest in the development of, product candidates. We cannot be sure that reimbursement in the United States, Europe or elsewhere will be available for any products we may develop or, if already available, will not be decreased in the future. We may not get reimbursement or reimbursement may be limited if authorities, private health insurers and other organizations are influenced by existing drugs and prices in determining our reimbursement. For example, the availability of numerous generic antibiotics at lower prices than branded antibiotics, such as oritavancin, if it were approved for commercial sale, may also substantially reduce the likelihood of reimbursement for oritavancin. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize our products, or may not be able to obtain a satisfactory financial return on our products.

In certain countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals and the level of reimbursement are subject to governmental control. In some countries, it can take an extended period of time to establish and obtain reimbursement, and reimbursement approval may be required at the individual patient level, which can lead to further delays. In addition, in some countries, it may take an extended period of time to collect payment even after reimbursement has been established.

Third-party payers increasingly are challenging prices charged for medical products and services. Also, the trend toward managed health care in the United States and the changes in health insurance programs, as well as legislative proposals, such as the health care reform legislation being discussed by Congress, 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



## **Table of Contents**

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 must comply with federal, state and foreign laws and regulations relating to the health care business, and, if we do not fully comply with such laws and regulations, we could face substantial penalties***

We and our customers are subject to extensive regulation by the federal government, and the governments of the states and foreign countries in which we may conduct our business. In the United States, the laws that directly or indirectly affect our ability to operate our business include the following:

the Federal Anti-Kickback Law, which prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual or furnishing or arranging for a good or service for which payment may be made under federal health care programs such as Medicare and Medicaid;

other Medicare laws and regulations that prescribe the requirements for coverage and payment for services performed by our customers, including the amount of such payment;

the Federal False Claims Act, which imposes civil and criminal liability on individuals and entities who submit, or cause to be submitted, false or fraudulent claims for payment to the government; and

the Federal False Statements Act, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with delivery of or payment for health care benefits, items or services.

If our operations are found to be in violation of any of the laws and regulations described above or any other law or governmental regulation to which we or our customers are or will be subject, we may be subject to civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and the curtailment or restructuring of our operations. Similarly, if our customers are found to be non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on us. Any penalties, damages, fines, curtailment or restructuring of our operations would adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation.

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

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

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

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

**Table of Contents****Risks Related to Regulatory Matters**

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

Except for Angiomax and Cleviprex, we do not have any other product approved for sale in the United States or any foreign market. Angiomax has been approved for sale in the United States for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing PCI and patients undergoing PCI with or at risk of HIT/HITS, for sale in the European Union for indications similar to those approved by the FDA and for adult patients with ACS and for sale in other countries for indications similar to those approved by the FDA. Cleviprex has been approved for sale in the United States for the reduction of blood pressure when oral therapy is not feasible or not desirable and in New Zealand for indications similar to those approved by the FDA. 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. Obtaining regulatory approval is uncertain, time-consuming and expensive. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the product commercially non-viable. Securing regulatory approval requires the submission of extensive pre-clinical and clinical data, information about product manufacturing processes and inspection of facilities and supporting information to the regulatory authorities for each therapeutic indication to establish the product's safety and efficacy. If we are unable to submit the necessary data and information, for example, because the results of clinical trials are not favorable, or if the applicable regulatory authority delays reviewing or does not approve our applications, we will be unable to obtain regulatory approval. Delays in obtaining or failure to obtain regulatory approvals may:

delay or prevent the successful commercialization of any of our product candidates;

diminish our competitive advantage; and

defer or decrease our receipt of revenue.

The regulatory review and approval process to obtain marketing approval for a new drug or indication takes many years and requires the expenditure of substantial resources. This process can vary substantially based on the type, complexity, novelty and indication of the product candidate involved. The regulatory authorities globally have substantial discretion in the approval process and may refuse to accept any application or may decide that data is insufficient for approval and require additional pre-clinical, clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. For example, the FDA issued a complete response letter to Targanta in December 2008 before it was acquired by us with respect to the oritavancin NDA indicating that the FDA could not approve the NDA in its present form and that it would be necessary for Targanta to perform an additional adequate and well-controlled study to demonstrate the safety and efficacy of oritavancin in patients with cSSSI before the application could be approved.

***We cannot expand the indications for which we are marketing Angiomax unless we receive regulatory approval for each additional indication. Failure to expand these indications will limit the size of the commercial market for Angiomax***

The FDA has approved Angiomax for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing PCI and patients undergoing PCI with or at risk of HIT/HITS. Angiox is approved for patients undergoing PCI and for adult patients with ACS in the European Union. One of our key objectives is to expand the indications for which Angiomax is approved. For example, in December 2008, we submitted an application to the EMEA for the approval of Angiox in the treatment of STEMI patients undergoing PCI. In October 2009, we received a positive opinion from CHMP regarding this filing. We expect, but cannot guarantee, a final approval from the EMEA to promote the use of Angiox for STEMI patients undergoing primary PCI in the European Union. In order to market Angiomax for expanded indications, we will need to conduct appropriate clinical trials, obtain positive results from those trials and obtain regulatory approval for such proposed indications. Obtaining regulatory approval is uncertain, time-consuming and expensive. The regulatory review and approval process to obtain marketing approval



for a new indication can take many years and require the expenditure of substantial resources. This process can vary substantially based on the type, complexity, novelty and indication of the product candidate involved. The regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that any data submitted is insufficient for approval and require additional pre-clinical, clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a new indication product candidate. For example, in 2006 we received a non-approvable letter from the FDA in connection with our application to market Angiomax in patients with or at risk of HIT/HITTS undergoing cardiac surgery. While we have indicated to the FDA that we are evaluating potential next steps, the FDA

## **Table of Contents**

may require additional studies which may require the expenditure of substantial resources. Even if any such studies are undertaken, we might not be successful in obtaining regulatory approval for this indication in a timely manner or at all. In addition, in May 2008, we received a non-approvable letter from the FDA with respect to an sNDA that we submitted to the FDA seeking approval of an additional indication for Angiomax for the treatment of patients with ACS in the emergency department. In its letter, the FDA indicated that the basis of their decision involved the appropriate use and interpretation of non-inferiority trials, including the ACUITY trial. We disagree with the FDA on these issues and have initiated discussions with the FDA to address them. We might not be successful in obtaining regulatory approval for these indications or any other indications in a timely manner or at all. If we are unsuccessful in expanding the Angiomax product label, the size of the commercial market for Angiomax will be limited.

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

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

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in pre-clinical testing or early clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. An unexpected result in one or more of our clinical trials can occur at any stage of testing. For example, in May 2009 we discontinued our Phase III CHAMPION clinical trial program of cangrelor in patients undergoing PCI after receiving a letter from the clinical program's independent Interim Analysis Review Committee that stated that the CHAMPION-PLATFORM trial would not meet the goal of demonstrating persuasive evidence of clinical effectiveness that could form the basis for regulatory approval. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent us from receiving regulatory approval or commercializing our products, including:

- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials which even if undertaken cannot ensure we will gain approval;

- data obtained from pre-clinical testing and clinical trials may be subject to varying interpretations, which could result in the FDA or other regulatory authorities deciding not to approve a product in a timely fashion, or at all;

- the cost of clinical trials may be greater than we currently anticipate;

- regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;

- we, or the FDA or other regulatory authorities, might suspend or terminate a clinical trial at any time on various grounds, including a finding that participating patients are being exposed to unacceptable health risks. For example, we have in the past voluntarily suspended enrollment in one of our clinical trials to review an interim analysis of safety data from the trial; and

- the effects of our product candidates may not be the desired effects or may include undesirable side effects or the product candidates may have other unexpected characteristics.

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

***If we or our contract manufacturers fail to comply with the extensive regulatory requirements to which we, our contract manufacturers and our products are subject, our products could be subject to restrictions or withdrawal from the market and we could be subject to penalties***

The testing, manufacturing, labeling, safety, advertising, promotion, storage, sales, distribution, export and marketing, among other things, of our products, both before and after approval, are subject to extensive regulation by governmental authorities in the United

## **Table of Contents**

States, Europe and elsewhere throughout the world. Both before and after approval of a product, quality control and manufacturing procedures must conform to current good manufacturing practice, or cGMP. Regulatory authorities, including the FDA, periodically inspect manufacturing facilities to assess compliance with cGMP. Our failure or the failure of our contract manufacturers to comply with the laws administered by the FDA, the European Medicines Agency or other governmental authorities could result in, among other things, any of the following:

delay in approving or refusal to approve a product;

product recall or seizure;

suspension or withdrawal of an approved product from the market;

interruption of production;

operating restrictions;

warning letters;

injunctions;

fines and other monetary penalties;

criminal prosecutions; and

unanticipated expenditures.

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

***We depend on single suppliers for the production of Angiomax, Cleviprex, cangrelor and oritavancin bulk drug substance and a limited number of suppliers to carry out all fill-finish activities***

We do not manufacture any of our products and do not plan to develop any capacity to manufacture them. We currently obtain all of our Angiomax bulk drug substance from one manufacturer, Lonza Braine, and rely on another manufacturer, Ben Venue Laboratories, Inc., to carry out all fill-finish activities for Angiomax, which includes final formulation and transfer of the drug into vials where it is then freeze-dried and sealed. The terms of our agreement with Lonza Braine require us to purchase from Lonza Braine a substantial portion of our Angiomax bulk drug product manufactured using the Chemilog process, a chemical synthesis process that we developed with UCB Bioproducts S.A., the predecessor to Lonza Braine.

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

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

All bulk drug substance of oritavancin is currently obtained from Abbott Laboratories under an agreement originally entered into between Targanta and Abbott for use in clinical trials and for commercial supply. We obtain oritavancin final drug product from contract fill/finish providers, Catalent Pharma Solutions, Inc. (formerly known as Cardinal Health PTS, LLC) and Ben Venue. The Abbott Laboratories and Catalent agreements require the purchase of a minimum number of batches of oritavancin bulk drug substance and final drug product, respectively.

## Table of Contents

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

In the event that any of Lonza Braine, Johnson Matthey, Hospira, Ben Venue, Baxter, Abbott or Eagle is unable or unwilling to carry out its respective manufacturing or supply obligations or terminates or refuses to renew its arrangements with us, we may be unable to obtain alternative manufacturing or supply, or obtain such manufacturing or supply on commercially reasonable terms or on a timely basis. If we were required to transfer manufacturing processes to other third-party manufacturers, we would need to satisfy various regulatory requirements, which could cause us to experience significant delays in receiving an adequate supply of Angiomax, Cleviprex, cangrelor or oritavancin or ready-to-use formulation of Argatroban. Moreover, we may not be able to transfer processes that are proprietary to the manufacturer. Any delays in the manufacturing process may adversely impact our ability to meet commercial demands for Angiomax or Cleviprex on a timely basis and supply product for clinical trials of Angiomax, Cleviprex, cangrelor and oritavancin.

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

Our development and commercialization strategy involves entering into arrangements with corporate and academic collaborators, contract research organizations, distributors, third-party manufacturers, licensors, licensees and others to conduct development work, manage or conduct our clinical trials, manufacture our products and market and sell our products outside of the United States. We do not have the expertise or the resources to conduct such activities on our own and, as a result, are particularly dependent on third parties in most areas.

We may not be able to maintain our existing arrangements with respect to the commercialization or manufacture of Angiomax and Cleviprex or establish and maintain arrangements to develop, manufacture and commercialize cangrelor, oritavancin, CU2010 or any additional product candidates or products we may acquire on terms that are acceptable to us. Any current or future arrangements for development and commercialization may not be successful. If we are not able to establish or maintain agreements relating to Angiomax, Cleviprex, cangrelor, oritavancin, CU2010, a ready-to-use formulation of Argatroban or any additional products we may acquire on terms that we deem favorable, our results of operations would be materially adversely affected.

Third parties may not perform their obligations as expected. The amount and timing of resources that third parties devote to developing, manufacturing and commercializing our products are not within our control. Our collaborators may develop, manufacture or commercialize, either alone or with others, products and services that are similar to or competitive with the products that are the subject of the collaboration with us. Furthermore, our interests may differ from those of third parties that manufacture or commercialize our products. Our collaborators may reevaluate their priorities from time to time, including following mergers and consolidations, and change the focus of their development, manufacturing or commercialization efforts. Disagreements that may arise with these third parties could delay or lead to the termination of the development or commercialization of our product candidates, or result in litigation or arbitration, which would be time consuming and expensive.

If any third party that manufactures or supports the development or commercialization of our products breaches or terminates its agreement with us, or fails to commit sufficient resources to our collaboration or conduct its activities in a timely manner, or fails to comply with regulatory requirements, such breach, termination or failure could:

delay or otherwise adversely impact the manufacturing, development or commercialization of Angiomax, Cleviprex, cangrelor, oritavancin, CU2010 or any additional products that we may acquire or develop;

require us to seek a new collaborator or undertake unforeseen additional responsibilities or devote unforeseen additional resources to the manufacturing, development or commercialization of our products; or

result in the termination of the development or commercialization of our products.



## **Table of Contents**

### ***Use of third-party manufacturers may increase the risk that we will not have appropriate supplies of our product candidates***

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

reliance on the third party for regulatory compliance and quality assurance;

the possible breach of the manufacturing agreement by the third party; and

the possible termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

Angiomax and Cleviprex and our product candidates may compete with products and product candidates of third parties for access to manufacturing facilities. If we are not able to obtain adequate supplies of Angiomax, Cleviprex, and our other product candidates, it will be more difficult for us to compete effectively and develop our product candidates.

Our contract manufacturers are subject to ongoing, periodic, unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to evaluate compliance with the FDA's cGMP, regulations and other governmental regulations and corresponding foreign standards. We cannot be certain that our present or future manufacturers will be able to comply with cGMP regulations and other FDA regulatory requirements or similar regulatory requirements outside the United States. We do not control compliance by our contract manufacturers with these regulations and standards. Failure of our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines and other monetary penalties, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, interruption of production, warning letters, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of Angiomax, Cleviprex, cangrelor, oritavancin, CU2010 and our other product candidates.

### ***In order to satisfy regulatory authorities, we may need to reformulate the way in which our oritavancin bulk drug substance is created to remove animal source product***

Oritavancin bulk drug substance is manufactured using animal-sourced products, namely porcine-sourced products. Some non-U.S. regulatory authorities have historically objected to the use of animal-sourced products, particularly bovine-sourced products, during the preparation of finished drug product. As a result and in order to best position oritavancin for approval in foreign jurisdictions, under the agreement with Abbott, we and Abbott are seeking to develop a manufacturing process for oritavancin bulk drug substance that does not rely on the use of any animal-sourced products.

If we are unable to develop a manufacturing process for oritavancin bulk drug substance that does not rely on the use of animal-sourced product, it is possible that we will be unable to receive regulatory approval for oritavancin in certain foreign jurisdictions, which would likely have a negative impact on our ability to achieve our business objectives.

### ***If we use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages***

In connection with our acquisitions of Curacyte Discovery and Targanta, we now conduct research and development activities that involve the controlled use of potentially hazardous substances, including chemical, biological and radioactive materials and viruses. In addition, our operations produce hazardous waste products. Federal, state and local laws and regulations in each of the United States, Canada and Germany govern the use, manufacture, storage, handling and disposal of hazardous materials. Although we believe that our procedures for use, handling, storing and disposing of these materials comply with legally prescribed standards, we may incur significant additional costs to comply with applicable laws in the future. Also, even if we are in compliance with applicable laws, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials and we may incur liability as a result of any such contamination or injury. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We have only limited insurance for

liabilities arising from hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may restrict our research, development and production efforts, which could harm our business, operating results and financial condition.



## **Table of Contents**

### **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., relating to Cleviprex and cangrelor from AstraZeneca, through our acquisition of Targanta, relating to oritavancin from Eli Lilly and InterMune and relating to a ready-to-use formulation of Argatroban from Eagle. Under these agreements, we are subject to commercialization and development, sublicensing, royalty, patent prosecution and maintenance, insurance and other obligations. For example, we are required under our license for cangrelor to file an NDA for cangrelor by December 31, 2009, unless such filing is reasonably delayed as defined in the license agreement. Any failure by us to comply with any of these obligations or any other breach by us of our license agreements could give the licensor the right to terminate the license in whole, terminate the exclusive nature of the license or bring a claim against us for damages. Any such termination or claim, particularly relating to our agreements with respect to Angiomax, could have a material adverse effect on our financial condition, results of operations, liquidity or business. Even if we contest any such termination or claim and are ultimately successful, our stock price could suffer. In addition, we may be required to license to the licensor any related intellectual property that we developed.

We have entered into an agreement with Biogen Idec that suspends the statute of limitations relating to any claims, including claims for damages and/or license termination, that they may bring relating to the PTO's rejection of the application under the Hatch-Waxman Act for an extension of the term of the principal patent that covers Angiomax on the grounds that it was filed late. We have also entered into agreements with the law firms involved in the late filing that suspend the statute of limitations on our claims against them for the late filing.

In the third quarter of 2009, we initiated discussions with the two law firms involved in the late filing of the application under the Hatch-Waxman Act and are currently in related discussions with Biogen Idec with respect to the possible resolution of the potential claims among the parties. There can be no assurance that the parties will reach an agreement or as to the terms as of any such agreement.

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

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

- obtain and maintain U.S. and foreign patents, including defending those patents against adverse claims;
- secure patent term extension for the patents covering our approved products;
- protect trade secrets;
- operate without infringing the proprietary rights of others; and
- prevent others from infringing our proprietary rights.

We may not have any additional patents issued from any patent applications that we own or license. If additional patents are granted, the claims allowed may not be sufficiently broad to protect our technology. In addition, issued patents that we own or license may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection we may have for our products, and we may not be able to obtain patent term extension to prolong the terms of the principal patents covering our approved products. Changes in patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, or in some cases not at all,

## **Table of Contents**

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.

As of September 30, 2009, we exclusively licensed patents and patent applications for Angiomax, Cleviprex, cangrelor and oritavancin. The U.S. patents licensed by us are currently set to expire at various dates. In the case of Angiomax, the principal patent is set to expire in March 2010, with an additional six months of exclusivity until September 2010 granted by the FDA in connection with our pediatric study; in the case of Cleviprex, its principal patent is set to expire in January 2016; in the case of cangrelor, the principal patent is set to expire in February 2014, and in the case of oritavancin, the principal patent is set to expire in November 2015. We are seeking patent term extension for the principal patent for Cleviprex.

In connection with our acquisition of Targanta, we obtained an exclusive license to a portfolio of patents and patent applications covering oritavancin and its analogs. These patents and patent applications include those patents and patent applications exclusively licensed by Targanta from Eli Lilly, and also include a number of patent applications subsequently filed by Targanta. In connection with our acquisition of Curacyte Discovery, we also acquired a portfolio of patents and patent applications covering CU2010, its analogs or other similar protease inhibitors. We plan to prosecute and defend these patents and patent applications.

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

During and immediately after the third quarter of 2009, we were granted two U.S. patents. The first, the 727 patent, was issued on September 1, 2009. The 727 patent contains claims which relate to a more consistent and improved Angiomax drug product. The second, U.S. Patent No. 7,598,343, or the 343 patent, was issued on October 6, 2009. The 343 patent contains claims which also relate to a more consistent and improved Angiomax drug product made by processes described in the 343 patent. Both patents are listed in the Orange Book for Angiomax. In September 2009, we received Paragraph IV Certification Notice letters from Teva Parenteral Medicines, Inc., Pliva Hrvatska d.o.o., and APP Pharmaceuticals, LLC notifying us of ANDAs filed with the FDA seeking approval to market generic versions of Angiomax prior to the expiration of the 727 patent, which expires on July 27, 2028. On October 8, 2009, we filed three lawsuits alleging patent infringement by Teva Parenteral Medicines, Inc., Pliva Hrvatska d.o.o., APP Pharmaceuticals, LLC, and their related parent entities, in the U.S. District Court for the District of Delaware. On October 21, 2009, the three cases were reassigned in lieu of a vacant judgeship to the U.S. District Court for the Eastern District of Pennsylvania. We cannot predict the outcome of these lawsuits. During the period in which the litigations are pending, the uncertainty of their outcome may cause our stock price to decline. In addition, an adverse result in these litigations whether appealable or not, will likely cause our stock price to decline. Any final, unappealable, adverse result in these litigations will likely have a material adverse effect on our results of operations and financial conditions and cause our stock price to decline. In addition, involvement in litigation can be expensive.

On June 23, 2008, the United States House of Representatives passed a bill that, if enacted, would have provided the PTO with discretion to consider patent extension applications filed late unintentionally under the Hatch-Waxman Act. The United States Senate, however, adjourned without considering this bill. While we are hopeful that, in the current session, Congress will consider legislation similar to that passed by the House in June 2008, we can provide no assurance that a bill will be introduced or enacted or that, if it is enacted, the PTO will consider the application.

We have entered into an agreement with Biogen Idec that suspends the statute of limitations relating to any claims, including claims for damages and/or license termination, that they may bring relating to the PTO's rejection of the application under the Hatch-Waxman Act for an extension of the term of the principal patent that covers Angiomax on the grounds that it was filed late. We have also entered into agreements with the law firms involved in the late filing that suspend the statute of limitations on our claims against them for the late filing.

In the third quarter of 2009, we initiated discussions with the two law firms involved in the late filing of the application under the Hatch-Waxman Act and are currently in related discussions with Biogen Idec with respect to the possible resolution of the potential claims among the parties. There can be no assurance that the parties will reach an agreement or as to the terms as of any such agreement.

## **Table of Contents**

### ***We may be unable to utilize the Chemilog process if Lonza Braine breaches our agreement***

Our agreement with Lonza Braine for the supply of Angiomax bulk drug substance requires that Lonza Braine transfer the technology that was used to develop the Chemilog process to a secondary supplier of Angiomax bulk drug substance or to us or an alternate supplier at the expiration of the agreement, which is currently scheduled to occur in September 2010, but is subject to automatic renewals of consecutive three-year periods unless either party provides notice of non-renewal at least one year prior to the expiration of the initial term or any renewal term. If Lonza Braine fails or is unable to transfer successfully this technology, we would be unable to employ the Chemilog process to manufacture our Angiomax bulk drug substance, which could cause us to experience delays in the manufacturing process and increase our manufacturing costs in the future.

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

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

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

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

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

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

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

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

We sell and generate revenue from two products, Angiomax and Cleviprex. In order to generate additional revenue, we intend to acquire and develop additional product candidates or approved products. For example, in August 2008, we acquired Curacyte Discovery and its lead product candidate, CU2010, for the prevention of blood loss during surgery, in February 2009, we acquired



## **Table of Contents**

Targanta and its lead product candidate, oritavancin, and in September 2009 we entered into a license agreement with Eagle to obtain commercial rights to a ready-to-use formulation of Argatroban developed by Eagle. The success of this growth strategy depends upon our ability to identify, select and acquire pharmaceutical products that meet the criteria we have established. Because we have only the limited internal scientific research capabilities that we acquired in our acquisitions of Curacyte Discovery and Targanta, and we do not anticipate establishing additional scientific research capabilities, we are dependent upon pharmaceutical and biotechnology companies and other researchers to sell or license product candidates to us. We 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. For example, CU2010 commenced Phase I clinical testing in July 2009. With respect to oritavancin, the FDA issued a complete response letter to Targanta with respect to its oritavancin NDA indicating that the FDA could not approve the NDA in its present form and that it would be necessary for Targanta to perform an additional adequate and well-controlled study to demonstrate the safety and efficacy of oritavancin in patients with cSSSI before the application could be approved. We are in discussions with the FDA regarding the FDA's issues with the NDA filed by Targanta and expect to commence a Phase III trial in early 2010 based on guidance we receive from the FDA. In August 2009, we withdrew the European MAA for oritavancin.

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, our Executive Vice President and Chief Financial Officer, Glenn P. Sblendorio, or other key employees or consultants, our ability to implement successfully our business strategy could be seriously harmed. Our ability to replace these key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with

the breadth of skills and experience required to acquire, develop and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate such additional personnel.



**Table of Contents**

**Risks Related to Our Common Stock**

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

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

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

Our common stock has been and in the future may be subject to substantial price volatility. From January 1, 2008 to November 5, 2009, the last reported sale price of our common stock ranged from a high of \$27.68 per share to a low of \$6.47 per share. The value of your investment could decline due to the effect of any of the following factors upon the market price of our common stock:

- changes in securities analysts' estimates of our financial performance;
- changes in valuations of similar companies;
- variations in our operating results;
- acquisitions and strategic partnerships;
- announcements of technological innovations or new commercial products by us or our competitors;
- disclosure of results of clinical testing or regulatory proceedings by us or our competitors;
- the timing, amount and receipt of revenue from sales of our products and margins on sales of our products;
- governmental regulation and approvals;
- developments in patent rights or other proprietary rights;
- changes in our management; and
- general market conditions.

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

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

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



**Table of Contents**

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 5. Other Information**

On September 29, 2009, John P. Kelley resigned as President and Chief Operating Officer and as director of our company, effective October 1, 2009. Mr. Kelley is currently serving as a Special Advisor to our Chief Executive Officer until the earlier of December 31, 2009 or until he commences other full-time employment. On October 22, 2009, we entered into a severance letter agreement, or the Severance Agreement, with Mr. Kelley, pursuant to which Mr. Kelley is entitled to receive the following severance benefits following his termination as Special Advisor:

a lump sum payment equal to two years of his current annual base salary, less all applicable statutory tax withholdings and deductions;

for the shorter of a period of twelve months after the termination date or until Mr. Kelley commences employment with a new employer, reimbursement of COBRA health insurance premiums actually paid by Mr. Kelley and payment for reasonable outplacement services; and

accelerated vesting of all stock options that Mr. Kelley held immediately prior to termination which would have vested within two year after the termination date if Mr. Kelley had continued to be employed by us during such two-year period.

As part of the Severance Agreement, Mr. Kelley has also entered into a general release of us, including our affiliates, successors and assigns for all claims through the date of termination of his employment. Mr. Kelley remains subject to the non-compete, non-solicitation, confidentiality and related provisions of his invention and non-disclosure agreement and non-competition and non-solicitation agreement with us.

**Item 6. Exhibits**

**Exhibits**

See the Exhibit Index on the page immediately preceding the exhibits for a list of exhibits filed as part of this Quarterly Report on Form

10-Q, which Exhibit Index is incorporated herein by this reference.

**Table of Contents**

**SIGNATURES**

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

THE MEDICINES COMPANY

Date: November 9, 2009

By: /s/ Glenn P. Sblendorio  
Glenn P. Sblendorio  
Executive Vice President and Chief  
Financial  
Officer (Principal Financial and  
Accounting  
Officer)  
53

---

**Table of Contents**

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
10.1	Severance Agreement dated October 22, 2009 by and between John P. Kelley and the registrant
10.2	Amendment No 3 to the Amended and Restated Distribution Agreement dated August 12, 2009 between the registrant and Integrated Commercialization Solutions, Inc.
31.1	Chairman and Chief Executive Officer Certification pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Chief Financial Officer Certification pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Chairman and Chief Executive Officer Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Chief Financial Officer Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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