

MEDICINES CO /DE  
Form 10-Q  
August 09, 2013

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-Q  
(Mark One)

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

For the quarterly period ended: June 30, 2013

OR  
 TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT  
OF 1934 (No Fee Required)

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 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

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(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 August 2, 2013 there were 56,716,779 shares of Common Stock, \$0.001 par value per share, outstanding (excluding 2,192,982 shares held in the treasury).

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THE MEDICINES COMPANY

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Part I. Financial Information  
Item 1. Financial Statements

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

	June 30, 2013	December 31, 2012
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$292,891	\$519,446
Available for sale securities	8,112	50,875
Accrued interest receivable	75	348
Accounts receivable, net of allowances of approximately \$23.4 million and \$17.7 million at June 30, 2013 and December 31, 2012, respectively	90,333	85,893
Inventory	86,750	76,355
Deferred tax assets	13,881	13,881
Prepaid expenses and other current assets	10,598	9,577
Total current assets	502,640	756,375
Fixed assets, net	30,053	16,100
Intangible assets, net	462,486	119,576
Goodwill	135,627	14,671
Restricted cash	1,558	1,571
Deferred tax assets, net	—	46,625
Other assets	17,559	17,264
Total assets	\$1,149,923	\$972,182
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$5,067	\$25,378
Accrued expenses	113,235	107,453
Deferred revenue	2,319	2,375
Total current liabilities	120,621	135,206
Contingent purchase price	100,524	18,971
Deferred tax liabilities	34,504	—
Convertible senior notes (due 2017)	231,025	226,109
Other liabilities	5,815	5,674
Total liabilities	492,489	385,960
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; 58,797,762 issued and 56,604,780 outstanding at June 30, 2013 and 56,153,140 issued and 53,960,158 outstanding at December 31, 2012, respectively	58	56
Additional paid-in capital	763,127	697,427
Treasury stock, at cost; 2,192,982 shares at June 30, 2013 and December 31, 2012, respectively	(50,000)	(50,000)
Accumulated deficit	(53,890)	(60,411)
Accumulated other comprehensive loss	(1,684)	(766)
Total The Medicines Company stockholders' equity	657,611	586,306
Non-controlling interest in joint venture	(177)	(84)
Total stockholders' equity	657,434	586,222
Total liabilities and stockholders' equity	\$1,149,923	\$972,182

See accompanying notes to unaudited consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Net revenue	\$172,826	\$135,702	\$328,579	\$262,312
Operating expenses:				
Cost of revenue	63,938	42,681	120,653	81,344
Research and development	27,025	32,962	85,221	65,740
Selling, general and administrative	52,944	40,467	116,426	83,653
Total operating expenses	143,907	116,110	322,300	230,737
Income from operations	28,919	19,592	6,279	31,575
Co-promotion income	4,068	2,500	7,818	2,500
Interest expense	(3,704)	(784)	(7,377)	(784)
Other income	605	697	803	759
Income before income taxes	29,888	22,005	7,523	34,050
Provision for income taxes	(11,854)	(8,251)	(1,095)	(12,725)
Net income	18,034	13,754	6,428	21,325
Net loss attributable to non-controlling interest	60	1	93	1
Net income attributable to The Medicines Company	\$18,094	\$13,755	\$6,521	\$21,326
Basic earnings per common share attributable to The Medicines Company	\$0.33	\$0.25	\$0.12	\$0.39
Diluted earnings per common share attributable to The Medicines Company	\$0.30	\$0.25	\$0.11	\$0.38
Weighted average number of common shares outstanding:				
Basic	55,553	54,035	54,804	54,036
Diluted	60,261	55,556	59,154	55,614

See accompanying notes to unaudited consolidated financial statements.

THE MEDICINES COMPANY  
 CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME  
 (in thousands)  
 (unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Net income	\$18,034	\$13,754	\$6,428	\$21,325
Other comprehensive (loss) income:				
Unrealized (loss) gain on available for sale securities	(10 )	66	(5 )	(23 )
Foreign currency translation adjustment	(672 )	(936 )	(913 )	(634 )
Other comprehensive (loss)	(682 )	(870 )	(918 )	(657 )
Comprehensive income	\$17,352	\$12,884	5,510	20,668

See accompanying notes to unaudited consolidated financial statements.



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

	Six Months Ended June 30,	
	2013	2012
Cash flows from operating activities:		
Net income	\$6,428	\$21,325
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	12,815	3,686
Amortization of net premiums and discounts on available for sale securities	203	279
Amortization of long term debt financing costs	572	58
Amortization of debt discount	4,915	519
Unrealized foreign currency transaction loss (gain), net	49	(201 )
Non-cash stock compensation expense	10,460	7,295
Loss on disposal of fixed assets	26	28
Deferred tax provision	(2,631 )	4,133
Excess tax benefit from share-based compensation arrangements	(5,682 )	(239 )
Adjustment to contingent purchase price	(5,648 )	1,137
Changes in operating assets and liabilities:		
Accrued interest receivable	273	74
Accounts receivable	(4,729 )	8,725
Inventory	(10,482 )	(2,085 )
Prepaid expenses and other current assets	(739 )	(950 )
Accounts payable	(20,185 )	780
Accrued expenses	6,668	(40,006 )
Deferred revenue	(29 )	1,401
Other liabilities	133	89
Net cash (used in) provided by operating activities	(7,583 )	6,048
Cash flows from investing activities:		
Purchases of available for sale securities	—	(65,354 )
Proceeds from maturities and sales of available for sale securities	42,556	25,036
Purchases of fixed assets	(3,159 )	(488 )
Acquisitions, net of cash acquired	(301,700 )	
Acquisition of intangible assets	(10,000 )	(36,678 )
Other investments	(875 )	—
Decrease in restricted cash	7	2,008
Net cash used in investing activities	(273,171 )	(75,476 )
Cash flows from financing activities:		
Proceeds from issuances of common stock	49,561	10,073
Purchase of treasury stock		(50,000 )
Proceeds from issuance of convertible senior notes		275,000
Proceeds from issuance of warrants		38,425
Purchase of convertible note hedge		(58,223 )
Debt issuance costs		(8,774 )
Excess tax benefit from stock-based compensation arrangements	5,682	239
Net cash provided by financing activities	55,243	206,740
Effect of exchange rate changes on cash	(1,044 )	(354 )
(Decrease) increase in cash and cash equivalents	(226,555 )	136,958

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Cash and cash equivalents at beginning of period	519,446	315,382
Cash and cash equivalents at end of period	\$292,891	\$452,340
Supplemental disclosure of cash flow information:		
Interest paid	\$1,891	\$—
Taxes paid	\$1,100	\$1,019
See accompanying notes to unaudited consolidated financial statements.		

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## THE MEDICINES COMPANY

### NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

The Medicines Company® name and logo, Angiomax®, Angiox®, Cleviprex® and IONSYS™ 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) is a global biopharmaceutical company focused on saving lives, alleviating suffering and improving the economic efficiency of the world's leading hospitals. The Company markets Angiomax® (bivalirudin), Recothrom® Thrombin, topical (Recombinant) and Cleviprex® (clevidipine) injectable emulsion. The Company also has a pipeline of acute and intensive care hospital products in development, including three late-stage development product candidates, cangrelor, oritavancin and IONSYS™ (fentanyl iontophoretic transdermal system) and early stage development product candidates MDCO-216 and ALN-PCS02 and ALN-PCSsc of its ALN-PCS program. The Company believes that these marketed products and products in development possess favorable attributes that competitive products do not provide, can satisfy unmet medical needs in the acute and intensive care hospital product market and offer, or, in the case of its products in development, have the potential to offer, improved performance to hospital businesses.

In addition to these products and product candidates, the Company sells a ready-to-use formulation of Argatroban and has a portfolio of ten generic drugs, which the Company refers to as its acute care generic products, that the Company has the non-exclusive right to market in the United States. The Company began selling three of its acute care generic products, midazolam, ondansetron and rocuronium, in the first quarter of 2013. The Company also co-promotes the oral tablet antiplatelet medicine BRILINTA® (ticagrelor) in the United States, as part of its global collaboration agreement with AstraZeneca LP (AstraZeneca).

On August 5, 2013, the Company completed its acquisition of all of the outstanding equity of ProFibrix B.V. (ProFibrix) pursuant to a share purchase agreement entered into with ProFibrix and its equityholders on June 4, 2013. Upon the completion of the acquisition, ProFibrix became a wholly owned subsidiary of the Company. Under the share purchase agreement, the closing of the transaction was subject to the Company's satisfactory review of the then pending Phase 3 clinical trial results of ProFibrix's lead biologic, Fibrocaps™. Fibrocaps is a dry powder topical formulation of fibrinogen and thrombin being developed to help stop bleeding during surgery. Following the Company's review of the Phase 3 trial results, on August 2, 2013, the Company notified ProFibrix that it wished to proceed with the consummation of the transaction.

#### 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 Company's annual report on Form 10-K for the year ended December 31, 2012 as filed with the Securities and Exchange Commission (SEC).

##### Basis of Presentation

The accompanying 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 consolidated financial statements include the accounts of the Company and its wholly owned and majority owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation. The Company records net income (loss) attributable to non-controlling interest, if any, in the Company's consolidated financial statements equal to the percentage of ownership interest retained in the respective operations by the non-controlling parties. The Company has no unconsolidated subsidiaries or significant investments accounted for under the equity method.

The Company's results of operations for the three and six months ended June 30, 2013 are not necessarily indicative of the results that may be expected from the Company for the entire fiscal year or any other quarter of the fiscal year ending December 31, 2013. These consolidated financial statements should be read in conjunction with the Company's audited financial statements included in the Company's annual report on Form 10-K for the year ended December 31, 2012 as filed with the SEC.

#### Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, costs, expenses and accumulated other comprehensive loss that are reported in the consolidated financial statements and accompanying disclosures. Actual results may be different.

#### Contingencies

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company continually assesses litigation to determine if an unfavorable outcome would lead to a probable loss or reasonably possible loss which could be estimated. In accordance with the guidance of the Financial Accounting Standards Board (FASB) on accounting for contingencies, the Company accrues for all contingencies at the earliest date at which the Company deems it probable that a liability has been incurred and the amount of such liability can be reasonably estimated. If the estimate of a probable loss is a range and no amount within the range is more likely than another, the Company accrues the minimum of the range. In the cases where the Company believes that a reasonably possible loss exists, the Company discloses the facts and circumstances of the litigation, including an estimable range, if possible.

#### Intangible Assets

Intangible assets with definite useful lives are amortized over their estimated useful lives and reviewed for impairment if certain events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

#### In-Process Research and Development

The cost of in-process research and development (IPR&D) acquired directly in a transaction other than a business combination is capitalized if the projects have an alternative future use; otherwise they are expensed. The fair values of IPR&D projects acquired in business combinations are capitalized. Several methods may be used to determine the estimated fair value of the IPR&D acquired in a business combination. The Company utilizes the "income method," which applies a probability weighting that considers the risk of development and commercialization 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. The estimated future net cash flows are then discounted to the present value using an appropriate discount rate. This analysis is performed for each project independently. These assets are treated as indefinite-lived intangible assets until completion or abandonment of the projects, at which time the assets are amortized over the remaining useful life or written off, as appropriate. IPR&D intangible assets which are determined to have had a drop in their fair value are adjusted downward and an expense recognized on the statement of income. These are tested at least annually or when a triggering event occurs that could indicate a potential impairment.

#### Goodwill

Goodwill represents the excess consideration in a business combination over the fair value of identifiable net assets acquired. Goodwill is not amortized, but subject to impairment testing at least annually or when a triggering event occurs that could indicate a potential impairment. The Company determines whether goodwill may be impaired by comparing the carrying value of its reporting unit to the fair value of its reporting unit. A reporting unit is defined as an operating segment.

#### Contingent Purchase Price from Business Combinations

Subsequent to the acquisition date, the Company measures contingent consideration arrangements at fair value for each period with changes in fair value recognized in operating earnings. Changes in fair values reflect new information about the likelihood of the payment of the contingent consideration and the passage of time. In the absence of new information, changes in fair value reflect only the passage of time as development work towards the achievement of the milestones progresses.



#### Impairment of Long-Lived Assets

Long-lived assets, such as property, plant and equipment and certain other long-term assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset or asset group to the estimated undiscounted future cash flows expected to be generated by the asset or asset group. If the carrying amount of the assets exceed their estimated future undiscounted net cash flows, an impairment charge is recognized for the amount by which the carrying amount of the assets exceed the fair value of the assets.

#### Research and Development

Research and development costs are expensed as incurred. Clinical study costs are accrued over the service periods specified in the contracts and adjusted as necessary based upon an ongoing review of the level of effort and costs actually incurred. Payments for a product license prior to regulatory approval of the product and payments for milestones achieved prior to regulatory approval of the product are expensed in the period incurred as research and development. Milestone payments made in connection with regulatory approvals are capitalized and amortized to cost of revenue over the remaining useful life of the asset.

#### Other Comprehensive Income

The Company's accumulated comprehensive loss is comprised of gains and losses on available for sale securities and recorded and presented net of income tax and foreign currency translation.

#### Recent Accounting Pronouncements

In February 2013, the FASB amended its guidance to require an entity to present the effect of certain significant reclassifications out of accumulated other comprehensive income on the respective line items in net income. The new accounting guidance does not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. The guidance is effective prospectively for fiscal years beginning after December 15, 2012. The Company adopted these new provisions for the quarter beginning January 1, 2013. As the guidance requires additional presentation only, there was no impact to the Company's consolidated results of operations or financial position.

### 3. Stock-Based Compensation

The Company recorded approximately \$5.8 million and \$10.5 million of stock-based compensation expense for the three and six months ended June 30, 2013, respectively. The Company recorded approximately \$4.2 million and \$7.3 million of stock-based compensation expense for the three and six months ended June 30, 2012, respectively. As of June 30, 2013, there was approximately \$24.8 million of total unrecognized compensation costs related to non-vested stock-based employee compensation arrangements granted under the Company's equity compensation plans. The Company expects to recognize those costs over a weighted average period of 1.38 years.

During the six months ended June 30, 2013, the Company issued a total of 2,644,622 shares of its common stock upon the exercise of stock options, pursuant to restricted stock grants and pursuant to purchases under the 2010 ESPP. During the six months ended June 30, 2012, the Company issued a total of 973,056 shares of its common stock upon the exercise of stock options, pursuant to restricted stock grants and pursuant to purchases under the 2010 ESPP. Cash received from the exercise of stock options and purchases through the 2010 ESPP during the six months ended June 30, 2013 and June 30, 2012 was approximately \$49.6 million and \$4.7 million, respectively, and is included within the financing activities section of the consolidated statements of cash flows.

At June 30, 2013, there were an aggregate of 4,793,759 shares of common stock reserved for future issuance under the 2010 ESPP and for future grants under the Company's 2013 stock incentive plan.





## 4. Earnings per Share

The following table sets forth the computation of basic and diluted earnings per share for the three and six months ended June 30, 2013 and 2012:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
	(in thousands, except per share amounts)			
Basic and diluted				
Net income attributable to The Medicines Company	\$ 18,094	\$ 13,755	\$ 6,521	\$ 21,326
Weighted average common shares outstanding, basic	55,553	54,035	54,804	54,036
Plus: net effect of dilutive stock options, restricted common shares and shares issuable upon conversion of Notes	4,708	1,521	4,350	1,578
Weighted average common shares outstanding, diluted	60,261	55,556	59,154	55,614
Earnings per share attributable to The Medicines Company, basic	\$0.33	\$0.25	\$0.12	\$0.39
Earnings per share attributable to The Medicines Company, diluted	\$0.30	\$0.25	\$0.11	\$0.38

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. For the three months ended June 30, 2013 and 2012, options to purchase 2,707,156 shares and 3,324,489 shares, respectively, of common stock that could potentially dilute basic earnings per share in the future were excluded from the calculation of diluted earnings per share as their effect would have been anti-dilutive. For the six months ended June 30, 2013 and 2012, options to purchase 2,706,534 shares and 3,436,743 shares, respectively, of common stock that could potentially dilute basic earnings per share in the future were excluded from the calculation of diluted earnings per share as their effect would have been anti-dilutive.

For the three and six months ended June 30, 2013 and 2012, there were no shares of unvested restricted stock excluded from the calculation of diluted earnings per common share.

In June 2012, the Company issued, at par value, \$275.0 million aggregate principal amount of 1.375% convertible senior notes due June 1, 2017 (the Notes) (see note 10 "Convertible Senior Notes"). In connection with the issuance of the Notes, the Company entered into convertible note hedge transactions with respect to its common stock (the Note Hedges) with several of the initial purchasers of the Notes, their affiliates and other financial institutions (the Hedge Counterparties). The options that are part of the Note Hedges are not considered for purposes of calculating the total shares outstanding under the basic and diluted net income per share, as their effect would be anti-dilutive. The Note Hedges are expected generally to reduce the potential dilution with respect to shares of the Company's common stock upon any conversion of the Notes in the event that the market price per share of the Company's common stock, as measured under the terms of the Note Hedges, is greater than the strike price of the Note Hedges, which initially corresponded to the conversion price of the Notes and is subject to anti-dilution adjustments substantially similar to those applicable to the conversion rate of the Notes. The shares of common stock issuable upon conversion of the Notes included in diluted shares for the three and six months ended June 30, 2013 were 1,626,162 shares and 1,251,775 shares, respectively.

In addition, in connection with the Note Hedges, the Company entered into warrant transactions with the Hedge Counterparties, pursuant to which the Company sold warrants (the Warrants) to the Hedge Counterparties to purchase, subject to customary anti-dilution adjustments, up to 9.8 million shares of the Company's common stock at a strike price of \$34.20 per share. For the three and six months ended June 30, 2013, the warrants did not have a dilutive effect on earnings per share because the average market price during the periods presented was below the strike price. The Warrants will have a dilutive effect with respect to the Company's common stock to the extent that the market price per share of the Company's common stock, as measured under the terms of the Warrants, exceeds the applicable strike price of the Warrants. However, subject to certain conditions, the Company may elect to settle all of the Warrants in cash.

#### 5. Income Taxes

For the three months ended June 30, 2013 and 2012, the Company recorded an \$11.9 million and an \$8.3 million provision for income taxes, respectively, based upon its estimated federal, state and foreign tax liability for the year. The worldwide effective income tax rates for the Company for the three months ended June 30, 2013 and 2012 were 39.7% and 37.5%, respectively. Both the 2013 and 2012 effective income tax rates include a non-cash tax expense arising from purchase accounting for future contingent payments related to the Company's acquisition of Targanta Therapeutics Corporation (Targanta). Effective tax rates for the 2013 period include non-cash tax expense due to purchase accounting for future contingent payments related to the Company's acquisition of Incline Therapeutics, Inc. (Incline).

For the six months ended June 30, 2013 and 2012, the Company recorded a \$1.1 million and a \$12.7 million provision for income taxes, respectively, based upon its estimated federal, state and foreign tax liability for the year. The worldwide effective income tax rates for the Company for the six months ended June 30, 2013 and 2012 were 14.6% and 37.4%, respectively. The effective income tax rate for the six months ended June 30, 2013 reflects the effect of a one-time \$2.2 million income tax benefit arising from the retroactive reinstatement of the research and development tax credit included in The American Tax Relief Act of 2012 which was signed into law on January 2, 2013. Both the 2013 and 2012 effective income tax rates include a non-cash tax expense arising from purchase accounting for future contingent payments related to the Company's acquisition of Targanta. Effective tax rates for the 2013 period include non-cash tax expense due to purchase accounting for future contingent payments related to the Company's acquisition of Incline.

The Company continues to evaluate its ability to realize its deferred tax assets 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 and the regulatory approval of products currently under development. Any changes to the valuation allowance or deferred tax assets in the future would impact the Company's income taxes.

#### 6. Cash, Cash Equivalents and Available for Sale Securities

The Company considers all highly liquid investments purchased with original maturities at the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents included cash of \$255.1 million and \$504.7 million at June 30, 2013 and December 31, 2012, respectively. Cash and cash equivalents at June 30, 2013 and December 31, 2012 also included investments of \$37.8 million and \$14.7 million, respectively, in money market funds and commercial paper with original maturities of less than three months.

At June 30, 2013 and December 31, 2012, the Company held available for sale securities with a fair value totaling \$8.1 million and \$50.9 million, respectively. These available for sale securities included corporate debt securities at June 30, 2013 and various U.S. government agency notes and corporate debt securities at December 31, 2012. At June 30, 2013 and December 31, 2012, all of the available for sale securities were due within one year. The Company evaluates securities with unrealized losses to determine whether such losses are other than temporary. The Company has determined that there were no other than temporary declines in fair values of its investments as of June 30, 2013.

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

	As of June 30, 2013				As of December 31, 2012			
	Cost	Fair Value	Carrying Value	Unrealized Gain	Cost	Fair Value	Carrying Value	Unrealized Gain
	(in thousands)							
U.S. government	\$—	\$—	\$—	\$—	\$7,093	\$7,097	\$7,097	\$4

agency notes								
Corporate debt securities	8,107	8,112	8,112	5	43,772	43,778	43,778	6
Total	\$8,107	\$8,112	\$8,112	\$5	\$50,865	\$50,875	\$50,875	\$10

Restricted Cash

The Company had restricted cash of \$1.6 million at June 30, 2013 and December 31, 2012, which consisted of \$1.0 million collateral for outstanding letters of credit associated with the Company's lease for the office space in Parsippany, New Jersey. The funds are invested in certificates of deposit. The letter of credit permits draws by the landlord to cure defaults by the Company. In addition, as a result of the acquisition of Targanta in 2009, the Company had restricted cash of \$0.3 million at June 30, 2013

and December 31, 2012, respectively, in the form of a guaranteed investment certificate collateralizing an available credit facility. The Company also had restricted cash of \$0.3 million at June 30, 2013 and December 31, 2012, respectively, related to certain foreign tender requirements.

## 7. Fair Value Measurements

FASB ASC 820-10 "Fair Value Measurements and Disclosures" (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 and U.S. treasury notes.
- 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 notes and corporate debt securities. Fair values are determined by utilizing quoted prices for similar assets and liabilities in active markets or other market observable inputs such as interest rates and yield curves.
- 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 prices associated with the Company's acquisitions of Targanta and Incline. The fair value of the contingent purchase prices was determined utilizing a probability weighted discounted financial model based on management's assessment of the likelihood of achievement of certain development, regulatory and sales milestones.

The following table sets forth the Company's assets and liabilities that were measured at fair value on a recurring basis at June 30, 2013 and December 31, 2012 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	As of June 30, 2013				As of December 31, 2012			
	Quoted Prices In Active Markets for Identical Assets (Level 1) (in thousands)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of June 30, 2013	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of December 31, 2012
<b>Assets:</b>								
Money market	\$37,831	\$ —	\$ —	\$37,831	\$14,751	\$ —	\$ —	\$14,751
U.S. government agency notes	—	—	—	—	—	7,097	—	7,097
Corporate debt securities	—	8,112	—	8,112	—	43,778	—	43,778
Total assets at fair value	\$37,831	\$ 8,112	\$ —	\$45,943	\$14,751	\$ 50,875	\$ —	\$65,626
<b>Liabilities:</b>								
Contingent purchase price	\$—	\$ —	\$ 100,524	\$100,524	\$—	\$ —	\$ 18,971	\$18,971
Total liabilities at fair value	\$—	\$ —	\$ 100,524	\$100,524	\$—	\$ —	\$ 18,971	\$18,971

The Company measures contingent purchase price at fair value based on significant inputs not observable in the market, which causes it to be classified as a Level 3 measurement within the fair value hierarchy. The valuation of contingent purchase price uses assumptions and estimates the Company believes would be made by a market participant in making the same valuation. The Company assesses these assumptions and estimates on an on-going basis as additional data impacting the assumptions and estimates are obtained. Changes in the fair value of contingent purchase price related to updated assumptions and estimates are recognized within selling, general and administrative expenses on the consolidated statements of income.

Contingent purchase price may change significantly as additional data is obtained, impacting the Company's assumptions regarding probabilities of successful achievement of related milestones used to estimate the fair value of the liability. In evaluating this information, considerable judgment is required to interpret the market data used to develop the assumptions and estimates. The estimates of fair value may not be indicative of the amounts that could be realized in a current market exchange. Accordingly, the use of different market assumptions and/or different valuation techniques may have a material effect on the estimated fair value amounts, and such changes could materially impact the Company's results of operations in future periods.

#### Level 3 Disclosures

The following table provides quantitative information associated with the fair value measurement of the Company's Level 3 inputs:

	Fair Value as of	Valuation Technique	Unobservable Input	Range (Weighted Average)
	June 30, 2013			
	(in thousands)			
Targanta:				
Contingent purchase price	\$5,424	Probability-adjusted discounted cash flow	Probability of success	20%
			Period in which milestone is expected to be achieved	2019
			Discount rate	11%
Incline:				
Contingent purchase price	\$95,100	Probability-adjusted discounted cash flow	Probabilities of success	60% - 80% (75%)
			Periods in which milestones are expected to be achieved	2013-2017
			Discount Rate	22%
	Fair Value as of			
	December 31, 2012	Valuation Technique	Unobservable Input	Range (Weighted Average)
	(in thousands)			
Targanta:				
Contingent purchase price	\$18,971	Probability-adjusted discounted cash flow	Probabilities of success	20% - 60% (49%)
			Periods in which milestones are expected to be achieved	2013 - 2019
			Discount rate	11%

The fair value of the contingent purchase price represents the fair value of the Company's liability for all potential payments under the Company's agreements with Targanta and Incline. The significant unobservable inputs used in the fair value measurement of the Company's contingent purchase prices are the probabilities of successful achievement of development, regulatory and sales milestones, which would trigger payments under the Targanta and Incline agreements, probabilities as to the periods in which the milestones are expected to be achieved and discount rates. Significant changes in any of the probabilities of success would result in a significantly higher or lower fair value measurement, respectively. Significant changes in the probabilities as to the periods in which milestones will be achieved would result in a significantly lower or higher fair value measurement, respectively.

The changes in fair value of the Company's Level 3 contingent purchase price during the three and six months ended June 30, 2013 and 2012 were as follows:

	Three Months Ended		Six Months Ended June	
	June 30, 2013	2012	30, 2013	2012
	(in thousands)			
Balance at beginning of period	\$ 105,807	\$ 20,995	\$ 18,971	\$ 20,431
Fair value of contingent purchase price with respect to Incline as of January 4, 2013	—	—	87,200	—
Fair value adjustment to contingent purchase prices included in net income	(5,283 )	573	(5,647 )	1,137
Balance at end of period	\$ 100,524	\$ 21,568	\$ 100,524	\$ 21,568

For the three and six months ended June 30, 2013, the changes in the fair value of the contingent purchase price obligations resulted from the Company's purchase of Incline, the passage of time as development work for IONSYS progresses towards the achievement of milestones and a reduction in the probability of successfully obtaining regulatory approval of oritavancin by December 31, 2013.

No other changes in valuation techniques or inputs occurred during the three and six months ended June 30, 2013. No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the three and six months ended June 30, 2013.

#### 8. Inventory

The major classes of inventory were as follows:

Inventory	June 30,	December 31,
	2013	2012
	(in thousands)	
Raw materials	\$43,821	\$40,244
Work-in-progress	22,536	26,594
Finished goods	20,393	9,517
Total	\$86,750	\$76,355

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

#### 9. Intangible Assets and Goodwill

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



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	As of June 30, 2013			As of December 31, 2012			
	Weighted Average Useful Life	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
		(in thousands)					
Identifiable intangible assets							
Customer relationships	8 years	\$7,457	\$ (4,868 )	\$ 2,589	\$7,457	\$ (4,106 )	\$ 3,351
Distribution agreements	5.7 years	9,125	(4,669 )	4,456	9,125	(3,469 )	5,656
Trademarks	8 years	3,024	(1,974 )	1,050	3,024	(1,665 )	1,359
Product licenses	5.7 years	71,000	(9,932 )	61,068	39,000	(1,129 )	37,871
Cleviprex milestones	13 years	2,000	(177 )	1,823	2,000	(161 )	1,839
Total	6.1 years	\$92,606	\$ (21,620 )	\$ 70,986	\$60,606	\$ (10,530 )	\$ 50,076

In February 2013, pursuant to a master transaction agreement with Bristol-Myers Squibb Company (BMS), the Company acquired the right to sell, distribute and market Recothrom on a global basis for a two-year period (the collaboration term) and BMS transferred to the Company certain limited assets exclusively related to Recothrom, primarily the biologics license application for Recothrom and certain related regulatory assets. The Company valued the intangible assets obtained from BMS in the United States at \$32.0 million and classified such assets as product license intangibles. The Company is amortizing the assets using a two year expected useful life (see note 13 “Acquisitions”).

The Company expects amortization expense related to its intangible assets to be \$12.4 million for the six months ending December 31, 2013. The Company expects annual amortization expense related to its intangible assets to be \$26.0 million, \$5.9 million, \$4.5 million, \$4.6 million and \$4.6 million for the years ending December 31, 2014, 2015, 2016, 2017 and 2018, respectively, with the balance of \$13.0 million being amortized thereafter. The Company records amortization of customer relationships, distribution agreements and trademarks in selling, general and administrative expense on the consolidated statements of income. The Company records amortization of Cleviprex milestones and product licenses in cost of revenue on the consolidated statements of income.

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

	As of June 30, 2013			As of December 31, 2012		
	Gross Carrying Amount	Adjustments	Net Carrying Amount	Gross Carrying Amount	Adjustments	Net Carrying Amount
	(in thousands)					
Intangible assets not subject to amortization:						
In-process research and development	\$319,500	—	\$319,500	\$69,500	—	\$69,500
Recothrom option	62,000	—	62,000	—	—	—
ProFibrix option	10,000	—	10,000	—	—	—
Total	\$391,500	—	\$391,500	\$69,500	—	\$69,500

The Company capitalized IPR&D of \$250.0 million related to the Incline acquisition, capitalized the option value of \$62.0 million related to the master transaction agreement with BMS and capitalized the option value of \$10.0 million related to the share purchase agreement with ProFibrix during the three and six months ended June 30, 2013. The

allocation of the preliminary purchase price to intangible assets is detailed in note 13 “Acquisitions” for each of the above noted transactions.

The changes in the carrying amount of goodwill for the six months ended June 30, 2013:

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	June 30, 2013 (in thousands)
Balance at January 1, 2013	\$ 14,671
Goodwill resulting from the acquisition of Incline	99,956
Goodwill resulting from the acquisition of Recothrom	21,000
Balance as of June 30, 2013	\$ 135,627

#### 10. Convertible Senior Notes

In June 2012, the Company issued, at par value, \$275.0 million aggregate principal amount of the Notes. The Notes bear cash interest at a rate of 1.375% per year, payable semi-annually on June 1 and December 1 of each year, beginning on December 1, 2012. The Notes will mature on June 1, 2017. The net proceeds to the Company from the offering were \$266.2 million after deducting the initial purchasers' discounts and commissions and the offering expenses payable by the Company.

The Notes are governed by an indenture dated as of June 11, 2012 (the Indenture), between the Company, as issuer, and Wells Fargo Bank, National Association, a national banking association, as trustee (the Trustee). The Notes do not contain any financial or operating covenants or any restrictions on the payment of dividends, the incurrence of other indebtedness, or the issuance or repurchase of securities by the Company.

The Notes are senior unsecured obligations of the Company and will rank senior in right of payment to the Company's future indebtedness, if any, that is expressly subordinated in right of payment to the Notes and equal in right of payment to the Company's existing and future unsecured indebtedness that is not so subordinated. The Notes are effectively junior in right of payment to any secured indebtedness of the Company to the extent of the value of the assets securing such indebtedness and are structurally junior to all existing and future indebtedness and other liabilities (including trade payables) incurred by the Company's subsidiaries.

Holders may convert their Notes at their option at any time prior to the close of business on the business day immediately preceding March 1, 2017 only under the following circumstances:

during any calendar quarter commencing on or after September 1, 2012 (and only during such calendar quarter), if the last reported sale price of the Company's common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price (described below) on each applicable trading day;

during the five business day period after any five consecutive trading day period (the Measurement Period) in which the trading price (as defined in the Indenture) per \$1,000 principal amount of Notes for each trading day of the Measurement Period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such trading day; or

upon the occurrence of specified corporate events, including a merger or a sale of all or substantially all of the Company's assets.

On or after March 1, 2017, until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their Notes at any time, regardless of the foregoing circumstances. Upon conversion, the Company will pay cash up to the aggregate principal amount of the Notes to be converted and deliver

shares of the Company's common stock in respect of the remainder, if any, of the Company's conversion obligation in excess of the aggregate principal amount of the Notes being converted, subject to a daily share cap, as described in the Indenture. Holders of Notes will not receive any additional cash payment or additional shares representing accrued and unpaid interest, if any, upon conversion of a Note, except in limited circumstances. Instead, accrued but unpaid interest will be deemed to be paid by the cash and shares, if any, of the Company's common stock, together with any cash payment for any fractional share, paid or delivered, as the case may be, upon conversion of a Note.

The conversion rate for the Notes was initially, and remains, 35.8038 shares of the Company's common stock per \$1,000 principal amount of Notes, which is equivalent to an initial conversion price of \$27.93 per share of the Company's common stock.

The conversion rate and the conversion price are subject to customary adjustments for certain events, including, but not limited to, the issuance of certain stock dividends on the Company's common stock, the issuance of certain rights or warrants, subdivisions, combinations, distributions of capital stock, indebtedness, or assets, cash dividends and certain issuer tender or exchange offers, as described in the Indenture.

The Company may not redeem the Notes prior to maturity and is not required to redeem or retire the Notes periodically. However, upon the occurrence of a "fundamental change" (as defined in the Indenture), subject to certain conditions, in lieu of converting their Notes, holders may require the Company to repurchase for cash all or part of their Notes at a repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. Following certain corporate transactions that constitute a change of control, the Company will increase the conversion rate for a holder who elects to convert the Notes in connection with such change of control in certain circumstances.

The Indenture contains customary events of default with respect to the Notes, including that upon certain events of default (including the Company's failure to make any payment of principal or interest on the Notes when due and payable) occurring and continuing, the Trustee by notice to the Company, or the holders of at least 25% in principal amount of the outstanding Notes by notice to the Company and the Trustee, may, and the Trustee at the request of such holders (subject to the provisions of the Indenture) shall, declare 100% of the principal of and accrued and unpaid interest, if any, on all the Notes to be due and payable. In case of an event of default involving certain events of bankruptcy, insolvency or reorganization, involving the Company or a significant subsidiary, 100% of the principal of and accrued and unpaid interest on the Notes will automatically become due and payable. Upon a declaration of acceleration, such principal and accrued and unpaid interest, if any, will be due and payable immediately.

In accounting for the issuance of the Notes, the Company separated the Notes into liability and equity components. The carrying amount of the liability component was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The carrying amount of the equity component representing the conversion option was determined by deducting the fair value of the liability component from the par value of the Notes as a whole. The excess of the principal amount of the liability component over its carrying amount, referred to as the debt discount, is amortized to interest expense over the five-year term of the Notes. The equity component is not re-measured as long as it continues to meet the conditions for equity classification.

In accounting for the transaction costs related to the issuance of the Notes, the Company allocated the total costs incurred to the liability and equity components of the Notes based on their relative values. Transaction costs attributable to the liability component are amortized to interest expense over the five-year term of the Notes, and transaction costs attributable to the equity component are netted with the equity components in stockholders' equity. The Notes consisted of the following:

Liability component	June 30, 2013	December 31, 2012
	(in thousands)	
Principal	\$275,000	\$275,000
Less: Debt discount, net <sup>(1)</sup>	(43,975 )	(48,891 )
Net carrying amount	\$231,025	\$226,109

<sup>(1)</sup> Included in the consolidated balance sheets within convertible senior notes (due 2017) and amortized to interest expense over the remaining life of the Notes using the effective interest rate method.

The fair value of the Notes was approximately \$242.7 million as of June 30, 2013. The Company estimates the fair value of its Notes utilizing market quotations for debt that have quoted prices in active markets. Since the Notes do not trade on a daily basis in an active market, the fair value estimates are based on market observable inputs based on borrowing rates currently available for debt with similar terms and average maturities (Level 2). As of June 30, 2013, the remaining contractual life of the Notes is approximately 3.9 years.

The following table sets forth total interest expense recognized related to the Notes:

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	Three Months Ended June		Six Months Ended June	
	30, 2013	2012	30, 2013	2012
	(in thousands)			
Contractual interest expense	\$945	\$207	\$1,891	\$207
Amortization of debt issuance costs	289	58	572	58
Amortization of debt discount	2,470	519	4,915	519
Total	\$3,704	\$784	\$7,378	\$784
Effective interest rate of the liability component	6.02	% 6.02	% 6.02	% 6.02

Note Hedges. In June 2012, the Company paid an aggregate amount of \$58.2 million for the Note Hedges, which was recorded as a reduction of additional paid-in-capital in stockholders' equity. The Note Hedges cover approximately 9.8 million shares of the Company's common stock, subject to anti-dilution adjustments substantially similar to those applicable to the Notes, have a strike price that corresponds to the initial conversion price of the Notes and are exercisable upon conversion of the Notes. The Note Hedges will expire upon the maturity of the Notes. The Note Hedges are expected generally to reduce the potential dilution with respect to shares of the Company's common stock upon conversion of the Notes in the event that the market price per share of the Company's common stock, as measured under the terms of the Note Hedges, at the time of exercise is greater than the strike price of the Note Hedges. The Note Hedges are separate transactions entered into by the Company with the Hedge Counterparties and are not part of the terms of the Notes or the Warrants. Holders of the Notes and Warrants will not have any rights with respect to the Note Hedges. As of June 30, 2013, the fair value of the Note Hedges was \$88.5 million. The Company estimates the fair value of its Note Hedges using Monte Carlo simulations model of its stock price (Level 2).

Warrants. The Company received aggregate proceeds of \$38.4 million from the sale to the Hedge Counterparties of the Warrants to purchase up to 9.8 million shares of the Company's common stock, subject to customary anti-dilution adjustments, at a strike price of \$34.20 per share, which the Company recorded as additional paid-in-capital in stockholders' equity. The Warrants will have a dilutive effect with respect to the Company's common stock to the extent that the market price per share of the Company's common stock, as measured under the terms of the Warrants, exceeds the applicable strike price of the Warrants. However, subject to certain conditions, the Company may elect to settle all of the Warrants in cash. The Warrants were anti-dilutive for the three and six months ended June 30, 2013. The Warrants are separate transactions entered into by the Company with the Hedge Counterparties and are not part of the terms of the Notes or Note Hedges. Holders of the Notes and Note Hedges will not have any rights with respect to the Warrants. The Warrants also meet the definition of a derivative under current accounting principles. Because the Warrants are indexed to the Company's common stock and are recorded in equity in the Company's consolidated balance sheets, the Warrants are exempt from the scope and fair value provisions of accounting principles related to accounting for derivative instruments.

#### 11. Treasury Stock

On June 5, 2012, the Company's Board of Directors authorized the Company to use a portion of the net proceeds of the Notes offering to repurchase up to an aggregate of \$50.0 million of its common stock. The Company repurchased 2,192,982 shares of its common stock in the second quarter of 2012 for an aggregate cost of \$50.0 million.

As of June 30, 2013, there were 2,192,982 shares of the Company's common stock held in treasury.

#### 12. Restructuring Costs and Other, Net

On February 27, 2013, the Company commenced a workforce reduction plan intended to improve efficiency and better align its costs and employment structure with its strategic plans. As a result of the workforce reduction, the Company reduced its personnel by 66 employees. Upon signing release agreements, affected employees received severance payments and fully paid health care coverage and outplacement services for specified periods. The Company completed this workforce reduction in March 2013.

The Company recorded, in the aggregate, one-time charges of \$6.4 million associated with the workforce reduction. The Company recorded these charges in cost of revenue, research and development expense and selling general and administrative expense based on the responsibilities of the affected employees. Of the charges related to the 2013 workforce reduction, \$0.3 million were non-cash charges, the Company paid \$5.5 million during the six months ended June 30, 2013 and the Company expects to pay out \$0.6 million during the remainder of 2013.



In September 2011, the Company commenced the closure of its drug discovery research and development facility and operations in Leipzig, Germany and terminated ten employees at its Leipzig facility. The Company transferred active pre-clinical projects from Leipzig to its research and development facility in Montreal, Canada and the MDCO-2010 back-up compound to the clinical team in Parsippany, New Jersey. Upon signing release agreements, the terminated employees received severance and other benefits. The Company recorded, in the aggregate, charges of \$2.2 million in 2011 associated with the 2011 Leipzig closure. These charges were recorded in research and development expenses in the Company's consolidated statements of income. Of these charges, \$0.3 million related to asset write-offs were noncash charges. The Company paid \$0.3 million during 2011 and \$0.8 million during 2012. During 2012, the Company recorded additional charges of \$0.2 million relating to the 2011 Leipzig closure due the Saxony government in Leipzig recalling subsidies higher than originally estimated that were received by the Company during past three years. In the second quarter of 2013, the Company received notification from the Saxony government that no additional liabilities were due for these subsidies.

Details of the activities described above and the movement in the accrual during the six-month period ended June 30, 2013 are as follows:

	Balance as of December 31, 2012 (in thousands)	Expenses, Net	Cash	Noncash	Balance as of June 30, 2013
2011 Leipzig closure other associated costs Employee severance and other personnel benefits:	\$1,009	\$—	\$—	\$(1,009)	) \$—
2013 workforce reduction	—	6,358	(5,483)	) (256)	) 619
Total	\$1,009	\$6,358	\$(5,483)	) \$(1,265)	) \$619

### 13. Acquisitions

#### Incline Therapeutics, Inc.

In January 2013, the Company acquired Incline, a company focused on the development of IONSYS, a compact, disposable, needleless patient-controlled system for the short-term management of acute postoperative pain in the hospital setting.

Under the terms of the Company's agreement with Incline, the Company paid to the holders of Incline's capital stock and the holders of options to purchase shares of Incline's capital stock (collectively, the Incline equityholders) an aggregate of approximately \$155.2 million in cash, which is subject to a post-closing purchase price adjustment process. In addition, the Company also paid approximately \$13 million to Cadence Pharmaceuticals, Inc. (Cadence) to terminate Cadence's option to acquire Incline pursuant to an agreement between Cadence and Incline and deposited \$18.5 million in cash into an escrow fund for the purposes of securing the indemnification obligations of the Incline equityholders to the Company for any and all losses for which the Company is entitled to indemnification pursuant to the merger agreement and to provide the source of recovery for any amounts payable to the Company as a result of the post-closing purchase price adjustment process.

The Company also agreed to pay up to \$205 million in cash in the aggregate, less certain transaction expenses and taxes, upon its entering into a license agreement in Japan, achieving certain regulatory approval and certain sales milestones with respect to IONSYS.

In accordance with the acquisition method of accounting, the Company allocated the acquisition cost for the Incline transaction to the underlying assets acquired and liabilities assumed by the Company, based primarily upon estimated fair values of those assets and liabilities at the date of acquisition and will classify the fair value of acquired IPR&D as indefinite-lived assets until the successful completion or abandonment of the associated research and development efforts.

The Company recognized as goodwill from the transaction an amount equal to the excess of the purchase price over the fair value amounts assigned to the assets acquired and liabilities assumed by the Company. The goodwill recorded as part of the acquisition is primarily related to establishing a deferred tax liability for the IPR&D intangible assets which have no tax basis and, therefore, will not result in a future tax deduction. The Company does not expect any portion of this goodwill to be deductible for tax purposes. The Company has recorded the goodwill attributable to the acquisition as a non-current asset on its consolidated

balance sheets. The goodwill attributable to the acquisition is not amortized, but the Company reviews its goodwill annually for impairment.

The Company accounted for the transaction as a business combination and is in the process of finalizing the valuation of intangible assets and fair value of the contingent purchase price. As a result, the preliminary measurements of intangible assets, certain tangible assets, goodwill and deferred income tax assets described below are subject to change. The results of Incline's operations have been included in the consolidated statements of income from the date of acquisition.

Acquisition related costs during the six months ending June 30, 2013 of approximately \$2.2 million for advisory, legal and regulatory costs incurred in connection with the Incline acquisition have been expensed in selling, general and administrative expenses.

Total estimated purchase price is summarized as follows:

	(in thousands)
Upfront cash consideration	\$ 186,699
Fair value of contingent purchase price	87,200
Total preliminary estimated purchase price	\$ 273,899

Below is a summary which details the preliminary allocation of assets acquired and liabilities assumed as a result of this acquisition:

Assets Acquired:	(in thousands)
Cash and cash equivalents	\$ 1,563
Prepaid expenses and other current assets	624
Fixed assets, net	12,577
In-process research and development	250,000
Goodwill	99,956
Other assets	34
Total Assets	\$ 364,754
Liabilities Assumed:	
Accrued expenses	1,413
Contingent purchase price	87,200
Deferred tax liabilities	89,442
Total Liabilities	178,055
 Total cash price paid upon acquisition	 \$ 186,699

#### Recothrom

In February 2013, pursuant to a master transaction agreement with BMS, the Company acquired the right to sell, distribute and market Recothrom on a global basis for the collaboration term and BMS transferred to the Company certain limited assets exclusively related to Recothrom, primarily the biologics license application for Recothrom and certain related regulatory assets. BMS also granted to the Company, under the master transaction agreement, an option to purchase from BMS and its affiliates, following the expiration or earlier termination of the collaboration term, certain other assets, including certain patent and trademark rights, contracts, inventory, equipment and related books and records, held by BMS which are exclusively related to Recothrom.

Under the master transaction agreement, the Company paid to BMS a one-time collaboration fee equal to \$105 million and a one-time option fee equal to \$10 million. The Company did not assume, and if the Company exercises the option, it will not assume, any pre-existing liabilities related to the Recothrom business, contingent or otherwise, arising prior to the collaboration period, and the Company did not acquire, and if the Company exercises the option, it will not acquire, any significant tangible

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assets related to the Recothrom business. Under the master transaction agreement, the Company agreed to pay to BMS quarterly tiered royalty payments during the collaboration term equal to a percentage of worldwide net sales of Recothrom.

If the Company exercises the option, it would, at the closing of the purchase of the option assets, acquire such assets and assume certain liabilities of BMS and its affiliates related to the assets and to pay to BMS a purchase price equal to the net book value of inventory included in the acquired assets, plus either:

a multiple of average net sales over each of the two 12-month periods preceding the closing of the purchase (unless the purchase closing occurs less than 24 months after February 8, 2013, in which case the measurement period would be the 12-month period preceding the purchase closing); or

if BMS has delivered a valid notice terminating the collaboration term early as a result of a material breach by the Company under the master transaction agreement, the amount described above plus an amount intended to give BMS the economic benefit of having received royalty fees for a 24-month collaboration term.

In connection with the master transaction agreement, the Company also entered into a supply agreement with BMS. Under the supply agreement, BMS or one or more of its affiliates will manufacture Recothrom and serve as the exclusive supplier of the Recothrom to the Company during the collaboration term at specified purchase prices.

In accordance with the acquisition method of accounting, the Company allocated the acquisition cost for the Recothrom transaction to the underlying assets acquired by the Company based primarily upon the estimated fair values of those assets at the date of acquisition.

The Company recognized as goodwill from the transaction an amount equal to the excess of purchase price over the fair value amounts assigned to the assets acquired by the Company. The goodwill recorded as part of the acquisition is primarily related to cost synergies and the acquired assembled workforce.

The Company accounted for the transaction as a business combination since it acquired the biologics license application for Recothrom and certain related regulatory assets, employees and an option to acquire certain other assets, including certain patent and trademark rights, contracts, inventory, equipment and related books and records, held by BMS which are exclusively related to Recothrom (inputs), including the infrastructure to the sell the product (processes) and net sales of Recothrom (outputs). In addition, the Company has control over sales and marketing of the product during the collaboration period. The Company is finalizing the valuation of intangible assets. As a result, the preliminary measurements of intangible assets, goodwill and product rights are subject to change.

Acquisition related costs during the six months ending June 30, 2013 of approximately \$1.6 million for advisory, legal and regulatory costs incurred in connection with the Recothrom acquisition have been expensed in selling, general and administrative expenses.

Below is a summary which details the preliminary allocation of assets acquired as a result of this acquisition:

Assets Acquired:	(in thousands)
Product license	\$ 32,000
Option	62,000
Goodwill	21,000
Total Assets	\$ 115,000
Total cash price paid upon acquisition	\$ 115,000

The following unaudited pro forma financial information reflects the consolidated statement of income of the Company as if the acquisition of Incline and licensing for Recothrom had occurred as of January 1, 2012. The pro forma information includes adjustments for the amortization of intangible assets. The pro forma financial information is not necessarily indicative of the results of operations as they would have been had the transaction been effected on the assumed date.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
	(in thousands, except per share amounts)			
Net revenue	\$ 172,826	\$ 152,314	\$ 334,932	\$ 295,536
Net (loss) income	\$ 18,094	\$ (65,162)	\$ 5,531	\$ (61,583)
Basic earnings (loss) per common share	\$ 0.33	\$ (1.21)	\$ 0.10	\$ (1.14)
Diluted earnings (loss) per common share	\$ 0.30	\$ (1.21)	\$ 0.09	\$ (1.14)

#### ProFibrix B.V.

On August 5, 2013, the Company completed its acquisition of all of the outstanding equity of ProFibrix, pursuant to a share purchase agreement entered into with ProFibrix and its equityholders on June 4, 2013. Under the share purchase agreement, the closing of the transaction was subject to the Company's satisfactory review of the then pending Phase 3 clinical trial results of ProFibrix's lead biologic, Fibrocaps. In connection with entering into the agreement, the Company paid ProFibrix a \$10.0 million option payment. Upon the completion of the acquisition, ProFibrix became a wholly owned subsidiary of the Company.

ProFibrix does not have any marketed products and has been engaged since its inception in developing fibrinogen based products for the hemostasis and regenerative medicine markets. Fibrocaps, the proposed name of ProFibrix's lead biologic, is a dry powder topical formulation of fibrinogen and thrombin being developed to help stop bleeding during surgery.

Following the Company's review of the Phase 3 trial results, on August 2, 2013, the Company notified ProFibrix that it wished to proceed with the consummation of the transaction. At the closing, the Company paid an aggregate purchase price of \$90.0 million in cash, plus an additional \$4.0 million based on a preliminary closing adjustment. The Company deposited \$9.0 million of the purchase price into an escrow fund for the purpose of (i) securing the indemnification obligations of the ProFibrix equityholders and optionholders to the Company for any and all losses for which the Company is entitled to indemnification under the share purchase agreement, and (ii) providing the source of recovery for any amounts payable to the Company as a result of the post-closing purchase price adjustment process.

Under the terms of the share purchase agreement, the Company is also obligated to pay up to an aggregate of \$140.0 million in cash to the ProFibrix equityholders and optionholders upon the achievement of certain U.S. and European regulatory approvals prior to January 1, 2016 and certain U.S. and European sales milestones during the 24 month period that follows the initial commercial sale of Fibrocaps.

At June 30, 2013, the Company recorded the \$10.0 million option payment as an intangible not subject to amortization. As the option may not be settled for cash, it is not a derivative instrument under the requirements of ASC 815. The Company will expense the carrying value of the option at the earliest of the date the Company exercises the option and closes the transaction, elects not to exercise the option or the option expires. Following closing, the Company will consolidate ProFibrix in its results from the closing date forward.

Due to the limited time since the date of the acquisition, the initial disclosure for this business combination is incomplete as of the date of this filing. As such, it is impracticable for the Company to make certain business combination disclosures at this time. The Company is unable to present the acquisition date fair value of and information related to assets acquired and liabilities assumed. The Company plans to provide this information in its

Quarterly Report on Form 10-Q for the quarter ending September 30, 2013.

14. Accumulated Other Comprehensive Loss

The changes in accumulated other comprehensive loss are as follows:

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	Foreign currency translation adjustment (in thousands)	Unrealized gain on available for sale securities	Total	
Balance at December 31, 2012	\$(825	) \$59	\$(766	)
Other comprehensive (loss) income before reclassifications	(913	) (5	) (918	)
Amounts reclassified from accumulated other comprehensive income*	—	—	—	
Total other comprehensive (loss) income	(913	) (5	) (918	)
Balance at June 30, 2013	\$(1,738	) \$54	\$(1,684	)

\* Amounts reclassified affect other income in the consolidated statements of income.

## 15. Segment and Geographic Information

The Company manages its business and operations as one segment and is focused on advancing the treatment of acute and intensive 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 segment information provided below is classified based on the major geographic regions in which the Company operates.

	Three Months Ended June 30,				Six Months Ended June 30,			
	2013		2012		2013		2012	
	(in thousands)				(in thousands)			
Net revenue:								
United States	\$159,590	92.3%	\$123,774	91.2%	\$303,786	92.5%	\$239,753	91.4%
Europe	10,698	6.2%	9,656	7.1%	21,083	6.4%	18,812	7.2%
Rest of world	2,538	1.5%	2,272	1.7%	3,710	1.1%	3,747	1.4%
Total net revenue	\$172,826	100.0%	\$135,702	100.0%	\$328,579	100.0%	\$262,312	100.0%

	June 30,			December 31,		
	2013			2012		
	(in thousands)					
Long-lived assets:						
United States	\$643,700	99.7	%	\$161,909	99.4	%
Europe	1,124	0.2	%	743	0.5	%
Rest of world	901	0.1	%	148	0.1	%
Total long-lived assets	\$645,725	100.0	%	\$162,800	100.0	%

## 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 at the earliest date at which the Company deems that it is

probable that a liability has been incurred and the amount of such loss can be reasonably estimated.

The Company is party to the legal proceedings described in Part II, Item 1, Legal Proceedings, of this quarterly report, which are principally patent litigation matters. The Company has assessed such legal proceedings and does not believe that it is probable that a liability has been incurred or that the amount of any potential liability can be reasonably estimated. As a result, the Company did not record any loss contingencies for any of these matters. While it is not possible to determine the outcome of the matters described in Part II, Item 1, Legal Proceedings, of this quarterly report, the Company believes that, the resolution of all such matters will not have a material adverse effect on its consolidated financial position or liquidity, but could possibly be material to the Company's consolidated results of operations in any one accounting period.

## 17. Collaboration Agreements

### AstraZeneca

In April 2012, the Company entered into an agreement with AstraZeneca pursuant to which the Company and AstraZeneca agreed to collaborate globally to develop and commercialize certain acute ischemic heart disease compounds. Under the terms of the collaboration agreement, a joint development and research committee and a joint commercialization committee have been established to prepare and deliver a global development plan and a country-by-country collaboration and commercialization plan, respectively, related to BRILINTA and Angiomax and cangrelor. Implementation of these plans is subject to agreement between both parties.

The first joint activity agreed upon by the parties under the collaboration agreement was a four-year co-promotion arrangement for BRILINTA in the United States. The Company and AstraZeneca have not agreed as to any development and commercialization activities to be performed with respect to Angiomax and cangrelor or as to any terms under which such activities would be performed.

Pursuant to the co-promotion arrangement, the Company's sales force began supporting promotion activities for BRILINTA in May 2012. Under the terms of the collaboration agreement, AstraZeneca agreed to pay the Company base consideration fees for conducting BRILINTA co-promotion activities during the specified periods, plus additional consideration fees for the same periods, if specified performance targets are achieved with respect to the number of new prescriptions written during the specified periods. The Company recognizes as co-promotion revenue both the base consideration fee and the additional consideration related to new prescriptions of BRILINTA as performance requirements are met. The base consideration fee for a specified time period is recognized ratably as our sales force activities meet the required performance target. The additional consideration fee for a specified time period related to the number of new prescriptions of BRILINTA written during the time period is recognized when the number of new prescriptions of BRILINTA exceeds the required performance target for such period. As of June 30, 2013, the Company has recognized a total co-promotion revenue of approximately \$17.8 million from AstraZeneca under the global collaboration agreement.

At the end of the second year of the agreement, AstraZeneca may terminate the agreement if performance targets for the second year are not achieved. Conversely, the Company may terminate the agreement at such time if the performance targets for the second year are achieved. Either party may terminate the agreement at the end of the third year of the agreement. If AstraZeneca elects to terminate the agreement at the end of the third year and the performance targets for the third year have been achieved, AstraZeneca must pay the Company a termination fee of \$5 million.

### Alnylam Pharmaceuticals, Inc.

In February 2013, the Company entered into a license and collaboration agreement with Alnylam Pharmaceuticals, Inc. (Alnylam) to develop, manufacture and commercialize therapeutic products targeting the proprotein convertase

subtilisin/kexin type 9 (PCSK9) gene, based on certain of Alnylam's RNA interference (RNAi) technology. Under the terms of the agreement, the Company obtained the exclusive, worldwide right under Alnylam's technology to develop, manufacture and commercialize PCSK-9 products for the treatment, palliation and/or prevention of all human diseases. Alnylam is responsible for the development costs of the products, subject to an agreed upon limit, until the completion of Phase 1 clinical studies. The Company is responsible for completing and funding the development costs of the products through commercialization, if successful. The Company paid Alnylam \$25 million in an initial license payment, which the Company recorded as research and development expense. The Company has also agreed to pay up to an aggregate of \$180 million in success-based development and commercialization milestones. In addition, the Company has agreed to pay specified royalties on net sales of these products. Royalties to Alnylam are payable by the Company on a product-by-product and country-by-country basis until the last to occur of the expiration of patent rights in the applicable country that cover the applicable product, the expiration of non-patent regulatory exclusivities for such product in such country, and the twelfth anniversary of the first commercial sale of the product in such country, subject to

reduction in specified circumstances. The Company is also responsible for paying royalties, and in some cases, milestone payments, owed by Alnylam to its licensors with respect to intellectual property covering these products. As of June 30, 2013, other than the initial \$25 million license payment, the Company has not made any payments to Alnylam under the agreement.

#### 18. Arbitration Award

The Company received a Demand for Arbitration filed by Eagle Pharmaceuticals, Inc. (Eagle) dated October 25, 2011. In the Demand for Arbitration, Eagle claimed that the Company had failed to meet its obligations under the license and development agreement between the Company, Eagle and certain other parties relating to the development of a new formulation of Angiomax, and to the Company's efforts to seek and obtain regulatory approval, market and sell that new formulation. As a result, Eagle alleged that it was damaged in an amount it believed exceeded \$306.0 million. In January 2013, an arbitration hearing took place before a three person panel. In February 2013, the Company and Eagle submitted post-hearing briefs, and, in April 2013, post-hearing arguments took place. On July 19, 2013, the Company received the final award determination from the three person arbitration panel deciding the matter, which directed that the Company pay Eagle \$5.0 million and denied the remainder of Eagle's claims for \$306.0 million in damages. The Company accrued for the \$5.0 million award in the three months ended June 30, 2013 and expects to pay the award to Eagle in the third quarter of 2013.

#### 19. Subsequent Event

On June 4, 2013, the Company entered into a share purchase agreement with ProFibrix and its equityholders to acquire all of the equity of ProFibrix, subject to the Company's satisfactory review of the then pending Phase 3 clinical trial results of ProFibrix's lead biologic, Fibrocaps. Following the Company's review of the Phase 3 trial results, on August 2, 2013, the Company notified ProFibrix that it wished to proceed to the closing of its acquisition of ProFibrix. The transaction closed on August 5, 2013 and, upon completion of the acquisition, ProFibrix became a wholly owned subsidiary of the Company (see note 13 "Acquisitions").

### 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 biopharmaceutical company focused on saving lives, alleviating suffering and improving the economic efficiency of the world's leading hospitals. We market Angiomax<sup>®</sup> (bivalirudin), Recothrom<sup>®</sup> Thrombin, topical (Recombinant) and Cleviprex<sup>®</sup> (clevidipine) injectable emulsion. We also have a pipeline of acute and intensive care hospital products in development, including three late-stage development product candidates, cangrelor, oritavancin and IONSYST<sup>™</sup> (fentanyl iontophoretic transdermal system), and early stage development product candidates, MDCO-216 and ALN-PCS02 and ALN-PCSsc of the ALN-PCS program. We believe that these marketed products and products in development possess favorable attributes that competitive products do not provide, can satisfy unmet medical needs in the acute and intensive care hospital product market and offer, or, in the case of our

products in development, have the potential to offer, improved performance to hospital businesses.

In addition to these products and product candidates, we sell a ready-to-use formulation of Argatroban and have a portfolio of ten generic drugs, which we refer to as our acute care generic products, that we have the non-exclusive right to market in the United States. We began selling three of our acute care generic products, midazolam, ondansetron and rocuronium, in the first quarter of 2013. We also co-promote the oral tablet antiplatelet medicine BRILINTA® (ticagrelor) in the United States as part of our global collaboration agreement with AstraZeneca LP, or AstraZeneca.

On August 5, 2013, we completed our acquisition of all of the outstanding equity of ProFibrix B.V., or ProFibrix, pursuant to a share purchase agreement entered into with ProFibrix and its equityholders on June 4, 2013. Under the share purchase agreement, the closing of the transaction was subject to our satisfactory review of the then pending Phase 3 clinical trial results of ProFibrix's lead biologic, Fibrocaps™. Fibrocaps is a dry powder topical formulation of fibrinogen and thrombin being developed to help stop bleeding during surgery. Following our review of the Phase 3 trial results, on August 2, 2013, we notified ProFibrix that we

wished to proceed with the consummation of the transaction. Upon the completion of the acquisition, ProFibrix became a wholly owned subsidiary of ours.

The following chart identifies each of our marketed products and our products in development, their stage of development, their mechanism of action and the indications for which they have been approved for use or which they are intended to address. The following chart also identifies each of our acute care generic products and the therapeutic areas which they are intended to address. All of our marketed products and products in development, except for Recothrom, IONSYS, ALN-PCSsc and FibroCaps, are administered intravenously. Recothrom is, and Fibrocaps is being developed as a, topical hemostat, IONSYS is being developed to be administered transdermally and ALN-PCSsc is being developed as a subcutaneous injectable. All of our acute care generic products are injectable products.

Product or Product in Development	Development Stage	Mechanism/Target	Clinical Indication(s)/Therapeutic Areas
Marketed Products			
Angiomax	Marketed	Direct thrombin inhibitor	U.S. - for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty, or PTCA, and for use in patients undergoing percutaneous coronary intervention, or PCI, including patients with or at risk of heparin induced thrombocytopenia and thrombosis syndrome, or HIT/HITTS Europe - for use as an anticoagulant in patients undergoing PCI, adult patients with acute coronary syndrome, or ACS, and for the treatment of patients with ST-segment elevation myocardial infarction, or STEMI, undergoing primary PCI For use as an aid to hemostasis to help control oozing blood and mild bleeding during surgical procedures
Recothrom	Marketed in the United States and Canada	Recombinant human thrombin	
Cleviprex		Calcium channel blocker	

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	Marketed in the United States		U.S. - Blood pressure reduction when oral therapy is not feasible or not desirable
	Approved in Australia, Austria, Canada, France, Germany, the Netherlands, Switzerland and the United Kingdom		Ex-U.S. - with indications for blood pressure control in perioperative settings
	Marketing Authorization Application, or MAA, submitted for other European Union countries		
Ready-to-use Argatroban	Marketed in the United States	Direct thrombin inhibitor	Approved for prophylaxis or treatment of thrombosis in adult patients with HIT and for use as an anticoagulant in adult patients with or at risk for HIT undergoing PCI
Acute care generic products: Midazolam, Ondansetron and Rocuronium	Marketed in the United States	Various	Neurocritical care



Acute care generic products: Adenosine, Amiodarone, Esmolol and Milrinone	Approved in the United States	Various	Cardiovascular
Acute care generic products: Azithromycin and Clindamycin	Approved in the United States	Various	Serious infection
Acute care generic products: Haloperidol	Approved in the United States	Various	Neurocritical care
Products in Development			
Cangrelor	New Drug Application, or NDA, filed in the United States; MAA submission in the European Union planned for the fourth quarter of 2013	Antiplatelet agent	Prevention of platelet activation and aggregation when oral therapy is not feasible or not desirable for use in patients undergoing PCI and patients that require bridging from oral antiplatelet therapy to surgery
Oritavancin	Phase 3 completed; NDA submission in the United States planned for the fourth quarter of 2013; MAA submission in the European Union planned for the first half of 2014	Antibiotic	Treatment of serious gram-positive bacterial infections, including acute bacterial skin and skin structure infections, or ABSSSI, and including infections that are resistant to conventional treatment
Fibrocaps	Phase 3 completed; Biologics License Application, or BLA, submission in the United States planned for the first quarter of 2014; MAA submission in the European Union planned for the fourth quarter of 2014	Dry powder topical formulation of fibrinogen and thrombin	For use as an aid to stop bleeding during surgery
IONSYS	Pre-registration stage; Supplemental New Drug Application, or sNDA, submission planned for first quarter of 2014; MAA submission in European Union planned for second quarter of 2014	Patient-controlled analgesia system	Short-term management of acute postoperative pain
MDCO-216	Phase 1	Naturally occurring variant of a protein found in high-density lipoprotein, or HDL	Reversal cholesterol transport agent to reduce atherosclerotic plaque burden development and thereby reduce the risk of

ALN-PCS program: ALN-PCS02 and ALN-PCSsc	Phase 1	PCSK-9 gene antagonist addressing low-density lipoprotein, or LDL, cholesterol disease modification	adverse thrombotic events  Treatment of hypercholesterolemia
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Our revenues to date have been generated primarily from sales of Angiomax in the United States. In the six months ended June 30, 2013, we had net revenue from sales of Angiomax of approximately \$294.0 million, net revenue from sales of Recothrom of approximately \$26.5 million and net revenue from sales of Cleviprex and ready-to-use Argatroban of approximately \$8.0 million in the aggregate. We commenced sales of Recothrom in February 2013.

We continue to expand our sales and marketing efforts outside the United States. We believe that by establishing operations outside the United States, we can increase our sales of Angiomax outside of the United States and be positioned to commercialize Cleviprex and Recothrom and our products in development, if and when they are approved and ready to be marketed outside of the United States.

Research and development costs are expensed as incurred for licenses of rights to products, clinical trials, nonclinical and preclinical studies, regulatory filings and manufacturing development efforts. We outsource much of our clinical trials, nonclinical and preclinical studies and all of our manufacturing development activities to third parties to maximize efficiency and minimize our internal overhead. Clinical study costs are accrued over the service periods specified in the contracts and adjusted as necessary based upon an ongoing review of the level of effort and costs actually incurred. Payments for a product license prior to regulatory approval of the product and payments for milestones achieved prior to regulatory approval of the product are expensed in the period incurred as research and development. Milestone payments made in connection with regulatory approvals are capitalized and amortized to cost of revenue over the remaining useful life of the asset.

Selling, general and administrative expenses consist primarily of salaries and related expenses, costs associated with 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.

#### Angiomax Patent Litigation

The principal U.S. patents covering Angiomax include U.S. Patent No. 5,196,404, or the '404 patent, U.S. Patent No. 7,582,727, or the '727 patent, and U.S. Patent No. 7,598,343, or the '343 patent.

In the second half of 2009, the U.S. Patent and Trademark Office, or PTO, issued to us the '727 patent and the '343 patent, covering a more consistent and improved Angiomax drug product and the processes by which it is made. The '727 patent and the '343 patent are set to expire in July 2028. In response to Paragraph IV Certification Notice letters we received with respect to abbreviated new drug applications, or ANDAs, filed by a number of parties with the FDA seeking approval to market generic versions of Angiomax, we have filed lawsuits against the ANDA filers alleging patent infringement of the '727 patent and '343 patent.

On September 30, 2011, we settled our '727 patent and '343 patent infringement litigation with Teva Pharmaceuticals USA, Inc. and its affiliates, which we collectively refer to as Teva. In connection with the Teva settlement, we entered into a license agreement with Teva under which we granted Teva a non-exclusive license under the '727 patent and '343 patent to sell a generic bivalirudin for injection product under a Teva ANDA in the United States beginning June 30, 2019 or earlier under certain conditions. The license agreement also contains a grant by Teva to us of an exclusive (except as to Teva), license under Teva's bivalirudin patents and right to enforce Teva's bivalirudin patents.

On January 22, 2012, we settled our patent litigation with APP, including our litigation with respect to the extension of the patent term of the '404 patent and our patent infringement litigation with respect to the '727 patent and the '343 patent. In connection with the APP settlement, we entered into a license agreement with APP under which we granted APP a non-exclusive license under the '727 patent and '343 patent to sell a generic bivalirudin for injection product under an APP ANDA in the United States beginning on May 1, 2019. In certain limited circumstances, the license to APP could become effective prior to May 1, 2019. In addition, in certain limited circumstances, this license to APP could include the right to sell a generic bivalirudin product under our NDA for Angiomax in the United States beginning on May 1, 2019 or, in certain limited circumstances, on June 30, 2019 or on a date prior to May 1, 2019.

We remain in patent infringement litigation involving the '727 patent and '343 patent with other ANDA filers, as described in Part II, Item 1, Legal Proceedings, of this quarterly report. If we are unable to maintain our market exclusivity for Angiomax in the United States through enforcement of our U.S. patents covering Angiomax, then Angiomax could be subject to generic competition earlier than May 1, 2019.

Oritavancin Phase 3 SOLO Clinical Trial Program

In July 2013, we announced the results of our Phase 3 clinical trial program, which was investigating oritavancin for the treatment of ABSSSI caused by susceptible gram-positive bacteria, including methicillin-resistant *Staphylococcus aureus*, or MRSA. The SOLO clinical trial program consisted of the Phase 3 SOLO I and SOLO II clinical trials, which were identical multicenter, double-blind, randomized clinical trials. We reported positive SOLO I results in December 2012 and in July 2013 reported that in SOLO II, all protocol-specified primary and secondary efficacy endpoints were met. The combined SOLO trial data demonstrated that oritavancin and vancomycin efficacy were similar for the Early Clinical Evaluation, or ECE, (or 48-72 hours after treatment initiation) endpoint required by the FDA and the Post Therapy Evaluation, or PTE, (7-14 days after end of treatment) required by the European Medicines Agency, or EMA.

The design of the Phase 3 SOLO clinical trial program was agreed to through the Special Protocol Assessment, or SPA, process with the FDA and was also reviewed formally by the EMA. The Phase 3 trials are designed to support the filing of an NDA in the United States, which we expect to file in the fourth quarter of 2013, as well as an MAA in the Europe Union, which we expect to file in the first half of 2014.

#### Eagle Pharmaceuticals, Inc. Arbitration

We received a Demand for Arbitration filed by Eagle Pharmaceuticals, Inc., or Eagle, dated October 25, 2011. In the Demand for Arbitration, Eagle claimed that we had failed to meet our obligations under the license and development agreement between us, Eagle and certain other parties relating to the development of a new formulation of our product, Angiomax, and to our efforts to seek and obtain regulatory approval, market and sell that new formulation. Eagle, as a result, alleged that it was entitled to an amount of damages totaling \$306.0 million. In January 2013, an arbitration hearing took place before a three person panel. In February 2013, we and Eagle submitted post-hearing briefs, and in April 2013, post-hearing arguments took place. On July 19, 2013, we received the final award determination from the three person arbitration panel deciding the matter, which directed that we pay Eagle \$5.0 million and denied the remainder of Eagle's claims for \$306.0 million in damages. We accrued for the \$5.0 million award in the three months ended June 30, 2013 and expect to pay the award to Eagle in the third quarter of 2013.

#### Business Development Activity

ProFibrix B.V. On August 5, 2013, we completed our acquisition of all of the outstanding equity of ProFibrix, pursuant to a share purchase agreement entered into with ProFibrix and its equityholders on June 4, 2013. Under the share purchase agreement, the closing of the transaction was subject to our satisfactory review of the then pending Phase 3 clinical trial results of ProFibrix's lead biologic, Fibrocaps. In connection with entering into the agreement, we paid ProFibrix a \$10.0 million option payment. Upon the completion of the acquisition, ProFibrix became our wholly owned subsidiary.

ProFibrix does not have any marketed products and has been engaged since its inception in developing fibrinogen based products for the hemostasis and regenerative medicine markets. Fibrocaps, the proposed name of ProFibrix's lead biologic, is a dry powder topical formulation of fibrinogen and thrombin being developed to help stop bleeding during surgery. On August 5, 2013, in connection with the closing, we announced that the Phase 3 clinical trial of Fibrocaps, FINISH-3, which studied 719 surgical patients with mild to moderate surgical bleeding, met all primary and secondary hemostasis efficacy endpoints in four distinct surgical indications of spinal surgery, hepatic resection, soft tissue dissection and vascular surgery.

Following our review of the Phase 3 trial results, on August 2, 2013, we notified ProFibrix that we wished to proceed with the consummation of the transaction. At the closing, we paid an aggregate purchase price of \$90 million in cash, plus an additional \$4.0 million based on a preliminary closing adjustment. We deposited \$9.0 million of the purchase price into an escrow fund for the purpose of (i) securing the indemnification obligations of the ProFibrix equityholders and optionholders to us for any and all losses for which we are entitled to indemnification under the share purchase agreement, and (ii) providing the source of recovery for any amounts payable to us as a result of the post-closing purchase price adjustment process.

Under the terms of the share purchase agreement, we are also obligated to pay up to an aggregate of \$140.0 million in cash to the ProFibrix equityholders and optionholders upon the achievement of certain U.S. and European regulatory approvals prior to January 1, 2016 and certain U.S. and European sales milestones during the 24-month period that follows the initial commercial sale of Fibrocaps. We expect amortization of intangibles and incremental operating expenses associated with the transaction, including \$4.0 million of one-time deal costs, to be approximately \$9.0 million to \$12.0 million in the third quarter of 2013 and \$19.0 million to \$22.0 million in the second half of 2013. Due to the limited time since the closing of the acquisition on August 5, 2013, the accounting for this business

combination is incomplete and, as a result, these estimates are preliminary in nature and subject to change.

ALN-PCS Program. In February 2013, we entered into a license and collaboration agreement with Alnylam Pharmaceuticals, Inc., or Alnylam, to develop, manufacture and commercialize therapeutic products targeting the human PCSK-9 gene based on certain of Alnylam's RNAi technology. Under the terms of the agreement, we obtained the exclusive, worldwide right under Alnylam's technology to develop, manufacture and commercialize PCSK-9 products for the treatment, palliation and/or prevention of all human diseases. We paid Alnylam \$25.0 million in an initial license payment and agreed to pay, upon achievement of certain milestones, up to \$180.0 million, including up to \$30.0 million in specified development milestones, \$50.0 million in specified regulatory milestones and \$100.0 million in specified commercialization milestones. In addition, Alnylam will be eligible to receive scaled double-digit royalties based on annual worldwide net sales of PCSK-9 products by us or our affiliates and sublicensees. Royalties to Alnylam are payable on a product-by-product and country-by-country basis until the last to occur of the expiration of patent rights in the applicable country that cover the applicable product, the expiration of non-patent regulatory exclusivities for such product in such country, and the twelfth anniversary of the first commercial sale of the product in such

country. The royalties are subject to reduction in specified circumstances. We are also responsible for paying royalties, and in some cases milestone payments, owed by Alnylam to its licensors with respect to intellectual property covering these products.

Recothrom. In February 2013, pursuant to a master transaction agreement with BMS, we acquired the right to sell, distribute and market Recothrom on a global basis for a two-year period, which we refer to as the collaboration term, and certain limited assets exclusively related to Recothrom, primarily the biologics license application for Recothrom and certain related regulatory assets. BMS also granted to us, under the master transaction agreement, an option to purchase from BMS and its affiliates, following the expiration or earlier termination of the collaboration term, certain other assets, including certain patent and trademark rights, contracts, inventory, equipment and related books and records, held by BMS which are exclusively related to Recothrom.

Under the master transaction agreement, we paid to BMS a one-time collaboration fee equal to \$105.0 million and a one-time option fee equal to \$10.0 million. We did not assume, and if we exercise the option, we will not assume, any pre-existing liabilities related to the Recothrom business, contingent or otherwise, arising prior to the collaboration period, and we did not acquire, and if we exercise the option, we will not acquire, any significant tangible assets related to the Recothrom business. Under the master transaction agreement, we agreed to pay to BMS quarterly tiered royalty payments during the two-year collaboration term equal to a percentage of worldwide net sales of Recothrom. If we exercise the option, we would acquire such assets and assume certain liabilities of BMS and its affiliates related to those assets and to pay to BMS a purchase price equal to the net book value of inventory included in the acquired assets, plus either:

a multiple of average net sales over each of the two 12-month periods preceding the closing of the purchase of the assets to be acquired in connection with exercising the option (unless such closing occurs less than 24 months after February 8, 2013, in which case the measurement period would be the 12-month period preceding such closing); or if BMS has delivered a valid notice terminating the collaboration term early as a result of a material breach by us under the master transaction agreement, the amount described above plus an amount intended to give BMS the economic benefit of having received royalty fees for a 24-month collaboration term.

We accounted for the transaction as a business combination and are in the process of finalizing the valuation of intangible assets.

Incline Therapeutics, Inc. In January 2013, we acquired Incline Therapeutics, Inc., or Incline, a company focused on the development of IONSYS, a compact, disposable, needleless patient-controlled system for the short-term management of acute postoperative pain in the hospital setting.

Under the terms of our agreement with Incline, we paid to the holders of Incline's capital stock and the holders of options to purchase shares of Incline's capital stock, or collectively, the Incline equityholders, an aggregate of approximately \$155.2 million in cash, which is subject to a post-closing purchase price adjustment process. In addition, we also paid approximately \$13 million to Cadence Pharmaceuticals, Inc., or Cadence, to terminate Cadence's option to acquire Incline pursuant to an agreement between Cadence and Incline and deposited \$18.5 million in cash into an escrow fund for the purposes of securing the indemnification obligations of the Incline equityholders to us for any and all losses for which we are entitled to indemnification pursuant to the merger agreement and to provide the source of recovery for any amounts payable to us as a result of the post-closing purchase price adjustment process.

Under the terms of our agreement with Incline, we agreed to pay up to \$205 million in cash in the aggregate, less certain transaction expenses and taxes, upon our entering into a license agreement in Japan, achieving certain regulatory approval and certain sales milestones with respect to IONSYS.

We accounted for the Incline transaction as a business combination and are in the process of finalizing the valuation of intangible assets and fair value of the contingent purchase price.

Collaboration with AstraZeneca. On April 25, 2012, we entered into a global collaboration agreement with AstraZeneca, LP, or AstraZeneca, pursuant to which we and AstraZeneca agreed to collaborate globally to develop

and commercialize certain acute ischemic heart disease compounds. Under the terms of the collaboration agreement, a joint development and research committee and a joint commercialization committee have been established to prepare and deliver a global development plan and a country-by-country collaboration and commercialization plan, respectively, related to BRILINTA and Angiomax and cangrelor. Implementation of these plans is subject to agreement between both parties. The first joint activity agreed upon by the parties under the global collaboration is a four-year co-promotion arrangement for BRILINTA in the United States. Pursuant to the agreement, our sales force began supporting promotion activities for BRILINTA in May 2012. Under the terms of the agreement, AstraZeneca paid us \$2.5 million for conducting BRILINTA co-promotion activities in the second quarter of 2012. In addition, under the terms of the agreement, AstraZeneca paid us \$7.5 million in base consideration for conducting BRILINTA co-promotion



activities during the period from July 1, 2012 to December 31, 2012 and agreed to pay us \$15.0 million in base consideration per year from 2013 through 2015 for conducting BRILINTA co-promotion activities, plus up to an additional \$5.0 million per year from 2013 to 2015 if certain performance targets with respect to new prescriptions are achieved and \$7.5 million in base consideration for conducting BRILINTA co-promotion activities during the period from January 1, 2016 until June 30, 2016, plus up to an additional \$2.5 million in additional consideration for the same period if certain performance targets with respect to new prescriptions are achieved. In the first six months of 2013, AstraZeneca has paid us \$7.8 million under the agreement.

#### Convertible Senior Note Offering

On June 11, 2012, we completed our private offering of \$275.0 million aggregate principal amount of our 1.375% convertible senior notes due 2017, or the Notes, and entered into an indenture with Wells Fargo Bank, National Association, a national banking association, as trustee, or the Trustee, governing the Notes, which we refer to as the Indenture. The net proceeds from the offering were \$266.2 million, after deducting the initial purchasers' discounts and commissions and our offering expenses.

The Notes bear cash interest at a rate of 1.375% per year, payable semi-annually on June 1 and December 1 of each year. We made our first payment of cash interest on the Notes on December 1, 2012 in the aggregate amount of \$1.8 million. The Notes will mature on June 1, 2017. The Notes do not contain any financial or operating covenants or any restrictions on the payment of dividends, the incurrence of other indebtedness, or the issuance or repurchase of securities by us.

The Notes are our senior unsecured obligations and will rank senior in right of payment to our future indebtedness, if any, that is expressly subordinated in right of payment to the Notes and equal in right of payment to our existing and future unsecured indebtedness that is not so subordinated. The Notes are effectively junior in right of payment to any of our secured indebtedness to the extent of the value of the assets securing such indebtedness and are structurally junior to all existing and future indebtedness and other liabilities, including trade payables, incurred by our subsidiaries.

Holder may convert their Notes at their option at any time prior to the close of business on the business day immediately preceding March 1, 2017 only under certain specified circumstances which are set forth in the Indenture. On or after March 1, 2017, until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their Notes at any time, regardless of the foregoing circumstances. Upon conversion, we will pay cash up to the aggregate principal amount of the Notes to be converted and deliver shares of our common stock in respect of the remainder, if any, of our conversion obligation in excess of the aggregate principal amount of the Notes being converted, subject to a daily share cap, as described in the Indenture. Holders of Notes will not receive any additional cash payment or additional shares representing accrued and unpaid interest, if any, upon conversion of a note, except in limited circumstances. Instead, accrued but unpaid interest will be deemed to be paid by the cash and shares, in any, of our common stock, together with any cash payment for any fractional share, paid or delivered, as the case may be, upon conversion of a Note.

The conversion rate for the Notes was initially, and remains, 35.8038 shares of our common stock per \$1,000 principal amount of Notes, which is equivalent to an initial conversion price of \$27.93 per share of our common stock. The conversion rate and the conversion price are subject to customary adjustments for certain events, including, but not limited to, the issuance of certain stock dividends on our common stock, the issuance of certain rights or warrants, subdivisions, combinations, distributions of capital stock, indebtedness, or assets, cash dividends and certain issuer tender or exchange offers, as described in the Indenture.

We may not redeem the Notes prior to maturity and are not required to redeem or retire the Notes periodically. However, upon the occurrence of a "fundamental change", as defined in the Indenture, subject to certain conditions, in lieu of converting their Notes, holders may require us to repurchase for cash all or part of their Notes at a repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. Following certain corporate transactions that constitute a change of control, we will increase the conversion rate for a holder who elects to convert the Notes in connection with such change of control in certain circumstances.

The Indenture contains customary events of default with respect to the Notes, including that upon certain events of default, including our failure to make any payment of principal or interest on the Notes when due and payable, occurring and continuing, the Trustee by notice to us, or the holders of at least 25% in principal amount of the outstanding Notes by notice to us and the Trustee, may, and the Trustee at the request of such holders, subject to the provisions of the Indenture, shall, declare 100% of the principal of and accrued and unpaid interest, if any, on all the Notes to be due and payable. In case of an event of default involving certain events of bankruptcy, insolvency or reorganization, involving us or a significant subsidiary of ours, 100% of the principal of and accrued and unpaid interest on the Notes will automatically become due and payable. Upon a declaration of acceleration, such principal and accrued and unpaid interest, if any, will be due and payable immediately.

#### Convertible Note Hedge and Warrant Transactions

On June 5, 2012, we entered into convertible note hedge transactions and warrant transactions with several of the initial purchasers of the Notes, their respective affiliates and other financial institutions, which we refer to as the Hedge Counterparties.

We used approximately \$19.8 million of the net proceeds from the offering of the Notes to pay the cost of the convertible note hedge transactions, after such cost was partially offset by the proceeds to us from the sale of warrants in the warrant transactions.

We expect the convertible note hedge transactions to reduce the potential dilution with respect to shares of our common stock upon any conversion of the Notes in the event that the market price per share of our common stock, as measured under the terms of the convertible note hedge transactions, is greater than the strike price of the convertible note hedge transactions, which initially corresponds to the conversion price of the Notes and is subject to anti-dilution adjustments substantially similar to those applicable to the conversion rate of the Notes. The warrant transactions will have a dilutive effect with respect to our common stock to the extent that the market price per share of our common stock, as measured under the terms of the warrant transactions, exceeds the applicable strike price of the warrants. However, subject to certain conditions, we may elect to settle all of the warrants in cash.

#### Share Repurchase

We used approximately \$50.0 million of the net proceeds of the offering of the Notes to repurchase 2,192,982 shares of our common stock in a privately negotiated transaction with one of the purchasers of the Notes. We repurchased the shares of our common stock in this transaction at a price of \$22.80 per share, which was the last reported sale price per share of our common stock on June 5, 2012, the date that we priced the private offering of the Notes.

#### Ready-to-Use Argatroban Recall

In December 2011, Eagle conducted a voluntary recall of ready-to-use Argatroban due to the presence of particulate matter in some vials. As a result, we were not able to sell ready-to-use Argatroban from December 2011 to April 2012. In April 2012, we re-commenced selling ready-to-use Argatroban to existing and new customers.

#### Biogen Letter Agreement

On August 7, 2012, we and Biogen Idec MA Inc., or Biogen, entered into a letter agreement resolving a disagreement between the parties as to the calculation and amount of the royalties required to be paid to Biogen by us under our license agreement with Biogen. The letter agreement amends the license agreement providing, among other things, that effective solely for the period from January 1, 2013 through and including December 15, 2014, each of the royalty rate percentages payable by us as set forth in the license agreement shall be increased by one percentage point.

#### MDCO-157 License Termination

Based on our review of data from the pharmacokinetic and pharmacodynamic study of several doses of MDCO-157 and oral clopidogrel in healthy volunteers, we believe it is unlikely that MDCO-157 will achieve dose equivalence with oral clopidogrel at approved doses. As a result, on July 30, 2013 we entered into a termination agreement with CyDex Pharmaceuticals, Inc., or CyDex, a subsidiary of Ligand Pharmaceuticals Incorporated, to mutually terminate our license agreement with CyDex. The rights to MDCO-157 reverted to CyDex upon execution of the termination agreement.

#### MDCO-2010 Development Discontinuation

On October 4, 2012, we voluntarily discontinued our Phase 2b dose-ranging study of MDCO-2010, a serine protease inhibitor which was being developed to reduce blood loss during surgery. We took this action in response to serious unexpected patient safety issues encountered during the trial, which at the time the trial was discontinued, had enrolled 44 of a planned 90 patients in the first stage of the study.

While we continue to investigate the cause of the safety issues and any potential link to the study drug, we decided to end the trial and further development of MDCO-2010 because of the evidence of risk to patients. We are conducting an assessment of patient data from the study. Once this evaluation is completed and reviewed with experts in the field,

we plan to publish our findings.

#### Workforce Reduction

On February 27, 2013, we commenced a workforce reduction plan intended to improve efficiency and better align our costs and employment structure with our strategic plans. As a result of the workforce reduction, we reduced our personnel by 66 employees. In the three and six months ended June 30, 2013, we recorded, in the aggregate, charges of \$6.4 million associated with the workforce reduction. We recorded these charges in cost of revenue, research and development expense and selling general and administrative expense based on the responsibilities of the affected employees. Of the approximately \$6.4 million of charges

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related to the 2013 workforce reduction, \$1.3 million were non-cash charges, we paid \$5.5 million during the six months ended June 30, 2013, and we expect to pay out \$0.6 million during the remainder of 2013.

#### U.S. Health Care Reform

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, or PPACA, which was amended by the Health Care and Education Reconciliation Act of 2010. The PPACA, as amended, contains numerous provisions that impact the pharmaceutical and healthcare industries that are expected to be implemented over the next several years. We are continually evaluating the impact of the PPACA on our business. As of the date of this quarterly report, we have not identified any provisions that currently materially impact our business or results of operations. However, we believe that the Biologics Price Competition and Innovation Act, or BPCIA, provisions of PPACA could impact our business or results of operations. Under the BPCIA, the FDA has the authority to approve biosimilar interchangeable versions of biological products through an abbreviated pathway following periods of data and marketing exclusivity. However, the potential impact of the PPACA and the BPCIA on our business and results of operations is inherently difficult to predict because many of the details regarding the implementation of this legislation have not been determined. In addition, the impact on our business and results of operations may change as and if our business evolves.

On July 9, 2012, President Obama signed the Food and Drug Administration Safety and Innovation Act, or FDASIA. Under the “Generating Antibiotic Incentives Now,” or GAIN, provisions of FDASIA, the FDA may designate a product as a qualified infectious disease product, or QIDP. A QIDP is defined as an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by either an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens or a so-called “qualifying pathogen” found on a list of potentially dangerous, drug-resistant organisms to be established and maintained by the FDA under the new law. The GAIN provisions describe several examples of “qualifying pathogens,” including methicillin-resistant *Staphylococcus aureus*, or MRSA, and *Clostridium difficile*. Upon the designation of a drug by the FDA as a QIDP, any non-patent exclusivity period awarded to the drug will be extended by an additional five years. This extension is in addition to any pediatric exclusivity extension awarded.

We are currently developing oritavancin for the treatment of ABSSSI, including infections caused by MRSA, and are exploring the development of oritavancin for other indications, including for the treatment of *Clostridium difficile*, prosthetic joint infections, anthrax and other Gram-positive bacterial infections. We believe that oritavancin may qualify as a QIDP and intend to request that oritavancin be designated as a QIDP. If we are successful in having oritavancin designated as a QIDP by the FDA under the GAIN provisions of the new FDASIA legislation, we expect the non-patent exclusivity awarded to oritavancin upon approval of an NDA to be extended by an additional five years.

#### Results of Operations

##### Net Revenue:

Net revenue increased 27.4% to \$172.8 million for the three months ended June 30, 2013 as compared to \$135.7 million for the three months ended June 30, 2012.

Net revenue increased 25.3% to \$328.6 million for the six months ended June 30, 2013 as compared to \$262.3 million for the six months ended June 30, 2012.

The following tables reflect the components of net revenue for the three and six months ended June 30, 2013 and 2012:

Net Revenue

	Three Months Ended June 30,		Change \$	Change %	
	2013	2012			
		(in thousands)			
Angiomax	\$151,159	\$133,101	\$18,058	13.6	%
Recothrom	17,925	—	17,925	100.0	%
Cleviprex/Ready-to-Use Argatroban	3,742	2,601	1,141	43.9	%
Total net revenue	\$172,826	\$135,702	\$37,124	27.4	%

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	Six Months Ended June 30,		Change \$	Change %	
	2013	2012			
		(in thousands)			
Angiomax	\$294,045	\$259,210	\$34,835	13.4	%
Recothrom	26,547	—	26,547	100.0	%
Cleviprex/Ready-to-Use Argatroban	7,987	3,102	4,885	157.5	%
Total net revenue	\$328,579	\$262,312	\$66,267	25.3	%

Net revenue increased by \$37.1 million, or 27.4%, to \$172.8 million in the three months ended June 30, 2013 compared to \$135.7 million in the three months ended June 30, 2012, reflecting increases of \$35.8 million, or 28.9%, in the United States and \$1.3 million, or 11.0%, in international markets. The net revenue increase was comprised of net volume increases of \$29.0 million due to increased unit shipments to customers of Angiomax and Recothrom, which we first began selling in February 2013, and price increases of \$8.9 million, principally due to a price increase for Angiomax effective as of January 1, 2013 in the United States, which were offset by the unfavorable impact from foreign exchange of \$0.8 million.

Net revenue increased by \$66.3 million, or 25.3%, to \$328.6 million in the six months ended June 30, 2013 compared to \$262.3 million in the six months ended June 30, 2012, reflecting increases of \$64.0 million, or 26.7%, in the United States and \$2.2 million, or 9.9%, in international markets. The net revenue increase was comprised of net volume increases of \$50.8 million due to increased unit shipments to customers of Angiomax and Recothrom which we first began selling in February 2013 and price increases of \$15.9 million, principally due to a price increase for Angiomax effective as of January 1, 2013 in the United States, which were offset by the unfavorable impact from foreign exchange of \$0.4 million.

Angiomax. Net revenue from sales of Angiomax increased by \$18.1 million, or 13.6%, to \$151.2 million in the three months ended June 30, 2013 compared to \$133.1 million in the three months ended June 30, 2012, primarily due to the January 1, 2013 price increase in the United States as of January 1, 2013 and increased unit sales globally. Net revenue in the United States in both the three months ended June 30, 2013 and 2012 reflect chargebacks related to the 340B Drug Pricing Program and rebates related to the PPACA. Under the 340B Drug Pricing Program, we offer qualifying entities a discount off the commercial price of Angiomax for patients undergoing PCI on an outpatient basis. Chargebacks related to the 340B Drug Pricing Program increased by \$1.8 million to \$14.5 million in the three months ended June 30, 2013 compared to \$12.7 million in the three months ended June 30, 2012, primarily due to higher amounts paid to eligible hospital customers. Rebates related to the PPACA increased by \$0.2 million to \$0.4 million in the three months ended June 30, 2013 compared to \$0.2 million in the three months ended June 30, 2012. Net revenue from sales of Angiomax outside the United States increased in the three months ended June 30, 2013 compared to the three months ended June 30, 2012 due to greater demand by existing hospital customers and the addition of new hospital customers in France, the United Kingdom, Italy, Sweden and Switzerland, which was offset by lower demand in Russia.

Net revenue from sales of Angiomax increased by \$34.8 million, or 13.4%, to \$294.0 million in the six months ended June 30, 2013 compared to \$259.2 million in the six months ended June 30, 2012, primarily due to a price increase in the United States and increased unit sales globally. Net revenue in the United States in both the six months ended June 30, 2013 and 2012 reflect chargebacks related to the 340B Drug Pricing Program under the Public Health Service Acts and rebates related to the PPACA. Chargebacks related to 340B Drug Pricing Program increased by \$3.1 million to \$25.2 million in the six months ended June 30, 2013 compared to \$22.1 million in the six months ended June 30, 2012, primarily due to increased usage by eligible hospital customers. Rebates related to the PPACA increased by \$0.3 million to \$0.7 million in the six months ended June 30, 2013 compared to \$0.4 million in the six months ended June 30, 2012. Net revenue from sales of Angiomax outside the United States increased in the six months ended June 30, 2013 compared to the six months ended June 30, 2012 due to greater demand by existing hospital customers

and the addition of new hospital customers in France, the United Kingdom, Italy, and Sweden, which was offset by lower demand in Russia.

Recothrom. Net revenue from Recothrom was \$17.9 million and \$26.5 million for the three and six month period ended June 30, 2013, respectively. We commenced sales of Recothrom on February 8, 2013 pursuant to the master transaction agreement with BMS.

Cleviprex/Ready-to-Use Argatroban. Net revenue from sales of Cleviprex and ready-to-use Argatroban increased by \$1.1 million to \$3.7 million in the three months ended June 30, 2013 from \$2.6 million in the three months ended June 30, 2012. Net revenue from sales of Cleviprex was \$1.1 million in the three months ended June 30, 2013, compared to \$0.6 million in the three months ended June 30, 2012. Net revenue from sales of ready-to-use Argatroban was \$2.6 million in the three months ended June 30, 2013 and \$2.0 million in the three months ended June 30, 2012.



Net revenue from sales of Cleviprex and ready-to-use Argatroban increased by \$4.9 million to \$8.0 million in the six months ended June 30, 2013 from \$3.1 million in the six months ended June 30, 2012. Net revenue from sales of Cleviprex was \$2.2 million in the six months ended June 30, 2013, compared to \$1.1 million in the six months ended June 30, 2012. Net revenue from sales of ready-to-use Argatroban was \$5.8 million in the six months ended June 30, 2013 and \$2.0 million in the six months ended June 30, 2012.

Our net revenue from sales of ready-to-use Argatroban in the 2012 periods was adversely impacted by the recall of the product in December 2011, as we did not sell ready-to-use Argatroban from December 2011 to April 2012.

Cost of Revenue:

Cost of revenue in the three months ended June 30, 2013 was \$63.9 million, or 37.0% of net revenue, compared to \$42.7 million, or 31.5% of net revenue, in the three months ended June 30, 2012.

Cost of revenue in the six months ended June 30, 2013 was \$120.7 million, or 36.7% of net revenue, compared to \$81.3 million, or 31.0% of net revenue, in the six months ended June 30, 2012.

Cost of revenue during these periods consisted of:

- expenses in connection with the manufacture of our products sold;

- royalty expenses under our agreements with Biogen and Health Research Inc., or HRI, related to Angiomax, our agreement with AstraZeneca related to Cleviprex, our agreement with Eagle related to ready-to-use Argatroban;

- amortization of the costs of license agreements, product rights and other identifiable intangible assets, which result from product and business acquisitions; and

- logistics costs related to Angiomax, Cleviprex and ready-to-use Argatroban, including distribution, storage, and handling costs.

Cost of revenue during the three and six months ended June 30, 2013 also includes expenses related to our license agreement with BMS for Recothrom and expenses related to our supply agreement for Recothrom with BMS including product cost and logistics as well as royalties and amortization related to Recothrom.

#### Cost of Revenue

	Three Months Ended June 30,				Six Months Ended June 30,				
	2013	% of Total	2012	% of Total	2013	% of Total	2012	% of Total	
	(in thousands)		(in thousands)		(in thousands)		(in thousands)		
Manufacturing/Logistics	\$19,791	31 %	\$12,076	28 %	\$38,442	32 %	\$23,181	28 %	
Royalty	39,146	61 %	30,379	71 %	73,408	61 %	57,711	71 %	
Amortization of product rights and intangible assets	5,001	8 %	226	1 %	8,803	7 %	452	1 %	
Total cost of revenue	\$63,938	100 %	\$42,681	100 %	\$120,653	100 %	\$81,344	100 %	

Cost of revenue increased by \$21.3 million during the three months ended June 30, 2013 compared to the three months ended June 30, 2012 and increased by \$39.3 million during the six months ended June 30, 2013 compared to

the six months ended June 30, 2012. These increases were primarily due to an increase in royalty expense to Biogen due to higher royalty-bearing sales under our agreement with Biogen, an increased royalty rate which commenced on January 1, 2013 under the letter agreement that we entered into with Biogen on August 7, 2012 and royalties to BMS in connection with our sales of Recothrom which commenced in February 2013. Manufacturing and logistics costs increases were associated with Recothrom. The increase in amortization of product rights and intangible assets reflects the amortization of product rights and intangible assets associated with Recothrom.

Research and Development Expenses:

Research and development expenses decreased to \$27.0 million for the three months ended June 30, 2013, compared to \$33.0 million for the three months ended June 30, 2012. The decrease is primarily the result of the completion of patient enrollments in our Phase 3 clinical trials of cangrelor in October 2012 and oritavancin in April 2013, and the discontinuation of the MDCO-2010 clinical program in October 2012. These decreases were offset by the initiation of clinical trials for Angiomax and MDCO-216 and spending on manufacturing development for IONSYS, following our January 2013 acquisition of Incline.

Research and development expenses increased to \$85.2 million for the six months ended June 30, 2013, compared to \$65.7 million for the six months ended June 30, 2012. The increase reflects costs incurred in connection with our business development activities, including the payment of \$25.0 million related to our license and collaboration agreement with Alnylam, spending on manufacturing development for IONSYS, following our acquisition of Incline, increased Angiomax clinical expenses associated with new trials and the initiation of a Phase 1 clinical trial of MDCO-216 in healthy volunteers. These increases were offset by decreased clinical trial expenses related to our Phase 3 products of cangrelor and oritavancin and the discontinuation of the MDCO-2010 clinical program in October 2012.

We expect to continue to invest in the development of Angiomax, Cleviprex and our products in development, during the remainder of 2013 and that our research and development expenses will increase in 2013 from their levels in 2012. In addition, we expect to invest in the development of Fibrocaps. We expect research and development expenses in 2013 to include costs associated with our license and collaboration agreement with Alnylam, global regulatory activities related to oritavancin, IONSYS, Cleviprex, cangrelor and Fibrocaps, manufacturing development activities for Angiomax, Cleviprex, cangrelor, MDCO-216, IONSYS and Fibrocaps, and our Phase 1 clinical trial of MDCO-216.

The following tables identify for each of our major research and development projects our spending for the three and six months ended June 30, 2013 and June 30, 2012. The table for the three months ended June 30, 2013 and June 30, 2012 does not include an ALN-PCS program as we did not incur any research and development expenses for such program during such period. Spending for past periods is not necessarily indicative of spending in future periods.

## Research and Development Spending

	Three Months Ended June 30,					
	2013	% of		2012	% of	
	(In	Total R&D		(In	Total R&D	
	thousands)			thousands)		
Angiomax						
Clinical trials	\$3,717	14	%	\$900	3	%
Manufacturing development	3	—	%	17	—	%
Administrative and headcount costs	2,091	8	%	660	2	%
Total Angiomax	5,811	22	%	1,577	5	%
Cleviprex						
Clinical trials	—	—	%	193	1	%
Manufacturing development	274	1	%	506	2	%
Administrative and headcount costs	647	2	%	384	1	%
Total Cleviprex	921	3	%	1,083	4	%
Cangrelor						
Clinical trials	983	4	%	10,646	32	%
Manufacturing development	968	4	%	562	2	%
Administrative and headcount costs	4,488	17	%	1,543	5	%
Total Cangrelor	6,439	25	%	12,751	39	%
Oritavancin						
Clinical trials	1,308	5	%	7,840	24	%
Manufacturing development	960	4	%	1,901	6	%
Administrative and headcount costs	3,134	12	%	1,103	3	%
Total Oritavancin	5,402	21	%	10,844	33	%
MDCO-157						
Clinical trials	23	—	%	68	—	%
Manufacturing development	167	1	%	256	1	%
Administrative and headcount costs	321	1	%	552	2	%
Total MDCO-157	511	2	%	876	3	%
MDCO-2010						
Clinical trials	—	—	%	290	1	%
Manufacturing development	—	—	%	404	1	%
Administrative and headcount costs	—	—	%	700	2	%
Total MDCO-2010	—	—	%	1,394	4	%
MDCO-216						
Clinical trials	373	1	%	294	1	%
Manufacturing development	710	3	%	368	1	%
Administrative and headcount costs	981	4	%	372	1	%
Total MDCO-216	2,064	8	%	1,034	3	%
IONSYS						
Clinical trials	114	—	%	—	—	%
Manufacturing development	2,268	8	%	—	—	%
Administrative and headcount costs	2,204	8	%	—	—	%
Total IONSYS	4,586	16	%	—	—	%
Other	1,291	3	%	3,403	10	%
Total	\$27,025	100	%	\$32,962	100	%



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	Six Months Ended June 30,				
	2013	% of	2012	% of	
	(In	Total R&D	(In	Total R&D	
	thousands)		thousands)		
Angiomax					
Clinical trials	\$5,381	6	% \$2,480	4	%
Manufacturing development	9	—	% 56	—	%
Administrative and headcount costs	3,606	5	% 1,045	1	%
Total Angiomax	8,996	11	% 3,581	5	%
Cleviprex					
Clinical trials	—	—	% 188	—	%
Manufacturing development	311	—	% 687	1	%
Administrative and headcount costs	1,320	2	% 730	1	%
Total Cleviprex	1,631	2	% 1,605	2	%
Cangrelor					
Clinical trials	2,132	3	% 23,079	35	%
Manufacturing development	1,914	2	% 1,180	2	%
Administrative and headcount costs	7,858	9	% 3,002	4	%
Total Cangrelor	11,904	14	% 27,261	41	%
Oritavancin					
Clinical trials	9,474	11	% 15,478	23	%
Manufacturing development	4,107	5	% 1,957	3	%
Administrative and headcount costs	5,586	7	% 2,393	4	%
Total Oritavancin	19,167	23	% 19,828	30	%
MDCO-157					
Clinical trials	406	—	% 100	—	%
Manufacturing development	248	—	% 413	1	%
Administrative and headcount costs	646	1	% 1,233	2	%
Total MDCO-157	1,300	1	% 1,746	3	%
MDCO-2010					
Clinical trials	—	—	% 418	1	%
Manufacturing development	—	—	% 626	1	%
Administrative and headcount costs	—	—	% 1,418	2	%
Total MDCO-2010	—	—	% 2,462	4	%
MDCO-216					
Clinical trials	598	1	% 397	1	%
Manufacturing development	1,306	2	% 1,082	2	%
Administrative and headcount costs	1,843	2	% 651	1	%
Total MDCO-216	3,747	5	% 2,130	4	%
IONSYS					
Clinical trials	864				
Manufacturing development	3,329	4	% —	—	%
Administrative and headcount costs	4,463	5	% —	—	%
Total IONSYS	8,656	9	% —	—	%
ALN-PCS Program					
Administrative and headcount costs	25,000	29	% —	—	%
Total ALN-PCS Program	25,000	29	% —	—	%
Other	4,820	6	% 7,127	11	%

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Total	\$85,221	100	%	\$65,740	100	%
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Angiomax

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Research and development expenditures related to Angiomax during the three months ended June 30, 2013 increased by approximately \$4.2 million compared to the three months ended June 30, 2012. Clinical trial costs increased by \$2.8 million, primarily due to increased expenditures in connection with our EUROMAX, BRAVO-2 and GLOBAL LEADERS trials. Administrative and headcount costs increased by \$1.4 million primarily due to our efforts to further develop Angiomax for use in additional patient populations globally.

Research and development expenditures related to Angiomax during the six months ended June 30, 2013 increased by \$5.4 million compared to the six months ended June 30, 2012. Clinical trial costs increased by \$2.9 million and administrative and headcount costs increased by \$2.6 million. These increases were primarily due to our efforts to further develop Angiomax for use in additional patient populations globally.

During the three months ended June 30, 2013, we completed enrollment in our EUROMAX trial. In the trial, we enrolled 2,200 patients at sites in seven European countries to assess whether the early administration of Angio in STEMI patients intended for primary PCI presenting either via ambulance or to referral centers where PCI is not performed improves 30-day outcomes when compared to the current standard of care, heparin plus an optional glycoprotein IIb/IIIa receptor inhibitor, or GP IIb/IIIa inhibitor. We commenced enrollment in our EUROMAX clinical trial in March 2010. We anticipate presenting the data from this trial in the second half of 2013.

During the three months ended June 30, 2013, we commenced activity related to our GLOBAL LEADERS trial and continued enrollment in our BRAVO-2 trial. GLOBAL LEADERS trial is an investigator-driven trial in which we aim to enroll approximately 16,000 patients to compare the effectiveness of two different pharmaco-intervention strategies. The main objective of this study is to determine if there is a better medication strategy involving Angiomax to prevent blood from clotting and at the same time minimize the number of complications following a stent procedure than the current common practice of prescribing anti-platelet medication to prevent the blood from clotting. BRAVO-2 is a clinical trial that we are conducting in patients undergoing transcatheter aortic valve replacement, or TAVR, to determine the treatment effect (both safety and efficacy) of using Angiomax instead of heparin. We commenced enrollment in our BRAVO-2 clinical trial in October 2012. As of June 30, 2013, we had enrolled 275 patients in the trial.

We expect that our total research and development expenses relating to Angiomax will increase in 2013 as compared to 2012 levels in connection with our efforts to further develop Angiomax for use in additional patient populations, including our GLOBAL LEADERS and BRAVO-2 trials, as well as continued research and development expenses related to our product lifecycle management activities.

#### Cleviprex

Research and development expenditures related to Cleviprex decreased by approximately \$0.2 million during the three months ended June 30, 2013 compared to the three months ended June 30, 2012. The decrease in 2013 was primarily due to a decrease in manufacturing development costs related to product lifecycle activities and a decrease in clinical trial costs. These decreased costs were offset in part by increased regulatory costs in connection with our efforts to obtain marketing approval of Cleviprex outside the United States.

Research and development expenditures related to Cleviprex remained the same during the six months ended June 30, 2013 compared to the six months ended June 30, 2012. Decreases in manufacturing development expenses and decreases in clinical trial costs were offset by an increase in administrative and headcount costs and increased regulatory costs in connection with our efforts to obtain marketing approval of Cleviprex outside the United States.



We expect that we will incur increased research and development expenses in 2013 as compared to 2012 levels in connection with our efforts to obtain marketing approval of Cleviprex outside the United States, in preparation for our study of Cleviprex in the pediatric setting and in connection with the continuation of product lifecycle management activities.

Cangrelor

Research and development expenditures related to cangrelor decreased by approximately \$6.3 million in the three months ended June 30, 2013 compared to the three months ended June 30, 2012. The decrease primarily reflects decreased clinical trial expenses related to our Phase 3 CHAMPION PHOENIX clinical trial, which completed patient enrollment in October 2012. The decrease was offset by an increase in costs associated with administrative and headcount expenses associated with product lifecycle management activities.

Research and development expenditures related to cangrelor decreased by approximately \$15.4 million during the six months ended June 30, 2013 compared to the six months ended June 30, 2012. The decrease primarily reflects a \$20.9 million decrease in clinical trial costs offset by increases of \$0.7 million in manufacturing development costs and \$4.9 million in administrative and headcount costs.

In July 2013, we reported that the FDA accepted the filing of the NDA for cangrelor. We anticipate submitting an MAA in the European Union in the fourth quarter of 2013. The decrease also reflects decreased manufacturing development costs offset by increased administrative and headcount costs.

We expect total research and development expenses relating to cangrelor will decrease in 2013 compared to 2012 levels, primarily due to our completion of research and development activities associated with the CHAMPION PHOENIX clinical trial.

#### Oritavancin

Research and development expenditures related to oritavancin decreased by approximately \$5.4 million in the three months ended June 30, 2013 compared to the three months ended June 30, 2012. This decrease primarily reflects the completion of patient enrollment in the SOLO I clinical trial in October 2012 and in the SOLO II clinical trial in April 2013. The decrease also reflects decreased manufacturing development costs offset by increased administrative and headcount costs.

Research and development expenditures related to oritavancin decreased by approximately \$0.7 million during the six months ended June 30, 2013 compared to the six months ended June 30, 2012. The decrease in total research and development expense reflects decreases in clinical trial costs due to the completion of patient enrollment in the SOLO clinical studies, which decreases were offset by increases in manufacturing development costs and administrative and headcount costs incurred.

In July 2013, we reported positive results for the SOLO II trial and the combined SOLO clinical trial program. We anticipate submitting an NDA to the FDA for oritavancin in the fourth quarter of 2013 and an MAA in the European Union in the first half of 2014.

We expect that our research and development expenses relating to oritavancin will decrease in 2013 as compared to 2012 due to completion of enrollment of the SOLO I clinical trial in October 2012 and the SOLO II clinical trial in April 2013, which will be partially offset by cost related to our global regulatory activities related to oritavancin.  
MDCO-157

Research and development expenses related to MDCO-157 decreased by \$0.4 million in the three months ended June 30, 2013 compared to the three months ended June 30, 2012 due to a reduction in administrative and headcount costs and manufacturing development activities.

Research and development expenses related to MDCO-157 decreased by \$0.4 million in the six months ended June 30, 2013 compared to the six months ended June 30, 2012 primarily due to a reduction in administrative and headcount costs of \$0.6 million, offset by a \$0.3 million increase in clinical costs related to a dose-response pharmacodynamic study in healthy volunteers.

We do not expect additional research and development expenses relating to MDCO-157 as we have elected to discontinue development of MDCO-157. On July 30, 2013, we entered into a termination agreement with CyDex to mutually terminate our license agreement with CyDex. The rights to MDCO-157 reverted to CyDex upon execution of the termination agreement.

#### MDCO-2010

Research and development expenditures related to MDCO-2010 decreased by approximately \$1.4 million in the three months ended June 30, 2013 compared to the three months ended June 30, 2012 and by approximately \$2.5 million in the six months ended June 30, 2013 compared to the six months ended June 30, 2012. These decreases were primarily due to the discontinuation in October 2012 of a Phase 2b dose ranging clinical trial of MDCO-2010, which we commenced in the first quarter of 2012, and our determination in October 2012 to discontinue development of MDCO-2010.

We expect that our total research and development expenses relating to MDCO-2010 will decrease in 2013 as compared to 2012, as a result of discontinuation the Phase 2b dose ranging trial and further development of MDCO-2010. We still expect to incur limited costs in 2013 as we are conducting an assessment of patient data from the study.

MDCO-216

Research and development expenditures related to MDCO-216 increased by approximately \$1.0 million in the three months ended June 30, 2013 as compared to the three months ended June 30, 2012 and by approximately \$1.6 million in the six months ended June 30, 2013 compared to the six months ended June 30, 2012 primarily due to a Phase 1 study of MDCO-216 in healthy volunteers that we commenced in February 2013 and increased manufacturing development costs primarily related to process optimization activities.

We expect that our total research and development expenses relating to MDCO-216 will increase in 2013 as compared to 2012, as we expect to complete the Phase 1 study and commence manufacturing of MDCO-216 for subsequent clinical development in the fourth quarter of 2013.

#### IONSYS

In January 2013, we acquired Incline, a company focused on the development of IONSYS, a compact, disposable, needle-less patient-controlled system for the short-term management of acute postoperative pain in the hospital setting. Research and development costs related to IONSYS were \$4.6 million and \$8.7 million for the three months and six months ended June 30, 2013, respectively. Costs incurred during the three and six months ended June 30, 2013 primarily related to administrative and headcount expenses and manufacturing development expenses.

#### ALN-PCS Program

In February 2013, we entered into a license and collaboration agreement with Alnylam to develop, manufacture and commercialize therapeutic products targeting the human PCSK-9 gene based on certain of Alnylam's RNAi technology. We refer to two of the licensed products, ALN-PCS02 and ALN-PCSsc, as our ALN-PCS program. Research and development cost related to the ALN-PCS program for the three and six months ended June 30, 2013 consisted of an upfront payment of \$25.0 million made to Alnylam under the license and collaboration agreement during the first quarter of 2013. We did not incur any research and development cost for this program in the three months ended June 30, 2013. Alnylam is responsible for the development costs of the product candidates, subject to an agreed upon limit, until the completion of Phase I clinical studies. We are responsible for completing and funding the development costs of the products thereafter through commercialization, if successful.

#### Other Research and Development Expense

Research and development expenditures in this category include 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 data and product safety as well as expenses related to business development activities 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 decreased by approximately \$2.1 million and \$2.3 million during the three and six months ended June 30, 2013 compared to the three and six months ended June 30, 2012 primarily due to a decrease in administrative and headcount expenses associated with the reversal of a reserve which had been recorded in 2011 for the potential repayment of certain subsidies from the Saxony government in Leipzig, Germany after being informed that no repayment would be required by the Saxony government and some reductions in infrastructure costs.

Our success in further developing Angiomax and obtaining marketing approvals for Angiomax in additional countries and for additional patient populations, developing and obtaining marketing approvals for Cleviprex outside the United States, and developing and obtaining marketing approvals for our products in development, is highly uncertain. We cannot predict expenses associated with ongoing data analysis or regulatory submissions, if any. In addition, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts necessary to continue the development of Angiomax, Cleviprex and our products in development, the period in which material net cash inflows are expected to commence from further developing Angiomax and Cleviprex, the timing and estimated costs of

obtaining marketing approvals for Angiomax in additional countries and additional patient populations, the timing and estimated costs of obtaining marketing approvals for Cleviprex outside the United States, or the timing and estimated costs of developing and obtaining marketing approvals for our products in development, 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 products and 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:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2013	2012	Change \$	Change %	2013	2012	Change \$	Change %
	(in thousands)				(in thousands)			
Selling, general and administrative expenses	\$52,944	\$40,467	\$12,477	30.8 %	\$116,426	\$83,653	\$32,773	39.2 %

The increase in selling, general and administrative expenses of approximately \$12.5 million in the three months ended June 30, 2013 as compared to the three months ended June 30, 2012 reflects a \$5.8 million increase in selling, marketing and promotional expense and a \$6.6 million increase in general corporate and administrative expenses.

Selling, marketing and promotional expenses increased by \$5.8 million, primarily due to the promotion of Recothrom, increased promotional efforts for Angiomax and Cleviprex globally and ready-to-use Argatroban in the United States and spending in preparation for the commercial sale of our late stage product candidates, if and when approved.

General corporate and administrative expenses increased by \$6.6 million, primarily due to a \$4.9 million increase in legal costs associated with our ongoing patent infringement litigation and the now completed Eagle arbitration and a \$5.0 million arbitration award to Eagle, a \$3.6 million increase in accretion costs as a result of adjustments to the fair value of the contingent consideration due to the former stockholders of Incline, \$0.5 million in legal costs incurred in connection with the ProFibrix transaction, and a \$1.2 million increase in stock-based compensation costs, offset by a \$8.9 million gain associated with a reduction in the fair value of the contingent consideration due to the former stockholders of Targanta Therapeutics Corporation, or Targanta. The gain associated with a reduction in the contingent consideration due to the former Targanta shareholders is the result of our determination that it is not probable that we obtain regulatory approval of oritavancin in the United States by December 31, 2013.

The increase in selling, general and administrative expenses of approximately \$32.8 million in the six months ended June 30, 2013 as compared to the six months ended June 30, 2012 reflects a \$13.7 million increase in selling, marketing and promotional expenses and a \$19.0 million increase in general corporate and administrative expenses. Selling, marketing and promotional expenses increased by \$13.7 million primarily due to the promotion of Recothrom, increased promotional efforts for Angiomax and Cleviprex globally and ready-to-use Argatroban in the United States, and spending in preparation for the commercial sale of our late-stage product candidates, if and when approved.

General corporate and administrative expenses increased by \$19.0 million primarily due to \$11.3 million increase in legal costs associated with our ongoing patent infringement litigation and the now completed Eagle arbitration and a \$5.0 million arbitration award to Eagle, a \$4.4 million increase in employee severance and other employee related termination costs associated with the 2013 reduction in force, \$2.5 million in additional costs related to Incline, Recothrom and the ProFibrix transaction, a \$7.9 million increase in accretion costs as a result of adjustments to the fair value of the Incline contingent consideration due to former Incline stockholders, and a \$2.4 million increase in stock-based compensation costs, offset by a \$13.5 million gain associated with reduction in the fair value of the contingent consideration due to the former Targanta stockholders. The gain associated with a reduction in the fair value of the contingent consideration due to the former Targanta stockholders is the result of a reduction in the probability of oritavancin successfully obtaining regulatory approval in the United States by December 31, 2013.

Co-promotion Income:

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	Three Months Ended June 30,				Six Months Ended June 30,			
	2013	2012	Change \$	Change %	2013	2012	Change \$	Change %
	(in thousands)				(in thousands)			
Co-promotion income	\$4,068	\$2,500	\$1,568	62.7 %	\$7,818	\$2,500	\$5,318	100.0 %

During the three and six months ended June 30, 2013, we recorded income of approximately \$4.1 million and \$7.8 million respectively, in connection with our collaboration with AstraZeneca for the co-promotion of BRILINTA in the United States. Pursuant to the agreement, our sales force began supporting promotion activities for BRILINTA in May 2012. As a result, we did not begin to record co-promotion income until the middle of the second quarter of 2012.

Interest Expense:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2013	2012	Change \$	Change %	2013	2012	Change \$	Change %
	(in thousands)				(in thousands)			
Interest expense	\$(3,704)	\$(784)	\$(2,920)	*	\$(7,377)	\$(784)	\$(6,593)	*

\*Represents an increase of or in excess of 100%

During the three and six months ended June 30, 2013, we recorded approximately \$3.7 million and \$7.4 million, respectively, in interest expense related to the Notes. We recorded \$0.8 million of interest expense for the three and six months ended June 30, 2012 as we issued the Notes on June 11, 2012 and accrued interest from that date.

Other Income:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2013	2012	Change \$	Change %	2013	2012	Change \$	Change %
	(in thousands)				(in thousands)			
Other income	\$605	\$697	\$(92)	(13.2)%	\$803	\$759	\$44	5.8 %

Other income, which is comprised of interest income and gains and losses on foreign currency transactions decreased by approximately \$0.1 million to \$0.6 million for the three months ended June 30, 2013. This decrease was primarily due to higher gains on foreign currency transactions in the three months ended June 30, 2013.

Other income during the six months ended June 30, 2013, remained consistent with the six months ended June 30, 2012.

(Provision) for Income Tax:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2013	2012	Change \$	Change %	2013	2012	Change \$	Change %
	(in thousands)				(in thousands)			
(Provision) for income tax	\$(11,854)	\$(8,251)	\$(3,603)	43.7 %	\$(1,095)	\$(12,725)	\$11,630	(91.4)%



We recorded an \$11.9 million and an \$8.3 million provision for income taxes for the three months ended June 30, 2013 and 2012, respectively, based on income before taxes of \$29.9 million and \$22.0 million for the same periods. Our effective income tax rates for the three months ended June 30, 2013 and 2012 were approximately 39.7% and 37.5%, respectively. Both the 2013 and 2012 effective tax rates include a non-cash tax expense arising from purchase accounting for in-process research and development, or IPR&D, acquired in our acquisition of Targanta. The 2013 effective tax rate also includes a non-cash tax expenses due to the purchase accounting for future contingent payments related to the acquisition of Incline.

We recorded a \$1.1 million and a \$12.7 million provision for income taxes for the six months ended June 30, 2013 and 2012, respectively, based on income before taxes for such periods of \$7.5 million and \$34.1 million. Our effective income tax rates for the six months ended June 30, 2013 and 2012 were approximately 14.6% and 37.4%, respectively. Both the 2013 and 2012 effective tax rates include a non-cash tax expense arising from purchase accounting for in-process research and development, or IPR&D, acquired in our acquisition of Targanta. The 2013 effective tax rate also includes a non-cash tax expenses due to the purchase accounting for future contingent payments related to the acquisition of Incline.

It is possible that our full-year effective tax rate could change because of other discrete events, our mix of U.S. to foreign earnings, specific transactions, or the receipt of new information affecting our current projections.

We will continue to evaluate our future ability to realize our deferred tax assets on a periodic basis in light of changing facts and circumstances. These include but are not limited to projections of future taxable income, tax legislation, rulings by relevant tax authorities, the progress of ongoing tax audits, the regulatory approval of products currently under development and the ability to achieve future anticipated revenues.

## Liquidity and Capital Resources

### Sources of Liquidity

Since our inception, we have financed our operations principally through revenues from sales of Angiomax, the sale of common stock, convertible promissory notes and warrants and interest income. We had \$301.0 million in cash, cash equivalents and available for sale securities as of June 30, 2013.

### Cash Flows

As of June 30, 2013, we had \$292.9 million in cash and cash equivalents, as compared to \$519.4 million as of December 31, 2012. The decrease in cash and cash equivalents in the six months ended June 30, 2013 was primarily due to \$7.6 million of net cash used in operating activities and \$273.2 million of net cash used in investing activities, which uses of cash were partially offset by \$55.2 million of net cash provided by financing activities.

Net cash used in operating activities was \$7.6 million in the six months ended June 30, 2013, compared to net cash provided by operating activities of \$6.0 million in the six months ended June 30, 2012. The decrease in cash from operating activities was primarily due to the timing of changes in working capital. The cash used in operating activities in the six months ended June 30, 2013 included a net income of \$6.4 million, primarily due to \$25.0 million initial license payment to Alnylam, and a \$29.1 million decrease resulting from changes in working capital items, which were offset by non-cash items of \$15.1 million consisting primarily of stock-based compensation expense, deferred tax provision, adjustment to contingent purchase price, depreciation and amortization. The changes in working capital items reflect a decrease in accounts payable and accrued expenses of \$13.5 million primarily due to payments related to inventory of active pharmaceutical ingredient bivalirudin and payment of certain corporate expenses, an increase in accounts receivable of \$4.7 million, which was due in part to the timing of receipts and related sales volume, an increase in inventory of \$10.5 million due to purchases under our supply agreement with Teva API, Inc., or Teva API, which was formerly known as Plantex USA Inc., of certain minimum quantities of active pharmaceutical ingredient bivalirudin for our commercial supply, and an increase in prepaid and other current assets of \$0.7 million primarily due to an increase in prepaid corporate income and ad valorem taxes.

Net cash provided by operating activities in the six months ended June 30, 2012 included net income of \$21.3 million offset by non-cash items of \$16.7 million consisting primarily of stock-based compensation expense and depreciation

and amortization, and an increase of \$32.0 million resulting from changes in working capital items. The changes in working capital items reflect an increase in accounts payable and accrued expenses of \$39.2 million primarily due to payments related to inventory of active pharmaceutical ingredient bivalirudin and payment of certain corporate expenses, a decrease in accounts receivable of \$8.7 million, which was due in part to the timing of receipts and related sales volume, and an increase in inventory of \$2.1 million due to purchases under our supply agreement with Teva API of certain minimum quantities of the active pharmaceutical ingredient bivalirudin for our commercial supply.

During the six months ended June 30, 2013, \$273.2 million in net cash was used in investing activities, which reflected \$301.7 million incurred in connection with our Incline and Recothrom transactions, consisting of \$186.7 million used in the acquisition of Incline and \$115.0 million used for the Recothrom transaction, and \$10.0 million used for the ProFibrix transaction, the purchase of fixed assets and additions to other investments, offset by \$42.6 million in proceeds from the maturity and sale of available for sale securities.

During the six months ended June 30, 2012, \$75.5 million in net cash was used in investing activities, which reflected \$65.4 million used to purchase available for sale securities and \$36.7 million used to acquire intangible assets related to our acute care generic products in connection with our settlement with APP and the reacquisition of our rights to sell Angiomax in Australia and New Zealand from CSL Limited, offset by \$25.0 million in proceeds from the maturity and sale of available for sale securities and a \$2.0 million decrease in restricted cash resulting from a reduction of our outstanding letter of credit associated with the lease of our principal executive offices in Parsippany, New Jersey.

Net cash provided by financing activities was \$55.2 million in the six months ended June 30, 2013, which reflected \$49.6 million of proceeds from option exercises and \$5.7 million in excess tax benefits and purchases of stock under our employee stock purchase plan.

We received \$206.7 million in the six months ended June 30, 2012 in net cash provided by financing activities, which reflected \$275.0 million in proceeds from the issuance of the Notes, \$38.4 million in proceeds from the issuance of warrants in connection with the issuance of the Notes and \$10.1 million of proceeds to us from option exercises, excess tax benefits and purchases of stock under our employee stock purchase plan. These were partially offset by \$58.2 million purchase of a convertible note hedge, \$50.0 million for the purchase of treasury shares and \$8.8 million in issuance costs in connection with our convertible note offering.

#### Funding Requirements

We expect to devote substantial financial resources to our research and development efforts, clinical trials, nonclinical and preclinical studies and regulatory approvals and to our commercialization and manufacturing programs associated with our products and our products in development. We also will require cash to pay interest on the \$275.0 million aggregate principal amount of Notes and to make principal payments on the Notes at maturity or upon conversion. In addition, we will require cash to make payments under the license agreements and other acquisition agreements to which we are a party, including potentially a payment to BMS if we exercise the option granted to us, of a purchase price equal to the net book value of inventory included in the acquired assets, plus an additional amount to be determined in accordance with the terms of the master transaction agreement, and contingent payments under the definitive agreements for the acquisition of Targanta, Incline and ProFibrix and our license and collaboration agreement with Alnylam of up to \$50.0 million in cash in the aggregate under the Targanta transaction, of up to \$205.0 million in cash in the aggregate under the Incline transaction, of up to \$140.0 million in cash in the aggregate under the ProFibrix transaction and of up to \$180.0 million in cash in the aggregate under the Alnylam license and collaboration agreement, in each case, upon the achievement of specified regulatory, sales and other milestones.

Our future capital requirements will depend on many factors, including:

- the extent to which Angiomax is commercially successful globally;

- our ability to maintain market exclusivity for Angiomax in the United States through the enforcement of the '727 patent and the '343 patent during the period following the expiration of the patent term of the '404 patent on December 15, 2014 and the six month pediatric exclusivity on June 15, 2015 through at least May 1, 2019, the date on which we agreed APP may sell a generic version of Angiomax;

- the extent to which Recothrom, Cleviprex, ready-to-use Argatroban and the acute care generic products for which we acquired the non-exclusive right to sell and distribute from APP are commercially successful in the United States;

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the extent to which our global collaboration with AstraZeneca, including our four-year co-promotion arrangement for BRILINTA in the United States, is successful;

the extent to which we are successful in our efforts to establish a commercial infrastructure outside the United States;

the consideration paid by us and to be paid by us in connection with acquisitions and licenses of development-stage compounds, clinical-stage product candidates, approved products, or businesses, and in connection with other strategic arrangements;

the progress, level, timing and cost of our research and development activities related to our clinical trials and non-clinical studies with respect to Angiomax, Cleviprex and our products in development;

the cost and outcomes of regulatory submissions and reviews for approval of Angiomax in additional countries and for additional indications, of Recothrom and Cleviprex outside the United States and of our other products in development globally, including the recently acquired Fibrocaps;

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

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

the amounts of our payment obligations to third parties as to our products and products in development; and

our ability to defend and enforce our intellectual property rights.

We believe that our cash on hand after giving effect to the \$90.0 million cash payment we paid upon the closing of the ProFibrix transaction and the cash we generate from our operations will be sufficient to meet our ongoing funding requirements, including our obligations with respect to the Notes and under the license agreements and other acquisition agreements to which we are a party, but excluding any future material acquisition activity. If our existing cash resources, together with revenues that we generate from sales of our products and other sources, are insufficient to satisfy our funding requirements due to slower than anticipated sales of Angiomax, Recothrom, Cleviprex, ready-to-use Argatroban and the acute generic products for which we acquired the non-exclusive right to sell and distribute from APP or higher than anticipated costs globally, we may need to sell additional equity or debt securities or seek additional financing through other arrangements. Any sale of additional equity or debt securities may result in dilution to our stockholders. Debt financing may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures. Moreover, our ability to obtain additional debt financing may be limited by the Notes. We cannot be certain that public or private financing will be available in amounts or on terms acceptable to us, if at all. Further, we may seek additional financing to fund our acquisitions of development stage compounds, clinical stage product candidates and approved products and/or the companies that have such products or if we determine that raising capital would be in our interest and in the interest of our stockholders, and we may not be able to obtain such financing on terms acceptable to us or 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:

We may be, from time to time, a party to various disputes and claims arising from normal business activities. We accrue for loss contingencies at the earliest date at which we deem that it is probable that a liability has been incurred and the amount of such loss can be reasonably estimated.

Currently, we are party to the legal proceedings described in Part II, Item 1, Legal Proceedings, of this quarterly report. We have assessed such legal proceedings and do not believe that it is probable that a liability has been incurred and the amount of such liability can be reasonably estimated. As a result, we have not recorded a loss contingency related to these legal proceedings.

#### 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 royalties, milestone payments, option exercise and

other contingent payments due under our license and acquisition agreements, purchases of inventory of our products, research and development service agreements, income tax contingencies, operating leases, selling, general and administrative obligations and restricted cash in connection with our lease of our principal office space in Parsippany, New Jersey as of June 30, 2013.

In addition to the specified contractual obligations set forth in the contractual obligations table included in our annual report on Form 10-K for the year ended December 31, 2012 and set forth in our quarterly report on Form 10-Q for March 31, 2013, the following obligation was incurred during the three months ended June 30, 2013:

As described above under “Business Development Activity-ProFibrix B.V.,” on June 4, 2013, we entered into a share purchase agreement with ProFibrix and its equityholders to acquire all of the equity of ProFibrix, subject to our satisfactory review of the then pending Phase 3 clinical trial results of ProFibrix's lead biologic, Fibrocaps. Following our review of

the Phase 3 trial results, on August 2, 2013, we notified ProFibrix that we wished to proceed with the closing of our acquisition of ProFibrix, and on August 5, 2013, we completed our acquisition of all of the outstanding equity of ProFibrix. Upon the completion of the acquisition, ProFibrix became our wholly owned subsidiary.

#### Application of Critical Accounting Estimates

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

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

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

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

Our significant accounting policies are more fully described in note 2 of our unaudited 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, 2012. 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, 2012 are “critical accounting estimates.”

#### 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, or the Exchange Act. 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 identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations expressed or implied in our forward-looking statements. There are a number of important factors that could cause actual results, levels of activity, performance or events to differ materially from those expressed or implied in the forward-looking statements we make. These important factors include our “critical accounting estimates” described in Part I, Item 2 of this quarterly report and the factors set forth under the caption “Risk Factors” in Part II, Item 1A of this quarterly report. 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.



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 June 30, 2013, we held \$301.0 million in cash, cash equivalents and available for sale securities which had an average interest rate of approximately 0.37%. A 10 basis point change in such average interest rate would have had an approximate \$0.1 million impact on our interest income. At June 30, 2013, all cash, cash equivalents and available for sale securities were due on demand or within one year.

Most of our transactions are conducted in U.S. dollars. We do have certain agreements with parties located outside the United States. Transactions under certain of these agreements are conducted in U.S. dollars, subject to adjustment based on significant fluctuations in currency exchange rates. Transactions under certain other of these agreements are conducted in the local foreign currency. As of June 30, 2013, we had receivables denominated in currencies other than the U.S. dollar. A 10% change in foreign exchange rates would have had an approximate \$1.3 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 June 30, 2013. 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 rules and forms of the Securities and Exchange Commission, or SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2013, 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 June 30, 2013 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.

#### '727 Patent and '343 Patent Litigations

##### Hospira, Inc.

In July 2010, we were notified that Hospira, Inc., or Hospira, had submitted two ANDAs seeking permission to market its generic version of Angiomax prior to the expiration of the '727 patent and '343 patent. On August 19, 2010, we filed suit against Hospira in the U.S. District Court for the District of Delaware for infringement of the '727 patent and '343 patent. On August 25, 2010, the case was reassigned in lieu of a vacant judgeship to the U.S. District Court for the Eastern District of Pennsylvania. Hospira's answer denied infringement of the '727 patent and '343 patent and raised counterclaims of non-infringement and invalidity of the '727 patent and '343 patent. On September 24, 2010, we filed a reply denying the counterclaims raised by Hospira. The Hospira action was consolidated for discovery purposes with the then pending and now settled cases against Teva and APP. The case was reassigned back to the U.S. District Court for the District Court of Delaware. A Markman hearing was held on December 5, 2012. On July 12, 2013, the Court issued its Markman decision as to the claim construction of the '727 patent and the '343 patent. The Court's decision varied from the other Markman decisions that we have received in our other patent infringement litigations. On July 22, 2013, we filed a motion for reconsideration of the Court's claim construction ruling on the grounds that the Court (i) impermissibly imported process limitations disclosed in a preferred embodiment into the claims, (ii) improperly transformed product claims into product-by-process claims, (iii) improperly rendered claim language superfluous and violated the doctrine of claim differentiation, and (iv) improperly construed limitations based on validity arguments that have not yet been presented. The Court has set a September 23, 2013 trial date.

##### Mylan Pharmaceuticals, Inc.

In January 2011, we were notified that Mylan Pharmaceuticals, Inc. had submitted an ANDA seeking permission to market its generic version of Angiomax prior to the expiration of the '727 patent and '343 patent. On February 23, 2011, we filed suit against Mylan Inc., Mylan Pharmaceuticals Inc. and Bioniche Pharma USA, LLC, which we refer to collectively as Mylan, in the U.S. District Court for the Northern District of Illinois for infringement of the '727 patent and '343 patent. Mylan's answer denied infringement of the '727 patent and '343 patent and raised counterclaims of non-infringement and invalidity of the '727 patent and '343 patent. On April 13, 2011, we filed a reply denying the counterclaims raised by Mylan. On May 4, 2011 the Court set a pretrial schedule. Following a joint request, the Court issued an amended scheduling order on September 22, 2011. On November 29, 2011, Mylan moved to amend its answer to add counterclaims and affirmative defenses of inequitable conduct and unclean hands. Following motion practice, the Court granted Mylan's request to add counterclaims and affirmative defenses of inequitable conduct and to add affirmative defenses of unclean hands. On March 7, 2012, we filed a reply denying these counterclaims. A Markman hearing was held on July 30, 2012. The Court issued a Markman Order on August 6, 2012. The parties have completed fact and expert discovery. On June 21, 2013, Mylan filed a summary judgment motion of non-infringement. Our opposition papers are due August 27, 2013 and Mylan's reply is due September 17, 2013. No trial date has been set.

##### Dr. Reddy's Laboratories, Inc.

In March 2011, we were notified that Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. had submitted an ANDA seeking permission to market its generic version of Angiomax prior to the expiration of the '727 and '343 patents. On April 28, 2011, we filed suit against Dr. Reddy's Laboratories, Ltd., Dr. Reddy's Laboratories, Inc. and Gland Pharma, Inc., which we refer to collectively as Dr. Reddy's, in the U.S. District Court for the District of New Jersey for infringement of the '727 patent and '343 patent. Dr. Reddy's answer denied infringement of the '727 patent and '343 patent and raised counterclaims of non-infringement and invalidity of the '727 patent and '343 patent. On May 11, 2012, Dr. Reddy's filed a motion for summary judgment. On October 2, 2012, the Court held oral argument on Dr. Reddy's summary judgment motion and conducted a Markman hearing. On October 15, 2012, the Court denied Dr. Reddy's summary judgment motion. A Markman decision was issued by the Court on January 2, 2013. On January 25, 2013, Dr. Reddy's filed a second summary judgment motion this time for non-infringement. During a March 13, 2013 status conference, the Dr. Reddy's and Sun Pharmaceuticals Industries LTD actions were consolidated.

On April 17, 2013, during a conference with the Magistrate Judge, a final schedule was set for pretrial purposes for the consolidated matter. No trial date has been set.

#### Sun Pharmaceutical Industries LTD

In October 2011, we were notified that Sun Pharmaceutical Industries LTD had submitted an ANDA seeking permission to market its generic version of Angiomax prior to the expiration of the '727 and '343 patents. On November 21, 2011, we filed suit against Sun Pharma Global FZE, Sun Pharmaceutical Industries LTD., Sun Pharmaceutical Industries Inc., and Caraco Pharmaceutical Laboratories, LTD., which we refer to collectively as Sun, in the U.S. District Court for the District of New Jersey for infringement of the '727 patent and '343 patent. The case has been assigned to the same judge and Magistrate Judge as the Dr. Reddy's action. Sun's answer denied infringement of the '727 patent and '343 patent. On June 7, 2012, the Court held an initial case scheduling conference. At a subsequent conference on March 13, 2013, the Court consolidated the Sun case with the Dr. Reddy's action. On April 17, 2013, during a conference with the Magistrate Judge, a final schedule was set for pretrial purposes for the consolidated matter. No trial date has been set.

#### Apotex Inc.

In March 2013, we were notified that Apotex Inc. had submitted an ANDA seeking permission to market its generic version of Angiomax prior to the expiration of the '727 and '343 patents. On May 1, 2013, we filed suit against Apotex Inc. and Apotex Corp., which we refer to collectively as Apotex, in the U.S. District Court for the District of New Jersey for infringement of the '727 and '343 patents. The case has been assigned to the same judge and Magistrate Judge as the Dr. Reddy's and Sun actions. Apotex filed its answer on July 19, 2013 and raised counterclaims of non-infringement and invalidity. The Court has not yet set any schedules.

#### Eagle Pharmaceuticals, Inc. Arbitration

We received a Demand for Arbitration filed by Eagle, dated October 25, 2011. In the Demand for Arbitration, Eagle claimed that we had failed to meet our obligations under the license and development agreement between us, Eagle and certain other parties relating to the development of a new formulation of our product, Angiomax, and to our efforts to seek and obtain regulatory approval, market and sell that new formulation. Eagle, as a result, alleged that it was entitled to an amount of damages totaling \$306 million. In January 2013, an arbitration hearing took place before a three person panel. In February 2013, we and Eagle submitted post-hearing briefs, and, in April 2013, post-hearing arguments took place. On July 19, 2013, we received the final award determination from the three person arbitration panel deciding the matter, which directed that we pay Eagle \$5 million and denied the remainder of Eagle's claims for \$306 million in damages. We expect to pay Eagle \$5.0 million in the third quarter of 2013.

#### Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should consider carefully 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. Updated risk factors associated with our business are set forth below.

#### Risks Related to Our Financial Results

Our business is very dependent on the commercial success of Angiomax. If Angiomax does not generate the revenues we anticipate, our business may be materially harmed

Angiomax has accounted for substantially all of our revenue since we began selling this product in 2001. We expect revenue from Angiomax to account for the significant majority of our revenue in 2013. The commercial success of Angiomax depends upon:

our ability to maintain market exclusivity for Angiomax in the United States through the enforcement of the '727 patent and the '343 patent during the period following the expiration of the patent term of the '404 patent on December 15, 2014 and the six month pediatric exclusivity on June 15, 2015 through at least May 1, 2019, the date on which we agreed APP may sell a generic version of Angiomax;

the continued acceptance by regulators, physicians, patients and other key decision-makers of Angiomax 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 and obtain marketing approval of Angiomax for use in additional patient populations and the clinical data we generate to support expansion of the product label;

the overall number of PCI procedures performed;

the ability of our third-party supply and manufacturing partners to provide us with sufficient quantities of Angiomax;

the impact of competition from existing competitive products and from competitive products that may be approved in the future;

the continued safety and efficacy of Angiomax;

to what extent and in what amount government and third-party payors cover or reimburse for the costs of Angiomax; and

our success and the success of our international distributors in selling and marketing Angiomax in Europe and in other countries outside the United States.

We continue to develop Angiomax for use in additional patient populations, including in patients with structural heart disease, patients undergoing peripheral angioplasty, carotid angioplasty and cardiovascular surgery and patients with or at risk of HIT/HITTS. We may not be successful in developing Angiomax and obtaining marketing approval of Angiomax for these additional patient populations. However, even if we are successful in obtaining approval for the use of Angiomax in additional patient populations, our ability to sell Angiomax for use in these additional patient populations may not result in higher revenue or income on a continuing basis.

As of June 30, 2013, our inventory of Angiomax was \$79.2 million and we had inventory-related purchase commitments totaling \$12.0 million for the last two quarters of 2013, \$26.6 million for 2014 and \$20.1 million for 2015 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, which could negatively impact our results of operations and our financial condition.

We may need to raise additional capital. If we are unable to obtain such capital on favorable terms or at all, we may not be able to execute on our business plans and our business, financial condition and results of operations may be adversely affected

We expect to devote substantial financial resources to our research and development efforts, clinical trials, nonclinical and preclinical studies and regulatory approvals and to our commercialization and manufacturing programs associated with our products and our products in development. We also will require cash to pay interest on the \$275.0 million aggregate principal amount of our 1.375% convertible senior notes due 2017, or the Notes, and to make principal payments on the Notes at maturity or upon conversion. In addition, we will require cash to make payments under the license agreements and acquisition agreements to which we are a party, including potentially a payment to BMS, if we exercise the option granted to us, of a purchase price equal to the net book value of inventory included in the acquired assets, plus an additional amount to be determined in accordance with the terms of the master transaction agreement, and contingent payments under the definitive agreements for the acquisition of Targanta, Incline and ProFibrix and the license and collaboration agreement with Alnylam of up to \$50.0 million in cash in the aggregate under the Targanta

transaction, of up to \$205.0 million in cash in the aggregate under the Incline transaction, of up to \$140.0 million in cash in the aggregate under the ProFibrix transaction and of up to \$180.0 million in cash in the aggregate under the Alnylam license and collaboration, in each case, upon the achievement of specified regulatory, sales and other milestones.

Our future capital requirements will depend on many factors, including:

• the extent to which Angiomax is commercially successful globally;

• our ability to maintain market exclusivity for Angiomax in the United States through the enforcement of the '727 patent and the '343 patent during the period following the expiration of the patent term of the '404 patent on December 15, 2014 and the six month pediatric exclusivity on June 15, 2015 through at least May 1, 2019, the date on which we agreed APP may sell a generic version of Angiomax;



the extent to which Recothrom, Cleviprex, ready-to-use Argatroban and the acute care generic products that we acquired the non-exclusive right to sell and distribute from APP are commercially successful in the United States;

the extent to which our global collaboration with AstraZeneca, including our four-year co-promotion arrangement for BRILINTA in the United States, is successful;

the extent to which we are successful in our efforts to establish a commercial infrastructure outside the United States;

the consideration paid by us and to be paid by us in connection with acquisitions and licenses of development-stage compounds, clinical-stage product candidates, approved products, or businesses, and in connection with other strategic arrangements;

the progress, level, timing and cost of our research and development activities related to our clinical trials and non-clinical studies with respect to Angiomax, Cleviprex and our products in development;

the cost and outcomes of regulatory submissions and reviews for approval of Angiomax in additional countries and for additional indications, of Recothrom and Cleviprex outside the United States and of our other products in development globally, including the recently acquired Fibrocaps;

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

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

the amounts of our payment obligations to third parties as to our products and products in development; and

our ability to defend and enforce our intellectual property rights.

If our existing resources, together with revenues that we generate from sales of our products and other sources, are insufficient to satisfy our funding requirements, we may need to sell equity or debt securities or seek additional financing through other arrangements. Public or private financing may not 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, products in development or technologies that we would not otherwise relinquish or grant licenses on terms that may not be favorable to us. Moreover, our ability to obtain additional debt financing may be limited by the Notes. 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 adversely affect our business, financial condition and operating results.

If we seek to raise capital to fund acquisitions of development-stage compounds, clinical-stage product candidates, approved products, or businesses or for other reasons by selling equity or debt securities or through other arrangements, our stockholders could be subject to dilution and we may become subject to financial restrictions and covenants, which may limit our activities

If we seek to acquire any development-stage compounds, clinical-stage product candidates, approved products, or businesses or determine that raising capital would be in our interest and in the interest of our stockholders, we may seek to sell equity or debt securities or seek financings through other arrangements. Any sale of equity or debt securities may result in dilution to our stockholders and increased liquidity requirements. Moreover, our ability to obtain debt financing may be limited by the Notes. Debt financing may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures. Our ability to comply with these financial restrictions and covenants could be dependent on our future performance, which is subject to

prevailing economic conditions and other factors, including factors that are beyond our control such as foreign exchange rates, interest rates and changes in the level of competition. Failure to comply with the financial restrictions and covenants would adversely affect our business, financial condition and operating results.

Our revenue in the United States from sales of our products is completely dependent on our sole source distributor, Integrated Commercialization Solutions, or ICS, and our revenue outside the United States is substantially dependent on a limited number of international distributors. If the buying patterns of ICS or these international distributors for our products are not consistent with underlying hospital demand, then our revenue will be subject to fluctuation from quarter to quarter based on these buying patterns and not underlying demand for the products. Any change in these buying patterns could adversely affect our financial results and our stock price

We distribute Angiomax, Recothrom, Cleviprex, ready-to-use Argatroban and three of our acute care products in the United States through a sole source distribution model. Under this model, we currently sell Angiomax, Recothrom, Cleviprex, ready-to-

use Argatroban and the three acute care generic products to our sole source distributor, ICS. ICS then sells Angiomax, Recothrom, Cleviprex, ready-to-use Argatroban and the three acute care generic products 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. We expect that we will also sell our other acute care generic products through the same sole source distribution model. Our revenue from sales of Angiomax, Recothrom, Cleviprex, ready-to-use Argatroban and the three acute care generic products in the United States is exclusively from sales to ICS pursuant to our agreement with them. We anticipate that our revenue from sales of our other acute care generic products that we sell will be exclusively from sales to ICS. In connection with a reduction in marketing, sales and distribution fees payable to ICS, in October 2010 we amended our agreement with ICS to extend the ICS payment terms under our distribution agreement with them from 30 days to 45 days, which can be further extended to 49 days if ICS pays by wire transfer. The amendment has caused, and we expect to continue to cause, an increase in accounts receivable. As a result of our relationship with ICS, we expect that our revenue will continue to be subject to fluctuation from quarter to quarter based on the buying patterns of ICS, which may be independent of underlying hospital demand.

In some countries outside the European Union and in a few countries in the European Union, we 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, independent 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 material and adverse effect on our revenue in periods in which such purchase reductions occur.

We may not realize the anticipated benefits of past or future acquisitions or product licenses and integration of these acquisitions and any products and product candidates acquired or licensed may disrupt our business and management

We have in the past and may in the future acquire or license additional development-stage compounds, clinical-stage product candidates, approved products, technologies or businesses. For example, recently we acquired ProFibrix and Incline, obtained the exclusive right to promote, market and sell Recothrom from BMS and entered into a license and collaboration agreement with Alnylam to develop, manufacture and commercialize RNAi therapeutics targeting the PCSK9 gene for the treatment of hypercholesterolemia and other human diseases. We may not realize the anticipated benefits of an acquisition, license or collaboration, each of which involves numerous risks. These risks include:

- difficulty in integrating the operations, products or product candidates and personnel of an acquired company;
- entry into markets in which we have no or limited direct prior experience and where competitors in such markets have stronger market positions;
- failure to successfully further develop the acquired or licensed business, product, compounds, programs or technology or to achieve strategic objectives, including commercializing and marketing successfully the development stage compounds and clinical stage candidates that we acquire or license;
- disruption of our ongoing business and distraction of our management and employees from other opportunities and challenges;
- inadequate or unfavorable clinical trial results from acquired or contracted for product candidates;
- inability to retain personnel, key customers, distributors, vendors and other business partners of the acquired company, or acquired or licensed product or technology;

potential failure of the due diligence processes to identify significant problems, liabilities or other shortcomings or challenges of an acquired company, or acquired or licensed product or technology, including but not limited to, problems, liabilities or other shortcomings or challenges with respect to intellectual property, product quality, revenue recognition or other accounting practices, employee, customer or partner disputes or issues and other legal and financial contingencies and known and unknown liabilities;

liability for activities of the acquired company or licensor before the acquisition or license, including intellectual property infringement claims, violations of laws, commercial disputes, tax liabilities, and other known and unknown liabilities;

exposure to litigation or other claims in connection with, or inheritance of claims or litigation risk as a result of, an acquisition or license, including but not limited to, claims from terminated employees, customers, former stockholders or other third-parties; and

difficulties in the integration of the acquired company's departments, systems, including accounting, human resource and other administrative systems, technologies, books and records, and procedures, as well as in maintaining uniform standards, controls, including internal control over financial reporting required by the Sarbanes–Oxley Act of 2002 and related procedures and policies.

Acquisitions and licensing arrangements are inherently risky, and ultimately, if we do not complete an announced acquisition or license transaction or integrate an acquired business, or an acquired or licensed product or technology successfully and in a timely manner, we may not realize the benefits of the acquisition or license to the extent anticipated and the perception of the effectiveness of our management team and our company may suffer in the marketplace. In addition, even if we are able to achieve the long-term benefits associated with our strategic transactions, our expenses and short-term costs may increase materially and adversely affect our short-term profitability. Further, if we cannot successfully integrate acquired businesses, or acquired or licensed products or technologies we may experience material negative consequences to our business, financial condition or results of operations. Future acquisitions or licenses could also result in dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities, or amortization expenses, or impairment of goodwill, and restructuring charges, any of which could harm our business, financial condition or results of operations.

We have a history of net losses and may not achieve profitability in future periods or maintain profitability on an annual basis

We have incurred net losses in many years and on a cumulative basis since our inception. As of June 30, 2013, we had an accumulated deficit of approximately \$53.9 million. We expect to make substantial expenditures to further develop and commercialize our products, including costs and expenses associated with research and development, clinical trials, nonclinical and preclinical studies, regulatory approvals and commercialization. We anticipate needing to generate greater revenue in future periods from our marketed products and from our products in development in order to achieve and maintain profitability in light of our planned expenditures. If we are unable to generate greater revenue, we may not achieve profitability in future periods, and may not be able to maintain any profitability we do achieve. Our ability to generate future revenue will be substantially dependent on our ability to maintain market exclusivity for Angiomax. 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.

#### Risks Related to Our Notes

Servicing the Notes will require a significant amount of cash, and we may not have sufficient cash flow from our business to pay the Notes

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance the Notes depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be unfavorable to us or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at the time we seek such refinancing. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

We may not have the ability to raise the funds necessary to settle conversions of the Notes or to repurchase the Notes upon a fundamental change, and our future debt may contain limitations on our ability to pay cash upon conversion or repurchase of the Notes

Holders of the Notes will have the right to require us to repurchase their Notes upon the occurrence of a fundamental change, as defined in the indenture with Wells Fargo Bank, National Association, a national banking association, as trustee, governing the Notes, which we refer to as the Indenture, at a repurchase price equal to 100% of their principal amount, plus accrued and unpaid interest, if any, as described in the Indenture. In addition, upon conversion of the Notes, we will be required to make with respect to each \$1,000 in principal amount of Notes converted cash payments of at least the lesser of \$1,000 and the sum of the daily conversion values as described in the Indenture. However, we may not have enough available cash or be able to obtain financing at the time we are required to repurchase Notes or to pay cash upon conversions of Notes. In addition, our ability to repurchase

Notes or to pay cash upon conversions of Notes may be limited by law, by regulatory authority or by agreements governing our future indebtedness. Our failure to repurchase Notes at a time when the repurchase is required by the Indenture or to pay any cash payable on future conversions of the Notes as required by the Indenture would constitute a default under the Indenture. A default under the Indenture or the fundamental change itself could also lead to a default under agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Notes or make cash payments upon conversions thereof.

The conditional conversion feature of the Notes, if triggered, may adversely affect our financial condition and operating results

Holders of the Notes are entitled to convert the Notes at any time during specified periods at their option upon the occurrence of certain conditions, which are set forth in the Indenture. If one or more holders elect to convert their Notes, we would be required to settle any converted principal through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

The accounting method for convertible debt securities that may be settled in cash, such as the Notes, could have a material effect on our reported financial results

In May 2008, the Financial Accounting Standards Board, or FASB, issued FASB Staff Position No. APB 14-1, "Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement)", which has subsequently been codified as Accounting Standards Codification 470-20, "Debt with Conversion and Other Options", which we refer to as ASC 470-20. Under ASC 470-20, an entity must separately account for the liability and equity components of the convertible debt instruments (such as the Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. The effect of ASC 470-20 on the accounting for the Notes is that the equity component is required to be included in the additional paid-in capital section of stockholders' equity on our consolidated balance sheet and the value of the equity component is treated as original issue discount for purposes of accounting for the liability component of the Notes. As a result, we will be required to record non-cash interest expense in current periods presented as a result of the amortization of the excess of the principal amount of the liability component of the Notes over its carrying amount over the term of the Notes. We will report lower net income in our financial results because ASC 470-20 will require interest expense to include the current period's amortization of the debt discount and transaction costs, as well as the Notes' contractual interest, which could adversely affect our reported or future financial results, the market price of our common stock and the trading price of the Notes.

In addition, under certain circumstances, convertible debt instruments (such as the Notes) that may be settled entirely or partly in cash are currently accounted for utilizing the treasury stock method, the effect of which is that the shares issuable upon conversion of the Notes are not included in the calculation of diluted earnings per share except to the extent that the conversion value of the Notes exceeds their principal amount. Under the treasury stock method, for diluted earnings per share purposes, the transaction is accounted for as if the number of shares of common stock that would be necessary to settle such excess, if we elected to settle such excess in shares, are issued. We cannot be sure that the accounting standards in the future will continue to permit the use of the treasury stock method. If we are unable to use the treasury stock method in accounting for the shares issuable upon conversion of the Notes, then our diluted earnings per share would be adversely affected.

We have incurred substantial indebtedness, and our leverage and maintenance of high levels of indebtedness may adversely affect our business, financial condition and results of operations

As a result of the sale of the Notes, we have a greater amount of debt than we have maintained in the past. Our maintenance of higher levels of indebtedness could have adverse consequences including:

• impacting our ability to satisfy our obligations;

• increasing our vulnerability to general adverse economic and industry conditions;

• limiting our ability to obtain additional financing in the future;

• increasing the portion of our cash flows that may have to be dedicated to interest and principal payments and may not be available for operations, research and development, working capital, capital expenditures, expansion, acquisitions or general corporate or other purposes;



limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and

placing us at a possible competitive disadvantage to less leveraged competitors and competitors that have better access to capital resources.

#### Risks Related to Commercialization

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. Competitors in the United States and other countries include major pharmaceutical 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.

Our competitors may develop, market or license products or other novel technologies that are more effective, safer, more convenient or less costly than any that have been or are being developed or sold by us, or may obtain marketing approval for their products from the FDA or equivalent foreign regulatory bodies more rapidly than we may obtain approval for ours. There are well established products, including generic products, that are approved and marketed for the indications for which Angiomax, Recothrom, Cleviprex, ready-to-use Argatroban and our acute care generic products are approved for and the indications for which we are developing our products in development. In addition, competitors are developing additional products for such indications. In the case of the ready-to-use Argatroban, GlaxoSmithKline markets a branded formulation of Argatroban and Sandoz markets generic formulations of ready-to-use Argatroban that compete with our ready-to-use formulation of Argatroban. In the case of the acute care generic products, such products will compete with their respective brand name reference products and other equivalent generic products that may be sold by APP and other third-parties.

We compete, in the case of Angiomax, Recothrom, Cleviprex and ready-to-use Argatroban, and expect to compete, in the cases of our products in development, on the basis of product efficacy, safety, ease of administration, price and economic value compared to drugs used in current practice or currently being developed. If we are not successful in demonstrating these attributes, physicians and other key healthcare decision makers may choose other products over our products, switch from our products to new products or choose to use our products only in limited circumstances, which could adversely affect our business, financial condition and results of operations.

Angiomax faces significant competition from all categories of anticoagulant drugs, which may limit the use of Angiomax and adversely affect our revenue

Due to the incidence and severity of cardiovascular diseases, the market for anticoagulant therapies is large and competition is intense. There are a number of anticoagulant drugs currently on the market, awaiting regulatory approval or in development, including orally administered agents. Angiomax competes with, or may compete with in the future, these anticoagulant drugs to the extent Angiomax and any of these anticoagulant drugs are approved for the same or similar indications.

We have positioned Angiomax to compete primarily with heparin, platelet inhibitors such as GP IIb/IIIa inhibitors, and treatment regimens combining heparin and GP IIb/IIIa inhibitors. Because heparin is generic and inexpensive and has been widely used for many years, physicians and medical decision-makers may be hesitant to adopt Angiomax instead of heparin. GP IIb/IIIa inhibitors that Angiomax competes with include ReoPro from Eli Lilly and Company and Johnson & Johnson/Centocor, Inc., Integrilin from Merck & Co., Inc., and Aggrastat from Iroko Pharmaceuticals,

LLC and MediCure Inc. GP IIb/IIIa inhibitors are widely used and some physicians believe they offer superior efficacy to Angiomax. Physicians may choose to use heparin combined with GP IIb/IIIa inhibitors due to their years of experience with this combination therapy and reluctance to change existing hospital protocols and pathways. Physician resistance to the use of Angiomax due to either custom or efficacy could adversely affect our revenue.

In some circumstances, Angiomax competes with other anticoagulant drugs for the use of hospital financial resources. For example, many U.S. hospitals receive a fixed reimbursement amount per procedure for the angioplasties and other treatment procedures they perform. As this amount is not based on the actual expenses the hospital incurs, hospitals may choose to use either Angiomax or other anticoagulant drugs or a GP IIb/IIIa inhibitor but not necessarily more than one of these drugs. If hospitals do not choose Angiomax in these instances, our revenue will be adversely affected.

If we are unable to maintain our market exclusivity for Angiomax in the United States as a result of our inability to enforce our U.S. patents covering Angiomax, Angiomax could become subject to generic competition in the United States earlier than we anticipate. We have agreed that APP may sell a generic version of Angiomax beginning May 1, 2019 or earlier under certain

conditions, and that Teva may sell a generic version of Angiomax beginning June 30, 2019, or earlier under certain conditions. Competition from generic equivalents that would be sold at a price that is less than the price at which we currently sell Angiomax could have a material adverse impact on our business, financial condition and operating results.

Recothrom faces significant competition from all classes of topical hemostats and related sealant products, which may limit the use of Recothrom and adversely affect our revenue

Recothrom is a surgical hemostat that is applied topically during surgery to stop bleeding. There are a number of different classes of topical hemostats including:

- the GELFOAM Plus hemostasis kit marketed by Baxter Healthcare Corporation;

- mechanical hemostats, such as absorbable gelatin sponges;

- collagen, cellulose, or polysaccharide-based hemostats applied as sponges, fleeces, bandages, or microspheres which do not contain thrombin or any other active biologic compounds;

- active hemostats, which are thrombin products that may be derived from bovine or human pooled plasma purification or human recombinant manufacturing processes;

- flowable hemostats, which consists of granular collagen or gelatin component that is mixed with saline or reconstituted thrombin to form a semi-solid, flowable putty; and

- fibrin sealants, which consists of thrombin and fibrinogen that can be sprayed or applied directly to the bleeding surface.

The choice of a surgical hemostat depends on the surgical procedure, type and strength of bleeding, surgeon preference, price and availability of products within the operating room or hospital.

Recothrom competes with each of these types of surgical hemostats as well as other active hemostats. Recothrom is the only active hemostat that is not derived from bovine or human pooled plasma and can be used as a stand-alone product or in combination with a variety of other currently available mechanical and flowable hemostat products that are labeled for use with thrombin. Currently, there are two other stand-alone topical thrombin products commercially available in the United States, Thrombin-JMI, a bovine derived thrombin marketed by Pfizer, Inc., or Pfizer, and Evithrom, a human pooled plasma thrombin marketed by Ethicon, Inc., a subsidiary of Johnson & Johnson. In addition, Baxter International, Inc. markets the GELFOAM Plus Hemostasis Kit, which is Pfizer's GELFOAM sterile sponge co-packaged with human plasma-derived thrombin. Further, a number of companies, including Johnson & Johnson, Pfizer and Baxter International, Inc., currently market other hemostatic agents that may compete with Recothrom, including passive agents such as gelatin and collagen pads and flowable hemostats, as well as fibrin sealants and tissue glues. Many of these alternative hemostatic agents are relatively inexpensive and have been widely used for many years, and hospital purchasers continue to seek to limit growth of expenditures. Consequently, some physicians and hospital formulary decision-makers may be hesitant to adopt Recothrom. The active hemostat class has seen minor usage contraction recently while the flowable hemostats and fibrin sealants have shown growth. If physicians do not accept the potential advantages of Recothrom or resist the use of Recothrom due to either custom or cost containment measures, or the active hemostat class continues to decline, our revenues could be adversely affected.

If we are unable to successfully identify and acquire or license development stage compounds, clinical stage product candidates or approved products and develop or commercialize those compounds and products, our business, financial condition and results of operations may be adversely affected

Our business strategy is based on us selectively licensing or acquiring and then successfully developing and commercializing development stage compounds, clinical stage product candidates and approved products. Our success will be based in part on our ability to build and actively manage a portfolio of drugs that addresses unmet medical needs and creates value in patient therapy. However, the acquisition and licensing of pharmaceutical products is a competitive area. A number of more established companies, which have acknowledged strategies to license and acquire products, may have competitive advantages over us due to their size, cash flows and institutional experience.

In addition, we may compete with emerging companies taking similar or different approaches to product acquisition.

Because of the intense competition for these types of product candidates and approved products, the cost of acquiring, in-licensing or otherwise obtaining rights to such candidates and products has grown dramatically in recent years and are often at levels that we cannot afford or that we believe are not justified by market potential. Any acquisition or license of product candidates or approved products that we pursue may not result in any short or long term benefit to us. We may incorrectly judge the value

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or worth of an acquired or licensed product candidate or approved product. Even if we succeed in acquiring product candidates, we may not be successful in developing them and obtaining marketing approval for them, manufacturing them economically or commercializing them successfully. We have previously acquired or licensed rights to clinical or development stage compounds and, after having conducted development activities, determined not to devote further resources to those compounds. For example, in October 2012, we voluntarily discontinued our clinical trials and further development of MDCO-2010, which we had acquired in connection with our acquisition of Curacyte Discovery GmbH, or Curacyte Discovery, in August 2008, in response to serious unexpected patient safety issues encountered during a clinical trial. Similarly, following our review of data from the pharmacokinetic and pharmacodynamic study of several doses of MDCO-157 and oral clopidogrel in healthy volunteers, we elected not to proceed with the further development of MDCO-157, which we had licensed from CyDex.

In addition, our future success would depend in part on our ability to manage any required growth associated with some of these acquisitions and licenses. Any acquisition might distract resources from the development of our existing product candidates and could otherwise negatively impact sales of our other marketed products. Furthermore, the development or expansion of any licensed or acquired product candidate or approved product may require a substantial capital investment by us, and we may not have these necessary funds to do so.

If we are unable to identify and acquire additional promising candidates or to develop and commercialize successfully those candidates we have, we will not be able to implement our business strategy and our business, operating results and financial condition may be materially and adversely affected.

If we are not able to convince hospitals to include our products on their approved formulary lists, our revenues may not meet expectations and our business, results of operations and financial condition may be adversely affected

Hospitals establish formularies, which are lists of drugs approved for use in the hospital. If a drug is not included on the formulary, the ability of our engagement partners and engagement managers to promote and sell the drug may be limited or denied. For example, in connection with the launch of Cleviprex, we experienced difficulties in getting Cleviprex included on hospitals' formulary lists, in part because hospital formularies may limit the number of IV-AHT drugs in each drug class, and revenues from Cleviprex were adversely affected. If we fail to secure and maintain formulary inclusion for our products on favorable terms or are significantly delayed in doing so, we may have difficulty achieving market acceptance of our products and our business, results of operations and financial condition could be materially adversely affected.

If we are unable to negotiate and maintain satisfactory arrangements with group purchasing organizations with respect to the purchase of our products, our sales, results of operations and financial condition could be adversely affected

Our ability to sell our products to hospitals in the United States depends in part on our relationships with group purchasing organizations, or GPOs. Many existing and potential customers for our products become members of GPOs. GPOs negotiate pricing arrangements and contracts, sometimes on an exclusive basis, with medical supply manufacturers and distributors. These negotiated prices are then made available to a GPO's affiliated hospitals and other members. If we are not one of the providers selected by a GPO, affiliated hospitals and other members may be less likely to purchase our products, and if the GPO has negotiated a strict sole source, market share compliance or bundling contract for another manufacturer's products, we may be precluded from making sales to members of the GPO for the duration of the contractual arrangement. Our failure to renew contracts with GPOs may cause us to lose market share and could have a material adverse effect on our sales, financial condition and results of operations. We cannot assure you that we will be able to renew these contracts at the current or substantially similar terms. If we are unable to keep our relationships and develop new relationships with GPOs, our competitive position may suffer.

If the number of PCI procedures performed decreases, sales of Angiomax may be negatively impacted

The commercial success of Angiomax depends, in part, on the overall number of PCI procedures performed. The number of PCI procedures performed in the United States declined in 2007 due in part to the reaction to 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 to the controversy regarding the use of drug-eluting stents. Since 2007, PCI procedure volume has remained similar to the 2007 levels and has not returned to the level of PCI procedures performed prior to the 2007 decline. With ongoing economic pressures on our hospital customers, PCI procedure volume might further decline and might not return to its previous levels. Because PCI procedures are the primary procedures during which Angiomax is used, a decline in the number of procedures may negatively impact sales of Angiomax, possibly materially.

If we are unable to successfully expand our business infrastructure and develop our global operations, our ability to generate future product revenue will be adversely affected and our business, results of operations and financial condition may be adversely affected

To support the global sales and marketing of Angiomax, Cleviprex and our products in development, if and when they are approved for sale and marketed outside the United States, we are developing our business infrastructure globally. Our ability to do this successfully will depend on our ability to expand our internal organization and infrastructure to accommodate additional anticipated growth. To manage the existing and planned future growth and the increasing breadth and complexity of our activities, we will need to continue building our organization and making significant additional investments in personnel, infrastructure, information management systems and other operational resources. If we are unable to expand our global operations successfully and in a timely manner, the growth of our business may be limited. Such expansion may be more difficult, more expensive or take longer than we anticipate. If we are not able to successfully market and sell our products globally, our business, results of operations and financial condition may be adversely affected.

Future rapid expansion could strain our operational, human and financial resources. For instance, we may be required to allocate additional resources to the expanded business, which we would have otherwise allocated to another part of our business. 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.

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.

The success of our global operations may be adversely affected by international risks and uncertainties. If these operations are not successful, our business, results of operations and financial condition could be adversely affected

Our future profitability will depend in part on our ability to grow and ultimately maintain our product sales in foreign markets, particularly in Europe. For the year ended December 31, 2012 and the six months ended June 30, 2013, we had \$46.5 million and \$24.8 million, respectively, in sales outside of the United States and we have historically encountered difficulty in selling Angiomax outside of the United States. Our foreign operations subject us to additional risks and uncertainties, particularly because we have limited experience in marketing, servicing and distributing our products or otherwise operating our business outside of the United States. These risks and uncertainties include:

- political and economic determinations that adversely impact pricing or reimbursement policies;
- our customers' ability to obtain reimbursement for procedures using our products in foreign markets;
- compliance 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 foreign currency fluctuations, which could result in increased operating expenses and reduced revenues;

- trade restrictions and restrictions on direct investment by foreign entities;
- 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 operations 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.



If reimbursement by government payors or other third-party payors is not available or limited for our products, drug pricing is delayed or set at unfavorable levels or access to our products is reduced or terminated by governmental and other third-party payors, our ability to generate revenue would be adversely affected

Acceptable levels of coverage and reimbursement of drug treatments by government payors, such as Medicare and Medicaid programs, private health insurers and other organizations, have a significant effect on our ability to successfully commercialize our products. Reimbursement in the United States, Europe or elsewhere may not be available for any products we may develop or, if already available, may be decreased in the future. We may not get reimbursement or reimbursement may be limited if government payors, private health insurers and other organizations are influenced by the prices of existing drugs in determining whether our products will be reimbursed and at what levels. For example, the availability of numerous generic antibiotics at lower prices than branded antibiotics, such as oritavancin, if it were approved for commercial sale, could substantially affect the likelihood of reimbursement and the level of reimbursement for oritavancin. If reimbursement is not available or is available only at 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, pricing and reimbursement are set with limited, if any, participation in the process by the marketing authorization holder. In addition, it can take an extended period of time after the receipt of initial approval of a product to establish and obtain reimbursement or pricing approval. Reimbursement approval also 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. If prices are set at unsatisfactory levels, such prices may negatively impact our revenues from sales in those countries. An increasing number of countries are taking initiatives to attempt to reduce large budget deficits by focusing cost-cutting efforts on pharmaceuticals for their state-run health care systems. These international price control efforts have impacted all regions of the world, but have been most drastic in the European Union. Further, a number of European Union countries use drug prices from other countries of the European Union as “reference prices” to help determine pricing in their own countries. Consequently, a downward trend in drug prices for some countries could contribute to similar occurrences elsewhere. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

Third-party payors, including Medicare and Medicaid increasingly are challenging prices charged for and the cost-effectiveness of medical products and services and they increasingly are limiting both coverage and the level of reimbursement for drugs. Also, the trend toward managed health care in the United States and the changes in health insurance programs may result in lower prices for pharmaceutical products and health care reform. The PPACA may also have a significant impact on pricing as the legislation contains a number of provisions that are intended to reduce or limit the growth of healthcare costs. The provisions of the PPACA, as amended, could, among other things, increase pressure on drug pricing and, as a result, the number of procedures that are performed. In addition to federal legislation, state legislatures and foreign governments have also shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. The establishment of limitations on patient access to our drugs, adoption of price controls and cost-containment measures in new jurisdictions or programs, and adoption of more restrictive policies in jurisdictions with existing controls and measures could adversely impact our business and future results. If governmental organizations and third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not reimburse providers or consumers of our products or, if they do, the level of reimbursement may not be sufficient to allow us to sell our products on a profitable basis.

Use or misuse of our products may result in serious injuries or even death to patients and may subject us to significant claims for product liability. If we are unable to obtain insurance at acceptable costs and adequate levels or otherwise protect ourselves against potential product liability claims, we could be exposed to significant liability

Our business exposes us to potential significant 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 or study.

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 all or any product liability claims that we face

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.

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

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

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

We have no manufacturing or supply capabilities and are completely dependent on third parties for the manufacture and supply of our products. We depend on a limited number of suppliers for the production of bulk drug substance for our products and products in development and to carry out fill-finish activities. If any of these suppliers does not or cannot fulfill its manufacturing or supply obligations to us, our ability to meet commercial demands for our products and to conduct clinical trials of our products and products in development could be impaired and our business could be harmed

We do not manufacture any of our products and do not plan to develop any capacity to manufacture them. We currently rely on a limited number of manufacturers and other third parties for bulk substance and to carry out fill-finish activities for our products and products in development. We expect to continue this manufacturing arrangement for Angiomax, Recothrom and all of our other approved products and products in development for the foreseeable future.

In the event that any third party 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 on commercially reasonable terms on a timely basis or at all. In such cases, the third-party manufacturers have made no commitment to supply the drug product to us on a long-term basis and could reject our purchase orders. Only a limited number of manufacturers are capable of manufacturing our products and products in development. 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.

If we were required to transfer manufacturing processes to other third-party manufacturers and we were able to identify an alternative manufacturer, we would still need to satisfy various regulatory requirements. Satisfaction of these requirements could cause us to experience significant delays in receiving an adequate supply of our products and products in development and could be costly. 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 our products on a timely basis, which could reduce our revenue, and to supply product for clinical trials of Angiomax, Cleviprex and our products in development, which could affect our ability to complete clinical trials on a timely basis.

If third parties on whom we rely to manufacture and support the development and commercialization of our products do not fulfill their obligations or we are unable to establish or maintain such arrangements, the development and commercialization of our products may be terminated or delayed, and the costs of development and commercialization may increase

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 many of these activities on our own and, as a result, are particularly dependent on third parties in many areas.

We may not be able to maintain our existing arrangements with respect to the commercialization or manufacture of our products or establish and maintain arrangements to develop, manufacture and commercialize our products in development 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 our products, our products in development or any additional products or product candidates we may acquire, 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 our products, our products in development or any additional products or product candidates 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.

Our reliance on third-party manufacturers and suppliers to supply our products and product candidates may increase the risk that we will not have appropriate supplies of our products or our product candidates, which could adversely affect our business, results of operations and financial condition

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

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

- the possible breach of the manufacturing or supply 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.

For example, in December 2009 and March 2010 we conducted voluntary recalls of manufactured lots of Cleviprex due to the presence of visible particulate matter at the bottom of some vials that were manufactured for us by a third party. As a result, we were not able to supply the market with Cleviprex or sell Cleviprex from the first quarter of 2010 until April 2011. In addition, in December 2011 Eagle, the licensor and sole supplier of ready-to-use Argatroban, conducted a voluntary recall of the product due to the presence of particulate matter in some vials. As a result, we were not able to sell ready-to-use Argatroban from December 2011 to April 2012. In April 2012, we re-commenced selling ready-to-use Argatroban to existing and new customers.

Our products and products in development 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 our products and products in

development, it will be more difficult for us to compete effectively, market and sell our approved products and develop our products in development.

Our 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 current good manufacturing practices, or 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 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, suspension of clinical trials, 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 our products and products in development.

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

We 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 the United States and Canada govern the use, manufacture, storage, handling and disposal of hazardous materials. We may incur significant additional costs to comply with applicable laws in the future. Also, 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.

If we fail to acquire and develop additional development-stage compounds, clinical-stage product candidates or approved products, it will impair our ability to grow our business

In order to generate additional revenue, our business plan is to acquire or license, and then develop and market, additional development-stage compounds, clinical-stage product candidates and approved products. From 2008 through August 2013, for instance, we acquired Curacyte Discovery, Targanta, Incline and ProFibrix, licensed marketing rights to the ready-to-use formulation of Argatroban, licensed development and commercialization rights to MDCO-216, MDCO-157 and the ALN-PCS program, licensed the non-exclusive rights to sell and distribute ten acute care generic products and entered into a collaboration arrangement with BMS with respect to the commercialization of Recothrom. The success of this growth strategy depends upon our ability to identify, select and acquire or license 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, Targanta, Incline and ProFibrix, 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. In addition, proposing, negotiating and implementing an economically viable acquisition or license 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 or license of development-stage compounds, clinical-stage product candidates and approved products. We may not be able to acquire or license the rights to additional product candidates and approved products on terms that we find acceptable, or at all.

#### Risks Related to Regulatory Matters

If we do not obtain regulatory approvals for our product candidates in any jurisdiction or for our products in any additional jurisdictions, we will not be able to market our products and product candidates in those jurisdictions and our ability to generate additional revenue could be materially impaired

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. In addition, we must obtain approval from foreign regulatory authorities in order to sell our U.S.-approved products in other countries. Obtaining regulatory approval is uncertain, time-consuming and expensive. Any regulatory approval we ultimately obtain may limit the

indicated uses for the product or subject the product to restrictions or post-approval commitments that render the product commercially non-viable. Securing regulatory approval requires the submission of extensive non-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 the products or product candidates in the jurisdiction for which approval is sought;

- diminish our competitive advantage; and

- defer or decrease our receipt of revenue.



The regulatory review and approval process to obtain marketing approval 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 involved. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that data are 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. Moreover, recent events, including complications experienced by patients taking FDA-approved drugs, have raised questions about the safety of marketed drugs and may result in new legislation by the U.S. Congress or foreign legislatures and increased caution by the FDA and comparable foreign regulatory authorities in reviewing applications for marketing approval.

We conducted our SOLO I and SOLO II clinical trials of oritavancin pursuant to an SPA with the FDA. Many companies which have been granted SPAs have ultimately failed to obtain final approval to market their drugs. Since we are developing oritavancin under an SPA, based on protocol designs negotiated with the FDA, we may be subject to enhanced scrutiny. Additionally, even though the primary endpoints in the SOLO trials were achieved, an SPA does not guarantee approval. An SPA is not binding on the FDA if public health concerns unrecognized at the time the SPA was entered into become evident; the data, assumptions or information underlying the SPA request change or are called into question; other new scientific concerns regarding product safety or efficacy arise; or if we fail to comply with the agreed upon trial protocols. The FDA may raise issues of safety, study conduct, bias, deviation from the protocol, statistical power, patient completion rates, changes in scientific or medical parameters or internal inconsistencies in the data prior to making its final decision. The FDA may also seek the guidance of an outside advisory committee prior to making its final decision.

We intend to submit an application to the FDA requesting that it designate oritavancin as a QIDP under the "Generating Antibiotic Incentives Now," or GAIN, provisions of the Food and Drug Administration Safety and Innovation Act, or FDASIA. Upon the designation of a drug by the FDA as a QIDP, if given, any non-patent exclusivity period awarded to the drug will be extended by an additional five years. It is unclear whether FDA will determine that oritavancin is eligible to be designated as a QIDP. If it is not eligible, then oritavancin will not be granted this additional period of non-patent exclusivity or other benefits of the GAIN Act.

The procedures to obtain marketing approvals vary among countries and can involve additional clinical trials or other pre-filing requirements. The time required to obtain foreign regulatory approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all the risks associated with obtaining FDA approval, or different or additional risks. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by the regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by the FDA or regulatory authorities in other foreign countries. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products and products in development in any market.

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

In order to market our products 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 involved. The regulatory authorities have substantial discretion in the approval process and may refuse to accept any application. Alternatively, they may decide that any data submitted is insufficient for approval and require additional pre-clinical, clinical or

other studies, which studies could require the expenditure of substantial resources. Even if we undertook such studies, we might not be successful in obtaining regulatory approval for these indications or any other indications in a timely manner or at all. 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 for a product. If we are unsuccessful in expanding the product label of our products, the size of the commercial market for our products will be limited.

For example, 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 May 2008 letter, the FDA indicated that the basis of their decision involved the appropriate use and interpretation of non-inferiority trials, including the ACUITY trial. If we determine to pursue these indications, the FDA may require that we conduct additional studies of Angiomax, which studies could require the expenditure of substantial resources. Even if we undertook such studies, 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. If we are unable to conduct clinical trials that demonstrate the safety and efficacy of our product candidates on a timely basis, then our costs of developing the product candidates may increase and we may not be able to obtain regulatory approval for our product candidates on a timely basis or at all.

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 October 2012, we voluntarily discontinued our Phase 2b dose-ranging study of MDCO-2010, a serine protease inhibitor which we were developing to reduce blood loss during surgery, in response to serious unexpected patient safety issues encountered during the trial. Further, in November 2009, we discontinued enrollment in our Phase 3 clinical trials of cangrelor prior to completion after the independent Interim Analysis Review Committee for the program reported to us that the efficacy endpoints of the trial program would not be achieved.

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, ethics committees 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 the contract manufacturers manufacturing our products and product candidates fail to comply with the extensive regulatory requirements to which we, our contract manufacturers and our products and product candidates

are subject, our products could be subject to restrictions or withdrawal from the market, the development of our product candidates could be jeopardized, and we could be subject to penalties

The research, testing, manufacturing, labeling, safety, advertising, promotion, storage, sales, distribution, import, export and marketing, among other things, of our products, both before and after approval, are subject to extensive regulation by governmental authorities in the United States, Europe and elsewhere throughout the world. Both before and after approval of a product, quality control and manufacturing procedures must conform to cGMP. Regulatory authorities, including the FDA, periodically inspect manufacturing facilities to assess compliance with cGMP. Our failure or the failure of contract manufacturers to comply with the laws administered by the FDA, the EMA 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;
- delays in, suspension of or prohibition of commencing, clinical trials of products in development;
- interruption of production;
- operating restrictions;
- untitled or warning letters;
- injunctions;
- fines and other monetary penalties;
- the imposition of civil or criminal penalties;
- disruption of importing and exporting activities; and
- unanticipated expenditures.

We may incur significant liability if it is determined that we are promoting the “off-label” use of any of our products

Physicians may prescribe drug products for uses that are not described in the product's labeling and that differ from those approved by the FDA or other applicable regulatory agencies. Off-label uses are common across medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDA and other regulatory agencies do restrict communications on the subject of off-label use. Companies may not promote drugs for off-label uses. The FDA and other regulatory and enforcement authorities actively enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained. A company that is found to have promoted off-label uses may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific exchange concerning their products. We engage in medical education activities and communicate with investigators and potential investigators regarding our clinical trials. If the FDA or another regulatory or enforcement authority determines that our communications regarding our marketed products are not in compliance with the relevant regulatory requirements and that we have improperly promoted off-label uses, we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

If we do not comply with federal, state and foreign laws and regulations relating to the health care business, 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:

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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;

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; and

various state laws that impose similar requirements and liability with respect to state healthcare reimbursement and other programs.

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.

Failure to comply with the U.S. Foreign Corrupt Practices Act, or FCPA, as well as the anti-bribery laws of the nations in which we conduct business, could subject us to penalties and other adverse consequences

We are subject to the FCPA, which generally prohibits U.S. companies from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business and requires companies to maintain accurate books and records and internal controls, including at foreign-controlled subsidiaries. In addition, we are subject to other anti-bribery laws of the nations in which we conduct business that apply similar prohibitions as the FCPA. Our employees or other agents may engage in prohibited conduct without our knowledge under our policies and procedures and the Foreign Corrupt Practices Act and other anti-bribery laws that we may be subject to for which we may be held responsible. If our employees or other agents are found to have engaged in such practices, we could suffer severe penalties and other consequences that may have a material adverse effect on our business, financial condition and results of operations.

#### Risks Related to Our Intellectual Property

If we are unable to maintain our market exclusivity for Angiomax in the United States as a result of our inability to enforce our U.S. patents covering Angiomax, Angiomax could be subject to generic competition earlier than we anticipate. Generic competition for Angiomax would have a material adverse effect on our business, financial condition and results of operations

The principal U.S. patents covering Angiomax include the '404 patent, the '727 patent and the '343 patent. The '404 patent was set to expire in March 2010, but the term was extended to December 15, 2014 by the PTO under the Hatch-Waxman Act. As a result of our study of Angiomax in the pediatric setting, we are entitled to a six-month period of pediatric exclusivity following expiration of the '404 patent. In the second half of 2009, the PTO issued to us the '727 patent and the '343 patent, covering a more consistent and improved Angiomax drug product and the processes by which it is made. The '727 patent and the '343 patent are set to expire in July 2028. In response to Paragraph IV Certification Notice letters we received with respect to abbreviated new drug applications, or ANDAs, filed by a number of parties with the FDA seeking approval to market generic versions of Angiomax, we have filed lawsuits against the ANDA filers alleging patent infringement of the '727 patent and '343 patent.

In September 2011, we settled our patent infringement litigation with Teva. In connection with the Teva settlement we entered into a license agreement with Teva under which we granted Teva a non-exclusive license under the '727 patent and '343 patent to sell a generic bivalirudin for injection product under a Teva ANDA in the United States beginning

June 30, 2019 or earlier under certain conditions.

In January 2012, we settled our patent infringement litigation with APP. In connection with the APP settlement, we entered into a license agreement with APP under which we granted APP a non-exclusive license under the '727 patent and '343 patent to sell a generic bivalirudin for injection product under an APP ANDA in the United States beginning on May 1, 2019. In certain limited circumstances, the license to APP could include the right to sell a generic bivalirudin product under our NDA for Angiomax in the United States beginning on May 1, 2019 or, in certain limited circumstances, on June 30, 2019 or on a date prior to May 1, 2019.

We remain in infringement litigation involving the '727 patent and '343 patent with the other ANDA filers, as described in Part II, Item 1, Legal Proceedings, of this quarterly report. On July 12, 2013, the Court in the Hospira matter issued its Markman decision as to the claim construction of the '727 patent and the '343 patent. The Court's decision varied from the other Markman decisions that we have received in our other patent infringement litigations. On July 22, 2013, we filed a motion for reconsideration



of the Court's claim construction ruling on the grounds that the Court (i) impermissibly imported process limitations disclosed in a preferred embodiment into the claims, (ii) improperly transformed product claims into product-by-process claims, (iii) improperly rendered claim language superfluous and violated the doctrine of claim differentiation, and (iv) improperly construed limitations based on validity arguments that have not yet been presented. The Court has set a September 23, 2013 trial date.

There can be no assurance to the outcome of litigation. If we are unable to maintain our market exclusivity for Angiomax in the United States as a result of our inability to enforce our U.S. patents covering Angiomax, Angiomax could become subject to generic competition in the United States earlier than May 1, 2019. Competition from generic equivalents that would be sold at a price that is less than the price at which we currently sell Angiomax would have a material adverse impact on our business, financial condition and operating results.

Following our settlements with Teva and APP, we submitted the settlement documents for each settlement to the U.S. Federal Trade Commission, or the FTC, and the U.S. Department of Justice, or the DOJ. The FTC and the DOJ could seek to challenge our settlements with Teva and APP, or a third party could initiate a private action under antitrust or other laws challenging our settlements with Teva and APP. While we believe our settlements are lawful, we may not prevail in any such challenges or litigation, in which case the other party might obtain injunctive relief, remedial relief, or such other relief as a court may order. In any event, we may incur significant costs in the event of an investigation or in defending any such action and our business and results of operations could be materially impacted if we fail to prevail against any such challenges.

If we breach any of the agreements under which we license rights to products or technology from others, we could lose license rights that are material to our business or be subject 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 each of our products and products in development. Under these agreements, we are subject to a range of commercialization and development, sublicensing, royalty, patent prosecution and maintenance, insurance and other obligations.

Any failure by us to comply with any of these obligations or any other breach by us of 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, such dispute could lead to delays in the development or commercialization of potential products and result in time-consuming and expensive litigation or arbitration. In addition, on termination we may be required to license to the licensor any related intellectual property that we developed.

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

The patent positions of pharmaceutical companies like us are generally uncertain and involve complex legal, scientific and factual issues. We cannot be certain that our patents and patent applications, including our own and those that we have rights through licenses from third parties will adequately protect our intellectual property. Our success protecting our intellectual property 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

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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.

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the value of patents, once obtained, and with regard to our ability to obtain patents in the future. Depending on decisions by the U.S. Congress, the federal courts, and the PTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that others have not filed or maintained patent applications for technology used by us or covered by our pending patent applications without our being aware of these applications.

We exclusively license patents and patent applications for each of our products and products in development, for which we own the patents and patent applications, and we license on a non-exclusive basis the acute care generic products from APP which are not covered by any patents or patent applications. The patents covering our approved products and our product candidates are currently set to expire at various dates:

Angiomax. The principal U.S. patents covering Angiomax include the '404 patent, the '727 patent and the '343 patent. The '404 patent, was set to expire in March 2010, but the term was extended to December 15, 2014 by the PTO under the Hatch-Waxman Act. As a result of our study of Angiomax in the pediatric setting, we are entitled to a six-month period of pediatric exclusivity following expiration of the '404 patent.

In the second half of 2009, the PTO issued to us the '727 patent and the '343 patent, covering a more consistent and improved Angiomax drug product and the processes by which it is made. The '727 patent and the '343 patent are set to expire in July 2028 and are also entitled to a six-month period of pediatric exclusivity following expiration of the patents. In response to Paragraph IV Certification Notice letters we received with respect to ANDAs filed with the FDA seeking approval to market generic versions of Angiomax, we have filed lawsuits against the ANDA filers alleging patent infringement of the '727 patent and '343 patent. In September 2011, we settled our patent infringement litigation with Teva. In connection with the settlement, we entered into a license agreement with Teva under which we granted Teva a non-exclusive license under the '727 patent and '343 patent to sell a generic bivalirudin for injection product under a Teva ANDA in the United States beginning June 30, 2019 or earlier under certain conditions. The license agreement also contains a grant by Teva to us of an exclusive (except as to Teva), license under Teva's bivalirudin patents and right to enforce Teva's bivalirudin patents. In January 2012, we settled our patent infringement litigation with APP. In connection with the settlement, we entered into a license agreement with APP under which we granted APP a non-exclusive license under the '727 patent and '343 patent to sell a generic bivalirudin for injection product under an APP ANDA in the United States beginning on May 1, 2019. In addition, in certain limited circumstances, the license to APP could include the right to sell a generic bivalirudin product under our NDA for Angiomax in the United States beginning on May 1, 2019 or, in certain limited circumstances, on June 30, 2019 or on a date prior to May 1, 2019. We remain in infringement litigation involving the '727 patent and '343 patent with the other ANDA filers. If we are unable to maintain our market exclusivity for Angiomax in the United States through enforcement of our U.S. patents covering Angiomax, Angiomax could be subject to generic competition earlier than May 1, 2019.

In Europe, the principal patent covering Angiomax expires in 2015.

Recothrom. We have exclusively licensed from BMS rights to patents and patent applications covering Recothrom's pharmaceutical compositions, formulations and methods of manufacturing for purposes of promoting, marketing and selling Recothrom. The expiration dates of these patents range from 2013 to 2029 in the United States. BMS has also filed and is currently prosecuting a number of patent applications relating to Recothrom in the United States and in foreign countries. As a biologic, we believe Recothrom is entitled to regulatory exclusivity as a "reference product" in the United States expiring in January 2020. The FDA, however, has not issued any regulations or final guidance explaining how it will implement the abbreviated BLA provisions enacted in 2010 under the BPCIA, including the exclusivity provisions for reference products. It is thus possible that the FDA will decide to interpret the provisions in such a way that our products are not considered to be reference products for purposes of the statute or to be entitled to any period of data or marketing exclusivity. Even if our products are considered to be reference products eligible for exclusivity, such exclusivity will not prevent other companies marketing competing versions of Recothrom, including competing recombinant thrombin product, if such companies can complete, and FDA permits the submission of and approves, full BLAs with complete human clinical data packages for such products.

Cleviprex. The principal U.S. patent for Cleviprex is U.S. Patent No. 5,856,346, or the '346 patent, which was set to expire in January 2016, but the term has been extended to January 2021 by the PTO under the Hatch-Waxman Act. In Europe, the principal patent covering Cleviprex was set to expire in November 2014, but the term has been extended to November 2019 under patent term extensions, also known as supplementary protection certificates, in most European countries where we have received regulatory approval. In addition, we have filed and are currently prosecuting a number of patent applications relating to Cleviprex covering compositions of matter and uses in the United States, Europe and other foreign countries.

Ready-to-Use Argatroban. We exclusively licensed from Eagle rights to two U.S. patents covering certain formulations of Argatroban. Our exclusive license is limited to the United States and Canada. The patents are set to expire in September 2027. In February 2012, we were notified that Sandoz had submitted an ANDA seeking permission to market its second generic version of ready-to-use Argatroban prior to the expiration of these patents. On March 29, 2012, Eagle, which directed and controlled the enforcement of its intellectual property rights with respect to ready-to-use Argatroban, filed suit against Sandoz in the U.S. District Court for the District of New Jersey for infringement of its ready-to-use Argatroban patents. In November 2012, Eagle advised us that it entered into a settlement agreement with Sandoz, and as part of the settlement, Eagle agreed to give Sandoz the right to introduce an authorized generic version of ready-to-use Argatroban. Sandoz currently markets two ready-to-use generic formulations of Argatroban.

Cangrelor. The principal U.S. and European patents for cangrelor are set to expire in February 2014 if no patent term extension is obtained. In addition, we have issued patents directed to cangrelor pharmaceutical compositions which expire in 2017 and 2018 if no patent term extension is obtained. We have also filed and are currently prosecuting a number of patent applications related to cangrelor.

Oritavancin. The principal patent for oritavancin in both the United States and Europe will expire in November 2015 if no patent term extension is obtained. We have issued patents directed to the process of making oritavancin. These patents are set to expire in 2017 if no patent term extension is obtained. We also have an issued patent covering the use of oritavancin in treating certain skin infections that expires in August 2029 if no patent term extension is obtained. We have also filed and are prosecuting a number of patent applications relating to oritavancin and its uses.

IONSYS. As a result of our acquisition of Incline, we acquired a portfolio of patents and patent applications covering the IONSYS device and its uses. Some of these patents and patent applications were exclusively licensed from ALZA Corporation. The expiration dates of patents covering the IONSYS device and its use range from September 2014 to June 2032 in the United States. In Europe, the expiration date of patents covering the IONSYS device range from June 2015 to January 2021. We are also currently prosecuting patent applications relating to IONSYS in the United States and in certain foreign countries.

MDCO-216. We are maintaining a number of U.S. patents with respect to MDCO-216, including patents that claim the use of MDCO-216 in certain disease indications. One of these U.S. patents is directed to the use of MDCO-216 for the treatment of ACS and is set to expire in October 2024 if no patent term extension is obtained. We have also filed and are prosecuting a number of patent applications related to the use and production of MDCO-216 in the United States, Europe and other foreign countries. As a biologic, we believe MDCO-216 is entitled to receive 12 years of regulatory exclusivity as a "reference product" in the United States and 10 years of regulatory exclusivity in Europe from the date of the initial marketing approval of MDCO-216, if approved.

ALN-PCS Program. We have exclusively licensed from Alnylam patents covering RNAi therapeutics targeting PCSK9 for the treatment of hypercholesterolemia and other human diseases for purposes of developing and commercializing such RNAi therapeutics. Some of these patents are directed to general RNAi technology and expire

between 2015 and 2021 both in the United States and in certain foreign countries. Other patents are directed to specific compositions of the PCSK9 product being developed under the license and methods of treatment using such PCSK9 product and expire from May 2027 to June 2030. In addition, Alnylam has filed and is prosecuting a number of patent applications in the United States and in certain foreign countries.

Fibrocaps. As a result of our acquisition of ProFibrix, we acquired a portfolio of patents and patent applications, including patents with respect to Fibrocaps licensed from Quadrant Drug Delivery Limited, or Quadrant. The U.S. patent licensed from Quadrant is directed to the composition of matter of Fibrocaps, and is set to expire in May 2017. ProFibrix has also filed and is prosecuting a number of patent applications related to the use and production of Fibrocaps. As a biologic, we believe Fibrocaps is entitled to receive 12 years of regulatory exclusivity as a "reference product" in the United States and 10 years of regulatory exclusivity in Europe from the date of the initial marketing approval of Fibrocaps, if approved.

We plan to file applications for patent term extension for our products in development upon their approval. If we do not receive patent term extensions for the periods requested by us or at all, our patent protection for our products in development could be limited.

We are a party to a number of lawsuits that we brought against pharmaceutical companies that have notified us that they have filed ANDAs seeking approval to market generic versions of Angiomax. We cannot predict the outcome of these lawsuits. Involvement in litigation, regardless of its outcome, is time-consuming and expensive and may divert our management's time and attention. During the period in which these matters are pending, the uncertainty of their outcome may cause our stock price to decline. An adverse result in these matters whether appealable or not, will likely cause our stock price to decline. Any final, unappealable, adverse result in these matters will likely have a material adverse effect on our results of operations and financial conditions and cause our stock price to decline.

If upon expiration of our agreement with Lonza Braine S.A., or Lonza Braine, Lonza Braine breaches our agreement and fails to transfer the technology that was used to develop the Chemilog process, we would be unable to employ the Chemilog process to manufacture Angiomax bulk drug substance, which could cause us to experience delays in the manufacturing process and increase our manufacturing costs in the future

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 2016, 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 and invention assignment 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 or invention assignment 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, our business may be adversely affected

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. Patent litigation and other proceedings may also absorb significant management time. 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 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 and underlying hospital demand for our products, 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.

The warrant transactions and the derivative transactions that we entered into in connection with the convertible note hedge and warrant transactions may affect the price of our common stock

In connection with sale of the Notes, we entered into convertible note hedge and warrant transactions with several of the initial purchasers of the Notes, their affiliates and other financial institutions, or the Hedge Counterparties. Upon settlement, the warrants could have a dilutive effect on our earnings per share and the market price of our common stock to the extent that the market price per share of our common stock exceeds the then applicable strike price of the warrants. However, subject to certain conditions, we may elect to settle all of the warrants in cash.

In connection with establishing their hedges of the convertible note hedge and warrant transactions, the Hedge Counterparties or their affiliates entered into various derivative transactions with respect to our common stock. These parties may modify their hedge positions in the future by entering into or unwinding various derivatives with respect to our common stock and/or purchasing or selling our common stock or other securities of ours in secondary market transactions prior to the maturity of the Notes (and are likely to do so during any observation period related to a conversion of the Notes). These activities could cause a decrease or avoid an increase in the market price of our common stock.

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, 2010 to August 2, 2013, the last reported sale price of our common stock ranged from a high of \$37.10 per share to a low of \$7.00 per share. The value of your investment could decline due to the effect upon the market price of our common stock of any of the following factors, many of which are beyond our control:

- achievement or rejection of regulatory approvals of our product candidates and our products;
- regulatory actions by the FDA or a foreign jurisdiction limiting or revoking the use of our products;
- changes in securities analysts' estimates of our financial performance;
- changes in valuations of similar companies;
- variations in our operating results;
- acquisitions and strategic partnerships;
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announcements of technological innovations or new commercial products by us or our competitors or the filing of ANDAs, NDAs or BLAs for products competitive with ours;

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;

changes in governmental regulations;

developments in patent rights or other proprietary rights, particularly with respect to our U.S. Angiomax patents;

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the extent to which Angiomax is commercially successful globally;

our ability to maintain market exclusivity for Angiomax in the United States through the enforcement of the '727 patent and the '343 patent during the period following the expiration of the patent term of the '404 patent on December 15, 2014 and the six month pediatric exclusivity on June 15, 2015 through at least May 1, 2019, the date on which we agreed APP may sell a generic version of Angiomax;

significant new litigation;

developments or issues with our contract manufacturers;

changes in our management; and

general market conditions.

We believe that period-to-period comparisons of our financial results will not necessarily be indicative of our future performance. If our revenues in any particular period do not meet expectations, we may not be able to adjust our expenditures in that period, which could cause our operating results to suffer. If our operating results in any future period fall below the expectations of securities analysts or investors, our stock price may fall by a significant amount.

The stock markets in general, and The NASDAQ Global Market and the market for biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations recently. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. These broad market and industry factors may adversely affect the market price of our common stock, regardless of our actual operating performance.

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

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

Section 203 of the Delaware General Corporation Law, which provides that we may not enter into a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in the manner prescribed in Section 203;

our board of directors has the authority to issue, without a vote or action of stockholders, up to 5,000,000 shares of a new series of preferred stock and to fix the price, rights, preferences and privileges of those shares, each of which could be superior to the rights of holders of our common stock;

our directors are elected to staggered terms, which prevents our entire board of directors from being replaced in any single year;

our directors may be removed only for cause and then only by the affirmative vote of the holders of at least 75% of the votes which all stockholders would be entitled to cast in any annual election of directors;

the size of our board of directors is determined by resolution of the board of directors;

any vacancy on our board of directors, however occurring, including a vacancy resulting from an enlargement of our board, may only be filled by vote of a majority of our directors then in office, even if less than a quorum;

only our board of directors, the chairman of the board or our president may call special meetings of stockholders;

our by-laws may be amended, altered or repealed by (i) the affirmative vote of a majority of our directors, subject to any limitations set forth in the by-laws, or (ii) the affirmative vote of the holders of at least 75% of the votes which all the stockholders would be entitled to cast in any annual election of directors;

• stockholders must provide us with advance notice, and certain information specified in our by-laws, in connection with nominations or proposals by such stockholder for consideration at an annual meeting;

• stockholders may not take any action by written consent in lieu of a meeting; and

our certificate of incorporation may only be amended or repealed by the affirmative vote of a majority of our directors and the affirmative vote of the holders of at least 75% of the votes which all the stockholders would be entitled to cast in any annual election of directors (and plus any separate class vote that might in the future be required pursuant to the terms of any series of preferred stock that might be outstanding at the time any of these amendments are submitted to stockholders).

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.

Our business could be negatively affected as a result of the actions of activist shareholders

Proxy contests have been waged against many companies in the biopharmaceutical industry over the last few years. If faced with a proxy contest, we may not be able to successfully defend against the contest, which would be disruptive to our business. Even if we are successful, our business could be adversely affected by a proxy contest because:

- responding to proxy contests and other actions by activist shareholders may be costly and time-consuming and may disrupt our operations and divert the attention of management and our employees;

perceived uncertainties as to our future direction may result in our inability to consummate potential acquisitions, collaborations or in-licensing opportunities and may make it more difficult to attract and retain qualified personnel and business partners; and

• if individuals are elected to our board of directors with a specific agenda different from ours, it may adversely affect our ability to effectively and timely implement our strategic plan and create additional value for our stockholders.

## Item 5. Other Information

At our annual meeting of stockholders held on May 30, 2013, our stockholders voted to approve the 2013 Stock Incentive Plan, or the 2013 plan. Our board of directors had previously adopted the 2013 plan on April 23, 2013, subject to approval by our stockholders. The 2013 plan replaced our Amended and Restated 2004 Stock Incentive Plan, which terminated upon stockholder approval of the 2013 plan.

The 2013 plan is administered by our board of directors. Pursuant to the terms of the 2013 plan and to the extent permitted by applicable law, our board of directors may delegate authority under the 2013 plan to one or more committees or subcommittees of the board. Our board of directors has authorized the compensation committee to administer certain aspects of the 2013 plan, including the granting of options to executive officers. The 2013 plan permits us to grant incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and other stock-based and cash-based awards, including the grant of shares to be delivered in the future, to our employees, officers, directors, consultants and advisors. Subject to adjustment in the event of stock splits and other similar changes in capitalization or events, up to 13,742,134 shares of our common stock may be issued pursuant to awards granted under the 2013 plan.

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For a more detailed description of the 2013 plan, see Proposal Two of our Definitive Proxy Statement on Schedule 14A, or proxy statement, filed with the SEC on April 29, 2013. A copy of the 2013 plan is attached as Appendix I to our proxy statement and is filed as Exhibit 10.1 to this quarterly report on Form 10-Q.

Item 6. Exhibits

Exhibits

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

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SIGNATURES

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

THE MEDICINES COMPANY

Date: August 9, 2013

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



EXHIBIT INDEX

Exhibit Number	Description
10.1	2013 Stock Incentive Plan
10.2	Form of employee stock option agreement under 2013 Stock Incentive Plan
10.3	Form of non-employee director stock option agreement under 2013 Stock Incentive Plan
10.4	Form of employee restricted stock agreement under 2013 Stock Incentive Plan
10.5	Form of non-employee director restricted stock agreement under 2013 Stock Incentive Plan
10.6*	Share Purchase Agreement, dated June 4, 2013, by and among the registrant, ProFibrix B.V., the equityholders of ProFibrix, certain members of the management team of ProFibrix in their capacities as warrantors of certain information in the Share Purchase Agreement, the holders of options to acquire equity interests in ProFibrix and the representative (filed as Exhibit 2.1 of the registrant's current report on Form 8-K, filed on August 7, 2013)
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
101	The following materials from The Medicines Company Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Balance Sheet, (ii) the Consolidated Statement of Income, (iii) the Consolidated Statement of Cash Flow, and (iv) Notes to Consolidated Financial Statements.

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