MEDICINES CO /DE
Form 10-Q
May 09, 2016
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q
(Mark One)
þ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended: March 31, 2016
OR
o 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	04-3324394
(State or other jurisdiction of incorporation or organization)	(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 þ No o

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 þ No o

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 þ Accelerated filer o Non-accelerated filer o

		Smaller reporting company o
	(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 o No þ

As of May 5, 2016, there were 70,072,431 shares of Common Stock, $0.001 par value per share, outstanding (excluding 2,192,982 shares held in treasury).

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THE MEDICINES COMPANY
QUARTERLY REPORT ON FORM 10-Q
For the Quarterly Period Ended March 31, 2016
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Part I. Financial Information

Item 1. Condensed Financial Statements

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

	March 31, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$430,196	$373,173
Accounts receivable, net of allowances of approximately $13.7 million and $17.6 million at March 31, 2016 and December 31, 2015	42,834	52,328
Inventory	68,454	64,584
Prepaid expenses and other current assets	19,337	19,995
Current assets held for sale	—	322,837
Total current assets	560,821	832,917
Fixed assets, net	34,416	34,780
Intangible assets, net	629,935	636,220
Goodwill	289,441	289,441
Restricted cash	1,406	1,428
Contingent purchase price from sale of business	78,000	—
Other assets	750	730
Total assets	$1,594,769	$1,795,516
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$15,526	$36,038
Accrued expenses	103,109	128,558
Current portion of contingent purchase price	29,939	26,800
Convertible senior notes	258,800	255,473
Deferred revenue	21,869	19,863
Current liabilities held for sale	—	67,515
Total current liabilities	429,243	534,247
Contingent purchase price	89,673	96,957
Convertible senior notes	315,080	312,107
Deferred tax liabilities	89,150	89,996
Other liabilities	12,530	13,346
Total liabilities	935,676	1,046,653
Equity component of currently redeemable convertible senior notes (Note 10)	14,167	17,089
Stockholders' equity:		
Preferred stock, $1.00 par value per share, 5,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $.001 par value per share; 187,500,000 authorized, 72,131,960 issued and 69,938,978 outstanding at March 31, 2016 and 71,767,371 issued and 69,574,389 outstanding at December 31, 2015	72	72
Additional paid-in capital	1,223,024	1,208,058
Treasury stock, at cost; 2,192,982 shares at March 31, 2016 and December 31, 2015	(50,000)	(50,000)
Accumulated deficit	(522,313)	(429,865)
Accumulated other comprehensive (loss) income	(5,377)	3,973
Total The Medicines Company stockholders' equity	645,406	732,238
Non-controlling interest in joint venture	(480)	(464)

Total stockholders' equity	644,926	731,774
Total liabilities and stockholders' equity	$1,594,769	$1,795,516

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2016	2015
Net product revenues	$31,375	$110,115
Royalty revenues	18,931	—
Total net revenues	50,306	110,115
Operating expenses:		
Cost of revenue	18,797	20,538
Research and development	33,491	23,283
Selling, general and administrative	79,298	80,785
Total operating expenses	131,586	124,606
Loss from operations	(81,280)	(14,491)
Co-promotion and license income	975	8,388
Gain on remeasurement of equity investment	—	22,741
Loss in equity investment	—	(144)
Interest expense	(9,746)	(8,615)
Other (loss) income	(262)	467
(Loss) income from continuing operations before income taxes	(90,313)	8,346
Provision for income taxes	(46)	(4,001)
Net (loss) income from continuing operations	(90,359)	4,345
(Loss) income from discontinued operations, net of tax	(2,105)	661
Net (loss) income	(92,464)	5,006
Net loss attributable to non-controlling interest	16	28
Net (loss) income attributable to The Medicines Company	$(92,448)	$5,034
Amounts attributable to The Medicines Company:		
Net (loss) income from continuing operations	$(90,343)	$4,373
(Loss) income from discontinued operations, net of tax	(2,105)	661
Net (loss) income attributable to The Medicines Company	$(92,448)	$5,034
Basic (loss) earnings per common share attributable to The Medicines Company:		
(Loss) earnings from continuing operations	$(1.31)	$0.07
(Loss) earnings from discontinued operations	(0.03)	0.01
Basic (loss) earnings per share	$(1.34)	$0.08
Diluted (loss) earnings per common share attributable to The Medicines Company:		
(Loss) earnings from continuing operations	$(1.31)	$0.07
(Loss) earnings from discontinued operations	(0.03)	0.01
Diluted (loss) earnings per share	$(1.34)	$0.08
Weighted average number of common shares outstanding:		
Basic	69,210	65,174
Diluted	69,210	66,929

See accompanying notes to condensed consolidated financial statements.

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THE MEDICINES COMPANY
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME
(Unaudited, in thousands)

	Three Months Ended March 31,	
	2016	2015
Net (loss) income	$(92,464)	$5,006
Other comprehensive income (loss):		
Foreign currency translation adjustment	315	2,706
Amounts reclassified from accumulated other comprehensive income	(9,665)	—
Other comprehensive (loss) income	(9,350)	2,706
Comprehensive (loss) income	(101,814)	7,712
Less: comprehensive loss attributable to non-controlling interest	16	28
Comprehensive (loss) income attributable to The Medicines Company	$(101,798)	$7,740

See accompanying notes to condensed consolidated financial statements.

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THE MEDICINES COMPANY
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited, in thousands)

	Three Months Ended March 31,	
	2016	2015
Cash flows from operating activities:		
Net (loss) income	$(92,464)	$5,006
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Depreciation and amortization	7,343	7,561
Amortization of debt discount	6,300	5,516
Unrealized foreign currency transaction gains, net	(573)	(151)
Non-cash stock compensation expense	6,940	7,618
Gain on sale of business	(1,004)	—
Loss on disposal of fixed assets	—	530
Deferred tax benefit	(867)	(433)
Excess tax expense from share-based compensation arrangements	—	282
Gain on remeasurement of equity investment	—	(22,741)
Change in contingent consideration obligation	(1,372)	1,417
Loss in equity investment	—	144
Changes in operating assets and liabilities:		
Accounts receivable	9,580	56,032
Inventory, net	(2,347)	(46,006)
Prepaid expenses and other current assets	635	1,214
Accounts payable	(20,559)	(6,142)
Accrued expenses	(31,181)	(44,230)
Deferred revenue	1,993	(933)
Other liabilities	(804)	(5,713)
Net cash used in operating activities	(118,380)	(41,029)
Cash flows from investing activities:		
Proceeds from sale of fixed assets	—	250
Purchases of fixed assets	—	(632)
Acquisition of business, net of cash acquired	—	(28,397)
Payments for intangible assets	—	(90,617)
Proceeds from sale of business	174,068	—
Change in restricted cash	(13)	17
Net cash provided by (used in) investing activities	174,055	(119,379)
Cash flows from financing activities:		
Proceeds from issuances of common stock, net	5,104	11,975
Milestone payments	(2,773)	(1,000)
Proceeds from the issuance of convertible senior notes	—	400,000
Debt and equity issuance costs	—	(12,769)
Excess tax expense from share-based compensation arrangements	—	(282)
Net cash provided by financing activities	2,331	397,924
Effect of exchange rate changes on cash	(983)	(1,184)
Increase in cash and cash equivalents	57,023	236,332
Cash and cash equivalents at beginning of period	373,173	370,741
Cash and cash equivalents at end of period	$430,196	$607,073
Supplemental disclosure of cash flow information:		

Interest paid	$5,000	$—
Taxes paid	$24	$45

See accompanying notes to condensed consolidated financial statements.

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THE MEDICINES COMPANY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

The Medicines Company® name and logo, Angiomax®, Angiox®, Cleviprex®, Carbavance®, Ionsys®, Kengreal®, Kengrexal® and Orbactiv® are registered 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, and references to "Kengreal" mean Kengreal and Kengrexal, 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 contributing to the economics of healthcare by focusing on leading acute/intensive care hospitals worldwide. The Company markets Angiomax® (bivalirudin), Cleviprex® (clevidipine) injectable emulsion, Ionsys® (fentanyl iontophoretic transdermal system), Kengreal® (cangrelor), Minocin (minocycline) for injection and Orbactiv® (oritavancin). The Company also has a pipeline of acute and intensive care hospital products in development, including ABP-700, ALN-PCSsc, Carbavance® and MDCO-216. The Company has the right to develop, manufacture and commercialize ALN-PCSsc under its collaboration agreement with Alnylam Pharmaceuticals, Inc. (Alnylam). The Company believes that its 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 products in development, the Company sells a ready-to-use formulation of Argatroban and has a portfolio of ten generic drugs, which it refers to as its acute care generic products, that the Company has the non-exclusive right to market in the United States. The Company is currently selling three of its acute care generic products, midazolam, ondansetron and rocuronium.

On July 2, 2015, the Company entered into a supply and distribution agreement with Sandoz Inc. (Sandoz), under which the Company granted Sandoz the exclusive right to sell in the United States an authorized generic of Angiomax (bivalirudin). The Company entered into the supply and distribution agreement as a result of the July 2, 2015 U.S. Court of Appeals for the Federal Circuit (Federal Circuit Court) ruling against the Company in its patent infringement litigation with Hospira, Inc. (Hospira) with respect to U.S. Patent No. 7,582,727 ('727 patent) and U.S. Patent No. 7,598,343 ('343 patent), covering a more consistent and improved Angiomax drug product and the processes by which it is made. In its July 2, 2015 ruling, the Federal Circuit Court held the '727 patent and the '343 patent invalid. On July 15, 2015, Hospira's Abbreviated New Drug Applications (ANDA) for its generic versions of bivalirudin were approved by the FDA and Hospira began selling its generic versions of bivalirudin. In November 2015, the Company's petition for en banc review of the Federal Circuit Court's July 2, 2015 decision was granted and the Federal Circuit Court vacated its July 2, 2015 decision. Notwithstanding the granting of the Company's petition for en banc review, due to the July 2, 2015 decision and the Company's resulting entry into a supply and distribution agreement with Sandoz and Hospira's entry into the market, Angiomax is now subject to generic competition with the authorized generic and Hospira's generic bivalirudin products.

On November 3, 2015, the Company announced that it was in the process of evaluating its operations with a goal of unlocking stockholder value. In particular, the Company stated its current intention was to explore strategies for optimizing its capital structure and liquidity position and to narrow the Company's operational focus by strategically

separating non-core businesses and products in order to generate non-dilutive cash and reduce associated cash burn and capital requirements, including, among other things, by potentially divesting or partnering its hemostasis portfolio, consisting of PreveLeak (surgical sealant), Raplixa (fibrin sealant) and Recothrom Thrombin topical (Recombinant) (the Hemostasis Business).

On February 1, 2016, the Company completed the sale of its Hemostasis Business, to wholly owned subsidiaries of Mallinckrodt plc (collectively, Mallinckrodt) pursuant to the Purchase and Sale Agreement dated December 18, 2015 (the Purchase and Sale Agreement) between the Company and Mallinckrodt. At completion of the sale, the Company received approximately $174.1 million in cash from Mallinckrodt, and may receive up to an additional $235.0 million in the aggregate following the achievement of certain specified calendar year net sales milestones with respect to net sales of PreveLeak™ and Raplixa™. As a result of the transaction, the Company accounted for the assets and liabilities of the Hemostasis Business as held for sale at December 31, 2015. As a result of the classification as held for sale, the Company recorded impairment charges of $133.3 million, including $24.5 million related to goodwill, to reduce the Hemostasis Business disposal group’s carrying value to its estimated fair value, less costs to sell for the year ended December 31, 2015. Further, the financial results of the Hemostasis Business held for sale have been

reclassified to discontinued operations for all periods presented in our condensed consolidated financial statements. See Note 16, “Discontinued Operations,” for further details.

2. Significant Accounting Policies

The Company’s significant accounting policies are described in Note 2 “Significant Accounting Policies” in the notes to the condensed consolidated financial statements included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2015.

Basis of Presentation

The accompanying condensed consolidated financial statements are unaudited and 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 unaudited condensed consolidated financial statements include all adjustments considered necessary for a fair presentation of the Company’s financial position, results of operations, comprehensive (loss) income, and cash flows for the periods presented.

The accompanying condensed 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 in the Company’s condensed 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.

The Company’s results of operations for the three months ended March 31, 2016 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, 2016. These unaudited condensed consolidated financial statements should be read in conjunction with the Company’s audited consolidated financial statements included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2015 (the 2015 Form 10-K) 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)/income that are reported in the condensed 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 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.

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THE MEDICINES COMPANY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) — (Continued)

Contingent purchase price from sale of business

Contingent purchase price from sale of business is measured at fair value utlizing the "income method," which applies a probability weighting that considers the estimated future net sales of each of the respective products to determine the probability that each sale milestone will be met. These projections are based on factors such as relevant market size, patent protection, historical pricing of similar products and expected industry trends. The Company also considers qualitative factors such as development of competing drugs, regulatory developments and other qualitative factors. Once the year in which each of the sales milestones would be achieved is determined, the respective milestones are then discounted to the present value using an appropriate discount rate. The Company will recognize any increases in the carrying amount or impairments of the contingent purchase price if and when the milestones are achieved or determined to have no value. These increases in carrying amount or impairments would be recorded in selling, general and administrative expenses.

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.

The Company performs research and development for U.S. government agencies under a cost-reimbursable contract in which the Company is reimbursed for direct costs incurred plus allowable indirect costs. The Company recognizes the reimbursements under research contracts when a contract has been executed, the contract price is fixed and determinable, delivery of services or products has occurred, and collection of the contract price is reasonably assured. The reimbursements are classified as an offset to research and development expenses. The Company recorded reductions of research and development expenses of approximately $6.3 million and $3.2 million for the three months ended March 31, 2016 and 2015, respectively.

Recent Accounting Pronouncements

In May 2014, the FASB issued a comprehensive new revenue recognition Accounting Standards Update, "Revenue from Contracts with Customers (Topic 606)" (ASU No. 2014-09). ASU No. 2014-09 provides guidance to clarify the principles for recognizing revenue. This guidance includes the required steps to achieve the core principle that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. With the issuance of ASU No. 2015-14 in August 2015, the FASB deferred the effective date of the revenue recognition guidance to reporting periods beginning after December 15, 2017. Early adoption of the standard is permitted but not before the original effective date, which was for reporting periods beginning after December 15, 2016. With the issuance of ASU No. 2016-08 in March 2016 and ASU No. 2016-10 in April 2016, the FASB further amended guidance on recording revenue on a gross versus a net basis and on identifying performance obligations and licensing, respectively. The Company expects to adopt this guidance when effective and continues to evaluate the effect that the updated standard, as well as additional amendments, may have on its consolidated financial statements and related disclosures.

In August 2014, the FASB issued ASU No. 2014-15, "Presentation of Financial Statements - Going Concern (Subtopic 310-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern" (ASU No. 2014-15), which provides guidance on determining when and how to disclose going-concern uncertainties in the financial

statements. This new ASU requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date the financial statements are issued. An entity must provide certain disclosures if "conditions or events raise substantial doubt about the entity's ability to continue as a going concern." The ASU is effective for annual periods ending after December 15, 2016, and interim periods thereafter, with early adoption permitted. The Company is currently evaluating the possible impact of ASU No. 2014-15 on its consolidated financial statements and related disclosures.

In April 2015, the FASB issued ASU No. 2015-03, "Interest - Interpretation of Interest (Subtopic 835-35)" which simplifies the presentation of debt issuance costs by requiring debt issuance costs to be presented as a deduction from the corresponding debt liability. This will make the presentation of debt issuance costs consistent with the presentation of debt discounts or premiums. The guidance is effective for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption is permitted. The Company adopted this guidance in the quarter ended March 31, 2016. As a result of adopting this guidance, the Company has reclassified $2.4 million and $9.0 million of debt issuance costs from noncurrent other assets to current convertible senior notes and noncurrent convertible senior notes, respectively, on its balance sheet as of December 31, 2015.

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THE MEDICINES COMPANY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) — (Continued)

In July 2015, the FASB issued ASU No. 2015-11, "Inventory 9 (Topic 330) - Simplifying the Measurement of Inventory" (ASU No. 2015-11). ASU No. 2015-11 requires an entity to measure inventory at the lower of cost and net realizable value, except for inventory that is measured using the last-in, first-out method or the retail inventory method. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. ASU No. 2015-11 is effective for fiscal years beginning after December 15, 2016 and is to be applied prospectively with early adoption permitted. The Company is currently evaluating the impact of adopting ASU No. 2015-11 on its consolidated financial statements and related disclosures.

In January 2016, the FASB issued ASU No. 2016-01, "Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities" (ASU No. 2016-01). ASU No. 2016-01 enhances the reporting model for financial instruments, which includes amendments to address aspects of recognition, measurement, presentation and disclosure. The new guidance affects all reporting organizations (whether public or private) that hold financial assets or owe financial liabilities. The ASU is effective for years beginning after December 15, 2017, including interim periods within those fiscal years. The Company expects to adopt this guidance when effective and is currently evaluating the effect that the updated standard will have on its consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)" (ASU No. 2016-02). ASU No. 2016-02 will require organizations that lease assets with lease terms of more than 12 months to recognize assets and liabilities for the rights and obligations created by those leases on their balance sheets. The ASU will also require new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. ASU No. 2016-02 will be effective for public companies for fiscal years, and interim periods within those fiscal years, beginning after Dec. 15, 2018, with early adoption permitted. The Company expects to adopt this guidance when effective and is currently evaluating the effect that the updated standard will have on its consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, "Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting" (ASU No. 2016-09). This ASU makes several modifications to Topic 718 related to the accounting for forfeitures, employer tax withholding on share-based compensation, and the financial statement presentation of excess tax benefits or deficiencies. ASU No. 2016-09 also clarifies the statement of cash flows presentation for certain components of share-based awards. The standard is effective for interim and annual reporting periods beginning after December 15, 2016, with early adoption permitted. The Company expects to adopt this guidance when effective and is currently evaluating the effect that the updated standard will have on its consolidated financial statements and related disclosures.

3. Share-Based Compensation

The Company recorded share-based compensation expense of approximately $6.9 million and $7.6 million for the three months ended March 31, 2016 and 2015, respectively. As of March 31, 2016, there was approximately $45.7 million of total unrecognized compensation costs related to non-vested share-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 1.59 years.

During the three months ended March 31, 2016 and 2015, the Company issued a total of 409,220 and 732,686, respectively, of shares of its common stock upon the exercise of stock options, grants of restricted stock, and

purchases under the Company's 2010 employee stock purchase plan (ESPP). Cash received from the exercise of stock options and purchases through the ESPP during the three months ended March 31, 2016 and 2015 was $5.1 million and $12.0 million, respectively, and is included within the financing activities section of the accompanying condensed consolidated statements of cash flows.

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THE MEDICINES COMPANY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) — (Continued)

4. (Loss) Earnings per Share

The following table sets forth the computation of basic and diluted (loss) earnings per share for the three months ended March 31, 2016 and 2015:

	Three Months Ended March 31,	
	2016	2015
	(in thousands, except per share amounts)	
Net (loss) income from continuing operations attributable to The Medicines Company	$(90,343)	$4,373
(Loss) income from discontinued operations, net of tax	(2,105)	661
Net (loss) income attributable to The Medicines Company	$(92,448)	$5,034
Weighted average common shares outstanding, basic	69,210	65,174
Plus: net effect of dilutive stock options, warrants, restricted common shares and shares issuable upon conversion of Notes	—	1,755
Weighted average common shares outstanding, diluted	69,210	66,929
Basic (loss) earnings per common share attributable to The Medicines Company:		
(Loss) earnings from continuing operations	$(1.31)	$0.07
(Loss) earnings from discontinued operations	(0.03)	0.01
Basic (loss) earnings per share	$(1.34)	$0.08
Diluted (loss) earnings per common share attributable to The Medicines Company:		
(Loss) earnings from continuing operations	$(1.31)	$0.07
(Loss) earnings from discontinued operations	(0.03)	0.01
Diluted (loss) earnings per share	$(1.34)	$0.08

Basic (loss) earnings per share is computed by dividing consolidated net (loss) income attributable to The Medicines Company by the weighted average number of shares of common stock outstanding during the period, excluding unvested restricted common shares. The number of potentially dilutive common shares equivalents is calculated using the treasury stock method.

For periods of net loss, diluted loss per share is calculated similar to basic loss per share as the effect of including all potentially dilutive common share equivalents is anti-dilutive. Due to the period of net loss from continuing operations attributable to The Medicines Company, the calculation of diluted loss per share for the three months ended March 31, 2016 excluded 2,897,451 potentially dilutive stock options, warrants, restricted common shares, and shares issuable upon conversion of the 2017 and 2022 Notes as their inclusion would have an anti-dilutive effect.

For periods of net income when the effects are not anti-dilutive, diluted earnings per share is computed by dividing the net income attributable to The Medicines Company by the weighted average number of shares outstanding and the impact of all potential dilutive common shares, consisting primarily of stock options, unvested restricted common stock, shares issuable upon conversion of convertible senior notes due 2017 and 2022 and stock purchase warrants. For the three months ended March 31, 2015, there were 4,718,541 shares of unvested restricted stock excluded from

the calculation of diluted earnings per share as their effect would have been anti-dilutive.

In January 2015, the Company issued the 2022 Notes (see Note 10, “Convertible Senior Notes”). The conversion rate for the 2022 Notes was initially, and remains, 29.8806 shares of the Company’s common stock per $1,000 principal amount of the 2022 Notes, which is equivalent to an initial conversion price of approximately $33.47 per share of the Company’s common stock. For the three months ended March 31, 2015, there was no dilutive effect of the 2022 Notes as the stock price did not exceed the conversion price.

In June 2012, the Company issued the 2017 Notes (see Note 10, “Convertible Senior Notes”). In connection with the issuance of the 2017 Notes, the Company entered into convertible note hedge transactions with respect to its common stock (2017 Note

Hedges) with several of the initial purchasers of the 2017 Notes, their affiliates and other financial institutions (2017 Hedge Counterparties). The options that are part of the 2017 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 2017 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 2017 Notes in the event that the market price per share of the Company's common stock, as measured under the terms of the 2017 Note Hedges, is greater than the strike price of the 2017 Note Hedges, which initially corresponded to the conversion price of the 2017 Notes and is subject to anti-dilution adjustments substantially similar to those applicable to the conversion rate of the 2017 Notes. For the three months ended March 31, 2015, there were 55,740 shares of common stock issuable upon conversion of the 2017 Notes included in diluted shares.

In addition, in connection with the 2017 Note Hedges, the Company entered into warrant transactions with the 2017 Hedge Counterparties, pursuant to which the Company sold warrants (2017 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. The 2017 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 2017 Warrants, exceeds the applicable strike price of the 2017 Warrants. However, subject to certain conditions, the Company may elect to settle all of the 2017 Warrants in cash. For the three months ended March 31, 2015, the 2017 Warrants did not have a dilutive effect on earnings per share because the average market price during the period presented was below the strike price.

5. Income Taxes

For the three months ended March 31, 2016 and 2015, the Company recorded a provision of $0.05 million and $4.0 million for income taxes, respectively, based upon its estimated federal, state and foreign (loss)/income for the year. The worldwide effective income tax rates for the Company for the three months ended March 31, 2016 and 2015 were (0.1)% and 45.8%, respectively. This decrease in effective tax rates was primarily driven by the Company’s projected loss for the year 2016 and its inability to realize any benefit from this loss due to the establishment of a valuation allowance against substantial portions of its deferred tax assets during the fourth quarter of 2015. For the three months ended March 31, 2016, the Company’s provision for income taxes is the result of state tax minimums and estimated taxes due by profitable foreign subsidiaries.

The Company considers all available evidence, both positive and negative, to determine whether, based on the weight of that evidence, a valuation allowance is needed to reduce its deferred tax assets to the amount that is more likely than not to be realized. The Company placed significant weight on the fact that the Company expects to be in a cumulative net book loss for the three-year period ending December 31, 2016 in recording valuation allowances on substantial portions of its deferred tax assets as of March 31, 2016. The cumulative net book loss is primarily the result of Angiomax facing generic competition in the U.S. since the July 2, 2015 decision by the Federal Circuit Court which held the ‘727 patent and ‘343 patent invalid.

The Company will continue 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 additional changes to the valuation allowance recorded on deferred tax assets in the future would impact the Company’s income taxes.

6. Cash and Cash Equivalents

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 $424.2 million and $367.2 million at March 31, 2016 and December 31, 2015, respectively. Cash and cash equivalents at both March 31, 2016 and December 31, 2015 also included investments of $6.0 million in money market funds with original maturities of less than three months.

Restricted Cash

The Company had restricted cash of $1.4 million at both March 31, 2016 and December 31, 2015, which included $1.0 million at both March 31, 2016 and December 31, 2015 for an outstanding letter 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 Therapeutics Corporation (Targanta) in 2009, the Company had restricted cash of $0.1 million at both March 31, 2016 and December 31, 2015, in the form of a guaranteed

investment certificate collateralizing an available credit facility. The Company also had restricted cash of $0.3 million at both March 31, 2016 and December 31, 2015, related to certain foreign tender requirements.

7. Fair Value Measurements

The Company applies a fair value framework in order to measure and disclose its financial assets and liabilities. Fair value is defined 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. The fair value hierarchy requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. There are 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 asset consists of money market investments.
Level 2	Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.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 dispositions and business combinations, respectively. The fair value of certain development or regulatory milestone based contingent purchase prices was determined in a discounted cash flow framework by probability weighting the future contractual payment with management's assessment of the likelihood of achieving these milestones and present valuing them using a risk-adjusted discount rate. Certain sales milestone based payments were determined in a discounted cash flow framework where risk-adjusted revenue scenarios were estimated using Monte Carlo simulation models to compute contractual payments which were present valued using a risk-adjusted discount rate.

Financial assets measured at fair value on a nonrecurring basis

As part of the Purchase and Sale Agreement with Mallinckrodt, the Company may receive up to an additional $235.0 million in the aggregate following the achievement of certain specified calendar year net sales milestones with respect to net sales of PreveLeak™ and Raplixa™. In evaluating this information, considerable judgment is required to interpret the market data used to develop the assumptions and estimates. The Company utilized the “income method,” which applies a probability weighting that considers the estimated future net sales of each of the respective products to determine the probability that each sale milestone will be met. These projections were based on factors such as relevant market size, patent protection, historical pricing of similar products and expected industry trends. The Company anticipates payment from Malinckrodt on these sales milestones between 2017 and 2022 with probabilities of achievement ranging from 15% to 85%. The Company also considers qualitative factors such as development of competing drugs, regulatory developments and other qualitative factors. The Company determined the year in which it believes each of the sales milestones will be achieved. The respective milestones were then discounted to the present value using a discount rate of 10%. Any changes to fair value will be recorded if and when the sales milestones are achieved. The Company calculated the fair value of these contingent payments to be received from Mallinckrodt as $78.0 million, which are reflected as a contingent purchase price from sale of business on the condensed consolidated balance sheet at March 31, 2016. The Company classified these contingent payments as Level 3 assets. Any increases

in the carrying amount or impairments of sales milestones would be recognized in selling, general and administrative expenses if and when the milestones are achieved or determined to have no value.

Financial assets and liabilities measured at fair value on a recurring basis

Financial 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.

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Except for the Company's Level 2 liabilities and hedges which are discussed in Note 10, "Convertible Senior Notes," the following table sets forth the Company's assets and liabilities that are measured at fair value on a recurring basis at March 31, 2016 and December 31, 2015, by level, within the fair value hierarchy:

	As of March 31, 2016				As of December 31, 2015			
Assets and Liabilities	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of March 31, 2016	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, 2015
	(in thousands)							
Assets:								
Money market	$6,036	$ —	$ —	$6,036	$6,033	$ —	$ —	$6,033
Total assets at fair value	$6,036	$ —	$ —	$6,036	$6,033	$ —	$ —	$6,033
Liabilities:								
Contingent purchase price	$—	$ —	$ 119,612	$119,612	$—	$ —	$ 123,757	$123,757
Total liabilities at fair value	$—	$ —	$ 119,612	$119,612	$—	$ —	$ 123,757	$123,757

There were no transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy that occurred during the three months ended March 31, 2016.

Level 3 disclosures

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 in the accompanying condensed consolidated statements of operations.

The 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.

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

	Fair Value as of March 31, 2016 (in thousands)	Valuation Technique	Unobservable Input	Range (Weighted Average)
Targanta:				
Contingent purchase price	$ 6,012	Probability-adjusted discounted cash flow	Probability of success	20%
			Period in which milestone is expected to be achieved	2020
			Discount rate	11%
Incline:				
Contingent purchase price	$ 25,900	Probability-adjusted discounted cash flow	Probabilities of successes	64% - 72% (67%)
			Period in which milestones are expected to be achieved	2018 - 2019
			Discount rate	18%
Rempex:				
Contingent purchase price: commercial milestones	$ 60,800	Probability-adjusted discounted cash flow	Probabilities of successes	11% - 95% (55%)
			Period in which milestones are expected to be achieved	2016 - 2021
			Discount rate	3.4% - 5.8%
Contingent purchase price: sales milestones	$ 10,900	Risk-adjusted revenue simulation	Probabilities of successes	11% - 63% (25%)
			Period in which milestones are expected to be achieved	2018 - 2022
			Discount rate	4.9% - 6.0%
Annovation:				
Contingent purchase price	$ 16,000	Probability-adjusted discounted cash flow	Probability of success	9% - 50% (32%)
			Period in which milestones are expected to be achieved	2017 - 2030
			Discount rate	3.8% - 7.3%

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	Fair Value as of December 31, 2015 (in thousands)	Valuation Technique	Unobservable Input	Range (Weighted Average)
Targanta:				
Contingent purchase price	$ 5,857	Probability-adjusted discounted cash flow	Probability of success	20%
			Period in which milestone is expected to be achieved	2020
			Discount rate	11%
Incline:				
Contingent purchase price	$ 28,600	Probability-adjusted discounted cash flow	Probabilities of successes	64% - 72% (67%)
			Period in which milestones are expected to be achieved	2017 - 2018
			Discount rate	18%
Rempex:				
Contingent purchase price: commercial milestones	$ 63,000	Probability-adjusted discounted cash flow	Probabilities of successes	11% - 95% (56%)
			Period in which milestones are expected to be achieved	2016 - 2020
			Discount rate	3.6% - 6.0%
Contingent purchase price: sales milestones	$ 10,300	Risk-adjusted revenue simulation	Probabilities of successes	11% - 63% (30%)
			Period in which milestones are expected to be achieved	2018 - 2022
			Discount rate	5.5% - 6.7%
Annovation:				
Contingent purchase price	$ 16,000	Probability-adjusted discounted cash flow	Probability of success	8% - 50% (31%)
			Period in which milestones are expected to be achieved	2016 - 2030
			Discount rate	4.1% - 8.2%

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 acquisition agreements for Targanta, Incline Therapeutics, Inc. (Incline), Rempex Pharmaceuticals, Inc. (Rempex) and Annovation BioPharma, Inc. (Annovation). 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, Incline, Rempex and Annovation 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 or periods in which milestones will be achieved would result in a significantly higher or lower fair value measurement.

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The changes in fair value of the Company's Level 3 contingent purchase price during the three months ended March 31, 2016 and 2015 were as follows:

	Three Months Ended March 31,	
	2016	2015
	(in thousands)	
Balance at beginning of period	$123,757	$351,134
Fair value of contingent purchase price with respect to Annovation as of February 2, 2015	—	18,000
Settlements	(2,773)	(1,100)
Fair value adjustment to contingent purchase prices included in net income (loss)	(1,372)	1,518
Balance at end of period	$119,612	$369,552

For the quarters ended March 31, 2016 and 2015, changes in the carrying value of the contingent purchase price obligations resulted from changes in the fair value of the contingent consideration due to either the passage of time, changes in discount rates, changes in probabilities of success, or milestones payments. Additionally, for the quarter ended March 31, 2015, changes in the carrying value of the contingent purchase price obligations included the initial estimate of the fair value of the contingent consideration related to the Company's acquisition of Annovation.

No other changes in valuation techniques or inputs occurred during the three months ended March 31, 2016 and 2015.

8. Inventory

The major classes of inventory were as follows:

	March 31, 2016	December 31, 2015
	(in thousands)	
Raw materials	$37,556	$ 31,354
Work-in-progress	18,298	21,487
Finished goods	12,600	11,743
Total	$68,454	$ 64,584

The Company reviews inventory, including inventory purchase commitments, for slow moving or obsolete amounts based on expected volume and provides reserves against the carrying amount of inventory as appropriate.

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9. Intangible Assets and Goodwill

The following table sets forth the carrying amounts and accumulated amortization of the Company's intangible assets:

	As of March 31, 2016				As of December 31, 2015		
	Weighted Average Useful Life (years)	Gross Carrying Amount	Accumulated Amortization and Other Charges	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization and Other Charges	Net Carrying Amount
		(in thousands)					
Amortizable intangible assets:							
Product licenses[1]	15.5	$24,500	$ (1,403)	$23,097	$31,500	$ (7,869)	$23,631
Developed product rights[2]	16.3	372,560	(19,342)	353,218	373,090	(14,121)	358,969
Total amortizable intangible assets	16.2	397,060	(20,745)	376,315	404,590	(21,990)	382,600
Intangible assets not subject to amortization:							
In-process research and development	—	$253,620	$ —	$253,620	$253,620	$ —	$253,620
Total intangible assets not subject to amortization:	—	253,620	—	253,620	253,620	—	253,620
Total intangible assets	—	$650,680	$ (20,745)	$629,935	$658,210	$ (21,990)	$636,220

(1) The Company amortizes intangible assets related to the product licenses over their expected useful lives.
(2) The Company amortizes intangible assets related to developed product rights over the remaining life of the patents.

The Company recognized amortization expense of $6.3 million and $1.7 million related to its intangible assets in the three months ended March 31, 2016 and 2015, respectively. The Company expects amortization expense related to its intangible assets to be $18.9 million for the last nine months of 2016. The Company expects annual amortization expense related to its intangible assets to be $25.2 million, $24.8 million, $24.5 million, $24.4 million and $24.1 million for the years ending December 31, 2017, 2018, 2019, 2020 and 2021, respectively, with the balance of $234.4 million being amortized thereafter. The Company records amortization expense in cost of revenue in the accompanying condensed consolidated statements of operations.

There were no changes in the carrying amount of goodwill for the three months ended March 31, 2016.

10. Convertible Senior Notes
Convertible Senior Notes Due 2022

In January 2015, the Company issued, at par value, $400 million aggregate principal amount of 2.5% convertible senior notes due 2022 (the "2022 Notes"). The 2022 Notes bear cash interest at a rate of 2.5% per year, payable semi-annually on January 15 and July 15 of each year, beginning on July 15, 2015. The 2022 Notes will mature on January 15, 2022. The net proceeds to the Company from the offering were $387.2 million after deducting the initial purchasers' discounts and commissions and the offering expenses payable by the Company.

The 2022 Notes are governed by an indenture (the “2022 Notes Indenture”) with Wells Fargo Bank, National Association, a national banking association, as trustee (the “2022 Notes Trustee”).

The 2022 Notes are senior unsecured obligations of the Company and will rank senior in right of payment to the Company’s future indebtedness that is expressly subordinated in right of payment to the 2022 Notes; equal in right of payment to the Company’s existing and future unsecured indebtedness that is not so subordinated; effectively junior in right of payment to any of the Company’s secured indebtedness to the extent of the value of the assets securing such indebtedness; and structurally junior to all existing and future indebtedness and other liabilities (including trade payables) incurred by the Company’s subsidiaries.

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Holders may convert their 2022 Notes at their option at any time prior to the close of business on the business day immediately preceding October 15, 2021 only under the following circumstances:

- during any calendar quarter commencing on or after March 31, 2015 (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 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 2022 Notes Indenture) per $1,000 principal amount of 2022 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;

- during any period after the Company has issued notice of redemption until the close of business on the scheduled trading day immediately preceding the relevant redemption date; or

- upon the occurrence of specified corporate events.

On or after October 15, 2021, until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their 2022 Notes at any time, regardless of the foregoing circumstances. Upon conversion, the Company will pay cash up to the aggregate principal amount of the 2022 Notes to be converted and deliver shares of its common stock in respect of the remainder, if any, of its conversion obligation in excess of the aggregate principal amount of 2022 Notes being converted, subject to a daily share cap.

The conversion rate for the 2022 Notes was initially, and remains, 29.8806 shares of the Company's common stock per $1,000 principal amount of the 2022 Notes, which is equivalent to an initial conversion price of approximately $33.47 per share of the Company's common stock.

The Company may not redeem the 2022 Notes prior to January 15, 2019. The Company may redeem for cash all or any portion of the 2022 Notes, at its option, on or after January 15, 2019 if the last reported sale price of its common stock has been at least 130% of the conversion price then in effect on the last trading day of, and for at least 19 other trading days (whether or not consecutive) during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which the Company provides notice of redemption, at a redemption price equal to 100% of the principal amount of the 2022 Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. No sinking fund is provided for the 2022 Notes, which means that the Company is not required to redeem or retire the 2022 Notes periodically.

If the Company undergoes a "fundamental change" (as defined in the Indenture governing the 2022 Notes Indenture), subject to certain conditions, holders of the 2022 Notes may require the Company to repurchase for cash all or part of their 2022 Notes at a repurchase price equal to 100% of the principal amount of the 2022 Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

The 2022 Notes Indenture contains customary events of default with respect to the 2022 Notes, including that upon certain events of default (including the Company's failure to make any payment of principal or interest on the 2022 Notes when due and payable) occurring and continuing, the 2022 Notes Trustee by notice to the Company, or the holders of at least 25% in principal amount of the outstanding 2022 Notes by notice to the Company and the 2022

Notes Trustee, may, and the 2022 Notes Trustee at the request of such holders (subject to the provisions of the 2022 Notes Indenture) shall, declare 100% of the principal of and accrued and unpaid interest, if any, on all the 2022 Notes to be due and payable. In case of 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 2022 Notes will automatically become due and payable. Upon such 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 2022 Notes, the Company separated the 2022 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 2022 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 seven-year term of the 2022 Notes. The equity component is not re-measured as long as it continues to meet the conditions for

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equity classification. The equity component related to the 2022 Notes is $54.3 million and is recorded in additional paid-in capital on the accompanying condensed consolidated balance sheets.

In accounting for the transaction costs related to the issuance of the 2022 Notes, the Company allocated the total costs incurred to the liability and equity components of the 2022 Notes based on their relative values. Transaction costs attributable to the liability component are amortized to interest expense over the seven-year term of the 2022 Notes, and transaction costs attributable to the equity component are netted with the equity components in stockholders' equity. Additionally, the Company initially recorded a net deferred tax liability of $31.8 million in connection with the 2022 Notes.

The 2022 Notes consist of the following:

Liability component	March 31, 2016	December 31, 2015
	(in thousands)	
Principal	$400,000	$ 400,000
Less: Debt discount, net[(1)]	(84,920)	(87,893)
Net carrying amount	$315,080	$ 312,107

(1) Included in the accompanying condensed consolidated balance sheets within convertible senior notes (due 2022) and amortized to interest expense over the remaining life of the 2022 Notes using the effective interest rate method.

The fair value of the 2022 Notes was approximately $334.7 million as of March 31, 2016. The Company estimates the fair value of its 2022 Notes utilizing market quotations for debt that have quoted prices in active markets. Since the 2022 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, which are classified as Level 2 measurements within the fair value hierarchy. See Note 7, "Fair Value Measurements," for definitions of hierarchy levels. As of March 31, 2016, the remaining contractual life of the 2022 Notes is approximately 5.8 years.

The following table sets forth total interest expense recognized related to the 2022 Notes:

	Three Months Ended March 31,	
	2016	2015
	(in thousands)	
Contractual interest expense	$2,500	$2,152
Amortization of debt discount	2,974	2,403
Total	$5,474	$4,555
Effective interest rate of the liability component	6.5 %	6.5 %

Convertible Senior Notes Due 2017

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 "2017 Notes). The 2017 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 2017 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 2017 Notes are governed by an indenture dated as of June 11, 2012 (the "2017 Notes Indenture"), between the Company, as issuer, and Wells Fargo Bank, National Association, a national banking association, as trustee (the "2017 Notes Trustee"). The 2017 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 2017 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 2017 Notes and equal in right of payment to the Company's existing and future unsecured indebtedness that is not so subordinated. The 2017 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 2017 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 2017 Notes Indenture) per $1,000 principal amount of 2017 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.

Since the third quarter of 2015, the conditional conversion feature of the 2017 Notes was triggered and the holders have been entitled to convert the notes into the Company's common stock through June 30, 2016. In any period when holders of the 2017 Notes are eligible to exercise their conversion option, the liability component related to these instruments is classified as current and the equity component related to these instruments is classified as mezzanine (temporary) equity, as the Company is required to settle the aggregate principal amount of the notes in cash. If in any future period the conversion threshold requirements of the 2017 Notes are not met, then the liability component of the instrument is classified as non-current and the difference between (1) the amount of cash deliverable upon conversion (i.e., par value of debt) and (2) the carrying value of the debt component will be reclassified from mezzanine equity to permanent equity, and will continue to be reported as permanent equity for any period in which the debt is not currently convertible. No holders of the 2017 Notes exercised their conversion option in 2015. An immaterial amount of 2017 Notes were converted during the three months ended March 31, 2016.

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 2017 Notes at any time, regardless of the foregoing circumstances. Upon conversion, the Company will pay cash up to the aggregate principal amount of the 2017 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 2017 Notes being converted, subject to a daily share cap, as described in the 2017 Notes Indenture. Holders of 2017 Notes will not receive any additional cash payment or additional shares representing accrued and unpaid interest, if any, upon conversion of a 2017 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 2017 Note.

The conversion rate for the 2017 Notes was initially, and remains, 35.8038 shares of the Company's common stock per $1,000 principal amount of the 2017 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 2017 Notes Indenture.

The Company may not redeem the 2017 Notes prior to maturity and is not required to redeem or retire the 2017 Notes periodically. However, upon the occurrence of a “fundamental change” (as defined in the 2017 Notes Indenture), subject to certain conditions, in lieu of converting their 2017 Notes, holders may require the Company to repurchase for cash all or part of their 2017 Notes at a repurchase price equal to 100% of the principal amount of the 2017 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 2017 Notes in connection with such change of control in certain circumstances.

The 2017 Notes Indenture contains customary events of default with respect to the 2017 Notes, including that upon certain events of default (including the Company’s failure to make any payment of principal or interest on the 2017 Notes when due and

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payable) occurring and continuing, the 2017 Notes Trustee by notice to the Company, or the holders of at least 25% in principal amount of the outstanding 2017 Notes by notice to the Company and the 2017 Notes Trustee, may, and the 2017 Notes Trustee at the request of such holders (subject to the provisions of the 2017 Notes Indenture) shall, declare 100% of the principal of and accrued and unpaid interest, if any, on all the 2017 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 2017 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 2017 Notes, the Company separated the 2017 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 2017 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 2017 Notes. The equity component is not re-measured as long as it continues to meet the conditions for equity classification. The equity component recorded at issuance related to the 2017 Notes is $55.7 million and is recorded in stockholders' equity on the accompanying condensed consolidated balance sheets.

In accounting for the transaction costs related to the issuance of the 2017 Notes, the Company allocated the total costs incurred to the liability and equity components of the 2017 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 2017 Notes, and transaction costs attributable to the equity component are netted with the equity components in stockholders' equity. Additionally, the Company initially recorded a deferred tax asset of $1.5 million in connection with the 2017 Notes.

The 2017 Notes consist of the following:

Liability component	March 31, 2016	December 31, 2015
	(in thousands)	
Principal	$275,000	$ 275,000
Less: Debt discount, net[1]	(16,200)	(19,527)
Net carrying amount	$258,800	$ 255,473

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

The fair value of the 2017 Notes was approximately $270.7 million as of March 31, 2016. The Company estimates the fair value of its 2017 Notes utilizing market quotations for debt that have quoted prices in active markets. Since the 2017 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, which are classified as Level 2 measurements within the fair value hierarchy. See Note 7, "Fair Value Measurements," for definitions of hierarchy levels. As of March 31, 2016, the remaining contractual life of the 2017 Notes is approximately 1.2 years.

The following table sets forth total interest expense recognized related to the 2017 Notes:

	Three Months Ended March 31,	
	2016	2015
	(in thousands)	
Contractual interest expense	$945	$945
Amortization of debt discount	3,327	3,113
Total	$4,272	$4,058
Effective interest rate of the liability component	6.02 %	6.02 %

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Note Hedges

In June 2012, the Company paid an aggregate amount of $58.2 million for the 2017 Note Hedges, which was recorded as a reduction of additional paid-in-capital in stockholders' equity. The 2017 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 2017 Notes, have a strike price that corresponds to the initial conversion price of the 2017 Notes, and are exercisable upon conversion of the 2017 Notes. The 2017 Note Hedges will expire upon the maturity of the 2017 Notes. The 2017 Note Hedges are expected generally to reduce the potential dilution with respect to shares of the Company's common stock upon conversion of the 2017 Notes in the event that the market price per share of the Company's common stock, as measured under the terms of the 2017 Note Hedges, at the time of exercise is greater than the strike price of the 2017 Note Hedges. The 2017 Note Hedges are separate transactions entered into by the Company with the 2017 Hedge Counterparties and are not part of the terms of the 2017 Notes or the 2017 Warrants. Holders of the 2017 Notes and 2017 Warrants will not have any rights with respect to the 2017 Note Hedges. As of March 31, 2016, the fair value of the 2017 Note Hedges was $75.8 million. The Company estimates the fair value of its 2017 Note Hedges using Monte Carlo simulations model of its stock prices, which are classified as Level 2 measurements within the fair value hierarchy. See Note 7, "Fair Value Measurements," for definitions of hierarchy levels.

Warrants

The Company received aggregate proceeds of $38.4 million from the sale to the 2017 Hedge Counterparties of the 2017 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 2017 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 2017 Warrants, exceeds the applicable strike price of the 2017 Warrants. However, subject to certain conditions, the Company may elect to settle all of the 2017 Warrants in cash. The 2017 Warrants are separate transactions entered into by the Company with the 2017 Hedge Counterparties and are not part of the terms of the 2017 Notes or 2017 Note Hedges. Holders of the 2017 Notes and 2017 Note Hedges will not have any rights with respect to the 2017 Warrants. The 2017 Warrants also meet the definition of a derivative. Because the 2017 Warrants are indexed to the Company's common stock and are recorded in equity in the Company's condensed consolidated balance sheets, the 2017 Warrants are exempt from the scope and fair value provisions related to accounting for derivative instruments.

11. Accumulated Other Comprehensive Income

The following tables provide a reconciliation of the components of accumulated other comprehensive income, net of tax, attributable to The Medicines Company for the three months ended March 31, 2016 and 2015:

	Three Months Ended March 31,					
	2016			2015		
	Foreign currency translation adjustments	Unrealized (gain) loss on available for sale	Total	Foreign currency translation adjustments	Unrealized (gain) loss on available for sale	Total

		securities			securities	
	(in thousands)					
Balance at beginning of period	$3,924	$ 49	$3,973	$2,479	$ 49	$2,528
Other comprehensive income before reclassifications	315	—	315	2,706	—	2,706
Amounts reclassified from accumulated other comprehensive income[1] [2]	(9,616)	(49)	(9,665)	—	—	—
Total other comprehensive (loss) income	(9,301)	(49)	(9,350)	2,706	—	2,706
Balance at end of period	$(5,377)	$ —	$(5,377)	$5,185	$ 49	$5,234

(1) Amounts were reclassified to other income in the accompanying condensed consolidated statements of operations. There is generally no tax impact related to foreign currency translation adjustments, as earnings are considered permanently reinvested. In addition, there were no material tax impacts related to unrealized gains or losses on available for sale securities in the periods presented.

(2) See Note 16, “Discontinued Operations,” for a discussion of this reclass of foreign currency translation adjustment.

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12. 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. The Company allocates resources and assesses financial performance on a consolidated basis. Revenues reported to date are derived primarily from 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. Long-lived assets are comprised of the Company's noncurrent assets.

	Three Months Ended March 31,					
	2016 (in thousands)			2015 (in thousands)		
Net revenues:						
United States	$46,436	92.3	%	$104,458	94.9	%
Europe	3,080	6.1	%	4,993	4.5	%
Rest of world	790	1.6	%	664	0.6	%
Total net revenues	$50,306	100.0	%	$110,115	100.0	%

	March 31, 2016 (in thousands)			December 31, 2015 (in thousands)		
Long-lived assets:						
United States	$1,027,783	99.4	%	$956,298	99.3	%
Europe	6,165	0.6	%	6,301	0.7	%
Rest of world	—	—	%	—	—	%
Total long-lived assets	$1,033,948	100.0	%	$962,599	100.0	%

13. Contingencies

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company accrues for loss contingencies when information becomes available indicating that it is probable that a liability has been incurred and the amount of such loss can be reasonably estimated.

The Company is currently party to the legal proceedings described in Part II, Item 1. Legal Proceedings, of this Quarterly Report on Form 10-Q, 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, other than the class action litigation. As a result, the Company did not record any loss contingencies for any of these matters other than the class action litigation. While it is not possible to determine the outcome of the matters described in Part II, Item 1. Legal Proceedings, of this Quarterly Report on Form 10-Q, 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 its consolidated results of operations in any one accounting period.

14. Collaboration Agreements

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 was 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. In December 2014, under the terms of the license and collaboration agreement with Alnylam, Alnylam initiated a Phase 1 clinical trial of ALN-PCSsc in the UK. Upon initiation of the Phase I clinical trial, the Company incurred a $10.0 million milestone which it recorded as research and development expense.

SciClone Pharmaceuticals

On December 16, 2014, the Company entered into a strategic collaboration with SciClone Pharmaceuticals (“SciClone”) under which the Company granted SciClone a license and the exclusive rights to promote, market, and sell Angiomax and Cleviprex in China. Under the terms of the collaboration, SciClone will be responsible for all aspects of commercialization, including pre- and post-launch activities, for both products in the China market (excluding Hong Kong and Macau) and will assist the Company in the registration process for both products in China. The Company has filed in China for marketing approval of Angiomax and to conduct clinical trials of Cleviprex. SciClone agreed to pay the Company an upfront payment of $10.0 million, a product support services fee and regulatory/commercial success milestone payments of up to an aggregate of $50.5 million, and royalties based on net sales of Angiomax and Cleviprex in China.

Activities under the SciClone agreement were evaluated to determine if they represented a multiple element revenue arrangement. The SciClone agreement includes the following deliverables: (1) an exclusive license to commercialize Angiomax and Cleviprex in China, excluding Hong Kong and Macau; (2) the Company’s obligation to conduct research and development activities related to the approvals of Angiomax and Cleviprex; and (3) the Company’s obligation to participate on the joint operating committee established under the terms of the SciClone agreement and related subcommittees. All of these deliverables were deemed to have stand-alone value and to meet the criteria to be accounted for as separate units of accounting. Factors considered in this determination included, among other things, the subject of the licenses and the research and development and commercial capabilities of SciClone. Accordingly, each unit will be accounted for separately. For the three months ended March 31, 2016 and 2015, the Company recorded approximately $0.1 million and $7.8 million, respectively, of revenue associated with the SciClone agreement as co-promotion and license income.

The Company believes the regulatory approval milestones that may be achieved under the SciClone agreement are consistent with the definition of a milestone, and accordingly, the Company will recognize payments related to the achievement of such milestones, if any, when the applicable milestones are achieved. Factors considered in this determination included scientific and regulatory risks that must be overcome to achieve each milestone, the level of effort and investment required to achieve each milestone, and the monetary value attributed to each milestone.

Symbio Pharmaceuticals Limited

On October 2, 2015, the Company entered into strategic collaboration with Symbio Pharmaceuticals Limited (“Symbio”) under which the Company granted Symbio a license and the exclusive rights to promote, market, and sell

Ionsys in Japan. Under the terms of the collaboration, Symbio will be responsible for all aspects of commercialization, including pre- and post-launch activities, for both products in the Japan market and will assist the Company in the registration process for Ionsys. Symbio paid the Company an upfront payment of $10.0 million, regulatory/commercial success milestone payments of up to an aggregate of $20.9 million, and royalties based on net sales of Ionsys in Japan.

Factors considered in the determination of deliverables included, among other things, the subject of the licenses and the research and development and commercial capabilities of Symbio. For the three months ended March 31, 2016, the Company recorded approximately $0.6 million of revenue associated with the Symbio agreement as co-promotion and license income.

The Company believes the regulatory approval milestones that may be achieved under the Symbio agreement are consistent with the definition of a milestone and, accordingly, the Company will recognize payments related to the achievement of such milestones, if any, when the applicable milestones are achieved.

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15. Restructuring

On October 22, 2014, the Company commenced implementation of a reorganization of its European operations intended to improve efficiency and better align the Company's costs and employment structure with its strategic plans. The reorganization includes a workforce reduction and the consolidation of European sites into a single location in Zurich, Switzerland. As a result of the workforce reduction, the Company reduced its personnel by 46 employees. Upon signing release agreements, impacted employees were eligible to receive severance payments in specified amounts, and general benefits and outplacement services for specified periods in accordance with our policies and local requirements. The Company completed its reorganization of its European operations in December 2014.

In the year ended December 2014, the Company recorded, in the aggregate, a one-time charge of approximately $9.0 million associated with the reorganization of its European operations, including $0.5 million of non-cash charges. Lease charges were recorded in selling, general and administrative expenses. The Company recorded $8.7 million associated with the work-force reduction. The Company recorded these charges in research and development expense and selling, general and administrative expense based on responsibilities of the impacted employees. Of the charges related to the 2014 European work-force reduction, $0.3 million were non-cash charges. During the three months ended March 31, 2016, the Company made lease payments as shown in the table below. The Company expects to pay the remainder of these lease payments in 2016.

The following table summarizes the restructuring accrual activity during the three months ended March 31, 2016:

	Balance as of January 1, 2016	Expenses, Net	Cash	Noncash	Balance as of March 31, 2016
	(in thousands)				
Employee severance and other personnel benefits:					
2014 European workforce reduction	$523	$—	$—	$—	$523
2014 European leases and equipment write-off	58	—	(22)	(3)	33
Total	$581	$—	$(22)	$(3)	$556

16. Discontinued Operations

Sale of Hemostasis Business

On February 1, 2016, the Company completed the sale of its Hemostasis Business to Mallinckrodt pursuant to the Purchase and Sale Agreement dated December 18, 2015 between the Company and Mallinckrodt. At the completion of the sale, the Company received approximately $174.1 million in cash from Mallinckrodt, and may receive up to an additional $235.0 million in the aggregate following the achievement of certain specified calendar year net sales milestones with respect to net sales of PreveLeak and Raplixa. As a result of the transaction, the Company accounted for the assets and liabilities of the Hemostasis Business that were sold as held for sale at December 31, 2015. As a result of the classification as held for sale, the Company recorded impairment charges of $133.3 million, including $24.5 million related to goodwill, to reduce the Hemostasis Business disposal group's carrying value to its estimated fair value, less costs to sell for the year ended December 31, 2015. The determination of fair value for these assets was based on the best information available that resided within Level 3 of the fair value hierarchy, including internal cash

flow estimates discounted at an appropriate interest rate.

Financial results of the Hemostasis Business are presented as “(Loss) income from discontinued operations, net of tax” on the accompanying condensed consolidated statements of operations for the three months ended March 31, 2016 and 2015. Assets and liabilities of the Hemostasis Business to be disposed of are presented as “Current assets held for sale” and “Current liabilities held for sale” on the accompanying condensed consolidated balance sheet as of December 31, 2015.

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The following table presents key financial results of the Hemostasis Business included in "(Loss) income from discontinued operations, net of tax" for the three months ended March 31, 2016 and 2015:

	Three Months Ended March 31,	
	2016	2015
	(in thousands)	
Net product revenues	$62	$16,402
Operating expenses:		
Cost of product revenue	2,293	13,199
Research and development	146	666
Selling, general and administrative	693	(250)
Total operating expenses	3,132	13,615
(Loss) income from operations	(3,070)	2,787
Gain from sale of business	1,004	—
Other expense, net	(39)	(350)
(Loss) income from discontinuing operations before income taxes	(2,105)	2,437
Provision for income taxes	—	1,776
Net (loss) income from discontinued operations	$(2,105)	$661

Cumulative translation adjustment ("CTA") gains or losses of foreign subsidiaries related to divested businesses are reclassified into income once the liquidation of the respective foreign subsidiaries is substantially complete. At the completion of the sale of the Hemostasis Business, the Company reclassified $9.6 million, net of tax, of CTA gains from accumulated comprehensive loss to the Company's results of discontinued operations. Of this amount, $8.4 million was included in the impairment loss recorded to reduce the Hemostasis Business disposal group's carrying value to its estimated fair value, less costs to sell as of December 31, 2015 and $1.2 million was included in gain from sale of business for the quarter ended March 31, 2016.

The following table presents the major classes of assets and liabilities at December 31, 2015 related to the Hemostasis Business which were reclassified as held for sale:

	December 31, 2015
	(in thousands)
Assets:	
Inventory	$ 53,765
Prepaid expenses and other current assets	1,153
Fixed assets, net	1,913
Intangibles, net	374,779
Allowance for reduction of assets of business held for sale	(108,773)
Total assets held for sale	$ 322,837
Liabilities:	
Contingent purchase price - current	$ 28,600
Deferred tax liability	38,915
Total liabilities held for sale	$ 67,515

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Depreciation and amortization were ceased upon determination that the held for sale criteria were met in the fourth quarter of 2015. The significant cash flow items from discontinued operations for the three months ended March 31, 2016 and 2015 were as follows:

	Three Months Ended March 31,
	2016	2015
	(in thousands)	
Depreciation from discontinued operations	$ —	$ 25
Amortization from discontinued operations	—	4,730
Gain on sale of business	(1,004)	—
Change in contingent consideration obligation	—	(1,600)
Proceeds from sale of business	174,068	—
Capital expenditures	—	82

17. Subsequent Events

On May 9, 2016, the Company entered into a purchase and sale agreement pursuant to which the Company agreed to sell to Chiesi USA, Inc. and its parent company, Chiesi Farmaceutici S.p.A., substantially all of its assets relating to Cleviprex, Kengreal and Argatroban for Injection for an upfront payment equal to approximately $260.0 million payable at the closing of the transaction, subject to certain post-closing adjustments, and potential milestone payments of up to $480.0 million following achievement of specified U.S. net sales milestones with respect to Cleviprex and Kengreal. The closing of the transaction is subject to the satisfaction or waiver of customary conditions, including the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended. The purchase and sale agreement contains representations, warranties and covenants as to the parties' business, financial and legal obligations and provides for indemnification by each of the parties in certain circumstances and subject to certain limitations.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and accompanying notes included elsewhere in this Quarterly Report on Form 10-Q. In addition to the historical information, the discussion in this Quarterly Report on Form 10-Q contains certain forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated by the forward-looking statements due to our critical accounting estimates discussed below and important factors set forth in this Quarterly Report on Form 10-Q, including under "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Overview

Our Business

We are a global biopharmaceutical company focused on saving lives, alleviating suffering and contributing to the economics of healthcare by focusing on leading acute/intensive care hospitals worldwide. We market Angiomax® (bivalirudin), Cleviprex® (clevidipine) injectable emulsion, Ionsys® (fentanyl iontophoretic transdermal system), Kengreal® (cangrelor), Minocin (minocycline) for injection, and Orbactiv® (oritavancin). We also have a pipeline of acute and intensive care hospital products in development, including ABP-700, ALN-PCSsc, Carbavance® and MDCO-216. We have the right to develop, manufacture and commercialize ALN-PCSsc under our collaboration agreement with Alnylam Pharmaceuticals, Inc., or Alnylam. We believe that our 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 products in development, 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 are currently selling three of our acute care generic products, midazolam, ondansetron and rocuronium.

On July 2, 2015, we entered into a supply and distribution agreement with Sandoz Inc., or Sandoz, under which we granted Sandoz the exclusive right to sell in the United States an authorized generic of Angiomax (bivalirudin). We entered into the supply and distribution agreement as a result of the July 2, 2015 U.S. Court of Appeals for the Federal Circuit, or Federal Circuit Court, ruling against us in our patent infringement litigation with Hospira, Inc., or Hospira, with respect to U.S. Patent No. 7,582,727, or the '727 patent, and U.S. Patent No. 7,598,343, or the '343 patent, covering a more consistent and improved Angiomax drug product and the processes by which it is made. In its July 2, 2015 ruling, the Federal Circuit Court held the '727 patent and the '343 patent invalid. On July 15, 2015, Hospira's Abbreviated New Drug Applications, or ANDAs, for its generic versions of bivalirudin were approved by the FDA and Hospira began selling its generic versions of bivalirudin. In November 2015, our petition for en banc review of the Federal Circuit Court's July 2, 2015 decision was granted and the Federal Circuit Court vacated its July 2, 2015 decision. Notwithstanding the granting of our petition for en banc review, due to the July 2, 2015 decision and our resulting entry into a supply and distribution agreement with Sandoz and Hospira's entry into the market, Angiomax is now subject to generic competition with the authorized generic and Hospira's generic bivalirudin products.

On November 3, 2015, we announced that we were in the process of evaluating our operations with a goal of unlocking stockholder value. In particular, we stated our current intention was to explore strategies for optimizing our capital structure and liquidity position and to narrow our operational focus by strategically separating non-core businesses and products in order to generate non-dilutive cash and reduce associated cash burn and capital

requirements, including, among other things, by potentially divesting or partnering our hemostasis portfolio, consisting of PreveLeak, Raplixa and Recothrom. On February 1, 2016, we completed the sale of our hemostasis portfolio to wholly owned subsidiaries of Mallinckrodt plc, or Mallinckrodt. At the completion of the sale, we received approximately $174.1 million in cash, and may receive up to an additional $235.0 million in the aggregate following the achievement of certain specified calendar year net sales milestones with respect to net sales of PreveLeak and Raplixa.

The following table identifies each of our marketed and approved 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 table also identifies each of our acute care generic products and the therapeutic areas which they are intended to address. All of our products and products in development, except for ALN PCSsc and Ionsys are administered intravenously. Ionsys is administered transdermally and ALN PCSsc is being developed as a subcutaneous injectable. All of our acute care generic products are injectable products.

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Product or Product in Development Marketed and Approved Products	Development Stage	Mechanism/Target	Clinical Indication(s)/Therapeutic Areas
Angiomax	Marketed as a branded product, and as an authorized generic in the United States through Sandoz	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
	Marketed in the United States, Australia, Germany, Spain and Switzerland		
Cleviprex	Approved in Austria, Belgium, Canada, France, Kazakhstan, Luxembourg, the Netherlands, New Zealand, Sweden and the United Kingdom	Calcium channel blocker	U.S. - Blood pressure reduction when oral therapy is not feasible or not desirable Ex-U.S. - with various indications for blood pressure control in perioperative settings
	Marketing Authorization Application, or MAA, submitted for other European Union countries		
Ionsys	Marketed in the United States; Marketed in the European Union	Patient-controlled analgesia system	Short-term management of acute postoperative pain in hospitalized patients
Kengreal	Marketed in the United States; Marketed in the European Union	Antiplatelet agent	Adjunct to PCI for reducing risk of periprocedural thrombotic events in patients who have not been treated with a P2Y12 inhibitor and are not being given a GPI
Minocin IV	Marketed in the United States	Tetracycline-class antibiotic	Treatment of bacterial infections due to susceptible isolates of designated microorganisms, including

			Acinetobacter species. Treatment of adult patients with acute bacterial skin and skin structure infections, or ABSSSI, caused or suspected to be caused by susceptible isolates of the label-designated gram-positive microorganisms, including methicillin-resistant Staphylococcus aureus, or MRSA
Orbactiv	Marketed in the United States; Approved in the European Union	Antibiotic	

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Product or Product in Development	Development Stage	Mechanism/Target	Clinical Indication(s)/Therapeutic Areas
Ready-to-use Argatroban	Marketed in the United States	Direct thrombin inhibitor	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: Adenosine, Amiodarone, Esmolol and Milrinone	Approved in the United States	Various	Acute cardiovascular
Acute care generic products: Azithromycin and Clindamycin	Approved in the United States	Various	Serious infectious disease
Acute care generic products: Haloperidol, Midazolam, Ondansetron and Rocuronium	Approved in the United States; Midazolam, Ondansetron and Rocuronium marketed in the United States	Various	Surgery and perioperative
Research and Development Stage			
ABP-700	Phase 1	Analogue of etomidate, an intravenous imidazole agent used for induction of general anesthesia	Sedative-hypnotic used to induce and maintain sedation for procedural care and general anesthesia for surgical care
ALN-PCSsc	Phase 2	PCSK-9 gene antagonist addressing low-density lipoprotein cholesterol disease modification	Treatment of hypercholesterolemia
Carbavance	Phase 3	Combination of vaborbactam (formerly known as RPX-7009), a proprietary, novel beta-lactamase inhibitor, with meropenem, a carbapenem antibiotic	Treatment of hospitalized patients with serious gram-negative bacterial infections
MDCO-216	Phase 1/2	Naturally occurring variant of a protein found in high-density lipoprotein	Reverse cholesterol transport agent to reduce atherosclerotic plaque burden development and thereby reduce the risk of adverse thrombotic events

Our revenues to date have been generated primarily from sales of Angiomax in the United States. In the three months ended March 31, 2016, we had net product revenue from sales of Angiomax of approximately $16.9 million and aggregate net revenue from sales of Cleviprex, Minocin IV, Orbactiv, ready-to-use Argatroban, Kengreal and Ionsys of approximately $14.5 million. During this period, net product revenues from sales of Angiomax decreased by $83.8

million from the three months ended March 31, 2015. As a result of our July 2015 supply and distribution agreement with Sandoz, we recognized $18.9 million of royalty revenues related to the authorized generic sales of Angiomax (bivalirudin) in the three months ended March 31, 2016. We expect that net revenue from sales of Angiomax will continue to decline in 2016 and in future years due to competition from generic versions of bivalirudin following the loss of market exclusivity in the United States in July 2015 and in Europe in August 2015. Based on our current business, we expect to incur net losses for the foreseeable future.

Cost of revenue represents expenses in connection with contract manufacture of our products sold and logistics, product costs, royalty expenses and amortization of the costs of license agreements, amortization and impairments of product rights and other identifiable intangible assets from product and business acquisitions and expenses related to excess inventory. Research and development expenses represent costs 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. We expense our research and development costs as they are incurred. Selling, general and administrative expenses consist primarily of salaries and related expenses, costs associated with general corporate activities, changes in fair value of contingent purchase price obligations related to our acquisitions, and costs associated with marketing and promotional activities. Research and development expense, selling, general and administrative expense and cost of revenue also include share-based compensation expense, which we allocate based on the responsibilities of the recipients of the share-based compensation.

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Angiomax Developments

The principal U.S. patents covering Angiomax included U.S. Patent No. 5,196,404, or the ‘404 patent, the ‘727 patent and the ‘343 patent. The term of the ‘404 patent expired on December 15, 2014 and the six-month period of pediatric exclusivity following expiration of the ‘404 patent resulting from our study of Angiomax in the pediatric setting ended June 15, 2015. The ‘727 patent and the ‘343 patent, issued to us by the U.S. Patent and Trademark Office, or PTO, in the second half of 2009, covering a more consistent and improved Angiomax drug product and the processes by which it is made, were set to expire in July 2028. In response to Paragraph IV Certification Notice letters we received with respect to ANDAs filed by a number of parties with the FDA seeking approval to market generic versions of Angiomax, we filed lawsuits against such ANDA filers alleging patent infringement of the ‘727 patent and ‘343 patent. We have since entered into settlement agreements with respect to our suits against three ANDA filers, Teva Pharmaceuticals USA, Inc. and its affiliates, or Teva, APP Pharmaceuticals LLC, or APP, and Sun Pharmaceutical Industries LTD, or Sun Pharmaceuticals Industries Ltd. and affiliates, or Sun.

On July 2, 2015, the Federal Circuit Court ruled against us in our patent infringement litigation with Hospira with respect to the ‘727 patent and the ‘343 patent. In its ruling, the Federal Circuit Court held the ‘727 patent and ‘343 patent invalid. As a result of the ruling, we do not have market exclusivity for Angiomax (bivalirudin) in the United States. On July 15, 2015, Hospira’s ANDAs for its generic versions of bivalirudin were approved by the FDA. As a result of the Federal Circuit Court’s ruling in the Hospira matter and the FDA’s approval of Hospira’s ANDAs, Angiomax is subject to generic competition from Hospira in the United States. On July 31, 2015, we filed a combined petition for panel rehearing and rehearing en banc with respect to the Federal Circuit Court’s July 2, 2015 decision. On August 24, 2015, the Federal Circuit Court invited Hospira to respond to the petition and on September 8, 2015, Hospira filed a response. On November 13, 2015, the Federal Circuit Court granted our petition for rehearing en banc and vacated its earlier July 2, 2015 decision. The Federal Circuit Court set a briefing schedule, specified specific questions to be answered, invited the DOJ to file a brief expressing the views of the United States and also invited any other amicii curiae to file briefs on the en banc issues raised. Hospira filed its opening brief on January 11, 2016. We filed our response on February 24, 2016 and Hospira filed its reply brief on March 10, 2016. Nine amicus briefs were filed: Department of Justice, American Intellectual Property Law Association, Intellectual Property Owners Association, a Texas law firm, Miller Patti Pershern PLLC, Pharmaceutical Research and Manufacturers of America, Biotechnology Innovation Organization, Gilead Sciences, Inc., an individual, Roberta J. Morris, Esq., and Houston Intellectual Property Law Association. The Federal Circuit Court sitting en banc heard oral argument from the parties and the government on May 5, 2016. The court did not indicate when it would issue its opinion.

In light of the decision by the Federal Circuit Court in the Hospira matter, on July 2, 2015, we entered into a Supply and Distribution Agreement with Sandoz under which we granted Sandoz the exclusive right to sell in the United States an authorized generic of Angiomax (bivalirudin). The authorized generic of Angiomax is sold under our approved NDA for Angiomax but labeled and sold under the Sandoz name. Under the agreement, we have agreed to supply Sandoz with Angiomax, and Sandoz has agreed to purchase Angiomax exclusively from us. Sandoz has agreed to pay us a price per vial equal to our cost of goods. Sandoz has agreed to use commercially reasonable efforts to market, distribute and sell the authorized generic Angiomax in the United States during the term of the agreement. Sandoz will pay us on a quarterly basis a high double digit percentage of its net profits (net sales less our cost of goods and certain agreed expenses of Sandoz) on sales of authorized generic Angiomax. The term of the agreement will continue until July 2, 2020 and will automatically renew for successive one-year periods thereafter unless either party provides notice of non-renewal at least six months prior to the end of the applicable term. Either party may terminate the agreement at any time if the other party is in material breach of the agreement and does not cure such breach within 60 days, the other party undergoes bankruptcy events, the other party is unable to perform its obligations under the agreement for more than 120 consecutive days due to a force majeure event, compliance with the agreement would

violate law or net profits related to sales of the authorized generic Angiomax in any month fall below a low double digit percentage of net sales of the authorized generic Angiomax in such month. We may also terminate the agreement at any time that no other pharmaceutical product containing bivalirudin in a lyophilized form as its sole active ingredient is being sold in the United States.

In addition to Hospira's generic versions of bivalirudin, Sandoz's authorized generic and, if approved, Eagle Pharmaceuticals, Inc., or Eagle's, formulation of bivalirudin, Angiomax could be subject to generic competition in the United States from Teva, APP and Sun under the circumstances set forth in our respective settlement agreements with such parties and upon the approval of each companies' ANDA filings by the FDA. Further, 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 Form 10-Q. There can be no assurance as to the outcome of our infringement litigation. We may continue to incur substantial legal expenses related to these matters.

In addition, the principal patent covering Angiomax in Europe expired in August 2015. As a result, we could face generic competition in Europe.

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Business Development Activity

Sale of Hemostasis Business. On February 1, 2016, we completed the sale of our hemostasis business to Mallinckrodt. Under the terms of the purchase and sale agreement, Mallinckrodt acquired all of the outstanding equity of Tenaxis Medical, Inc. and ProFibrix B.V. and assets exclusively related to the Recothrom product. Mallinckrodt assumed all liabilities arising out of Mallinckrodt's operation of the businesses and the acquired assets after closing, including all obligations with respect to milestones relating to the PreveLeak and Raplixa products. At the completion of the sale, we received approximately $174.1 million in cash from Mallinckrodt, and may receive up to an additional $235.0 million in the aggregate following the achievement of certain specified calendar year net sales milestones with respect to net sales of PreveLeak and Raplixa. The amount paid at closing is subject to a post-closing purchase price adjustment process with respect to the Recothrom inventory and the net working capital of the hemostasis business as of the date of the closing. As a result of the transaction, we accounted for the assets and liabilities of the hemostasis business that were sold as held for sale at December 31, 2015. As a result of the classification as held for sale, we recorded impairment charges of $133.3 million, including $24.5 million related to goodwill, to reduce the hemostasis business disposal group’s carrying value to its estimated fair value, less costs to sell for the year ended December 31, 2015.

Annovation BioPharma, Inc. In February 2015, we completed the acquisition of Annovation BioPharma, Inc., or Annovation, and Annovation became our wholly owned subsidiary. As a result of the acquisition of Annovation, we acquired ABP-700, a novel intravenous anesthetic. Under the terms of the terms of the acquisition agreement, we paid to the holders of Annovation’s capital stock and the holders of options to purchase shares of Annovation’s capital stock, which we refer to collectively as the Annovation equityholders, an aggregate of approximately $28.4 million in cash. In addition, we may be required to pay Annovation equityholders up to an additional $26.3 million in milestone payments subsequent to the closing if we achieve certain development and regulatory approval milestones at the times and on the conditions set forth in the acquisition agreement. We have also agreed to pay Annovation equityholders a low single digit percentage of worldwide net sales, if any, of certain Annovation products, including ABP-700, during a specified earnout period. In addition, as a result of our acquisition of Annovation, we, through our subsidiary Annovation, are a party to a license agreement with The General Hospital Corporation. Under the agreement, we will be obligated to pay General Hospital Corporation up to an aggregate of $6.5 million upon achievement of specified development, regulatory and sales milestones. We will also be obligated to pay General Hospital Corporation low single-digit percentage royalties on a product-by-product and country-by-country basis based on net sales of ABP-700 products until the later of the duration of the licensed patent rights which are necessary to manufacture, use or sell ABP-700 products in a country and the date ten years from our first commercial sale of ABP-700 products in such country.

Promus PREMIER Stent System Co-Promotion. In December 2013, we entered into a co-promotion agreement with Boston Scientific Corporation, or BSX, for the Promus PREMIER Everolimus Eluting Platinum Chromium Coronary Stent System, or Promus PREMIER Stent System, to provide promotional support for the Promus PREMIER Stent System in U.S. hospitals. For the year ended December 31, 2014, we recognized $5.0 million in co-promotion income from BSX. Effective December 31, 2014, our co-promotion agreement with BSX was terminated and we ceased to co-promote the Promus PREMIER Stent System.

Rempex Pharmaceuticals, Inc. In December 2013, we acquired Rempex Pharmaceuticals, Inc., or Rempex, and Rempex became our wholly-owned subsidiary. As a result of the transaction, we acquired Rempex’s marketed product, Minocin IV, a broad-spectrum tetracycline antibiotic, and Rempex’s portfolio of product candidates, including RPX-602, a proprietary reformulation of Minocin IV utilizing magnesium sulfate, Carbavance, an investigational agent that is a combination of vaborbactam, a proprietary, novel beta-lactamase inhibitor, with a carbapenem, and

Rempex's other product candidates.

Under the terms of the merger agreement for the acquisition, we paid to the holders of Rempex's capital stock, the holders of options to purchase shares of Rempex's capital stock and the holders of certain phantom stock units, which we collectively refer to as the Rempex equityholders, an aggregate of approximately $140.0 million in cash, plus approximately $0.3 million in purchase price adjustments.

In addition, we agreed to pay to the Rempex equityholders milestone payments subsequent to the closing, if we achieve certain development and regulatory approval milestones and commercial sales milestones with respect to Minocin IV, RPX-602, Carbavance and Rempex's other product candidates, at the times and on the conditions set forth in the merger agreement. In the event that all of the milestones set forth in the merger agreement are achieved in accordance with the terms of the merger agreement, we will pay the Rempex equityholders an additional $214.0 million in cash in the aggregate for achieving development and regulatory milestones and an additional $120.0 million in cash in the aggregate for achieving commercial milestones, in each case, less certain transaction expenses and employer taxes owing because of the milestone payments.

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Pursuant to the terms of the merger agreement, as a result of certain milestone payments becoming due within eighteen months following the closing, in October 2014, we entered into an escrow agreement and deposited an aggregate of $14.0 million into an escrow fund during the fourth quarter of 2014. In June 2015, the escrow fund was released to the Rempex equityholders.

Alnylam License Agreement. 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. 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 up to $180.0 million in success-based development, regulatory and 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. Alnylam was responsible for developing the lead product through the end of the first Phase 1 clinical trial and to supply the lead product for the first Phase 1 clinical trial and the first phase 2 clinical trial. Alnylam will bear the costs for these activities, subject to certain caps on its costs. If Alnylam's development and supply costs exceed the applicable cap, Alnylam need not bear any additional development and supply costs except for costs directly caused by Alnylam's gross negligence and we shall have the option to assume such excess costs. We will direct and pay for all other development, manufacturing and commercialization activities under the agreement.
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 merger agreement with Incline, we paid to Incline's equityholders and optionholders an aggregate of approximately $155.2 million in cash. In addition, we paid approximately $13.0 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 an additional $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 merger agreement, to the extent that any amounts remained in the escrow fund after July 4, 2014 and were not subject to claims by us, such amounts were to be released to Incline's equityholders and optionholders, subject to certain conditions set forth in the merger agreement. In December 2014, we entered into a settlement and amendment to the merger agreement, which resulted in revisions to certain milestone triggers, a reduction in total potential milestone payments and the immediate release of the escrow fund to us.

Under the terms of our agreement with Incline, as amended, we agreed to pay up to $189.3 million in cash in the aggregate, less certain related expenses, to Incline's former equityholders and optionholders and up to $115.5 million in additional payments to other third parties.

Collaboration with AstraZeneca LP. 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. For the year ended December 31, 2014, AstraZeneca

LP paid us $16.0 million under the agreement. Effective December 31, 2014, our global collaboration agreement with AstraZeneca LP was terminated and we ceased to co-promote AstraZeneca LP's BRILINTA.

Targanta Therapeutics Corporation. In February 2009, we acquired Targanta Therapeutics Corporation, or Targanta, a biopharmaceutical company focused on developing and commercializing innovative antibiotics to treat serious infections in the hospital and other institutional settings.

Under the terms of our agreement with Targanta, we paid Targanta shareholders an aggregate of approximately $42.0 million in cash at closing. In addition, we originally agreed to pay contingent cash payments up to an additional $90.4 million in the aggregate. This amount has been reduced to $49.4 million as certain milestones have not been achieved by specified dates. We will owe $49.4 million if aggregate net sales of Orbactiv in four consecutive calendar quarters ending on or before December 31, 2021 reach or exceed $400.0 million, and up to an additional $40.0 million in additional payments to other third parties.

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BARDA Agreement

In February 2014, our subsidiary Rempex entered into an agreement with the Biomedical Advanced Research and Development Authority, or BARDA, of the U.S. Department of Health and Human Services. Under this agreement, as modified, Rempex has the potential to receive up to $91.8 million in funding to support the development of Carbavance. The BARDA agreement is a cost-sharing arrangement that consists of an initial base period and seven option periods that BARDA may exercise in its sole discretion pursuant to the BARDA agreement. The BARDA agreement provides for an initial commitment by BARDA of an aggregate of $19.8 million for the initial base period and the first option period, and up to an additional $70.0 million if the remaining six option periods are exercised by BARDA. In October 2014, BARDA exercised the second option, increasing BARDA's total commitment to $37.8 million. In September 2015, BARDA exercised the third option, increasing BARDA's total commitment to $53.8 million. In December 2015, BARDA increased the amount authorized under the third option by $2.0 million, thus increasing BARDA's total commitment to $55.8 million. Under the cost-sharing arrangement, Rempex will be responsible for a designated portion of the costs associated with each period of work. If all option periods are exercised by BARDA, the estimated period of performance would be extended until approximately July 31, 2019. BARDA is entitled to terminate the agreement, including the projects under the BARDA agreement for convenience, in whole or in part, at any time and is not obligated to provide continued funding beyond current year amounts from Congressionally approved annual appropriations. We expect to use the total award under the BARDA agreement to support non-clinical development activities, clinical studies, manufacturing and associated regulatory activities designed to obtain marketing approval of Carbavance in the United States for treatment of serious gram-negative infections. The BARDA agreement also covers initial non-clinical studies to assess the potential usefulness of Carbavance for treatment of certain gram-negative bioterrorism agents. Under the terms of our agreement with Rempex, we agreed to pay former Rempex equityholders on a quarterly basis, as part of our development milestones, a specified percentage of amounts actually received by us from BARDA. We recorded approximately $6.3 million and $3.2 million as reductions of research and development expenses for the three months ended March 31, 2016 and 2015, respectively.

Convertible Senior Note Offerings

2022 Notes

On January 13, 2015, we completed our private offering of $400.0 million aggregate principal amount of our 2.50% convertible senior notes due 2022, or the 2022 notes, and entered into an indenture with Wells Fargo Bank, National Association, a national banking association, as trustee, governing the 2022 notes. The aggregate principal amount of 2022 notes sold reflects the exercise in full by the initial purchasers of the 2022 notes of their option to purchase up to an additional $50.0 million in aggregate principal amount of the 2022 notes. The net proceeds from the offering were $387.2 million, after deducting the initial purchasers' discounts and commissions and our offering expenses.

The 2022 notes bear cash interest at a rate of 2.50% per year, payable semi-annually on January 15 and July 15 of each year, beginning on July 15, 2015. The 2022 notes will mature on January 15, 2022. The 2022 notes do not contain any financial or operating covenants or any restrictions on the payment of dividends, incurrence of other indebtedness, or issuance or repurchase of securities by us.

Holders may convert their 2022 notes at their option at any time prior to the close of business on the business day immediately preceding October 15, 2021 only under the following circumstances: (1) during any calendar quarter commencing on or after March 31, 2015 (and only during such calendar quarter), if the last reported sale price of our 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 on each applicable trading day; (2) during the five business day period after any five consecutive trading day period, or measurement period, in which the trading price, as defined in the indenture governing the 2022

notes, per $1,000 principal amount of 2022 notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day; (3) during any period after we have issued notice of redemption until the close of business on the scheduled trading day immediately preceding the relevant redemption date; or (4) upon the occurrence of specified corporate events. On or after October 15, 2021, until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their 2022 notes at any time, regardless of the foregoing circumstances. Upon conversion, we will pay cash up to the aggregate principal amount of the 2022 notes to be converted and deliver shares of our common stock in respect of the remainder, if any, of its conversion obligation in excess of the aggregate principal amount of 2022 notes being converted, subject to a daily share cap, as described in the indenture governing the 2022 notes. Holders of 2022 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 our common stock, together with any cash payment for any fractional share, paid or delivered, as the case may be, upon conversion of a 2022 note.

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The conversion rate for the 2022 notes was initially, and remains, 29.8806 shares of our common stock per $1,000 principal amount of the 2022 notes, which is equivalent to an initial conversion price of approximately $33.47 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 governing the 2022 notes.

We may not redeem the 2022 notes prior to January 15, 2019. We may redeem for cash all or any portion of the 2022 notes, at our option, on or after January 15, 2019 if the last reported sale price of our common stock has been at least 130% of the conversion price then in effect on the last trading day of, and for at least 19 other trading days (whether or not consecutive) during, any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which we provides notice of redemption, at a redemption price equal to 100% of the principal amount of the 2022 notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. No sinking fund is provided for the 2022 notes, which means that we are not required to redeem or retire the 2022 notes periodically.

If we undergo a fundamental change, as defined in the indenture governing the 2022 notes, subject to certain conditions, holders of the 2022 notes may require us to repurchase for cash all or part of their 2022 notes at a repurchase price equal to 100% of the principal amount of the 2022 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 would increase the conversion rate for a holder who elects to convert the 2022 notes in connection with such change of control in certain circumstances.

The 2022 notes are our senior unsecured obligations and will rank senior in right of payment to our future indebtedness that is expressly subordinated in right of payment to the 2022 notes; equal in right of payment to our existing and future unsecured indebtedness that is not so subordinated (including the 2017 notes); 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 structurally junior to all existing and future indebtedness and other liabilities (including trade payables) incurred by our subsidiaries.

The indenture governing the 2022 notes contains customary events of default with respect to the 2022 notes, including that upon certain events of default (including our failure to make any payment of principal or interest on the 2022 notes when due and payable) occurring and continuing, the trustee for the 2022 notes by notice to us, or the holders of at least 25% in principal amount of the outstanding 2022 notes by notice to us and the trustee for the 2022 notes, may, and the trustee at the request of such holders (subject to the provisions of the indenture governing the 2022 notes) shall, declare 100% of the principal of and accrued and unpaid interest, if any, on all the 2022 notes to be due and payable. In case of certain events of bankruptcy, insolvency or reorganization, involving us or a significant subsidiary, 100% of the principal of and accrued and unpaid interest on the 2022 notes will automatically become due and payable. Upon such a declaration of acceleration, such principal and accrued and unpaid interest, if any, will be due and payable immediately.

2017 Notes

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 2017 notes, and entered into an indenture with Wells Fargo Bank, National Association, a national banking association, as trustee, governing the 2017 notes. The net proceeds from the offering were $266.2 million, after deducting the initial purchasers' discounts and commissions and our offering expenses.

The 2017 notes bear cash interest at a rate of 1.375% per year, payable semi-annually on June 1 and December 1 of each year. The 2017 notes will mature on June 1, 2017. The 2017 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.

Holders may convert their 2017 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: (1) during any calendar quarter commencing on or after September 1, 2012 (and only during such calendar quarter), if the last reported sale price of

our 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 on each applicable trading day; (2) during the five business day period after any five consecutive trading day period, or measurement period, in which the trading price, as defined in the indenture governing the 2017 notes, per $1,000 principal amount of 2017 notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day; or (3) upon the occurrence of specified corporate events. The conditional conversion feature of the 2017 notes has been triggered and the holders are currently entitled to convert the notes into our common stock through June 30, 2016 pursuant to the terms of the 2017 notes indenture. Additionally, 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 2017 notes at any time, regardless of the foregoing circumstances. Upon conversion, we will pay cash up to the aggregate principal amount of the 2017 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

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the aggregate principal amount of the 2017 notes being converted, subject to a daily share cap, as described in the indenture governing the 2017 notes. Holders of 2017 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 our common stock, together with any cash payment for any fractional share, paid or delivered, as the case may be, upon conversion of a 2017 note.

The conversion rate for the 2017 notes was initially, and remains, 35.8038 shares of our common stock per $1,000 principal amount of 2017 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 governing the 2017 notes.

We may not redeem the 2017 notes prior to maturity and are not required to redeem or retire the 2017 notes periodically. However, upon the occurrence of a “fundamental change”, as defined in the indenture governing the 2017 notes, subject to certain conditions, in lieu of converting their 2017 notes, holders may require us to repurchase for cash all or part of their 2017 notes at a repurchase price equal to 100% of the principal amount of the 2017 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 2017 notes in connection with such change of control in certain circumstances.

The 2017 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 2017 notes and equal in right of payment to our existing and future unsecured indebtedness that is not so subordinated (including the 2022 notes). The 2017 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.

The indenture governing the 2017 notes contains customary events of default with respect to the 2017 notes, including that upon certain events of default, including our failure to make any payment of principal or interest on the 2017 notes when due and payable, occurring and continuing, the trustee for the 2017 notes by notice to us, or the holders of at least 25% in principal amount of the outstanding 2017 notes by notice to us and the trustee for the 2017 notes, may, and the trustee at the request of such holders, subject to the provisions of the indenture governing the 2017 notes, shall, declare 100% of the principal of and accrued and unpaid interest, if any, on all the 2017 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 2017 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

In connection with the offering of the 2017 notes, on June 5, 2012, we entered into convertible note hedge transactions and warrant transactions with several of the initial purchasers of the 2017 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 2017 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 2017 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 2017 notes and is subject to anti-dilution adjustments substantially similar to those applicable to the conversion rate of the 2017 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.

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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 under which Biogen licensed Angiomax to us. 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. As of December 15, 2014, we no longer owe royalties to Biogen or Health Research, Inc. relating to sales of Angiomax in the United States. In the third quarter of 2015, Biogen completed an audit of our books and records and indicated its belief that additional amounts are owed to Biogen under the license agreement. In September 2015, we filed suit in the United States District Court for the District of New Jersey seeking declaratory judgments that we have satisfied our obligations under the license agreement. In November 2015, Biogen answered the complaint denying our claims and asserting counterclaims for breach of contract. See Part II, Item 1. Legal Proceedings, of this Quarterly Report on Form 10-Q for additional information.

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 on Form 10-Q, we have not identified any provisions that currently materially impact our business or results of operations other than the Biologics Price Competition and Innovation Act provisions of PPACA . However, the potential impact of the PPACA 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 developed Orbactiv for the treatment of ABSSSI, including infections caused by MRSA, and are exploring the development of Orbactiv for other indications, including ABSSSI in children, uncomplicated bacteremia, endocarditis, prosthetic joint infections, and other gram-positive bacterial infections. We developed the new formulation of Minocin IV, which is approved by the FDA for the treatment of infections due to susceptible strains of designated gram-negative bacteria, including those due to Acinetobacter spp, and designated gram-positive bacteria. We are also developing Carbavance for the treatment of hospitalized patients with serious gram-negative bacterial infections. In November 2013, the FDA designated Orbactiv a QIDP. In August 2014, following approval of Orbactiv, the FDA informed us that Orbactiv met the criteria for an additional five years of non-patent exclusivity to be added to the five year exclusivity period already provided by the Food, Drug and Cosmetic Act. As a result, Orbactiv’s non-patent

regulatory exclusivity is scheduled to expire in August 2024. In December 2013, the FDA designated Carbavance a QIDP. We expect that, if we submit an NDA for Carbavance and the NDA is approved, Carbavance would receive an additional five years of non-patent exclusivity. In April 2015, the FDA designated the new formulation of Minocin IV a QIDP for certain additional potential indications involving gram-negative bacteria, and we expect that if we submit a supplemental NDA for one or more of those indications and such supplemental NDA is approved, Minocin IV would receive an additional five years of non-patent exclusivity with respect to such indications.

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Results of Operations

Three Months Ended March 31, 2016 Compared to Three Months Ended March 31, 2015

Net Revenues:

Net revenues decreased 54.3% to $50.3 million for the three months ended March 31, 2016 as compared to $110.1 million for the three months ended March 31, 2015.

	Three Months Ended March 31,			
	2016	2015	Change $	Change %
	(in thousands)			
Net product revenues	$31,375	$110,115	$(78,740)	(71.5)%
Royalty revenues	18,931	—	18,931	100.0 %
Total net revenues	$50,306	$110,115	$(59,809)	(54.3)%

Net Product Revenues:

The following table reflects the components of net product revenues for the three months ended March 31, 2016 and 2015:

	Three Months Ended March 31,			
	2016	2015	Change $	Change %
	(in thousands)			
Angiomax	$16,877	$100,679	$(83,802)	(83.2)%
Other products	14,498	9,436	5,062	53.6 %
Total net product revenues	$31,375	$110,115	$(78,740)	(71.5)%

Net product revenues decreased by $78.7 million, or 71.5%, to $31.4 million in the three months ended March 31, 2016 compared to $110.1 million in the three months ended March 31, 2015, reflecting decreases of $77.0 million in the United States and of $1.7 million in international markets.

Angiomax. Net product revenue from sales of Angiomax decreased by $83.8 million, or 83.2%, to $16.9 million in the three months ended March 31, 2016 compared to $100.7 million in the three months ended March 31, 2015, primarily due to volume decreases in the United States. Volume and price decreases for Angiomax in the three months ended March 31, 2016 were primarily due to the launch of generic versions of bivalirudin in the United States in July 2015. On July 2, 2015, the Federal Circuit Court ruled that our '343 patent and our '727 patent, each covering Angiomax, were invalid. On July 15, 2015, Hospira's ANDAs for its generic versions of bivalirudin were approved by the FDA and Hospira began selling its generic version of bivalirudin. In November 2015, our petition for en banc review of the Federal Circuit Court's July 2, 2015 decision was granted and the Federal Circuit Court vacated its July 2, 2015 decision. Notwithstanding the granting of our petition for en banc review, due to the July 2, 2015 decision and our resulting entry into a supply and distribution agreement with Sandoz and Hospira's entry into the market, Angiomax is now subject to generic competition with the authorized generic and Hospira's generic bivalirudin products. Of the $16.9 million, $4.4 million related to shipments of generic Angiomax to Sandoz for the three months ended March 31, 2016.

Net product revenue from sales of Angiomax in the United States in the three months ended March 31, 2016 and 2015 reflect chargebacks related to the 340B Drug Pricing Program under the Public Health Services Act 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 percutaneous coronary intervention, or PCI, on an outpatient basis. Chargebacks related to the 340B Drug Pricing Program were $2.8 million and $23.2 million in the three months ended March 31, 2016 and 2015, respectively. Rebates related to the PPACA were $0.4 million and $0.6 million in the three months ended March 31, 2016 and 2015, respectively.

Other Products. Net revenue from sales of Cleviprex, ready-to-use Argatroban, Minocin IV, Orbactiv, Kengreal and Ionsys increased by $5.1 million, or 53.6%, to $14.5 million in the three months ended March 31, 2016 from $9.4 million in the three months ended March 31, 2015, primarily due to increases in revenue due to increased volume from Orbactiv, Cleviprex and Kengreal. This is partially offset by a decrease in ready-to-use Argatroban. Net revenue from sales of Cleviprex was $4.4 million in the three months ended March 31, 2016, compared to $2.2 million in the three months ended March 31, 2015. Net revenue from

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sales of Minocin IV and Orbactiv were $1.3 million and $3.0 million, respectively, in the three months ended March 31, 2016, compared to $0.8 million and $1.2 million, respectively, in the three months ended March 31, 2015. Net revenue from sales of Kengreal, which was launched in the third quarter of 2015, were $2.2 million in the three months ended March 31, 2016. Net revenue from sales of ready-to-use Argatroban were $3.6 million in the three months ended March 31, 2016, compared to $5.3 million in the three months ended March 31, 2015.

Royalty Revenues:

For the three months ended March 31, 2016, we recognized $18.9 million in royalty revenues related to the authorized generic sale of Angiomax to hospitals by Sandoz. Royalty revenues may decline in 2016 and in future years due to competition from generic versions of bivalirudin.

Cost of Revenue:

Cost of revenue for the three months ended March 31, 2016 was $18.8 million, or 59.9% of net product revenue, compared to $20.5 million, or 18.7% of net product revenue, for the three months ended March 31, 2015.

Cost of revenue during these periods consisted of:

- expenses in connection with the manufacture of our products sold, including expenses related to excess inventory;
- royalty expenses under our agreement with Eli Lilly and Company related to Orbactiv, our agreement with AstraZeneca related to Cleviprex and our agreement with Eagle Pharmaceuticals, Inc. related to ready-to-use Argatroban;
- amortization of the costs of selling rights agreements, product licenses, developed product rights and other identifiable intangible assets, which result from product and business acquisitions; and
- logistics costs related to Angiomax, Cleviprex, Orbactiv, Minocin IV, ready-to-use Argatroban, Kengreal and Ionsys, including distribution, storage, and handling costs.

	Three Months Ended March 31,			
	2016	% of Total	2015	% of Total
	(in thousands)		(in thousands)	
Manufacturing/Logistics	$10,299	54.8 %	$ 14,413	70.2 %
Royalties	2,213	11.8 %	4,446	21.6 %
Amortization of acquired product rights and intangible assets	6,285	33.4 %	1,680	8.2 %
Total cost of revenue	$18,797	100.0%	$ 20,539	100.0%

Cost of revenue decreased by $1.7 million during the three months ended March 31, 2016 compared to the three months ended March 31, 2015. This is primarily related to a decrease in Angiomax product sales due to generic competition, offset by an increase in amortization of product rights related to the launch of Ionsys.

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Research and Development Expenses:

	Three Months Ended March 31,					
	2016	% of Total		2015	% of Total	
	(in thousands)			(in thousands)		
Marketed products	$5,437	16.2	%	$ 5,828	25.0	%
Registration stage product candidates	—	—	%	5,476	23.5	%
Research and development product candidates	28,054	83.8	%	11,979	51.5	%
Total research and development expenses	$33,491	100.0	%	$ 23,283	100.0	%

Research and development expenses increased by $10.2 million during the three months ended March 31, 2016 compared to the three months ended March 31, 2015, primarily due to increases in expenses associated with MDCO-216, ALN-PCSsc and Carbavance. Research and development expenses associated with MDCO-216 increased by $9.0 million, reflecting higher costs incurred in 2016 to support manufacturing development scale up efforts. Research and development expenses related to ALN-PCSsc and Carbavance increased $2.4 million and $2.0 million, respectively, due to increased costs in support of the ongoing Phase II clinical trials for ALN-PCSsc and the Phase III clinical trial for Carbavance. These increases are partially offset by decreases in research and development costs for Orbactiv and Kengreal as these products were FDA approved and launched in 2015.

We expect research and development expenses in 2016 to increase primarily due to increased costs related to manufacturing development activities for Carbavance, clinical trials of MDCO-216, ABP-700 and ALN-PCSsc, and the continuation of our ongoing Phase 3 clinical trial of Carbavance.

Selling, General and Administrative Expenses:

	Three Months Ended March 31,			
	2016	2015	Change $	Change %
	(in thousands)			
Selling, general and administrative expenses	$79,298	$80,785	$(1,487)	(1.8)%

Selling, general and administrative expenses decreased by $1.5 million for the three months ended March 31, 2016 as compared to the three months ended March 31, 2015, primarily due decreases of $0.9 million in selling, marketing and promotional expenses and $0.6 million in general corporate and administrative expenses. Selling, marketing and promotional expenses decreased by $0.9 million primarily to support our recent product launches of Orbactiv, Minocin IV and Ionsys. General corporate and administrative expenses decreased by $0.6 million primarily due to a decrease of $4.5 million reflecting adjustments to the fair value of the contingent consideration due to the former equityholders of Targanta, Incline, Rempex and Annovation. This is partially offset by corporate infrastructure and legal costs of $3.9 million.

We expect our selling, general and administrative expenses will continue to decrease in 2016 due to a decrease in sales.

Co-promotion and License Income:

Three Months Ended March 31,

	2016	2015	Change $	Change %
	(in thousands)			
Co-promotion and license income	$975	$8,388	$(7,413)	(88.4)%

During the three months ended March 31, 2016 and 2015, we recorded license income of $0.1 million and $7.8 million, respectively, under our collaboration agreement with SciClone and $0.2 million and $0.6 million, respectively in co-promotion income under our license agreement with Eagle related to ready-to-use Argatroban. The decrease in SciClone revenue is due to the one-time revenue recognized in the three months ended March 31, 2015 related to commercialization rights. During the three months ended March 31, 2016, we recognized $0.6 million in license income under our collaboration agreement with Symbio.

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Loss in Equity Investment:

	Three Months Ended March 31,			
	2016	2015	Change $	Change %
	(in thousands)			
Loss in equity investment	$—	$(144)	$ 144	100.0%

We completed the acquisition of Annovation in February 2015 and Annovation became our wholly owned subsidiary. During the three months ended March 31, 2015, we recorded a loss of $0.1 million for our proportionate share of Annovation's losses under the equity method of accounting prior to the completion of our acquisition of Annovation.

Gain on Remeasurement of Equity Investment:

	Three Months Ended March 31,			
	2016	2015	Change $	Change %
	(in thousands)			
Gain on remeasurement of equity investment	$—	$22,741	$(22,741)	(100.0)%

We completed the acquisition of Annovation in February, 2015 and Annovation became our wholly owned subsidiary. We accounted for our acquisition of Annovation as a step acquisition which required that we remeasure the fair value of our existing 35.8% ownership interest (previously accounted for as an equity method investment). The fair value of our interest in Annovation was $25.9 million upon the closing of the acquisition, resulting in a non-cash pre-tax gain of $22.7 million for the three months ended March 31, 2015.

Interest Expense:

	Three Months Ended March 31,			
	2016	2015	Change $	Change %
	(in thousands)			
Interest expense	$9,746	$8,615	$1,131	13.1 %

During the three months ended March 31, 2016 and 2015, we recorded approximately $9.7 million and $8.6 million, respectively, in interest expense related to the 2017 Notes and 2022 Notes. We issued the 2017 notes on June 11, 2012 and the 2022 notes on January 13, 2015 and have recorded interest from those dates. We expect interest expense to continue to increase in 2016 as compared to 2015 as a result of the interest expense due under the 2022 notes.

Other (Expense) Income:

	Three Months Ended March 31,			
	2016	2015	Change $	Change %
	(in thousands)			
Other (expense) income	$(262)	$467	$(729)	*

*Represents a change in excess of 100%

Other income decreased by $0.7 million for the three months ended March 31, 2016, as compared to the three months ended March 31, 2015, primarily due to increased losses on foreign currency transactions, partially offset by a loss on the sale of fixed assets in the first quarter of 2015.

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Provision for Income Taxes:

	Three Months Ended March 31,			
	2016	2015	Change $	Change %
	(in thousands)			
Provision for income taxes	$(46)	$(4,001)	$3,955	98.9 %

We recorded a provision for income taxes of $0.05 million and $4.0 million for the three months ended March 31, 2016 and 2015, respectively, based on loss from continuing operations before income taxes of $90.3 million and income from continuing operations before income taxes of $8.3 million for the three months ended March 31, 2016 and 2015, respectively. Our effective income tax rates for the three months ended March 31, 2016 and 2015 were approximately (0.1)% and 45.8%, respectively. This decrease in the effective tax rate was primarily driven by our projected loss for the year 2016 and its inability to realize any benefit from this loss due to the establishment of a valuation allowance against substantial portions of its deferred tax assets during the fourth quarter of 2015. For the three months ended March 31, 2016, our provision for income taxes is the result of state tax minimums and estimated taxes due by profitable foreign subsidiaries.

(Loss) Income from Discontinued Operations, net of tax:

	Three Months Ended March 31,			
	2016	2015	Change $	Change %
	(in thousands)			
(Loss) income from discontinued operations, net of tax	$(2,105)	$661	$(2,766)	*

*Represents a change in excess of 100%

For details on discontinued operations see Note 16, “Discontinued Operations,” in the accompanying notes to condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

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 expect revenue from sales of Angiomax will be significantly lower in 2016 and in future years due to generic competition. These reduced revenues are likely to significantly impact our cash and cash equivalents and how we finance our operations.

Cash Flows

As of March 31, 2016, we had $430.2 million in cash and cash equivalents, as compared to $373.2 million as of December 31, 2015. The increase in cash and cash equivalents in the three months ended March 31, 2016 was primarily due to $174.1 million and $2.3 million of net cash provided by investing activities and financing activities, respectively. The increase in cash is partially offset by $118.4 million of net cash used in operating activities.

Net cash used in operating activities was $118.4 million in the three months ended March 31, 2016, compared to net cash used in operating activities of $41.0 million in the three months ended March 31, 2015. The cash used in

operating activities during the three months ended March 31, 2016 is primarily due to a net loss of $92.5 million and changes in working capital items of $42.7 million, partially offset by increases due to non-cash items of $16.8 million. Non-cash items consist of depreciation and amortization, amortization of debt discount and share-based compensation expense.

Net cash used in operating activities was $41.0 million in the three months ended March 31, 2015. The cash used in operating activities during the three months ended March 31, 2015 is primarily due to changes in working capital items of $45.8 million and non-cash items of $0.3 million, partially offset by net income of $5.0 million. The changes in working capital items reflect an increase in inventory balances due to the purchase of Recothrom inventory for approximately $44.0 million from Bristol-Myers Squibb Company in February 2015. Decreases to accounts payable and accrued expenses were offset by decreases in accounts receivable primarily due to timing of payments of certain corporate expenses and customer payments. Non-cash items consist of depreciation and amortization, amortization of debt discount, share-based compensation expense, recognition of a gain on

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remeasurement of equity interest in Annovation and adjustments in contingent purchase price.

Net cash provided by investing activities was $174.1 million in the three months ended March 31, 2016, which were primarily due to the sale of the hemostasis business that was completed in February 2016.

Net cash used in investing activities was $119.4 million in the three months ended March 31, 2015. The cash used in investing activities were primarily due to the payment of $28.4 million in connection with our acquisition of Annovation in February 2015 and $88.1 million in connection with our acquisition of the remaining Recothrom assets in February 2015.

Net cash provided by financing activities was $2.3 million in the three months ended March 31, 2016, which reflected $5.1 million of proceeds from issuance of common stock and purchases of stock under our employee stock purchase plan, offset by $2.8 million in milestone payments.

Net cash provided by financing activities was $397.9 million in the three months ended March 31, 2015, which reflected $387.2 million in net proceeds from the issuance of convertible notes in January 2015 and $12.0 million of proceeds from option exercises, offset by $0.3 million in excess tax benefits and purchases of stock under our employee stock purchase plan.

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 the 2017 notes and the $400.0 million aggregate principal amount of the 2022 notes, and to make principal payments on the 2017 notes and the 2022 notes at maturity or upon conversion. In addition, as part of our business development strategy, we generally structure our license agreements and acquisition agreements so that a significant portion of the total license or acquisition cost is contingent upon the successful achievement of specified development, regulatory or commercial milestones. As a result, we will require cash to make payments upon achievement of these milestones under the license agreements and acquisition agreements to which we are a party. As of May 9, 2016, we may have to make contingent cash payments upon the achievement of specified development, regulatory or commercial milestones of up to:

- $49.4 million due to the former equityholders of Targanta and up to $25.0 million in additional payments to other third parties related to the Targanta transaction;
- $60.0 million due to the former equityholders of Incline and up to $93.0 million in additional payments to other third parties related to the Incline transaction;
- $285.3 million for the Rempex transaction;
- $26.3 million for the Annovation transaction and up to $6.5 million in additional payments to other third parties related to the Annovation transaction;
- $170.0 million for the license and collaboration agreement with Alnylam;
- $422.0 million due to our licensing of MDCO-216 from Pfizer Inc., or Pfizer; and

- $50.0 million due to our licensing of Kengreal from AstraZeneca.

As of May 9, 2016, our total potential milestone payment obligations related to development, regulatory and commercial milestones for our products and products in development under our license agreements and acquisition agreements, assuming all milestones are achieved in accordance with the terms of these agreements, would be approximately $1,187.5 million. Of this amount, approximately $160.0 million relates to development milestones, $233.8 million relates to regulatory approval milestones and $793.7 million relates to commercial milestones. In addition, of the total potential milestone payment obligations, based on our anticipated timeline for the achievement of development, regulatory and commercial milestones, we expect that we would make total milestone payments under our license agreements and acquisition agreements of approximately $24.3 million during the remainder of 2016. The majority of these anticipated payments for 2016 relate to the achievement of development and commercial milestones. We may pay additional

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milestone payments under our license agreements and acquisition agreements during 2016 if we achieve additional development, regulatory and commercial milestones during the year.

Net revenue from sales of Angiomax were significantly lower in the year ended December 31, 2015 and the three months ended March 31, 2016 than in previous comparable periods, and we expect these revenues will decline further. These reduced revenues are likely to significantly impact our cash and cash equivalents and how we fund our future capital requirements.

We continually evaluate our liquidity requirements, capital needs and availability of resources in view of, among other things, alternative sources and uses of capital, debt service requirements, the cost of debt and equity capital and estimated future operating cash flow. We may raise additional capital; sell interests in subsidiaries or other assets, including asset sales of products or businesses that generate a material portion of our revenue; restructure or refinance outstanding debt; repurchase material amounts of outstanding debt or equity; or take a combination of such steps or other steps to increase or manage our liquidity and capital resources. Any such actions or steps could have a material effect on us.

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

- the extent to which our products are commercially successful globally;
- the decline in Angiomax sales and the extent to which royalties on sales of the authorized generic of Angiomax offset the expected decrease in sales of Angiomax;
- whether we are successful in narrowing our operational focus by strategically separating non-core businesses and products, and the amount of consideration paid to us in connection with any related sales or divestitures;
- the extent to which our submissions and planned submissions for regulatory approval of products in development are approved on a timely basis, if at all;
- 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 our products and products in development;
- the cost and outcomes of regulatory submissions and reviews for approval of our approved products in additional countries and for additional indications, and of our products in development globally;
- whether we develop and commercialize our products in development on our own or through licenses and collaborations with third parties and the terms and timing of such arrangements, if any;
- 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 and the cash we generate from sales of our products will be sufficient to meet our anticipated funding requirements for the next twelve months, including our obligations with respect to interest payments under the 2017 notes and the 2022 notes and our short term obligations under the license agreements and acquisition agreements to which we are a party. The conditional conversion feature of the 2017 notes has been triggered and the holders are currently entitled to convert the notes into our common stock through June 30, 2016 pursuant to the terms of the 2017 notes indenture. If one or more holders elect to convert their notes, we would be required, with respect to each $1,000 principal amount of notes, to make cash payments equal to the lesser of $1,000 and the sum of the daily conversion values, which could adversely affect our liquidity.

With respect to both our short-term and long-term cash requirements, if our existing cash resources, together with cash that we generate from sales of our products and other sources, are insufficient to satisfy our product launch, research and development and other funding requirements, we will need to sell additional equity or debt securities, engage in asset sales, including asset

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sales of products or businesses that generate a material portion of our revenue, engage in other strategic transactions, or seek additional financing through other arrangements, any of which could be material. In addition, we will need to sell additional equity or debt securities, seek additional financing through other arrangements or engage in other cash generating transactions in order to meet our obligations with respect to the principal under the 2017 notes (which mature on June 1, 2017) and the 2022 notes, or we will need to restructure or refinance such notes. Any sale of additional equity or convertible debt securities may result in dilution to our stockholders. 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 2017 notes and the 2022 notes, market conditions or otherwise. If we are unable to obtain additional financing or otherwise increase our cash resources, 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.

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 when available information indicates that it is probable that a liability has been incurred and the amount of such loss can be reasonably estimated. In the cases where we believe that a reasonably possible loss exists, we disclose the facts and circumstances of the litigation, including an estimable range, if possible.

Currently, we are party to the legal proceedings described in Part II, Item 1, Legal Proceedings, of this Quarterly Report on Form 10-Q, which include patent litigation matters, a class action litigation and litigation related to a license agreement. 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, other than the class action litigation. As a result, we have not recorded a loss contingency related to these legal proceedings, other than the class action litigation. Particularly with respect to the litigation related to a Company license agreement, we are presently unable to predict the outcome of such lawsuit or to reasonably estimate the possible loss, or range of potential losses, if any, related to such lawsuit. While it is not possible to determine the outcome of the matters described in Part II, Item 1, Legal Proceedings, of this Quarterly Report on Form 10-Q, we believe it is possible that the resolution of all such matters could have a material adverse effect on our business, financial condition or results of operations.

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 increases to our restricted cash in connection with our lease of our principal office space in Parsippany, New Jersey as of March 31, 2016.

During the quarter ended March 31, 2016 there were no other material changes outside the ordinary course of business 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, 2015.

Application of Critical Accounting Estimates

The discussion and analysis of our financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with 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.

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Our significant accounting policies are more fully described in Note 2, “Significant Accounting Policies,” of our unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q and Note 2 of our consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2015. Not all of these significant accounting policies, however, require that we make estimates and assumptions that we believe are “critical accounting estimates.” We believe that our estimates relating to revenue recognition, inventory, share-based compensation, income taxes, in-process research and development, contingent purchase price from business combinations and impairment of long-lived assets and goodwill 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, 2015 are “critical accounting estimates.” Please refer to Note 2, “Significant Accounting Policies,” in the accompanying notes to the condensed consolidated financial statements for a discussion on changes to certain accounting policies during the three months ended March 31, 2016.

Recent Accounting Pronouncements

Refer to Note 2, “Significant Accounting Policies,” in the accompanying notes to the condensed consolidated financial statements for a discussion of recent accounting pronouncements.

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, liquidity, 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 to 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 on Form 10-Q and the factors set forth under the caption “Risk Factors” in Part II, Item 1A of this Quarterly Report on Form 10-Q. Although we may elect to update forward-looking statements in the future, we specifically disclaim any obligation to do so, even if our estimates change, and readers should not rely on those forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Market risk is the risk of change in fair value of a financial instrument due to changes in interest rates, equity prices, creditworthiness, financing, exchange rates or other factors. Our primary market risk exposure relates to changes in interest rates in our cash, cash equivalents and available for sale securities. We place our investments in high-quality financial instruments, primarily money market funds, corporate debt securities, asset backed securities and U.S. government agency notes with maturities of less than two years, which we believe are subject to limited interest rate and credit risk. We currently do not hedge interest rate exposure. At March 31, 2016, we held $430.2 million in cash and cash equivalents, which had an average interest rate of approximately 0.19%. A 10% change in such average interest rate would have had an approximate $0.1 million impact on our annual interest income. At March 31, 2016, all cash and cash equivalents were due on demand and 97.9% was held in the United States.

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 March 31, 2016, we had receivables denominated in currencies other than the U.S. dollar. A 10% change in foreign exchange rates would have had an approximate $0.4 million impact on our other income and cash.

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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 March 31, 2016. 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 March 31, 2016, 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 March 31, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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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 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. On August 22, 2013, the district court denied the motion for reconsideration. A three day bench trial was held in September 2013 and a post-trial briefing was completed in December 2013. On March 31, 2014, the Court issued its trial opinion. With respect to patent validity, the Court held that the ‘727 and ‘343 patents were valid on all grounds. Specifically, the Court found that Hospira had failed to prove that the patents were either anticipated and/or obvious. The Court further held that the patents satisfied the written description requirement, were enabled and were not indefinite. With respect to infringement, based on its July 2013 Markman decision, the Court found that Hospira’s ANDAs did not meet the “efficient mixing” claim limitation and thus did not infringe the asserted claims of the ‘727 and ‘343 patents. The Court found that the other claim limitations in dispute were present in Hospira’s ANDA products. The Court entered a final judgment on April 15, 2014. On May 9, 2014, we filed a notice of appeal to the United States Court of Appeals for the Federal Circuit. On May 23, 2014, Hospira filed a notice of cross-appeal. We filed our opening appeal brief on August 13, 2014. Hospira filed its opening appeal brief on September 26, 2014 asserting that the claim constructions and non-infringement findings were correct. Hospira also seeks to overturn the finding of patent validity. Briefing was completed in December 2014. An oral argument before the United States Court of Appeals for the Federal Circuit was held on March 6, 2015. On July 2, 2015, the Federal Circuit Court issued an opinion finding the asserted claims of the ‘727 patent and ‘343 patent invalid. The decision was based on a finding that third-party manufacturer, Ben Venue Laboratories, “sold” manufacturing services for three validation batches to us before a critical date. On July 15, 2015, Hospira received final approval for its ANDAs. On July 31, 2015, we filed with the Federal Circuit Court a combined petition for panel rehearing and rehearing en banc. On August 24, 2015, the Federal Circuit Court invited Hospira to respond to the petition. On September 8, 2015, Hospira filed a response. On November 13, 2015, the Federal Circuit Court granted our petition for rehearing en banc and vacated its earlier July 2, 2015 decision. The Federal Circuit Court set a briefing

schedule, specified specific questions to be answered, invited the DOJ to file a brief expressing the views of the United States and also invited any other amicii curiae to file briefs on the en banc issues raised. Hospira filed its opening brief on January 11, 2016. We filed our response on February 24, 2016 and Hospira filed its reply brief on March 10, 2016. Nine amicus briefs were filed: Department of Justice, American Intellectual Property Law Association, Intellectual Property Owners Association, a Texas law firm, Miller Patti Pershern PLLC, Pharmaceutical Research and Manufacturers of America, Biotechnology Innovation Organization, Gilead Sciences, Inc., an individual, Roberta J. Morris, Esq., and Houston Intellectual Property Law Association. The Federal Circuit Court sitting en banc heard oral argument from the parties and the government on May 5, 2016. The court did not indicate when it would issue its opinion.

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

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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 of the ‘727 and ‘343 patents and alternatively that the ‘727 patent was invalid. The Court’s decision granted non-infringement of the ‘343 patent and denied the motion with respect to non-infringement and invalidity of the ‘727 patent. A six day trial directed to the ‘727 patent was completed on June 18, 2014. Post-trial briefs were filed on July 1, 2014 and July 11, 2014. On October 27, 2014, the Court issued an opinion and order finding that Mylan’s ANDA product infringes all of the asserted claims of the ‘727 patent. The Court further found that Mylan failed to prove that the same asserted claims of the ‘727 patent are invalid or unenforceable. Specifically, the Court found that Mylan failed to prove its allegations of anticipation, obviousness, non-enablement and unenforceability due to inequitable conduct. On October 28, 2014 and November 13, 2014, Mylan filed Notices of Appeal to the U.S. Court of Appeals for the Federal Circuit. On November 25, 2014, we filed a Notice of Cross Appeal of the district court’s summary judgment of noninfringement of the asserted claims of the ‘343 patent that it had issued on December 16, 2013 and the district court’s Markman Order on August 6, 2012. Appellate briefing was completed in April 2015. An oral argument before the U.S. Court of Appeals for the Federal Circuit was scheduled for September 11, 2015. On July 29, 2015, following a Mylan motion for disposition of its appeal in view of the July 2, 2015 Hospira decision, the Federal Circuit Court granted the motion (1) reversing the district court’s judgment as to the ‘727 patent (2) dismissing as moot our cross-appeal (3) vacating the district court’s entry of an injunction, and (4) holding that each party shall bear its own costs. On August 27, 2015, we filed a petition for panel rehearing. Following the November 13, 2015 decision granting our en banc hearing request in the Hospira appeal and vacating the July 2, 2015 decision, we moved to vacate the Federal Circuit's July 29, 2015 Order terminating the Mylan appeal. Following briefing, the Federal Circuit granted our motion and reopened the appeal, vacated its July 29, 2015 Order and then stayed the Mylan appeal pending resolution of the Hospira appeal.

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. At the direction of the Court, on May 13, 2013, the motion was withdrawn by Dr. Reddy’s. We have pending motions seeking further fact discovery of Dr. Reddy’s. The parties have yet to enter the expert phase of the case. On May 12, 2015 the Court issued a Stipulation and Order staying the case as Dr. Reddy's had yet to respond to an FDA Complete Response Letter dated December 7, 2012. The parties are to inform the Court when Dr. Reddy's submits its response to the FDA and then

within 14 days provide a schedule to complete fact and expert discovery in the case.

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. The parties proceeded with fact discovery. Following a December 20, 2013 status conference, the parties began discussing a stay in the case. Following further conferences with the Court a stipulation to stay the case was submitted and subsequently entered by the Court on April 1, 2014. Following settlement discussions, the case was settled and a final judgment finding the ‘727 and ‘343 patents valid, enforceable and infringed by Sun’s ANDA product was entered by the Court on March 27, 2015. In connection with the Sun settlement, we entered into a license agreement with Sun under which we granted Sun a

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non-exclusive license under the ‘727 patent and ‘343 patent to sell a generic bivalirudin for injection product under Sun’s ANDA in the United States beginning on June 30, 2019 or earlier in certain circumstances. The settlement documents were submitted to the U.S. Federal Trade Commission and U.S. Department of Justice in March 2015.

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. A scheduling conference before the magistrate judge was held on December 16, 2013. Following a subsequent conference on April 15, 2014 and further directions from the Court to resubmit a discovery schedule, the Court entered a revised discovery schedule on July 17, 2014. A Markman hearing commenced on January 22, 2015 and was completed on March 3, 2015. Following the July 2, 2015 Hospira decision, the parties requested and the Court entered an order staying the case until the Federal Circuit Court issues a mandate in the Hospira appeal.

Exela Pharma Sciences, LLC

In March 2014, we were notified that Exela Pharma Sciences, LLC, 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 25, 2014, we filed suit against Exela Pharma Sciences, LLC, Exela PharmSci, Inc. and Exela Holdings, Inc., which we collectively refer to as Exela, in the U.S. District Court for the Western District of North Carolina for infringement of the ‘727 and ‘343 patents. Exela filed its answer on June 3, 2014 and raised counterclaims of non-infringement, invalidity and unenforceability due to inequitable conduct. We filed a reply on July 11, 2014. The parties have conducted a Rule 26 conference. The Court has set a pretrial schedule through a June 2015 Markman hearing. On November 4, 2014, Exela filed a motion for judgment on the pleadings based on noninfringement. The motion was fully briefed on December 23, 2014. Claim construction discovery was under way. Following the July 2, 2015 Hospira decision, the parties requested and the court entered an order staying the case until the Federal Circuit Court issues a mandate in the Hospira appeal. On January 29, 2016, even though no mandate from the Hospira appeal has issued, Exela filed a motion to lift the stay and resume claim construction proceedings and other pretrial matters. On February 29, 2016, the court denied Exela's motion to lift the stay on the case.

Accord Healthcare Inc., USA

In June 2014, we were notified that Accord Healthcare Inc., or Accord, had submitted an ANDA seeking permission to market its generic version of Angiomax prior to the expiration of the ‘727 and ‘343 patents. On July 24, 2014, we filed suit against Accord and its parent, Intas Pharmaceuticals Ltd., or Intas, in the U.S. District Court for the Middle District of North Carolina for infringement of the ‘727 patent and ‘343 patent. On September 26, 2014, Accord and Intas filed an answer denying infringement and asserting that the ‘727 and ‘343 patents are invalid. The parties have conducted a Rule 26 conference. The Court has set February 17, 2016 for the close of all discovery and October 3, 2016 as a trial date. Following the July 2, 2015 Hospira decision, the parties requested and the Court entered an order staying the case until the Federal Circuit Court issues a mandate in the Hospira appeal.

Aurobindo Pharma Limited

In March 2014, we were notified that Aurobindo Pharma Limited 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 11, 2014, we filed suit against Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc., which we refer to collectively as Aurobindo, 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, Sun and Apotex actions. Aurobindo filed its answer on July 3, 2014 and raised counterclaims of non-infringement and invalidity. A scheduling conference before the magistrate judge was held on November 20, 2014. The parties engaged in fact discovery and claim construction exchanges. On April 6, 2015, the Court entered a revised fact and expert discovery schedule. Thereafter, the parties proposed a stay of the case pending a decision in the above-referenced Hospira appeal to the Court, which the Court entered on April 15, 2015. Following the July 2, 2015 Hospira decision, the Court was informed of the decision and the parties requested the present stay to remain in effect until Federal Circuit Court issues a mandate in the Hospira appeal. The Court entered this request on July 20, 2015.

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Sagent Pharmaceuticals Inc.

In July 2015, we were notified that Sagent Pharmaceuticals Inc., or Sagent, 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 August 26, 2015, we filed suit against Sagent in the U.S. District Court for the Northern District of Illinois for infringement of the ‘727 patent and ‘343 patent. Sagent filed its answer on November 30, 2015 and raised counterclaims of non-infringement and invalidity. We filed a reply on December 22, 2015. A scheduling conference was held on January 21, 2016. The case has been stayed pending resolution of the Hospira en banc appeal. A further status conference is scheduled for September 13, 2016.

Class Action Litigation

On February 21, 2014, a class action lawsuit was filed against us and certain of our current and former officers in the United States District Court for the District of New Jersey by David Serr on behalf of stockholders who purchased or otherwise acquired our common stock between February 20, 2013 through February 12, 2014, which we refer to as the class period. On July 22, 2014, the Court entered an order appointing one of our stockholders, Warren H. Schuler, the lead plaintiff and Pomerantz LLP the lead counsel. Plaintiffs filed an amended complaint on September 17, 2014, which asserts claims under Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder, including allegations that our stock was artificially inflated during the class period because we and certain current and former officers allegedly made misrepresentations or did not make proper disclosures regarding the results of clinical trials, which tested the efficacy and safety of cangrelor. Specifically, the amended complaint alleges that statements made throughout the class period about the trials were misleading because they failed to disclose that cangrelor did not show superiority to the drug clopidogrel, that the clinical trials were unethically and inappropriately administered, that clopidogrel was not administered optimally, and that cangrelor patients exhibited higher bleeding rates. The amended complaint seeks, among other relief, class certification of the lawsuit, unspecified damages, interest, attorneys’ fees, expert fees and other costs. On November 17, 2014, we and certain of our current and former officers moved to dismiss the amended complaint. Plaintiffs filed an opposition to the motion to dismiss on December 19, 2014 and we filed a reply brief in further support of the motion on January 16, 2015. Briefing is now complete. On July 16, 2015, the court heard oral argument on the motion, which remains under consideration by the court. On February 12, 2016, the parties executed a stipulation for a proposed class settlement, subject to court approval. On February 25, 2016, the court preliminarily approved the settlement and set a final approval hearing for June 7, 2016.

Biogen Idec Litigation

On September 15, 2015, Biogen Idec , notified us that after completing an audit of our books and records for the fourth quarter of 2014, Biogen Idec believes it is owed additional royalties relating to Angiomax under our license agreement with Biogen Idec. On September 23, 2015, we filed suit against Biogen Idec in the United States District Court for the District of New Jersey seeking, inter alia, declaratory judgments that we have satisfied our obligations under the license agreement. On November 12, 2015, Biogen Idec answered the complaint denying our claims and asserting counterclaims for breach of contract. The parties are currently engaged in fact discovery and a trial date has not been set by the court. We believe we will prevail in this suit, however, there can be no assurance that we will be successful. An adverse resolution could have a material adverse effect on our business, financial condition or results of operations.

Eagle Litigation

On February 2, 2016, we filed suit against Eagle, SciDose LLC and TherDose Pharma Pvt. Ltd. for infringement of U.S. Patent Nos. 7,713,928, or the ’928 patent, and 7,803,762, or the ’762 patent, by Eagle’s New Drug Application No.

208298 for ready-to-use bivalirudin. In the lawsuit, we assert that the ‘928 and ‘762 patents are co-owned by us and Eagle and are exclusively licensed to us. The complaint also seeks a declaration that we are an owner and exclusive licensee of U.S. Patent Application No. 14/711,359 pursuant to the parties’ License and Development Agreement, which Eagle represents covers the product described in its NDA No. 208298. On March 25, 2016 defendants filed a motion to dismiss. On April 18, 2016 we filed an amended complaint reasserting the original claims and raising additional claims of, inter alia, trademark infringement, unfair competition and tortious interference. The trademark infringement claim asserts that Eagle’s mark for its ready-to-use bivalirudin, Kangio, infringes our Angiomax® and Kengreal® marks. The defendants have yet to respond to the amended complaint.

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 on Form 10-Q. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer. In that case, the trading price of our common stock could decline. In addition to the risk factors identified under the captions below, the operation

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and results of our business are subject to risks and uncertainties identified elsewhere in this Quarterly Report on Form 10-Q as well as general risks and uncertainties such as those relating to general economic conditions and demand in the market for our products.

Risks Related to Our Financial Results

We no longer have market exclusivity for Angiomax and face generic and other competition that will cause our net revenue to decline significantly.

A substantial majority of our historic revenue has come from sales of Angiomax (bivalirudin) in the United States. The principal U.S. patents covering Angiomax include the ‘727 patent and the ‘343 patent and included the ‘404 patent. The term of the ‘404 patent expired on December 15, 2014 and the six-month period of pediatric exclusivity following expiration of the ‘404 patent resulting from our study of Angiomax in the pediatric setting ended June 15, 2015. On July 2, 2015, the Federal Circuit Court ruled against us in our patent infringement litigation with Hospira with respect to the ‘727 patent, and the ‘343 patent, covering a more consistent and improved Angiomax drug product and the processes by which it is made. In its ruling, the Federal Circuit Court held the '727 patent and '343 patent invalid. In November 2015, our petition for en banc review of the Federal Circuit Court's July 2, 2015 decision was granted and the Federal Circuit Court vacated its July 2, 2015 decision. In July 2015, as a result of the Federal Circuit Court's now vacated July 2, 2015 decision, we entered into a supply and distribution agreement with Sandoz under which we granted Sandoz the exclusive right to sell in the United States an authorized generic of Angiomax (bivalirudin). In July 2015, Hospira's ANDAs for its generic versions of bivalirudin were approved by the FDA and Hospira began selling its generic versions of bivalirudin. Notwithstanding the granting of our petition for en banc review, due to the July 2, 2015 decision and our resulting entry into a supply and distribution agreement with Sandoz and Hospira's entry into the market, Angiomax is now subject to generic competition with the authorized generic and Hospira's generic bivalirudin products, which we expect will continue to cause our net revenue to decline significantly.

In addition to Hospira, a number of companies have filed ANDAs for their generic versions of Angiomax. The FDA has accepted for filing a 505(b)(2) NDA filed by Eagle for a ready to use liquid formulation of bivalirudin. Although Eagle received a complete response letter from the FDA in March 2016, if Eagle is ultimately successful in receiving FDA approval then Eagle may launch commercial sales of the product in the United States.

In addition to Hospira’s generic versions of bivalirudin, Sandoz’s authorized generic and, if approved, Eagle’s formulation of bivalirudin, Angiomax could be subject to generic competition in the United States from Teva, APP and Sun under the circumstances set forth in our respective settlement agreements with such parties and upon the approval of each companies’ ANDA filings by the FDA. We remain in patent infringement litigation involving the '727 patent and '343 patent with Hospira and other ANDA filers, as described in Part II, Item 1. Legal Proceedings, of this Quarterly Report on Form 10-Q. There can be no assurance as to the outcome of our infringement litigation. We may continue to incur substantial legal expenses related to these matters.

In addition, the principal patent covering Angiomax in Europe expired in August 2015. As a result, we could face generic competition in Europe.

Net product revenue from sales of Angiomax decreased from $100.7 million for the three months ended March 31, 2015 to $16.9 million for the three months ended March 31, 2016. We expect that net revenue from sales of Angiomax will continue to decline in 2016 and in future years due to generic and other competition. Although we have entered into a supply and distribution agreement with Sandoz to sell an authorized generic version of Angiomax, the royalty income from the sale of the authorized generic, which for the three months ended March 31, 2016 was approximately $18.9 million, is expected to only partially offset the expected further decline in Angiomax net

revenue.

We have a history of net losses and may not achieve profitability in future periods or maintain profitability on an annual basis due in particular to expected decreases in net revenue from sales of Angiomax and other results of our loss of exclusivity on Angiomax.

We have incurred net losses in many years and on a cumulative basis since our inception, and we expect to continue to incur net losses. As of March 31, 2016, we had an accumulated deficit of approximately $522.3 million. In those periods in which we were able to achieve profitability, our profitability was based on revenue from sales of Angiomax, as a substantial majority of our historic revenue has been generated from sales of Angiomax in the United States. However, generic competition for Angiomax commenced in the United States in July 2015 and we lost market exclusivity for Angiomax in Europe in August 2015. We expect that net revenue from sales of Angiomax will continue to decline in future years due to competition from generic versions of

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bivalirudin, including our authorized generic being marketed by Sandoz and other generic versions of bivalirudin which have been and may be approved by the FDA .

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, including milestone payments under our license agreements and acquisition agreements. We will need to generate greater revenue in future periods from our marketed products other than Angiomax 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 successfully commercialize our approved products and our product candidates upon approval. 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.

We review our inventory, including inventory purchase commitments, and provide reserves, as appropriate, against the carrying amount of inventory. For the year ended December 31, 2015, we recorded a $29.5 million inventory obsolescence charge and a charge of $12.1 million for potential losses on future inventory purchases primarily due to the loss of exclusivity of Angiomax. As of March 31, 2016, our inventory of Angiomax was $54.3 million and we had inventory-related purchase commitments totaling $17.3 million for 2016 for Angiomax bulk drug substance. If sales of Angiomax decline more than our current expectations, we could be required to make an additional allowance for excess or obsolete inventory, increase our accrual for product returns or increase our deferred tax valuation allowance, or we could incur other costs related to operating our business, each of which could negatively impact our results of operations and our financial condition.

We have commercially launched or plan to commercially launch and commence sales of several of our recently approved products in the United States. If we are not successful with the commercial launches of these products, or launches of other products, or experience significant delays in doing so, our business likely would be materially harmed.

We commercially launched Orbactiv in the United States in the third quarter of 2014. We also launched Ionsys, Kengreal and the new formulation of Minocin IV in the United States in 2015. We may also commercially launch by ourselves or through arrangements with third parties several additional products and products in development in the United States and Europe, in the coming years, subject to receiving regulatory approval. Commercial launches of this number of products in such a short period of time will require significant efforts from us and the devotion of substantial resources as we will need to finalize regulatory submissions, work with regulatory authorities in their evaluation of our submissions, have manufactured sufficient quantities of product to commence commercial sales and establish the infrastructure necessary to commercially launch these products and products in development.

Our ability to successfully commercially launch these products and products in development will depend on our ability to:

- make regulatory submissions and obtain regulatory approvals in the timeframes anticipated;
- train our existing sales force to market and sell the products that are to be sold by it;
- train, deploy and support a qualified sales force to market and sell newly launched products;
- secure formulary approvals at our hospital customers;
- have third parties manufacture and release the products in sufficient quantities;
- implement and maintain agreements with wholesalers, distributors and group purchasing organizations;
- receive adequate levels of coverage and reimbursement for these products from governments and third-party payors;
- develop and execute marketing and sales strategies and programs for the products.

We expect that the revenues from these products and products in development will represent a significant portion of our revenues in the future, particularly given that Angiomax is subject to generic competition. As a result, if we are

unable to successfully commercialize these products and products in development, our business, results of operations and financial condition likely would be materially harmed.

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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.

On November 3, 2015, we announced that our current intention was to explore strategies for optimizing our capital structure and liquidity position. At March 31, 2016, we had approximately $430.2 million of cash and cash equivalents. 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 the 2017 notes and the $400.0 million aggregate principal amount of the 2022 notes, and to make principal payments on the 2017 notes and the 2022 notes at maturity or upon conversion. In addition, as part of our business development strategy, we generally structure our license agreements and acquisition agreements so that a significant portion of the total license or acquisition cost is contingent upon the successful achievement of specified development, regulatory or commercial milestones. As a result, we will require cash to make payments upon achievement of these milestones under the license agreements and acquisition agreements to which we are a party. As of May 9, 2016, we may have to make contingent cash payments upon the achievement of specified development, regulatory or commercial milestones of up to:

- $49.4 million due to the former equityholders of Targanta and up to $25.0 million in additional payments to other third parties related to the Targanta transaction;
- $60.0 million due to the former equityholders of Incline and up to $93.0 million in additional payments to other third parties related to the Incline transaction;
- $285.3 million for the Rempex transaction;
- $26.3 million for the Annovation transaction and up to $6.5 million in additional payments to other third parties related to the Annovation transaction;
- $170.0 million for the license and collaboration agreement with Alnylam;
- $422.0 million due to our licensing of MDCO 216 from Pfizer; and
- $50.0 million due to our licensing of Kengreal from AstraZeneca.

As of May 9, 2016, our total potential milestone payment obligations related to development, regulatory and commercial milestones for our products and products in development under our license agreements and acquisition agreements, assuming all milestones are achieved in accordance with the terms of these agreements, would be approximately $1,187.5 million. Of this amount, approximately $160.0 million relates to development milestones, $233.8 million relates to regulatory approval milestones and $793.7 million relates to commercial milestones. In addition, of the total potential milestone payment obligations, based on our anticipated timeline for the achievement of development, regulatory and commercial milestones, we expect that we would make total milestone payments under our license agreements and acquisition agreements of approximately $24.3 million during the remainder of 2016. The majority of these anticipated payments for 2016 relate to the achievement of development and commercial milestones. We may pay additional milestone payments under our license agreements and acquisition agreements during 2016 if we achieve additional development, regulatory and commercial milestones during the year.

Net revenue from sales of Angiomax were significantly lower in the year ended December 31, 2015 and the three months ended March 31, 2016 than in previous comparable periods, and we expect these revenues will decline further. These reduced revenues are likely to significantly impact our cash and cash equivalents and how we fund our future

capital requirements.

We continually evaluate our liquidity requirements, capital needs and availability of resources in view of, among other things, alternative sources and uses of capital, debt service requirements, the cost of debt and equity capital and estimated future operating cash flow. We may raise additional capital; sell interests in subsidiaries or other assets, including asset sales of products or businesses that generate a material portion of our revenue; restructure or refinance outstanding debt; repurchase material amounts of outstanding debt or equity; or take a combination of such steps or other steps to increase or manage our liquidity and capital resources. Any such actions or steps could have a material effect on us.

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

- the extent to which our products are commercially successful globally;
- the decline in Angiomax sales and the extent to which royalties on sales of the authorized generic of Angiomax offset the expected decrease in sales of Angiomax;
- whether we are successful in narrowing our operational focus by strategically separating non-core businesses and products, and the amount of consideration paid to us in connection with any related sales or divestitures;
- the extent to which our submissions and planned submissions for regulatory approval of products in development are approved on a timely basis, if at all;
- 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 our products and products in development;
- the cost and outcomes of regulatory submissions and reviews for approval of our approved products in additional countries and for additional indications, and of our products in development globally;
- whether we develop and commercialize our products in development on our own or through licenses and collaborations with third parties and the terms and timing of such arrangements, if any;
- 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 cash resources, together with cash that we generate from sales of our products and other sources, are insufficient to satisfy our product launch, research and development and other funding requirements, we will need to sell additional equity or debt securities, engage in asset sales, including asset sales of products or businesses that generate a material portion of our revenue, engage in other strategic transactions, or seek additional financing through other arrangements, any of which could be material. In addition, we will need to sell additional equity or debt securities, seek additional financing through other arrangements or engage in other cash generating transactions in order to meet our obligations with respect to the principal under the 2017 notes (which mature on June 1, 2017) and the 2022 notes, or we will need to restructure or refinance such notes. Any sale of additional equity or convertible debt securities may result in dilution to our stockholders. 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 2017 notes and the 2022 notes, market conditions or otherwise. If we

are unable to obtain additional financing or otherwise increase our cash resources, 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 additional capital by selling equity or debt securities or through other arrangements in the future, 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 otherwise 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 financing through other arrangements. Any sale of equity or debt securities may result in dilution to our stockholders and increased liquidity requirements. 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

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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 dependent in part 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 for certain products 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 the products we sell in the United States through a sole source distribution model, other than our authorized generic Angiomax (bivalirudin) which is sold by Sandoz. Under this model, we currently sell these products to a sole source distributor. The sole source distributor then sells these 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 most of our future products in the United States through the same sole source distribution model. Most of our revenue from sales of our products in the United States, other than our authorized generic Angiomax (bivalirudin), comes from sales to ICS pursuant to our agreement with them. 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 may continue to cause, an increase in accounts receivable. As a result of our relationship with ICS, we expect that our revenue for certain products 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 certain products to international distributors and these distributors then sell these products to hospitals. Our reliance on a small number of distributors for international sales of products 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, we have acquired Annovation, Incline and Rempex, and we have 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 have also recently sold our hemostasis business to Mallinckrodt. 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;
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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 products in development;

- inability to retain personnel, key customers, distributors, vendors and other business partners of the acquired company, or acquired or licensed product or technology;

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- 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 liquidity and 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. Further, if we sell products that have been acquired through acquisitions or licensing arrangements, we may incur losses depending on the consideration received and structure of the transaction. For example, in connection with our sale of our hemostasis business consisting of PreveLeak, Raplixa and Recothrom, which we completed on February 1, 2016, we incurred impairment charges of $133.3 million, including $24.5 million related to goodwill. 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 intangible assets, and restructuring charges, any of which could harm our business, financial condition or results of operations.

Risks Related to Our Notes

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. Servicing this debt, including the 2017 notes and the 2022 notes, will require a significant amount of cash, and we may not have sufficient cash flow from our business to pay the 2017 notes, the 2022 notes or our other debt.

We have incurred a significant amount of indebtedness. Our maintenance of this level of indebtedness could have adverse consequences, including:

- requiring us to dedicate a substantial portion of cash flow from operations to the payment of interest on, and principal of, our debt, which will reduce the amounts available to fund working capital, capital expenditures, product development efforts and other general corporate purposes;

- increasing our vulnerability to general adverse economic, industry and market conditions;

- limiting our ability to obtain additional financing in the future or engage in certain strategic transactions without securing bondholder consent;

- 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 less debt, better debt servicing options or better access to capital resources.

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In addition, our ability to make scheduled payments of the principal of, to pay interest on or to refinance the 2017 notes or the 2022 notes depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt, including the notes. 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, any of which may be material to the holders of our common stock. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at the time we seek to refinance such indebtedness. 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 2017 notes or the 2022 notes or to repurchase the 2017 notes or the 2022 notes upon a fundamental change, and our future debt may contain limitations on our ability to pay cash upon conversion or repurchase of the 2017 notes or 2022 notes.

Holders of the 2017 notes and the 2022 notes will have the right to require us to repurchase their notes upon the occurrence of a fundamental change, as defined in the applicable indenture, at a repurchase price equal to 100% of their principal amount, plus accrued and unpaid interest, if any, as described in the applicable indenture. In addition, upon conversion of the 2017 notes and the 2022 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 applicable indenture. However, we may not have enough available cash or be able to obtain financing at the time we are required to repurchase notes, to pay the notes at maturity 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 existing indebtedness (including, in the case of the 2017 notes, the 2022 notes) and future indebtedness. Our failure to repurchase notes at a time when the repurchase is required by the applicable indenture or to pay any cash payable on future conversions of the notes as required by the applicable indenture would constitute a default under the applicable indenture. A default under the applicable indenture governing the 2017 notes or the 2022 notes, respectively, or the fundamental change itself could also lead to a default under agreements governing our existing indebtedness (including, in the case of the 2017 notes, the 2022 notes) and 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 2017 notes or the 2022 notes, if triggered, may adversely affect our financial condition and operating results.

The conditional conversion feature of the 2017 notes has been triggered and the holders are currently entitled to convert the notes into our common stock through June 30, 2016 pursuant to the terms of the 2017 notes indenture. In the event the conditional conversion feature of the 2017 notes is again triggered or the conditional conversion feature of the 2022 notes is triggered, holders of such notes will be entitled to convert the notes at any time during specified periods at their option, which are set forth in the applicable indenture. If one or more holders elect to convert their notes, we would be required, with respect to each $1,000 principal amount of notes, to make cash payments equal to the lesser of $1,000 and the sum of the daily conversion values, 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 2017 notes and the 2022 notes, could have a material effect on our reported financial results.

Under Accounting Standards Codification 470-20, “Debt with Conversion and Other Options”, which we refer to as ASC 470-20, an entity must separately account for the liability and equity components of the convertible debt instruments that may be settled entirely or partially in cash upon conversion (such as the 2017 notes and the 2022 notes) in a manner that reflects the issuer’s economic interest cost. The effect of ASC 470-20 on the accounting for the 2017 notes and the 2022 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 would be treated as original issue discount for purposes of accounting for the debt component of the 2017 notes and the 2022 notes. As a result, we will be required to record a greater amount of non-cash interest expense in current periods presented as a result of the amortization of the discounted carrying value of the notes to their face amount over the term of the 2017 notes and the 2022 notes. We will report lower net income in our financial results because ASC 470-20 will require interest to include both the current period’s amortization of the debt discount and the instrument’s coupon interest, which could adversely affect our reported or future financial results, the market price of our common stock and the trading price of the 2017 notes and 2022 notes.

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In addition, under certain circumstances, convertible debt instruments that may be settled entirely or partly in cash (such as the 2017 notes and 2022 notes) 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 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 2017 notes or the 2022 notes, then our diluted earnings per share would be adversely affected.

We may incur substantially more debt or take other actions which would intensify the risks discussed above.
We and our subsidiaries may be able to incur substantial additional debt in the future, some of which may be secured debt. We and our subsidiaries are not restricted under the terms of the applicable indenture governing the 2017 notes or the 2022 notes from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that are not limited by the terms of the applicable indenture governing the 2017 notes or the 2022 notes that could have the effect of diminishing our ability to make payments on the notes when due.

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, specialty pharmaceutical companies and biotechnology firms, universities and other research institutions. Many of our competitors are substantially larger than we are and 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 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 in many cases generic products, that are approved and marketed for the indications for which our products are approved and the indications for which we are developing our products in development. In addition, competitors are developing products for such indications. Set forth in the first risk factor above regarding Angiomax and the risk factor that immediately follows this risk factor is additional information regarding competition for two marketed products, Angiomax and Orbactiv. We have also launched, or expect to launch, other products that face competition. A description of the competition for our other products and products in development is included under the caption “Part I, Item 1. Business-Competition” of our Annual Report on Form 10 K for the year ended December 31, 2015.

We compete, in the case of our approved and marketed products, 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.

Orbactiv faces significant competition from branded and generic drugs treating ABSSSI, which may limit the use of Orbactiv and adversely affect our anticipated revenue.

Orbactiv is an intravenous antibiotic approved by the FDA for the treatment of ABSSSI, caused or suspected to be caused by susceptible gram positive bacteria, including MRSA.

Competition in the market for therapeutic products that address gram positive bacterial infections is intense. In particular, there are a variety of available therapies marketed for the treatment of ABSSSI. Some of these products are branded and subject to patent protection, and others are available on a generic basis. Many of these approved products, including vancomycin, ceftaroline (Teflaro), clindamycin , daptomycin (Cubicin), telavancin (Vibativ) and linezolid (Zyvox) are well established therapies and are widely accepted by physicians, patients and hospital decision makers. Additionally, insurers and other third party payers may encourage the use of generic products. Vancomycin, for instance, which is sold in a relatively inexpensive generic form, has been

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widely used for over 50 years, is the most frequently used IV antibiotic, and we believe, based on our market research, is prescribed to approximately two thirds of all hospitalized ABSSSI patients. If physicians and hospital decision makers do not accept the potential advantages of Orbactiv, or are otherwise hesitant or slow to adopt Orbactiv, our anticipated revenues could be adversely affected.

There are also a number of products recently approved or in clinical development by third parties to treat ABSSSI. Recently approved products include Sivextro from Cubist Pharmaceuticals, Inc., (now a subsidiary of Merck & Co, Inc.), and Dalvance from Durata Therapeutics, Inc. (now a subsidiary of Allergan plc). Additionally, several companies have products in development that, if approved, may compete with Orbactiv. If any of these product candidates or any other products developed by our competitors are more effective, safer, more convenient or less costly than Orbactiv, or would otherwise render Orbactiv obsolete or non competitive, our anticipated revenues from Orbactiv 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. Because we have only the limited internal scientific research capabilities that we acquired in some of our acquisitions 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 to us development stage compounds, clinical stage product candidates or approved products. Since 2008, for instance, we have acquired, among others, Targanta, Incline, Rempex, and Annovation, licensed marketing rights to the ready to use formulation of Argatroban, licensed development and commercialization rights to MDCO-216 and ALN PCSsc, and licensed the non exclusive rights to sell and distribute ten acute care generic products. The success of this business strategy depends upon our ability to identify, select and acquire or license pharmaceutical products that meet the criteria we have established. 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, available cash flows and institutional experience. In addition, we may compete with emerging companies taking similar or different approaches to product acquisition. Therefore, we may not be able to acquire or license the rights to additional product candidates or approved products on terms that we find acceptable, or at all.

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 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 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 Pharmaceuticals, Inc.

In addition, our future success will 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 products in development 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 the 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.

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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 customer solutions 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 intravenous antihypertensive 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 we are unable to successfully develop our business infrastructure and 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.

Our ability to support the sales and marketing of our products in the United States and globally will depend on our ability to properly scale our internal organization and infrastructure to accommodate the development and, upon approval, commercialization of our products and products in development. To manage our existing and planned future growth and the increasing breadth and complexity of our activities, we need to properly invest in personnel, infrastructure, information management systems and other operational resources. If we are unable to scale global operations successfully and in a timely manner, the growth of our business may be limited. Developing our business infrastructure and operations may be more difficult, more expensive or take longer than we anticipate. We may also need to revise our strategy for developing the proper infrastructure and operations periodically. In the fourth quarter of 2014, we implemented a reorganization of our European operations, including a workforce reduction and the consolidation of European sites, for which we recorded, in the aggregate, a one time charge of approximately $9.0 million in the fourth quarter of 2014. 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 development of our business infrastructure and operations could strain our operational, human and financial resources. In order to manage the development of our business infrastructure and global operations, 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 business, then our operations may be less successful than anticipated.

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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, 2015 and the three months ended March 31, 2016, we had $19.4 million and $3.9 million, respectively, in sales outside of the United States, most of which are sales of Angiomax. The principal patent covering Angiomax in Europe expired in August 2015 and, as a result, we may face generic competition in Europe. 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 payers or other third-party payers is not available or limited for our products, pricing is delayed or set at unfavorable levels or access to our products is reduced or terminated by governmental and other third-party payers, our ability to generate revenue would be adversely affected.

Acceptable levels of coverage and reimbursement of drug treatments by government payers, 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 payers, 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 Orbactiv, could substantially affect the likelihood of reimbursement and the level of reimbursement for Orbactiv. 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.

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Third-party payers, 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. If these third-party payers do not consider our products to be economically beneficial compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit. Third-party payers may provide coverage, but place stringent limitations on such coverage, such as requiring alternative treatments to be tried first. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. For example, in a final rule adopted in late 2014 regarding the Medicare Hospital Outpatient Prospective Payment System, CMS finalized a new "bundling" policy that affects reimbursement for a number of medicines prescribed in connection with certain Medicare hospital outpatient services, including PCI, beginning on January 1, 2015. The medicines affected by this policy include, among others, Angiomax. This particular policy is one example of a broader trend in health care in which the government and other payors are seeking to move from individualized "fee for service" payments toward a system focused on "bundled" payments for more comprehensive packages of services and episodes of care. 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 could, among other things, increase pressure on pricing and, as a result, the number of procedures that are performed. Since the PPACA was enacted, other legislative changes have been proposed and adopted. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding. 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 payers 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 $10.0 million per occurrence and $10.0 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.

Our reliance on government funding for Carbavance adds uncertainty to our research and commercialization efforts with respect to Carbavance.

We expect that a significant portion of the funding for the development of Carbavance will come from a contract with BARDA. BARDA is entitled to terminate our BARDA contract for convenience at any time, in whole or in part, and is not required to provide continued funding beyond amounts currently obligated under the existing contract, and there can be no assurance that our BARDA

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contract will not be terminated. Changes in government budgets and agendas may result in a decreased and deprioritized emphasis on supporting the development of antibacterial products such as Carbavance. If our BARDA contract is terminated or suspended, or if there is any reduction or delay in funding under our BARDA contract, we may be forced to seek alternative sources of funding, which may not be available on non-dilutive terms, terms favorable to us or at all. If alternative sources of funding are not available, we may be forced to suspend or terminate development activities related to Carbavance.

Our reliance on government funding for Carbavance may impose requirements that increase the costs of commercialization and production of Carbavance developed under that government-funded program.

Our BARDA contract includes provisions that reflect the U.S. government's substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to:

- unilaterally reduce or modify the government's obligations under such contracts, including by imposing equitable price adjustments, without the consent of the other party;
- cancel multi-year contracts and related orders if funds for contract performance for any subsequent year become unavailable;
- decline, in whole or in part, to exercise an option to renew the contract;
- claim rights to data, including intellectual property rights, developed under such contracts;
- audit contract-related costs and fees, including allocated indirect costs;
- suspend the contractor from receiving new contracts pending resolution of alleged violations of procurement laws or regulations in the event of wrongdoing by us;
- take actions that result in a longer development timeline than expected;
- direct the course of a development program in a manner not chosen by the government contractor;
- impose U.S. manufacturing requirements for products that embody inventions conceived or first reduced to practice under such contracts;
- suspend or debar the contractor from doing future business with the government or a specific government agency;
- pursue criminal or civil remedies under the False Claims Act, False Statements Act and similar remedy provisions specific to government agreements; and
- limit the government's financial liability to amounts appropriated by the U.S. Congress on a fiscal-year basis, thereby leaving some uncertainty about the future availability of funding for a program even after it has been funded for an initial period.

We may not have the right to prohibit the U.S. government from using certain technologies funded by the government and developed by us related to Carbavance, and we may not be able to prohibit third party companies, including our competitors, from using those technologies in providing products and services to the U.S. government. The U.S. government generally takes the position that it has the right to royalty-free use of technologies that are developed

under U.S. government contracts.

In addition, government contracts normally contain additional requirements that may increase our costs of doing business, reduce our profits, and expose us to liability for failure to comply with these terms and conditions. These requirements include, for example:

- specialized accounting systems unique to government contracts;
- potential liability for price adjustments or recoupment of government funds after such funds have been spent;
- public disclosures of certain non-proprietary contract information, which may enable competitors to gain insights into our research program; and

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- mandatory socioeconomic compliance requirements, including labor standards, non-discrimination and affirmative action programs and environmental compliance requirements.

As a U.S. government contractor, we are subject to financial audits and other reviews by the U.S. government of our costs and performance under our BARDA contract, as well as our accounting and general business practices related to our BARDA contract. Based on the results of its audits, the government may adjust our contract-related costs and fees, including allocated indirect costs.

Laws and regulations affecting government contracts, including our BARDA contract, make it more costly and difficult for us to successfully conduct our business. Failure to comply with these laws and regulations could result in significant civil and criminal penalties and adversely affect our business.

We must comply with numerous laws and regulations relating to the administration and performance of our BARDA contract. Among the most significant government contracting regulations are:

- the Federal Acquisition Regulation, or FAR, and agency-specific regulations supplemental to the FAR, which comprehensively regulate the procurement, formation, administration and performance of government contracts;

- the business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and incorporate other requirements such as the Anti-Kickback Act, the Procurement Integrity Act, the False Claims Act and the Foreign Corrupt Practices Act;

- export and import control laws and regulations; and

- laws, regulations and executive orders restricting the exportation of certain products and technical data.

In addition, U.S. government agencies such as the Department of Health and Human Services, or DHHS, and the Defense Contract Audit Agency, or DCAA, routinely audit and investigate government contractors for compliance with applicable laws and standards. These agencies review a contractor's performance under its contracts, including contracts with BARDA, cost structure and compliance with applicable laws, regulations and standards.

These agencies also review the adequacy of, and a contractor's compliance with, its internal control systems and policies, including the contractor's purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a specific contract will not be paid, while such costs already paid must be refunded. If we are audited and such audit uncovers improper or illegal activities, we may be subject to civil and criminal penalties and administrative sanctions, including:

- termination of any government contracts, including our BARDA contract;

- suspension of payments;

- fines; and

- suspension or prohibition from conducting business with the U.S. government.

In addition, we could suffer serious reputational harm if allegations of impropriety were made against us, which could cause our stock price to decrease.

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. At our company, for example, Glenn P. Sblendorio, President and Chief Financial Officer, announced his retirement from the company in the fourth quarter of 2015, and Brent Furse, Executive Vice President, Chief Customer Officer, and Cees Heiman, Executive Vice President, Chief Innovation Officer, departed from our company in the fourth quarter of 2014. 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 Chief Executive Officer, Clive A. Meanwell, 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.

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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 do not have 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 or products in development, 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 strategy for all of our other 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 our products and products in development, which could affect our ability to complete clinical trials of our products and products in development 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.

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If any third party that manufactures or supports the development or commercialization of our products breaches or terminates its agreement with us, 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 products in development may increase the risk that we will not have appropriate supplies of our products or our products in development, 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 non-renewal 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.

Our products and products in development may compete with products and products in development 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 products in development, delays, suspension or withdrawal of approvals, suspension of clinical trials, license revocation, seizures or recalls of products in development 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.

We may depend on collaborations with third parties for the development and commercialization of certain of our products in development. If those collaborations are not successful, we may not be able to capitalize on the market potential of these products in development.

We may seek to develop and commercialize certain of our products in development through a variety of types of collaboration arrangements. Our likely collaborators for any marketing, distribution, development, licensing or broader collaboration arrangements include large and mid size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We may not be able to enter into these types of arrangements on a timely basis, on favorable terms or at all. Our ability to enter into such arrangements with respect to products in development that are subject to licenses may be limited by the terms of those licenses. If we do enter into any such arrangements with any third parties in the future, we will likely

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have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our products in development. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. Collaborations involving our products in development could pose a number of risks to us, including:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not pursue development and commercialization of our products in development or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products in development if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or otherwise expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our products or products in development or that result in costly litigation or arbitration that diverts management attention and resources; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable products and products in development.

Collaboration agreements may not lead to development or commercialization of products in development in the most efficient manner or at all. If a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

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

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.

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Risks Related to Regulatory Matters

If we do not obtain regulatory approvals for our products in development in any jurisdiction or for our products in any additional jurisdictions, we will not be able to market our products and products in development 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 products in development in the United States and from foreign regulatory authorities in order to sell our products in development 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.

We have a pipeline of acute and intensive care hospital products in development, including, ABP-700, ALN-PCSsc, Carbavance and MDCO-216. We cannot be assured that we will make our planned submissions when we anticipate, that the submissions will be accepted for filing, or that the applicable regulatory authorities will approve our applications on a timely basis or at all.

Developing and obtaining regulatory approval for product candidates is a lengthy process, often taking a number of years, is uncertain and is expensive. All of the product candidates that we are developing, or may develop in the future, require research and development, preclinical studies, nonclinical testing and clinical trials prior to seeking regulatory approval and commencing commercial sales. In addition, we may need to address a number of technological challenges in order to complete development of our product candidates. As a result, the development of product candidates may take longer than anticipated or not be successful at all.

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.

Certain of our products in development have experienced regulatory and/or clinical setbacks in the past. For example, in February 2014, the FDA Cardiovascular and Renal Drugs Advisory Committee advised against approval of cangrelor for use in patients undergoing PCI or those that require bridging from oral antiplatelet therapy to surgery, and in April 2014, the FDA issued a complete response letter regarding our NDA for cangrelor.

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.

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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.

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 in development, 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;
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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.

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If we or the contract manufacturers manufacturing our products and products in development fail to comply with the extensive regulatory requirements to which we, our contract manufacturers and our products and products in development 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.

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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:

- 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 FCPA 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.

The production of fentanyl hydrochloride, which is used in Ionsys, is highly regulated through an annual allocation quota made by the Drug Enforcement Administration, or DEA, in the United States and our specific allocation by the DEA could significantly limit the development, production or sale of Ionsys.

Fentanyl hydrochloride is subject to the DEA's production and procurement quota scheme where the DEA establishes annually an aggregate quota for how much fentanyl may be produced in total in the United States based on an estimate of the quantity needed to meet legitimate scientific and medicinal needs that is then allocated among individual companies based on applications submitted annually by these individual companies to request an individual production and procurement quotas. These applications generally require substantial evidence and documentation of expected legitimate medical and scientific needs before the DEA makes its decision in allocating annual quotas to those manufacturers. The aggregate production quotas and individual production and procurement quotas may be adjusted from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. The DEA may choose to set the aggregate fentanyl hydrochloride quota lower than the total amount requested by the companies.

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While it is possible to petition the DEA for an increase in the annual aggregate quota allocated to us after it is fixed, there is no guarantee that the DEA would act favorably upon such a petition. Our production and procurement quota of fentanyl hydrochloride may not be sufficient to meet commercial demand or clinical development needs. Any delay or refusal by the DEA in establishing the production and/or procurement quota or a reduction in our quota for fentanyl or a failure to increase it over time as we anticipate could delay or stop the development, production or sale of Ionsys or cause us to fail to achieve our expected operating results, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

Risks Related to Our Intellectual Property

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 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 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 to 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 in contested proceedings such as opposition, derivation,

reexamination, inter partes review, post-grant review or interference proceedings and may be narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection we may have for our products, and we may not be able to obtain patent term extension to prolong the terms of the principal patents covering our approved products. Changes in patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

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

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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 products in development are currently set to expire at various dates.

Angiomax. The principal U.S. patents covering Angiomax include the ‘727 patent and the ‘343 patent and included the ‘404 patent. The ‘404 patent covered the composition of matter of Angiomax. 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 had an additional six-month period of pediatric exclusivity following expiration of the ‘404 patent. This period of exclusivity expired in June 2015.

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 ANDAs filed by a number of parties with the FDA seeking approval to market generic versions of Angiomax, we filed lawsuits against the ANDA filers alleging patent infringement of the ‘727 patent and ‘343 patent and have since entered into settlement agreements with respect to our suits against three ANDA filers, Teva, APP and Sun. In our lawsuit against Hospira, on July 2, 2015, the Federal Circuit Court ruled against us, finding the ‘727 patent and ‘343 patent invalid. In November 2015, our petition for en banc review of the Federal Circuit Court's July 2, 2015 decision was granted and the Federal Circuit Court vacated its July 2, 2015 decision. In July 2015, as a result of the Federal Circuit Court's now vacated July 2, 2015 decision, we entered into a supply and distribution agreement with Sandoz under which we granted Sandoz the exclusive right to sell in the United States an authorized generic of Angiomax (bivalirudin). On July 15, 2015, Hospira's ANDAs for its generic versions of bivalirudin were approved by the FDA and Hospira began selling its generic versions of bivalirudin. Notwithstanding the granting of our petition for en banc review, due to the July 2, 2015 decision and our resulting entry into a supply and distribution agreement with Sandoz and Hospira's entry into the market, Angiomax is now subject to generic competition with the authorized generic and Hospira's generic bivalirudin products.

In addition to Hospira's generic versions of bivalirudin, Sandoz's authorized generic and, if approved, Eagle's formulation of bivalirudin, Angiomax could be subject to generic competition in the United States from Teva, APP and Sun under the circumstances set forth in our respective settlement agreements with such parties and upon the approval of each companies' ANDA filings by the FDA. Further, we remain in infringement litigation involving the '727 patent and '343 patent with the other ANDA filers. Our patent infringement litigation involving the ‘727 patent and ‘343 patent is described in more detail in Part II, Item 1. Legal Proceedings, of this Quarterly Report on Form 10-Q. If we are unable to enforce our U.S. patents covering Angiomax, Angiomax could become subject to further generic competition, which could have a material adverse impact on our business, financial condition and operating results. Following our settlements with Teva, APP and Sun, 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, the DOJ and state attorney general offices could seek to challenge our settlements with Teva, APP or Sun, or a third party could initiate a private action under antitrust or other laws challenging our settlements with Teva, APP or Sun. 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.

In Europe, the principal patent covering Angiomax expired in August 2015. This patent covered the composition of matter of Angiomax. As a result, we do not have market exclusivity for Angiomax in Europe.

Cleviprex. The principal U.S. patent for Cleviprex is U.S. Patent No. 5,856,346 or the ‘346 patent. The ‘346 patent was set to expire in January 2016, but the term was extended to January 2021 by the PTO under the Hatch-Waxman Act. We also have an issued patent, U.S. Patent No. 8,658,676, or the ‘676 patent, which covers the Cleviprex formulation and is set to expire in October 2031. In Europe, the principal patent covering Cleviprex was set to expire in November 2014, but the term has been extended to November 2019 in most European countries where Cleviprex has been approved via a supplementary protection certificate. The

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European patent office has also issued to us a patent covering compositions of matter of Cleviprex having certain stability profiles, which will expire in July 2029. 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.

Kengreal. We have issued patents directed to Kengreal pharmaceutical compositions which expire in 2017 and 2018, and applications for patent term extension for extending these patents have been filed and are currently pending. We have issued patents directed to Kengreal composition and various methods of administering Kengreal, expiring from 2029 to 2035, in the United States. We have also filed and are currently prosecuting a number of patent applications related to Kengreal.

Orbactiv. The principal patent for Orbactiv in both the United States and Europe is set to expire in November 2016. We have filed for a patent term extension for this patent in the United States. We also have issued patents directed to the process of making Orbactiv. These patents are set to expire in 2017 if no patent term extension is obtained. We also have a U.S. patent covering the use of Orbactiv in treating certain skin infections that expires in August 2029. In Europe, we have an allowed patent application with claims directed to Orbactiv composition for treating certain diseases and the resulting patent, upon issuance, expires in August 2029. We have also filed and are prosecuting a number of patent applications relating to Orbactiv 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. The expiration dates of patents covering the Ionsys device and its use range from December 2016 to February 2033 in the United States. In Europe, the expiration dates of patents covering the Ionsys device range from May 2016 to September 2021. In addition, we have an allowed application, which, upon issuance, expires in March 2032, covering the Ionsys device in Europe. We are also currently prosecuting patent applications relating to Ionsys in the United States and in certain foreign countries.

Minocin. As a result of our acquisition of Rempex, we acquired a family of patent applications covering certain minocycline formulations and certain methods of administering minocycline. We have two issued patents covering Minocin composition and certain methods of administering minocycline. These patents expire in May 2031. We are also prosecuting a number of patent applications relating to minocycline formulations and use 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 March 2025 if no patent term extension is obtained. We have issued patents related to the use of MDCO-216 in certain European countries expiring in October 2024. 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.

ABP-700. In connection with our acquisition of Annovation, we obtained an exclusive license from The General Hospital Corporation pertaining to certain patents and patent applications covering ABP-700 and its analogs. One of the patents contains claims directed specifically to ABP-700 and expires in January 2033. These patent applications, some of which are jointly owned by Annovation and The General Hospital Corporation, are currently being prosecuted by The General Hospital Corporation in the United States and in certain foreign countries. We are also prosecuting certain other patent applications relating to ABP-700.

ALN-PCS. 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 2016 and 2028 in the United States. Other patents are directed to compositions of the PCSK9 product being developed under our license from Alnylam and to methods of treatment using such PCSK9 product and expire in May 2027 in the United States. In addition, Alnylam has filed and is prosecuting a number of patent applications in the United States and in certain foreign countries. One of these applications, which, if issued, expires in

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December 2033, contains claims directed to specific compositions of the PCSK9 product we are developing and methods of administrating such compositions.

Carbavance. As a result of our acquisition of Rempex, we acquired a portfolio of patent applications covering the composition of matter of Carbavance and its formulation and use. The principal U.S. patent for Carbavance is set to expire in August 2031 if no patent term extension is obtained. A corresponding patent application is pending in Europe and other foreign countries. In addition, we are currently prosecuting other patent applications relating to Carbavance's composition of matter and its use in the United States and in certain foreign countries.

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.

In addition to seeking to enforce our patent rights, we have in the past and may in the future seek to enforce our other intellectual property rights, including, for example, our trademark rights in order to prevent third parties from using the same or confusingly similar trademarks. We may not be successful in enforcing such rights and preventing such use. Further, certain of our trademark rights are licensed to us by third parties and, in certain circumstances, on a non-exclusive basis, which does not afford us the right to prevent third parties from using such trademarks. Failure to adequately pursue and enforce our intellectual property rights could damage our brands, enable others to compete with our products and impair our competitive position.

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

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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 the sale of the 2017 notes, we entered into convertible note hedge and warrant transactions with several of the initial purchasers of the 2017 notes, their affiliates and other financial institutions, whom we refer to as 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 2017 notes (and are likely to do so during any observation period related to a conversion of the 2017 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, 2014 to May 6, 2016, the last reported sale price of our common stock ranged from a high of $43.31 per share to a low of $20.36 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:

- approval or rejection of submissions for marketing approval for our products and products in development;
-

regulatory actions by the FDA or a foreign jurisdiction limiting or revoking the use of our products or products in development;

- changes in securities analysts' estimates of our financial performance;
- changes in valuations of similar companies;
- variations in our operating results;
- whether we are successful in narrowing our operational focus by strategically separating non-core businesses and products, and the amount of consideration paid to us in connection with any related sales or divestitures ;
- 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;
- announcements of results of clinical trials or nonclinical studies by us or third parties relating to our products, products in development or those of our competitors or of 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;
- the extent to which our products are commercially successful globally;
- developments in our ongoing litigation and 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 Select 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.

We are currently subject to securities class action litigation and may be subject to similar or other litigation in the future, which may divert management's attention and have a material adverse effect on our business, financial condition and results of operations.

In February 2014, a class action lawsuit was filed against us and certain of our current and former officers alleging, among other things, that we and certain of our current and former officers violated federal securities laws because we and certain current and former officers allegedly made misrepresentations or did not make proper disclosures regarding the results of clinical trials which tested the efficacy and safety of Kengreal. On February 12, 2016, the parties executed a stipulation for a proposed class settlement, subject to court approval. On February 25, 2016, the court preliminarily approved the settlement and set a final approval hearing for June 7, 2016. The class action lawsuit is described in more detail in Part II, Item 1, Legal Proceedings, of this Quarterly Report on Form 10-Q.

There may be additional suits or proceedings brought in the future. Monitoring and defending against legal actions, whether or not meritorious, is time-consuming for our management and detracts from our ability to fully focus our internal resources on our business activities, and we cannot predict how long it may take to resolve these matters. In addition, we may incur substantial legal fees and costs in connection with litigation. Although we have insurance,

coverage could be denied or prove to be insufficient.

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;

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

- our directors currently 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 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.

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Item 6. Exhibits

Exhibits

See the Exhibit Index on the page immediately preceding the exhibits for a list of exhibits filed as part of this Quarterly Report on Form 10-Q, which Exhibit Index is incorporated herein by this reference.

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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: May 9, 2016 By: /s/ William B. O'Connor
William B. O'Connor
Chief Financial Officer
(Principal Financial and Accounting Officer)

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EXHIBIT INDEX

Exhibit Number	Description
10.1†	Eighth Amendment to Second Amended and Restated Distribution Agreement, effective April 1, 2016, by and between the registrant and Integrated Commercialization Solutions, Inc.
31.1	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	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 March 31, 2016, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Comprehensive (Loss) Income, (iv) the Condensed Consolidated Statements of Cash Flows, and (v) Notes to Condensed Consolidated Financial Statements.

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