MEDICINES CO /DE
Form 10-Q
August 07, 2015

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: June 30, 2015
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 (State or other jurisdiction of incorporation or organization)	04-3324394 (I.R.S. Employer Identification No.)
8 Sylvan Way Parsippany, New Jersey (Address of principal executive offices)	07054 (Zip Code)

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

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

Yes 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 August 5, 2015 there were 66,768,215 shares of Common Stock, $0.001 par value per share, outstanding (excluding 2,192,982 shares held in treasury).

THE MEDICINES COMPANY

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Part I. Financial Information
Item 1. Financial Statements

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

	June 30, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$462,743	$370,741
Accounts receivable, net of allowances of $39.7 million and $47.0 million at June 30, 2015 and December 31, 2014, respectively	52,615	155,691
Inventory	127,779	81,450
Deferred tax assets	—	33,080
Prepaid expenses and other current assets	17,309	16,012
Total current assets	660,446	656,974
Fixed assets, net	38,564	40,060
Intangible assets, net	1,039,159	892,659
Goodwill	313,508	286,532
Restricted cash	1,454	1,446
Other assets	13,500	8,034
Total assets	$2,066,631	$1,885,705
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$17,701	$19,799
Accrued expenses	121,976	159,252
Current portion of contingent purchase price	59,900	210,422
Deferred revenue	9,126	14,350
Total current liabilities	208,703	403,823
Contingent purchase price	147,260	140,712
Deferred tax liabilities	163,949	164,459
Convertible senior notes (due 2017 and 2022)	568,044	246,676
Other liabilities	6,883	9,944
Total liabilities	1,094,839	965,614
Stockholders' equity:		
Preferred stock, $1.00 par value per share, 5,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.001 par value per share, 187,500,000 shares authorized; 68,875,522 issued and 66,682,540 outstanding at June 30, 2015 and 125,000,000 authorized; 67,667,468 issued and 65,474,486 outstanding at December 31, 2014, respectively	68	68
Additional paid-in capital	1,136,358	1,045,078
Treasury stock, at cost; 2,192,982 shares at June 30, 2015 and December 31, 2014, respectively	(50,000)	(50,000)
Accumulated deficit	(118,667)	(77,109)
Accumulated other comprehensive income	4,482	2,528
Total The Medicines Company stockholders' equity	972,241	920,565
Non-controlling interest in joint venture	(449)	(474)
Total stockholders' equity	971,792	920,091
Total liabilities and stockholders' equity	$2,066,631	$1,885,705

See accompanying notes to unaudited consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Net revenue	$90,472	$183,774	$216,988	$361,009
Operating expenses:				
Cost of revenue	36,999	85,687	70,736	152,554
Research and development	36,221	41,228	60,170	72,324
Selling, general and administrative	96,246	88,745	176,780	153,266
Total operating expenses	169,466	215,660	307,686	378,144
Loss from operations	(78,994)	(31,886)	(90,698)	(17,135)
Co-promotion and license income	638	7,326	9,026	13,346
Gain on remeasurement of equity investment	—	—	22,741	—
Gain on sale of investment	19,773	—	19,773	—
Loss in equity investment	—	—	(144)	—
Interest expense	(9,348)	(3,892)	(17,955)	(7,752)
Other income (expense)	94	(150)	203	29
Loss before income taxes	(67,837)	(28,602)	(57,054)	(11,512)
Benefit for income taxes	21,298	23,428	15,521	1,333
Net loss	(46,539)	(5,174)	(41,533)	(10,179)
Net (income) loss attributable to non-controlling interest	(53)	17	(25)	26
Net loss attributable to The Medicines Company	$(46,592)	$(5,157)	$(41,558)	$(10,153)
Basic loss per common share attributable to The Medicines Company	$(0.71)	$(0.08)	$(0.63)	$(0.16)
Diluted loss per common share attributable to The Medicines Company	$(0.71)	$(0.08)	$(0.63)	$(0.16)
Weighted average number of common shares outstanding:				
Basic	65,903	64,400	65,541	64,277
Diluted	65,903	64,400	65,541	64,277

See accompanying notes to unaudited consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Net loss	$(46,539)	$(5,174)	$(41,533)	$(10,179)
Other comprehensive (loss) income:				
Foreign currency translation adjustment	(751)	914	1,954	785
Other comprehensive (loss) income	(751)	914	1,954	785
Comprehensive loss	$(47,290)	$(4,260)	$(39,579)	$(9,394)

See accompanying notes to unaudited consolidated financial statements.

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

	Six Months Ended June 30,	
	2015	2014
Cash flows from operating activities:		
Net loss	$(41,533)	$(10,179)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	14,929	17,026
Asset impairment charges	3,613	15,100
Amortization of long term debt financing costs	1,163	646
Amortization of debt discount	10,273	5,216
Unrealized foreign currency transaction gain, net	(146)	(528)
Non-cash share-based compensation expense	16,283	16,323
Undistributed loss on equity method investments	144	—
Loss on disposal of fixed assets	530	12
Deferred tax benefit	(18,312)	(532)
Excess tax expense (benefit) from share-based compensation arrangements	53	(1,667)
Gain on sale of investment	(19,773)	—
Gain on remeasurement of equity investment	(22,741)	—
Loss from inventory obsolescence	8,437	—
Adjustment to contingent purchase price	13,676	19,617
Changes in operating assets and liabilities:		
Accounts receivable	102,953	(18,415)
Inventory	(54,644)	1,086
Prepaid expenses and other current assets	(1,276)	(411)
Accounts payable	(2,165)	(19,448)
Accrued expenses	(36,286)	28,310
Deferred revenue	(2,399)	(2,696)
Contingent purchase price	(48,867)	—
Other liabilities	(5,918)	(4,917)
Net cash (used in) provided by operating activities	(82,006)	44,543
Cash flows from investing activities:		
Proceeds from sale of fixed assets	250	—
Proceeds from sale of investment	19,773	—
Purchases of fixed assets	(1,488)	(5,431)
Cash used for acquisitions, net	(28,397)	(58,871)
Payments for intangible assets	(97,617)	—
Other investments	—	(625)
Decrease in restricted cash	13	75
Net cash used in investing activities	(107,466)	(64,852)
Cash flows from financing activities:		
Proceeds from issuances of common stock	20,785	9,506
Milestone payments	(126,783)	—
Proceeds from issuance of convertible senior notes	400,000	—
Debt issuance costs	(12,769)	—
Excess tax (expense) benefit from share-based compensation arrangements	(53)	1,667
Net cash provided by financing activities	281,180	11,173

Effect of exchange rate changes on cash	294	679
Increase (decrease) in cash and cash equivalents	92,002	(8,457)
Cash and cash equivalents at beginning of period	370,741	376,727
Cash and cash equivalents at end of period	$462,743	$368,270
Supplemental disclosure of cash flow information:		
Interest paid	$1,891	$1,890
Taxes paid	$61	$1,200

See accompanying notes to unaudited consolidated financial statements.

THE MEDICINES COMPANY

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

The Medicines Company® name and logo, Angiomax®, Angiox®, Cleviprex®, Carbavance™, Ionsys®, Kengreal™, Kengrexal™, Orbactiv®, PreveLeak™, Raplixa™ and Recothrom® are either registered trademarks or trademarks of The Medicines Company in the United States and/or other countries. All other trademarks, service marks or other tradenames appearing in this quarterly report on Form 10-Q are the property of their respective owners. Except where otherwise indicated, or where the context may otherwise require, references to “Angiomax” in this quarterly report on Form 10-Q mean Angiomax and Angiox, collectively, and references to "Kengreal" means 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, Minocin® (minocycline) for injection, Orbactiv® (oritavancin), PreveLeak™ and Recothrom® Thrombin topical (Recombinant). The Company received marketing approval in the United States for four of its product candidates during the second quarter of 2015: Ionsys® (fentanyl iontophoretic transdermal system), Kengreal™ (cangrelor), Raplixa™, and RPX-602, a new formulation of Minocin IV. 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 U.S. Court of Appeals for the Federal Circuit (Federal Circuit Court) ruled against the Company in its patent infringement litigation with Hospira, Inc. (Hospira) with respect to the principal U.S. patents covering Angiomax. In its ruling, the Federal Circuit Court held U.S. Patent Nos. 7,582,727 ('727 patent) and 7,598,343 ('343 patent) invalid. As a result, the Company does not have market exclusivity for Angiomax in the United States. In light of such events, in July 2015 the Company entered into a supply and distribution agreement with Sandoz Inc. (Sandoz) under which it granted Sandoz the exclusive right to sell in the United States an authorized generic of Angiomax (bivalirudin). In addition, in July 2015 Hospira's Abbreviated New Drug Applications (ANDA) for its generic versions of bivalirudin were approved by the U.S. Food and Drug Administration (FDA). As a result, Angiomax is now subject to generic competition with the authorized generic and Hospira's generic bivalirudin products. Given the generic competition, the Company has determined to suspend its efforts and expenditures with respect to Angiomax other than for supply chain, quality and safety monitoring and other necessary activities.

2. Significant Accounting Policies

The Company's significant accounting policies are described in note 2 of the notes to the consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2014 as filed with the Securities and Exchange Commission (SEC).

Basis of Presentation

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

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

The Company's results of operations for the six months ended June 30, 2015 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, 2015. These consolidated financial statements should be read in conjunction with the Company's audited financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2014 as filed with the SEC.

Use of Estimates

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

Contingencies

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

In-Process Research and Development

The cost of in-process research and development (IPR&D) acquired directly in a transaction other than a business combination is capitalized if the projects have an alternative future use; otherwise it is expensed. The fair values of IPR&D projects acquired in business combinations are capitalized. Several methods may be used to determine the estimated fair value of the IPR&D projects acquired in a business combination. The Company utilizes the "income method," which applies a probability weighting that considers the risk of development and commercialization to the estimated future net cash flows that are derived from projected sales revenues and estimated costs. These projections are based on factors such as relevant market size, patent protection, historical pricing of similar products and expected industry trends. The estimated future net cash flows are then discounted to the present value using an appropriate discount rate. This analysis is performed for each project independently. These assets are treated as indefinite-lived intangible assets until completion or abandonment of the projects, at which time the assets are amortized over the remaining useful life or written off, as appropriate. These are tested at least annually or when a triggering event occurs that could indicate a potential impairment. Once the research and development efforts are completed, the Company performs an impairment test immediately prior to the change in classification to developed products.

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. Payments received in advance of work performed are deferred. The Company recorded approximately \$2.3 million and \$5.5 million of reimbursements by the government as a reduction of research and development expenses for the three and six months ended June 30, 2015, respectively, and approximately \$2.9 million for the three and six months ended June 30, 2014.

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 2014-09). ASU 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. This guidance is effective for fiscal years and interim periods beginning after December 15, 2017. Early adoption is not 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 April 2015, the FASB issued final guidance to simplify 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 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 June 2015, the FASB issued ASU 2015-10, Technical Corrections and Improvements. With regard to fair value measurement disclosures, ASU 2015-10 clarified that, for nonrecurring measurements estimated at a date during the reporting period other than the end of the reporting period, an entity should clearly indicate that the fair value information presented is not as of the period’s end as well as the date or period that the measurement was taken. This change was effective immediately upon issuance of ASU 2015-10 (12 June 2015). The adoption of ASU 2015-10 did not have a significant impact on the Company's consolidated financial statements and related disclosures.

In July 2015, the FASB issued ASU 2015-11, "Inventory (Topic 330): Simplifying the Measurement of Inventory" ("ASU 2015-11") requires an entity to measure in scope inventory at the lower of cost and net realizable value. Subsequent measurement is unchanged for inventory measured using LIFO or the retail inventory method. The amendments do not apply to inventory that is measured using last-in, first-out (LIFO) or the retail inventory method. The amendments apply to all other inventory, which includes inventory that is measured using first-in, first-out (FIFO) or average cost. The pronouncement is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. The amendments should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. The Company expects to adopt this guidance when effective and is currently evaluating the effect of ASU 2015-11 on its consolidated financial statements and related disclosures.

On April 15, 2015, the FASB issued Accounting Standards Update No. 2015-05, "Customer’s Accounting for Fees Paid in a Cloud Computing Arrangement" (ASU 2015-05). ASU 2015-05 provides guidance to help companies evaluate the accounting for fees paid by a customer in a cloud computing arrangement. The new guidance clarifies that if a cloud computing arrangement includes a software license, the customer should account for the license consistent with its accounting for other software licenses. If the arrangement does not include a software license, the customer should account for the arrangement as a service contract. ASU 2015- 05 is effective for us beginning in the first quarter of 2016. The Company 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 approximately $8.7 million and $8.9 million of share-based compensation expense for the three months ended June 30, 2015 and June 30, 2014, respectively, and approximately $16.3 million in each of the six month periods ended June 30, 2015 and June 30, 2014. As of June 30, 2015, there was approximately $37.3 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 1.49 years.

During the six months ended June 30, 2015, the Company issued a total of 1,208,054 shares of its common stock upon the exercise of stock options, pursuant to restricted stock grants and pursuant to purchases under the Company's 2010 employee stock purchase plan (ESPP). During the six months ended June 30, 2014, the Company issued a total of 725,612 shares of its common stock upon the exercise of stock options, pursuant to restricted stock grants and pursuant to purchases under the ESPP. Cash received from the exercise of stock options and purchases through the ESPP during the six months ended June 30, 2015 and June 30, 2014 was $20.8 million and $9.5 million, respectively, and is included within the financing activities section of the consolidated statements of cash flows.

4. Loss per Share

The following table sets forth the computation of basic and diluted loss per share for the three and six months ended June 30, 2015 and 2014:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
	(in thousands, except per share amounts)			
Basic and diluted				
Net loss attributable to The Medicines Company	$(46,592)	$(5,157)	$(41,558)	$(10,153)
Weighted average common shares outstanding, basic	65,903	64,400	65,541	64,277
Plus: net effect of dilutive stock options, restricted common shares and shares issuable upon conversion of convertible senior notes due 2017	—	—	—	—
Weighted average common shares outstanding, diluted	65,903	64,400	65,541	64,277
Loss per share attributable to The Medicines Company, basic	$(0.71)	$(0.08)	$(0.63)	$(0.16)
Loss per share attributable to The Medicines Company, diluted	$(0.71)	$(0.08)	$(0.63)	$(0.16)

Basic loss per share is computed using the weighted average number of shares of common stock outstanding during the period, reduced where applicable for outstanding yet unvested shares of restricted common stock. The number of dilutive common stock equivalents was calculated using the treasury stock method. For the three months ended June 30, 2015 and 2014, options to purchase 1,243,124 shares and 1,426,987 shares, respectively, of common stock that could potentially dilute basic loss per share in the future were excluded from the calculation of diluted earnings per share as their effect would have been anti-dilutive. For the six months ended June 30, 2015 and 2014, options to purchase 1,313,494 shares and 1,777,605 shares, respectively, of common stock that could potentially dilute basic loss per share in the future were excluded from the calculation of diluted earnings per share as their effect would have been anti-dilutive.

For the three and six months ended June 30, 2015, there were 220,021 and 267,399 shares, respectively, of unvested restricted stock excluded from the calculation of diluted loss per common share as their effect would be anti-dilutive. For the three and six months ended June 30, 2014, there were 233,761 and 303,829 shares, respectively, of unvested restricted stock excluded from the calculation of diluted loss per common share.

In January 2015, the Company issued, at par value, $400.0 million aggregate principal amount of 2.5% convertible senior notes due 2022 (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 and six months ended June 30, 2015, there was no dilutive effect of the 2022 Notes as the stock price did not exceed the conversion price and the Company reported a loss.

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) (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 (the 2017 Note Hedges) with several of the initial purchasers of the 2017 Notes, their affiliates and other financial institutions (the 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 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. The number of shares of common stock issuable upon conversion of the 2017 Notes excluded from the calculation of diluted loss per share for the three months ended June 30, 2015 was zero. For the six months ended June 30, 2015, the number of shares issuable upon conversion of the 2017 Notes excluded from the diluted loss per share calculation was 27,870 as their effect would be anti-dilutive.

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 (the 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. For the three and six months ended June 30, 2015 and June 30, 2014, the 2017 Warrants did not have a dilutive effect on loss per share because the average market price during the periods presented was below the strike price and the Company reported a loss for all periods. 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.

5. Income Taxes

For the three months ended June 30, 2015 and 2014, the Company recorded a $21.3 million benefit and a $23.4 million benefit for income taxes, respectively, based upon its estimated federal, state and foreign tax liability for the year. The worldwide effective income tax rates for the Company for the three months ended June 30, 2015 and 2014 were 31.4% and 81.9%, respectively. This decrease in effective tax rate was primarily driven by a projected loss for the year 2015 and a discrete tax benefit related to a partial release of a valuation allowance related to Dutch net operating losses associated with ProFibrix B.V. as a result of the regulatory approvals of Raplixa in both the United States and European Union, which were offset by the establishment of a valuation allowance against certain deferred tax assets, an increase in foreign taxable income, and an increase in the non-cash tax impact arising from changes in the value of contingent consideration under the Company's agreements for the acquisitions of Targanta Therapeutics Corporation (Targanta), Incline Therapeutics, Inc. (Incline), ProFibrix B.V. (ProFibrix), Rempex Pharmaceuticals, Inc. (Rempex),Tenaxis Medical, Inc. (Tenaxis) and Annovation BioPharma, Inc. (Annovation).

According to the standards of ASC 740, 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. During the three months ended June 30, 2015, the Company placed significant weight on the following pieces of negative evidence in recording valuation allowances on certain of its deferred tax assets as of June 30, 2015:

- The Company expects to be in a cumulative net loss for the three year period ended December 31, 2015 as Angiomax will now face generic competition in the U.S. due to the July 2, 2015 decision by the Federal Circuit Court which held the ‘727 patent and ‘343 patent invalid.
- The commercial success of the Company's marketed and approved products is not assured.

For the six months ended June 30, 2015 and 2014, the Company recorded a $15.5 million benefit and a $1.3 million benefit for income taxes, respectively, based upon its estimated federal, state and foreign tax liability for the year. The worldwide effective income tax rates for the Company for the six months ended June 30, 2015 and 2014 were 27.2% and 11.6%, respectively. This increase in the effective tax rate is primarily due the establishment of a valuation allowance against certain deferred tax assets, an increase in foreign taxable income, and an increase in the non-cash tax impact arising from changes in the value of contingent consideration related to the Company's acquisitions of Targanta, Incline, ProFibrix, Rempex and Tenaxis and Annovation, offset primarily by a discrete tax benefit related to a partial release in a valuation allowance related to Dutch net operating losses associated with ProFibrix B.V. as a result of the regulatory approvals of Raplixa in both the United States and European Union.

According to the standards of ASC 740, 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 places significant weight on the following pieces of negative evidence:

- The Company expects to be in a cumulative net loss for the three year period ended December 31, 2015 as Angiomax will now face generic competition in the U.S. due to the July 2, 2015 decision by the Federal Circuit Court which held the ‘727 patent and ‘343 patent invalid.

- The commercial success of the Company's marketed and approved products is not assured.

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 $456.7 million and $364.7 million at June 30, 2015 and December 31, 2014, respectively. Cash and cash equivalents at June 30, 2015 and December 31, 2014 also included at both dates investments of $6.0 million in money market funds and commercial paper with original maturities of less than three months.

Restricted Cash

The Company had restricted cash of $1.5 million at June 30, 2015 and $1.4 million at December 31, 2014, which included at both dates $1.0 million collateral for outstanding letters of credit associated with the Company's lease for the office space in Parsippany, New Jersey. The funds are invested in certificates of deposit. The letter of credit permits draws by the landlord to cure defaults by the Company. In addition, as a result of the acquisition of Targanta in 2009, the Company had restricted cash of $0.2 million at June 30, 2015 and $0.1 million at December 31, 2014, in the form of a guaranteed investment certificate collateralizing an available credit facility. The Company also had restricted cash of $0.3 million at June 30, 2015 and $0.3 million at December 31, 2014, related to certain foreign tender requirements.

7. Fair Value Measurements

FASB ASC 820-10 “Fair Value Measurements and Disclosures” (ASC 820-10) provides a framework for measuring fair value under GAAP and requires expanded disclosures regarding fair value measurements. ASC 820-10 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820-10 also establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

Level 1	Quoted prices in active markets for identical assets or liabilities. The Company's Level 1 asset consists of money market investments. The Company does not have Level 1 liabilities as of June 30, 2015 or December 31, 2014.
Level 2	Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. The Company does not have Level 2 assets or liabilities as of June 30, 2015 or December 31, 2014.
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 liabilities consist of the contingent purchase prices associated with the Company's business combinations. 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.

The following table sets forth the Company's assets and liabilities that were measured at fair value on a recurring basis at June 30, 2015 and December 31, 2014 by level within the fair value hierarchy. As required by ASC 820-10, assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the asset or liability:

Assets and Liabilities	As of June 30, 2015 Quoted Prices In Active Markets for Identical Assets (Level 1) (in thousands)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of June 30, 2015	As of December 31, 2014 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, 2014
Assets:								
Money market	$6,031	$ —	$ —	$6,031	$6,030	$ —	$ —	$6,030
Total assets at fair value	$6,031	$ —	$ —	$6,031	$6,030	$ —	$ —	$6,030
Liabilities:								
Contingent purchase price	$—	$ —	$ 207,160	$207,160	$—	$ —	$ 351,134	$351,134
Total liabilities at fair value	$—	$ —	$ 207,160	$207,160	$—	$ —	$ 351,134	$351,134

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

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

Level 3 Disclosures

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

	Fair Value as of June 30, 2015 (in thousands)	Valuation Technique	Unobservable Input	Range (Weighted Average)
Targanta:				
Contingent purchase price	$5,560	Probability-adjusted discounted cash flow	Probability of success	20%
				2020

			Period in which milestone is expected to be achieved	
			Discount rate	11%
Incline:				
Contingent purchase price	$69,800	Probability-adjusted discounted cash flow	Probabilities of success	64% -95% (79%)
			Periods in which milestones are expected to be achieved	2015 - 2018
			Discount Rate	18%

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ProFibrix:				
Contingent purchase price	$3,700	Probability-adjusted discounted cash flow	Probabilities of success	5% - 15% (13%)
			Periods in which milestones are expected to be achieved	2017
			Discount rate	26% - 29%
Rempex:				
Contingent purchase price: commercial milestone	$66,300	Probability-adjusted discounted cash flow	Probabilities of success	11% - 95% (58%)
			Periods in which milestones are expected to be achieved	2015 - 2020
			Discount rate	1.9% - 5.6%
Contingent purchase price: sales milestone	$10,100	Risk-adjusted revenue simulation	Probabilities of success	9% - 49% (22%)
			Periods in which milestone is expected to be achieved	2016 - 2022
			Discount rate	2.1% - 6.6%
Tenaxis:				
Contingent purchase price	$34,700	Probability-adjusted discounted cash flow	Probabilities of success	5% - 100% (87%)
			Periods in which milestones are expected to be achieved	2015 - 2029
			Discount rate	4.0% - 25%
Annovation:				
Contingent purchase price	$17,000	Probability-adjusted discounted cash flow	Probabilities of success	8% - 50% (45%)
			Periods in which milestones are expected to be achieved	2016 - 2030
			Discount rate	3.1% - 8.0%

	Fair Value as of December 31, 2014 (in thousands)	Valuation Technique	Unobservable Input	Range (Weighted Average)
Targanta:				
Contingent purchase price	$6,334	Probability-adjusted discounted cash flow	Probability of success	20%
			Period in which milestone is expected to be achieved	2019
			Discount rate	11%
Incline:				
Contingent purchase price	$123,800	Probability-adjusted discounted cash flow	Probabilities of success	64% -100% (83%)
			Periods in which milestones are expected to be achieved	2015 - 2018
			Discount Rate	18%
ProFibrix:				
Contingent purchase price	$88,600	Probability-adjusted discounted cash flow	Probabilities of success	5% - 95% (92%)
			Periods in which milestones are expected to be achieved	2015 - 2017
			Discount rate	2.5% - 24.1%
Rempex:				
Contingent purchase price: commercial milestone	$80,800	Probability-adjusted discounted cash flow	Probabilities of success	11% - 95% (63%)
			Periods in which milestones are expected to be achieved	2015 - 2019
			Discount rate	1.5% - 3.7%
Contingent purchase price: sales milestone	$10,900	Risk-adjusted revenue simulation	Probabilities of success	9% - 49% (17%)
			Periods in which milestones are expected to be achieved	2016 - 2022
			Discount rate	1.5% - 4.5%
Tenaxis:				
Contingent purchase price	$40,700	Probability-adjusted discounted cash flow	Probabilities of success	5% - 100% (84%)
			Periods in which milestones are expected to be achieved	2015 - 2026
			Discount rate	1% - 20%

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, ProFibrix, Rempex, Tenaxis and

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, ProFibrix, Rempex, Tenaxis 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 would result in a significantly higher or lower fair value measurement. Significant changes in the probabilities as to the periods in which milestones will be achieved would result in a significantly lower or higher fair value measurement.

The changes in fair value of the Company's Level 3 contingent purchase price during the three and six months ended June 30, 2015 and 2014 were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
	(in thousands)			
Balance at beginning of period	369,552	304,627	351,134	302,363
Fair value of contingent purchase price with respect to Tenaxis as of May 1, 2014	—	38,800	—	38,800
Fair value of contingent purchase price with respect to Annovation as of February 2, 2015	—	—	18,000	—
Settlements	(174,550)	—	(175,650)	—
Fair value adjustment to contingent purchase prices included in net loss.	12,158	17,353	13,676	19,617
Balance at end of period	$207,160	$360,780	$207,160	$360,780

For the three months ended June 30, 2015, the 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 or changes in probabilities of success or discount rate and payments made for milestones achieved. For the six months ended June 30, 2015, the changes in the carrying value of the contingent purchase price obligations resulted from the initial estimate of the fair value of the contingent consideration related to the Company's acquisition of Annovation, subsequent changes in the fair value of the contingent consideration due to either the passage of time or changes in probabilities of success or discount rate and payments made for milestones achieved.

No other changes in valuation techniques or inputs occurred during the three and six months ended June 30, 2015. No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the three and six months ended June 30, 2015.

8. Inventory

The major classes of inventory were as follows:

Inventory	June 30, 2015	December 31, 2014
	(in thousands)	
Raw materials	$35,712	$40,533
Work-in-progress	77,150	34,095
Finished goods	14,917	6,822
Total	$127,779	$81,450

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. During the three-month period ended June 30, 2015 upon review of expected future Angiomax volumes, the Company recorded a $7.6 million inventory obsolescence charge due primarily to the loss of market exclusivity for Angiomax in the United States.

9. Intangible Assets and Goodwill

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

	Weighted Average Useful Life	As of June 30, 2015 Gross Carrying Amount (in thousands)	Accumulated Amortization and Other Charges	Net Carrying Amount	As of December 31, 2014 Gross Carrying Amount	Accumulated Amortization and Other Charges	Net Carrying Amount
Identifiable intangible assets							
Selling rights agreements	3.5 years	$9,126	$ (9,085)	$41	$9,125	$ (8,961)	$164
Product licenses	10.2 years	80,500	(71,000)	9,500	71,000	(65,602)	5,398
Developed product rights	15.5 years	793,107	(17,109)	775,998	180,930	(6,513)	174,417
Total	15.4 years	$882,733	$ (97,194)	$785,539	$261,055	$ (81,076)	$179,979

In the three months ended June 30, 2015, the Company reclassified $250.0 million, $36.1 million and $176.0 million of IPR&D assets to developed product rights due to the approval of Ionsys in the United States, RPX-602 in the United States and Raplixa in the United States and Europe, respectively. During the three months ended June 30, 2015, the Company recorded an impairment charge of $3.6 million to cost of sales as a result of the loss of Angiomax exclusivity in the United States, resulting from the July 2015 decision by the U.S. Court of Appeals for the Federal Circuit. In February 2015, the Company completed the acquisition of the remaining assets held by Bristol-Myers Squibb Company (BMS) which were exclusively related to Recothrom. The Company paid BMS approximately $132.4 million in the aggregate, including approximately $44.0 million for inventory. In the six months ended June 30, 2015, the Company reclassified the value of the purchase option related to Recothrom and additional amounts paid to BMS to developed product rights and commenced amortization.

The Company recognized an amortization expense and impairment charge of $9.6 million and $16.1 million related to its intangible assets in the three and six months ended June 30, 2015, respectively. The Company expects amortization expense related to its intangible assets to be $24.1 million for the last six months of 2015. The Company expects annual amortization expense related to its intangible assets to be $52.7 million, $52.8 million, $52.4 million, $52.0 million and $52.0 million for the years ending December 31, 2016, 2017, 2018, 2019 and 2020, respectively, with the balance of $499.5 million being amortized thereafter. The Company records amortization of selling rights agreements in selling, general and administrative expense on the consolidated statements of income. The Company records amortization of product licenses and developed product rights in cost of revenue on the consolidated statements of income.

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

	As of June 30, 2015 Gross Carrying Amount (in thousands)	Adjustments	Net Carrying Amount	As of December 31, 2014 Gross Carrying Amount	Adjustments	Net Carrying Amount
Intangible assets not subject to amortization:						
	$253,620	—	$253,620	$650,680	—	$650,680

In-process research and development						
Recothrom option	—	—	—	62,000	—	62,000
Total	$253,620	—	$253,620	$712,680	—	$712,680

On February 2, 2015, the Company completed the acquisition of Annovation, and Annovation became the Company's wholly owned subsidiary. As a result of the acquisition of Annovation, the Company recorded $65.0 million of in-process research and development for the acquisition of ABP-700, a novel intravenous anesthetic. See Note 12 "Acquisitions" for further information regarding the Company's acquisition of Annovation.

The changes in the carrying amount of goodwill for the six months ended June 30, 2015 are as follows:

	June 30, 2015 (in thousands)
Balance as of December 31, 2014	$286,532
Goodwill resulting from the acquisition of Annovation	24,530
Translation adjustments	2,446
Balance as of June 30, 2015	$313,508

10. Convertible Senior Notes

Convertible Senior Notes Due 2022

In January 2015, the Company issued, at par value, $400.0 million aggregate principal amount of 2.5% convertible senior notes due 2022. 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.

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.

The Company accounts for the 2022 Notes as a liability and equity component where the carrying value of the liability component will be valued based on a similar instrument. 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 equity classification.

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 Notes.

The 2022 Notes consist of the following:

Liability component	June 30, 2015		December 31, 2014
	(in thousands)		
Principal	$400,000		$—
Less: Debt discount, net[1]	(84,166	)	—
Net carrying amount	$315,834		$—

(1) Included in the 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 $337.2 million as of June 30, 2015. 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 (Level 2). As of June 30, 2015, the remaining contractual life of the 2022 Notes is approximately 6.6 years.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
	(in thousands)			
Contractual interest expense	$2,482	$—	$4,634	$—
Amortization of debt issuance costs	233	—	436	—
Amortization of debt discount	2,538	—	4,739	—
Total	$5,253	$—	$9,809	$—
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 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.

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 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 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.

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. The 2017 Notes consist of the following:

Liability component	June 30, 2015	December 31, 2014
	(in thousands)	
Principal	$275,000	$275,000
Less: Debt discount, net[1]	(22,790)	(28,324)
Net carrying amount	$252,210	$246,676

[1] Included in the 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 $267.1 million as of June 30, 2015. 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 (Level 2). As of June 30, 2015, the remaining contractual life of the 2017 Notes is approximately 1.9 years.
The following table sets forth total interest expense recognized related to the 2017 Notes:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
	(in thousands)			
Contractual interest expense	$945	$945	$1,891	$1,890
Amortization of debt issuance costs	367	326	728	646
Amortization of debt discount	2,781	2,621	5,534	5,216
Total	$4,093	$3,892	$8,153	$7,752
Effective interest rate of the liability component	6.02 %	6.02 %	6.02 %	6.02 %

Note Hedges. In June 2012, the Company paid an aggregate amount of $58.2 million for the 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 June 30, 2015, the fair value of the 2017 Note Hedges was $56.2 million. The Company estimates the fair value of its 2017 Note Hedges using Monte Carlo simulations model of its stock price (Level 2).

Warrants. The Company received aggregate proceeds of $38.4 million from the sale to the 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 were anti-dilutive for the three and six months ended June 30, 2015. 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 under current accounting principles. Because the 2017 Warrants are indexed to the Company's common stock and are recorded in equity in the Company's consolidated balance sheets, the 2017 Warrants are exempt from the scope and fair value provisions of accounting principles related to accounting for derivative instruments.

11. Treasury Stock

As of June 30, 2015 and December 31, 2014 there were 2,192,982 shares of the Company's common stock held in treasury.

12. Acquisitions

Annovation

On February 2, 2015, the Company completed the acquisition of Annovation, and Annovation became the Company's wholly owned subsidiary. As a result of the acquisition of Annovation, the Company acquired ABP-700, a novel intravenous anesthetic.

Under the terms of the terms of the acquisition agreement, the Company paid to the holders of Annovation’s capital stock and the holders of options to purchase shares of Annovation’s capital stock, (collectively, the Annovation equityholders), an aggregate of approximately $28.4 million in cash. In addition, the Company may be obligated to pay Annovation's equityholders up to an additional $26.3 million in milestone payments subsequent to the closing if the Company achieves certain development and regulatory approval milestones at the times and on the conditions set forth in the acquisition agreement. The Company has 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 accordance with ASC 805, the Company accounted for this transaction as a step acquisition which required that the Company remeasure its then existing 35.8% ownership interest (previously accounted for as an equity method investment) to fair value. The fair value of the Company's interest in Annovation was $25.9 million at closing, resulting in a non-cash pre-tax gain of $22.7 million, recorded as gain on remeasurement of equity investment in the Company's consolidated statements of income. The Company's previously recorded equity method investment in Annovation was derecognized from the Company's consolidated balance sheets. Since the date of the step acquisition, the financial results of Annovation were included within the Company's consolidated financial statements. In accordance with the acquisition method of accounting, the Company allocated the acquisition cost for the Annovation transaction to the underlying assets acquired and liabilities assumed by the Company, based upon estimated fair values of those assets and liabilities at the date of acquisition and will classify the fair value of acquired IPR&D as indefinite-lived assets until the successful completion or abandonment of the associated research and development efforts.

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

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

The Company did not incur any significant acquisition related costs in connection with the Annovation acquisition during the three and six months ended June 30, 2015.

Total purchase price is summarized as follows:

	(In thousands)
Upfront cash consideration	$28,397
Fair value of existing equity interest in Annovation	25,886
Total cash consideration and fair value of existing equity interest	54,283
Fair value of contingent cash payment	18,000
Total purchase price	$72,283

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

Assets Acquired:	(In thousands)
Cash and cash equivalents	$1,482
Other current assets	692
IPR&D	65,000
Goodwill	24,530
Total assets	$91,704
Liabilities assumed:	
Accrued expenses	$398
Contingent purchase price	18,000
Deferred tax liability	19,023
Total liabilities	$37,421
Total cash price paid upon acquisition and fair value of existing equity interest	$54,283

Pro forma results of operations for the acquisition of Annovation have not been presented because this acquisition is not material to the Company's consolidated results of operations.

13. Accumulated Other Comprehensive Income
The changes in accumulated other comprehensive income are as follows:

	Foreign currency translation adjustment (in thousands)	Total
Balance as of December 31, 2014	$2,528	$2,528
Other comprehensive income before reclassifications	1,954	1,954
Amounts reclassified from accumulated other comprehensive income*	—	—
Total other comprehensive income	1,954	1,954
Balance as of June 30, 2015	$4,482	$4,482

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

14. Segment and Geographic Information

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

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

	Three Months Ended June 30,						Six Months Ended June 30,			
	2015			2014			2015		2014	
	(in thousands)						(in thousands)			
Net revenue:										
United States	$85,261	94.2	%	$172,898	94.1	%	$206,025	94.9%	$340,377	94.3%
Europe	4,547	5.0	%	9,790	5.3	%	9,637	4.4%	18,509	5.1%
Rest of world	664	0.8	%	1,086	0.6	%	1,326	0.7%	2,123	0.6%
Total net revenue	$90,472	100.0	%	$183,774	100.0	%	$216,988	100.0%	$361,009	100.0%

	June 30,			December 31,		
	2015			2014		
	(in thousands)					
Long-lived assets:						
United States	$1,397,423	99.4	%	$1,218,370	99.3	%
Europe	8,762	0.6	%	8,899	0.7	%
Rest of world	—	—	%	15	—	%
Total long-lived assets	$1,406,185	100.0	%	$1,227,284	100.0	%

15. 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 available information indicates 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 include both patent litigation matters and class action litigation. The Company has assessed such legal proceedings and does not believe that it is probable that a liability has been incurred or that the amount of any potential liability can be reasonably estimated. As a result, the Company did not record any loss contingencies for any of these matters. While it is not possible to determine the outcome of the matters described in Part II, Item 1, Legal Proceedings, of this quarterly report 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 the Company's consolidated results of operations in any one accounting period.

16. Collaboration Agreements

Alnylam Pharmaceuticals, Inc.

In February 2013, the Company entered into a license and collaboration agreement with Alnylam to develop, manufacture and commercialize therapeutic products targeting the proprotein convertase subtilisin/kexin type 9 (PCSK9) gene, based on certain of Alnylam's RNA interference (RNAi) technology. Under the terms of the agreement, the Company obtained the exclusive, worldwide right under Alnylam's technology to develop, manufacture and commercialize PCSK-9 products for the treatment, palliation and/or prevention of all human diseases. Alnylam is responsible for the development costs of the products, subject to an agreed upon limit, until the completion of Phase 1 clinical studies. The Company is responsible for completing and funding the development costs of the products through commercialization, if successful. The Company paid Alnylam $25 million in an initial license payment and an additional $10 million upon the achievement of a milestone, which payments the Company recorded as research and development expenses. The Company has also agreed to pay up to an aggregate of $170 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 I clinical trial of ALN-PCSsc in the UK.

SciClone Pharmaceuticals

On December 16, 2014, the Company entered into 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 has agreed to pay the Company an upfront payment, 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 under ASC 605-25, Revenue Recognition-Multiple Element Arrangements (ASC 605-25) (as amended by ASU 2009-13, Revenue Recognition) 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 under ASC 605-25. 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. Since inception and for the six months ended June 30, 2015, the Company recorded $8.0 million of revenue associated with the SciClone agreement as co-promotion and license income.

The Company believes the regulatory approval milestone that may be achieved under the SciClone agreement are consistent with the definition of a milestone included in ASU 2010-17, Revenue Recognition-Milestone Method, and accordingly, the Company will recognize payment related to the achievement of such milestone, if any, when the applicable milestone is 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.

17. 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 Company completed its reorganization of its European operations in December 2014 and recorded a one-time charge of $9.0 million for the year ended December 31, 2014. Of the $9.0 million in one-time charges, $8.7 million related to work-force reduction, recorded in research and development and selling, general and administrative expenses, and $0.3 million in lease charges recorded in selling, general and administrative expenses.

During the six months ended June 30, 2015, the Company paid $5.4 million in work-force reduction charges and $0.1 million in lease payments. The Company expects to pay the remainder during 2015.

	Balance as of January 1,	Expenses, Net	Cash	Noncash	Balance as of

	2015				June 30, 2015
	(In thousands)				
Employee severance and other personnel benefits:					
2014 European workforce reduction	$7,694	$(713)	$(5,410)	$(6)	$1,565
2014 European leases and equipment write-off	200	—	(130)	—	70
Total	$7,894	$(713)	$(5,540)	$(6)	$1,635

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18. Subsequent Event

On July 2, 2015, the Federal Circuit Court ruled against the Company in its patent infringement litigation with Hospira with respect to the principal U.S. patents covering Angiomax. In its ruling, the Federal Circuit Court held the '727 patent and '343 patent invalid. As a result, the Company does not have market exclusivity for Angiomax (bivalirudin) in the United States. The effect of this decision has been included in the financial statements. In light of the decision by the Federal Circuit Court, in July 2015 the Company entered into a supply and distribution agreement with Sandoz under which it granted Sandoz the exclusive right to sell in the United States an authorized generic of Angiomax (bivalirudin). In addition, in July 2015 Hospira's ANDAs for its generic versions of bivalirudin were approved by the FDA. As a result, Angiomax is now subject to generic competition with the authorized generic and Hospira's generic bivalirudin. Given the generic competition, the Company has determined to suspend its efforts and expenditures with respect to Angiomax other than for supply chain, quality and safety monitoring and other necessary activities.

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, Minocin® (minocycline) for injection, Orbactiv® (oritavancin), PreveLeak™ and Recothrom® Thrombin topical (Recombinant). We received marketing approval in the United States for four of our product candidates during the second quarter of 2015: Ionsys® (fentanyl iontophoretic transdermal system), Kengreal™ (cangrelor), Raplixa™ and RPX-602, a new formulation of Minocin IV. 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. In addition, 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.

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, Ionsys, PreveLeak, Raplixa and Recothrom, are administered intravenously. Each of PreveLeak, Recothrom, and Raplixa is a topical hemostat, Ionsys is administered transdermally and ALN PCSsc is being developed as a subcutaneous injectable. All of our acute care generic products are injectable products.

Product or Product in Development	Development Stage	Mechanism/Target	Clinical Indication(s)/Therapeutic

Areas

Marketed and Approved
Products

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Angiomax	Marketed	Direct thrombin inhibitor	U.S. - for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty, or PTCA, and for use in patients undergoing percutaneous coronary intervention, or PCI, including patients with or at risk of heparin induced thrombocytopenia and thrombosis syndrome, or HIT/HITTS Europe - for use as an anticoagulant in patients undergoing PCI, adult patients with acute coronary syndrome, or ACS, and for the treatment of patients with ST-segment elevation myocardial infarction, or STEMI, undergoing primary PCI
Cleviprex	Marketed in the United States, Australia, Germany, Spain and Switzerland Approved in Austria, Belgium, Canada, France, Liechtenstein, Luxembourg, the Netherlands, New Zealand, Sweden and the United Kingdom Marketing Authorization Application, or MAA, submitted for other European Union countries	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
Ionsys	Approved in the United States in April 2015; MAA accepted for review in European Union in the third quarter of 2014	Patient-controlled analgesia system	Short-term management of acute postoperative pain in hospitalized patients
Kengreal	Approved in the United States in June 2015; Approved in the European Union in the first quarter of 2015	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; RPX-602 new	Tetracycline-class antibiotic	Treatment of bacterial infections due to susceptible isolates of designated

	formulation approved in the United States in April 2015		microorganisms, including Acinetobacter species.
Orbactiv	Marketed in the United States; Approved in the European Union in the first quarter of 2015	Antibiotic	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
PreveLeak	Approved in the United States; Marketed in the European Union	Mechanical vascular and surgical sealant	U.S. - for use as a vascular sealant Europe - for use in cardiac, vascular and soft tissue reconstructions to achieve adjunctive hemostasis by mechanically sealing areas of leakage

Raplixa	Approved in the United States in April 2015; Approved in the European Union in the first quarter of 2015	Dry powder topical formulation of fibrinogen and thrombin	For use as an aid to control mild to moderate bleeding during surgery
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
Recothrom	Marketed in the United States	Recombinant human thrombin	For use as an aid to hemostasis to help control oozing blood and mild bleeding during surgical procedures
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, Ondansteron 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 1 being conducted by Alnylam	PCSK-9 gene antagonist addressing low-density lipoprotein cholesterol disease modification	Treatment of hypercholesterolemia
Carbavance	Phase 3 clinical trial commenced in the fourth quarter of 2014	Combination of 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 completed		

	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 six months ended June 30, 2015, we had net revenue from sales of Angiomax of approximately $166.3 million, net revenue from sales of Recothrom of approximately $32.1 million and aggregate net revenue from sales of Cleviprex, Minocin IV, PreveLeak, Orbactiv and ready-to-use Argatroban of approximately $18.6 million. During this period, net revenue from sales of Angiomax decreased by $152.5 million from the six months ended June 30, 2014. We expect that net revenue from sales of Angiomax will continue to decline in 2015 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 after August 2015.

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 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 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.

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.

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.

On July 29, 2015, the Federal Circuit Court terminated the appeal by Mylan Pharmaceuticals, Inc., or Mylan, and our cross-appeal in the matter, related to the October 27, 2014 decision of the U.S. District Court for the Northern District of Illinois finding that Mylan’s ANDA product infringes all of the asserted claims of the ‘727 patent and that Mylan failed to prove that the same asserted claims of the ‘727 patent are invalid or unenforceable.

As a result of the Federal Circuit Court's rulings Angiomax could be subject to generic competition in the United States from Mylan, Teva, APP and Sun and, if we are unsuccessful in our petition for rehearing in the Hospira matter, from the other ANDA filers 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.

Recent Regulatory Developments

Kengreal. On June 22, 2015, we received FDA approval of our New Drug Application, or NDA, for Kengreal (cangrelor) in the United States. On March 23, 2015, the European Commission granted marketing authorization for Kengrexal (cangrelor) in the European Union.

Ionsys. On April 30, 2015, we received FDA approval of our Supplemental New Drug Application, or sNDA, for Ionsys. In September 2014, the EMA accepted for review the MAA for Ionsys that we had submitted in the European Union.

Raplixa. On April 30, 2015, we received FDA approval of our Biologics License Application, or BLA, for Raplixa. On March 19, 2015, the European Commission granted marketing authorization for Raplixa in the European Union.

Minocin IV. On April 17, 2015, we received FDA approval of our sNDA for RPX-602, our new formulation of Minocin IV. On the same day, the FDA designated the new RPX-602 formulation of Minocin IV a qualified infectious disease product, or QIDP, for certain additional potential indications involving gram-negative indications.

Business Development Activity

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.

Tenaxis Medical, Inc. In May 2014, we completed our acquisition of Tenaxis Medical, Inc., or Tenaxis, and Tenaxis became our wholly owned subsidiary. As a result of the acquisition of Tenaxis, we acquired Tenaxis's sole product, PreveLeak, a vascular and surgical sealant that mechanically seals both human tissue and artificial grafts. In the United States, PreveLeak received a premarket approval from the FDA in March 2013 for use as a vascular sealant, but it has not yet been commercialized in the United States. We expect to begin selling PreveLeak in the United States in 2015. In the European Union, PreveLeak is approved with a European CE Mark for sale as a surgical sealant indicated for vascular, cardiac and soft tissue reconstructions to achieve hemostasis by mechanically sealing areas of leakage. Pursuant to this approval, PreveLeak has been sold in the European Union since September 2008.

Under the merger agreement, we paid to the holders of Tenaxis's capital stock, the holders of options to purchase shares of Tenaxis's capital stock (whether or not such capital stock or options were vested or unvested as of immediately prior to the closing) and the holders of certain warrants and side letters, which we refer to collectively as the Tenaxis equityholders, an aggregate purchase price of approximately $58.9 million in cash, subject to customary adjustments at and after the closing. At the closing, we deposited approximately $5.4 million of the purchase price into an escrow fund for the purposes of securing the indemnification obligations of the Tenaxis 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. During the third quarter of 2014, we finalized the purchase price adjustment process, which resulted in an insignificant adjustment to the purchase price. To the extent that any amounts remain in the escrow fund after October 1, 2015 and are not subject to claims by us, such amounts will be released to the Tenaxis equityholders, subject to certain conditions set forth in the merger agreement.

In addition, we have agreed to pay to the Tenaxis equityholders milestone payments subsequent to the closing, if we achieve certain regulatory approval milestones and commercial net sales milestones with respect to PreveLeak, 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 Tenaxis equityholders up to an additional $112.0 million in cash in the aggregate.

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 terminated and we ceased to co-promote the Promus PREMIER Stent System.

Rempex Pharmaceuticals, Inc. In December 2013, we completed our acquisition of 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 RPX-7009, 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.

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.

ProFibrix B.V. On August 5, 2013, we completed our acquisition of all of the outstanding equity of ProFibrix, pursuant to a share purchase agreement entered into with ProFibrix and its equityholders on June 4, 2013 and ProFibrix became our wholly owned subsidiary. Under the share purchase agreement, the closing of the transaction was subject to our satisfactory review of the results of the then pending FINISH-3 clinical trial, a Phase 3 clinical trial of ProFibrix's lead biologic, Raplixa. Raplixa is a dry powder topical formulation of fibrinogen and thrombin developed to help stop bleeding during surgery. In connection with entering into the agreement, we paid ProFibrix a $10.0 million option payment.

Following our review of the Phase 3 trial results on August 2, 2013, we notified ProFibrix that we wished to proceed with the consummation of the transaction. At the closing, we paid an aggregate purchase price of $90.9 million in cash. We deposited $9.0 million of the purchase price into an escrow fund for the purpose of (i) securing the indemnification obligations of the ProFibrix equityholders and optionholders to us for any and all losses for which we are entitled to indemnification under the share purchase agreement, and (ii) providing the source of recovery for any amounts payable to us as a result of the post-closing purchase price adjustment process. To the extent that any amounts remain in the escrow fund after December 4, 2015 and not subject to claims by us, such amounts will be released to the ProFibrix equityholders, subject to certain conditions set forth in the merger agreement.

Under the terms of the share purchase agreement, we agreed to pay up to an aggregate of $140.0 million in cash to the ProFibrix equityholders and optionholders upon the achievement of certain U.S. and European regulatory approvals prior to January 1, 2016 and certain U.S. and European sales milestones during the 24-month period that follows the initial commercial sale of Raplixa. As a result of our acquisition of ProFibrix, we acquired a portfolio of patents and patent applications, including patents licensed from Quadrant Drug Delivery Limited, or Quadrant, which included the U.S. patent directed to the composition of matter of Raplixa. Under the terms of a license agreement between ProFibrix and Quadrant, we are required to pay low single digit percentage royalties based on annual worldwide net sales of licensed products, including Raplixa, by us or our affiliates and sublicensees. The royalties are subject to reduction in specified circumstances.

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.

Recothrom. In February 2013, pursuant to a master transaction agreement with Bristol-Myers Squibb Company, or BMS, we acquired the right to sell, distribute and market Recothrom on a global basis for a two-year period, which we refer to as the collaboration term, and certain limited assets exclusively related to Recothrom, primarily the biologics license application for Recothrom and certain related regulatory assets. BMS also granted to us, under the master transaction agreement, an option to purchase from BMS and its affiliates, following the expiration or earlier termination of the collaboration term, certain other assets, including certain patent and trademark rights, contracts, inventory, equipment and related books and records, held by BMS which are exclusively related to Recothrom. Pursuant to the agreement, we exercised our option and on February 6, 2015 we completed our acquisition of the remaining assets held by BMS which are exclusively related to Recothrom.

Under the master transaction agreement, in February 2013 we paid to BMS a one-time collaboration fee equal to $105.0 million and a one-time option fee equal to $10.0 million. Upon closing the exercise of the option, in February 2015 we paid BMS approximately $127.7 million in the aggregate, including approximately $39.3 million for inventory. In March 2015, we paid BMS $4.7 million upon the delivery of certain additional inventory following the closing.

We did not assume any pre-existing liabilities related to the Recothrom business, contingent or otherwise, arising prior to the collaboration period, and we did not acquire any significant tangible assets related to the Recothrom business, other than inventory. Under the master transaction agreement, we paid BMS quarterly tiered royalty payments during the two-year collaboration term equal to a percentage of worldwide net sales of Recothrom.

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 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, if we enter into a license agreement in Japan or achieve certain regulatory approval or sales milestones with respect to Ionsys.

Collaboration with AstraZeneca. On April 25, 2012, we entered into a global collaboration agreement with AstraZeneca LP, or AstraZeneca, pursuant to which we and AstraZeneca agreed to collaborate globally to develop and commercialize certain acute ischemic heart disease compounds. 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.

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 which Rempex has the potential to receive up to $89.8 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. 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 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 $2.3 million and $5.5 million of reimbursements by the government as a reduction of research and development expenses for the three and six months ended June 30, 2015.

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.

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.

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.

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.

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; 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.

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. 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.

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 certain specified circumstances which are set forth in the indenture governing the 2017 notes. 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 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 notes.

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 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.

See note 10, "Convertible Senior Notes," in the accompanying notes to condensed consolidated financial statements for additional information with respect to the 2017 notes and 2022 notes.

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. Consistent with past practice, Biogen is in the process of auditing our books and records to verify the accuracy of the amounts paid to Biogen under the license agreement.

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 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 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 RPX-602 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 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, the FDA informed us that Orbactiv meets 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 RPX-602 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.

Results of Operations

Net Revenue:

Net revenue decreased 50.8% to $90.5 million for the three months ended June 30, 2015 as compared to $183.8 million for the three months ended June 30, 2014. Net revenue decreased to $217.0 million for the six months ended June 30, 2015, a 39.9% decrease from $361.0 million for the six months ended June 30, 2014.

The following table reflects the components of net revenue for the three and six months ended June 30, 2015 and 2014:

Net Revenue

	Three Months Ended June 30,	Six Months Ended June 30,

	2015	2014	Change $	Change %	2015	2014	Change $	Change %
	(in thousands)							
Angiomax	$65,576	163,097	$(97,521)	(59.8)%	$166,255	$318,801	$(152,546)	(47.8)%
Recothrom	15,856	16,283	(427)	(2.6)%	32,136	29,776	2,360	7.9%
Other products	9,040	4,394	4,646	105.7%	18,597	12,432	6,165	49.6%
Total net revenue	$90,472	$183,774	$(93,302)	(50.8)%	$216,988	$361,009	$(144,021)	(39.9)%

Net revenue decreased by $93.3 million, or 50.8%, to $90.5 million in the three months ended June 30, 2015 compared to $183.8 million in the three months ended June 30, 2014, reflecting decreases in net revenue in the United States of $87.6 million and in international markets of $5.7 million.

Net revenue decreased by $144.0 million, or 39.9%, to $217.0 million in the six months ended June 30, 2015 compared to $361.0 million in the six months ended June 30, 2014, reflecting decreases of $134.3 million in the United States and of $9.7 million in international markets.
Angiomax. Net revenue from sales of Angiomax decreased by $97.5 million, or 59.8%, to $65.6 million in the three months ended June 30, 2015 compared to $163.1 million in the three months ended June 30, 2014, primarily due to volume decreases of $90.1 million in the United States and in international markets and $11.1 million associated with reduction in sales prices, offset by a favorable impact of foreign exchange of $3.6 million. We believe that volume decreases for Angiomax in the three months ended June 30, 2015 were primarily the result of reductions in wholesaler purchases due to uncertainty regarding Angiomax's patent exclusivity in the United States past June 2015. On July 2, 2015, the Federal Circuit Court ruled that our '343 patent and '727 patent, each covering Angiomax, were invalid. As a result, the Company does not have market exclusivity for Angiomax in the United States. We expect that net revenue from sales of Angiomax will continue to decline in 2015 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 after August 2015.
Net revenue in the United States in both the three months ended June 30, 2015 and 2014 reflect chargebacks related to the 340B Drug Pricing Program and rebates related to the PPACA. Under the 340B Drug Pricing Program, we offer qualifying entities a discount off the commercial price of Angiomax for patients undergoing PCI on an outpatient basis. Chargebacks related to the 340B Drug Pricing Program decreased by $6.6 million to $15.7 million in the three months ended June 30, 2015 compared to $22.3 million in the three months ended June 30, 2014, primarily due to the reduction in wholesaler purchases, which were partially offset by higher amounts paid to eligible hospital customers. Rebates related to the PPACA increased by $0.4 million to $0.6 million in the three months ended June 30, 2015 compared to $0.2 million in the three months ended June 30, 2014.
Net revenue from sales of Angiomax decreased by $152.5 million, or 47.8%, to $166.3 million in the six months ended June 30, 2015 compared to $318.8 million in the six months ended June 30, 2014, primarily due to volume decreases in the United States. We believe that the volume decrease for Angiomax in the six months ended June 30, 2015 is primarily the result of a reduction in wholesaler purchases due to uncertainty regarding Angiomax's patent exclusivity in the United States past June 2015. Net revenue in the United States in both the six months ended June 30, 2015 and 2014 reflect chargebacks related to the 340B Drug Pricing Program under the Public Health Service Acts and rebates related to the PPACA. Chargebacks related to the 340B Drug Pricing Program decreased by $1.3 million to $38.9 million in the six months ended June 30, 2015 compared to $40.2 million in the six months ended June 30, 2014, primarily due to primarily due to reduction in wholesaler purchases, partially offset by higher amounts paid to eligible hospital customers. Rebates related to the PPACA increased by $0.3 million to $1.2 million in the six months ended June 30, 2015 compared to $0.9 million in the six months ended June 30, 2014.
Recothrom. Net revenue from Recothrom decreased by $0.4 million, or 2.6%, to $15.9 million in the three months ended June 30, 2015 compared to $16.3 million in the three months ended June 30, 2014 primarily due to a slight decreases in volume.
Net revenue from Recothrom increased by $2.4 million, or 7.9%, to $32.1 million in the six months ended June 30, 2015 compared to $29.8 million in the six months ended June 30, 2014 due to increases in both price and volume.
Other Products. Net revenue from sales of Cleviprex, Minocin IV, PreveLeak, Orbactiv and ready-to-use Argatroban increased by approximately $4.6 million, or 105.7%, to $9.0 million in the three months ended June 30, 2015 from $4.4 million in the three months ended June 30, 2014, primarily due to the increase in revenue from Cleviprex, Orbactiv and Minocin IV. We commenced the sale of PreveLeak in Europe in May 2014 after our acquisition of Tenaxis, and the sale of Orbactiv in the United States in October 2014. Net revenue from sales of Cleviprex was $3.3 million in the three months ended June 30, 2015, compared to $1.4 million in the three months ended June 30, 2014. Net revenue from sales of ready-to-use Argatroban was $2.8 million in the three months ended June 30, 2015, compared to $2.6 million in the three months ended June 30, 2014. Net revenue from sales of Minocin IV was $0.8 million in the three months ended June 30, 2015 compared to $0.3 million in the three months ended June 30, 2014. Net revenue from sales of PreveLeak was $0.1 million in the three months ended June 30, 2015, compared to $0.1 million in the three months ended June 30, 2014. Net revenue from sales of Orbactiv was $1.9 million in the three

months ended June 30, 2015. Under our revised revenue recognition policy, beginning with the first quarter for 2014, we recognize revenue for Cleviprex and ready-to-use Argatroban as product was sold to Integrated Commercialization Solutions, or ICS. For periods prior to 2014, we recognized revenue for Cleviprex and ready-to-use Argatroban using the deferred revenue model.

Net revenue from sales of Cleviprex, Minocin IV, PreveLeak, Orbactiv and ready-to-use Argatroban increased by $6.2 million, or 49.6%, to $18.6 million in the six months ended June 30, 2015 from $12.4 million in the six months ended June 30, 2014, primarily due to increases in revenue from Orbactiv, Cleviprex, Minocin IV and ready-to-use Argatroban. During the first quarter of 2014, we recognized one-time increases of $0.7 million in net sales of Cleviprex and $1.6 million in net sales of ready-to-use Argatroban, representing product sales previously deferred as of December 31, 2013, net of chargebacks and other discounts or accruals for product returns, rebates and fee-for-service charges. Net revenue from sales of Cleviprex was $5.5 million in the six months ended June 30, 2015, compared to $4.0 million in the six months ended June 30, 2014. Net revenue from sales of ready-to-use Argatroban was $8.1 million in the six months ended June 30, 2015, compared to $7.6 million in the six months ended June 30, 2014. Net revenue from sales of Minocin IV and PreveLeak was $1.6 million and $0.2 million, respectively, in the six months ended June 30, 2015, compared to $0.6 million and $0.1 million, respectively, in the six months ended June 30, 2014. Net revenue from sales of Orbactiv was $3.1 million in the six months ended June 30, 2015.

Cost of Revenue:

Cost of revenue for the three months ended June 30, 2015 was $37.0 million, or 40.9% of net revenue, compared to $85.7 million, or 46.6% of net revenue, in the three months ended June 30, 2014. Cost of revenue for the six months ended June 30, 2015 was $70.7 million, or 32.6% of net revenue, compared to $152.6 million, or 42.3% of net revenue, for the six months ended June 30, 2014

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 during the six months ended June 30, 2014 under our agreements with Biogen and HRI related to Angiomax;
- royalty expenses during the six months ended June 30, 2014 and 2015 under our agreement with AstraZeneca related to Cleviprex, and our agreement with Eagle Pharmaceuticals, Inc., or Eagle, related to ready-to-use Argatroban;
- royalty expenses during the six months ended June 30, 2015 under our agreement with Eli Lilly and Company, or Lilly, related to Orbactiv;
- amortization and impairment of the costs of license agreements, product rights, developed product rights and other identifiable intangible assets, which result from product and business acquisitions;
- logistics costs related to Angiomax, Recothrom, Cleviprex, Orbactiv, Minocin IV, PreveLeak and ready-to-use Argatroban, including distribution, storage, and handling costs; and
- during the six months ended June 30, 2014 and the six months ended June 30, 2015, expenses related to our license agreement with BMS for Recothrom and expenses related to our supply agreement for Recothrom with BMS including product cost and logistics as well as royalties and amortization related to Recothrom.

Cost of Revenue

	Three Months Ended June 30,				Six Months Ended June 30,			
	2015	% of Total	2014	% of Total	2015	% of Total	2014	% of Total
	(in thousands)		(in thousands)		(in thousands)		(in thousands)	
Manufacturing/Logistics	$25,659	69 %	$23,472	27 %	$47,932	68 %	$44,764	30 %
Royalties	1,757	5 %	40,697	48 %	6,819	10 %	81,182	53 %
Amortization and impairment of inventory acquired product rights and intangible assets	9,583	26 %	21,518	25 %	15,986	22 %	26,608	17 %
Total cost of revenue	$36,999	100 %	$85,687	100 %	$70,737	100 %	$152,554	100 %

Cost of revenue decreased by $48.7 million during the three months ended June 30, 2015 compared to the three months ended June 30, 2014, and by $81.8 million during the six months ended June 30, 2015 compared to the six months ended June 30, 2014, primarily due to decreases in Angiomax product sales, decreases in Angiomax royalty expenses due to the termination on December 15, 2014 of our royalty obligations to Biogen and HRI on sales of Angiomax in the United States and decreases in royalty expenses associated with Recothrom from the termination on February 6, 2015 of our royalty obligations to BMS as a result of our acquisition of the remaining Recothrom assets from BMS. In addition, the decrease in cost of revenue in both periods reflects a $15.1 million of each decrease was due to an impairment charge on product licenses recorded in the three months ended June 30, 2014 as a result of an expectation of reduced cash flows to be generated by acute care generic products. These decreases were offset by $3.6 million and $7.6 million of impairment charges on product licenses and potential inventory obsolescence for the three and six months ended June 30, 2015, respectively. Both charges are primarily related to the loss of Angiomax exclusivity in the United States announced in July of 2015.

Research and Development Expenses:

Research and Development Spending

(in thousands, except percentages)	Three Months Ended June 30, 2015	% of Total	2014	% of Total	Six Months Ended June 30, 2015	% of Total	2014	% of Total
Marketed products	$13,869	38 %	$5,826	14 %	$19,931	33 %	$10,745	15 %
Registration stage product candidates	—	— %	15,183	37 %	5,908	10 %	31,534	44 %
Research and development product candidates	22,353	62 %	20,219	49 %	34,332	57 %	30,045	41 %
Total research and development expenses	$36,222	100 %	$41,228	100 %	$60,171	100 %	$72,324	100 %

Research and development expenses decreased by $5.0 million during the three months ended June 30, 2015 compared to the three months ended June 30, 2014, primarily due to decreases in expenses associated with MDCO-216, Ionsys, Raplixa and Kengreal. Research and development expenses associated with MDCO-216 decreased by $4.0 million, reflecting higher costs incurred in 2014 to support manufacturing development scale up efforts. Research and development expenses associated with Ionsys, Raplixa and Kengreal decreased by $2.3 million, $1.7 million and $1.4 million, respectively, reflecting the completion of required regulatory filings for marketing approval during 2014. These decreases in our research and development expenses were offset partially by increases in expenses associated with our Phase I clinical trial for ALN-PCSsc , the ongoing Phase 3 clinical trial for Carbavance and the ongoing Phase 1 clinical trial of ABP-700.

Research and development expenses decreased by $12.2 million during the six months ended June 30, 2015 compared to the six months ended June 30, 2014, primarily due to decreases in expenses associated with Raplixa, MDCO-216, Kengreal, Ionsys and Orbactiv. Research and development expenses associated with Raplixa, Ionsys and Kengreal decreased by $7.1 million, $2.3 million and $2.5 million respectively, reflecting the completion of required regulatory filings for marketing approval during 2014. Research and development expenses associated with MDCO-216 decreased by $4.1 million, reflecting higher costs incurred in 2014 to support manufacturing development scale up efforts. Research and development expenses related to Orbactiv decreased by $2.2 million as a result of the completion of research and development activities related to its approval by the FDA during 2014. These decreases in our research and development expenses were offset partially by increases in expenses associated with our Phase I clinical trial for ALN-PCSsc , the ongoing Phase 3 clinical trial for Carbavance and the ongoing Phase 1 clinical trial of ABP-700.

We expect research and development expenses in 2015 to continue to increase primarily due to increased costs related to manufacturing development activities for Carbavance, Ionsys, Orbactiv, MDCO-216 and ALN-PCSsc; and clinical trials of MDCO-216, ABP-700 and ALN-PCSsc; continuation of our ongoing Phase 3 clinical trial of Carbavance; and additional clinical trials of Kengreal, Cleviprex and Orbactiv for use in additional patient populations and lifecycle management activities.

Selling, General and Administrative Expenses:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2015	2014	Change $	Change %	2015	2014	Change $	Change %
	(in thousands)				(in thousands)			
Selling, general and administrative expenses	$96,246	$88,745	$7,501	8.5 %	$176,780	$153,266	$23,514	15.3 %

Selling, general and administrative expenses increased by $7.5 million for the three months ended June 30, 2015 as compared to the three months ended June 30, 2014, primarily due to a $13.9 million increase in selling, marketing and promotional expenses and partially offset by a $6.4 million decrease in general corporate and administrative expenses.

Selling, marketing and promotional expenses increased by $13.9 million primarily to support our late 2014 product launches of Orbactiv and Minocin IV and the anticipated launches of Raplixa and Ionsys.

General corporate and administrative expenses decreased by $6.4 million for the three months ended June 30, 2015 as compared to the three months ended June 30, 2014, primarily due to a decrease of $4.9 million reflecting adjustments to the fair value of the contingent consideration due to the former equityholders of Targanta, Incline, ProFibrix, Rempex, Tenaxis and Annovation, a decrease of $1.4 million in amortization expenses due to the intangibles related to Angiomax becoming fully amortized during 2014.

Selling, general and administrative expenses increased by $23.5 million for the six months ended June 30, 2015 as compared to the six months ended June 30, 2014, primarily due to a $27.1 million increase in selling, marketing and promotional expenses and partially offset by a $3.6 million decrease in general corporate and administrative expenses.

Selling, marketing and promotional expenses increased by $27.1 million primarily to support our late 2014 product launches of Orbactiv and Minocin IV and the anticipated launches of recently approved products of Raplixa and Ionsys.

General corporate and administrative expenses decreased by $3.6 million for the six months ended June 30, 2015 as compared to the six months ended June 30, 2014, primarily due to a decrease of $5.9 million reflecting adjustments to the fair value of the contingent consideration due to the former equityholders of Targanta, Incline, ProFibrix, Rempex, Tenaxis and Annovation and a decrease of $2.7 million in amortization expenses due to the intangibles related to Angiomax becoming fully amortized during 2014, which were partially offset by an increase of $4.4 million in corporate infrastructure costs to support our growing product portfolio resulting from our acquisitions during 2013, 2014 and 2015 and an increase of $0.6 million in share based compensation.

We expect our selling, general and administrative expenses will continue to increase in 2015 due to increased costs related to the commercial launches of our approved product candidates.

Co-promotion and license income:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2015	2014	Change $	Change %	2015	2014	Change $	Change %
	(in thousands)				(in thousands)			
Co-promotion and license income	$638	$7,326	$(6,688)	(91.3)%	$9,026	$13,346	$(4,320)	(32.4)%

During the three months ended June 30, 2015, we recorded license income of $0.1 million under our collaboration agreement with SciClone Pharmaceuticals, or SciClone, and $0.5 million in co-promotion income under our license agreement with Eagle related to ready-to- use Argatroban.

During the three months ended June 30, 2014, we recorded $7.3 million of co-promotion income, primarily related to our collaboration agreements with BSX and AstraZeneca. The collaboration agreements with BSX and AstraZeneca terminated effective December 31, 2014.

During the six months ended June 30, 2015, we recorded license income of $8.0 million under our collaboration agreement with SciClone and $1.1 million in co-promotion income under our license agreement with Eagle related to ready-to-use Argatroban.

During the six months ended June 30, 2014, we recorded $13.3 million of co-promotion income related to our collaboration agreements with BSX and AstraZeneca and our license agreement with Eagle related to ready-to-use Argatroban. The collaboration agreements with BSX and AstraZeneca terminated effective December 31, 2014.

Gain on sale of investment:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2015	2014	Change $	Change %	2015	2014	Change $	Change %
	(in thousands)				(in thousands)			
Gain on sale of investment	$19,773	$—	$19,773	*	$19,773	$—	$19,773	*

* Represents a change in excess of 100%

In the second quarter of 2015, we sold an investment in a specialty pharmaceutical company that had a zero cost basis as the carrying amount was deemed impaired in 2009 and realized a net gain on sale of approximately $19.8 million. This amount is reflected in our consolidated statement of income as a gain on sale of investment during the second quarter of 2015.

Loss in equity investment:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2015	2014	Change $	Change %	2015	2014	Change $	Change %
	(in thousands)				(in thousands)			
Loss in equity investment	$—	—	$—	—%	$(144)	$—	$(144)	*

*Represents an increase in excess of 100%

We completed the acquisition of Annovation in February 2015 and Annovation became our wholly owned subsidiary. During the six months ended June 30, 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 June 30,				Six Months Ended June 30,			
	2015	2014	Change $	Change %	2015	2014	Change $	Change %
	(in thousands)				(in thousands)			
Gain on remeasurement of equity investment	$—	—	$—	—%	$22,741	$—	$22,741	*

*Represents an increase in excess of 100%

We completed the acquisition of Annovation in February, 2015 and Annovation became our wholly owned subsidiary. We accounted in connection with 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 six months ended June 30, 2015. Please refer to Note 12, Acquisitions, to the consolidated financial statements included herein for additional information.

Interest Expense:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2015	2014	Change $	Change %	2015	2014	Change $	Change %
	(in thousands)				(in thousands)			
Interest expense	$(9,348)	$(3,892)	$(5,456)	140.2 %	$(17,955)	$(7,752)	$(10,203)	131.6 %

During the three months ended June 30, 2015, we recorded approximately $9.3 million in interest expense related to the 2017 notes and 2022 notes as compared to $3.9 million in interest expense related to the 2017 notes during the three months ended June 30, 2014. During the six months ended June 30, 2015, we recorded approximately $18.0 million in interest expense related to the 2017 notes and 2022 notes as compared to $7.8 million in interest expense related to the 2017 notes during the six months ended June 30, 2014.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 2015 as compared to 2014 as a result of the interest expense due under the 2022 notes.

Other (expense) income:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2015	2014	Change $	Change %	2015	2014	Change $	Change %
	(in thousands)				(in thousands)			
Other income	$94	(150)	$244	*	$203	$29	$174	*

*Represents a change in excess of 100%.

Other income, which is comprised of interest income and gains and losses on foreign currency transactions increased by $0.2 million for the three months ended June 30, 2015 as compared to the three months ended June 30, 2014. This increase was primarily due to increased interest income and reduced losses on foreign currency transactions in the three months ended June 30, 2015.

Other income increased by $0.2 million for the six months ended June 30, 2015, as compared to the six months ended June 30, 2014, primarily due to increased interest income and reduced losses on foreign currency transactions, partially offset by a loss on the sale of fixed assets in the first quarter of 2015.

Benefit for Income Tax:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2015	2014	Change $	Change %	2015	2014	Change $	Change %
	(in thousands)							
Benefit for income tax	$21,298	$23,428	$(2,130)	(9.1)%	$15,521	$1,333	$14,188	*

*Represents a change in excess of 100%.

We recorded a $21.3 million benefit for income taxes and a $23.4 million benefit for income taxes for the three months ended June 30, 2015 and 2014, respectively, based on loss before taxes of $67.8 million and $28.6 million for the same periods. Our effective income tax rates for the three months ended June 30, 2015 and 2014 were approximately 31.4% and 81.9%, respectively. This decrease in effective tax rate was primarily driven by a projected loss for the year 2015 and a discrete tax benefit related to a partial release in a valuation allowance related to Dutch net operating losses associated with ProFibrix B.V., as a result of the regulatory approvals of Raplixa in both the United States and European Union, which were offset by the establishment of a valuation allowance against certain deferred tax assets, an increase in foreign taxable income, and an increase in the non-cash tax impact arising from changes in the value of contingent consideration under our agreements for the acquisitions of Targanta, Incline, ProFibrix, Rempex, Tenaxis and Annovation.

According to the standards of ASC 740, we consider all available evidence, both positive and negative, to determine whether, based on the weight of that evidence, a valuation allowance is needed to reduce our deferred tax assets to the amount that is more likely than not to be realized. We place significant weight on the following pieces of negative evidence:

- We expect to be in a cumulative net loss for the three-year period ended December 31, 2015 as Angiomax will now face generic competition in the U.S. due to the July 2, 2015 decision by the Federal Circuit Court which held the ‘727 patent and ‘343 patent invalid.

- The commercial success of our marketed and approved products is not assured.

We recorded a $15.5 million benefit for income taxes and a $1.3 million benefit for income taxes for the six months ended June 30, 2015 and June 30, 2014, respectively, based on loss before taxes of $57.1 million and $11.5 million for the same periods. Our effective income tax rates for the six months ended June 30, 2015 and June 30, 2014 were approximately 27.2% and 11.6%, respectively. This increase in the effective tax rate is primarily due the establishment of a valuation allowance against certain deferred tax assets, an increase in foreign taxable income, and an increase in the non-cash tax impact arising from changes in the value of contingent consideration related to the Company's acquisitions of Targanta, Incline, ProFibrix, Rempex and Tenaxis and Annovation., offset primarily by a discrete tax benefit related to a partial release in a valuation allowance related to Dutch net operating losses associated with ProFibrix B.V., as a result of the regulatory approvals of Raplixa in both the United States and European Union.

According to the standards of ASC 740, we consider all available evidence, both positive and negative, to determine whether, based on the weight of that evidence, a valuation allowance is needed to reduce our deferred tax assets to the amount that is more likely than not to be realized. We place significant weight on the following pieces of negative evidence:

- We expect to be in a cumulative net loss for the three-year period ended December 31, 2015 as Angiomax will now face generic competition in the U.S. due to the July 2, 2015 decision by the Federal Circuit Court which held the ‘727 patent and ‘343 patent invalid.

- The commercial success of our marketed and approved products is not assured.

We expect that our full year 2015 effective tax rate will be lower than 2014 due to an anticipated decrease in pre-tax income compared to 2014 and our recording of certain valuation allowances against such losses and other deferred tax assets during the current period. It is possible that our full year effective tax rate could change because of discrete events, our mix of U.S. to foreign earnings, specific transactions, or the receipt of new information affecting our current projections.

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

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have financed our operations principally through revenues from sales of Angiomax, the sale of common stock, convertible promissory notes and warrants and interest income. We expect revenue from sales of Angiomax will be significantly lower in 2015 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 June 30, 2015, we had $462.7 million in cash and cash equivalents, as compared to $370.7 million as of December 31,

2014. The increase in cash and cash equivalents in the six months ended June 30, 2015 was primarily due to $281.2 million of net cash provided by financing activities, partially offset by $107.5 million of net cash used in investing activities and $82.0 million of net cash used in operating activities.

Net cash used in operating activities was $82.0 million in the six months ended June 30, 2015, compared to net cash provided by operating activities of $44.5 million in the six months ended June 30, 2014. The cash used by operating activities in the six months ended June 30, 2015 is primarily due to a net loss of $41.5 million and changes in working capital items of $48.6 million, partially offset by increases due to non-cash items of $8.1 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 BMS in February 2015. Decreases to accounts payable and accrued expenses were offset by decreases in accounts receivable primarily due to timing of customer payments and lower overall revenue. Non-cash items consist of depreciation and amortization, amortization of debt discount, share-based compensation expense, recognition of a gain on remeasurement of equity interest in Annovation, deferred tax provision and excess tax benefit from share-based compensation arrangements and adjustments in contingent purchase price.

Net cash provided by operating activities was $44.5 million in the six months ended June 30, 2014. The cash provided by operating activities in the six months ended June 30, 2014 primarily relates to non-cash items of $71.2 million offset by $16.5 million decrease resulting from changes in working capital items. Non-cash items consist of depreciation and amortization, impairment charge, amortization of debt discount, share-based compensation expense, deferred tax provision and excess tax benefit from share-based compensation arrangements and adjustment in contingent purchase price. The changes in working capital items reflect a decrease in accounts payable and accounts receivable of $37.9 million primarily due to timing of payments of certain corporate expenses and customer payments, a decrease of $2.7 million in deferred revenue, a decrease of $4.9 million in other liabilities and increases of $28.3 million in accrued expenses and $1.1 million in inventory.

During the six months ended June 30, 2015, $107.5 million in net cash was used in investing activities, primarily due to the payment of $28.4 million in connection with our acquisition of Annovation in February 2015, $88.1 million in connection with our acquisition of the remaining Recothrom assets in February 2015, partially offset by $19.8 million from the sale of an investment.

During the six months ended June 30, 2014, $64.9 million in net cash was used in investing activities, primarily for the purchase of Tenaxis.

Net cash provided by financing activities was $281.2 million in the six months ended June 30, 2015, which reflected $387.2 million in net proceeds from the issuance of convertible notes in January 2015 and $20.8 million of proceeds from option exercises, offset by $126.8 million in milestone payments and $0.1 million in excess tax benefits and purchases of stock under our employee stock purchase plan.

Net cash provided by financing activities was $11.2 million in the six months ended June 30, 2014, which reflected $9.5 million of proceeds from option exercises and $1.7 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 August 7, 2015, 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;

- $115.0 million due to the former equityholders of Incline and up to $108.0 million in additional payments to other third parties related to the Incline transaction;

- $50.0 million for the ProFibrix transaction;
- $300.2 million for the Rempex transaction;
- $110.0 million for the Tenaxis 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 cangrelor from AstraZeneca.

As of August 7, 2015, 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 $1,433.0 million. Of this amount, approximately $175.0 million relates to development milestones, $296.0 million relates to regulatory approval milestones and $962.0 million relates to commercial milestones.
In addition, of the total potential milestone payment obligations, based on our earliest 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 up to $77.7 million during the remainder of 2015. The majority of our anticipated payments for 2015 relate to the achievement of regulatory approval and commercial milestones for Ionsys and the remainder of these payments relate to the achievement of development milestones for our other products in development.

Net revenue from sales of Angiomax were significantly lower in the three months ended June 30, 2015, 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.

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;
- 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 expect to generate from our operations will be sufficient to meet our ongoing funding requirements, 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, but excluding any future material acquisition activity. If our existing cash resources, together with revenues that we generate from sales of our products and other sources, are insufficient to satisfy these funding requirements due to lower than anticipated sales of our marketed products, including Angiomax which we expect will generate significantly lower revenues, or due to higher than anticipated costs associated with product launches, investments in research and development or otherwise, we will need to sell additional equity or debt securities or seek additional financing through other arrangements to increase our cash resources. In addition, we will need to sell additional equity or debt securities or seek additional financing through other arrangements to increase our cash resources or enter into other arrangements to meet our obligations with respect to the principal under the 2017 notes and the 2022 notes. Any sale of additional equity or 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. Further, we may seek additional financing to fund our acquisitions of development stage compounds, clinical stage product candidates and approved products and/or the companies that have such products, and we may not be able to obtain such financing on terms acceptable to us or at all. If we are unable to obtain additional financing, we may be required to delay, reduce the scope of, or eliminate one or more of our planned research, development and commercialization activities, which could adversely affect our business, financial condition and operating results.

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.

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 both patent litigation matters and class action litigation. We have assessed such legal proceedings and do not believe that it is probable that a liability has been incurred and the amount of such liability can be reasonably estimated. As a result, we have not recorded a loss contingency related to these legal proceedings.

Contractual Obligations

Our long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business. These include commitments related to royalties, milestone payments, option exercise and other contingent payments due under our license and acquisition agreements, purchases of inventory of our products, research and development service agreements, income tax contingencies, operating leases, selling, general and administrative obligations and increases to our restricted cash in connection with our lease of our principal office space in Parsippany, New Jersey as of June 30, 2015.

During the quarter ended June 30, 2015 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, 2014.

Application of Critical Accounting Estimates

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

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

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

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

Our significant accounting policies are more fully described in note 2 of our unaudited consolidated financial statements in this Quarterly Report 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, 2014. We do not recognize revenue from product sales until there is persuasive evidence of an arrangement, delivery has occurred, the price is fixed and determinable, the buyer is obligated to pay us, the obligation to pay is not contingent on resale of the product, the buyer has economic substance apart from us, we have no obligation to bring about the sale of the product, the amount of returns can be reasonably estimated and collectability is reasonably assured. We distribute Angiomax in the United States through a sole source distribution model with ICS under which ICS sells Angiomax to a limited number of national medical and pharmaceutical wholesalers and distribution centers located throughout the United States and, in certain cases, directly to hospitals. Under this model and in accordance with our revenue recognition policy, we have recorded revenue upon shipment of Angiomax to ICS. However Angiomax's market exclusivity in the United States ended July 2, 2015 and Angiomax has become subject to generic competition in the United States, including by our authorized generic sold by Sandoz and Hospira's generic bivalirudin products. As a result, we expect that in the near term, we may not be able to reasonably conclude that our price is fixed and determinable at the point when we ship to ICS as there may be uncertainty over finalization of pricing due to expected generic competition and the impact generic competition will have on our pricing of Angiomax. As a result, in the third quarter of 2015, we may defer Angiomax revenues and its related costs until Angiomax is sold to the end customers (i.e. hospitals) if we consider that the sale prices are not fixed or determinable at the time of shipment to ICS. We estimate that the impact of this change in revenue recognition accounting policy for Angiomax may result in lower net revenues and cost of revenues for Angiomax in the third quarter of 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 asset including in-process R&D 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, 2014 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 six months ended June 30, 2015.

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. There were no new accounting pronouncements adopted during the three months ended June 30, 2015 that had a material effect on our financial statements.

Forward-Looking Information

This Quarterly Report on Form 10-Q includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. For this purpose, any statements contained herein regarding our strategy, future operations, financial position, future revenue, projected costs, prospects, plans and objectives of management, other than statements of historical facts, are forward-looking statements. The words “anticipates,” “believes,” “estimates,” “expects,” “intends,” “may,” “plans,” “projects,” “will,” “would” and similar expression 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 June 30, 2015, we held $462.7 million in cash and cash equivalents, which had an average interest rate of approximately 0.32%. A 10% change in such average interest rate would have had an approximate $0.1 million impact on our interest income. At June 30, 2015, all cash and cash equivalents were due on demand or within one year.

Most of our transactions are conducted in U.S. dollars. We do have certain agreements with parties located outside the United States. Transactions under certain of these agreements are conducted in U.S. dollars, subject to adjustment based on significant fluctuations in currency exchange rates. Transactions under certain other of these agreements are conducted in the local foreign currency. As of June 30, 2015, we had receivables denominated in currencies other than the U.S. dollar. A 10% change in foreign exchange rates would have had an approximate $0.5 million impact on our other income and cash.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2015. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission, or SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2015, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended June 30, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Part II. Other Information

Item 1. Legal Proceedings

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

'727 Patent and '343 Patent Litigations

Hospira, Inc.

In July 2010, we were notified that Hospira, Inc., or Hospira, had submitted two ANDAs seeking permission to market its generic version of Angiomax prior to the expiration of the '727 patent and '343 patent. On August 19, 2010, we filed suit against Hospira in the U.S. District Court for the District of Delaware for infringement of the '727 patent and '343 patent. On August 25, 2010, the case was reassigned in lieu of a vacant judgeship to the U.S. District Court for the Eastern District of Pennsylvania. Hospira's answer denied infringement of the '727 patent and '343 patent and raised counterclaims of non-infringement and invalidity of the '727 patent and '343 patent. On September 24, 2010, we filed a reply denying the counterclaims raised by Hospira. The Hospira action was consolidated for discovery purposes with the then pending and now settled cases against Teva and APP. The case was reassigned back to the U.S. District Court for the District 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 31, 2015, we filed a combined petition for panel rehearing and rehearing en banc. On July 15, 2015, Hospira received final approval for its ANDAs.

Mylan Pharmaceuticals, Inc.

In January 2011, we were notified that Mylan Pharmaceuticals, Inc. had submitted an ANDA seeking permission to market its generic version of Angiomax prior to the expiration of the '727 patent and '343 patent. On February 23, 2011, we filed suit against Mylan Inc., Mylan Pharmaceuticals Inc. and Bioniche Pharma USA, LLC, which we refer to collectively as Mylan, in the U.S. District Court for the Northern District of Illinois for infringement of the '727 patent and '343 patent. Mylan's answer denied infringement of the '727 patent and '343 patent and raised counterclaims of non-infringement and invalidity of the '727 patent and '343 patent. On April 13, 2011, we filed a reply denying the counterclaims raised by Mylan. On May 4, 2011 the Court set a pretrial schedule. Following a joint request, the Court issued an amended scheduling order on September 22, 2011. On November 29, 2011, Mylan moved to amend its answer to add counterclaims and affirmative defenses of inequitable conduct and unclean hands. Following motion practice, the Court granted Mylan's request to add counterclaims and affirmative defenses of inequitable conduct and to add affirmative defenses of unclean hands. On March 7, 2012, we filed a reply denying these counterclaims. A Markman hearing was held on July 30, 2012. The Court issued a Markman Order on August 6, 2012. The parties have completed fact and expert discovery. On June 21, 2013, Mylan filed a summary judgment motion of non-infringement 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.

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. No schedule or trial date has been set.

Sun Pharmaceutical Industries LTD

In October 2011, we were notified that Sun Pharmaceutical Industries LTD had submitted an ANDA seeking permission to market its generic version of Angiomax prior to the expiration of the '727 and '343 patents. On November 21, 2011, we filed suit against Sun Pharma Global FZE, Sun Pharmaceutical Industries LTD., Sun Pharmaceutical Industries Inc., and Caraco Pharmaceutical Laboratories, LTD., which we refer to collectively as Sun, in the U.S. District Court for the District of New Jersey for infringement of the '727 patent and '343 patent. The case has been assigned to the same judge and magistrate judge as the Dr. Reddy's action. Sun's answer denied infringement of the '727 patent and '343 patent. On June 7, 2012, the Court held an initial case scheduling conference. 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 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 is 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.

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.

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.

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. We are presently evaluating the materials provided by Sagent.

Eagle Pharmaceuticals, Inc.

In July 2015, we were notified that Eagle had submitted a 505(b)(2) application seeking permission to market a version of Angiomax prior to the expiration of the ‘727 patent and ‘343 patent. We have requested Eagle to provide a copy of its application for evaluation.

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 is now under consideration by the Court. We believe we have valid defenses to the claims in the lawsuit, will deny liability and intend to defend ourselves vigorously. There can be no assurance, however, that we will be successful. An adverse resolution of the lawsuit could have a material adverse effect on our business, financial condition or results of operations. We are presently unable to predict the outcome of the lawsuit or to reasonably estimate a range of potential losses, if any, related to the lawsuit.

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 fall. Updated risk factors associated with our business are set forth below.

Risks Related to Our Financial Results

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.

We have incurred net losses in many years and on a cumulative basis since our inception. As of June 30, 2015, we had an accumulated deficit of approximately $118.7 million. In those periods in which we were able to achieve profitability, including the three months ended March 31, 2015, our profitability was based on revenues from sales of Angiomax as our revenues to date have been generated primarily from sales of Angiomax in the United States. However, in the three months ended June 30, 2015, net revenue from sales of Angiomax decreased by $97.5 million from the three months ended June 30, 2014, which we believe was primarily the result of a reduction in wholesaler purchases due to uncertainty regarding Angiomax's market exclusivity in the United States past June 2015. We expect that with the loss of market exclusivity in the United States in July 2015 and in Europe in August 2015 net revenue from sales of Angiomax will continue to decline in 2015 and in future years due to competition from generic versions of bivalirudin, including our authorized generic being marketed by Sandoz and Hospira's generic versions of bivalirudin which were approved by the FDA in July 2015. Although we have entered into a supply and distribution agreement with Sandoz to sell an authorized generic version of Angiomax (bivalirudin), the royalty income from the sale of the authorized generic is expected to only partially offset the expected decline in Angiomax revenue.

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 three month period ended June 30, 2015, we recorded a $7.6 million inventory obsolescence charge primarily due to the loss of exclusivity of Angiomax. As of June 30, 2015, our inventory of Angiomax was $55.2 million and we had inventory-related purchase commitments totaling $15.4 million for 2015 and $9.6 million commitments 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 or 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 plan to have commercially launched and commenced sales of five of our recently approved products in the United States by the end of 2015. If we are not successful with the commercial launches of these 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 have also launched or plan to launch Ionsys, Kengreal, PreveLeak, Raplixa and RPX-602 in the United States in 2015. We may also commercially launch or relaunch by ourselves or through arrangements with third parties up to five of our products and products in development in Europe by the end of 2015, subject to receiving regulatory approval. The 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 commercial 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 has become 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.

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

We expect to devote substantial financial resources to our research and development efforts, clinical trials, nonclinical and preclinical studies and regulatory approvals and to our commercialization and manufacturing programs associated with our products and our products in development. We also will require cash to pay interest on the $275.0 million aggregate principal amount of 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 August 7, 2015, 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;
- $115.0 million due to the former equityholders of Incline and up to $108.0 million in additional payments to other third parties related to the Incline transaction;

- $50.0 million for the ProFibrix transaction;

- $300.2 million for the Rempex transaction;

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- $110.0 million for the Tenaxis 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 cangrelor from AstraZeneca.

As of August 7, 2015, 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 $1,433.0 million. Of this amount, approximately $175.0 million relates to development milestones, $296.0 million relates to regulatory approval milestones and $962.0 million relates to commercial milestones.
In addition, of the total potential milestone payment obligations, based on our earliest 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 up to $77.7 million during the remainder of 2015. The majority of our anticipated payments for 2015 relate to the achievement of regulatory approval and commercial milestones for Ionsys and the remainder of these payments relate to the achievement of development milestones for our products in development.
Net revenue from sales of Angiomax were significantly lower in the three months ended June 30, 2015, 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.
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;
- 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 revenues that we generate from sales of our products and other sources, are insufficient to satisfy our funding requirements due to lower than anticipated sales of our marketed products, including Angiomax which we expect will generate significantly lower revenues, or due to higher than anticipated costs associated with product launches, investments in research and development or otherwise, we will need to sell additional equity or debt securities or seek additional financing through other arrangements to increase our cash resources. Any sale of additional equity or 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. Further, we may seek additional financing to fund our acquisitions of development stage compounds, clinical stage product candidates and approved products and/or the companies that have such products, and we may not be able to obtain such financing on terms acceptable to us or at all. If we are unable to obtain additional financing, we may be required to delay, reduce the scope of, or eliminate one or more of our planned research, development and commercialization activities, which could adversely affect our business, financial condition and operating results.

If we seek to raise 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 determine that raising capital would be in our interest and in the interest of our stockholders, we may seek to sell equity or debt securities or seek financings through other arrangements. Any sale of equity or debt securities may result in dilution to our stockholders and increased liquidity requirements. Debt financing may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures. Our ability to comply with these financial restrictions and covenants could be dependent on our future performance, which is subject to prevailing economic conditions and other factors, including factors that are beyond our control such as foreign exchange rates, interest rates and changes in the level of competition. Failure to comply with the financial restrictions and covenants would adversely affect our business, financial condition and operating results.

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

We distribute all of the products we sell in the United States through a sole source distribution model. Under this model, we currently sell these products to our sole source distributor, ICS. ICS 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. Our revenue from sales of these products in the United States is exclusively 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 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, recently we acquired Annovation, Incline, ProFibrix, Rempex, Tenaxis and the Recothrom product and related assets from BMS, and we entered into a license and collaboration agreement with Alnylam to develop, manufacture and commercialize RNAi therapeutics targeting the PCSK9 gene for the treatment of hypercholesterolemia and other human diseases. We may not realize the anticipated benefits of an acquisition, license, or collaboration, each of which involves numerous risks. These risks include:

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

- 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.

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. 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.

In the event the conditional conversion feature of the 2017 notes or 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.

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 for 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 risk factors that follow this risk factor is additional information regarding competition for our three marketed products that generate or are expected to generate a significant portion of our revenue, Angiomax, Recothrom and Orbactiv. 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, 2014.

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.

We do not have market exclusivity for Angiomax and will face generic and other competition that will adversely affect our revenue.

The principal U.S. patents covering Angiomax included 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. 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 held the '727 patent and '343 patent invalid. As a result of the ruling, we do not have market exclusivity for Angiomax in the United States. 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 version of Angiomax (bivalirudin).

On July 15, 2015, Hospira's ANDAs for its generic versions of bivalirudin were approved by the FDA. In addition, a number of companies have filed ANDAs for their generic versions of Angiomax. In addition, the FDA has accepted for filing a 505(b)(2) NDA filed by Eagle for a ready to use liquid formulation of bivalirudin. Eagle has announced that it expects an FDA decision on its NDA in March 2016 and, if approved, expects to launch commercial sales of the product in the United States immediately following such decision.

In addition to Hospira's generic versions of bivalirudin, Sandoz's authorized generic and, if approved, Eagle's formulation of bivalirudin, as a result of the Federal Circuit Court's rulings, Angiomax could be subject to generic competition in the United States from Mylan, Teva, APP and Sun and, if we are unsuccessful in our petition for rehearing in the Hospira matter, from the other ANDA filers upon the approval of each companies' ANDA filings by the FDA. In addition, the principal patent covering Angiomax in Europe expires in August 2015 and, as a result, we could face generic competition in Europe. As a result, we expect our global net revenue from Angiomax to decline significantly, which could adversely affect our business, financial condition and results of operations.

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.

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

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

- mechanical hemostats, such as absorbable gelatin sponge, collagen, cellulose, or polysaccharide-based hemostats applied as sponges, fleeces, bandages, or microspheres, which do not contain thrombin or any other active biologic compounds;
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active hemostats, which are thrombin products that may be derived from bovine or human pooled plasma purification or human recombinant manufacturing processes;

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

- fibrin sealants, which consist of thrombin and fibrinogen that can be sprayed or applied via patch directly to the bleeding surface; and

- surgical sealants, which can be composed of glutaraldehyde and bovine serum albumin, polyethylene glycol polymers, and cyanoacrolates.

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The choice of a surgical hemostat or sealant depends on the surgical procedure, type and severity of bleeding, surgeon preference, price and availability of products within the operating room or hospital.
Recothrom competes primarily with other active hemostats (bovine thrombin and human plasma-derived thrombin). Recothrom is the only topical thrombin that is not derived from bovine or human pooled plasma and can be used as a stand-alone product or with gelatin in sponge or granular form. Currently, there are two other stand-alone topical thrombin products commercially available in the United States, THROMBIN-JMI®, a bovine derived thrombin marketed by Pfizer, and EVITHROM®, a human pooled plasma thrombin marketed by Ethicon, Inc., a subsidiary of Johnson & Johnson. In addition, Baxter International, Inc. markets the GELFOAM Plus Hemostasis Kit, which is Pfizer Inc.'s GELFOAM sterile sponge co-packaged with human plasma-derived thrombin. Further, a number of companies, including Johnson & Johnson, Pfizer and Baxter International, Inc., currently market other hemostatic agents that may compete with Recothrom, including mechanical hemostats such as gelatin and collagen pads, flowable hemostats and fibrin sealants. Many of these competitive hemostatic agents are relatively inexpensive and have been widely used for many years.

Consequently, some physicians and hospital formulary decision-makers may be hesitant to adopt Recothrom. The active hemostat class has seen minor usage contraction recently while the flowable hemostats and fibrin sealants have shown growth. If physicians do not accept the potential advantages of Recothrom or resist the use of Recothrom due to either custom or cost containment measures, or the active hemostat class continues to decline, our revenues from Recothrom could be adversely affected.

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 serious 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 (Cleocin), daptomycin (Cubicin) 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 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.), Dalvance from Durata Therapeutics, Inc. (now a subsidiary of Allergan plc) and Vibativ from Theravance Biopharma, Inc. Additionally, several companies have products in development that, if approved, may compete with Orbactiv, including Cempra, Inc., Debiopharm Group (through acquisition of Affinium Pharmaceuticals), Melinta Therapeutics, Inc. (formerly Rib X Pharmaceuticals, Inc.), Paratek Pharmaceuticals, Inc., Nabriva Therapeutics AG and Furiex Pharmaceuticals, Inc. (a subsidiary of Allergan plc). 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 Targanta, Curacyte Discovery, Incline, ProFibrix, Rempex, Tenaxis, Annovation, and the Recothrom product and related assets from BMS, licensed marketing rights to the ready to use formulation of Argatroban, licensed development and commercialization rights to MDCO 216, MDCO 157 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 these necessary funds to do so.

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

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

Hospitals establish formularies, which are lists of drugs approved for use in the hospital. If a drug is not included on the formulary, the ability of our engagement partners and engagement managers to promote and sell the drug may be limited or denied. For example, in connection with the launch of Cleviprex, we experienced difficulties in getting Cleviprex included on hospitals' formulary lists, in part because hospital formularies may limit the number of 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.
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, 2014 and the six months ended June 30, 2015, we had $36.6 million and $11.0 million, respectively, in sales outside of the United States, most of which are sales of Angiomax, and we have historically encountered difficulty in selling Angiomax outside of the United States. In addition, the principal patent covering Angiomax in Europe expires in August 2015 and, as a result, we could 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.

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 recent final rule regarding the Medicare Hospital Outpatient Prospective Payment System, CMS finalized a new “bundling” policy that will affect 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 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
- 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.

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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. For example, in the fourth quarter of 2014, Brent Furse, Executive Vice President, Chief Customer Officer, and Cees Heiman, Executive Vice President, Chief Innovation Officer, departed from our company. We are highly dependent on our ability to attract and retain qualified personnel for the acquisition, development and commercialization activities we conduct or sponsor. If we lose one or more of the members of our senior management, including our Chairman and Chief Executive Officer, Clive A. Meanwell, our President and Chief Financial Officer, Glenn P. Sblendorio, or other key employees or consultants, our ability to implement successfully our business strategy could be seriously harmed. Our ability to replace these key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to acquire, develop and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate such additional personnel.

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

We do not have manufacturing or supply capabilities and are completely dependent on third parties for the manufacture and supply of our products, other than for PreveLeak. 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, other than for PreveLeak. 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, other than PreveLeak, 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, other than PreveLeak. 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.

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

- delay or otherwise adversely impact the manufacturing, development or commercialization of our products, our products in development or any additional products or product candidates that we may acquire or develop;
- require us to seek a new collaborator or undertake unforeseen additional responsibilities or devote unforeseen additional resources to the manufacturing, development or commercialization of our products; or
- result in the termination of the development or commercialization of our products.

Our reliance on third-party manufacturers and suppliers to supply our products and 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. Other than our collaboration arrangements with Alnylam and SciClone, we are not currently a party to any such arrangement and we may not be able to enter into any similar 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 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.

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 four research and development products, 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 Kengreal for use in patients undergoing PCI or those that require bridging from oral antiplatelet therapy to surgery. On April 30, 2014, the FDA issued a Complete Response Letter regarding our NDA for cangrelor. For the PCI indication, the FDA stated that the NDA cannot be approved at the present time. The FDA suggested that we perform a series of clinical data analyses of the CHAMPION PHOENIX study, review certain processes regarding data management, and provide bioequivalence information on the clopidogrel clinical supplies for the CHAMPION trials. For the BRIDGE indication, the FDA concluded that a prospective, adequate and well controlled study in which outcomes such as bleeding are studied would be required to provide the clinical data necessary to assess the benefit risk relationship in this indication. The FDA also provided additional comments for us to address, stating that the comments were not approvability issues, but could affect labeling.

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

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

In order to market our products for expanded indications, we will need to conduct appropriate clinical trials, obtain positive results from those trials and obtain regulatory approval for such proposed indications. Obtaining regulatory approval is uncertain, time-consuming and expensive. The regulatory review and approval process to obtain marketing approval for a new indication can take many years and require the expenditure of substantial resources. This process can vary substantially based on the type, complexity, novelty and indication of the product involved. The regulatory authorities have substantial discretion in the approval process and may refuse to accept any application. Alternatively, they may decide that any data submitted is insufficient for approval and require additional pre-clinical, clinical or other studies, which studies could require the expenditure of substantial resources. Even if we undertook such studies, we might not be successful in obtaining regulatory approval for these indications or any other indications in a timely manner or at all. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a new indication for a product. If we are unsuccessful in expanding the product label of our products, the size of the commercial market for our products will be limited.

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;
- regulators, ethics committees or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we, or the FDA or other regulatory authorities, might suspend or terminate a clinical trial at any time on various grounds, including a finding that participating patients are being exposed to unacceptable health risks. For example, we have in the past voluntarily suspended enrollment in one of our clinical trials to review an interim analysis of safety data from the trial; and
- the effects of our product candidates may not be the desired effects or may include undesirable side effects or the product candidates may have other unexpected characteristics.

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

If we or the contract manufacturers manufacturing our products and 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.

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, 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.

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 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 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 included the '404 patent, the '727 patent and the '343 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 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 the ANDA filers alleging patent infringement of the '727 patent and '343 patent. In our lawsuit against Hospira, on July 2, 2015, the Federal Circuit Court ruled against us, finding the '727 patent and '343 patent invalid. As a result of the ruling, we do not have market exclusivity for Angiomax in the United States. 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.

In Europe, the principal patent covering Angiomax expires in August 2015. This patent covers the composition of matter of Angiomax.

Recothrom. In February 2015, we acquired from BMS its portfolio of patents and patent applications pertaining to Recothrom's pharmaceutical formulations and methods of manufacturing. The expiration dates of these patents range from July 2015 to February 2029 in the United States. Prior to the acquisition of BMS's portfolio of patents and patent applications pertaining to Recothrom, BMS also filed and we are currently prosecuting a number of patent applications relating to Recothrom in the United States and in foreign countries. We believe that, as a biologic, Recothrom is entitled to regulatory exclusivity as a "reference product" in the United States expiring in January 2020. Although the FDA has issued draft guidance documents, to date it has not issued any regulations or final guidance explaining how it will implement the abbreviated BLA or biosimilar provisions enacted in 2010 under the Biologics Price Competition and Innovation Act of 2009, including the exclusivity provisions for reference products. As a result, it is possible that the FDA will decide to interpret the provisions in such a way that Recothrom is not considered to be a reference product for the purposes of the statute or to be entitled to any period of regulatory exclusivity. Moreover, even if Recothrom is considered to be a reference product eligible for such exclusivity, that exclusivity will not prevent other companies from filing full BLAs for competing versions of Recothrom, including competing recombinant thrombin products. As a result, if such companies can complete and the FDA permits the submission of and approves such full BLAs, competing products may get onto the market before the regulatory exclusivity period for Recothrom expires in January 2020.

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. We have filed for patent term extensions, also known as supplementary protection certificates, in European countries where we have received regulatory approval and expect to file for supplementary protection certificates in other European countries as we receive approvals. 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 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 cangrelor pharmaceutical compositions which expire in 2017 and 2018 if no patent term extension is obtained, and issued patents directed to certain use of Kengreal. We have also filed and are currently prosecuting a number of patent applications related to cangrelor.

Orbactiv. The principal patent for Orbactiv in both the United States and Europe is set to expire in November 2015. 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. We have also filed and are prosecuting a number of patent applications relating to Orbactiv and its uses.

Raplixa. As a result of our acquisition of ProFibrix, we acquired a portfolio of patents and patent applications, including patents licensed from Quadrant Drug Delivery Limited, or Quadrant. One U.S. patent licensed from Quadrant covers the composition of matter of Raplixa and is set to expire in May 2017 if no patent term extension is obtained. We also have an issued U.S. patent, which covers Raplixa suitable for certain applications that expires in January 2031. We have also filed and are prosecuting a number of patent applications related to the use and production of Raplixa. As a biologic, we believe Raplixa 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 Raplixa, if approved.

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 2015 to January 2033 in the United States. In Europe, the expiration date of patents covering the Ionsys device range from May 2016 to September 2021. 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. In July 2015, the U.S. Patent and Trademark Office issued to us a patent covering certain methods of administering minocycline. This patent expires 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. 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.

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 specific 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.

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.

PreveLeak. As a result of our acquisition of Tenaxis, we acquired a portfolio of patents and patent applications covering PreveLeak, its uses and the process of making PreveLeak. The expiration dates of these U.S. patents range from September 2022 to December 2028. In Europe, we have an issued patent covering PreveLeak which expires in December 2028. We are also currently prosecuting patent applications relating to PreveLeak 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 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, 2013 to August 6, 2015, the last reported sale price of our common stock ranged from a high of $40.39 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;
- acquisitions and strategic partnerships;
- 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, particularly with respect to our U.S. Angiomax patents;
- 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 cangrelor. The plaintiffs seek unspecified monetary damages on behalf of the putative class and an award of costs and expenses, including attorney's fees. The class action lawsuit is described in more detail in Part II, Item 1, Legal Proceedings, of this Quarterly Report on Form 10-Q.

While we believe we have meritorious defenses, we cannot predict the outcome of this lawsuit. 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. We are not currently able to estimate the possible cost to us from this lawsuit, as it is currently at an early stage, and we cannot be certain how long it may take to resolve or the possible amount of any damages, if any, that we may be required to pay. We have not established any reserves for any potential liability relating to this lawsuit. It is possible that we could, in the future, incur judgment or enter into settlement of claims for monetary damages. A decision adverse to our interests on this lawsuit could result in the payment of substantial damages and could have a material adverse effect on our business, results of operations and financial condition. In addition, the uncertainty of the currently pending lawsuit could lead to more volatility in our stock price.

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

The General Corporation Law of the State of Delaware and our certificate of incorporation and by-laws contain provisions that might enable our management to resist a takeover of our company or discourage a third party from attempting to take over our company. These provisions include

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

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

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

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

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

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

- only our board of directors, the chairman of the board or our president may call special meetings of stockholders;
- our by-laws may be amended, altered or repealed by (i) the affirmative vote of a majority of our directors, subject to any limitations set forth in the by-laws, or (ii) the affirmative vote of the holders of at least 75% of the votes which all the stockholders would be entitled to cast in any annual election of directors;
- stockholders must provide us with advance notice, and certain information specified in our by-laws, in connection with nominations or proposals by such stockholder for consideration at an annual meeting;

- stockholders may not take any action by written consent in lieu of a meeting; and
- our certificate of incorporation may only be amended or repealed by the affirmative vote of a majority of our directors and the affirmative vote of the holders of at least 75% of the votes which all the stockholders would be entitled to cast in any annual election of directors (and plus any separate class vote that might in the future be required pursuant to the terms of any series of preferred stock that might be outstanding at the time any of these amendments are submitted to stockholders).

These provisions could have the effect of delaying, deferring, or preventing a change in control of us or a change in our management that stockholders may consider favorable or beneficial. These provisions could also discourage proxy contests and make it more difficult for stockholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock or our other securities.

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

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

- responding to proxy contests and other actions by activist shareholders may be costly and time-consuming and may disrupt our operations and divert the attention of management and our employees;
- perceived uncertainties as to our future direction may result in our inability to consummate potential acquisitions, collaborations or in-licensing opportunities and may make it more difficult to attract and retain qualified personnel and business partners; and
- if individuals are elected to our board of directors with a specific agenda different from ours, it may adversely affect our ability to effectively and timely implement our strategic plan and create additional value for our stockholders.

Item 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.

SIGNATURES

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

THE MEDICINES COMPANY

Date: August 7, 2015

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

EXHIBIT INDEX

Exhibit Number	Description
3.1	Third Amended and Restated Certificate of Incorporation of the registrant, as amended.
10.1	Amendment No. 2 to the 2013 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the registrant's current report on Form 8-K, filed June 2, 2015) .
10.2	Form of Amended and Restated Management Severance Agreement by and between the registrant and each of Clive Meanwell and Glenn Sblendorio.
10.3	Form of Amended and Restated Management Severance Agreement by and between the registrant and William O’Connor.
31.1	Chairman and Chief Executive Officer Certification pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Chief Financial Officer Certification pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Chairman and Chief Executive Officer Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Chief Financial Officer Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	The following materials from The Medicines Company Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Balance Sheet, (ii) the Consolidated Statement of Income, (iii) the Consolidated Statement of Cash Flow, and (iv) Notes to Consolidated Financial Statements