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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 10-Q**

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

For the quarterly period ended September 30, 2014

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 0-24006

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**NEKTAR THERAPEUTICS**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**94-3134940**  
(IRS Employer  
Identification No.)

**455 Mission Bay Boulevard South  
San Francisco, California 94158**  
(Address of principal executive offices)

**415-482-5300**  
(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

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Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>

Indicate by check mark whether the registrant is a shell company (as defined by Rule 12b-2 of the Exchange Act). Yes  No

The number of outstanding shares of the registrant's Common Stock, \$0.0001 par value, was 128,441,406 on October 30, 2014.

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## **Forward-Looking Statements**

This report includes “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act). All statements other than statements of historical fact are “forward-looking statements” for purposes of this quarterly report on Form 10-Q, including any projections of earnings, revenue, milestone payments, royalties, sales or other financial items, any statements of the plans and objectives of management for future operations (including, but not limited to, preclinical development, clinical trials and manufacturing), any statements related to our financial condition and future working capital needs, any statements regarding potential future financing alternatives, any statements concerning proposed drug candidates, any statements regarding the timing for the start or end of clinical trials or submission of regulatory approval filings, any statements regarding future economic conditions or performance, any statements regarding the success of our collaboration arrangements or future payments that may come due to us under these arrangements, any statements regarding our plans and objectives to initiate or continue clinical trials, and any statements of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as “may,” “will,” “expects,” “plans,” “anticipates,” “estimates,” “potential” or “continue,” or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, such expectations or any of the forward-looking statements may prove to be incorrect and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including, but not limited to, the risk factors set forth in Part II, Item 1A “Risk Factors” below and for the reasons described elsewhere in this quarterly report on Form 10-Q. All forward-looking statements and reasons why results may differ included in this report are made as of the date hereof and we do not intend to update any forward-looking statements except as required by law or applicable regulations. Except where the context otherwise requires, in this quarterly report on Form 10-Q, the “Company,” “Nektar,” “we,” “us,” and “our” refer to Nektar Therapeutics, a Delaware corporation, and, where appropriate, its subsidiaries.

## **Trademarks**

The Nektar brand and product names, including but not limited to Nektar®, contained in this document are trademarks and registered trademarks of Nektar Therapeutics in the United States (U.S.) and certain other countries. This document also contains references to trademarks and service marks of other companies that are the property of their respective owners.

## PART I: FINANCIAL INFORMATION

## Item 1. Condensed Consolidated Financial Statements—Unaudited:

## NEKTAR THERAPEUTICS

CONDENSED CONSOLIDATED BALANCE SHEETS  
(In thousands, except par value)  
(Unaudited)

	September 30, 2014	December 31, 2013
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 32,008	\$ 39,067
Restricted cash	25,000	—
Short-term investments	204,635	197,959
Accounts receivable, net	46,074	2,229
Inventory	11,695	13,452
Other current assets	4,708	5,175
Total current assets	324,120	257,882
Restricted cash	—	25,000
Property and equipment, net	69,275	66,974
Goodwill	76,501	76,501
Other assets	7,006	8,170
Total assets	<u>\$ 476,902</u>	<u>\$ 434,527</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 5,428	\$ 9,115
Accrued compensation	13,753	14,254
Accrued expenses	7,760	6,243
Accrued clinical trial expenses	9,643	16,905
Interest payable	3,167	6,917
Deferred revenue, current portion	24,626	23,664
Other current liabilities	16,172	21,123
Total current liabilities	80,549	98,221
Senior secured notes	125,000	125,000
Capital lease obligations, less current portion	5,339	8,049
Liability related to receipt of refundable milestone payment	—	70,000
Liability related to sale of future royalties, less current portion	120,492	121,520
Deferred revenue, less current portion	82,902	82,384
Other long-term liabilities	15,402	19,256
Total liabilities	429,684	524,430
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, \$0.0001 par value; 10,000 shares authorized, no shares designated, issued or outstanding at September 30, 2014 or December 31, 2013, respectively	—	—
Common stock, \$0.0001 par value; 300,000 authorized; 128,248 shares and 116,494 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	12	11
Capital in excess of par value	1,789,010	1,643,660
Accumulated other comprehensive loss	(1,178)	(1,181)
Accumulated deficit	(1,740,626)	(1,732,393)
Total stockholders' equity (deficit)	47,218	(89,903)
Total liabilities and stockholders' equity (deficit)	<u>\$ 476,902</u>	<u>\$ 434,527</u>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

## NEKTAR THERAPEUTICS

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(In thousands, except per share information)  
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
<b>Revenue:</b>				
Product sales and royalty revenue	\$ 6,172	\$ 15,026	\$ 17,980	\$ 37,836
Non-cash royalty revenue related to sale of future royalties	6,143	4,523	16,753	12,744
License, collaboration and other revenue	120,556	41,360	146,422	67,195
Total revenue	<u>132,871</u>	<u>60,909</u>	<u>181,155</u>	<u>117,775</u>
<b>Operating costs and expenses:</b>				
Cost of goods sold	9,220	12,877	22,235	29,549
Research and development	34,200	43,914	109,240	141,762
General and administrative	9,130	10,643	28,677	30,700
Total operating costs and expenses	<u>52,550</u>	<u>67,434</u>	<u>160,152</u>	<u>202,011</u>
Income (loss) from operations	80,321	(6,525)	21,003	(84,236)
<b>Non-operating income (expense):</b>				
Interest income	133	116	399	639
Interest expense	(4,391)	(4,587)	(13,412)	(13,888)
Non-cash interest expense on liability related to sale of future royalties	(5,203)	(5,616)	(15,725)	(16,644)
Other income (expense), net	(7)	262	136	385
Total non-operating expense, net	<u>(9,468)</u>	<u>(9,825)</u>	<u>(28,602)</u>	<u>(29,508)</u>
Income (loss) before provision for income taxes	70,853	(16,350)	(7,599)	(113,744)
Provision for income taxes	248	193	634	610
Net income (loss)	<u>\$ 70,605</u>	<u>\$ (16,543)</u>	<u>\$ (8,233)</u>	<u>\$ (114,354)</u>
<b>Net income (loss) per share:</b>				
Basic	<u>\$ 0.55</u>	<u>\$ (0.14)</u>	<u>\$ (0.07)</u>	<u>\$ (0.99)</u>
Diluted	<u>\$ 0.53</u>	<u>\$ (0.14)</u>	<u>\$ (0.07)</u>	<u>\$ (0.99)</u>
<b>Weighted average shares outstanding used in computing net income (loss) per share:</b>				
Basic	<u>127,504</u>	<u>115,812</u>	<u>126,043</u>	<u>115,557</u>
Diluted	<u>132,177</u>	<u>115,812</u>	<u>126,043</u>	<u>115,557</u>

**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)**  
(In thousands)  
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Comprehensive income (loss)	<u>\$70,314</u>	<u>\$ (16,896)</u>	<u>\$ (8,230)</u>	<u>\$ (115,686)</u>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

**NEKTAR THERAPEUTICS**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)  
(Unaudited)

	Nine months ended September 30,	
	2014	2013
<b>Cash flows from operating activities:</b>		
Net loss	\$ (8,233)	\$(114,354)
Adjustments to reconcile net loss to net cash used in operating activities:		
Recognition of previously received milestone payment which is no longer refundable	(70,000)	—
Non-cash royalty revenue related to sale of future royalties	(16,753)	(12,744)
Non-cash interest expense on liability related to sale of future royalties	15,725	16,644
Stock-based compensation	12,647	13,165
Depreciation and amortization	9,733	10,882
Other non-cash transactions	313	332
Changes in operating assets and liabilities:		
Accounts receivable, net	(43,845)	1,248
Inventory	1,757	3,193
Other assets	679	6,817
Accounts payable	(3,670)	697
Accrued compensation	(501)	5,137
Accrued expenses	1,667	2,741
Accrued clinical trial expenses	(7,262)	(2,261)
Interest payable	(3,750)	(3,916)
Deferred revenue	1,480	(14,914)
Other liabilities	(7,366)	(4,825)
Net cash used in operating activities	<u>(117,379)</u>	<u>(92,158)</u>
<b>Cash flows from investing activities:</b>		
Maturities of investments	171,826	274,011
Purchases of investments	(200,160)	(140,569)
Sales of investments	21,661	—
Purchases of property and equipment	(6,090)	(1,382)
Net cash (used in) provided by investing activities	<u>(12,763)</u>	<u>132,060</u>
<b>Cash flows from financing activities:</b>		
Payment of capital lease obligations	(2,578)	(2,201)
Repayment of proceeds from sale of future royalties	(7,000)	(3,000)
Issuance of common stock, net of issuance costs	116,536	—
Proceeds from shares issued under equity compensation plans	16,168	5,253
Net cash provided by financing activities	<u>123,126</u>	<u>52</u>
Effect of exchange rates on cash and cash equivalents	(43)	20
Net (decrease) increase in cash and cash equivalents	(7,059)	39,974
Cash and cash equivalents at beginning of period	39,067	25,437
Cash and cash equivalents at end of period	<u>\$ 32,008</u>	<u>\$ 65,411</u>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	<u>\$ 16,487</u>	<u>\$ 17,097</u>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

NEKTAR THERAPEUTICS

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2014

(Unaudited)

**Note 1 — Organization and Summary of Significant Accounting Policies**

**Organization**

We are a clinical-stage biopharmaceutical company headquartered in San Francisco, California and incorporated in Delaware. We are developing a pipeline of drug candidates that utilize our PEGylation and advanced polymer conjugate technology platforms with the objective to improve the benefits of drugs for patients.

Our research and development activities have required significant ongoing investment to date and are expected to continue to require significant investment. As a result, we expect to continue to incur substantial losses and negative cash flows from operations in the future. We have financed our operations primarily through cash generated from licensing, collaboration and manufacturing agreements and financing transactions. At September 30, 2014, we had approximately \$261.6 million in cash and investments in marketable securities, of which \$25.0 million was restricted in relation to our 12% senior secured notes, and \$158.3 million in indebtedness. The indebtedness includes \$125.0 million in aggregate principal amount of 12.0% senior secured notes due July 15, 2017, but excludes our long-term liability relating to the sale of future royalties. As is further described in Note 4, this royalty obligation liability will not be settled in cash.

**Basis of Presentation and Principles of Consolidation**

Our consolidated financial statements include the financial position, results of operations and cash flows of our wholly-owned subsidiaries: Nektar Therapeutics (India) Private Limited (Nektar India) and Nektar Therapeutics UK Limited. All intercompany accounts and transactions have been eliminated in consolidation.

We prepared our Condensed Consolidated Financial Statements following the requirements of the Securities and Exchange Commission (SEC) for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. generally accepted accounting principles (GAAP) for annual periods can be condensed or omitted. In the opinion of management, these financial statements include all normal and recurring adjustments that we consider necessary for the fair presentation of our financial position and operating results.

Our Condensed Consolidated Financial Statements are denominated in U.S. dollars. Accordingly, changes in exchange rates between the applicable foreign currency and the U.S. dollar will affect the translation of each foreign subsidiary's financial results into U.S. dollars for purposes of reporting our consolidated financial results. Translation gains and losses are included in accumulated other comprehensive loss in the stockholders' equity (deficit) section of the Condensed Consolidated Balance Sheets. To date, such cumulative currency translation adjustments have not been significant to our consolidated financial position.

Our comprehensive income (loss) consists of our net income (loss) plus our foreign currency translation gains and losses and unrealized holding gains and losses on available-for-sale securities, neither of which were significant during the three and nine month periods ended September 30, 2014 and 2013. In addition, there were no significant reclassifications out of accumulated other comprehensive income (loss) to the statements of operations during the three and nine month periods ended September 30, 2014 and 2013.

The accompanying Condensed Consolidated Financial Statements are unaudited. The Condensed Consolidated Balance Sheet data as of December 31, 2013 was derived from the audited consolidated financial statements which are included in our Annual Report on Form 10-K for the year ended December 31, 2013 filed with the SEC on February 27, 2014. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with the consolidated financial statements and the accompanying notes to those financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2013.

Revenue, expenses, assets, and liabilities can vary during each quarter of the year. The results and trends in these interim Condensed Consolidated Financial Statements are not necessarily indicative of the results to be expected for the full year or any other periods.

**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 and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Accounting estimates and assumptions are inherently uncertain. Actual results could differ materially from those estimates and assumptions. On an ongoing basis, we evaluate our estimates, including those related to collaboration agreements and deferred revenue recognition periods, inventory, the impairment of investments, the impairment of goodwill and long-lived assets, contingencies, accrued clinical trial expenses, estimated interest

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expense from our liability related to our sale of future royalties, stock-based compensation, and ongoing litigation, among other estimates. We base our estimates on historical experience and on other assumptions that management believes are reasonable under the circumstances. These estimates form the basis for making judgments about the carrying values of assets and liabilities when these values are not readily apparent from other sources.

### **Reclassifications**

Certain items previously reported in specific financial statement captions have been reclassified to conform to the current period presentation. Such reclassifications do not materially impact previously reported revenue, operating income (loss), net income (loss), total assets, liabilities or stockholders' equity (deficit).

### **Segment Information**

We operate in one business segment which focuses on applying our technology platforms to improve the performance of established and novel drug candidates. We operate in one segment because our business offerings have similar economics and other characteristics, including the nature of products and manufacturing processes, types of customers, distribution methods and regulatory environment. We are comprehensively managed as one business segment by our Chief Executive Officer and his management team.

### **Significant Concentrations**

Our customers are primarily pharmaceutical and biotechnology companies that are located in the U.S. and Europe. Our accounts receivable balance contains billed and unbilled trade receivables from product sales and royalties, as well as milestones and time and materials based billings from collaborative research and development agreements. When appropriate, we provide for an allowance for doubtful accounts by reserving for specifically identified doubtful accounts. We generally do not require collateral from our customers. We perform a regular review of our customers' payment histories and associated credit risk. We have not experienced significant credit losses from our accounts receivable and our allowance for doubtful accounts was not significant at either September 30, 2014 or December 31, 2013.

We are dependent on our suppliers and contract manufacturers to provide raw materials, drugs and devices of appropriate quality and reliability and to meet applicable contract and regulatory requirements. In certain cases, we rely on single sources of supply of one or more critical materials. Consequently, in the event that supplies are delayed or interrupted for any reason, our ability to develop and produce our drug candidates or our ability to meet our supply obligations could be significantly impaired, which could have a material adverse effect on our business, financial condition and results of operations.

### **Revenue Recognition**

We enter into arrangements with pharmaceutical and biotechnology collaboration partners that may involve multiple deliverables. Our arrangements may contain one or more of the following elements: upfront fees, contract research and development, milestone payments, manufacturing and supply payments, royalties and license fees. Each deliverable in the arrangement is evaluated to determine whether it meets the criteria to be accounted for as a separate unit of accounting or whether it should be combined with other deliverables. Revenue is recognized separately for each element.

At the inception of each new multiple-element arrangement or the material modification of an existing multiple-element arrangement, we allocate all consideration received under multiple-element arrangements to all units of accounting based on the relative selling price method, generally based on our best estimate of selling price (ESP). The objective of ESP is to determine the price at which we would transact a sale if the product or service was sold on a stand-alone basis. We determine ESP for the elements in our collaboration arrangements by considering multiple factors including, but not limited to, technical complexity of the performance obligation and similarity of elements to those performed under previous arrangements. Since we apply significant judgment in arriving at the ESPs, any material change in our estimates would significantly affect the allocation of the total consideration to the different elements of a multiple element arrangement.

### **Product sales**

Product sales are primarily derived from cost-plus and fixed price manufacturing and supply agreements with our collaboration partners and revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed or determinable, and collection is reasonably assured. We have not experienced any significant returns from our customers.



### *Royalty revenue*

Generally, we are entitled to royalties from our partners based on the net sales of their approved drugs that are marketed and sold in one or more countries where we hold royalty rights. We recognize royalty revenue when the cash is received or when the royalty amount to be received is estimable and collection is reasonably assured. With respect to the non-cash royalties related to sale of future royalties described in Note 4, revenue is recognized when estimable, otherwise, revenue is recognized during the period in which the related royalty report is received, which generally occurs in the quarter after the applicable product sales are made.

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### *License, collaboration and other revenue*

Upfront fees received by us in license and collaboration arrangements that include future obligations, such as manufacturing and supply obligations, are recognized ratably over our estimated expected performance period under each respective arrangement. We make our best estimate of the period over which we expect to fulfill our performance obligations, which may include technology transfer assistance, research activities, clinical development activities, and manufacturing activities from development through the commercialization of the product. Given the uncertainties of these collaboration arrangements, significant judgment is required to determine the duration of the performance period.

Contingent consideration received from the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved, which we believe is consistent with the substance of our performance under our various license and collaboration agreements. A milestone is defined as an event (i) that can only be achieved based in whole or in part either on our performance or on the occurrence of a specific outcome resulting from our performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to us. A milestone is substantive if the consideration earned from the achievement of the milestone is consistent with our performance required to achieve the milestone or the increase in value to the collaboration resulting from our performance, relates solely to our past performance, and is reasonable relative to all of the other deliverables and payments within the arrangement.

Our license and collaboration agreements with our partners provide for payments to us upon the achievement of development milestones, such as the completion of clinical trials or regulatory submissions, approvals by health authorities, and commercial launches of drugs. Given the challenges inherent in developing, obtaining regulatory approvals for and achieving commercial launches of drug products, there was substantial uncertainty whether any such milestones would be achieved at the time of execution of these licensing and collaboration agreements. In addition, we evaluate whether the development milestones meet the remaining criteria to be considered substantive. As a result of our analysis, we consider our remaining development milestones under all of our license and collaboration agreements to be substantive and, accordingly, we expect to recognize as revenue future payments received from such milestones only if and as each milestone is achieved.

Our license and collaboration agreements with certain partners also provide for contingent payments to us based solely upon the performance of the respective partner. For such contingent amounts we expect to recognize the payments as revenue when earned under the applicable contract, which is generally upon completion of performance by the respective partner, provided that collection is reasonably assured.

Our license and collaboration agreements with our partners also provide for payments to us upon the achievement of specified sales volumes of approved drugs. We consider these payments to be similar to royalty payments and we will recognize such sales-based payments upon achievement of such sales volumes, provided that collection is reasonably assured.

### ***Research and Development Expense***

Research and development costs are expensed as incurred and include salaries, benefits and other operating costs such as outside services, supplies and allocated overhead costs. We perform research and development for our proprietary drug candidates and technology development and for certain third parties under collaboration agreements. For our proprietary drug candidates and our internal technology development programs, we invest our own funds without reimbursement from a third party.

We record accruals for the estimated costs of our clinical trial activities performed by third parties. We generally accrue costs associated with the start-up and reporting phases of the clinical trials ratably over the estimated duration of the start-up and reporting phases. We generally accrue costs associated with the treatment phase of clinical trials based on the total estimated cost of the treatment phase on a per patient basis and we expense the per patient cost ratably over the estimated patient treatment period based on patient enrollment in the trials. In specific circumstances, such as for certain time-based costs, we recognize clinical trial expenses using a methodology that we consider to be more reflective of the timing of costs incurred.

### ***Income Taxes***

For the three and nine month periods ended September 30, 2014 and 2013, we recorded an income tax provision for our Nektar India operations at an effective tax rate of approximately 34%. The U.S. federal deferred tax assets generated from our net operating losses have been fully reserved, as we believe it is not more likely than not that the benefit will be realized.

### ***Recently Issued Accounting Pronouncements***

In May 2014, the Financial Accounting Standards Board (FASB) issued guidance codified in ASC 606, *Revenue Recognition — Revenue from Contracts with Customers*, which amends the guidance in former ASC 605, *Revenue Recognition*, and is effective for public companies for fiscal years beginning after December 15, 2016. We are currently evaluating the impact of the provisions of ASC 606.

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In August 2014, the FASB issued Accounting Standards Update No. 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (ASU 2014-15). ASU 2014-15 requires management to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. ASU 2014-15 is effective for us in 2016 with early adoption permitted. We do not believe the impact of adopting ASU 2014-15 on our consolidated financial statements will be significant.

### Note 2 — Cash and Investments in Marketable Securities

Cash and investments in marketable securities, including cash equivalents and restricted cash, are as follows (in thousands):

	Estimated Fair Value at	
	September 30, 2014	December 31, 2013
Cash and cash equivalents	\$ 32,008	\$ 39,067
Short-term investments	204,635	197,959
Restricted cash	25,000	25,000
Total cash and investments in marketable securities	<u>\$ 261,643</u>	<u>\$ 262,026</u>

We invest in liquid, high quality debt securities. Our investments in debt securities are subject to interest rate risk. To minimize the exposure due to an adverse shift in interest rates, we invest in securities with maturities of two years or less and maintain a weighted average maturity of one year or less. Investments in securities with remaining maturities of less than one year, or where our intent is to use the investments to fund current operations or to make them available for current operations, are classified as short-term investments. As of September 30, 2014 and December 31, 2013, all of our investments had maturities of one year or less.

Gross unrealized gains and losses were not significant at either September 30, 2014 or December 31, 2013. During the three and nine month periods ended September 30, 2014, we sold available-for-sale securities totaling \$21.7 million and gross realized gains and losses on those sales were not significant. During the three and nine month periods ended September 30, 2013, we did not sell any of our available-for-sale securities. The cost of securities sold is based on the specific identification method.

Restricted cash of \$25.0 million is required to be maintained in a separate account until July 1, 2015 under the terms of our 12% senior secured notes due July 2017. From July 1, 2015 through the quarter ending June 30, 2017, the aggregate balance of our unrestricted cash and cash equivalents at the end of any two consecutive fiscal quarters may not be less than \$25.0 million, subject to certain conditions.

Our portfolio of cash and investments in marketable securities includes (in thousands):

	Fair Value Hierarchy Level	Estimated Fair Value at	
		September 30, 2014	December 31, 2013
Corporate notes and bonds	2	\$ 177,168	\$ 138,515
Corporate commercial paper	2	27,467	59,444
Available-for-sale investments		204,635	197,959
Money market funds	1	28,216	26,453
Cash, including restricted cash	N/A	28,792	37,614
Total cash and investments in marketable securities		<u>\$ 261,643</u>	<u>\$ 262,026</u>

*Level 1* — Quoted prices in active markets for identical assets or liabilities.

*Level 2* — Inputs other than Level 1 that are observable, either directly or indirectly, 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.

*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.

All of our investments are categorized as Level 1 or Level 2, as explained in the table above. We use a market approach to value our Level 2 investments. The disclosed fair value related to our investments is based primarily on the reported fair values in our period-end brokerage statements, which are based on market prices from a variety of industry standard data providers and generally represent quoted prices for similar assets in active markets or have been derived from observable market data. We independently validate these fair values using available market quotes and other information. During the three and nine month periods ended September 30, 2014 and 2013, there were no transfers between Level 1 and Level 2 of the fair value hierarchy.

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Additionally, as of September 30, 2014, based on a discounted cash flow analysis using Level 3 inputs including financial discount rates, we believe the \$125.0 million carrying amount of our 12% senior secured notes due July 2017 is consistent with its fair value.

### **Note 3 — Inventory**

Inventory consists of the following (in thousands):

	September 30, 2014	December 31, 2013
Raw materials	\$ 1,726	\$ 3,947
Work-in-process	8,313	6,146
Finished goods	1,656	3,359
Total inventory	<u>\$ 11,695</u>	<u>\$ 13,452</u>

Inventory is generally manufactured upon receipt of firm purchase orders from our collaboration partners. Inventory includes direct materials, direct labor, and manufacturing overhead and cost is determined on a first-in, first-out basis. Inventory is valued at the lower of cost or market and defective or excess inventory is written down to net realizable value based on historical experience or projected usage.

### **Note 4 — Liability Related to Sale of Future Royalties**

On February 24, 2012, we entered into a Purchase and Sale Agreement (the Purchase and Sale Agreement) with RPI Finance Trust (RPI), an affiliate of Royalty Pharma, pursuant to which we sold, and RPI purchased, our right to receive royalty payments (the Royalty Entitlement) arising from the worldwide net sales, from and after January 1, 2012, of (a) CIMZIA<sup>®</sup>, under our license, manufacturing and supply agreement with UCB Pharma (UCB), and (b) MIRCERA<sup>®</sup>, under our license, manufacturing and supply agreement with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (together referred to as Roche). We received aggregate cash proceeds for the Royalty Entitlement of \$124.0 million. Although we sold all of our rights to receive royalties from the CIMZIA<sup>®</sup> and MIRCERA<sup>®</sup> products, as a result of our ongoing manufacturing and supply obligations related to the generation of these royalties, we will continue to account for these royalties as revenue. We recorded the \$124.0 million in proceeds from this transaction as a liability (Royalty Obligation) that will be amortized using the interest method over the estimated life of the Purchase and Sale Agreement as royalties from the CIMZIA<sup>®</sup> and MIRCERA<sup>®</sup> products are remitted directly to RPI. During the nine months ended September 30, 2014 and 2013, we recognized \$16.8 million and \$12.7 million, respectively, in aggregate royalties from net sales of CIMZIA<sup>®</sup> and MIRCERA<sup>®</sup>.

Since its inception, our estimate of the total interest expense on the Royalty Obligation resulted in an effective annual interest rate of approximately 17%. We periodically assess the estimated royalty payments to RPI from UCB and Roche and to the extent such payments are greater or less than our initial estimates, or the timing of such payments is materially different than our original estimates, we will prospectively adjust the amortization of the Royalty Obligation.

Pursuant to the Purchase and Sale Agreement, in March 2014 and March 2013, we were required to pay RPI \$7.0 million and \$3.0 million, respectively, as a result of worldwide net sales of MIRCERA<sup>®</sup> for the 12 month periods ended on December 31, 2013 and 2012 not reaching certain minimum thresholds. As of September 30, 2014, we do not expect to make any further payments related to the Purchase and Sale Agreement.

The Purchase and Sale Agreement grants RPI the right to receive certain reports and other information relating to the Royalty Entitlement and contains other representations and warranties, covenants and indemnification obligations that are customary for a transaction of this nature. In particular, if we breach our obligations under the Purchase and Sale Agreement, we could be required to pay damages to RPI that are not limited to the purchase price we received in the sale transaction.

## **Note 5 — Commitments and Contingencies**

### ***Legal Matters***

From time to time, we are involved in lawsuits, arbitrations, claims, investigations and proceedings, consisting of intellectual property, commercial, employment and other matters, which arise in the ordinary course of business. We make provisions for liabilities when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. Such provisions are reviewed at least quarterly and adjusted to reflect the impact of settlement negotiations, judicial and administrative rulings, advice of legal counsel, and other information and events pertaining to a particular case. Litigation is inherently unpredictable. If any unfavorable ruling were to occur in any specific period, it could have a material adverse impact on the results of our operations of that period and on our cash flows and liquidity.

### ***Indemnifications in Connection with Commercial Agreements***

As part of our collaboration agreements with our partners related to the license, development, manufacture and supply of drugs based on our proprietary technologies, we generally agree to defend, indemnify and hold harmless our partners from and against third party liabilities arising out of the agreement, including product liability (with respect to our activities) and infringement of intellectual property to the extent the intellectual property is developed by us and licensed to our partners. The term of these indemnification obligations is generally perpetual any time after execution of the agreement. There is generally no limitation on the potential amount of future payments we could be required to make under these indemnification obligations.

As part of the sale of our royalty interest in the CIMZIA® and MIRCERA® products, we and RPI made representations and warranties and entered into certain covenants and ancillary agreements which are supported by indemnity obligations. Additionally, as part of our pulmonary asset sale to Novartis in 2008, we and Novartis made representations and warranties and entered into certain covenants and ancillary agreements which are supported by an indemnity obligation. In the event it is determined that we breached certain of the representations and warranties or covenants and agreements made by us in any such agreements, we could incur substantial indemnification liabilities depending on the timing, nature, and amount of any such claims.

To date, we have not incurred costs to defend lawsuits or settle claims related to these indemnification obligations. If any of our indemnification obligations is triggered, we may incur substantial liabilities. Because the aggregate amount of any potential indemnification obligation is not a stated amount, the overall maximum amount of any such obligations cannot be reasonably estimated. No liabilities have been recorded for these obligations in our Condensed Consolidated Balance Sheets at either September 30, 2014 or December 31, 2013.

## **Note 6 — Stockholders' Equity**

On January 28, 2014, we completed the issuance and sale of 9,775,000 shares of our common stock in a public offering with total proceeds to the Company of approximately \$117.2 million after deducting the underwriting commissions and discounts of approximately \$7.5 million. Additionally, we incurred approximately \$0.7 million in legal and accounting fees, filing fees, and other costs in connection with this offering.

## **Note 7 — License and Collaboration Agreements**

We have entered into various collaboration agreements including license agreements and collaborative research, manufacturing, development and commercialization agreements with various pharmaceutical and biotechnology companies. Under these collaboration agreements, we are entitled to receive license fees, upfront payments, milestone payments, royalties, sales milestones, and payments for the manufacture and supply of our proprietary PEGylation materials and reimbursement for research and development activities. All of our collaboration agreements are generally cancelable by our partners without significant financial penalty. Our costs of performing these services are generally included in research and development expense, except that costs for product sales to our collaboration partners are included in cost of goods sold.

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In accordance with our collaboration agreements, we recognized license, collaboration and other revenue as follows (in thousands):

Partner	Drug or Drug Candidate	Three months ended September 30,		Nine months ended September 30,	
		2014	2013	2014	2013
AstraZeneca AB	MOVANTIK™ (NKTR-118) and MOVANTIK™ fixed-dose combination program (NKTR-119)	\$105,000	\$25,000	\$105,001	\$25,016
Baxter Healthcare	BAX 855 (Hemophilia)	9,096	201	10,103	1,499
Roche	PEGASYS® and MIRCERA®	3,200	2,625	9,614	7,875
Bayer Healthcare LLC	BAY41-6551 (Amikacin Inhale)	793	779	3,939	14,604
Amgen, Inc.	Neulasta®	1,250	1,250	3,750	3,750
Other		1,217	11,505	14,015	14,451
	License, collaboration, and other revenue	<u>\$120,556</u>	<u>\$41,360</u>	<u>\$146,422</u>	<u>\$67,195</u>

As of September 30, 2014, our collaboration agreements include potential aggregate future payments for development milestones of approximately \$138.3 million, including the milestone amounts from our collaboration agreements with Bayer and Baxter described below. In addition, we are entitled to receive up to \$140.0 million and \$75.0 million of contingent payments related to the MOVANTIK™ (previously referred to as naloxegol and NKTR-118) and MOVANTIK™ fixed-dose combination (previously referred to as NKTR-119) drug development programs, respectively, based on development and regulatory events to be pursued and completed solely by AstraZeneca.

There have been no material changes to our collaboration agreements in the three or nine months ended September 30, 2014, except as described below.

**AstraZeneca AB:** MOVANTIK™ (naloxegol oxalate), previously referred to as naloxegol and NKTR-118, and MOVANTIK™ fixed-dose combination program, previously referred to as NKTR-119

In September 2009, we entered into a license agreement with AstraZeneca AB (AstraZeneca), as amended by AstraZeneca and us in August 2013, under which we granted AstraZeneca a worldwide, exclusive, perpetual, royalty-bearing, and sublicensable license under our patents and other intellectual property to develop, market, and sell MOVANTIK™ and MOVANTIK™ fixed-dose combination program. AstraZeneca is responsible for all costs associated with research, development and commercialization and is responsible for all drug development and commercialization decisions for MOVANTIK™ and the MOVANTIK™ fixed-dose combination program.

On September 16, 2014, the United States Food and Drug Administration (FDA) approved MOVANTIK™ for the treatment of opioid-induced constipation (OIC) in adult patients with chronic, non-cancer pain. As a result, on September 16, 2014, we were entitled to a \$35.0 million non-refundable payment from AstraZeneca, which was fully recognized as revenue in September 2014 and was received in October 2014. In addition, the FDA's approval of MOVANTIK™ extinguished our contingent obligation to repay the \$70.0 million payment made to us by AstraZeneca in November 2013 after the MOVANTIK™ New Drug Application was accepted for review by the FDA. As a result, in September 2014, we fully recognized this \$70.0 million payment, which was previously recorded in the line item "Liability related to receipt of refundable milestone payment" on our Condensed Consolidated Balance Sheet.

As part of its approval of MOVANTIK™, the FDA required AstraZeneca to perform a post-marketing, observational epidemiological study comparing MOVANTIK™ to other treatments of OIC in patients with chronic, non-cancer pain. As a result, the royalty rate payable to us from net sales of MOVANTIK™ in the U.S. by AstraZeneca will be reduced by up to two percentage points to fund 33% of the external costs incurred by AstraZeneca to fund such post approval study subject to a \$35.0 million aggregate cap. Any costs incurred by AstraZeneca can only be recovered by the reduction of the royalty paid to us. In no case can amounts be recovered by the reduction of a contingent payment due from AstraZeneca to us or through a payment from us to AstraZeneca.

We will be entitled to up to an additional \$140.0 million of contingent payments, as well as royalties and annual sales milestones, upon the first commercial sale of MOVANTIK™, \$100.0 million of which will be payable upon the first commercial sale in the U.S. and \$40.0 million of which will be payable upon the first commercial sale in one major European Union country. We are also entitled to receive up to \$75.0 million of commercial launch contingent payments related to the MOVANTIK™ fixed-dose combination program, based on development events to be pursued and completed solely by AstraZeneca. In addition, we are entitled to royalties and sales milestone payments based on annual worldwide net sales of MOVANTIK™ and MOVANTIK™ fixed-dose combination products.

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### **Roche: PEGASYS® and MIRCERA®**

In February 1997, we entered into a license, manufacturing and supply agreement with Roche, under which we granted Roche a worldwide, exclusive license to certain intellectual property related to our proprietary PEGylation materials used in the manufacture and commercialization of PEGASYS®. As of September 30, 2014, we have deferred revenue of approximately \$6.4 million related to this agreement, which we expect to recognize through December 2015, the period through which we are required to provide back-up manufacturing and supply services related to PEGASYS®.

In February 2012, we entered into a toll-manufacturing agreement with Roche under which we will manufacture the proprietary PEGylation material used by Roche to produce MIRCERA®. Roche entered into the toll-manufacturing agreement with the objective of establishing us as a secondary back-up supply source on a non-exclusive basis. Under the terms of our toll-manufacturing agreement, Roche paid us an upfront payment of \$5.0 million and an additional \$22.0 million in performance-based milestone payments upon our achievement of certain manufacturing readiness, validation and production milestones, including the delivery of specified quantities of PEGylation materials, all of which were completed as of January 2013. Roche will also pay us additional consideration for any future orders of the PEGylation materials for MIRCERA® beyond the initial quantities manufactured through January 2013. Roche has the right to terminate the toll-manufacturing agreement due to an uncured material default by us. As of September 30, 2014, we have deferred revenue of approximately \$12.1 million related to this agreement, which we expect to recognize through December 2016, the estimated end of our obligations under this agreement.

In August 2013, we agreed to deliver additional quantities of PEGylation materials used by Roche to produce PEGASYS® and MIRCERA®, all of which were delivered in the last quarter of 2013, for total consideration of \$18.6 million. We determined that these incremental activities should be considered a material modification of the existing PEGASYS® and MIRCERA® -related arrangements described above. As a result, we allocated the \$18.6 million consideration to each of these arrangements and determined the amounts to be recognized or deferred based on the estimated selling prices of the undelivered obligations. As of September 30, 2014, we have deferred revenue of approximately \$5.1 million related to these activities, which we expect to recognize through December 2016, the estimated end of our obligations under the modified arrangements.

### **Bayer Healthcare LLC: BAY41-6551 (Amikacin Inhale)**

In August 2007, we entered into a co-development, license and co-promotion agreement with Bayer Healthcare LLC (Bayer) to develop a specially-formulated inhaled Amikacin. We are responsible for development and manufacturing and supply of the nebulizer device included in the Amikacin product. In April 2013, Bayer initiated a Phase 3 clinical trial in the treatment of intubated and mechanically ventilated patients with Gram-negative pneumonia. As of September 30, 2014, we have received an upfront payment of \$40.0 million in 2007 and milestone payments totaling \$30.0 million. In addition, in June 2013, we made a \$10.0 million payment to Bayer for the reimbursement of its costs of the Phase 3 clinical trial.

In addition, we are entitled to receive a total of up to \$50.0 million for development milestones upon achievement of certain development objectives, as well as sales milestones upon achievement of annual sales targets and royalties based on annual worldwide net sales of Amikacin Inhale. As of September 30, 2014, we have deferred revenue of approximately \$21.2 million related to this agreement, which we expect to recognize through December 2026, the estimated end of our obligations under this agreement.

### **Amgen, Inc.: Neulasta®**

In October 2010, we amended and restated an existing supply and license agreement by entering into a supply, dedicated suite and manufacturing guarantee agreement (the amended and restated agreement) and a license agreement with Amgen Inc. and Amgen Manufacturing, Limited. As of September 30, 2014, we have deferred revenue of approximately \$30.4 million related to this agreement, which we expect to recognize through October 2020, the estimated end of our obligations under this agreement.

### **Baxter Healthcare: Hemophilia**

In September 2005, we entered into an exclusive research, development, license and manufacturing and supply agreement with Baxter Healthcare SA and Baxter Healthcare Corporation (together referred to as Baxter) to develop products designed to improve therapies for Hemophilia A patients using our PEGylation technology. Under the terms of this agreement, as of September 30, 2014, we are entitled to up to \$20.0 million of development milestones related to Hemophilia A upon achievement of certain development objectives, as well as sales milestones upon achievement of annual sales targets and royalties based on annual worldwide net sales of products resulting from this agreement. This Hemophilia A program includes BAX 855. In August 2014, Baxter announced positive top-line results from its Phase 3 pivotal clinical trial of BAX 855 which met the primary endpoint for the control and prevention of bleeding, routine prophylaxis and perioperative management for patients who were 12 years or older. As a result of this Phase 3 clinical trial meeting its primary endpoint, we achieved development milestones totaling \$8.0 million. Given our significant efforts in the development of this product, we consider these milestones to be substantive and we recognized the milestones in their entirety in the three months ended September 30, 2014. As of September 30, 2014, we do not have significant deferred revenue related to this agreement.

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### **Ophthotech Corporation: Fovista®**

We are a party to an agreement with Ophthotech Corporation (Ophthotech), dated September 30, 2006, under which Ophthotech received a worldwide, exclusive license to certain of our proprietary PEGylation technology to develop, manufacture and sell Fovista®. Under the terms of our agreement, we are the exclusive supplier of all of Ophthotech's clinical and commercial requirements for our proprietary PEGylation reagent used in Fovista®. On May 19, 2014, Ophthotech entered into a Licensing and Commercialization Agreement with Novartis Pharma AG for Fovista®. Under our agreement with Ophthotech, we were entitled to a \$19.75 million payment in connection with this licensing agreement, which was received in June 2014. As of September 30, 2014, we have deferred revenue of approximately \$19.3 million related to this agreement, which we expect to recognize through March 2028, the estimated end of our obligations under our agreement with Ophthotech.

In addition, we are entitled to up to \$9.5 million in additional payments based upon Ophthotech's potential achievement of certain regulatory and sales milestones. We are also entitled to low- to mid- single-digit royalties on net sales of Fovista® that vary based on sales levels. Our right to receive royalties in any particular country will expire upon the later of ten years after the first commercial sale of Fovista® or expiration of patent rights in such country.

### **Other**

During the nine months ended September 30, 2014, two of our collaboration partners achieved the successful transfer of our commercial manufacturing process in connection with the PEGylation materials used in their products. In connection with our assistance with these manufacturing technology transfers, we received a total of \$9.0 million of milestone payments. We concluded that these payments are substantive milestones and recognized them in their entirety in the three months ended June 30, 2014.

In addition, we have a number of collaboration agreements, including agreements with our collaboration partners UCB and Regado Biosciences, Inc., under which we are entitled to up to a total of \$61.8 million of development milestones upon achievement of certain development objectives, as well as sales milestones upon achievement of annual sales targets and royalties based on net sales of commercialized products, if any. However, given the current phase of development of the potential products under these collaboration agreements, we cannot estimate the probability or timing of achieving these milestones.

### **Note 8 — Stock-Based Compensation**

Total stock-based compensation expense was recognized in our Condensed Consolidated Statements of Operations as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Cost of goods sold	\$ 268	\$ 327	\$ 867	\$ 974
Research and development expense	1,774	2,071	5,579	5,923
General and administrative expense	2,080	2,166	6,201	6,268
Total stock-based compensation	<u>\$ 4,122</u>	<u>\$ 4,564</u>	<u>\$ 12,647</u>	<u>\$ 13,165</u>

During the three months ended September 30, 2014 and 2013, we granted 632,550 and 449,010 stock options, respectively, at a weighted average grant-date fair value of \$5.80 per share and \$7.11 per share, respectively.

During the nine months ended September 30, 2014 and 2013, we granted 4,408,590 and 3,438,320 stock options, respectively, at a weighted average grant-date fair value of \$5.84 per share and \$4.95 per share, respectively.

As a result of stock issuances under our equity compensation plans, during the three months ended September 30, 2014 and 2013, we issued 961,395 and 306,859 common shares, respectively, and during the nine months ended September 30, 2014 and 2013, we issued 1,979,282 and 731,073 common shares, respectively.

### **Note 9 — Net Income (Loss) Per Share**

Basic net income (loss) per share is calculated based on the weighted-average number of common shares outstanding during the periods presented. Diluted net income (loss) per share is calculated based on the weighted-average number of common shares outstanding, including potential dilutive securities. For all periods presented in the accompanying Condensed Consolidated Statements of Operations, the net income (loss) available to common stockholders is equal to the reported net income (loss).

The calculation of diluted net income per share for the three months ended September 30, 2014 includes the weighted average of potentially dilutive securities, which consists of approximately 4.7 million stock options.

For periods in which we have generated a net loss, basic and diluted net loss per share are the same due to the requirement to exclude potentially dilutive securities which would have an anti-dilutive effect on net loss per share. The weighted average of these potentially dilutive securities for the three months ended September 30, 2013 consisted of approximately 9.7 million stock options, and for the nine months ended September 30, 2014 and 2013 consisted of approximately 10.1 million and 13.0 million, respectively, stock options.



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

The following discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed here. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in this section as well as factors described in "Part II, Item 1A-Risk Factors."

### Overview

#### *Strategic Direction of Our Business*

We are a clinical-stage biopharmaceutical company developing a pipeline of drug candidates that utilize our PEGylation and advanced polymer conjugate technology platforms, which are designed to enable the development of new molecular entities that target known mechanisms of action. Our current proprietary pipeline is comprised of drug candidates across a number of therapeutic areas including oncology, pain, anti-infectives, and immunology. Our research and development activities involve small molecule drugs, peptides and other biologic drug candidates. We create innovative drug candidates by using our proprietary advanced polymer conjugate technologies and expertise to modify the chemical structure of pharmacophores to create new molecular entities. Polymer chemistry is a science focused on the synthesis or bonding of polymer architectures with drug molecules to alter the properties of a molecule. Additionally, we may utilize established pharmacologic targets to engineer a new drug candidate relying on a combination of the known properties of these targets and our proprietary polymer chemistry technology and expertise. Our drug candidates are designed to improve the overall benefits and use of a drug for patients by improving the metabolism, distribution, pharmacokinetics, pharmacodynamics, half-life and/or bioavailability of drugs. Our objective is to apply our advanced polymer conjugate technology platform to create new drug candidates in multiple therapeutic areas that address large potential markets.

Our most advanced proprietary product candidate, MOVANTI<sup>TM</sup> (naloxegol), is the first once-daily peripherally acting mu-opioid receptor agonist (PAMORA) for the treatment of opioid induced constipation (OIC) in adult patients with chronic non-cancer pain. The FDA approved MOVANTI<sup>TM</sup> on September 16, 2014, and on September 26, 2014, AstraZeneca announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency adopted a positive opinion recommending approval of MOVENTIG<sup>®</sup> (the naloxegol brand name in the European Union). The CHMP's positive opinion on MOVENTIG<sup>®</sup> will be reviewed by the European Commission, which has the authority to approve medicines for the European Union. The final decision from the European Commission is expected in December 2014 and will be applicable to all 28 European Union member countries plus Iceland and Norway. Should the European Commission approve MOVENTIG<sup>®</sup>, it will be the first once-daily, oral PAMORA available in these markets for the treatment of OIC in adult patients who have had an inadequate response to laxatives. AstraZeneca's commercial launch of MOVANTI<sup>TM</sup> in both the U.S. and EU is subject to the completion of the U.S. Drug Enforcement Agency's (DEA) determination that MOVANTI<sup>TM</sup> is an unscheduled drug under the Controlled Substances Act (CSA). On October 29, 2014, the DEA published a notice of public rule making in the Federal Register designating MOVANTI<sup>TM</sup> as a decontrolled substance under the CSA. We currently expect the decontrol process to be completed during the first quarter of 2015 although there is no prescribed timeframe for the DEA to complete the final rule-making process.

We are a party to an exclusive worldwide license agreement with AstraZeneca for the global development and commercialization of MOVANTI<sup>TM</sup> and MOVANTI<sup>TM</sup> fixed-dose combination products (formerly known as NKTR-119). The core Phase 3 clinical development program for MOVANTI<sup>TM</sup>, which AstraZeneca called the KODIAC program, was comprised of four clinical trials which were designed to investigate the safety and efficacy of MOVANTI<sup>TM</sup> for the treatment of OIC in adult patients with non-cancer related pain. The timing of the DEA's completion of the decontrol process and AstraZeneca's planned commercial launch of MOVANTI<sup>TM</sup> in the United States will have a significant impact on our financial condition in 2015 with a \$100 million commercial launch milestone becoming payable upon the first commercial sale of MOVANTI<sup>TM</sup>. The outcome of the European Commission's final regulatory decision on MOVENTIG<sup>®</sup>, and if approved, the timing of AstraZeneca's first commercial sale of MOVENTIG<sup>®</sup> in a major European Union country will determine if and when we would receive the \$40 million EU commercial launch milestone. AstraZeneca is responsible for all clinical, regulatory and commercialization costs for both the MOVANTI<sup>TM</sup> drug candidate and all drug candidates within the MOVANTI<sup>TM</sup> fixed-dose combination program.

Our second most advanced proprietary drug candidate, etirinotecan pegol, is a next-generation topoisomerase I inhibitor. Etirinotecan pegol is currently being evaluated as a single-agent therapy in a Phase 3 open-label, randomized, multicenter clinical study in patients with metastatic breast cancer. This Phase 3 clinical study, which we call the BEACON study (BrEAsT Cancer Outcomes with etirinotecan pegol), enrolled 852 patients with metastatic breast cancer that have previously received treatment with an anthracycline, a taxane, and capecitabine. We completed enrollment in the BEACON study in late July 2013. On January 14, 2014, we announced that the Independent Data Monitoring Committee created to provide safety oversight for the BEACON study recommended continuation of the Phase 3 BEACON study following an interim data analysis which was performed after reaching 50% of the events needed to achieve the primary endpoint of overall survival. In November 2012, the development program for metastatic breast cancer was granted Fast Track designation by the FDA. The BEACON study will continue to require a substantial investment through 2015.

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Our third most advanced proprietary drug candidate, NKTR-181, is a novel mu-opioid analgesic drug candidate for chronic pain conditions. The molecule has been designed to have a slow rate of entry into the brain, which is expected to reduce the attractiveness of the molecule as a target of abuse and reduce other serious central nervous system-related side effects, such as sedation and respiratory depression, which are commonly associated with standard opioid therapies. In May 2012, the development program for NKTR-181 for the treatment of moderate to severe chronic pain was granted Fast Track designation by the FDA. On June 19, 2013, we announced positive data from a human abuse liability study of NKTR-181. On September 26, 2013, we announced preliminary topline results from a Phase 2 clinical study of NKTR-181 in patients with moderate to severe chronic pain from osteoarthritis of the knee. The Phase 2 study utilized a double-blind, placebo-controlled, randomized withdrawal study design to assess the efficacy, safety and tolerability of NKTR-181. Of the 295 patients that entered the study, only nine (3%) patients did not achieve meaningful pain relief with NKTR-181. During the titration period, 53 (18%) patients discontinued treatment because of adverse events, most of which are those commonly associated with opioids. A total of 213 patients achieved an average 40% reduction in pain and entered the randomized phase of the study. NKTR-181 performed as expected as an opioid analgesic throughout the study. However, patients who were randomized to the placebo arm did not show the expected increase in pain scores observed in similar enriched enrollment, randomized withdrawal studies. This lack of a placebo rebound caused the Phase 2 study to miss the primary endpoint, which was the average change in a patient's pain score from baseline to the end of the double-blind, randomized treatment period. We are working with the FDA to finalize the appropriate Phase 3 clinical study design for NKTR-181 and expect to begin dosing in a Phase 3 clinical study in early 2015.

We have a significant collaboration with Bayer Healthcare LLC (Bayer) to develop BAY41-6551 (Amikacin Inhale, formerly known as NKTR-061), which is an inhaled solution of amikacin, an aminoglycoside antibiotic. Bayer has initiated a Phase 3 clinical development of BAY41-6551 with the first patient enrolled in April 2013. We originally developed the liquid aerosol inhalation platform and Amikacin Inhale and entered into a collaboration agreement with Bayer in August 2007 to further advance the development and potential commercialization of this drug candidate. In 2011, Bayer achieved agreement with the FDA on the design of the planned Phase 3 clinical studies of BAY41-6551 under the Special Protocol Assessment process that is intended to support the submission of an NDA if the ongoing Phase 3 clinical study is successful.

We also have a significant collaboration with Baxter Healthcare to identify and develop PEGylated drug candidates with the objective of providing new long-acting therapies for hemophilia patients. Under the terms of this collaboration, we have granted Baxter a license to our PEGylation intellectual property, technology and expertise and we have performed research and development activities. Baxter is responsible for all clinical development. The first drug candidate in this collaboration, BAX 855, is a longer-acting (PEGylated) form of a full-length recombinant factor VIII (rFVIII) protein which has completed Phase 3 clinical development in patients with Hemophilia A. In August 2014, Baxter announced positive top-line results from its global, multi-center Phase 3 pivotal clinical trial of BAX 855 called PROLONG-ATE which met the primary endpoint for the control and prevention of bleeding, routine prophylaxis and perioperative management for patients who were 12 years or older. Baxter has announced that it plans to file a biologic license application with the FDA prior to the end of this year. If BAX 855 is approved by health authorities and is successfully commercialized by Baxter, this will represent a substantial royalty revenue opportunity for us, subject to significant risks and uncertainties relating to the health authority regulatory review process, and if approved, subsequent commercial success.

While the late stage clinical development programs described above are key elements of the future success of our company, we believe it is critically important that we continue to make substantial investments in our earlier-stage drug candidate pipeline. We have several drug candidates in research that we are preparing to advance into the clinic in future years. While we believe that our substantial investment in research and development has the potential to create significant value if one or more of our drug candidates demonstrate positive clinical results, receive regulatory approval in one or more major markets and achieve commercialization success, drug research and development is an inherently uncertain process and there is a high risk of failure at every stage prior to approval and the timing and outcome of clinical trial results are extremely difficult to predict. Clinical development successes and failures can have a disproportionate positive or negative impact on our scientific and medical prospects, financial condition and prospects, results of operation and market value.

Historically, we have entered into a number of license and supply contracts under which we manufactured and supplied our proprietary PEGylation reagents on a cost-plus or fixed price basis. Our current strategy is to manufacture and supply PEGylation reagents to support our proprietary drug candidates or our third-party collaborators where we have a strategic development and commercialization relationship or where we derive substantial economic benefit.

### ***Key Developments and Trends in Liquidity and Capital Resources***

On January 28, 2014, we completed the issuance and sale of 9,775,000 shares of our common stock in a public offering with total proceeds of approximately \$117.2 million after deducting the underwriting commissions and discounts of approximately \$7.5 million. In addition, we incurred approximately \$0.7 million in legal and accounting fees, filing fees, and other costs in connection with this offering.

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As of September 30, 2014, we estimated that we had at least twelve months of working capital to fund our current business plans. At September 30, 2014, we had approximately \$261.6 million in cash and investments in marketable securities, of which \$25.0 million was restricted in relation to our 12.0% senior secured notes, and \$158.3 million in indebtedness. The indebtedness includes \$125.0 million in aggregate principal amount of 12.0% senior secured notes due July 15, 2017, but excludes our long-term liability relating to the sale of future royalties under the Purchase and Sale Agreement with RPI Finance Trust. As is further described in Note 4 to our Condensed Consolidated Financial Statements, this royalty obligation liability will not be settled in cash.

### **Results of Operations**

*Three and Nine Months Ended September 30, 2014 and 2013*

*Revenue (in thousands, except percentages)*

	Three months ended September 30, 2014	Three months ended September 30, 2013	Increase / (Decrease) 2014 vs. 2013	Percentage Increase / (Decrease) 2014 vs. 2013
Product sales and royalty revenue	\$ 6,172	\$ 15,026	\$ (8,854)	(59)%
Non-cash royalty revenue related to sale of future royalties	6,143	4,523	1,620	36%
License, collaboration and other revenue	120,556	41,360	79,196	>100%
Total revenue	<u>\$ 132,871</u>	<u>\$ 60,909</u>	<u>\$ 71,962</u>	>100%

  

	Nine months ended September 30, 2014	Nine months ended September 30, 2013	Increase / (Decrease) 2014 vs. 2013	Percentage Increase / (Decrease) 2014 vs. 2013
Product sales and royalty revenue	\$ 17,980	\$ 37,836	\$ (19,856)	(52)%
Non-cash royalty revenue related to sale of future royalties	16,753	12,744	4,009	31%
License, collaboration and other revenue	146,422	67,195	79,227	>100%
Total revenue	<u>\$ 181,155</u>	<u>\$ 117,775</u>	<u>\$ 63,380</u>	54%

Our revenue is derived from our collaboration agreements, under which we may receive product sales revenue, royalties, license fees, milestone payments or contract research payments. Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed or determinable, and collection is reasonably assured. The amount of upfront fees received under our license and collaboration agreements allocated to continuing obligations, such as manufacturing and supply commitments, are recognized ratably over our expected performance period under the arrangement. As a result, there may be significant variations in the timing of receipt of cash payments and our recognition of revenue. We make our best estimate of the period over which we expect to fulfill our performance obligations. Given the uncertainties in research and development collaborations, significant judgment is required by us to determine the performance periods.

### **Product sales and royalty revenue**

Product sales include fixed price and cost-plus manufacturing and supply agreements with our collaboration partners. The timing of product shipments is based on the demand and requirements of our collaboration partners and is not ratable throughout the year. We receive royalty revenue from certain of our collaboration partners based on their net sales of commercial products.

Product sales and royalty revenue decreased for the three and nine months ended September 30, 2014 compared to the three and nine months ended September 30, 2013 primarily due to decreased product sales as a result of decreased product demand from collaboration partners. We expect product sales and royalty revenue for the full year of 2014 to be substantially lower than 2013.

### **Non-cash royalty revenue related to sale of future royalties**

In February 2012, we sold all of our rights to receive future royalty payments on CIMZIA® and MIRCERA®. As described in Note 4 to our Condensed Consolidated Financial Statements, this royalty sale transaction has been recorded as a liability that amortizes over the estimated royalty payment period. As a result of this liability accounting, even though the royalties from UCB and Roche are remitted directly to the purchaser of these royalty interests, we will continue to record revenue for these royalties. During the three months ended September 30, 2014 and 2013, we recognized \$6.1 million and \$4.5 million, respectively, in aggregate royalties from net sales of CIMZIA® and MIRCERA®. During the nine months ended September 30, 2014 and 2013, we recognized \$16.8 million and \$12.7 million in aggregate royalties from net sales of CIMZIA® and MIRCERA®. We expect non-cash royalties from net sales of CIMZIA® and MIRCERA® in the full year of 2014 to be substantially consistent with 2013.

**License, Collaboration and Other Revenue**

License, collaboration and other revenue includes the recognition of upfront payments and milestone payments received from our license and collaboration agreements and reimbursed research and development expenses. The level of license, collaboration and other revenue depends on a combination of factors including the estimated amortization period of the upfront payments, the achievement of milestones, the continuation of existing collaborations, the amount of reimbursed research and development work, and entering into new collaboration agreements, if any.

License, collaboration and other revenue increased for the three and nine months ended September 30, 2014 compared to the three and nine months ended September 30, 2013 primarily as a result of the recognition of \$35.0 million and \$70.0 million milestone payments from AstraZeneca as a result of the FDA's approval of MOVANTI<sup>TM</sup> in September 2014 as well as \$8.0 million of milestones related to Baxter's BAX 855 Phase 3 study in September 2014. These increases in 2014 as compared to 2013 were partially offset by the recognition of a \$25.0 million payment from AstraZeneca achieved in September 2013 on the acceptance for review by the EMA of the MOVANTI<sup>TM</sup> regulatory approval application filed by AstraZeneca as well as the recognition in July 2013 of the remaining \$6.7 million deferred revenue balance related to our agreement with Affymax as a result of the termination of that agreement. In addition, in April 2013, we recognized a \$10.0 million milestone achieved upon the start of the Amikacin Inhale Phase 3 clinical trial by Bayer.

We expect license, collaboration and other revenue for the full year of 2014 to be higher than 2013 due primarily to the MOVANTI<sup>TM</sup> related milestones discussed above.

**Cost of Goods Sold and Product Gross Margin (in thousands, except percentages)**

	Three months ended September 30, 2014	Three months ended September 30, 2013	Increase / (Decrease) 2014 vs. 2013	Percentage Increase / (Decrease) 2014 vs. 2013
Cost of goods sold	\$ 9,220	\$ 12,877	\$ (3,657)	(28)%
Product gross profit	\$ (3,048)	\$ 2,149	\$ (5,197)	(>100)%
Product gross margin	(49)%	14%		

  

	Nine months ended September 30, 2014	Nine months ended September 30, 2013	Increase / (Decrease) 2014 vs. 2013	Percentage Increase / (Decrease) 2014 vs. 2013
Cost of goods sold	\$ 22,235	\$ 29,549	\$ (7,314)	(25)%
Product gross profit	\$ (4,255)	\$ 8,287	\$ (12,542)	(>100)%
Product gross margin	(24)%	22%		

Cost of goods sold decreased during the three months ended September 30, 2014 compared to the three months ended September 30, 2013 primarily due to the decrease in product sales of \$8.6 million in the three months ended September 30, 2014 compared to the three months ended September 30, 2013. Cost of goods sold decreased during the nine months ended September 30, 2014 compared to the nine months ended September 30, 2013 primarily due to the decrease in product sales of \$19.1 million in the nine months ended September 30, 2014 compared to the nine months ended September 30, 2013.

The decrease in product gross profit and product gross margin during the three and nine months ended September 30, 2014 compared to the three and nine months ended September 30, 2013 is primarily due to the different mix of products sold as well as decreased manufacturing activity in 2014.

We expect product gross margin to continue to fluctuate in future periods depending on the level and mix of manufacturing orders due to the fixed cost base for our manufacturing activities. We currently expect product gross margin to be negative for the full year of 2014 as a result of the anticipated reduction in product sales in 2014 as compared to 2013, as well as based on the anticipated product mix.

[Table of Contents](#)**Research and Development Expense (in thousands, except percentages)**

	Three months ended September 30, 2014	Three months ended September 30, 2013	Increase / (Decrease) 2014 vs. 2013	Percentage Increase / (Decrease) 2014 vs. 2013
Research and development expense	\$ 34,200	\$ 43,914	\$ (9,714)	(22)%

  

	Nine months ended September 30, 2014	Nine months ended September 30, 2013	Increase / (Decrease) 2014 vs. 2013	Percentage Increase / (Decrease) 2014 vs. 2013
Research and development expense	\$ 109,240	\$ 141,762	\$ (32,522)	(23)%

Research and development expense consists primarily of personnel costs (including salaries, benefits, and stock-based compensation), clinical study costs, costs of third party research, materials, supplies, licenses and fees. Research and development expense also includes overhead allocations of support and facilities related costs.

Research and development expense decreased during the three and nine months ended September 30, 2014 compared to the three and nine months ended September 30, 2013 primarily due to reduced activities on our ongoing Phase 3 BEACON study for etirinotecan pegol as the study progresses toward completion as well as the completion of our Phase 2 clinical study for NKTR-181 in the third quarter of 2013.

Research and development expense is not expected to be ratable over the four quarters of the year. Overall, we expect research and development expense to decrease significantly in the full year of 2014 as compared to 2013.

Other than as described in the Overview section above, there have been no material changes to the status of clinical programs in the nine months ended September 30, 2014 from the activities discussed in our Annual Report on Form 10-K for the year ended December 31, 2013 on file with the Securities and Exchange Commission.

**General and Administrative Expense (in thousands, except percentages)**

	Three months ended September 30, 2014	Three months ended September 30, 2013	Increase / (Decrease) 2014 vs. 2013	Percentage Increase / (Decrease) 2014 vs. 2013
General and administrative expense	\$ 9,130	\$ 10,643	\$ (1,513)	(14)%

  

	Nine months ended September 30, 2014	Nine months ended September 30, 2013	Increase / (Decrease) 2014 vs. 2013	Percentage Increase / (Decrease) 2014 vs. 2013
General and administrative expense	\$ 28,677	\$ 30,700	\$ (2,023)	(7)%

General and administrative expense includes the cost of administrative staffing, business development, marketing, finance and legal activities. General and administrative expense during the three and nine months ended September 30, 2014 decreased marginally compared to the three and nine months ended September 30, 2013. We expect general and administrative expense during the full year of 2014 to be consistent with 2013.

[Table of Contents](#)**Interest Expense (in thousands, except percentages)**

	Three months ended September 30, 2014	Three months ended September 30, 2013	Increase / (Decrease) 2014 vs. 2013	Percentage Increase / (Decrease) 2014 vs. 2013
Interest expense	\$ 4,391	\$ 4,587	\$ (196)	(4)%
Non-cash interest expense on liability related to sale of future royalties	\$ 5,203	\$ 5,616	\$ (413)	(7)%
	Nine months ended September 30, 2014	Nine months ended September 30, 2013	Increase / (Decrease) 2014 vs. 2013	Percentage Increase / (Decrease) 2014 vs. 2013
Interest expense	\$ 13,412	\$ 13,888	\$ (476)	(3)%
Non-cash interest expense on liability related to sale of future royalties	\$ 15,725	\$ 16,644	\$ (919)	(6)%

In July 2012, we issued \$125.0 million of 12% senior secured notes due July 15, 2017. Interest expense for the three and nine month periods ended September 30, 2014 decreased marginally as compared to the three and nine month periods ended September 30, 2013. We expect interest expense during the full year of 2014 to be consistent with 2013.

Non-cash interest expense on the liability related to sale of future royalties for the three and nine month periods ended September 30, 2014 decreased marginally as compared to the three and nine month periods ended September 30, 2013. We sold all of our rights to receive future royalty payments on CIMZIA® and MIRCERA® to RPI in exchange for a cash payment of \$124.0 million in a royalty sale transaction in February 2012 as described in Note 4 to our Condensed Consolidated Financial Statements. We impute interest on the transaction and record interest expense at the effective interest rate, which we currently estimate to be approximately 17%. There are a number of factors that could materially affect the estimated interest rate and we assess this estimate on a periodic basis. As a result, future interest rates could differ significantly and any such change in interest rate will be adjusted prospectively. Unless we adjust our estimated interest rate, we expect non-cash interest expense on the liability related to sale of future royalties during the full year of 2014 to decrease marginally compared to 2013.

**Liquidity and Capital Resources**

We have financed our operations primarily through revenue from product sales, royalties and research and development contracts, as well as public offering and private placements of debt and equity securities. At September 30, 2014, we had approximately \$261.6 million in cash and investments in marketable securities, of which \$25.0 million was restricted in relation to our 12.0% senior secured notes, and \$158.3 million in indebtedness. The indebtedness includes \$125.0 million in aggregate principal amount of 12.0% senior secured notes due July 15, 2017, but excludes our long-term liability relating to the sale of future royalties. As is further described in Note 4 to our Condensed Consolidated Financial Statements, this royalty obligation liability will not be settled in cash.

As of September 30, 2014, we estimated that we had at least twelve months of working capital to fund our current business plans. We expect the clinical development of our proprietary drug candidates, including etirinotecan pegol, Amikacin Inhale, NKTR-181, and NKTR-171, will require significant investment in order to continue to advance in clinical development with the objective of entering into a collaboration partnership or obtaining regulatory approval. However, we have no credit facility or any other sources of committed capital. In addition, while in the past we have received a number of significant payments from collaboration agreements and other significant transactions, we do not currently anticipate completing new transactions with substantial upfront payments in the near term. Our current business plan is also subject to significant uncertainties and risks as a result of, among other factors, expenses being higher than anticipated, unplanned expenses, cash receipts being lower than anticipated, and the need to satisfy contingent liabilities, including litigation matters and indemnification obligations.

The availability and terms of various financing alternatives substantially depend on the success or failure of our drug development programs, including MOVANTI<sup>TM</sup>, etirinotecan pegol, BAX 855, Amikacin Inhale, NKTR-181, NKTR-171, as well as other early stage development programs. The availability and terms of financing alternatives and any future significant payments from existing or new collaborations all depend on the positive outcome of ongoing or planned clinical studies, whether we or our partners are successful in obtaining health authority approvals in major markets, and if approved, the commercial success of these drugs. In the event we do not enter into any new collaboration partnerships with significant upfront payments or do not receive the MOVANTI<sup>TM</sup> milestone payments as described above, we would likely be required to pursue financing alternatives. In the event we determine to pursue financing alternatives, our objective would be to first explore financing alternatives that are not dilutive to the ownership of our common stock security holders. However, if non-dilutive financing alternatives are not available to us on commercially reasonable terms or at all, we could be required to pursue dilutive equity-based financing alternatives such as an offering of convertible debt or common stock. If we do not receive substantial milestone payments from our existing collaboration agreements, execute new high-value collaborations or other arrangements, or are unable to raise additional capital in one or more financing transactions, we would be unable to continue our current level of investment in research and development.

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Due to the potential for adverse developments in the credit markets in 2014 and thereafter, we may experience reduced liquidity with respect to some of our investments in marketable securities. These investments are generally held to maturity, which, in accordance with our investment policy, is less than two years. However, if the need arises to liquidate such securities before maturity, we may experience losses on liquidation. At September 30, 2014, the average time to maturity of the investments held in our portfolio was approximately four months and the maturity of any single investment did not exceed one year. To date we have not experienced any liquidity issues with respect to these securities, but if such issues arise, we may be required to hold some, or all, of these securities until maturity. We believe that, even allowing for potential liquidity issues with respect to these securities, our remaining cash and investments in marketable securities will be sufficient to meet our anticipated cash needs for at least the next twelve months.

### *Cash flows from operating activities*

Cash flows used in operating activities for the nine months ended September 30, 2014 totaled \$117.4 million, which includes \$131.2 million of net operating cash uses as well as \$15.0 million for interest payments on our senior secured notes, partially offset by the receipt of \$28.8 million for milestones from collaboration agreements. During the nine months ended September 30, 2014, we recognized as revenue a \$70.0 million payment made to us from AstraZeneca in November 2013, which was previously recorded in the line item "Liability related to receipt of refundable milestone payment" on our Condensed Consolidated Balance Sheets. As of September 30, 2014, the accounts receivable balance in our Condensed Consolidated Balance Sheet includes \$35.0 million and \$8.0 million of milestone payments receivable from AstraZeneca and Baxter, respectively. Because of the nature and timing of certain cash receipts and payments, net cash utilization is not expected to be ratable over the four quarters of the year. We expect cash flows used in operating activities, excluding upfront and milestone payments received, if any, will increase for the full year of 2014 as compared to 2013.

Cash flows used in operating activities for the nine months ended September 30, 2013 totaled \$92.2 million, which includes \$124.5 million of net operating cash uses as well as \$15.2 million for interest payments on our senior secured notes, partially offset by the receipt of \$47.5 million for milestones from collaboration agreements.

### *Cash flows from investing activities*

We paid \$6.1 million and \$1.4 million to purchase property and equipment in the nine months ended September 30, 2014 and 2013, respectively.

### *Cash flows from financing activities*

On January 28, 2014, we completed the issuance and sale of 9,775,000 shares of our common stock in a public offering with total proceeds of approximately \$117.2 million after deducting the underwriting commissions and discounts of approximately \$7.5 million. In addition, we incurred approximately \$0.7 million in legal and accounting fees, filing fees, and other costs in connection with this offering.

On February 24, 2012, we sold all of our rights to receive future royalty payments on CIMZIA® and MIRCERA® in exchange for a cash payment of \$124.0 million. During the nine month periods ended September 30, 2014 and 2013, we made payments of \$7.0 million and \$3.0 million, respectively, to the purchaser of these royalties because certain minimum MIRCERA® net sales thresholds were not met. The remaining \$120.5 million royalty obligation liability at September 30, 2014 will not be settled in cash.

We received \$16.2 million and \$5.3 million from issuances of common stock to employees under our equity compensation plans during the nine months ended September 30, 2014 and 2013, respectively.

### **Contractual Obligations**

There were no material changes during the nine months ended September 30, 2014 to the summary of contractual obligations included in our Annual Report on Form 10-K for the year ended December 31, 2013 on file with the Securities and Exchange Commission.

### **Off-Balance Sheet Arrangements**

We do not utilize off-balance sheet financing arrangements as a source of liquidity or financing.

### **Critical Accounting Policies and Estimates**

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (GAAP) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period.

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We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form our basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates on an ongoing basis. Actual results may differ from those estimates under different assumptions or conditions. There have been no material changes to our critical accounting policies and estimates discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013.

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

Our market risks at September 30, 2014 have not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2013 on file with the Securities and Exchange Commission.

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

#### ***Disclosure Controls and Procedures***

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Securities Exchange Act of 1934 (Exchange Act) reports is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15. Based upon, and as of the date of, this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective.

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

We continuously seek to improve the efficiency and effectiveness of our internal controls. This results in refinements to processes throughout the Company. However, there was no change in our internal control over financial reporting that occurred in the three months ended September 30, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

#### ***Limitations on the Effectiveness of Controls***

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple errors or mistakes. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

## **PART II: OTHER INFORMATION**

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

Reference is hereby made to our disclosures in "Legal Matters" under Note 5 to our Condensed Consolidated Financial Statements in this Quarterly Report on Form 10-Q and the information under the heading "Legal Matters" is incorporated by reference herein.



**Item 1A. Risk Factors**

Investors in Nektar Therapeutics should carefully consider the risks described below before making an investment decision. The risks described below may not be the only ones relating to our company. This description includes any material changes to and supersedes the description of the risk factors associated with our business previously disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2013. Additional risks that we currently believe are immaterial may also impair our business operations. Our business, results of operations, financial condition, cash flows and future prospects and the trading price of our common stock and our abilities to repay our senior secured notes could be harmed as a result of any of these risks, and investors

may lose all or part of their investment. In assessing these risks, investors should also refer to the other information contained or incorporated by reference in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2013, including our consolidated financial statements and related notes, and our other filings made from time to time with the Securities and Exchange Commission (SEC).

## Risks Related to Our Business

### ***Drug development is a long and inherently uncertain process with a high risk of failure at every stage of development.***

We have a number of proprietary drug candidates and partnered drug candidates in research and development ranging from the early discovery research phase through preclinical testing and clinical trials. Preclinical testing and clinical studies are long, expensive and highly uncertain processes. It will take us, or our collaborative partners, several years to complete clinical studies. The start or end of a clinical study is often delayed or halted due to changing regulatory requirements, manufacturing challenges, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparator drug or required prior therapy, clinical outcomes, or our and our partners' financial constraints.

Drug development is a highly uncertain scientific and medical endeavor, and failure can unexpectedly occur at any stage of preclinical and clinical development. Typically, there is a high rate of attrition for drug candidates in preclinical and clinical trials due to scientific feasibility, safety, efficacy, changing standards of medical care and other variables. The risk of failure increases for our drug candidates that are based on new technologies, such as the application of our advanced polymer conjugate technology to small molecules, including MOVANTI<sup>TM</sup>, etirinotecan pegol, NKTR-181, NKTR-171 and other drug candidates currently in discovery research or preclinical development. The failure of one or more of our drug candidates could have a material adverse effect on our business, financial condition and results of operations.

### ***If we or our partners do not obtain regulatory approval for our drug candidates on a timely basis, or at all, or if the terms of any approval impose significant restrictions or limitations on use, our business, results of operations and financial condition will be negatively affected.***

We or our partners may not obtain regulatory approval for drug candidates on a timely basis, or at all, or the terms of any approval (which in some countries includes pricing approval) may impose significant restrictions or limitations on use. Drug candidates must undergo rigorous animal and human testing and an extensive review process for safety and efficacy by the FDA and equivalent foreign government health authorities. The time required for obtaining regulatory decisions is uncertain and difficult to predict. The FDA and other U.S. and foreign health authorities have substantial discretion, at any phase of development, to terminate clinical studies, require additional clinical development or other testing, delay or withhold registration and marketing approval and mandate product withdrawals, including recalls. Further, health authorities have the discretion to analyze data using their own methodologies that may differ from those used by us or our partners which could lead such authorities to arrive at different conclusions regarding the safety or efficacy of a drug candidate. In addition, undesirable side effects caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restricted label or the delay or denial of regulatory approval by regulatory authorities. For example, AstraZeneca will be conducting a post-marketing, observational epidemiological study comparing MOVANTI<sup>TM</sup> to other treatments of OIC in patients with chronic, non-cancer pain and the results of this study could at some point in the future negatively impact the label, regulatory status, and commercial potential of MOVANTI<sup>TM</sup>.

Even if we or our partners receive regulatory approval of a product, the approval may limit the indicated uses for which the drug may be marketed. Our partnered drugs that have obtained regulatory approval, and the manufacturing processes for these products, are subject to continued review and periodic inspections by the FDA and other regulatory authorities. Discovery from such review and inspection of previously unknown problems may result in restrictions on marketed products or on us, including withdrawal or recall of such products from the market, suspension of related manufacturing operations or a more restricted label. The failure to obtain timely regulatory approval of product candidates, any product marketing limitations or a product withdrawal would negatively impact our business, results of operations and financial condition.

### ***Even with success in previously completed clinical trials, the risk of clinical failure for any drug candidate remains high prior to regulatory approval.***

A number of companies have suffered significant unforeseen failures in late stage clinical studies due to factors such as inconclusive efficacy or safety, even after achieving positive results in earlier clinical studies that were satisfactory both to them and to reviewing government health authorities. While etirinotecan pegol and Amikacin Inhale have each demonstrated positive results from earlier clinical studies, there is a substantial risk that Phase 3 clinical study outcomes for these drug candidates from larger patient populations will not demonstrate positive efficacy, safety or other clinical outcomes sufficient to support regulatory filings and achieve regulatory approval. Phase 3 clinical study outcomes remain very unpredictable and it is possible that one or more of these Phase 3 clinical studies could fail at any time due to efficacy, safety or other important clinical findings or regulatory requirements. If one or more of these drug candidates fail in Phase 3 clinical studies, it would have a material adverse effect on our business, financial condition and results of operations.

***We are a party to numerous collaboration agreements and other significant agreements which contain complex commercial terms that could result in disputes, litigation or indemnification liability that could adversely affect our business, results of operations and financial condition.***

We currently derive, and expect to derive in the foreseeable future, all of our revenue from collaboration agreements with biotechnology and pharmaceutical companies. These collaboration agreements contain complex commercial terms, including:

- clinical development and commercialization obligations that are based on certain commercial reasonableness performance standards that can often be difficult to enforce if disputes arise as to adequacy of our partner's performance;
- research and development performance and reimbursement obligations for our personnel and other resources allocated to partnered drug candidate development programs;
- clinical and commercial manufacturing agreements, some of which are priced on an actual cost basis for products supplied by us to our partners with complicated cost allocation formulas and methodologies;
- intellectual property ownership allocation between us and our partners for improvements and new inventions developed during the course of the collaboration;
- royalties on drug sales based on a number of complex variables, including net sales calculations, geography, scope of patent claim coverage, patent life, generic competitors, bundled pricing and other factors; and
- indemnity obligations for intellectual property infringement, product liability and certain other claims.

We are a party to certain significant agreements, including an asset purchase agreement with Novartis pursuant to which we sold a significant portion of our pulmonary business at the end of 2008, the worldwide exclusive license agreement with AstraZeneca related to the further development and commercialization of MOVANTI<sup>TM</sup>, and the purchase and sale agreement with RPI Finance Trust (RPI) related to the sale of our royalty interests in UCB's CIMZIA<sup>®</sup> and Roche's MIRCERA<sup>®</sup> that we completed in February 2012. Each of these agreements contains complex representations and warranties, covenants and indemnification obligations. If we breach any of our agreements with Novartis, AstraZeneca, RPI or any other third party agreements, it could subject us to substantial liabilities and harm our financial condition.

From time to time, we have informal dispute resolution discussions with third parties regarding the appropriate interpretation of the complex commercial terms contained in our agreements. One or more disputes may arise or escalate in the future regarding our collaboration agreements, transaction documents, or third-party license agreements that may ultimately result in costly litigation and unfavorable interpretation of contract terms, which would have a material adverse effect on our business, financial condition and results of operations.

***We have substantial future capital requirements and there is a risk we may not have access to sufficient capital to meet our current business plan. If we do not receive substantial milestone payments from our existing collaboration agreements, execute new high value collaborations or other arrangements, or are unable to raise additional capital in one or more financing transactions, we would be unable to continue our current level of investment in research and development.***

As of September 30, 2014, we had cash and investments in marketable securities valued at approximately \$261.6 million, of which \$25.0 million was restricted in relation to our 12.0% senior secured notes, and indebtedness of approximately \$158.3 million. The indebtedness includes approximately \$125.0 million in senior secured notes due July 2017, but excludes our long-term liability relating to the sale of future royalties as this royalty obligation liability will not be settled in cash. While we believe that our cash position will be sufficient to meet our liquidity requirements through at least the next 12 months, our future capital requirements will depend upon numerous unpredictable factors, including:

- the cost, timing and outcomes of clinical studies and regulatory reviews of our proprietary drug candidates that we have licensed to our collaboration partners —important examples include MOVANTI<sup>TM</sup> that has been licensed to AstraZeneca, Amikacin Inhale that has been licensed to Bayer, and BAX 855 that is being developed by Baxter;
- the timing of the commercial launch of MOVANTI<sup>TM</sup> by AstraZeneca will be impacted by the timing of the completion of the DEA decontrol process —we are entitled to milestone payments of \$100.0 million and \$40.0 million from AstraZeneca upon the first commercial sale of MOVANTI<sup>TM</sup> by AstraZeneca in the United States and European Union, respectively. Although MOVENTIG<sup>®</sup> has received a positive opinion from the CHMP, the final regulatory approval decision has not yet been made by the European Commission and therefore remains subject to regulatory uncertainty.
- if and when we receive potential milestone payments and royalties from our existing collaborations if the drug candidates subject to those collaborations achieve clinical, regulatory or commercial success;
- the progress, timing, cost and results of our clinical development programs — in particular our Phase 3 BEACON study for etirinotecan pegol and our clinical studies for NKTR-181;
- the success, progress, timing and costs of our efforts to implement new collaborations, licenses and other transactions that increase our current net cash, such as the sale of additional royalty interests held by us, term loan or other debt arrangements, and the issuance of securities;

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- the outcome of the regulatory review process and commercial success of drug products for which we are entitled to receive royalties (e.g., MOVANTIK™ being developed by AstraZeneca);
- the number of patients, enrollment criteria, primary and secondary endpoints, and the number of clinical studies required by the government health authorities in order to consider for approval our drug candidates and those of our collaboration partners;
- our general and administrative expenses, capital expenditures and other uses of cash; and
- disputes concerning patents, proprietary rights, or license and collaboration agreements that negatively impact our receipt of milestone payments or royalties or require us to make significant payments arising from licenses, settlements, adverse judgments or ongoing royalties.

A significant multi-year capital commitment is required to advance our drug candidates through the various stages of research and development in order to generate sufficient data to enable high value collaboration partnerships with significant upfront payments or to successfully achieve regulatory approval. In the event we do not enter into any new collaboration partnerships with significant upfront payments and we choose to continue our later stage research and development programs, we may need to pursue financing alternatives, including dilutive equity-based financings, such as an offering of convertible debt or common stock, which would dilute the percentage ownership of our current common stockholders and could significantly lower the market value of our common stock. If sufficient capital is not available to us or is not available on commercially reasonable terms, it could require us to delay or reduce one or more of our research and development programs. If we are unable to sufficiently advance our research and development programs, it could substantially impair the value of such programs and result in a material adverse effect on our business, financial condition and results of operations.

***While we have conducted numerous experiments using laboratory and home-based chemistry techniques that have not been able to convert NKTR-181 into a rapid-acting and more abusable opioid, there is a risk that a technique could be discovered in the future to convert NKTR-181 into a rapid-acting and more abusable opioid, which would significantly diminish the value of this drug candidate.***

An important objective of our NKTR-181 drug development program is to create a unique opioid molecule that does not rapidly enter a patient's central nervous system and therefore has the potential to be less susceptible to abuse than alternative opioid therapies. To date, we have conducted numerous experiments using laboratory and home-based chemistry techniques that have been unable to convert NKTR-181 into a rapidly-acting, more abusable form of opioid. In the future, an alternative chemistry technique, process or method of administration, or combination thereof, may be discovered to enable the conversion of NKTR-181 into a more abusable opioid, which could significantly and negatively impact the commercial potential or diminish the value of NKTR-181.

***If we are unable to establish and maintain collaboration partnerships on attractive commercial terms, our business, results of operations and financial condition could suffer.***

We intend to continue to seek partnerships with pharmaceutical and biotechnology partners to fund a portion of our research and development capital requirements. The timing of new collaboration partnerships is difficult to predict due to availability of clinical data, the outcomes from our clinical studies, the number of potential partners that need to complete due diligence and approval processes, the definitive agreement negotiation process and numerous other unpredictable factors that can delay, impede or prevent significant transactions. If we are unable to find suitable partners or negotiate collaboration arrangements with favorable commercial terms with respect to our existing and future drug candidates or the licensing of our intellectual property, or if any arrangements we negotiate, or have negotiated, are terminated, it could have a material adverse effect on our business, financial condition and results of operations.

***Preliminary and interim data from our clinical studies that we announce or publish from time to time are subject to audit and verification procedures that could result in material changes in the final data and may change as more patient data become available.***

From time to time, we publish preliminary or interim data from our clinical studies. Preliminary data remain subject to audit confirmation and verification procedures that may result in the final data being materially different from the preliminary data we previously published. Interim data are also subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. As a result, preliminary and interim data should be viewed with caution until the final data are available. Material adverse changes in the final data could significantly harm our business prospects.

***Delays in clinical studies are common and have many causes, and any significant delay in clinical studies being conducted by us or our partners could result in delay in regulatory approvals and jeopardize the ability to proceed to commercialization.***

We or our partners may experience delays in clinical trials of drug candidates. Etirinotecan pegol in patients with metastatic breast cancer is currently in Phase 3 clinical studies, and Bayer has initiated Phase 3 clinical development of BAY41-6551 with the first patient enrolled in April 2013. We are currently in the planning stage for a Phase 3 clinical study for NKTR-181 including

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continuing consultations with leaders in the pain clinical trial field and interactions with the FDA. Because it is unlikely that we will be able to identify a single cause for the Phase 2 study for NKTR-181 not meeting its primary efficacy endpoint, there is an increased risk in effectively designing a Phase 3 clinical study to demonstrate the efficacy of NKTR-181. These and other of our planned clinical studies may not begin on time, have an effective design, enroll a sufficient number of patients or be completed on schedule, if at all. Our clinical trials for any of our product candidates could be delayed for a variety of reasons, including:

- delays in obtaining regulatory approval to commence a clinical study;
- delays in reaching agreement with applicable health authorities on a clinical study design;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other health authorities;
- suspension or termination of a clinical study by us, our partners, the FDA or foreign health authorities due to adverse side effects of a drug on subjects in the trial;
- delays in recruiting suitable patients to participate in a trial;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial to the detriment of enrollment rates;
- delays in manufacturing and delivery of sufficient supply of clinical trial materials; and
- changes in health authorities policies or guidance applicable to our drug candidates.

If the initiation or completion of any of the planned clinical studies for our drug candidates is delayed for any of the above or other reasons, the regulatory approval process would be delayed and the ability to commercialize and commence sales of these drug candidates could be materially harmed, which could have a material adverse effect on our business, financial condition and results of operations.

***The commercial potential of a drug candidate in development is difficult to predict. If the market size for a new drug is significantly smaller than we anticipate, it could significantly and negatively impact our revenue, results of operations and financial condition.***

It is very difficult to estimate the commercial potential of product candidates due to important factors such as safety and efficacy compared to other available treatments, including potential generic drug alternatives with similar efficacy profiles, changing standards of care, third party payer reimbursement standards, patient and physician preferences, drug scheduling status, the availability of competitive alternatives that may emerge either during the long drug development process or after commercial introduction, and the availability of generic versions of our successful product candidates following approval by government health authorities based on the expiration of regulatory exclusivity or our inability to prevent generic versions from coming to market by asserting our patents. If due to one or more of these risks the market potential for a drug candidate is lower than we anticipated, it could significantly and negatively impact the commercial terms of any collaboration partnership potential for such drug candidate or, if we have already entered into a collaboration for such drug candidate, the revenue potential from royalty and milestone payments could be significantly diminished and would negatively impact our business, financial condition and results of operations.

***We may not be able to obtain intellectual property licenses related to the development of our drug candidates on a commercially reasonable basis, if at all.***

Numerous pending and issued U.S. and foreign patent rights and other proprietary rights owned by third parties relate to pharmaceutical compositions, methods of preparation and manufacturing, and methods of use and administration. We cannot predict with any certainty which, if any, patent references will be considered relevant to our or our collaboration partners' technology or drug candidates by authorities in the various jurisdictions where such rights exist, nor can we predict with certainty which, if any, of these rights will or may be asserted against us by third parties. In certain cases, we have existing licenses or cross-licenses with third parties; however, the scope and adequacy of these licenses is very uncertain and can change substantially during long development and commercialization cycles for biotechnology and pharmaceutical products. There can be no assurance that we can obtain a license to any technology that we determine we need on reasonable terms, if at all, or that we could develop or otherwise obtain alternate technology. If we are required to enter into a license with a third party, our potential economic benefit for the products subject to the license will be diminished. If a license is not available on commercially reasonable terms or at all, we may be prevented from developing and selling the drug, which could significantly harm our business, results of operations, and financial condition.

***If any of our pending patent applications do not issue, or are deemed invalid following issuance, we may lose valuable intellectual property protection.***

The patent positions of pharmaceutical and biotechnology companies, such as ours, are uncertain and involve complex legal and factual issues. We own more than 175 U.S. and 500 foreign patents and a number of pending patent applications that cover various aspects of our technologies. There can be no assurance that patents that have issued will be held valid and enforceable in a court of law. Even for patents that are held valid and enforceable, the legal process associated with obtaining such a judgment is time

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consuming and costly. Additionally, issued patents can be subject to opposition or other proceedings that can result in the revocation of the patent or maintenance of the patent in amended form (and potentially in a form that renders the patent without commercially relevant and/or broad coverage). Further, our competitors may be able to circumvent and otherwise design around our patents. Even if a patent is issued and enforceable, because development and commercialization of pharmaceutical products can be subject to substantial delays, patents may expire early and provide only a short period of protection, if any, following the commercialization of products encompassed by our patents. We may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office, which could result in a loss of the patent and/or substantial cost to us.

We have filed patent applications, and plan to file additional patent applications, covering various aspects of our PEGylation and advanced polymer conjugate technologies and our proprietary product candidates. There can be no assurance that the patent applications for which we apply would actually issue as patents, or do so with commercially relevant and/or broad coverage. The coverage claimed in a patent application can be significantly reduced before the patent is issued. The scope of our claim coverage can be critical to our ability to enter into licensing transactions with third parties and our right to receive royalties from our collaboration partnerships. Since publication of discoveries in scientific or patent literature often lags behind the date of such discoveries, we cannot be certain that we were the first inventor of inventions covered by our patents or patent applications. In addition, there is no guarantee that we will be the first to file a patent application directed to an invention.

An adverse outcome in any judicial proceeding involving intellectual property, including patents, could subject us to significant liabilities to third parties, require disputed rights to be licensed from or to third parties or require us to cease using the technology in dispute. In those instances where we seek an intellectual property license from another, we may not be able to obtain the license on a commercially reasonable basis, if at all, thereby raising concerns on our ability to freely commercialize our technologies or products.

***We are involved in legal proceedings and may incur substantial litigation costs and liabilities that will adversely affect our business, financial condition and results of operations.***

From time to time, third parties have asserted, and may in the future assert, that we or our partners infringe their proprietary rights, such as patents and trade secrets, or have otherwise breached our obligations to them. The third party often bases its assertions on a claim that its patents cover our technology platform or drug candidates or that we have misappropriated its confidential or proprietary information. Similar assertions of infringement could be based on future patents that may issue to third parties. In certain of our agreements with our partners, we are obligated to indemnify and hold harmless our collaboration partners from intellectual property infringement, product liability and certain other claims, which could cause us to incur substantial costs and liability if we are called upon to defend ourselves and our partners against any claims. If a third party obtains injunctive or other equitable relief against us or our partners, they could effectively prevent us, or our partners, from developing or commercializing, or deriving revenue from, certain drugs or drug candidates in the U.S. and abroad. Costs associated with litigation, substantial damage claims, indemnification claims or royalties paid for licenses from third parties could have a material adverse effect on our business, financial condition and results of operations.

Third-party claims involving proprietary rights or other matters could also result in substantial settlement payments or substantial damages to be paid by us. For instance, a settlement might require us to enter a license agreement under which we would pay substantial royalties or other compensation to a third party, diminishing our future economic returns from the related drug. In December 2013, we entered into a litigation settlement with the Research Foundation of the State University of New York (SUNY) pursuant to which we agree to the payment of a total of \$12.0 million in future installments and certain other terms and conditions in exchange for the full release of certain breach of contract claims by SUNY.

In addition, from time to time, we may pursue claims or initiate lawsuits to protect or enforce our patent or other intellectual property rights or for other reasons. The cost to us in defending or initiating any litigation or other proceeding, even if resolved in our favor, could be substantial, and litigation would divert our management's attention. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations.

***Our manufacturing operations and those of our contract manufacturers are subject to laws and other governmental regulatory requirements, which, if not met, would have a material adverse effect on our business, results of operations and financial condition.***

We and our contract manufacturers are required in certain cases to maintain compliance with current good manufacturing practices (cGMP), including cGMP guidelines applicable to active pharmaceutical ingredients, and with laws and regulations governing manufacture and distribution of controlled substances, and are subject to inspections by the FDA, the Drug Enforcement Administration or comparable agencies in other jurisdictions administering such compliance. We anticipate periodic regulatory inspections of our drug manufacturing facilities and the manufacturing facilities of our contract manufacturers for compliance with applicable regulatory requirements. Any failure to follow and document our or our contract manufacturers' adherence to such cGMP and other laws and governmental regulations or satisfy other manufacturing and product release regulatory requirements may disrupt our ability to meet our manufacturing obligations to our customers, lead to significant delays in the availability of products for

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commercial use or clinical study, result in the termination or hold on a clinical study or delay or prevent filing or approval of marketing applications for our products. Failure to comply with applicable laws and regulations may also result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could harm our business. The results of these inspections could result in costly manufacturing changes or facility or capital equipment upgrades to satisfy the FDA that our manufacturing and quality control procedures are in substantial compliance with cGMP. Manufacturing delays, for us or our contract manufacturers, pending resolution of regulatory deficiencies or suspensions would have a material adverse effect on our business, results of operations and financial condition.

***If we or our contract manufacturers are not able to manufacture drugs or drug substances in sufficient quantities that meet applicable quality standards, it could delay clinical studies, result in reduced sales or constitute a breach of our contractual obligations, any of which could significantly harm our business, financial condition and results of operations.***

If we or our contract manufacturers are not able to manufacture and supply sufficient drug quantities meeting applicable quality standards required to support large clinical studies or commercial manufacturing in a timely manner, it could delay our or our collaboration partners' clinical studies or result in a breach of our contractual obligations, which could in turn reduce the potential commercial sales of our or our collaboration partners' products. As a result, we could incur substantial costs and damages and any product sales or royalty revenue that we would otherwise be entitled to receive could be reduced, delayed or eliminated. In some cases, we rely on contract manufacturing organizations to manufacture and supply drug product for our clinical studies and those of our collaboration partners. Pharmaceutical manufacturing of drugs and devices involves significant risks and uncertainties related to the demonstration of adequate stability, sufficient purification of the drug substance and drug product, the identification and elimination of impurities, optimal formulations, process and analytical methods validations, device performance and challenges in controlling for all of these variables. We have faced and may in the future face significant difficulties, delays and unexpected expenses as we validate third party contract manufacturers required for drug and device supply to support our clinical studies and the clinical studies and products of our collaboration partners. Failure by us or our contract manufacturers to supply drug product or devices in sufficient quantities that meet all applicable quality requirements could result in supply shortages for our clinical studies or the clinical studies and commercial activities of our collaboration partners. Such failures could significantly and materially delay clinical trials and regulatory submissions or result in reduced sales, any of which could significantly harm our business prospects, results of operations and financial condition.

Building and validating large scale clinical or commercial-scale manufacturing facilities and processes, recruiting and training qualified personnel and obtaining necessary regulatory approvals is complex, expensive and time consuming. In the past we have encountered challenges in scaling up manufacturing to meet the requirements of large scale clinical trials without making modifications to the drug formulation, which may cause significant delays in clinical development. We experienced repeated significant delays in starting the Phase 3 clinical development program for Amikacin Inhale as we sought to finalize and validate the device design with a demonstrated capability to be manufactured at commercial scale. Drug/device combination products are particularly complex, expensive and time-consuming to develop due to the number of variables involved in the final product design, including ease of patient and doctor use, maintenance of clinical efficacy, reliability and cost of manufacturing, regulatory approval requirements and standards and other important factors. There continues to be substantial and unpredictable risk and uncertainty related to manufacturing and supply until such time as the commercial supply chain is validated and proven.

***Our revenue is exclusively derived from our collaboration agreements, which can result in significant fluctuation in our revenue from period to period, and our past revenue is therefore not necessarily indicative of our future revenue.***

Our revenue is exclusively derived from our collaboration agreements, from which we receive contract research payments, milestone payments based on clinical progress, regulatory progress or net sales achievements, royalties and manufacturing revenue. Significant variations in the timing of receipt of cash payments and our recognition of revenue can result from significant milestone payments based on the execution of new collaboration agreements, the timing of clinical outcomes, regulatory approval, commercial launch and the achievement of certain annual sales thresholds. The amount of our revenue derived from collaboration agreements in any given period will depend on a number of unpredictable factors, including our ability to find and maintain suitable collaboration partners, the timing of the negotiation and conclusion of collaboration agreements with such partners, whether and when we or our collaboration partners achieve clinical, regulatory and sales milestones, the timing of regulatory approvals in one or more major markets, reimbursement levels by private and government payers, and the market introduction of new drugs or generic versions of the approved drug, as well as other factors. Our past revenue generated from collaboration agreements is not necessarily indicative of our future revenue. If any of our existing or future collaboration partners fails to develop, obtain regulatory approval for, manufacture or ultimately commercialize any product candidate under our collaboration agreement, our business, financial condition, results of operations and prospectus could be materially and adversely affected.

***If our partners, on which we depend to obtain regulatory approvals for and to commercialize our partnered drug candidates, are not successful, or if such collaborations fail, the development or commercialization of our partnered drug candidates may be delayed or unsuccessful.***

When we sign a collaborative development agreement or license agreement to develop a drug candidate with a pharmaceutical or biotechnology company, the pharmaceutical or biotechnology company is generally expected to:

- design and conduct large scale clinical studies;
- prepare and file documents necessary to obtain government approvals to sell a given drug candidate; and/or
- market and sell the drugs when and if they are approved.

Our reliance on collaboration partners poses a number of risks to our business, including risks that:

- we may be unable to control whether, and the extent to which, our partners devote sufficient resources to the development programs or commercial marketing and sales efforts;
- disputes may arise or escalate in the future with respect to the ownership of rights to technology or intellectual property developed with partners;
- disagreements with partners could lead to delays in, or termination of, the research, development or commercialization of product candidates or to litigation or arbitration proceedings;
- contracts with our partners may fail to provide us with significant protection, or to be effectively enforced, in the event one of our partners fails to perform;
- partners have considerable discretion in electing whether to pursue the development of any additional product candidates and may pursue alternative technologies or products either on their own or in collaboration with our competitors;
- partners with marketing rights may choose to devote fewer resources to the marketing of our partnered products than they do to products of their own development or products in-licensed from other third parties;
- the timing and level of resources that our partners dedicate to the development program will affect the timing and amount of revenue we receive;
- we do not have the ability to unilaterally terminate agreements (or partners may have extension or renewal rights) that we believe are not on commercially reasonable terms or consistent with our current business strategy;
- partners may be unable to pay us as expected; and
- partners may terminate their agreements with us unilaterally for any or no reason, in some cases with the payment of a termination fee penalty and in other cases with no termination fee penalty.

Given these risks, the success of our current and future partnerships is highly unpredictable and can have a substantial negative or positive impact on our business. We have entered into collaboration agreements in the past that have been subsequently terminated, such as our collaboration agreement with Pfizer, Inc. for the development and commercialization of inhaled insulin that was terminated by Pfizer, Inc. in November 2007. If other collaboration agreements are suspended or terminated, our ability to commercialize certain other proposed product candidates could also be negatively impacted. If our collaborations fail, our product development or commercialization of product candidates could be delayed or cancelled, which would negatively impact our business, results of operations and financial condition.

***If we are unable either to create sales, marketing and distribution capabilities or to enter into agreements with third parties to perform these functions, we will be unable to commercialize our products successfully.***

We currently have no sales, marketing or distribution capabilities. To commercialize any of our drugs that receive regulatory approval for commercialization, we must either develop internal sales, marketing and distribution capabilities, which would be expensive and time consuming, or enter into collaboration arrangements with third parties to perform these services. If we decide to market our products directly, we must commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and with supporting distribution, administration and compliance capabilities. Factors that may inhibit our efforts to commercialize our products directly or indirectly with our partners include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to use or prescribe our products;
- the lack of complementary products or multiple product pricing arrangements may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating and sustaining an independent sales and marketing organization.



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***If we, or our partners through our collaborations, are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty commercializing our products, which would adversely affect our business, results of operations and financial condition.***

To the extent we rely on other pharmaceutical or biotechnology companies with established sales, marketing and distribution systems to market our products, we will need to establish and maintain partnership arrangements, and we may not be able to enter into these arrangements on acceptable terms or at all. To the extent that we enter into co-promotion or other arrangements, any revenue we receive will depend upon the efforts of third parties, which may not be successful and are only partially in our control. In the event that we market our products without a partner, we would be required to build a sales and marketing organization and infrastructure, which would require a significant investment and we may not be successful in building this organization and infrastructure in a timely or efficient manner.

***We purchase some of the starting material for drugs and drug candidates from a single source or a limited number of suppliers, and the partial or complete loss of one of these suppliers could cause production delays, clinical trial delays, substantial loss of revenue and contract liability to third parties.***

We often face very limited supply of a critical raw material that can only be obtained from a single, or a limited number of, suppliers, which could cause production delays, clinical trial delays, substantial lost revenue opportunity or contract liability to third parties. For example, there are only a limited number of qualified suppliers, and in some cases single source suppliers, for the raw materials included in our PEGylation and advanced polymer conjugate drug formulations. Any interruption in supply or failure to procure such raw materials on commercially feasible terms could harm our business by delaying our clinical trials, impeding commercialization of approved drugs or increasing our costs.

***We rely on trade secret protection and other unpatented proprietary rights for important proprietary technologies, and any loss of such rights could harm our business, results of operations and financial condition.***

We rely on trade secret protection for our confidential and proprietary information. No assurance can be given that others will not independently develop substantially equivalent confidential and proprietary information or otherwise gain access to our trade secrets or disclose such technology, or that we can meaningfully protect our trade secrets. In addition, unpatented proprietary rights, including trade secrets and know-how, can be difficult to protect and may lose their value if they are independently developed by a third party or if their secrecy is lost. Any loss of trade secret protection or other unpatented proprietary rights could harm our business, results of operations and financial condition.

***We expect to continue to incur substantial losses and negative cash flow from operations and may not achieve or sustain profitability in the future.***

For the nine months ended September 30, 2014, we reported a net loss of \$8.2 million. If and when we achieve profitability depends upon a number of factors, including the timing and recognition of milestone payments and royalties received, the timing of revenue under our collaboration agreements, the amount of investments we make in our proprietary product candidates and the regulatory approval and market success of our product candidates. We may not be able to achieve and sustain profitability.

Other factors that will affect whether we achieve and sustain profitability include our ability, alone or together with our partners, to:

- develop drugs utilizing our technologies, either independently or in collaboration with other pharmaceutical or biotech companies;
- effectively estimate and manage clinical development costs, particularly the cost of the BEACON study and the clinical studies for NKTR-181;
- receive necessary regulatory and marketing approvals;
- maintain or expand manufacturing at necessary levels;
- achieve market acceptance of our partnered products;
- receive royalties on products that have been approved, marketed or submitted for marketing approval with regulatory authorities; and
- maintain sufficient funds to finance our activities.

***If government and private insurance programs do not provide payment or reimbursement for our partnered products or proprietary products, those products will not be widely accepted, which would have a negative impact on our business, results of operations and financial condition.***

In both domestic and foreign markets, sales of our partnered and proprietary products that have received regulatory approval will depend in part on market acceptance among physicians and patients, pricing approvals by government authorities and the

availability of payment or reimbursement from third-party payers, such as government health administration authorities, managed care providers, private health insurers and other organizations. Such third-party payers are increasingly challenging the price and cost effectiveness of medical products and services. Therefore, significant uncertainty exists as to the pricing approvals for, and the payment or reimbursement status of, newly approved healthcare products. Moreover, legislation and regulations affecting the pricing of pharmaceuticals may change before regulatory agencies approve our proposed products for marketing and could further limit pricing approvals for, and reimbursement of, our products from government authorities and third-party payers. A government or third-party payer decision not to approve pricing for, or provide adequate coverage and reimbursements of, our products would limit market acceptance of such products.

***We depend on third parties to conduct the clinical trials for our proprietary product candidates and any failure of those parties to fulfill their obligations could harm our development and commercialization plans.***

We depend on independent clinical investigators, contract research organizations and other third-party service providers to conduct clinical trials for our proprietary product candidates. We rely heavily on these parties for successful execution of our clinical trials. Though we are ultimately responsible for the results of their activities, many aspects of their activities are beyond our control. For example, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trials, but the independent clinical investigators may prioritize other projects over ours or communicate issues regarding our products to us in an untimely manner. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The early termination of any of our clinical trial arrangements, the failure of third parties to comply with the regulations and requirements governing clinical trials or our reliance on results of trials that we have not directly conducted or monitored could hinder or delay the development, approval and commercialization of our product candidates and would adversely affect our business, results of operations and financial condition.

***Significant competition for our polymer conjugate chemistry technology platforms and our partnered and proprietary products and product candidates could make our technologies, products or product candidates obsolete or uncompetitive, which would negatively impact our business, results of operations and financial condition.***

Our PEGylation and advanced polymer conjugate chemistry platforms and our partnered and proprietary products and product candidates compete with various pharmaceutical and biotechnology companies. Competitors of our PEGylation and polymer conjugate chemistry technologies include Biogen Idec Inc., Savient Pharmaceuticals, Inc., Dr. Reddy's Laboratories Ltd., Enzon Pharmaceuticals, Inc., SunBio Corporation, Mountain View Pharmaceuticals, Inc., Novo Nordisk A/S (formerly assets held by Neose Technologies, Inc.), and NOF Corporation. Several other chemical, biotechnology and pharmaceutical companies may also be developing PEGylation technologies or technologies that have similar impact on target drug molecules. Some of these companies license or provide the technology to other companies, while others are developing the technology for internal use.

There are several competitors for our proprietary product candidates currently in development. For Amikacin Inhale, the current standard of care includes several approved intravenous antibiotics for the treatment of either hospital-acquired pneumonia or ventilator-associated pneumonia in patients on mechanical ventilators. For MOVANTI<sup>TM</sup>, there are currently several alternative therapies used to address opioid-induced constipation (OIC) and opioid-induced bowel dysfunction (OBD), including subcutaneous Relistor<sup>®</sup> (methylnaltrexone bromide), oral Amitizia (lubiprostone), and oral and rectal over-the-counter laxatives and stool softeners such as docusate sodium, senna and milk of magnesia. In addition, there are a number of companies developing potential products which are in various stages of clinical development and are being evaluated for the treatment of OIC and OBD in different patient populations, including Cubist Pharmaceuticals, Inc., Progenics Pharmaceuticals, Inc. in collaboration with Salix Pharmaceuticals, Ltd., Mundipharma Int. Limited, Sucampo Pharmaceuticals, Inc., Develco Pharma GmbH, Alkermes, Inc., GlaxoSmithKline plc, Theravance, Inc., and Takeda Pharmaceutical Company Limited. For etirinotecan pegol, there are a number of chemotherapies and cancer therapies approved today and in various stages of clinical development for breast and ovarian cancers, including, but not limited to: Abraxane<sup>®</sup> (paclitaxel protein-bound particles for injectable suspension (albumin bound)), Xeloda<sup>®</sup> (capecitabine), Afinitor<sup>®</sup> (everolimus), Doxil<sup>®</sup> (doxorubicin HCl), Ellence<sup>®</sup> (epirubicin), Gemzar<sup>®</sup> (gemcitabine), Halaven<sup>®</sup> (eribulin), Herceptin<sup>®</sup> (trastuzumab), Hycamtin<sup>®</sup> (topotecan), Ixempra<sup>®</sup> (ixabepilone), Navelbine<sup>®</sup> (vinorelbine), Iniparib, Paraplatin<sup>®</sup> (carboplatin), Taxol<sup>®</sup> (paclitaxel) and Taxotere<sup>®</sup> (docetaxel). Major pharmaceutical or biotechnology companies with approved drugs or drugs in development for these cancers include, but are not limited to, Bristol-Myers Squibb Company, Eli Lilly & Co., Roche, GlaxoSmithKline plc, Johnson and Johnson, Pfizer, Inc. Eisai, Inc., and Sanofi Aventis S.A. There are approved therapies for the treatment of colorectal cancer, including Eloxatin<sup>®</sup> (oxaliplatin), Camptosar<sup>®</sup> (irinotecan), Avastin<sup>®</sup> (bevacizumab), Zaltrap<sup>®</sup> (Ziv-aflibercept), Stivarga<sup>®</sup> (regorafenib), Erbitux<sup>®</sup> (cetuximab), Vectibix<sup>®</sup> (panitumumab), Xeloda<sup>®</sup> (capecitabine), Adrucil<sup>®</sup> (fluorouracil) and Wellcovorin<sup>®</sup> (leucovorin). In addition, there are a number of drugs in various stages of preclinical and clinical development from companies exploring cancer therapies or improved chemotherapeutic agents to potentially treat colorectal cancer, including, but not limited to, products in development from Bristol-Myers Squibb Company, Pfizer, Inc., GlaxoSmithKline plc, Antigenics, Inc., F. Hoffmann-La Roche Ltd., Novartis AG, Cell Therapeutics, Inc., Neopharm Inc. (acquired by Insys Therapeutics, Inc.), Mediatech Research Ltd, Alchemia Limited, and Enzon Pharmaceuticals, Inc.

There can be no assurance that we or our partners will successfully develop, obtain regulatory approvals for and commercialize next-generation or new products that will successfully compete with those of our competitors. Many of our competitors have greater

financial, research and development, marketing and sales, manufacturing and managerial capabilities. We face competition from these companies not just in product development but also in areas such as recruiting employees, acquiring technologies that might enhance our ability to commercialize products, establishing relationships with certain research and academic institutions, enrolling patients in clinical trials and seeking program partnerships and collaborations with larger pharmaceutical companies. As a result, our competitors may succeed in developing competing technologies, obtaining regulatory approval or gaining market acceptance for products before we do. These developments could make our products or technologies uncompetitive or obsolete.

***If product liability lawsuits are brought against us, we may incur substantial liabilities.***

The manufacture, clinical testing, marketing and sale of medical products involve inherent product liability risks. If product liability costs exceed our product liability insurance coverage, we may incur substantial liabilities that could have a severe negative impact on our financial position. Whether or not we are ultimately successful in any product liability litigation, such litigation would consume substantial amounts of our financial and managerial resources and might result in adverse publicity, all of which would impair our business. Additionally, we may not be able to maintain our clinical trial insurance or product liability insurance at an acceptable cost, if at all, and this insurance may not provide adequate coverage against potential claims or losses.

***Our future depends on the proper management of our current and future business operations and their associated expenses.***

Our business strategy requires us to manage our business to provide for the continued development and potential commercialization of our proprietary and partnered drug candidates. Our strategy also calls for us to undertake increased research and development activities and to manage an increasing number of relationships with partners and other third parties, while simultaneously managing the capital necessary to support this strategy. Our decision to bear a majority or all of the clinical development costs of etirinotecan pegol substantially increases our future capital requirements. If we are unable to manage effectively our current operations and any growth we may experience, our business, financial condition and results of operations may be adversely affected. If we are unable to effectively manage our expenses, we may find it necessary to reduce our personnel-related costs through reductions in our workforce, which could harm our operations, employee morale and impair our ability to retain and recruit talent. Furthermore, if adequate funds are not available, we may be required to obtain funds through arrangements with partners or other sources that may require us to relinquish rights to certain of our technologies, products or future economic rights that we would not otherwise relinquish or require us to enter into other financing arrangements on unfavorable terms.

***We are dependent on our management team and key technical personnel, and the loss of any key manager or employee may impair our ability to develop our products effectively and may harm our business, operating results and financial condition.***

Our success largely depends on the continued services of our executive officers and other key personnel. The loss of one or more members of our management team or other key employees could seriously harm our business, operating results and financial condition. The relationships that our key managers have cultivated within our industry make us particularly dependent upon their continued employment with us. We are also dependent on the continued services of our technical personnel because of the highly technical nature of our products and the regulatory approval process. Because our executive officers and key employees are not obligated to provide us with continued services, they could terminate their employment with us at any time without penalty. We do not have any post-employment noncompetition agreements with any of our employees and do not maintain key person life insurance policies on any of our executive officers or key employees.

***Because competition for highly qualified technical personnel is intense, we may not be able to attract and retain the personnel we need to support our operations and growth.***

We must attract and retain experts in the areas of clinical testing, manufacturing, research, regulatory and finance, and may need to attract and retain marketing and distribution experts and develop additional expertise in our existing personnel. We face intense competition from other biopharmaceutical companies, research and academic institutions and other organizations for qualified personnel. Many of the organizations with which we compete for qualified personnel have greater resources than we have. Because competition for skilled personnel in our industry is intense, companies such as ours sometimes experience high attrition rates with regard to their skilled employees. Further, in making employment decisions, job candidates often consider the value of the stock options they are to receive in connection with their employment. Our equity incentive plan and employee benefit plans may not be effective in motivating or retaining our employees or attracting new employees, and significant volatility in the price of our stock may adversely affect our ability to attract or retain qualified personnel. If we fail to attract new personnel or to retain and motivate our current personnel, our business and future growth prospects could be severely harmed.

***If earthquakes or other catastrophic events strike, our business may be harmed.***

Our corporate headquarters, including a substantial portion of our research and development operations, are located in the San Francisco Bay Area, a region known for seismic activity and a potential terrorist target. In addition, we own facilities for the manufacture of products using our PEGylation and advanced polymer conjugate technologies in Huntsville, Alabama and own and lease offices in Hyderabad, India. There are no backup facilities for our manufacturing operations located in Huntsville, Alabama. In the event of an earthquake or other natural disaster, political instability, or terrorist event in any of these locations, our ability to

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manufacture and supply materials for drug candidates in development and our ability to meet our manufacturing obligations to our customers would be significantly disrupted and our business, results of operations and financial condition would be harmed. Our collaborative partners may also be subject to catastrophic events, such as earthquakes, floods, hurricanes and tornadoes, any of which could harm our business, results of operations and financial condition. We have not undertaken a systematic analysis of the potential consequences to our business, results of operations and financial condition from a major earthquake or other catastrophic event, such as a fire, sustained loss of power, terrorist activity or other disaster, and do not have a recovery plan for such disasters. In addition, our insurance coverage may not be sufficient to compensate us for actual losses from any interruption of our business that may occur.

***We have implemented certain anti-takeover measures, which make it more difficult to acquire us, even though such acquisitions may be beneficial to our stockholders.***

Provisions of our certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, even though such acquisitions may be beneficial to our stockholders. These anti-takeover provisions include:

- establishment of a classified board of directors such that not all members of the board may be elected at one time;
- lack of a provision for cumulative voting in the election of directors, which would otherwise allow less than a majority of stockholders to elect director candidates;
- the ability of our board to authorize the issuance of “blank check” preferred stock to increase the number of outstanding shares and thwart a takeover attempt;
- prohibition on stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of stockholders;
- establishment of advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon by stockholders at stockholder meetings; and
- limitations on who may call a special meeting of stockholders.

Further, provisions of Delaware law relating to business combinations with interested stockholders may discourage, delay or prevent a third party from acquiring us. These provisions may also discourage, delay or prevent a third party from acquiring a large portion of our securities or initiating a tender offer or proxy contest, even if our stockholders might receive a premium for their shares in the acquisition over the then-current market prices. We also have a change of control severance benefit plan, which provides for certain cash severance, stock award acceleration and other benefits in the event our employees are terminated (or, in some cases, resign for specified reasons) following an acquisition. This severance plan could discourage a third party from acquiring us.

***The price of our common stock is expected to remain volatile.***

Our stock price is volatile. During the three months ended September 30, 2014, based on closing prices on The NASDAQ Global Select Market, our stock price ranged from \$10.55 to \$14.48 per share. We expect our stock price to remain volatile. A variety of factors may have a significant effect on the market price of our common stock, including the risks described in this section titled “Risk Factors” and the following:

- announcements of data from, or material developments in, our clinical studies and those of our collaboration partners, including data regarding efficacy and safety, delays in clinical development, regulatory approval or commercial launch;
- announcements by collaboration partners as to their plans or expectations related to drug candidates and approved drugs in which we have a substantial economic interest;
- announcements regarding terminations or disputes under our collaboration agreements;
- fluctuations in our results of operations;
- developments in patent or other proprietary rights, including intellectual property litigation or entering into intellectual property license agreements and the costs associated with those arrangements;
- announcements of technological innovations or new therapeutic products that may compete with our approved products or products under development;
- announcements of changes in governmental regulation affecting us or our competitors;
- litigation brought against us or third parties to whom we have indemnification obligations;
- public concern as to the safety of drug formulations developed by us or others;
- our financing needs and activities; and
- general market conditions.

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At times, our stock price has been volatile even in the absence of significant news or developments. The stock prices of biotechnology companies and securities markets generally have been subject to dramatic price swings in recent years.

***The indenture governing the senior secured notes imposes significant operating and financial restrictions on us and our subsidiaries that may prevent us from pursuing certain business opportunities and restrict our ability to operate our business.***

The indenture governing the senior secured notes contains covenants that restrict our and our subsidiaries' ability to take various actions, such as:

- incur or guarantee additional indebtedness or issue disqualified capital stock or cause certain of our subsidiaries to issue preferred stock;
- pay dividends or distributions, redeem equity interests or subordinated indebtedness or make certain types of investments;
- create or incur liens;
- transfer, sell, lease or otherwise dispose of assets and issue or sell equity interests in certain of our subsidiaries;
- incur restrictions on certain of our subsidiaries' ability to pay dividends or other distributions to the Company or to make intercompany loans or asset transfers;
- enter into transactions with affiliates;
- engage in any business other than businesses which are the same, similar, ancillary or reasonably related to our business as of July 11, 2012; and
- consummate a merger, consolidation, reorganization or business combination, or sell, assign, transfer, lease or otherwise dispose of all or substantially all of our assets.

In addition, the indenture governing the senior secured notes contains a financial maintenance covenant requiring us to maintain a \$25.0 million segregated cash reserve account until July 1, 2015 to be applied to interest payments on the notes in the event of a default, subject to certain conditions. This indenture also requires us not to permit, thereafter and through the quarter ending June 30, 2017, the aggregate balance of our unrestricted cash and cash equivalents at the end of any two consecutive fiscal quarters to be less than \$25.0 million, subject to certain conditions. Our ability to comply with these covenants will likely be affected by many factors, including events beyond our control, and we may not satisfy those requirements. Our failure to comply with our debt-related obligations could result in an event of default under our other indebtedness and the acceleration of our other indebtedness, in whole or in part, could result in an event of default under the indenture governing the senior secured notes.

The restrictions contained in the indenture governing the senior secured notes could also limit our ability to plan for or react to market conditions, meet capital needs or otherwise restrict our activities or business plans and adversely affect our ability to finance our operations, enter into acquisitions or to engage in other business activities that would be in our interest.

### **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

None, including no purchases of any class of our equity securities by us or any affiliate pursuant to any publicly announced repurchase plan in the three months ended September 30, 2014.

### **Item 3. Defaults Upon Senior Securities**

None.

### **Item 4. Mine Safety Disclosures**

Not applicable.

### **Item 5. Other Information**

None.

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### **Item 6. Exhibits**

Except as so indicated in Exhibits 32.1 and 101, the following exhibits are filed as part of, or incorporated by reference into, this Quarterly Report on Form 10-Q.

<u>Exhibit Number</u>	<u>Description of Documents</u>
31.1(1)	Certification of Nektar Therapeutics' principal executive officer required by Rule 13a-14(a) or Rule 15d-14(a).
31.2(1)	Certification of Nektar Therapeutics' principal financial officer required by Rule 13a-14(a) or Rule 15d-14(a).
32.1*	Section 1350 Certifications.
101**	The following materials from Nektar Therapeutics' Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, formatted in XBRL (Extensible Business Reporting Language): (i) the unaudited Condensed Consolidated Balance Sheets, (ii) the unaudited Condensed Consolidated Statements of Operations, (iii) the unaudited Condensed Consolidated Statements of Comprehensive Income (Loss), (iv) the unaudited Condensed Consolidated Statements of Cash Flows, and (v) Notes to Condensed Consolidated Financial Statements.

(1) Filed herewith.

\* Exhibit 32.1 is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall such exhibit be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended, or the Securities Exchange Act, except as otherwise stated in such filing.

\*\* XBRL information is filed herewith.

**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.

By: /s/ JOHN NICHOLSON

**John Nicholson**

**Senior Vice President and Chief Financial Officer**

Date: November 6, 2014

By: /s/ JILLIAN B. THOMSEN

**Jillian B. Thomsen**

**Senior Vice President, Finance and Chief Accounting Officer**

Date: November 6, 2014

**EXHIBIT INDEX**

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\*\* XBRL information is filed herewith.



## CERTIFICATIONS

I, Howard W. Robin, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Nektar Therapeutics;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)), for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2014

/s/ HOWARD W. ROBIN

**Howard W. Robin**

**Chief Executive Officer, President and Director**

## CERTIFICATIONS

I, John Nicholson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Nektar Therapeutics;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)), for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2014

/s/ JOHN NICHOLSON

**John Nicholson**

**Senior Vice President and Chief Financial Officer**

## SECTION 1350 CERTIFICATIONS\*

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Howard W. Robin, Chief Executive Officer, President and Director of Nektar Therapeutics (the "Company"), and John Nicholson, Senior Vice President and Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the three and nine months ended September 30, 2014, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 6, 2014

/s/ HOWARD W. ROBIN

**Howard W. Robin**  
**Chief Executive Officer, President and Director**

/s/ JOHN NICHOLSON

**John Nicholson**  
**Senior Vice President and Chief Financial Officer**

\* This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.