

NEKTAR THERAPEUTICS  
Form 10-Q  
November 06, 2015  
Table of Contents

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

**FORM 10-Q**

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

**For the quarterly period ended September 30, 2015**

**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**

**NEKTAR THERAPEUTICS**  
**(Exact name of registrant as specified in its charter)**

**Delaware**  
**(State or other jurisdiction of**  
**incorporation or organization)**  
**455 Mission Bay Boulevard South**  
**San Francisco, California 94158**  
**(Address of principal executive offices)**  
**415-482-5300**  
**(Registrant's telephone number, including area code)**

**94-3134940**  
**(IRS Employer**

**Identification No.)**

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

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  Accelerated filer

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

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 133,451,372 on October 29, 2015.



**Table of Contents**

**NEKTAR THERAPEUTICS**

**INDEX**

<b><u>PART I: FINANCIAL INFORMATION</u></b>	
Item 1.	4
<u>Condensed Consolidated Financial Statements – Unaudited:</u>	
<u>Condensed Consolidated Balance Sheets – September 30, 2015 and December 31, 2014</u>	4
<u>Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2015 and 2014</u>	5
<u>Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2015 and 2014</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2015 and 2014</u>	6
<u>Notes to Condensed Consolidated Financial Statements</u>	7
Item 2.	16
<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	
Item 3.	24
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	
Item 4.	24
<u>Controls and Procedures</u>	
<b><u>PART II: OTHER INFORMATION</u></b>	
Item 1.	25
<u>Legal Proceedings</u>	
Item 1A.	25
<u>Risk Factors</u>	
Item 2.	37
<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	
Item 3.	37
<u>Defaults Upon Senior Securities</u>	
Item 4.	37
<u>Mine Safety Disclosures</u>	
Item 5.	37
<u>Other Information</u>	
Item 6.	37
<u>Exhibits</u>	
<u>Signatures</u>	38

## **Table of Contents**

### **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, timing of commercial launches and product sales levels by our collaboration partners and 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 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.

Table of Contents**PART I: FINANCIAL INFORMATION****Item 1. Condensed Consolidated Financial Statements Unaudited:  
NEKTAR THERAPEUTICS****CONDENSED CONSOLIDATED BALANCE SHEETS****(In thousands, except par value)****(Unaudited)**

	<b>September 30, 2015</b>	<b>December 31, 2014</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 18,819	\$ 12,365
Short-term investments	249,000	225,459
Accounts receivable, net	2,966	3,607
Inventory	10,352	12,952
Restricted cash		25,000
Other current assets	5,214	8,817
<b>Total current assets</b>	<b>286,351</b>	<b>288,200</b>
Property, plant and equipment, net	72,532	70,368
Goodwill	76,501	76,501
Other assets	13,862	6,552
<b>Total assets</b>	<b>\$ 449,246</b>	<b>\$ 441,621</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,279	\$ 2,703
Accrued compensation	12,805	5,749
Accrued clinical trial expenses	11,102	7,708
Other accrued expenses	16,561	6,418
Interest payable	3,167	6,917
Capital lease obligations, current portion	5,883	4,512
Deferred revenue, current portion	20,611	24,473
Senior secured notes, current portion	125,000	
Other current liabilities	10,690	5,567
<b>Total current liabilities</b>	<b>208,098</b>	<b>64,047</b>
Senior secured notes, less current portion		125,000
Capital lease obligations, less current portion	1,335	4,139

Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

Liability related to sale of future royalties	121,147	120,471
Deferred revenue, less current portion	68,941	76,911
Other long-term liabilities	10,672	14,721
<b>Total liabilities</b>	<b>410,193</b>	<b>405,289</b>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.0001 par value, 10,000 shares authorized, no shares designated, issued or outstanding at September 30, 2015 or December 31, 2014		
Common stock, \$0.0001 par value, 300,000 authorized; 133,217 shares and 131,216 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	13	13
Capital in excess of par value	1,854,210	1,824,195
Accumulated other comprehensive loss	(1,821)	(1,567)
Accumulated deficit	(1,813,349)	(1,786,309)
<b>Total stockholders' equity</b>	<b>39,053</b>	<b>36,332</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 449,246</b>	<b>\$ 441,621</b>

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

**Table of Contents**

**NEKTAR THERAPEUTICS**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(In thousands, except per share information)

(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Revenue:				
Product sales and royalty revenue	\$ 7,427	\$ 6,172	\$ 27,239	\$ 17,980
Non-cash royalty revenue related to sale of future royalties	6,050	6,143	14,752	16,753
License, collaboration and other revenue	46,475	120,556	149,423	146,422
<b>Total revenue</b>	<b>59,952</b>	<b>132,871</b>	<b>191,414</b>	<b>181,155</b>
Operating costs and expenses:				
Cost of goods sold	6,760	9,220	25,738	22,235
Research and development	43,229	34,200	135,652	109,240
General and administrative	9,544	9,130	30,031	28,677
<b>Total operating costs and expenses</b>	<b>59,533</b>	<b>52,550</b>	<b>191,421</b>	<b>160,152</b>
<b>Income (loss) from operations</b>	<b>419</b>	<b>80,321</b>	<b>(7)</b>	<b>21,003</b>
Non-operating income (expense):				
Interest expense	(4,202)	(4,391)	(12,491)	(13,412)
Non-cash interest expense on liability related to sale of future royalties	(5,226)	(5,203)	(15,428)	(15,725)
Interest income and other income (expense), net	898	126	1,355	535
<b>Total non-operating expense, net</b>	<b>(8,530)</b>	<b>(9,468)</b>	<b>(26,564)</b>	<b>(28,602)</b>
<b>Income (loss) before provision for income taxes</b>	<b>(8,111)</b>	<b>70,853</b>	<b>(26,571)</b>	<b>(7,599)</b>
Provision for income taxes	92	248	469	634
<b>Net income (loss)</b>	<b>\$ (8,203)</b>	<b>\$ 70,605</b>	<b>\$ (27,040)</b>	<b>\$ (8,233)</b>
Net income (loss) per share:				
Basic	\$ (0.06)	\$ 0.55	\$ (0.21)	\$ (0.07)
Diluted	\$ (0.06)	\$ 0.53	\$ (0.21)	\$ (0.07)
Weighted average shares outstanding used in computing net income (loss) per share:				
Basic	132,631	127,504	131,882	126,043



Diluted	132,631	132,177	131,882	126,043
---------	---------	---------	---------	---------

**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)**

**(In thousands)**

**(Unaudited)**

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Comprehensive income (loss)	\$ (8,526)	\$ 70,314	\$ (27,294)	\$ (8,230)

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

Table of Contents

## NEKTAR THERAPEUTICS

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine months ended September 30,	
	2015	2014
<b>Cash flows from operating activities:</b>		
Net loss	\$ (27,040)	\$ (8,233)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Non-cash royalty revenue related to sale of future royalties	(14,752)	(16,753)
Non-cash interest expense on liability related to sale of future royalties	15,428	15,725
Stock-based compensation	14,499	12,647
Depreciation and amortization	9,109	9,733
Other non-cash transactions	(1,448)	313
Changes in operating assets and liabilities:		
Accounts receivable, net	641	(43,845)
Inventory	2,600	1,757
Other assets	3,843	679
Accounts payable	(525)	(3,670)
Accrued compensation	7,056	(501)
Accrued clinical trial expenses	3,394	(7,262)
Other accrued expenses	949	1,667
Interest payable	(3,750)	(3,750)
Deferred revenue	(11,832)	1,480
Liability related to receipt of refundable milestone payment		(70,000)
Other liabilities	3,854	(7,366)
Net cash provided by (used in) operating activities	2,026	(117,379)
<b>Cash flows from investing activities:</b>		
Maturities of investments	155,683	171,826
Purchases of investments	(202,870)	(200,160)
Sale of investments	23,778	21,661
Release of restricted cash	25,000	
Purchases of property, plant and equipment	(8,722)	(6,090)
Net cash used in investing activities	(7,131)	(12,763)
<b>Cash flows from financing activities:</b>		
Payment of capital lease obligations	(3,798)	(2,578)
Repayment of proceeds from sale of future royalties		(7,000)

Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

Issuance of common stock, net of issuance costs		116,536
Proceeds from shares issued under equity compensation plans	15,516	16,168
Net cash provided by financing activities	11,718	123,126
Effect of exchange rates on cash and cash equivalents	(159)	(43)
Net increase (decrease) in cash and cash equivalents	6,454	(7,059)
Cash and cash equivalents at beginning of period	12,365	39,067
Cash and cash equivalents at end of period	\$ 18,819	\$ 32,008
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	\$ 16,095	\$ 16,487
<b>Supplemental schedule of non-cash investing and financing activities:</b>		
Accrued debt issuance costs	\$ 8,503	\$

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

**Table of Contents**

**NEKTAR THERAPEUTICS**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2015**

**(Unaudited)**

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

***Organization***

We are a 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, 2015, we had approximately \$267.8 million in cash and investments in marketable securities. Also, as of September 30, 2015, we had \$132.2 million in debt, including \$125.0 million of senior secured notes and \$7.2 million of capital lease obligations. As is further described in Note 9, on October 5, 2015, we issued \$250.0 million in aggregate principal amount of 7.75% senior secured notes due October 2020 and used a portion of the proceeds from these notes to redeem the \$125.0 million in aggregate principal amount of 12.0% senior secured notes due July 2017, which is included in current liabilities in our Condensed Consolidated Balance Sheet at September 30, 2015, and to pay an \$11.3 million redemption premium and \$4.5 million in interest, due upon redemption of the 12% senior secured notes.

***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 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 loss consists of our net 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 months ended September 30, 2015 and 2014. In addition, there were no significant reclassifications out of accumulated other comprehensive loss to the statements of operations during the three and nine months ended September 30, 2015 and 2014.

The accompanying Condensed Consolidated Financial Statements are unaudited. The Condensed Consolidated Balance Sheet data as of December 31, 2014 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, 2014 filed with the SEC on February 26, 2015. 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, 2014.

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 consolidated 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

## **Table of Contents**

consolidated 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. Our estimates include those related to estimated selling prices of deliverables in collaboration agreements, estimated periods of performance, the net realizable value of inventory, the impairment of investments, the impairment of goodwill and long-lived assets, contingencies, accrued clinical trial expenses, estimated interest 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. As appropriate, estimates are assessed each period and updated to reflect current information and any changes in estimates will generally be reflected in the period first identified.

## ***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 loss, net loss, total assets, liabilities or stockholders' equity.

## ***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, 2015 or December 31, 2014.

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***

Our revenue is derived from our arrangements with pharmaceutical and biotechnology collaboration partners and may result from one or more of the following: upfront and license fees, payments for contract research and development,

milestone payments, manufacturing and supply payments, and royalties. Our performance obligations under our collaborations may include licensing our intellectual property, manufacturing and supply obligations, and research and development obligations. In order to account for the multiple-element arrangements, we identify the deliverables included within the arrangement and evaluate which deliverables represent separate units of accounting. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation. Revenue is recognized separately for each identified unit of accounting when the basic revenue recognition criteria are met: there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed or determinable, and collection is reasonably assured.

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.

## **Table of Contents**

### *Product sales*

Product sales are primarily derived from fixed price and cost-plus manufacturing and supply agreements with our collaboration partners. We have not experienced any significant returns from our customers.

### *Royalty revenue*

Generally, we are entitled to royalties from our collaboration 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.

### *License, collaboration and other revenue*

The amount of upfront fees and other payments received by us in license and collaboration arrangements that are allocated to continuing performance obligations, such as manufacturing and supply obligations, are deferred and generally recognized ratably over our 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 and this estimate is periodically re-evaluated.

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 the entity's performance or on the occurrence of a specific outcome resulting from the entity's 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 the entity. 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 regulatory authorities, and commercial launches of drugs. Given the challenges inherent in developing and obtaining regulatory approval for drug products and in achieving commercial launches, 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 evaluated whether the development milestones met 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 each milestone only if and as such 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. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows to our vendors. Payments under the contracts depend on factors such as the achievement of certain events, successful enrollment of patients, and completion of certain clinical trial activities. 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

---

**Table of Contents**

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. Advance payments for goods or services that will be used or rendered for future research and development activities are capitalized as prepaid expenses and recognized as expense as the related goods are delivered or the related services are performed. We base our estimates on the best information available at the time. However, additional information may become available to us which may allow us to make a more accurate estimate in future periods. In this event, we may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain. Such increases or decreases in cost are generally considered to be changes in estimates and will be reflected in research and development expenses in the period identified.

***Long-Lived Assets***

We assess the impairment of long-lived assets, primarily property, plant and equipment and goodwill, whenever events or changes in business circumstances indicate that the carrying amounts of the assets may not be fully recoverable. When such events occur, we determine whether there has been an impairment in value by comparing the carrying value of the asset with its fair value, as measured by the anticipated undiscounted net cash flows of the asset. In the case of goodwill impairment, market capitalization is generally used as the measure of fair value. If an impairment in value exists, the asset is written down to its estimated fair value. In March 2015, we announced that the primary endpoint for our BEACON Phase 3 clinical study for NKTR-102 as a single-agent therapy for women with advanced metastatic breast cancer did not achieve statistical significance. As a result, we performed an impairment analysis for our long-lived assets, including goodwill, as well as our primary long-lived asset group which is dedicated to NKTR-102. Based on this analysis, we concluded that there is no impairment as of the end of each of the first three quarters of 2015.

***Income Taxes***

For the three and nine months ended September 30, 2015 and 2014, 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.

***Recent Accounting Pronouncements***

In May 2014, the Financial Accounting Standards Board (FASB) issued guidance codified in Accounting Standards Codification (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, 2017. Entities have the option of using either a full retrospective or a modified retrospective approach to adopt this new guidance. We are currently evaluating the impact of the provisions of ASC 606.

In April 2015, the FASB issued guidance to simplify the presentation of debt issuance costs by requiring debt issuance costs to be presented as a deduction from the corresponding debt liability. This guidance is effective for our interim and annual periods beginning January 1, 2016 and early adoption is permitted. Upon adoption, the new guidance must be applied retrospectively to all periods presented. We do not believe the adoption of this guidance will have a material impact on our consolidated financial statements.

**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).

	<b>Estimated Fair Value at</b>	
	<b>September 30,</b>	<b>December 31,</b>
	<b>2015</b>	<b>2014</b>
Cash and cash equivalents	\$ 18,819	\$ 12,365
Short-term investments	249,000	225,459
Restricted cash		25,000
 Total cash and investments in marketable securities	 \$ 267,819	 \$ 262,824

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. As of September 30, 2015 and December 31, 2014, all of our investments had maturities of one year or less.

**Table of Contents**

Gross unrealized gains and losses were not significant at either September 30, 2015 or December 31, 2014. During the three and nine months ended September 30, 2015, we sold available-for-sale securities totaling \$18.6 million and \$23.8 million, respectively, and gross realized gains and losses on those sales were not significant. During the three and nine months 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. The cost of securities sold is based on the specific identification method.

Restricted cash of \$25.0 million was required to be maintained in a separate account until July 1, 2015 under the terms of our 12% senior secured notes due July 2017. This restriction expired on July 1, 2015 and the restricted funds were returned to us.

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

	<b>Fair Value Hierarchy Level</b>	<b>Estimated Fair Value at</b>	
		<b>September 30, 2015</b>	<b>December 31, 2014</b>
Corporate notes and bonds	2	\$ 180,300	\$ 182,544
Corporate commercial paper	2	65,770	42,915
Available-for-sale investments		246,070	225,459
Money market funds	1	17,230	11,229
Certificate of deposit	N/A	2,930	
Cash, including restricted cash	N/A	1,589	26,136
<b>Total cash and investments in marketable securities</b>		<b>\$ 267,819</b>	<b>\$ 262,824</b>

*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 months ended September 30, 2015 and 2014, there were no transfers between Level 1 and Level 2 of the fair value hierarchy.

Additionally, as of September 30, 2015, 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. As is further described in Note 9, on October 5, 2015, we redeemed the 12% senior secured notes.

### Note 3 Inventory

Inventory consists of the following (in thousands):

	September 30, 2015	December 31, 2014
Raw materials	\$ 1,777	\$ 2,200
Work-in-process	8,494	5,187
Finished goods	81	5,565
Total inventory	\$ 10,352	\$ 12,952

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

---

**Table of Contents**

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 of \$124.0 million for the Royalty Entitlement. 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, 2015 and 2014, we recognized \$14.8 million and \$16.8 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 December 31, 2013 and 2012 not reaching certain minimum thresholds. The Purchase and Sale Agreement does not include any other potential payments related to minimum net sales thresholds and, therefore, we do not expect to make any further payments to RPI related to this agreement.

In addition, 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. To our knowledge, we are currently in compliance with these provisions of the Purchase and Sale Agreement; however, if we were to breach our obligations, 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, there exists the possibility of 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 and drug candidates, 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.

From time to time we enter into other strategic agreements such as divestitures and financing transactions pursuant to which we are required to make representations and warranties and undertake to perform or comply with certain covenants. In the event it is determined that we breached certain of the representations and warranties or covenants 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. 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, 2015 or December 31, 2014.

**Table of Contents****Note 6 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/or 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. 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		Nine months ended	
		September 30, 2015	2014	September 30, 2015	2014
AstraZeneca AB	MOVANTI <sup>TM</sup> (NKTR-118) and MOVANTI <sup>TM</sup> fixed-dose combination program (NKTR-119)	\$ 40,000	\$ 105,000	\$ 130,000	\$ 105,001
Roche	PEGASYS <sup>®</sup> and MIRCERA <sup>®</sup>	3,212	3,200	9,619	9,614
Amgen, Inc.	Neulasta <sup>®</sup>	1,250	1,250	3,750	3,750
Bayer Healthcare LLC	BAY41-6551 (Amikacin Inhale)	357	793	1,562	3,939
Baxalta Incorporated	BAX 855 (Hemophilia)	409	9,096	607	10,103
Other		1,247	1,217	3,885	14,015
License, collaboration, and other revenue		\$ 46,475	\$ 120,556	\$ 149,423	\$ 146,422

As of September 30, 2015, our collaboration agreements with partners included potential future payments for development milestones totaling approximately \$128.3 million, including amounts from our agreements with Bayer, Baxalta, and Ophthotech described below. In addition, we are entitled to receive the contingent development payments related to MOVANTI<sup>TM</sup> fixed-dose combination drug development programs and contingent sales milestone and royalty payments related to the MOVANTI<sup>TM</sup> and MOVANTI<sup>TM</sup> fixed-dose combination drug development programs as described below.

There have been no material changes to our collaboration agreements in the nine months ended September 30, 2015, except as described below.

**AstraZeneca AB:** MOVANTI<sup>TM</sup> (naloxegol oxalate), previously referred to as naloxegol and NKTR-118, and MOVANTI<sup>TM</sup> fixed-dose combination program, previously referred to as NKTR-119

We are a party to an agreement with AstraZeneca AB (AstraZeneca) under which we granted AstraZeneca a worldwide, exclusive license under our patents and other intellectual property to develop, market, and sell MOVANTI<sup>TM</sup> and MOVANTI<sup>TM</sup> fixed-dose combination program. AstraZeneca is responsible for all research, development and commercialization and is responsible for all drug development and commercialization decisions for MOVANTI<sup>TM</sup> and the MOVANTI<sup>TM</sup> fixed-dose combination program. AstraZeneca paid us an upfront payment



of \$125.0 million, which we received in the fourth quarter of 2009 and which was fully recognized as of December 31, 2010. In addition, we have received the payments described further below based on development events related to MOVANTI<sup>TM</sup> completed solely by AstraZeneca. We are entitled to receive up to \$75.0 million of commercial launch contingent payments related to the MOVANTI<sup>TM</sup> fixed-dose combination program, based on development events to be pursued and completed solely by AstraZeneca. In addition, we are entitled to significant and escalating double-digit royalty payments and sales milestone payments based on annual worldwide net sales of MOVANTI<sup>TM</sup> and MOVANTI<sup>TM</sup> fixed-dose combination products.

On September 16, 2014, the United States Food and Drug Administration (FDA) approved MOVANTI<sup>TM</sup> for the treatment of opioid-induced constipation (OIC) in adult patients with chronic, non-cancer pain. On December 9, 2014, AstraZeneca announced that MOVENTIG<sup>®</sup> has been granted Marketing Authorisation by the European Commission (EC) for the treatment of opioid-induced constipation (OIC) in adult patients who have had an inadequate response to laxative(s). As a result of the FDA's approval, 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 MOVANTI<sup>TM</sup> extinguished our contingent obligation to repay the \$70.0 million payment made to us by AstraZeneca in November 2013 after the MOVANTI<sup>TM</sup> New Drug Application was accepted for review by the FDA. As a result, in September 2014, we fully recognized as revenue this \$70.0 million payment. On March 31, 2015, AstraZeneca announced that MOVANTI<sup>TM</sup> launched in the United States which resulted in our receipt of a \$100.0 million non-refundable commercial launch milestone payment on March 31, 2015, which was recognized as revenue in March 2015. In March 2015, we agreed to pay AstraZeneca a total of \$10.0 million to fund U.S. television advertising in consideration for certain additional commercial information rights. We recorded this \$10.0 million obligation as a

---

**Table of Contents**

liability, and made the initial \$5.0 million payment to AstraZeneca in July 2015. The remaining \$5.0 million, which will be paid in July 2016, is included in other current liabilities in our Condensed Consolidated Balance Sheet at September 30, 2015. We determined that this \$10.0 million obligation should be recorded as a reduction of revenue, which we recorded in the three months ended March 31, 2015. In August 2015, we received and recognized as revenue an additional \$40.0 million payment triggered by the first commercial sale of MOVENTIG® (the naloxegol brand name in the European Union or EU) in Germany. As of September 30, 2015, we do not have deferred revenue related to this agreement.

In general, other than as described above and in this paragraph, AstraZeneca has full responsibility for all research, development and commercialization costs under our license agreement. 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.

***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, 2015, we have deferred revenue of approximately \$1.3 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, 2015, we have deferred revenue of approximately \$6.7 million, 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, 2015, we have deferred revenue of approximately \$2.9 million related to these activities, which we expect to recognize through December 2016, the estimated end of our obligations under the modified arrangements.

***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 (together referred to as Amgen). Under the terms of the amended and restated agreement, we received a \$50.0 million payment in the fourth quarter of 2010 in return for our guaranteeing the supply of certain quantities of our proprietary PEGylation materials to Amgen. As of September 30, 2015, we have deferred revenue of approximately \$25.4 million related to this agreement, which we expect to recognize through October 2020, the estimated end of our obligations under this agreement.

***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, 2015, we have received an upfront payment of \$40.0 million (which was paid to us 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 some 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, 2015, we have deferred revenue of approximately \$19.6 million related to this agreement, which we expect to recognize through June 2029, the estimated end of our obligations under this agreement.

**Table of Contents*****Baxalta Incorporated: Hemophilia***

We are a party to an exclusive research, development, license and manufacturing and supply agreement with Baxalta Incorporated (Baxalta) executed in September 2005 to develop products designed to improve therapies for Hemophilia A patients using our PEGylation technology. This Hemophilia A program includes BAX 855, which will be marketed in the U.S. under the brand name ADYNOVATE upon approval. Under the terms of this agreement, as of September 30, 2015, we are entitled to up to \$20.0 million of development milestones upon achievement of certain development objectives, including \$10.0 million due upon marketing authorization in the U.S., 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. In August 2014, Baxalta 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 earned development milestones totaling \$8.0 million in September 2014. In December 2014, Baxalta announced that it filed a biologic license application with the FDA for BAX 855. As of September 30, 2015, we do not have significant deferred revenue related to this agreement.

***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®, which is currently in a Phase 3 clinical program. On May 19, 2014, Ophthotech entered into a Licensing and Commercialization Agreement with Novartis Pharma AG for Fovista®. Under our agreement with Ophthotech, we received a \$19.75 million payment in connection with this licensing agreement in June 2014. As of September 30, 2015, we have deferred revenue of approximately \$18.2 million related to this agreement, which we expect to recognize through March 2029, 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, including a \$2.5 million milestone due upon acceptance for review of a regulatory approval application in the U.S. or EU. We are also entitled to royalties on net sales of Fovista® that vary based on sales levels.

***Other***

In addition, as of September 30, 2015, we have a number of collaboration agreements, including with our collaboration partner UCB, under which we are entitled to up to a total of \$51.8 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. As of September 30, 2015, we have deferred revenue of approximately \$15.5 million related to these other collaboration agreements, which we expect to recognize through 2020, the estimated end of our obligations under those agreements.

**Note 7 Stock-Based Compensation**

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

	<b>Three months ended</b>		<b>Nine months ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Cost of goods sold	\$ 274	\$ 268	\$ 837	\$ 867
Research and development expense	2,208	1,774	6,755	5,579
General and administrative expense	2,280	2,080	6,907	6,201
Total stock-based compensation	\$ 4,762	\$ 4,122	\$ 14,499	\$ 12,647

During the three months ended September 30, 2015 and 2014, we granted 483,300 and 632,550 stock options, respectively, at a weighted average grant-date fair value of \$5.86 per share and \$5.80 per share, respectively. During the three and nine months ended September 30, 2015, we also granted 120,000 restricted stock unit awards (RSUs). No RSUs were granted in 2014.

During the nine months ended September 30, 2015 and 2014, we granted 962,310 and 4,408,590 stock options, respectively, at a weighted average grant-date fair value of \$6.10 per share and \$5.84 per share, respectively. The number of stock options granted during the nine months ended September 30, 2014 was significantly higher than the stock options granted during the nine months ended September 30, 2015 because we made our annual employee stock option grant for the 2013 performance period in February 2014 and our annual employee stock option grant for the 2014 performance period in December 2014.

## **Table of Contents**

As a result of stock issuances under our equity compensation plans, during the three months ended September 30, 2015 and 2014, we issued 1,031,573 and 961,395 common shares, respectively, and during the nine months ended September 30, 2015 and 2014, we issued 2,000,823 and 1,979,282 common shares, respectively.

### **Note 8 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 potentially 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 common shares underlying 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, consisting of common shares underlying outstanding stock options and RSUs, which would have an anti-dilutive effect on net loss per share. There were weighted average outstanding stock options and RSUs of 20.6 million during the three months ended September 30, 2015 and weighted average outstanding stock options and RSUs of 21.3 million and 21.9 million during the nine months ended September 30, 2015 and 2014, respectively.

### **Note 9 Subsequent Event**

On September 30, 2015, we entered into a purchase agreement with TC Lending, LLC and TAO Fund, LLC for the sale of \$250.0 million in aggregate principal amount of 7.75% senior secured notes due 2020 (the Notes). On October 5, 2015, we completed the sale and issuance of the Notes. The Notes are secured by a first-priority lien on substantially all of our assets. The Notes bear interest at a rate of 7.75% per annum payable in cash quarterly in arrears on January 15, April 15, July 15, and October 15 of each year, beginning on October 15, 2015. The Notes will mature on October 5, 2020, at which time the outstanding principal will be due and payable. The Notes contain customary covenants and indemnification provisions.

In connection with the issuance of the Notes, we paid fees and expenses of approximately \$8.8 million, including transaction fees and a one-time facility fee to the purchasers of the Notes, of which \$8.5 million were accrued in other accrued expenses and capitalized as direct issuance costs recorded in other assets in our Condensed Consolidated Balance Sheet at September 30, 2015. On October 5, 2015, we used a portion of the proceeds from the Notes to redeem the \$125.0 million in aggregate principal amount of 12.0% senior secured notes due in 2017, which is included in current liabilities in our Condensed Consolidated Balance Sheet at September 30, 2015. In addition, on October 5, 2015, we paid an \$11.3 million redemption premium and \$4.5 million in interest on the 12% notes, of which \$3.2 million was recorded in current liabilities in our Condensed Consolidated Balance Sheet at September 30, 2015. As a result of these transactions and related costs, on October 5, 2015, we received cash of approximately \$100.4 million.

## **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 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.

---

**Table of Contents**

In 2014, we achieved the first approval of one of our proprietary drug candidates, MOVANTIK™ (previously referred to as naloxegol and NKTR-118), under a global license agreement with AstraZeneca. MOVANTIK™ is an oral peripherally-acting opioid antagonist, for the treatment of opioid-induced constipation, or OIC, a side effect caused by chronic administration of prescription opioid pain medicines. MOVANTIK™ was developed using our oral small molecule polymer conjugate technology and we advanced this drug through the completion of Phase 2 clinical studies prior to licensing it to AstraZeneca. On September 16, 2014, the United States Food and Drug Administration, or FDA, approved MOVANTIK™ as the first once-daily oral peripherally-acting mu-opioid receptor antagonist (PAMORA) medication for the treatment of opioid-induced constipation (OIC), in adult patients with chronic, non-cancer pain. On December 9, 2014, the European Commission, or EC, granted Marketing Authorisation to MOVENTIG® (the naloxegol brand name in the EU) as the first once-daily oral PAMORA approved in the EU for the treatment of OIC in adult patients who have had an inadequate response to laxative(s). The EC's approval applies to all 28 European Union member countries plus Iceland and Norway. On March 31, 2015, AstraZeneca announced that it launched MOVANTIK™ in the United States, as a result of which we received a \$100 million commercial launch milestone on March 31, 2015. In August 2015, we received an additional \$40.0 million payment triggered by the first commercial sale of MOVENTIG® by AstraZeneca in Germany. Given the significant sales milestone and royalty opportunity for us associated with MOVANTIK™ under our AstraZeneca license agreement, the level of sales achieved by AstraZeneca for MOVANTIK™ will have a significant impact on our operating results and financial condition over the coming years.

Etirinotecan pegol (also known as NKTR-102), is our next-generation topoisomerase I inhibitor proprietary drug candidate. On March 17, 2015, we announced topline data from the BEACON Phase 3 clinical study for NKTR-102 as a single-agent therapy for women with advanced metastatic breast cancer. The BEACON study compared NKTR-102 to an active control arm comprised of a single chemotherapy agent of physician's choice (TPC) in patients who were heavily pre-treated with a median of three prior therapies for metastatic disease. In a topline analysis of 852 patients from the trial, NKTR-102 provided a 2.1 month improvement in median overall survival (OS) over TPC (12.4 months for patients receiving NKTR-102 compared to 10.3 months for patients receiving TPC). Based on a stratified log-rank analysis, the primary endpoint measuring the Hazard Ratio (HR) for survival in the NKTR-102 group compared to the active control arm was 0.87 with a p-value of 0.08, which did not achieve statistical significance. Secondary endpoints in the BEACON study included objective response rate and progression-free survival, which did not achieve statistical significance in the study. We also announced that we observed a significant overall survival benefit in two pre-specified subgroups—patients with a history of brain metastases and patients with baseline liver metastases at study entry.

We are currently exploring various future regulatory paths forward for NKTR-102 with the EU and U.S. regulatory authorities. In Europe, we have met with the European Union National Authorities in Sweden (MPA) and the United Kingdom (MHRA) to discuss the BEACON data. Based on the outcome of these meetings, we believe that there is a path forward to file a marketing approval application (MAA) for conditional approval of NKTR-102 for patients with metastatic breast cancer with brain metastases. If we decide to file the MAA, we would be required to start a confirmatory trial in conjunction with the MAA review. In the United States, we met with the FDA and the Oncology Division said that we would not be able to use the BEACON data to support an accelerated approval for a new drug application (NDA). However, the FDA staff also indicated that positive results from the potential completed confirmatory trial for the MAA could also support a NDA filing. We are currently evaluating next steps and potential designs and costs for a confirmatory trial. At this time, we do not plan to advance development of NKTR-102 without a collaboration partner.

NKTR-181 is a novel mu-opioid analgesic drug candidate for chronic pain conditions. NKTR-181 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. The potential differentiating properties of NKTR-181 are inherent to its molecular design and, as a new molecular structure, NKTR-181's potential abuse deterrent properties do not rely on a formulation approach, a common method used with opioid drugs to reduce their ease of conversion into abusable forms of an opioid. In May 2012, the FDA designated NKTR-181 as a Fast Track development program for the treatment of moderate to severe chronic pain. In June 2013, we announced results from a human abuse liability study that demonstrated that NKTR-181 had highly statistically significant lower drug liking scores and reduced feeling high scores as compared to oxycodone at all doses tested ( $p < 0.0001$ ). In September 2013, we announced topline results from a Phase 2 clinical study of NKTR-181 in patients with moderate to severe chronic pain from osteoarthritis of the knee. In this study, NKTR-181 performed as expected as an opioid analgesic throughout the study. However, patients who were randomized to the placebo arm following a drug titration phase did not show the expected increase in pain scores observed in similar enriched enrollment, randomized withdrawal studies. This lack of a placebo rebound in the maintenance phase of the trial caused the Phase 2 study to miss the primary endpoint.

In October 2014, we had an end-of-Phase 2 meeting for NKTR-181 with the FDA, which included discussions of certain considerations for the Phase 3 clinical study program. In this Phase 3 program for NKTR-181, we plan to include two separate efficacy studies in patients with chronic lower back pain, a long-term safety study, and a human abuse liability study. We enrolled the first patient in the first Phase 3 efficacy study in February 2015. In this first efficacy study, we plan to randomize approximately 416

---

**Table of Contents**

patients in an enriched enrollment randomized withdrawal design which will include a qualifying screening period, an open-label titration period where NKTR-181 is given to all patients, followed by a 12 week double-blind randomized period where subjects will be randomized on a 1:1 basis to receive either NKTR-181 or placebo. The study design also includes a single interim analysis for sample size reassessment which will be conducted by an independent data monitoring committee. The primary endpoint is change in weekly pain score in the double-blind randomized period relative to the baseline pain score and the key secondary endpoints will include percentage of responders (>30% reduction in pain score) and patient impression of change. Over the next two to three years, the NKTR-181 clinical development program will require a substantial investment.

We have a collaboration with Baxalta Incorporated (Baxalta) 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 are providing our PEGylation technology and expertise and Baxalta is responsible for all clinical development. The first drug candidate in this collaboration is BAX 855, an investigational, extended half-life recombinant factor VIII (rFVIII) treatment for hemophilia A based on ADVATE [Antihemophilic Factor (Recombinant)]. BAX 855 will be marketed in the U.S. under the brand name ADYNOVATE upon approval. In December 2014, Baxalta announced that it filed a biologic license application with the FDA for BAX 855. On April 16, 2015, Baxalta announced that it had submitted a new drug application to Japan's Ministry of Health, Labour and Welfare for the approval of BAX 855. This regulatory submission was based on positive results from a prospective, global, multi-center, open-label, two-arm Phase 3 study of BAX 855 in 137 previously treated patients. Baxalta reported that the results demonstrated that BAX 855 met its primary endpoint in the control and prevention of bleeding episodes and routine prophylaxis for patients who were 12 years or older.

We also have two significant drug development programs with Bayer. The first is a collaboration to develop BAY41-6551 (Amikacin Inhale, formerly known as NKTR-061), which is an inhaled solution of amikacin, an aminoglycoside antibiotic. We originally developed the liquid aerosol inhalation platform and the NKTR-061 drug candidate and entered into a collaboration agreement with Bayer to further advance the drug candidate's development and potential commercialization. Bayer is currently enrolling patients in a Phase 3 clinical study for Amikacin Inhale. Bayer is conducting this study under a Special Protocol Assessment process agreed to with the FDA. The second is our significant royalty rights in the Cipro DPI (Cipro Dry Powder Inhaler, previously called Cipro Inhale) program with Bayer that we transferred to Novartis as part of the 2008 pulmonary asset divestiture transaction. In August 2012, Bayer initiated a global Phase 3 program called RESPIRE for the Cipro DPI product candidate in patients with non-cystic fibrosis bronchiectasis. These programs represent a significant future economic opportunity for us.

While the approved drugs and 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 earlier stage clinical development or being explored in research that we are preparing to advance into the clinic in future years. We also have additional proprietary preclinical and clinical drug candidates in research and development. In June 2015, we and the University of Texas MD Anderson Cancer Center announced a research collaboration that includes a Phase 1/2 clinical study to evaluate NKTR-214 in a variety of tumor types as a monotherapy and in combination with other therapies, including PD-1 pathway inhibitors. NKTR-214 is an engineered immunostimulatory cytokine being developed to selectively activate IL-2 receptors on cytotoxic T cells that kill tumor cells, with relatively low affinity for IL-2 receptors on regulatory T cells that dampen the immune response to tumors. In October 2015, we announced that we submitted an Investigational New Drug application to the FDA for NKTR-214 and plan to initiate a Phase 1/2 clinical study by the end of 2015. The study will evaluate the safety, tolerability and efficacy of NKTR-214 in patients with solid tumor malignancies and will include expansion cohorts that will evaluate NKTR-214 both as a single agent and in combination with a checkpoint inhibitor. As a result of pipeline prioritization, at this time we do not plan to advance NKTR-171 into Phase 2 clinical development. We are also advancing numerous other drug candidates in preclinical

development in the areas of cancer immunotherapy, pain and other therapeutic indications. 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 operations 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 fixed price or cost-plus 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.

**Table of Contents****Key Developments and Trends in Liquidity and Capital Resources**

As of September 30, 2015, we estimated that we had at least twelve months of working capital to fund our current business plans. At September 30, 2015, we had approximately \$267.8 million in cash and investments in marketable securities. Also, as of September 30, 2015, we had \$132.2 million in debt, including \$125.0 million of senior secured notes and \$7.2 million of capital lease obligations. As is further described in Note 9 to our Condensed Consolidated Financial Statements, on October 5, 2015, we issued \$250.0 million in aggregate principal amount of 7.75% senior secured notes due October 2020 and used a portion of the proceeds from these notes to redeem the \$125.0 million in aggregate principal amount of 12.0% senior secured notes due July 2017, which is included in current liabilities in our Condensed Consolidated Balance Sheet at September 30, 2015, and to pay an \$11.3 million redemption premium and \$4.5 million in interest, due upon redemption of the 12% senior secured notes. As a result of these transactions and related costs, on October 5, 2015, we received cash of approximately \$100.4 million.

**Results of Operations***Three and Nine Months Ended September 30, 2015 and 2014***Revenue (in thousands, except percentages)**

	<b>Three months ended September 30, 2015</b>	<b>Three months ended September 30, 2014</b>	<b>Increase / (Decrease) 2015 vs. 2014</b>	<b>Percentage Increase / (Decrease) 2015 vs. 2014</b>
Product sales and royalty revenue	\$ 7,427	\$ 6,172	\$ 1,255	20%
Non-cash royalty revenue related to sale of future royalties	6,050	6,143	(93)	(2)%
License, collaboration and other revenue	46,475	120,556	(74,081)	(61)%
Total revenue	\$ 59,952	\$ 132,871	\$ (72,919)	(55)%

	<b>Nine months ended September 30, 2015</b>	<b>Nine months ended September 30, 2014</b>	<b>Increase / (Decrease) 2015 vs. 2014</b>	<b>Percentage Increase / (Decrease) 2015 vs. 2014</b>
Product sales and royalty revenue	\$ 27,239	\$ 17,980	\$ 9,259	51%
Non-cash royalty revenue related to sale of future royalties	14,752	16,753	(2,001)	(12)%
License, collaboration and other revenue	149,423	146,422	3,001	2%
Total revenue	\$ 191,414	\$ 181,155	\$ 10,259	6%

Our revenue is derived from our collaboration agreements, under which we may receive product sales revenue, royalties, license fees, milestone payments and/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, is recognized ratably over our expected performance period under the arrangement. As a result, there may be significant variations in the timing of cash receipts 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 and result from the receipt of firm purchase orders from those partners. The timing of shipments is based solely on the demand and requirements of our collaboration partners and is not ratable throughout the year. We also receive royalty revenue from certain of our collaboration partners based on their net sales of commercial products.

Product sales and royalty revenue increased for the three and nine months ended September 30, 2015 compared to the three and nine months ended September 30, 2014 primarily due to increased product sales as a result of increased product demand from a number of our collaboration partners. We expect product sales for the full year of 2015 will increase as compared to 2014 due to increased product demand from our collaboration partners.

**Table of Contents**

AstraZeneca launched MOVANTI<sup>TM</sup> in the U.S. in March 2015 and MOVENTIG<sup>®</sup> in the EU in August 2015. We expect royalty revenue for the full year of 2015 will increase as compared to 2014 due to royalties we expect to receive from net sales of this product by AstraZeneca.

***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<sup>®</sup> and MIRCERA<sup>®</sup>. 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. We expect non-cash royalties from net sales of CIMZIA<sup>®</sup> and MIRCERA<sup>®</sup> for the full year of 2015 will decrease as compared to 2014.

***License, Collaboration and Other Revenue***

License, collaboration and other revenue includes the recognition of upfront payments and milestone payments received in connection with our license and collaboration agreements and reimbursed research and development expenses. The level of license, collaboration and other revenue depends in part upon 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 nine months ended September 30, 2015 compared to the nine months ended September 30, 2014 primarily as a result of the recognition of the \$100.0 million milestone payment received from AstraZeneca in March 2015 as a result of the U.S. commercial launch of MOVANTI<sup>TM</sup> and the \$40.0 million milestone payment received in August 2015 as a result of the EU commercial launch of MOVENTIG<sup>®</sup>. During the nine months ended September 30, 2014, we recognized \$35.0 million and \$70.0 million of milestone payments from AstraZeneca as a result of the FDA's approval of MOVANTI<sup>TM</sup> in September 2014 and recognized \$9.0 million of milestone payments resulting from the transfer of our manufacturing technology to two of our collaboration partners. The increase in license, collaboration and other revenue in 2015 is offset by a total of \$10.0 million that we agreed in March 2015 to pay AstraZeneca, including \$5.0 million paid in July 2015 and \$5.0 million to be paid in July 2016, to fund U.S. television advertising in consideration for certain additional commercial information rights. We determined that this \$10.0 million obligation should be recorded as a reduction of revenue, which we recorded in the three months ended March 31, 2015.

License, collaboration and other revenue decreased for the three months ended September 30, 2015 compared to the three months ended September 30, 2014 primarily as a result of the recognition in September 2014 of the \$105.0 million of milestone payments from AstraZeneca noted above.

As a result of the milestone payments received in 2015 from AstraZeneca related to the U.S. and EU commercial launches of MOVANTI<sup>TM</sup>, we expect our license, collaboration and other revenue for the full year of 2015 will increase as compared to 2014.

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

Three months ended	Three months ended	Increase / (Decrease)	Percentage Increase
-----------------------	-----------------------	--------------------------	------------------------

Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

	<b>September 30, 2015</b>	<b>September 30, 2014</b>	<b>2015 vs. 2014</b>	<b>/ (Decrease) 2015 vs. 2014</b>
Cost of goods sold	\$ 6,760	\$ 9,220	\$ (2,460)	(27)%
Product gross profit (loss)	\$ 667	\$ (3,048)	\$ 3,715	>100%
Product gross margin	9%	(49)%		

	<b>Nine months ended September 30, 2015</b>	<b>Nine months ended September 30, 2014</b>	<b>Increase / (Decrease) 2015 vs. 2014</b>	<b>Percentage Increase / (Decrease) 2015 vs. 2014</b>
Cost of goods sold	\$ 25,738	\$ 22,235	\$ 3,503	16%
Product gross profit (loss)	\$ 1,501	\$ (4,255)	\$ 5,756	>100%
Product gross margin	6%	(24)%		

Cost of goods sold increased during the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014 primarily due to the increases in product sales in the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014. Cost of goods sold decreased during the three months ended September 30, 2015 compared to the three months ended September 30, 2014 primarily due to a more favorable mix of product sales in the three months ended September 30, 2015 compared to the three months ended September 30, 2014.

**Table of Contents**

The improvement in product gross profit (loss) and product gross margin during the three and nine months ended September 30, 2015 compared to the three and nine months ended September 30, 2014 is primarily due to a more favorable product mix in 2015 compared to 2014. In particular, the manufacturing arrangement with one of our collaboration partners includes a fixed price for proprietary PEGylation reagent sales, which is less than the fully burdened manufacturing cost for the reagent in 2014 and 2015 and we expect this situation to continue in future years. There were fewer shipments to this partner in total and relative to shipments to other customers during the three and nine months ended September 30, 2015 compared to the three and nine months ended September 30, 2014. In addition to product sales from reagent shipments to this partner, we also receive royalty revenues from this collaboration. In the three and nine months ended September 30, 2015 and 2014, the royalty revenue from the collaboration exceeded the related negative gross profit.

We expect product gross margin to continue to fluctuate in future periods depending on the level and mix of manufacturing orders from our customers due to the predominantly fixed cost base associated with our manufacturing activities. We expect product gross margin for the full year of 2015 to increase as compared to 2014 as a result of the anticipated increase in product sales, as well as based on the anticipated product mix.

**Research and Development Expense (in thousands, except percentages)**

	<b>Three months ended September 30, 2015</b>	<b>Three months ended September 30, 2014</b>	<b>Increase / (Decrease) 2015 vs. 2014</b>	<b>Percentage Increase / (Decrease) 2015 vs. 2014</b>
Research and development expense	\$ 43,229	\$ 34,200	\$ 9,029	26%

	<b>Nine months ended September 30, 2015</b>	<b>Nine months ended September 30, 2014</b>	<b>Increase / (Decrease) 2015 vs. 2014</b>	<b>Percentage Increase / (Decrease) 2015 vs. 2014</b>
Research and development expense	\$ 135,652	\$ 109,240	\$ 26,412	24%

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

Research and development expense increased during the three and nine months ended September 30, 2015 compared to the three and nine months ended September 30, 2014 primarily due to the initiation of Phase 3 clinical studies for NKTR-181 in the first quarter of 2015. 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 increase significantly in the full year of 2015 as compared to 2014 primarily due to costs incurred in connection with the Phase 3 clinical studies for NKTR-181.



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, 2015 from the activities discussed in our Annual Report on Form 10-K for the year ended December 31, 2014 on file with the Securities and Exchange Commission.

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

	<b>Three months ended September 30, 2015</b>	<b>Three months ended September 30, 2014</b>	<b>Increase / (Decrease) 2015 vs. 2014</b>	<b>Percentage Increase / (Decrease) 2015 vs. 2014</b>
General and administrative expense	\$ 9,544	\$ 9,130	\$ 414	5%

	<b>Nine months ended September 30, 2015</b>	<b>Nine months ended September 30, 2014</b>	<b>Increase / (Decrease) 2015 vs. 2014</b>	<b>Percentage Increase / (Decrease) 2015 vs. 2014</b>
General and administrative expense	\$ 30,031	\$ 28,677	\$ 1,354	5%

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, 2015 increased slightly compared to the three and nine months ended September 30, 2014. We expect general and administrative expenses in the full year of 2015 to increase slightly compared to 2014.

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

	<b>Three months ended September 30, 2015</b>	<b>Three months ended September 30, 2014</b>	<b>Increase / (Decrease) 2015 vs. 2014</b>	<b>Percentage Increase / (Decrease) 2015 vs. 2014</b>
Interest expense	\$ 4,202	\$ 4,391	\$ (189)	(4)%
Non-cash interest expense on liability related to sale of future royalties	\$ 5,226	\$ 5,203	\$ 23	<1%

  

	<b>Nine months ended September 30, 2015</b>	<b>Nine months ended September 30, 2014</b>	<b>Increase / (Decrease) 2015 vs. 2014</b>	<b>Percentage Increase / (Decrease) 2015 vs. 2014</b>
Interest expense	\$ 12,491	\$ 13,412	\$ (921)	(7)%
Non-cash interest expense on liability related to sale of future royalties	\$ 15,428	\$ 15,725	\$ (297)	(2)%

In July 2012, we issued \$125.0 million of 12% senior secured notes due July 15, 2017. Interest expense for the three and nine months ended September 30, 2015 decreased compared to the three and nine months ended September 30, 2014 due to decreased interest from capital leases and other obligations. As is further described in Note 9 to our Condensed Consolidated Financial Statements, on October 5, 2015, we issued \$250.0 million in aggregate principal amount of 7.75% senior secured notes due October 2020 and used a portion of the proceeds from these notes to redeem the \$125.0 million in aggregate principal amount of 12.0% senior secured notes due July 2017, which is included in current liabilities in our Condensed Consolidated Balance Sheet at September 30, 2015. We expect interest expense during the full year of 2015 to be consistent with 2014.

Non-cash interest expense on the liability related to sale of future royalties for the three and nine months ended September 30, 2015 was consistent with the three and nine months ended September 30, 2014. In February 2012, we sold all of our rights to receive future royalty payments on CIMZIA® and MIRCERA® in exchange for \$124.0 million. 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 CIMZIA® and MIRCERA® royalties are remitted directly to the purchaser. 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, in particular, the amount and timing of royalty payments from future net sales of CIMZIA® and MIRCERA®, and we will 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 2015 to be consistent with 2014.

**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 offerings and private placements of debt and equity securities. At

September 30, 2015, we had approximately \$267.8 million in cash and investments in marketable securities. Also, as of September 30, 2015, we had \$132.2 million in debt, including \$125.0 million of senior secured notes due July 2017 and \$7.2 million of capital lease obligations. As is further described in Note 9 to our Condensed Consolidated Financial Statements, on October 5, 2015, we issued \$250.0 million in aggregate principal amount of 7.75% senior secured notes due October 2020 and used a portion of the proceeds from these notes to redeem the \$125.0 million in aggregate principal amount of 12.0% senior secured notes due July 2017, which is included in current liabilities in our Condensed Consolidated Balance Sheet at September 30, 2015, and to pay an \$11.3 million redemption premium and \$4.5 million in interest, due upon redemption of the 12% senior secured notes. As a result of these transactions and related costs, on October 5, 2015, we received cash of approximately \$100.4 million.

As of September 30, 2015, 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 NKTR-102, Amikacin Inhale, NKTR-181, and NKTR-214, 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 the past we have received a number of significant payments from collaboration agreements and other significant transactions. In the future, we expect to receive royalties and sales milestone payments from commercial sales of products such as MOVANTIK™ and BAX 855 (if approved) and potential substantial payments from future collaboration transactions if drug candidates in our pipeline achieve positive clinical or regulatory outcomes. Our current business plan is also subject to significant uncertainties and risks as a result of, among other factors, the sales levels of products for which we are entitled to royalties such as

---

**Table of Contents**

MOVANTIK™, clinical program outcomes, whether, when and on what terms we are able to enter into new collaboration transactions, 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 many factors including the success or failure of drug development programs in our pipeline, including NKTR-102, BAX 855, Amikacin Inhale, NKTR-181, NKTR-214, 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 depend on the positive outcome of ongoing or planned clinical studies, whether we or our partners are successful in obtaining regulatory authority approvals in major markets, and if approved, the commercial success of these drugs, as well as general capital market conditions. We will pursue various financing alternatives as needed to continue to fund our research and development activities and to fund the expansion of our business as appropriate.

Due to the potential for adverse developments in the credit markets in 2015 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, 2015, the average time to maturity of the investments held in our portfolio was approximately five 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 provided by operating activities for the nine months ended September 30, 2015 totaled \$2.0 million, which includes the receipt of \$142.0 million for milestones from collaboration agreements, including the \$100.0 million payment received as a result of the U.S. launch of MOVANTIK™ and the \$40.0 million payment received as a result of the EU launch of MOVENTIG®, partially offset by \$125.0 million of net operating cash uses as well as \$15.0 million for interest payments on our senior secured notes. 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 decrease for the full year of 2015 as compared to 2014. While we expect increased spending on our proprietary research and development programs due primarily to the initiation of the NKTR-181 Phase 3 clinical program, we expect these increases will be offset by decreased payments for other operating activities in 2015 as compared to 2014.

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.

*Cash flows from investing activities*

We paid \$8.7 million and \$6.1 million to purchase property, plant and equipment in the nine months ended September 30, 2015 and 2014, respectively. We expect our capital expenditures in 2015, which include costs to build

commercial manufacturing capacity for Amikacin Inhale devices and other capital projects, to increase slightly as compared to 2014.

Restricted cash of \$25.0 million was required to be maintained in a separate account until July 1, 2015 under the terms of our 12% senior secured notes due July 2017. This restriction expired on July 1, 2015 and the restricted funds were returned to us.

*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 \$0.6 million in legal and accounting fees, filing fees, and other offering expenses in connection with this offering.

In February 2012, we sold all of our rights to receive future royalty payments on CIMZIA<sup>®</sup> and MIRCERA<sup>®</sup> in exchange for a cash payment of \$124.0 million. During the nine months ended September 30, 2014, we made a payment of \$7.0 million to the purchaser of these royalties because the minimum 2013 MIRCERA<sup>®</sup> net sales threshold was not met. As of September 30, 2015, we are not required to make any further payments to the purchaser of these royalties. The remaining \$121.1 million liability related to sale of future royalties at September 30, 2015 will not be settled in cash.

We received \$15.5 million and \$16.2 million from issuances of common stock to employees under our equity compensation plans during the nine months ended September 30, 2015 and 2014, respectively.

## **Table of Contents**

### ***Contractual Obligations***

There were no material changes during the nine months ended September 30, 2015 to the summary of contractual obligations included in our Annual Report on Form 10-K for the year ended December 31, 2014 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.

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, 2014.

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

Our market risks at September 30, 2015 have not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2014 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, 2015 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.

**Table of Contents**

**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, 2014. 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, 2014, including our consolidated financial statements and related notes, and our other filings made from time to time with the Securities and Exchange Commission (SEC).

***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 NKTR-102, NKTR-181, NKTR-214 and other drug candidates currently in discovery research or preclinical development. For example, while we recently started a Phase 3 clinical program for NKTR-181 which we believe employs the most appropriate clinical trial design, we were unable to identify a single cause for the Phase 2 study for NKTR-181 not meeting its primary efficacy endpoint, and therefore there is increased risk in effectively designing a Phase 3 clinical program for NKTR-181. 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.



***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 (i.e. Phase 3) 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 regulatory authorities. 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.

***Our results of operations and financial condition depend significantly on the ability of our collaboration partners to successfully develop and market drugs and they may fail to do so.***

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 significant risks to our business, including risks that:

we have very little control over the timing and level of resources that our collaboration partners dedicate to commercial marketing efforts such as the amount of investment in sales and marketing personnel, general marketing campaigns, direct-

**Table of Contents**

to-consumer advertising (where appropriate), product sampling, pricing agreements and rebate strategies with government and private payers, manufacturing and supply of drug product, and other marketing and selling activities that need to be undertaken and well executed for a drug to have the potential to achieve commercial success;

collaboration partners with commercial rights may choose to devote fewer resources to the marketing of our partnered drugs than they devote to their own drugs or other drugs that they have in-licensed;

we have very little control over the timing and amount of resources our partners devote to development programs in one or more major markets;

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;

disputes may arise or escalate in the future with respect to the ownership of rights to technology or intellectual property developed with partners;

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 collaboration partnerships is highly unpredictable and can have a substantial negative or positive impact on our business. In particular, we expect the commercial outcomes of MOVANTIK, and if approved, BAX 855, to have a particularly significant impact on our near to mid-term financial results and financial condition. If our collaboration arrangements underperform or fail, our drug development efforts for our proprietary drug candidate pipeline could be delayed or reduced unless we can secure capital funding from other sources. If we are unable to obtain sufficient capital resources to advance our drug candidate pipeline, it would negatively impact the value of our business, results of operations and financial condition.

***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 product candidates following approval by regulatory 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 this would negatively impact 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.

---

**Table of Contents**

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 MOVANTIK™, and the purchase and sale agreement with RPI Finance Trust (RPI) related to the sale of our royalty interests in UCB's CIMZIA® and Roche's MIRCERA® 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. For example, on January 23, 2015, we filed a lawsuit against Allergan and MAP seeking economic damages related to a dispute over the economic sharing provisions of our license agreement with MAP. 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.

***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 regulatory authorities. The time required for obtaining regulatory decisions is uncertain and difficult to predict. The FDA and other U.S. and foreign regulatory 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. For example, while data from certain pre-specified subgroups in the BEACON study was positive, the study did not achieve statistical significance for its primary endpoint and the FDA and European Medicines Agency rarely approve drugs on the basis of studies that do not achieve statistical significance on the primary endpoint. Further, regulatory 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 MOVANTIK™ 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 labeling, regulatory status, and commercial potential of MOVANTIK™.

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.



**Table of Contents**

***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 or royalty 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, 2015, we had cash and investments in marketable securities valued at approximately \$267.8 million. Also, as of September 30, 2015, we had \$132.2 million in debt, including \$125.0 million of senior secured notes and \$7.2 million of capital lease obligations. As is further described in Note 9 to our Condensed Consolidated Financial Statements, on October 5, 2015, we issued \$250.0 million in aggregate principal amount of 7.75% senior secured notes due October 2020 and used a portion of the proceeds from these notes to redeem the \$125.0 million in aggregate principal amount of 12.0% senior secured notes due July 2017, which is included in current liabilities in our Condensed Consolidated Balance Sheet at September 30, 2015, and to pay an \$11.3 million redemption premium and \$4.5 million in interest, due upon redemption of the 12% senior secured notes. As a result of these transactions and related costs, on October 5, 2015, we received cash of approximately \$100.4 million. 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 Amikacin Inhale and CIPRO Inhale licensed to Bayer, and BAX 855 that is being developed by Baxalta;

the commercial launch and sales levels of products marketed by our collaboration partners for which we are entitled to royalties and sales milestones – importantly, AstraZeneca’s level of success in marketing and selling MOVANTIK (or MOVENTIG<sup>®</sup>, the naloxegol brand name in the EU);

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;

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;

the number of patients, enrollment criteria, primary and secondary endpoints, and the number of clinical studies required by the regulatory 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.

**Table of Contents**

***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. We currently have ongoing clinical studies for NKTR-181 in patients with chronic lower back pain and plan to initiate a Phase 1 clinical study for NKTR-214 before the end of 2015. In addition, our collaboration partners have several ongoing Phase 3 clinical programs including Baxalta for BAX 855, Bayer for Amikacin Inhale and CIPRO Inhale, and Ophthotech for Fovista®. These and other clinical studies may not begin on time, enroll a sufficient number of patients or be completed on schedule, if at all. 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 regulatory authorities on a clinical study design;

imposition of a clinical hold following an inspection of 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 regulatory 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 regulatory 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.

***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

---

**Table of Contents**

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 commercializing 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 215 U.S. and 750 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 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 agreed to pay \$12.0 million 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 are involved in legal proceedings where we or other third parties are enforcing or seeking intellectual property rights, invalidating or limiting patent rights that have already been allowed or issued, or otherwise asserting proprietary rights through one or more potential legal remedies. For example, we are currently involved in a German litigation proceeding whereby Bayer is seeking co-ownership rights in certain of our patent filings pending at the European Patent Office covering (among other things) PEGylated Factor VIII which we have exclusively licensed to Baxalta. The subject matter of our patent filings in this proceeding relates to Bayer's investigational PEGylated recombinant Factor VIII compound. We believe that Bayer's claim to an ownership interest in these patent filings is without merit and are vigorously defending sole and exclusive ownership rights

---

**Table of Contents**

to this intellectual property. We are also regularly involved in opposition proceedings at the European Patent Office where third parties seek to invalidate or limit the scope of our allowed European patent applications covering (among other things) our drugs and platform technologies. We are also aware of an inter partes review petition that was filed with the U.S. Patent and Trademark Office by Neptune Generics, which is an affiliate of Gerchen Keller Capital. The filing is directed to one of six Orange Book listed patents covering MOVANTIK™. We believe this petition is without merit and AstraZeneca and Nektar will vigorously defend the validity of this patent. The cost to us in initiating or defending 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 or result in financial implications either in terms of seeking license arrangements or payment of damages or royalties.

***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 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. Regulatory 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 could 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.

---

**Table of Contents**

***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 or 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, and results of operations could be materially and adversely affected.

***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 product candidates 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.

***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. Important examples of this risk include MOVANTIK, which partnered with AstraZeneca and BAX 855, which partnered with Baxalta. 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 opportunities or contract liabilities 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.

**Table of Contents**

***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, 2015, we reported a net loss of \$27.0 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 clinical studies for NKTR-181, and NKTR-214;

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 the failure of third parties to properly conduct our clinical trials 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.

**Table of Contents**

***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 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 MOVANTIK™, there are currently several alternative therapies used to address opioid-induced constipation (OIC) and opioid-induced bowel dysfunction (OBD), including Relistor® (methylnaltrexone bromide) Subcutaneous Injection, 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 plc, GlaxoSmithKline plc, Theravance, Inc., and Takeda Pharmaceutical Company Limited. For etirinotecan pegol (also known as NKTR-102), there are a number of chemotherapies and cancer therapies approved today and in various stages of clinical development for breast cancer, including, but not limited to: Abraxane® (paclitaxel protein-bound particles for injectable suspension (albumin bound)), Xeloda® (capecitabine), Afinitor® (everolimus), Doxil® (doxorubicin HCl), Ellence® (epirubicin), Gemzar® (gemcitabine), Halaven® (eribulin), Herceptin® (trastuzumab), Hycamtin® (topotecan), Ibrance® (palbociclib), Ixempra® (ixabepilone), Navelbine® (vinorelbine), Iniparib, Paraplatin® (carboplatin), Taxol® (paclitaxel) and Taxotere® (docetaxel). Major pharmaceutical or biotechnology companies with approved drugs or drugs in development for breast cancers include, but are not limited to, Bristol-Meyers Squibb Company, Eli Lilly & Co., Roche, GlaxoSmithKline plc, Johnson and Johnson, Pfizer Inc., Eisai Inc., and Sanofi Aventis S.A.

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.

---

**Table of Contents**

***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 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

**Table of Contents**

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, 2015, based on closing prices on The NASDAQ Global Select Market, the closing price of our common stock ranged from \$9.50 to \$13.92 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;

the level of commercial sales achieved by our collaboration partners, particularly AstraZeneca's sales of MOVANTIK ;

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.

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 our 7.75% 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.***

On October 5, 2015, we issued \$250.0 million in aggregate principal amount of 7.75% senior secured notes due October 2020. The indenture governing the senior secured notes contains covenants that restrict our and our subsidiaries' ability to take various actions, including, among other things:

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, advances 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 the date of the indenture; and

consummate a merger, consolidation, reorganization or business combination, sell, lease, convey or otherwise dispose of all or substantially all of our assets or other change of control transaction.

This indenture also requires us to maintain a minimum cash balance of \$60.0 million. We have certain reporting obligations under the indenture regarding cash position and royalty revenue. The indenture specifies a number of

events of default, some of which are subject to applicable grace or cure periods, including, among other things, non-payment defaults, covenant defaults, cross-defaults



**Table of Contents**

to other material indebtedness, bankruptcy and insolvency defaults, non-payment of material judgments, loss of any material business license, criminal indictment of the Company, and certain civil forfeiture proceedings involving material assets of the Company. 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 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, 2015.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None.

**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.

**Exhibit**

**Number**

**Description of Documents**

10.1(1)	Purchase Agreement dated as of September 30, 2015, by and among Nektar Therapeutics and TC Lending, LLC and TAO Fund, LLC.
---------	--

Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

- 10.2(1) Indenture dated as of October 5, 2015, by and among Nektar Therapeutics, Wilmington Trust, National Association, and TC Lending, LLC.
- 10.3(1) Pledge and Security Agreement dated as of October 5, 2015, by and among Nektar Therapeutics and TC Lending, LLC.
- 31.1(2) Certification of Nektar Therapeutics principal executive officer required by Rule 13a-14(a) or Rule 15d-14(a).
- 31.2(2) 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, 2015, 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) Incorporated by reference to the indicated exhibit in Nektar Therapeutics Current Report on Form 8-K, filed on October 6, 2015.
- (2) 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.

Table of Contents

**SIGNATURES**

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

By: /s/ JOHN NICHOLSON

**John Nicholson**

**Senior Vice President and Chief Financial Officer**

Date: November 5, 2015

By: /s/ JILLIAN B. THOMSEN

**Jillian B. Thomsen**

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

Date: November 5, 2015

**Table of Contents****EXHIBIT INDEX**

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

<b>Exhibit</b>	
<b>Number</b>	<b>Description of Documents</b>
10.1(1)	Purchase Agreement dated as of September 30, 2015, by and among Nektar Therapeutics and TC Lending, LLC and TAO Fund, LLC.
10.2(1)	Indenture dated as of October 5, 2015, by and among Nektar Therapeutics, Wilmington Trust, National Association, and TC Lending, LLC.
10.3(1)	Pledge and Security Agreement dated as of October 5, 2015, by and among Nektar Therapeutics and TC Lending, LLC.
31.1(2)	Certification of Nektar Therapeutics principal executive officer required by Rule 13a-14(a) or Rule 15d-14(a).
31.2(2)	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, 2015, 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)	Incorporated by reference to the indicated exhibit in Nektar Therapeutics Current Report on Form 8-K, filed on October 6, 2015.
(2)	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.