

NEKTAR THERAPEUTICS  
Form 10-Q  
August 09, 2013  
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 June 30, 2013

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)

Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

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

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

**455 Mission Bay Boulevard South**

**San Francisco, California 94158**

(Address of principal executive offices)

**415-482-5300**

(Registrant's telephone number, including area code)

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

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 115,757,059 on August 1, 2013.

**Table of Contents**

**NEKTAR THERAPEUTICS**

**INDEX**

**PART I: FINANCIAL INFORMATION**

|         |  |    |
|---------|--|----|
| Item 1. | <u>Condensed Consolidated Financial Statements – Unaudited:</u>  | 4  |
|         | <u>Condensed Consolidated Balance Sheets – June 30, 2013 and December 31, 2012</u>                                       | 4  |
|         | <u>Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2013 and 2012</u>         | 5  |
|         | <u>Condensed Consolidated Statements of Comprehensive Loss for the three and six months ended June 30, 2013 and 2012</u> | 5  |
|         | <u>Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2013 and 2012</u>                   | 6  |
|         | <u>Notes to Condensed Consolidated Financial Statements</u>  | 7  |
| Item 2. | <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>                             | 15 |
| Item 3. | <u>Quantitative and Qualitative Disclosures About Market Risk</u>  | 22 |
| Item 4. | <u>Controls and Procedures</u>   | 22 |

**PART II: OTHER INFORMATION**

|          |  |    |
|----------|--|----|
| Item 1.  | <u>Legal Proceedings</u>   | 23 |
| Item 1A. | <u>Risk Factors</u>  | 23 |
| Item 2.  | <u>Unregistered Sales of Equity Securities and Use of Proceeds</u> | 35 |
| Item 3.  | <u>Defaults Upon Senior Securities</u>                             | 35 |
| Item 4.  | <u>Mine Safety Disclosures</u>                                     | 35 |
| Item 5.  | <u>Other Information</u>   | 36 |
| Item 6.  | <u>Exhibits</u>  | 36 |
|          | <u>Signatures</u>  | 37 |

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

### **Trademarks**

The Nektar brand and product names, including but not limited to Nektar®, contained in this document are trademarks, registered trademarks or service marks 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>June 30,<br/>2013</b> | <b>December 31,<br/>2012</b> |
|---|--------------------------|------------------------------|
| <b>ASSETS</b>   |                          |                              |
| Current assets:   |                          |                              |
| Cash and cash equivalents   | \$ 41,432                | \$ 25,437                    |
| Short-term investments  | 160,453                  | 251,757                      |
| Accounts receivable   | 6,041                    | 5,805                        |
| Inventory   | 20,479                   | 18,269                       |
| Other current assets  | 6,018                    | 13,363                       |
| Total current assets  | 234,423                  | 314,631                      |
| Restricted cash   | 25,000                   | 25,000                       |
| Property and equipment, net   | 67,849                   | 72,215                       |
| Goodwill  | 76,501                   | 76,501                       |
| Other assets  | 9,036                    | 9,443                        |
| Total assets  | \$ 412,809               | \$ 497,790                   |
| <b>LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)</b>                |                          |                              |
| Current liabilities:  |                          |                              |
| Accounts payable  | \$ 5,572                 | \$ 2,863                     |
| Accrued compensation  | 11,087                   | 8,773                        |
| Accrued expenses  | 11,356                   | 8,008                        |
| Accrued clinical trial expenses                                     | 16,935                   | 17,500                       |
| Deferred revenue, current portion                                   | 22,113                   | 21,896                       |
| Interest payable  | 6,917                    | 7,083                        |
| Other current liabilities   | 16,297                   | 12,414                       |
| Total current liabilities   | 90,277                   | 78,537                       |
| Senior secured notes  | 125,000                  | 125,000                      |
| Capital lease obligations, less current portion                     | 9,901                    | 11,607                       |
| Liability related to sale of future royalties, less current portion | 124,074                  | 128,266                      |
| Deferred revenue, less current portion                              | 93,516                   | 96,551                       |
| Deferred gain   | 1,967                    | 2,404                        |
| Other long-term liabilities   | 8,623                    | 8,407                        |
| Total liabilities   | 453,358                  | 450,772                      |
| Commitments and contingencies                                       |                          |                              |
| Stockholders' equity (deficit):                                     |                          |                              |

## Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

|   |             |             |
|---|-------------|-------------|
| Preferred stock, 10,000 shares authorized, \$0.0001 par value; no shares designated, issued or outstanding at June 30, 2013 or December 31, 2012 respectively       |             |             |
| Common stock, \$0.0001 par value; 300,000 authorized; 115,683 shares and 115,259 shares issued and outstanding at June 30, 2013 and December 31, 2012, respectively | 11          | 11          |
| Capital in excess of par value  | 1,628,967   | 1,617,744   |
| Accumulated other comprehensive loss  | (1,336)     | (357)       |
| Accumulated deficit   | (1,668,191) | (1,570,380) |
| <br>  |             |             |
| Total stockholders' equity (deficit)  | (40,549)    | 47,018      |
| <br>  |             |             |
| Total liabilities and stockholders' equity (deficit)  | \$ 412,809  | \$ 497,790  |

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)**

|   | <b>Three months ended</b> |                          | <b>Six months ended</b> |                          |
|---|---------------------------|--------------------------|-------------------------|--------------------------|
|   | <b>2013</b>               | <b>June 30,<br/>2012</b> | <b>2013</b>             | <b>June 30,<br/>2012</b> |
| <b>Revenue:</b>   |                           |                          |                         |                          |
| Product sales   | \$ 10,324                 | \$ 9,694                 | \$ 22,134               | \$ 16,639                |
| Royalty revenues  | 351                       | 290                      | 676                     | 3,467                    |
| Non-cash royalty revenue related to sale of future royalties                                      | 3,828                     | 3,469                    | 8,221                   | 3,469                    |
| License, collaboration and other revenue  | 19,359                    | 10,231                   | 25,835                  | 18,058                   |
| <b>Total revenue</b>  | <b>33,862</b>             | <b>23,684</b>            | <b>56,866</b>           | <b>41,633</b>            |
| <b>Operating costs and expenses:</b>  |                           |                          |                         |                          |
| Cost of goods sold  | 5,011                     | 7,203                    | 16,672                  | 15,910                   |
| Research and development  | 52,230                    | 33,201                   | 97,848                  | 68,286                   |
| General and administrative  | 9,226                     | 10,268                   | 20,057                  | 20,682                   |
| Impairment of long-lived assets   |                           |                          |                         | 1,675                    |
| <b>Total operating costs and expenses</b>   | <b>66,467</b>             | <b>50,672</b>            | <b>134,577</b>          | <b>106,553</b>           |
| <b>Loss from operations</b>   | <b>(32,605)</b>           | <b>(26,988)</b>          | <b>(77,711)</b>         | <b>(64,920)</b>          |
| <b>Non-operating income (expense):</b>  |                           |                          |                         |                          |
| Interest income   | 209                       | 630                      | 523                     | 1,262                    |
| Interest expense  | (4,656)                   | (2,562)                  | (9,301)                 | (5,109)                  |
| Non-cash interest expense on liability related to sale of future royalties                        | (5,485)                   | (5,369)                  | (11,028)                | (7,155)                  |
| Other income (expense), net   | (6)                       | 97                       | 123                     | 757                      |
| <b>Total non-operating expense, net</b>   | <b>(9,938)</b>            | <b>(7,204)</b>           | <b>(19,683)</b>         | <b>(10,245)</b>          |
| <b>Loss before provision for income taxes</b>   | <b>(42,543)</b>           | <b>(34,192)</b>          | <b>(97,394)</b>         | <b>(75,165)</b>          |
| Provision for income taxes  | 205                       | 93                       | 417                     | 217                      |
| <b>Net loss</b>   | <b>\$ (42,748)</b>        | <b>\$ (34,285)</b>       | <b>\$ (97,811)</b>      | <b>\$ (75,382)</b>       |
| <b>Basic and diluted net loss per share</b>   | <b>\$ (0.37)</b>          | <b>\$ (0.30)</b>         | <b>\$ (0.85)</b>        | <b>\$ (0.66)</b>         |
| <b>Weighted average shares outstanding used in computing basic and diluted net loss per share</b> | <b>115,544</b>            | <b>114,649</b>           | <b>115,427</b>          | <b>114,590</b>           |

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

Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

|                    | Three months ended |             | Six months ended |             |
|--------------------|--------------------|-------------|------------------|-------------|
|                    | June 30,           |             | June 30,         |             |
|                    | 2013               | 2012        | 2013             | 2012        |
| Comprehensive loss | \$ (43,689)        | \$ (34,862) | \$ (98,790)      | \$ (74,899) |

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)**

|  | <b>Six months ended<br/>June 30,</b> |                 |
|--|--------------------------------------|-----------------|
|  | <b>2013</b>                          | <b>2012</b>     |
| <b>Cash flows from operating activities:</b>   |                                      |                 |
| Net loss   | \$ (97,811)                          | \$ (75,382)     |
| Adjustments to reconcile net loss to net cash used in operating activities:                              |                                      |                 |
| Non-cash interest expense on liability related to sale of future royalties                               | 11,028                               | 7,155           |
| Non-cash royalty revenue related to sale of future royalties   | (8,221)                              | (3,469)         |
| Stock-based compensation   | 8,601                                | 8,035           |
| Depreciation and amortization  | 7,281                                | 6,952           |
| Impairment of long-lived assets  |                                      | 1,675           |
| Other non-cash transactions  | 159                                  | 688             |
| Changes in operating assets and liabilities:   |                                      |                 |
| Accounts receivable  | (236)                                | (6,423)         |
| Inventory  | (2,210)                              | (2,059)         |
| Other assets   | 5,508                                | 8,176           |
| Accounts payable   | 2,631                                | 80              |
| Accrued compensation   | 2,314                                | (2,288)         |
| Accrued expenses   | 3,280                                | 191             |
| Accrued clinical trial expenses  | (565)                                | 654             |
| Deferred revenue   | (2,818)                              | 1,075           |
| Interest payable   | (166)                                |                 |
| Other liabilities  | (1,223)                              | (269)           |
| <b>Net cash used in operating activities</b>   | <b>(72,448)</b>                      | <b>(55,209)</b> |
| <b>Cash flows from investing activities:</b>   |                                      |                 |
| Maturities of investments  | 200,477                              | 179,766         |
| Purchases of investments   | (109,400)                            | (120,410)       |
| Purchases of property and equipment  | (794)                                | (3,172)         |
| <b>Net cash provided by investing activities</b>   | <b>90,283</b>                        | <b>56,184</b>   |
| <b>Cash flows from financing activities:</b>   |                                      |                 |
| Payments of capital lease obligations  | (1,466)                              | (1,151)         |
| (Repayment of) proceeds from sale of future royalties, net of \$4.4 million of transaction costs in 2012 | (3,000)                              | 119,589         |
| Proceeds from shares issued under equity compensation plans  | 2,621                                | 1,337           |
| <b>Net cash (used in) provided by financing activities</b>   | <b>(1,845)</b>                       | <b>119,775</b>  |
| Effect of exchange rates on cash and cash equivalents  | 5                                    | 92              |
| <b>Net increase in cash and cash equivalents</b>   | <b>15,995</b>                        | <b>120,842</b>  |
| Cash and cash equivalents at beginning of period   | 25,437                               | 15,312          |

Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

|  |           |            |
|--|-----------|------------|
| Cash and cash equivalents at end of period               | \$ 41,432 | \$ 136,154 |
| <b>Supplemental disclosure of cash flow information:</b> |           |            |
| Cash paid for interest                                   | \$ 9,070  | \$ 5,179   |

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**

**June 30, 2013**

**(Unaudited)**

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

***Organization***

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

Our research and development activities have required significant resources to date and are expected to continue to require significant resources. 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 from licensing, collaboration and manufacturing agreements and financing transactions. At June 30, 2013, we had approximately \$226.9 million in cash and investments in marketable securities, of which \$25.0 million was restricted in relation to our 12% senior secured notes, and \$147.7 million in indebtedness. The indebtedness includes \$125.0 million in aggregate principal amount of 12.0% senior secured notes due July 15, 2017, but excludes our long-term liability relating to the sale of future royalties. As is further described in Note 4, this royalty obligation liability will not be settled in cash, but we may be required to make a payment of up to \$7.0 million in 2014 if a certain specified worldwide net sales threshold is not met.

***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 material 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 six month periods ended June 30, 2013 and 2012. In addition, there were no significant reclassifications out of accumulated other comprehensive loss to the statements of operations during the three and six month periods ended June 30, 2013 and 2012.

The accompanying Condensed Consolidated Financial Statements are unaudited. The Condensed Consolidated Balance Sheet data as of December 31, 2012 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, 2012 filed with the SEC on March 1, 2013. 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, 2012.

## Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

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

### *Use of Estimates*

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ materially from those estimates and assumptions. On an ongoing basis, we evaluate our estimates, including those related to deferred revenue recognition periods, inventories, the impairment of investments, the impairment of goodwill and long-lived assets, contingencies,

## **Table of Contents**

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.

### ***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 time and materials based billings from collaborative research and development agreements. 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 June 30, 2013 or December 31, 2012.

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

### ***Revenue Recognition***

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

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

### ***Product sales***

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

### ***Royalty revenues***

## Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

Generally, we are entitled to royalties from our partners based on the net sales of their approved drugs that are marketed and sold in one or more countries where we hold royalty rights. We recognize royalty revenue when the cash is received or when the royalty amount to be received is estimable and collection is reasonably assured. With respect to the non-cash royalties related to sale of future royalties described at Note 4, revenues are 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.

**Table of Contents***License, collaboration and other revenue*

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

Contingent consideration received from the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved, which we believe is consistent with the substance of our performance under our various license and collaboration agreements. A milestone is defined as an event (i) that can only be achieved based in whole or in part either on 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 health authorities, and commercial launches of drugs. Given the challenges inherent in developing, obtaining regulatory approvals for and achieving commercial launches of drug products, there was substantial uncertainty whether any such milestones would be achieved at the time of execution of these licensing and collaboration agreements. In addition, we evaluate whether the development milestones meet the remaining criteria to be considered substantive. As a result of our analysis, we consider our remaining development milestones under all of our license and collaboration agreements to be substantive and, accordingly, we expect to recognize as revenue future payments received from such milestones only if and as each milestone is achieved.

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

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

***Income Taxes***

For the three and six month periods ended June 30, 2013 and 2012, we recorded an income tax provision for our Nektar India operations at effective tax rates ranging from approximately 32% to 34% for each period. 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.

**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>June 30,<br/>2013</b>       | <b>December 31,<br/>2012</b> |
| Cash and cash equivalents                           | \$ 41,432                      | \$ 25,437                    |
| Short-term investments                              | 160,453                        | 251,757                      |
| Restricted cash                                     | 25,000                         | 25,000                       |
| Total cash and investments in marketable securities | \$ 226,885                     | \$ 302,194                   |





**Table of Contents**

Restricted cash of \$25.0 million is required to be maintained until July 1, 2017 under the terms of our 12% Senior Secured Notes due July 2017.

We invest in liquid, high quality debt securities. Our investments in debt securities are subject to interest rate risk. To minimize the exposure due to an adverse shift in interest rates, we invest in securities with maturities of two years or less and maintain a weighted average maturity of one year or less. Investments in securities with remaining maturities of less than one year, or where our intent is to use the investments to fund current operations or to make them available for current operations, are classified as short-term investments. As of June 30, 2013 and December 31, 2012, all of our investments had contractual maturities of one year or less and were classified as short-term.

Gross unrealized gains and losses were not significant at either June 30, 2013 or December 31, 2012. During the three and six month periods ended June 30, 2013 and 2012, we did not sell any of our available-for-sale securities.

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

|   | Fair Value<br>Hierarchy<br>Level | Estimated Fair Value at |                      |
|---|----------------------------------|-------------------------|----------------------|
|   |                                  | June 30,<br>2013        | December 31,<br>2012 |
| Corporate notes and bonds                           | 2                                | \$ 134,231              | \$ 241,158           |
| U.S. corporate commercial paper                     | 2                                | 36,725                  | 3,990                |
| Obligations of U.S. states and municipalities       | 2                                | 1,500                   | 1,504                |
| Obligations of U.S. government agencies             | 2                                |                         | 6,108                |
| Available-for-sale investments                      |                                  | 172,456                 | 252,760              |
| Money market funds                                  | 1                                | 26,934                  | 22,487               |
| Cash, including restricted cash                     | N/A                              | 27,495                  | 26,947               |
| Total cash and investments in marketable securities |                                  | \$ 226,885              | \$ 302,194           |

*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 six month periods ended June 30, 2013 and 2012, there were no transfers between Level 1 and Level 2 of the fair value hierarchy.

Additionally, as of June 30, 2013, based on a discounted cash flow analysis using Level 3 inputs including financial discount rates, we believe the \$125.0 million carrying amount of our 12% Senior Secured Notes due July 2017 is consistent with its fair value.

**Note 3 Inventory**

Inventory consists of the following (in thousands):

## Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

|                 | <b>June 30,<br/>2013</b> | <b>December 31,<br/>2012</b> |
|-----------------|--------------------------|------------------------------|
| Raw materials   | \$ 7,013                 | \$ 7,489                     |
| Work-in-process | 11,367                   | 6,661                        |
| Finished goods  | 2,099                    | 4,119                        |
| Total           | \$ 20,479                | \$ 18,269                    |

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 stated at the lower of cost or market and is net of reserves determined using specific identification plus an estimated reserve for defective or excess inventory based on historical experience or projected usage.

**Table of Contents****Note 4 Liability Related to Sale of Future Royalties**

On February 24, 2012, we entered into a Purchase and Sale Agreement (the Purchase and Sale Agreement) with RPI Finance Trust (RPI), an affiliate of Royalty Pharma, pursuant to which we sold, and RPI purchased, our right to receive royalty payments (the Royalty Entitlement) arising from the worldwide net sales, from and after January 1, 2012, of (a) CIMZIA<sup>®</sup>, under Nektar's license, manufacturing and supply agreement with UCB Pharma (UCB), and (b) MIRCERA<sup>®</sup>, under Nektar's license, manufacturing and supply agreement with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (together referred to as Roche). We received aggregate cash proceeds for the Royalty Entitlement of \$124.0 million. As part of this sale, we incurred approximately \$4.4 million in transaction costs, which will be amortized to interest expense over the estimated life of the Purchase and Sale Agreement. 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 six months ended June 30, 2013 and 2012, we recognized \$8.2 million and \$6.2 million, in aggregate royalties from net sales of CIMZIA<sup>®</sup> and MIRCERA<sup>®</sup>, respectively, of which the \$2.7 million recognized in the three months ended March 31, 2012 was retained by us as this amount resulted from royalties on product sales in the fourth quarter of 2011.

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, we were required to pay RPI \$3.0 million if worldwide net sales of MIRCERA<sup>®</sup> for the 12 month period ending on December 31, 2012 did not reach a required threshold. The minimum 2012 MIRCERA<sup>®</sup> net sales threshold was not met and, therefore, we made the \$3.0 million payment to RPI described above in the three months ended March 31, 2013. Furthermore, we are required to make an additional payment of up to \$7.0 million if the specified worldwide net sales threshold of MIRCERA<sup>®</sup> for the 12 month period ending on December 31, 2013 is not achieved.

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

**Note 5 Commitments and Contingencies*****Legal Matters***

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

On November 18, 2009, the Research Foundation of the State University of New York (SUNY) filed an action against Nektar in the United States District Court for the Northern District of New York. SUNY seeks to recover amounts it alleges it is owed pursuant to a technology licensing contract between Nektar and SUNY. On May 15, 2013, the court granted Nektar's motion for summary judgment regarding SUNY's claim for specific performance, granted SUNY summary judgment regarding one of the milestone payments at issue, and otherwise denied Nektar's motion for summary judgment and SUNY's motion for partial summary judgment. As a result of the granting of SUNY's summary judgment regarding one of the milestone payments at issue, in the three months ended June 30, 2013, we accrued a contingent liability of \$3.0 million (inclusive of interest). The court's decision is not a final judgment and we continue to dispute SUNY's claims, which we believe are without merit. We expect that a trial will be scheduled in the first half of 2014. Other than the \$3.0 million liability at June 30, 2013 noted above, no reasonable estimate of the possible loss or range of loss can be made at this time and no other liabilities have been recorded for this matter in our Condensed Consolidated Balance Sheets at either June 30, 2013 or December 31, 2012.



**Table of Contents****Indemnifications in Connection with Commercial Agreements**

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

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

To date we have not incurred costs to defend lawsuits or settle claims related to these indemnification obligations. If any of our indemnification obligations is triggered, we may incur substantial liabilities. Because the aggregate amount of any potential indemnification obligation is not a stated amount, the overall maximum amount of any such obligations cannot be reasonably estimated. No liabilities have been recorded for these obligations in our Condensed Consolidated Balance Sheets at either June 30, 2013 or December 31, 2012.

**Note 6 License and Collaboration Agreements**

We have entered into various license agreements and collaborative research, manufacturing, development and commercialization agreements with pharmaceutical and biotechnology companies. We refer to these types of agreements as collaboration agreements. Under these collaboration agreements, we are entitled to receive license fees, upfront payments, milestone payments, royalties, sales milestones, payment 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<br>June 30, |           | Six months ended<br>June 30, |           |
|---|------------------------------|--------------------------------|-----------|------------------------------|-----------|
|   |                              | 2013                           | 2012      | 2013                         | 2012      |
| Bayer Healthcare LLC                      | BAY41-6551 (Amikacin Inhale) | \$ 13,111                      | \$ 799    | \$ 13,825                    | \$ 1,543  |
| Roche                                     | PEGASYS® and MIRCERA®        | 2,625                          | 1,743     | 5,250                        | 3,124     |
| Amgen, Inc.                               | Neulasta®                    | 1,250                          | 1,250     | 2,535                        | 2,500     |
| Baxter Healthcare                         | Hemophilia                   | 597                            | 4,369     | 1,297                        | 5,053     |
| Affymax, Inc.                             | Omontys®                     | 193                            | 194       | 370                          | 2,411     |
| Other                                     |                              | 1,583                          | 1,876     | 2,558                        | 3,427     |
| License, collaboration, and other revenue |                              | \$ 19,359                      | \$ 10,231 | \$ 25,835                    | \$ 18,058 |

As of June 30, 2013, our collaboration agreements included potential future payments for development milestones totaling approximately \$150.6 million, including the milestone amounts from our agreements with Bayer and Baxter described below. In addition, we are entitled to receive up to \$270.0 million and \$75.0 million of contingent payments related to the naloxegol (formerly known as NKTR-118) and naloxegol fixed-dose combination (NKTR-119) programs, respectively, based on development and regulatory events to be pursued and completed solely by AstraZeneca.

There have been no material changes to our collaboration agreements in the three or six months ended June 30, 2013, except as described below.

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

## Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

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 the years prior to 2013, we received an upfront payment of \$40.0 million in 2007 and

**Table of Contents**

milestone payments of \$20.0 million, of which \$10.0 million was recorded as a liability to Bayer for the reimbursement of its costs of the Phase 3 clinical trial. This \$10.0 million obligation was recorded in accrued clinical trial expense in our Condensed Consolidated Balance Sheet at December 31, 2012. It is payable by us upon payment by Bayer to us of a development milestone amount of \$10.0 million triggered by the commencement by Bayer of the first Phase 3 clinical trial of BAY41-6551.

As a result of the start of the Phase 3 clinical trial by Bayer in the treatment of intubated and mechanically ventilated patients with Gram-negative pneumonia in April 2013, we achieved the \$10.0 million development milestone, which was received and recognized as revenue in the three months ended June 30, 2013. The receipt of this milestone also triggered the payment of our \$10.0 million obligation to Bayer, which was paid in June 2013. 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 June 30, 2013, we have deferred revenue of approximately \$23.4 million related to this agreement, which we expect to recognize through December 2026, the estimated end of our obligations under this agreement.

***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 June 30, 2013, we have deferred revenue of approximately \$12.8 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 June 30, 2013, we have deferred revenue of approximately \$18.8 million related to this agreement, which we expect to recognize through December 2016, the estimated end of our obligations under this agreement.

***Amgen, Inc.: Neulasta®***

In October 2010, we amended and restated an existing supply and license agreement by entering into a supply, dedicated suite and manufacturing guarantee agreement (the amended and restated agreement) and a license agreement with Amgen Inc. and Amgen Manufacturing, Limited. As of June 30, 2013, we have deferred revenue of approximately \$36.7 million related to this agreement, which we expect to recognize through October 2020, the estimated end of our obligations under this agreement.

***Baxter Healthcare: Hemophilia***

In September 2005, we entered into an exclusive research, development, license and manufacturing and supply agreement with Baxter Healthcare SA and Baxter Healthcare Corporation (together referred to as Baxter) to develop products designed to improve therapies for Hemophilia A patients using our PEGylation technology. Under the terms of this agreement, we are entitled to up to \$28.0 million of development milestones related to Hemophilia A upon achievement of certain development objectives, as well as sales milestones upon achievement of annual sales targets and royalties based on annual worldwide net sales of products resulting from this agreement. This Hemophilia A program includes BAX 855, which is currently in a Phase 3 clinical study initiated in February 2013. As of June 30, 2013, we do not have significant deferred revenue related to this agreement.

***Affymax, Inc.: OMONTYS®***

In April 2004, we entered into a license, manufacturing and supply agreement with Affymax, Inc. (Affymax) under which we provided Affymax with a worldwide, non-exclusive license under certain of our proprietary PEGylation technology to develop, manufacture and commercialize OMONTYS® (peginesatide). On March 27, 2012, the U.S. Food and Drug Administration (FDA) approved OMONTYS® to treat anemia in patients with chronic kidney disease on dialysis and OMONTYS® sales were initiated in the second quarter of 2012. Under our agreement, Affymax is obligated to purchase its entire requirements of the proprietary PEGylation materials required to manufacture OMONTYS® exclusively from Nektar. Affymax is responsible for all clinical development, regulatory and commercialization expenses. We are entitled to

## Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

royalties based on annual worldwide net sales of OMONTYS®. For a certain period of time, we will share a portion of our future royalty payments with Enzon Pharmaceuticals, Inc.



**Table of Contents**

On February 23, 2013, Affymax and Takeda Pharmaceutical Company Limited (Takeda) announced a voluntary recall of all lots of OMONTYS® drug product as a result of new post-marketing reports regarding serious hypersensitivity reactions, including anaphylaxis, which can be life-threatening or fatal. Effective as of April 1, 2013, Affymax announced that it had amended its collaboration agreement with Takeda to transfer regulatory, manufacturing, and development responsibilities for OMONTYS® to Takeda. In July 2013, Affymax terminated the license, manufacturing and supply agreement with Nektar.

We have received milestone and related payments under our agreement with Affymax and, as of June 30, 2013, we have deferred revenue of approximately \$6.8 million. During the third quarter of 2013, we will evaluate the impact of the termination of our agreement with Affymax on the remaining deferred revenue balance.

***AstraZeneca AB: naloxegol (NKTR-118) and naloxegol fixed-dose combination program (NKTR-119)***

In September 2009, we entered into a license agreement with AstraZeneca AB (AstraZeneca), as amended by AstraZeneca and us in August 2013, under which we granted AstraZeneca a worldwide, exclusive, perpetual, royalty-bearing, and sublicensable license under our patents and other intellectual property to develop, market, and sell naloxegol (NKTR-118) and naloxegol fixed-dose combination program (NKTR-119). AstraZeneca is responsible for all costs associated with research, development and commercialization and is responsible for all drug development and commercialization decisions for naloxegol and the naloxegol fixed-dose combination program. We are entitled to receive up to \$270.0 million and \$75.0 million of contingent payments related to naloxegol and the naloxegol fixed-dose combination program, respectively, based on development events to be pursued and completed solely by AstraZeneca.

On August 8, 2013, AstraZeneca agreed to submit naloxegol regulatory approval applications with the FDA and with the European Medicines Agency (EMA) in each case in September 2013. If the NDA submitted by AstraZeneca is accepted for review by the FDA, we will be entitled to a \$70.0 million milestone payment. If the FDA does not require a future clinical trial or other significant studies to assess the cardiovascular safety ( CV Safety Study ) of naloxegol prior to an approval decision, AstraZeneca is obligated to pay us an additional \$35.0 million. If the FDA does require a CV Safety Study, AstraZeneca may terminate the license agreement with us in its entirety or only with respect to its rights in the United States. If AstraZeneca elects to terminate the license agreement in its entirety due to a CV Safety Study, we will be required to repay them the \$70.0 million we received plus accrued interest at 4.5% compounded annually in four installments in accordance with the following payment schedule: \$10.0 million plus accrued interest on January 15, 2015, \$10.0 million plus accrued interest on January 15, 2016, \$20.0 million plus accrued interest on January 15, 2017 and \$30.0 million plus accrued interest on January 15, 2018. If AstraZeneca elects to terminate the license agreement only with respect to its rights in the U.S., then such repayment amount would be funded through a 50% reduction of non-U.S. royalty amounts otherwise payable to us until the aggregate amount of such royalty reduction equals the total principal amount of \$70.0 million plus accumulated interest at 4.5% compounded annually. If the FDA requires a post-approval cardiovascular safety study as a condition to approval of the naloxegol NDA, then the royalty rate payable to us from net sales of naloxegol in the U.S. by AstraZeneca would be reduced by two percentage points until the aggregate accumulated amount of such royalty payment reduction is equal to a maximum of \$35.0 million. If the naloxegol regulatory approval application is accepted for review by the EMA, we will be entitled to a \$25.0 million milestone payment. We will be entitled to the remaining \$140.0 million of these milestone payments if naloxegol is approved by the FDA and EMA and commercial launch is achieved in the U.S. and one major country in the European Union. In addition, we are also entitled to sales milestone payments and royalties based on annual worldwide net sales of naloxegol and naloxegol fixed-dose combination products. We did not earn significant revenues from this agreement during the three and six months ended June 30, 2013 or 2012.

***Other***

In addition, we have a number of collaboration agreements with other partners under which we are entitled to up to a total of \$72.6 million of development milestones upon achievement of certain development objectives, as well as sales milestones upon achievement of annual sales targets and royalties based on net sales of commercialized products, if any. However, given the current phase of development of the potential products under these collaboration agreements, we cannot estimate the probability or timing of achieving these milestones.

**Note 7 Stock-Based Compensation**

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

| Three months ended |      | Six months ended |      |
|--------------------|------|------------------|------|
| June 30,           |      | June 30,         |      |
| 2013               | 2012 | 2013             | 2012 |

## Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

|                                    |          |          |          |          |
|------------------------------------|----------|----------|----------|----------|
| Cost of goods sold                 | \$ 324   | \$ 360   | \$ 647   | \$ 768   |
| Research and development expense   | 1,977    | 1,703    | 3,852    | 3,626    |
| General and administrative expense | 2,055    | 1,738    | 4,102    | 3,641    |
| <br>                               |          |          |          |          |
| Total stock-based compensation     | \$ 4,356 | \$ 3,801 | \$ 8,601 | \$ 8,035 |

During the three months ended June 30, 2013 and 2012, we granted 162,080 and 249,330 stock options, respectively. The weighted average grant-date fair value of options granted during the three months ended June 30, 2013 and 2012 was \$5.23 per share and \$4.12 per share, respectively.

During the six months ended June 30, 2013 and 2012, we granted 2,989,310 and 2,982,720 stock options, respectively. The weighted average grant-date fair value of options granted during the six months ended June 30, 2013 and 2012 was \$4.63 per share and \$3.79 per share, respectively.

As a result of stock issuances under our equity compensation plans, during the three months ended June 30, 2013 and 2012, we issued 222,012 and 189,588 common shares, respectively, and during the six months ended June 30, 2013 and 2012, we issued 424,214 and 294,936 common shares, respectively.

**Table of Contents****Note 8 Net Loss Per Share**

Basic net loss per share is calculated based on the weighted-average number of common shares outstanding during the periods presented. For all periods presented in the accompanying Condensed Consolidated Statements of Operations, the net loss available to common stockholders is equal to the reported net loss. Basic and diluted net loss per share are the same due to our historical net losses and the requirement to exclude potentially dilutive securities which would have an anti-dilutive effect on net loss per share. The weighted average of these potentially dilutive securities has been excluded from the diluted net loss per share calculation and is as follows (in thousands):

|                                | Three months ended<br>June 30, |               | Six months ended<br>June 30, |               |
|--------------------------------|--------------------------------|---------------|------------------------------|---------------|
|                                | 2013                           | 2012          | 2013                         | 2012          |
| Convertible subordinated notes |                                | 9,989         |                              | 9,989         |
| Stock options                  | 13,268                         | 14,127        | 12,975                       | 13,581        |
| <b>Total</b>                   | <b>13,268</b>                  | <b>24,116</b> | <b>12,975</b>                | <b>23,570</b> |

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

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

*Overview**Strategic Direction of Our Business*

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

Our most advanced proprietary product candidate, naloxegol (formerly known as NKTR-118), is an oral peripheral opioid antagonist which has completed Phase 3 clinical studies for the treatment of opioid-induced constipation (OIC) in patients with non-cancer pain. We are a party to an exclusive worldwide license agreement with AstraZeneca AB (AstraZeneca) for the global development and commercialization of naloxegol and naloxegol fixed-dose combination products (formerly known as NKTR-119). The core Phase 3 clinical development program for naloxegol, which AstraZeneca calls the KODIAC program, is comprised of four clinical trials which are designed to investigate the safety and efficacy of naloxegol for the treatment of OIC in patients with non-cancer related pain. The outcome and timing of the naloxegol regulatory review events will have a substantial impact on our financial condition as we are entitled to up to \$130.0 million in regulatory milestones and \$140.0 million in commercial launch milestones. The naloxegol fixed-dose combination program is an early stage research and development program that is designed to combine various opioids with naloxegol. AstraZeneca is responsible for all clinical, regulatory and commercialization costs for both the naloxegol drug candidate and all drug candidates within the naloxegol fixed-dose combination program.

On November 12, 2012, AstraZeneca announced positive top-line results for naloxegol from two Phase 3 efficacy and safety clinical trials and from a safety extension trial (KODIAC-04, -05, and -07). On February 26, 2013, AstraZeneca announced positive top-line results from the long-term safety study (KODIAC-08) of naloxegol in patients with OIC. On August 8, 2013, AstraZeneca agreed to submit naloxegol regulatory

## Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

approval applications with the FDA and the EMA in September 2013. If the naloxegol NDA is accepted for review by the FDA, we will be entitled to a \$70.0 million milestone payment. If the FDA does not require a future clinical trial or other significant studies to assess the cardiovascular safety ( CV Safety Study ) of naloxegol prior to an approval decision, AstraZeneca is obligated to pay us an additional \$35.0 million. If the FDA does require a CV Safety Study, AstraZeneca may terminate the license agreement with us in its entirety or only with respect to its rights in the United States. If AstraZeneca elects to terminate the license agreement in its entirety due to a CV Safety Study, we will be required to repay them the \$70.0 million we received plus accrued interest at 4.5% compounded annually in four installments in accordance with the following payment schedule: \$10.0 million plus accrued interest on January 15, 2015, \$10.0 million plus accrued interest on January 15, 2016, \$20.0 million plus accrued interest on January 15, 2017 and \$30.0 million plus accrued interest on January 15, 2018. If AstraZeneca elects to terminate the license agreement only with respect to its rights in the U.S., then such repayment amount would be funded through a 50% reduction of non-U.S. royalty amounts otherwise payable to us until the aggregate amount of such royalty reduction equals the total principal amount of \$70.0 million plus accumulated interest at 4.5% compounded annually. If the FDA requires a post-approval cardiovascular safety study as a condition to approval of the naloxegol NDA, then the royalty rate payable to us from net sales of naloxegol in the U.S. by AstraZeneca would be reduced by two percentage points until the aggregate accumulated amount of such royalty payment reduction is equal to a maximum of \$35.0 million. If the naloxegol regulatory approval application is accepted for review by the EMA, we will be entitled to a \$25.0 million milestone payment. We will be entitled to the remaining \$140.0 million of these milestone payments if naloxegol is approved by the FDA and EMA and commercial launch is achieved in the U.S. and one major country in the European Union. In addition, we are also entitled to sales milestone payments and royalties based on annual worldwide net sales of naloxegol and naloxegol fixed-dose combination products. As a result, the filing of the naloxegol regulatory approval applications with the FDA and EMA by AstraZeneca and the subsequent acceptance of these applications by those health authorities is critical to our financial position in 2013 as well as our future business prospects as a result of the significant economic stake that we have in success of the potential commercialization of naloxegol.

---

**Table of Contents**

Our second most advanced proprietary drug candidate, etirinotecan pegol (formerly known as NKTR-102), is a next-generation topoisomerase I inhibitor. Etirinotecan pegol is currently being evaluated as a single-agent therapy in a Phase 3 open-label, randomized, multicenter clinical study in patients with metastatic breast cancer. This Phase 3 clinical study, which we call the BEACON study (BrEAsT Cancer Outcomes with NKTR-102), is scheduled to enroll approximately 840 patients with metastatic breast cancer that have previously received treatment with an anthracycline, a taxane, and capecitabine. We completed enrollment in the BEACON study in late July 2013. The BEACON study will require a substantial investment over the next two years. We have completed an expanded Phase 2 clinical study for etirinotecan pegol in patients with platinum-resistant ovarian cancer. We are currently in the process of finalizing the data in furtherance of planned meetings with health authorities in 2013 which will guide our future development and regulatory strategy for etirinotecan pegol in ovarian cancer. In addition, a Phase 2 clinical study for etirinotecan pegol in patients with metastatic colorectal cancer is still open for enrollment.

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

We also have a significant collaboration with Baxter Healthcare to identify and develop PEGylated drug candidates with the objective of providing new long-acting therapies for hemophilia patients. Under the terms of this collaboration, we are providing a license to our PEGylation intellectual property, technology and expertise. Baxter is responsible for all clinical development. The first drug candidate in this collaboration, BAX 855, is a longer-acting (PEGylated) form of a full-length recombinant factor VIII (rFVIII) protein which has completed Phase 1 clinical development in patients with Hemophilia A. In February 2013, Baxter initiated a Phase 3 multi-center, open-label clinical study called PROLONG-ATE that will enroll more than 100 previously treated adult patients with severe hemophilia A to assess the efficacy, safety and pharmacokinetics of BAX 855 for prophylaxis and on-demand treatment of bleeding. If BAX 855 is approved by health authorities and is successfully commercialized by Baxter, this will represent a substantial royalty revenue opportunity for us, subject to significant risks and uncertainties relating to the outcome of the ongoing Phase 3 clinical study, the health authority regulatory review process, and if approved, subsequent commercial success.

While the late stage clinical development programs described above are key elements of the future success of our company, we believe it is critically important that we continue to make substantial investments in our earlier-stage drug candidate pipeline. We are completing a Phase 2 clinical study for NKTR-181 and recently completed a human abuse liability study for NKTR-181. We are also beginning preparations for a potential Phase 3 clinical study program for NKTR-181. In addition, we plan to initiate a second Phase 1 study for NKTR-192 in the third quarter of 2013. Further, we have several drug candidates in research that we are preparing to advance into the clinic in future years. While we believe that our substantial investment in research and development has the potential to create significant value if one or more of our drug candidates demonstrate positive clinical results and receive regulatory approval in one or more major markets, 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 prospects, financial condition, and market value.

Historically, we have entered into a number of license and supply contracts under which we manufactured and supplied our proprietary PEGylation reagents on a cost-plus or fixed price basis. Our current strategy is to manufacture and supply PEGylation reagents to support our proprietary drug candidates or our third party collaborators where we have a strategic development and commercialization relationship or where we derive substantial economic benefit. As a result, whenever possible, we are renegotiating or not seeking renewal of legacy manufacturing supply arrangements that do not include a strategic development or commercialization component. For example, in October 2010, we entered into a supply, dedicated suite and manufacturing guarantee agreement with Amgen, Inc. and Amgen Manufacturing, Limited, which has significantly amended economic and other terms in the non-exclusive supply and license agreement we previously entered into with Amgen in 1995. In addition, in December 2010, we entered into an amended manufacturing and supply agreement with Merck (through its acquisition of Schering-Plough Corporation) to provide for transfer to an alternative manufacturer and revised economics for an interim supply arrangement until that transition is completed.

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

At June 30, 2013, we had approximately \$226.9 million in cash and investments in marketable securities, of which \$25.0 million was restricted in relation to our 12.0% senior secured notes, and \$147.7 million in indebtedness. The indebtedness includes \$125.0 million in aggregate principal amount of 12.0% senior secured notes due July 15, 2017, but excludes our long-term liability relating to



**Table of Contents**

the sale of future royalties under the Purchase and Sale Agreement with RPI Finance Trust. As is further described in Note 4 to our Condensed Consolidated Financial Statements, this royalty obligation liability will not be settled in cash, but we may be required to make a payment of up to \$7.0 million in 2014 if a specified worldwide net sales threshold of MIRCERA® in 2013 is not met.

As of June 30, 2013, we had at least twelve months of working capital to fund our current business plans. We expect the clinical development of our proprietary drug candidates including etirinotecan pegol, Amikacin Inhale, NKTR-181, and NKTR-192 will require significant investment in order to continue to advance in clinical development with the objective of entering into a collaboration partnership or obtaining regulatory approval. However, we have no credit facility or any other sources of committed capital. In addition, while in the past we have received a number of significant payments from license and collaboration agreements and other significant transactions, we do not currently anticipate completing new transactions with substantial upfront payments in the near term. Our current business plan is also subject to significant uncertainties and risks as a result of, among other factors, expenses being higher than anticipated, unplanned expenses, cash receipts being lower than anticipated, and the need to satisfy contingent liabilities including litigation matters and indemnification obligations.

The availability and terms of various financing alternatives substantially depend on the success or failure of our drug development programs including naloxegol, etirinotecan pegol, BAX 855, Amikacin Inhale, NKTR-181, and NKTR-192. The availability and terms of financing alternatives and any future significant payments from existing or new collaborations all depend on the positive outcome of ongoing or planned clinical studies, whether we or our partners are successful in obtaining health authority approvals in major markets, and if approved, the commercial success of these drugs. In particular, we are entitled to up to \$270.0 million of regulatory and commercial launch milestones under our naloxegol license agreement with AstraZeneca, \$95.0 million of which is related to AstraZeneca submitting regulatory approval applications for naloxegol with the FDA and with the EMA and these applications being accepted for review by those health authorities. On August 8, 2013, AstraZeneca agreed to submit naloxegol regulatory approval applications with the FDA and the EMA in September 2013, however we are only entitled to the \$95.0 million milestone payments upon acceptance of the regulatory approval applications for review by those health authorities (\$70.0 million based on the FDA acceptance and \$25.0 million based on the EMA acceptance).

In the event we do not enter into any new collaboration agreements with significant upfront payments or do not receive the naloxegol regulatory milestone payments in 2013, we would likely be required to pursue financing alternatives. In the event we determine to pursue financing alternatives, our objective would be to first explore financing alternatives that are not dilutive to the ownership of our common stock security holders. However, if non-dilutive financing alternatives are not available to us on commercially reasonable terms or at all, we could be required to pursue dilutive equity-based financing alternatives such as an offering of convertible debt or common stock. If we do not receive substantial milestone payments from our existing collaboration agreements, execute new high value collaborations or other arrangements, or are unable to raise additional capital in one or more financing transactions, we would be unable to continue our current level of investment in research and development.

**Results of Operations**

*Three and Six Months Ended June 30, 2013 and 2012*

*Revenue (in thousands, except percentages)*

|  | Three months<br>ended<br>June 30, 2013 | Three months<br>ended<br>June 30, 2012 | Increase /<br>(Decrease)<br>2013 vs. 2012 | Percentage<br>Increase /<br>(Decrease)<br>2013 vs. 2012 |
|--|--|--|---|---|
| Product sales  | \$ 10,324                              | \$ 9,694                               | \$ 630                                    | 7%  |
| Royalty revenues   | 351                                    | 290                                    | 61  | 21%   |
| Non-cash royalty revenue related to sale of future royalties | 3,828                                  | 3,469                                  | 359                                       | 10%   |
| License, collaboration and other revenue                     | 19,359                                 | 10,231                                 | 9,128                                     | 89%   |
| <b>Total revenue</b>   | <b>\$ 33,862</b>                       | <b>\$ 23,684</b>                       | <b>\$ 10,178</b>                          | <b>43%</b>  |
|  | Six months<br>ended<br>June 30,        | Six months<br>ended<br>June 30,        | Increase /<br>(Decrease)<br>2013 vs.      | Percentage<br>Increase /<br>(Decrease)                  |

Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

|  | 2013             | 2012             | 2012             | 2013 vs.<br>2012 |
|--|------------------|------------------|------------------|------------------|
| Product sales  | \$ 22,134        | \$ 16,639        | \$ 5,495         | 33%              |
| Royalty revenues   | 676              | 3,467            | (2,791)          | (81)%            |
| Non-cash royalty revenue related to sale of future royalties | 8,221            | 3,469            | 4,752            | >100%            |
| License, collaboration and other revenue                     | 25,835           | 18,058           | 7,777            | 43%              |
| <b>Total revenue</b>   | <b>\$ 56,866</b> | <b>\$ 41,633</b> | <b>\$ 15,233</b> | <b>37%</b>       |



---

**Table of Contents**

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

***Product sales***

Product sales include fixed price and cost-plus manufacturing and supply agreements with our collaboration partners. The timing of product shipments is based on the demand and requirements of our collaboration partners and is not ratably throughout the year.

Product sales increased for the three and six months ended June 30, 2013 compared to the three and six months ended June 30, 2012 primarily as a result of the timing of product demand from a number of our collaboration partners. Overall, we expect product sales in the full year of 2013 to be slightly higher than in 2012, however, we expect product sales to decrease during the remaining six month period of 2013 as compared to the six months ended June 30, 2013.

***Royalty revenues and non-cash royalty revenue related to sale of future royalties***

We receive royalty revenue from certain of our collaboration partners based on their net sales of commercial products. Royalty revenues received in cash increased slightly during the three months ended June 30, 2013 compared to the three months ended June 30, 2012. Royalty revenues received in cash decreased during the six months ended June 30, 2013 compared to the six months ended June 30, 2012 primarily as a result of the sale of our rights to receive the royalties from UCB's CIMZIA<sup>®</sup> and Roche's MIRCERA<sup>®</sup> product sales as is further described below. Royalties from CIMZIA<sup>®</sup> and MIRCERA<sup>®</sup> recognized after the royalty sale transaction took effect are presented on a separate revenue line item entitled Non-cash royalty revenue related to sale of future royalties. We expect royalty revenues received in cash during the full year of 2013 to decrease as compared to 2012.

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 on a separate revenue line item entitled Non-cash royalty revenue related to sale of future royalties. During the three months ended June 30, 2013 and 2012, we recognized \$3.8 million and \$3.5 million, respectively, in aggregate royalties from net sales of CIMZIA<sup>®</sup> and MIRCERA<sup>®</sup>. During the six months ended June 30, 2013 and 2012, we recognized \$8.2 million and \$6.2 million in aggregate royalties from net sales of CIMZIA<sup>®</sup> and MIRCERA<sup>®</sup>, of which the \$2.7 million recognized in the three months ended March 31, 2012 was retained by us as these amounts resulted from product sales in the fourth quarter of 2011. We expect non-cash royalties from net sales of CIMZIA<sup>®</sup> and MIRCERA<sup>®</sup> in the full year of 2013 to be higher than in 2012.

***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 on a combination of factors including the estimated amortization period of the upfront payments, the achievement of milestones, the continuation of existing collaborations, the amount of reimbursed research and development work, and entering into new collaboration agreements, if any.

License, collaboration and other revenue increased for the three and six months ended June 30, 2013 compared to the three and six months ended June 30, 2012 primarily as a result of the recognition of a \$10.0 million milestone achieved upon the start of the Amikacin Inhale Phase 3 clinical trial by Bayer in April 2013.

We expect license, collaboration and other revenue in the full year of 2013 to increase as compared to 2012 primarily as a result of the recognition of milestones under existing collaboration agreements. In particular, if naloxegol regulatory approval applications are accepted for review by the FDA and EMA, we are entitled to receive payments of \$70.0 million and \$25.0 million, respectively. If these filings are accepted in 2013, we expect to recognize the entire \$25.0 million payment related to the EMA acceptance as revenue in 2013, however, as a result of the risk sharing arrangement with AstraZeneca related to the FDA filing, we do not expect to recognize the \$70.0 million payment as revenue in 2013.



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

|                      | Three months<br>ended<br>June 30, 2013  | Three months<br>ended<br>June 30, 2012 | Increase /<br>(Decrease)<br>2013 vs. 2012    | Percentage<br>Increase /<br>(Decrease)<br>2013 vs. 2012 |
|----------------------|---|--|--|---|
| Cost of goods sold   | \$ 5,011                                | \$ 7,203                               | \$ (2,192)                                   | (30)%   |
| Product gross profit | \$ 5,313                                | \$ 2,491                               | \$ 2,822                                     | >100%   |
| Product gross margin | 51%                                     | 26%                                    |  |   |
|                      | Six months<br>ended<br>June 30,<br>2013 | Six months<br>ended<br>June 30, 2012   | Increase /<br>(Decrease)<br>2013 vs.<br>2012 | Percentage<br>Increase /<br>(Decrease)<br>2013 vs. 2012 |
| Cost of goods sold   | \$ 16,672                               | \$ 15,910                              | \$ 762                                       | 5%  |
| Product gross profit | \$ 5,462                                | \$ 729                                 | \$ 4,733                                     | >100%   |
| Product gross margin | 25%                                     | 4%                                     |  |   |

Cost of goods sold decreased during the three months ended June 30, 2013 compared to the three months ended June 30, 2012 primarily due to the timing and mix of customer orders which resulted in greater sales of higher margin products in the three months ended June 30, 2013. In addition, overhead costs per unit in 2013 are lower than in 2012 as a result of increased forecasted manufacturing activities in 2013. Cost of goods sold increased during the six months ended June 30, 2013 compared to the six months ended June 30, 2012 primarily due to a \$5.5 million increase in product sales in the six months ended June 30, 2013 compared to the six months ended June 30, 2012, partially offset by the decreased cost per unit sold as noted above.

The increase in product gross profit and product gross margin during the three and six months ended June 30, 2013 compared to the three and six months ended June 30, 2012 is primarily due to the different mix of products sold as well as the decreased overhead costs per unit in 2013 resulting from increased manufacturing activity.

We expect product gross margin to continue to fluctuate in future periods depending on the level and mix of manufacturing orders due to the fixed cost base for our manufacturing activities. During the remaining six month period of 2013, based on our current forecast of decreases in product sales activities, we expect product gross profit and product gross margin to decrease as compared to the six months ended June 30, 2013. We expect product gross profit and product gross margin for the full year of 2013 to be modestly positive.

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

|                                  | Three months<br>ended<br>June 30, 2013  | Three months<br>ended<br>June 30, 2012  | Increase /<br>(Decrease)<br>2013 vs. 2012    | Percentage<br>Increase /<br>(Decrease)<br>2013 vs. 2012    |
|----------------------------------|---|---|--|--|
| Research and development expense | \$ 52,230                               | \$ 33,201                               | \$ 19,029                                    | 57%  |
|                                  | Six months<br>ended<br>June 30,<br>2013 | Six months<br>ended<br>June 30,<br>2012 | Increase /<br>(Decrease)<br>2013 vs.<br>2012 | Percentage<br>Increase /<br>(Decrease)<br>2013 vs.<br>2012 |
| Research and development expense | \$ 97,848                               | \$ 68,286                               | \$ 29,562                                    | 43%  |

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

Research and development expense increased during the three and six months ended June 30, 2013 compared to the three and six months ended June 30, 2012 primarily due to our ongoing etirinotecan pegol Phase 3 BEACON study as well as the ongoing NKTR-181 Phase 2 clinical study.

## Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

Research and development expense is not expected to be ratable over the four quarters of the year. We expect research and development expense to increase throughout the remaining six month period of 2013 compared to the six months ended June 30, 2013 as we continue to advance our pipeline of drug candidates. Overall, we expect research and development expense in the full year of 2013 to significantly exceed 2012.

**Table of Contents**

Other than as described in the Overview section above, there have been no material changes to the status of clinical programs in the six months ended June 30, 2013 from the activities discussed in our Annual Report on Form 10-K for the year ended December 31, 2012 on file with the Securities and Exchange Commission.

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

|                                    | Three months<br>ended<br>June 30, 2013 | Three months<br>ended<br>June 30, 2012 | Increase /<br>(Decrease)<br>2013 vs. 2012 | Percentage<br>Increase /<br>(Decrease)<br>2013 vs. 2012 |
|------------------------------------|--|--|---|---|
| General and administrative expense | \$ 9,226                               | \$ 10,268                              | \$ (1,042)                                | (10)%   |

  

|                                    | Six months<br>ended<br>June 30,<br>2013 | Six months<br>ended<br>June 30,<br>2012 | Increase /<br>(Decrease)<br>2013 vs.<br>2012 | Percentage<br>Increase /<br>(Decrease)<br>2013 vs.<br>2012 |
|------------------------------------|---|---|--|--|
| General and administrative expense | \$ 20,057                               | \$ 20,682                               | \$ (625)                                     | (3)%   |

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 six months ended June 30, 2013 decreased modestly compared to the three and six months ended June 30, 2012. We expect general and administrative expenses during the full year of 2013 to increase modestly compared to 2012.

**Interest Expense (in thousands, except percentages)**

|  | Three months<br>ended<br>June 30, 2013 | Three months<br>ended<br>June 30, 2012 | Increase /<br>(Decrease)<br>2013 vs. 2012 | Percentage<br>Increase /<br>(Decrease)<br>2013 vs. 2012 |
|--|--|--|---|---|
| Interest expense   | \$ 4,656                               | \$ 2,562                               | \$ 2,094                                  | 82%   |
| Non-cash interest expense on liability related to sale of future royalties | \$ 5,485                               | \$ 5,369                               | \$ 116                                    | 2%  |

  

|  | Six months<br>ended<br>June 30,<br>2013 | Six months<br>ended<br>June 30,<br>2012 | Increase /<br>(Decrease)<br>2013 vs.<br>2012 | Percentage<br>Increase /<br>(Decrease)<br>2013 vs.<br>2012 |
|--|---|---|--|--|
| Interest expense   | \$ 9,301                                | \$ 5,109                                | \$ 4,192                                     | 82%  |
| Non-cash interest expense on liability related to sale of future royalties | \$ 11,028                               | \$ 7,155                                | \$ 3,873                                     | 54%  |

Interest expense increased for the three and six months ended June 30, 2013 compared to the three and six months ended June 30, 2012 primarily due to the interest expense recorded on the senior secured notes we issued in 2012. On July 11, 2012, we issued \$125.0 million of 12% senior secured notes due July 15, 2017. We retired \$215.0 million in principal amount of 3.25% convertible subordinated notes in the third quarter of 2012. As a result of the issuance of the senior secured notes in July 2012, we expect interest expense to increase during the full year of 2013 as compared to 2012.

The increase in non-cash interest expense on the liability related to sale of future royalties for the three and six months ended June 30, 2013 compared to the three and six months ended June 30, 2012 is attributable to the royalty sale transaction in February 2012. In the royalty sale transaction we sold all of our rights to receive future royalty payments on CIMZIA® and MIRCERA® in exchange for a cash payment of \$124.0 million. 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 and we will assess this estimate on a periodic basis. As a

## Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

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 to increase during the full year of 2013 as compared to 2012.

### ***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 and private placements of debt and equity. At June 30, 2013, we had approximately \$226.9 million in cash and investments in marketable securities, of which \$25.0 million was restricted in relation to our 12.0% senior secured notes, and

**Table of Contents**

\$147.7 million in indebtedness. The indebtedness includes \$125.0 million in aggregate principal amount of 12.0% senior secured notes due July 15, 2017, but excludes our long-term liability relating to the sale of future royalties. As is further described in Note 4 to our Condensed Consolidated Financial Statements, this royalty obligation liability will not be settled in cash, but we may be required to make a payment of up to \$7.0 million in 2014 if a specified worldwide net sales threshold of MIRCERA® in 2013 is not met.

As of June 30, 2013, we had at least twelve months of working capital to fund our current business plans. We expect the clinical development of our proprietary drug candidates including etirinotecan pegol (NKTR-102), Amikacin Inhale, NKTR-181, and NKTR-192 will require significant investment in order to continue to advance in clinical development with the objective of entering into a collaboration partnership or obtaining regulatory approval. However, we have no credit facility or any other sources of committed capital. In addition, while in the past we have received a number of significant payments from license and collaboration agreements and other significant transactions, we do not currently anticipate completing new transactions with substantial upfront payments in the near-term. Our current business plan is also subject to significant uncertainties and risks as a result of, among other factors, expenses being higher than anticipated, unplanned expenses, cash receipts being lower than anticipated, and the need to satisfy contingent liabilities including litigation matters and indemnification obligations.

The availability and terms of various financing alternatives substantially depend on the success or failure of our drug development programs including naloxegol, etirinotecan pegol, BAX 855, Amikacin Inhale, NKTR-181, and NKTR-192. The availability and terms of financing alternatives and any future significant payments from existing or new collaborations all depend on the positive outcome of ongoing or planned clinical studies, whether we or our partners are successful in obtaining health authority approvals in major markets, and if approved, the commercial success of these drugs. In the event we do not enter into any new collaboration partnerships with significant upfront payments or do not receive the \$95.0 million in naloxegol regulatory milestone payments in 2013 as discussed above, we would likely be required to pursue financing alternatives. In the event we determine to pursue financing alternatives, our objective would be to first explore financing alternatives that are not dilutive to the ownership of our common stock security holders. However, if non-dilutive financing alternatives are not available to us on commercially reasonable terms or at all, we could be required to pursue dilutive equity-based financing alternatives such as an offering of convertible debt or common stock. If we do not receive substantial milestone payments from our existing collaboration agreements, execute new high value collaborations or other arrangements, or are unable to raise additional capital in one or more financing transactions, we would be unable to continue our current level of investment in research and development.

Due to the potential for continued uncertainty in the credit markets in 2013 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 June 30, 2013, the average time to maturity of the investments held in our portfolio was approximately four months and the maturity of any single investment did not exceed one year. To date we have not experienced any liquidity issues with respect to these securities, but if such issues arise, we may be required to hold some, or all, of these securities until maturity. We believe that, even allowing for potential liquidity issues with respect to these securities, our remaining cash and investments in marketable securities will be sufficient to meet our anticipated cash needs for at least the next twelve months.

*Cash flows from operating activities*

Cash flows used in operating activities for the six months ended June 30, 2013 totaled \$72.4 million, which includes \$83.5 million of net operating cash uses as well as \$7.7 million for interest payments on our senior secured notes, partially offset by the receipt of \$18.8 million for milestones from collaboration agreements. Because of the nature and timing of certain cash receipts and payments, net cash utilization is not expected to be ratable over the four quarters of the year. We expect cash flows used in operating activities, excluding upfront and milestone payments received, if any, will increase throughout the remaining six month period of 2013 as compared to the same period in 2012 as a result of increased spending on our proprietary research and development programs, in particular, our BEACON study.

Cash flows used in operating activities for the six months ended June 30, 2012 totaled \$55.2 million, which includes \$3.5 million for a semi-annual interest payment on our convertible subordinated notes, and \$64.2 million of other net operating cash uses, partially offset by the receipt of \$12.5 million for milestones from collaboration agreements.

*Cash flows from investing activities*

We paid \$0.8 million and \$3.2 million to purchase property and equipment in the six months ended June 30, 2013 and 2012, respectively.

## **Table of Contents**

### *Cash flows from financing activities*

On February 24, 2012, we sold all of our rights to receive future royalty payments on CIMZIA® and MIRCERA® in exchange for a cash payment of \$124.0 million. As part of this sale, we incurred approximately \$4.4 million in transaction costs. During the six months ended June 30, 2013, we made a \$3.0 million payment to the purchaser of these royalties because the minimum 2012 MIRCERA® net sales threshold was not met.

We received \$2.6 million and \$1.3 million from issuances of common stock to employees under our equity compensation plans during the six months ended June 30, 2013 and 2012, respectively.

### *Contractual Obligations*

There were no material changes during the six months ended June 30, 2013 to the summary of contractual obligations included in our Annual Report on Form 10-K for the year ended December 31, 2012 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 revenues 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, 2012.

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

Our market risks at June 30, 2013 have not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2012 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*



## Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

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 June 30, 2013 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

**Table of Contents**

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

**PART II: OTHER INFORMATION****Item 1. Legal Proceedings**

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

**Item 1A. Risk Factors**

Investors in Nektar Therapeutics should carefully consider the risks described below before making an investment decision. The risks described below may not be the only ones relating to our company. This description includes any material changes to and supersedes the description of the risk factors associated with our business previously disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2012. 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, 2012, including our consolidated financial statements and related notes, and our other filings made from time to time with the Securities and Exchange Commission (SEC).

**Risks Related to Our Business*****Drug development is a long and inherently uncertain process with a high risk of failure at every stage of development.***

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

Drug development is a highly uncertain scientific and medical endeavor, and failure can unexpectedly occur at any stage of clinical development. Typically, there is a high rate of attrition for drug candidates in preclinical and clinical trials due to scientific feasibility, safety, efficacy, changing standards of medical care and other variables. The risk of failure increases for our drug candidates that are based on new technologies, such as the application of our advanced polymer conjugate technology to small molecules, including naloxegol, etirinotecan pegol, NKTR-181, NKTR-192, NKTR-171 and other drug candidates currently in discovery research or preclinical development. The failure of one or more of our drug candidates could have a material adverse effect on our business, financial condition and results of operations.

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

We or our partners may not obtain regulatory approval for drug candidates on a timely basis, or at all, or the terms of any approval (which in some countries includes pricing approval) may impose significant restrictions or limitations on use. Drug candidates must undergo rigorous animal and human testing and an extensive review process for safety and efficacy by the U.S. Food and Drug Administration (FDA) and equivalent foreign government health authorities. The time required for obtaining regulatory decisions is uncertain and difficult to predict. The

## Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

FDA and other U.S. and foreign health authorities have substantial discretion, at any phase of development, to terminate clinical studies, require additional clinical development or other testing, delay or withhold registration and marketing approval and mandate product withdrawals, including recalls. Further, health authorities have the discretion to analyze data using their own methodologies that may differ from those used by us or our partners which could lead such authorities

**Table of Contents**

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.

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.

***If the FDA requires a cardiovascular safety study for naloxegol, it could have a material adverse impact on the naloxegol program and our business prospects and financial condition.***

The FDA is exploring whether there is any evidence of potential elevated cardiovascular risk possibly related to mu-opioid antagonists and naloxegol is a mu-opioid antagonist. AstraZeneca completed a 52-week, long-term controlled safety trial of naloxegol as part of the Phase 3 naloxegol development program. The FDA has not yet reviewed the data package for naloxegol. The FDA's general safety concern is based on data from other mu-opioid antagonist programs that may indicate increased cardiovascular risk associated with opioid withdrawal or the antagonism of the delta subtype of the opioid receptor for which the FDA has not yet made a causal connection between these mechanisms and elevated cardiovascular risk. In interactions with the FDA, the FDA staff has indicated that a final determination as to whether a pre-approval cardiovascular study will be required for naloxegol will be a post-submission NDA review decision. However, the FDA staff has also indicated that, prior to reviewing the naloxegol NDA, its current position is that a pre-approval cardiovascular study will be required. Subsequently, on June 11, 2013, Salix Pharmaceuticals, Ltd. and Progenics Pharmaceuticals, Inc. announced that the FDA was convening and seeking input from an Advisory Committee for Salix's Supplemental New Drug Application (sNDA) for RELISTOR (methylnaltrexone bromide) Subcutaneous Injection, for opioid-induced constipation (OIC) in patients with chronic pain. In addition to addressing specific matters regarding Salix's sNDA, the FDA also indicated that one of the purposes of convening the Advisory Committee is that the FDA needs to provide consistent advice regarding the need for Major Adverse Cardiovascular Event (MACE) studies to applicants developing drug products in this class for this indication. For this reason, a broader discussion of the potential for cardiovascular events across the drug class is necessary. Because naloxegol is also a mu-opioid antagonist, the outcome of the review by this Advisory Committee could have an important impact on the naloxegol program. We do not currently know when the Advisory Committee meeting will be scheduled. A cardiovascular study for naloxegol, if it were ultimately required by the FDA, may or may not be clinically or financially feasible. The FDA has significant discretion over regulatory approval requirements and those requirements are very uncertain and difficult to predict.

We amended our license agreement with AstraZeneca to enter into a risk sharing arrangement in the event that pre-approval or post-approval cardiovascular safety studies are required by the FDA for naloxegol. The amendment provides that if the FDA requires a cardiovascular safety study as a condition to approval of naloxegol and, as a result, AstraZeneca terminates its agreement with us in its entirety, we would be required to repay AstraZeneca the \$70.0 million that we would receive upon the FDA's acceptance for review of the naloxegol NDA plus accrued interest at 4.5% compounded annually. If AstraZeneca elects to terminate the agreement only with respect to its license agreement rights in the U.S. due to a pre-approval cardiovascular safety study, then such amount would be paid through a 50% reduction of non-U.S. royalty amounts otherwise payable to us until the aggregate amount of such royalty reduction equals the total principal amount of \$70.0 million plus accumulated interest at 4.5% compounded annually. On the other hand, if the FDA determines a pre-approval cardiovascular safety study of naloxegol is not required, AstraZeneca is obligated to pay us an additional \$35.0 million milestone payment. However, if the FDA requires a post-approval cardiovascular safety study as a condition to regulatory approval, then the royalty rate payable to us from net sales of naloxegol in the U.S. by AstraZeneca would be reduced by two percentage points until the aggregate amount of such royalty payment reduction is equal to a maximum of \$35.0 million.

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

A number of companies have suffered significant unforeseen failures in late stage clinical studies due to factors such as inconclusive efficacy or safety, even after achieving positive results in earlier clinical studies that were satisfactory both to them and to reviewing government health authorities. While etirinotecan pegol, Amikacin Inhale, and BAX 855 have each demonstrated positive results from earlier clinical studies, there is a substantial risk that Phase 3 clinical study outcomes for these drug candidates from larger patient populations will not demonstrate positive efficacy, safety or other clinical outcomes sufficient to support regulatory filings and achieve regulatory approval. Phase 3 clinical study outcomes remain very unpredictable and it is possible that one or more of these Phase 3 clinical studies could fail at any time due to efficacy, safety or other important clinical findings or regulatory requirements. If one or more of these drug candidates fail in Phase 3 clinical studies, it

## Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

would have a material adverse effect on our business, financial condition and results of operations.

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

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

clinical development and commercialization obligations that are based on certain commercial reasonableness performance standards that can often be difficult to enforce if disputes arise as to adequacy of our partner's performance;

research and development performance and reimbursement obligations for our personnel and other resources allocated to partnered drug candidate development programs;

---

**Table of Contents**

clinical and commercial manufacturing agreements, some of which are priced on an actual cost basis for products supplied by us to our partners with complicated cost allocation formulas and methodologies;

intellectual property ownership allocation between us and our partners for improvements and new inventions developed during the course of the collaboration;

royalties on drug sales based on a number of complex variables, including net sales calculations, geography, scope of patent claim coverage, patent life, generic competitors, bundled pricing and other factors; and

indemnity obligations for intellectual property infringement, product liability and certain other claims.

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

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

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

As of June 30, 2013, we had cash and investments in marketable securities valued at approximately \$226.9 million, of which \$25.0 million was restricted in relation to our 12.0% senior secured notes, and indebtedness of approximately \$147.7 million. The indebtedness includes approximately \$125.0 million in senior secured notes due July 2017, but excludes our long-term liability relating to the sale of future royalties. While this royalty obligation liability will not be settled in cash, we may be required to make a payment of up to \$7.0 million in 2014 if certain performance targets are not met. 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 naloxegol that has been licensed to AstraZeneca, Amikacin Inhale that has been licensed to Bayer, and BAX 855 in connection with our licensing transaction with Baxter;

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. In particular, on August 8, 2013, AstraZeneca agreed to submit naloxegol regulatory approval applications with the FDA and the EMA in September 2013, however, we are only entitled to the \$95.0 million milestone payments upon acceptance of the regulatory approval applications for review by those health authorities (\$70.0 million based on the FDA acceptance and \$25.0 million based on the EMA acceptance);

the progress, timing, cost and results of our clinical development programs – in particular our Phase 3 BEACON study for etirinotecan pegol and our Phase 2 clinical study program for NKTR-181;

## Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

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 outcome of the regulatory review process and commercial success of drug products for which we are entitled to receive royalties (e.g., Allergan, Inc.'s LEVADEX);

the number of patients, enrollment criteria, primary and secondary endpoints, and the number of clinical studies required by the government health authorities in order to consider for approval our drug candidates and those of our collaboration partners;

our general and administrative expenses, capital expenditures and other uses of cash; and

disputes concerning patents, proprietary rights, or license and collaboration agreements that negatively impact our receipt of milestone payments or royalties or require us to make significant payments arising from licenses, settlements, adverse judgments or ongoing royalties.

**Table of Contents**

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.

***The results from the expanded Phase 2 clinical study for etirinotecan pegol in women with platinum-resistant/refractory ovarian cancer are unlikely to result in a review or an approval of an NDA by the FDA.***

We expanded the etirinotecan pegol Phase 2 study by 110 patients in women with platinum-resistant/refractory ovarian cancer that had received prior Doxil® therapy with the potential for us to consider an early New Drug Application (NDA) submission after we evaluate these expanded study results. We are currently in the process of compiling and performing verification procedures on the data from this study. Acceptance and approval of an NDA by the FDA almost always requires the sponsor to conduct comparative Phase 3 clinical studies prior to acceptance for review or approval of an NDA. As a result, acceptance for review or approval of an accelerated NDA submitted to the FDA based on overall response rate from our single-arm Phase 2 study in platinum-resistant/refractory ovarian cancer would be unusual and is highly unlikely. Therefore we do not expect the FDA to accept or approve a NDA based on this Phase 2 clinical study. The FDA has significant discretion to determine what constitutes a high unmet medical need, what therapies should be considered available to patients regardless of which therapies are approved or typically prescribed in a particular setting, the relevance of certain efficacy end points (e.g. overall response rate, progression free survival, overall survival), and the number of patients required to be studied to demonstrate sufficient therapeutic benefit and safety profile. One or more of such judgments and determinations by the FDA could impair our ability to submit an NDA for platinum resistant/refractory ovarian cancer patients, and even if submitted, whether the FDA would accept it for review or approve the NDA.

Further, this expansion of our Phase 2 clinical study in platinum resistant/refractory ovarian cancer will necessarily change the final efficacy (e.g., overall response rates, progression-free survival, overall survival) and safety (i.e., frequency and severity of serious adverse events) results, and, accordingly, the final results in this study remain subject to substantial change and could be materially and adversely different from previously announced results.

***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 in the future a technique could be discovered 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 potential of NKTR-181.

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

We intend to continue to seek partnerships with pharmaceutical and biotechnology partners to fund a portion of our research and development capital requirements. The timing of new collaboration partnerships is difficult to predict due to availability of clinical data, the outcomes from our clinical studies, the number of potential partners that need to complete due diligence and approval processes, the definitive agreement negotiation process and numerous other unpredictable factors that can delay, impede or prevent significant transactions. If we are unable to find suitable partners or to 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.



## **Table of Contents**

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

From time to time, we publish preliminary or interim data from our clinical studies. For example, we have announced preliminary tumor response rate data from our expanded Phase 2 clinical study for etirinotecan pegol in platinum resistant/refractory ovarian cancer. Preliminary data remains 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 is also subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data becomes available. As a result, preliminary and interim data should be viewed with caution until the final data are available. Material adverse changes in the final data could significantly harm our business prospects.

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

We or our partners may experience delays in clinical trials of drug candidates. Etirinotecan pegol in patients with metastatic breast cancer and BAX 855 are currently in Phase 3 clinical studies, and Bayer has initiated Phase 3 clinical development of BAY41-6551 with the first patient enrolled in April 2013. A Phase 2 clinical study for etirinotecan pegol in patients with metastatic colorectal cancer is still open for enrollment. In addition, we are completing a Phase 2 study for NKTR-181 and we recently completed a human abuse liability study for NKTR-181. We are also beginning preparations for a potential Phase 3 clinical study program for NKTR-181. These and other of our planned clinical studies may not begin on time, have an effective design, enroll a sufficient number of patients or be completed on schedule, if at all. Our clinical trials for any of our product candidates could be delayed for a variety of reasons, including:

delays in obtaining regulatory approval to commence a clinical study;

delays in reaching agreement with applicable health authorities on a clinical study design;

imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other health authorities;

we, our partners, the FDA or foreign health authorities could suspend or terminate a clinical study 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

any change in health authorities policies or guidance applicable to our drug candidates.

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

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

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

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

Numerous pending and issued U.S. and foreign patent rights and other proprietary rights owned by third parties relate to pharmaceutical compositions, methods of preparation and manufacturing, and methods of use and administration. We cannot predict

---

## **Table of Contents**

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

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

The patent positions of pharmaceutical and biotechnology companies, such as ours, are uncertain and involve complex legal and factual issues. We own more than 150 U.S. and 500 foreign patents and a number of pending patent applications that cover various aspects of our technologies. There can be no assurance that patents that have issued will be held valid and enforceable in a court of law. Even for patents that are held valid and enforceable, the legal process associated with obtaining such a judgment is time 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 could be 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. Currently, the Research Foundation of the State University of New York (SUNY) seeks to recover amounts it alleges it is owed pursuant to a technology licensing contract between SUNY and us. SUNY has filed an action in the United States District Court for the Northern District of New York. We dispute SUNY's claims. We expect that a trial will be scheduled for this matter in the first half of 2014. However, we cannot predict with certainty the eventual outcome of any pending or future litigation. Costs associated with such 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



---

**Table of Contents**

October 2011, we entered into a settlement related to a trade secret and breach of contract litigation where we agreed to make an upfront payment of \$2.7 million and a future contingent payment of \$3.0 million if a certain drug candidate receives FDA approval. In 2006, we entered into a litigation settlement related to an intellectual property dispute with the University of Alabama in Huntsville pursuant to which we paid \$11.0 million and agreed to pay an additional \$10.0 million in equal \$1.0 million installments over ten years ending with the last payment due on July 1, 2016.

In addition, from time to time, we may in the future assert claims against third parties, based on infringement of our proprietary rights or otherwise. Any such claims may not ultimately be successful, and we may incur substantial costs and liabilities in pursuing them.

***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, DEA or comparable agencies in other jurisdictions to confirm 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. The results of these inspections could result in costly manufacturing changes or facility or capital equipment upgrades to satisfy the FDA that our manufacturing and quality control procedures are in substantial compliance with cGMP. Manufacturing delays, for us or our contract manufacturers, pending resolution of regulatory deficiencies or suspensions would have a material adverse effect on our business, results of operations and financial condition.

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

If we or our contract manufacturers are not able to manufacture and supply sufficient drug quantities meeting applicable quality standards required to support large clinical studies or commercial manufacturing in a timely manner, we risk delaying our clinical studies or those of our collaboration partners, reducing drug sales by our collaboration partners or breaching contractual obligations. As a result, we could incur substantial costs and damages, and reduce or even eliminate product or royalty revenue. 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 derived from our collaboration agreements from which we receive contract research payments, milestone payments based on clinical progress, regulatory progress or net sales achievements, royalties and manufacturing revenue. Significant variations in the timing of receipt of cash payments and our recognition of revenue can result from significant milestone payments based on the execution of new collaboration agreements, the timing of clinical outcomes, regulatory approval, commercial launch and the achievement of certain annual sales thresholds. The amount of our revenue derived from collaboration agreements in any given period will depend on a number of unpredictable factors, including our ability to find and maintain suitable collaboration partners, the timing of the negotiation and conclusion of collaboration agreements with such partners, whether and when we or our collaboration partners achieve clinical, regulatory and sales milestones, the timing of regulatory approvals in one or more major markets, reimbursement levels by private and government payers, and the market introduction of new drugs or generic versions of the approved drug, as well as other factors.

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

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

design and conduct large scale clinical studies;

prepare and file documents necessary to obtain government approvals to sell a given drug candidate; and/or

market and sell the drugs when and if they are approved.

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

we may be unable to control whether, and the extent to which, our partners devote sufficient resources to the development programs or commercial marketing and sales efforts;

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

disagreements with partners could lead to delays in, or termination of, the research, development or commercialization of product candidates or to litigation or arbitration proceedings;

contracts with our partners may fail to provide us with significant protection, or to be effectively enforced, in the event one of our partners fails to perform;

partners have considerable discretion in electing whether to pursue the development of any additional product candidates and may pursue alternative technologies or products either on their own or in collaboration with our competitors;

## Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

partners with marketing rights may choose to devote fewer resources to the marketing of our partnered products than they do to products of their own development or products in-licensed from other third parties;

the timing and level of resources that our partners dedicate to the development program will affect the timing and amount of revenue we receive;

we do not have the ability to unilaterally terminate agreements (or partners may have extension or renewal rights) that we believe are not on commercially reasonable terms or consistent with our current business strategy;

partners may be unable to pay us as expected; and

partners may terminate their agreements with us unilaterally for any or no reason, in some cases with the payment of a termination fee penalty and in other cases with no termination fee penalty.

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

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

We currently have no sales, marketing or distribution capabilities. To commercialize any of our drugs that receive regulatory approval for commercialization, we must either develop internal sales, marketing and distribution capabilities, which would be



## **Table of Contents**

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 revenues we receive will depend upon the efforts of third parties, which may not be successful and are only partially in our control. In the event that we market our products without a partner, we would be required to build a sales and marketing organization and infrastructure, which would require a significant investment and we may not be successful in building this organization and infrastructure in a timely or efficient manner.

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

We often face very limited supply of a critical raw material that can only be obtained from a single, or a limited number of, suppliers, which could cause production delays, clinical trial delays, substantial lost revenue opportunity or contract liability to third parties. For example, there are only a limited number of qualified suppliers, and in some cases single source suppliers, for the raw materials included in our PEGylation and advanced polymer conjugate drug formulations, and 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 to the extent we cannot pass on increased costs to a manufacturing customer.

***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 six months ended June 30, 2013, we reported a net loss of \$97.8 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

## Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

product candidates. We may not be able to achieve and sustain profitability.

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

develop drugs utilizing our technologies, either independently or in collaboration with other pharmaceutical or biotech companies;

effectively estimate and manage clinical development costs, particularly the cost of the BEACON study and the Phase 2 clinical study for NKTR-181;

## **Table of Contents**

receive necessary regulatory and marketing approvals;

maintain or expand manufacturing at necessary levels;

achieve market acceptance of our partnered products;

receive royalties on products that have been approved, marketed or submitted for marketing approval with regulatory authorities; and

maintain sufficient funds to finance our activities.

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

In both domestic and foreign markets, sales of our partnered and proprietary products that have received regulatory approval will depend in part on market acceptance among physicians and patients, pricing approvals by government authorities and the availability of payment or reimbursement from third-party payers, such as government health administration authorities, managed care providers, private health insurers and other organizations. Such third-party payers are increasingly challenging the price and cost effectiveness of medical products and services. Therefore, significant uncertainty exists as to the pricing approvals for, and the payment or reimbursement status of, newly approved healthcare products. Moreover, legislation and regulations affecting the pricing of pharmaceuticals may change before regulatory agencies approve our proposed products for marketing and could further limit pricing approvals for, and reimbursement of, our products from government authorities and third-party payers. A government or third-party payer decision not to approve pricing for, or provide adequate coverage and reimbursements of, our products would limit market acceptance of such products.

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

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

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

Our PEGylation and advanced polymer conjugate chemistry platforms and our partnered and proprietary products and product candidates compete with various pharmaceutical and biotechnology companies. Competitors of our PEGylation and polymer conjugate chemistry technologies include Biogen, Savient, 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

## Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

patients on mechanical ventilators. For naloxegol, there are currently several alternative therapies used to address opioid-induced constipation (OIC) and opioid-induced bowel dysfunction (OBD), including subcutaneous Relistor® (methylnaltrexone bromide) 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, Progenics Pharmaceuticals, Inc. in collaboration with Salix Pharmaceuticals, Ltd., Mundipharma Int. Limited, Sucampo Pharmaceuticals and Takeda Pharmaceutical Company Limited. For etirinotecan pegol, there are a number of chemotherapies and cancer therapies approved today and in various stages of clinical development for breast and ovarian cancers including but not limited to: Abraxane® (paclitaxel protein-bound particles for injectable suspension (albumin bound)), Afinitor®

**Table of Contents**

(everolimus), Doxil<sup>®</sup> (doxorubicin HCl), Ellence<sup>®</sup> (epirubicin), Gemzar<sup>®</sup> (gemcitabine), Halaven<sup>®</sup> (eribulin), Herceptin<sup>®</sup> (trastuzumab), Hycamtin<sup>®</sup> (topotecan), Ixempra<sup>®</sup> (ixabepilone), Navelbine<sup>®</sup> (vinorelbine), Iniparib, Paraplatin<sup>®</sup> (carboplatin), Taxol<sup>®</sup> (paclitaxel) and Taxotere<sup>®</sup> (docetaxel). Major pharmaceutical or biotechnology companies with approved drugs or drugs in development for these cancers include, but are not limited to, Bristol-Myers Squibb, Eli Lilly & Co., Roche, GlaxoSmithKline plc, Johnson and Johnson, Pfizer, Inc. and Sanofi Aventis. There are approved therapies for the treatment of colorectal cancer, including Eloxatin<sup>®</sup> (oxaliplatin), Camptosar<sup>®</sup> (irinotecan), Avastin<sup>®</sup> (bevacizumab), Zaltrap<sup>®</sup> (Ziv-aflibercept), Stivarga<sup>®</sup> (regorafenib), Erbitux<sup>®</sup> (cetuximab), Vectibix<sup>®</sup> (panitumumab), Xeloda<sup>®</sup> (capecitabine), Adrucil<sup>®</sup> (fluorouracil) and Wellcovorin<sup>®</sup> (leucovorin). In addition, there are a number of drugs in various stages of preclinical and clinical development from companies exploring cancer therapies or improved chemotherapeutic agents to potentially treat colorectal cancer, including, but not limited to, products in development from Bristol-Myers Squibb Company, Pfizer, Inc., GlaxoSmithKline plc, Antigenics, Inc., F. Hoffmann-La Roche Ltd, Novartis AG, Cell Therapeutics, Inc., Neopharm Inc., Meditech Research Ltd, Alchemia Limited, and Enzon Pharmaceuticals, Inc.

There can be no assurance that we or our partners will successfully develop, obtain regulatory approvals for and commercialize next-generation or new products that will successfully compete with those of our competitors. Many of our competitors have greater financial, research and development, marketing and sales, manufacturing and managerial capabilities. We face competition from these companies not just in product development but also in areas such as recruiting employees, acquiring technologies that might enhance our ability to commercialize products, establishing relationships with certain research and academic institutions, enrolling patients in clinical trials and seeking program partnerships and collaborations with larger pharmaceutical companies. As a result, our competitors may succeed in developing competing technologies, obtaining regulatory approval or gaining market acceptance for products before we do. These developments could make our products or technologies uncompetitive or obsolete.

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

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

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

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

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

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

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

We must attract and retain experts in the areas of clinical testing, manufacturing, research, regulatory and finance, and may need to attract and retain marketing and distribution experts and develop additional expertise in our existing personnel. We face intense competition from other biopharmaceutical companies, research and academic institutions and other organizations for qualified

**Table of Contents**

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 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

## Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

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.

### **Risks Related to Our Securities**

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

Our stock price is volatile. During the three months ended June 30, 2013, based on closing prices on The NASDAQ Global Select Market, our stock price ranged from \$8.83 to \$11.70 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:

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;



**Table of Contents**

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; and

general market conditions.

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

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

incur or guarantee additional indebtedness or issue disqualified capital stock or cause certain of our subsidiaries to issue preferred stock;

pay dividends or distributions, redeem equity interests or subordinated indebtedness or make certain types of investments;

create or incur liens;

transfer, sell, lease or otherwise dispose of assets and issue or sell equity interests in certain of our subsidiaries;

incur restrictions on certain of our subsidiaries' ability to pay dividends or other distributions to the Company or to make intercompany loans or asset transfers;

enter into transactions with affiliates;

## Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

engage in any business other than businesses which are the same, similar, ancillary or reasonably related to our business as of July 11, 2012; and

consummate a merger, consolidation, reorganization or business combination, or sell, assign, transfer, lease or otherwise dispose of all or substantially all of our assets.

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

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

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

None, including no purchases of any class of our equity securities by us or any affiliate pursuant to any publicly announced repurchase plan in the three months ended June 30, 2013.

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

None.

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

Not applicable.

**Table of Contents**

**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.

| <b>Exhibit</b> |   |
|----------------|---|
| <b>Number</b>  | <b>Description of Documents</b>   |
| 31.1(1)        | Certification of Nektar Therapeutics principal executive officer required by Rule 13a-14(a) or Rule 15d-14(a).  |
| 31.2(1)        | Certification of Nektar Therapeutics principal financial officer required by Rule 13a-14(a) or Rule 15d-14(a).  |
| 32.1*          | Section 1350 Certifications.  |
| 101**          | The following materials from Nektar Therapeutics Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, 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 Loss, (iv) the unaudited Condensed Consolidated Statements of Cash Flows, and (v) Notes to Condensed Consolidated Financial Statements. |

(1) Filed herewith.

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

\*\* XBRL information is filed herewith.

**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: August 9, 2013

By: /s/ JILLIAN B. THOMSEN

**Jillian B. Thomsen**

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

Date: August 9, 2013

**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>   |
| 31.1(1)        | Certification of Nektar Therapeutics principal executive officer required by Rule 13a-14(a) or Rule 15d-14(a).  |
| 31.2(1)        | Certification of Nektar Therapeutics principal financial officer required by Rule 13a-14(a) or Rule 15d-14(a).  |
| 32.1*          | Section 1350 Certifications.  |
| 101**          | The following materials from Nektar Therapeutics Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, 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 Loss, (iv) the unaudited Condensed Consolidated Statements of Cash Flows, and (v) Notes to Condensed Consolidated Financial Statements. |

(1) Filed herewith.

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

\*\* XBRL information is filed herewith.