

NEKTAR THERAPEUTICS
Form 10-Q
November 04, 2011
[Table of Contents](#)

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

FORM 10-Q

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

For the quarterly period ended September 30, 2011

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 114,426,466 on October 31, 2011.

Table of Contents

NEKTAR THERAPEUTICS

INDEX

PART I: FINANCIAL INFORMATION

| | |
|--|----|
| <u>Item 1. Condensed Consolidated Financial Statements – Unaudited:</u> | 4 |
| <u>Condensed Consolidated Balance Sheets – September 30, 2011 and December 31, 2010</u> | 4 |
| <u>Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2011 and 2010</u> | 5 |
| <u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2011 and 2010</u> | 6 |
| <u>Notes to Condensed Consolidated Financial Statements</u> | 7 |
| <u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u> | 16 |
| <u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u> | 22 |
| <u>Item 4. Controls and Procedures</u> | 22 |

PART II: OTHER INFORMATION

| | |
|--|----|
| <u>Item 1. Legal Proceedings</u> | 24 |
| <u>Item 1A. Risk Factors</u> | 24 |
| <u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u> | 37 |
| <u>Item 3. Defaults Upon Senior Securities</u> | 37 |
| <u>Item 4. (Removed and Reserved)</u> | 37 |
| <u>Item 5. Other Information</u> | 37 |
| <u>Item 6. Exhibits</u> | 37 |
| <u>Signatures</u> | 38 |

Table of Contents

Forward-Looking Statements

This report includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (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 or other financial items, any statements of the plans and objectives of management for future operations (including, but not limited to, pre-clinical development, clinical trials and manufacturing), any statements concerning proposed drug candidates or other new products or services, any statements regarding future economic conditions or performance, any statements regarding the success of our collaboration arrangements, any statements regarding our plans and objectives to initiate Phase 3 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, anticipate, 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, 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)**

| | September 30, 2011 | December 31, 2010 |
|--|-------------------------------|------------------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 43,008 | \$ 17,755 |
| Short-term investments | 223,479 | 298,177 |
| Accounts receivable | 12,914 | 25,102 |
| Inventory | 10,654 | 7,266 |
| Other current assets | 7,565 | 5,679 |
| Total current assets | 297,620 | 353,979 |
| Long-term investments | 191,478 | |
| Property and equipment, net | 81,649 | 89,773 |
| Goodwill | 76,501 | 76,501 |
| Other assets | 845 | 972 |
| Total assets | \$ 648,093 | \$ 521,225 |
| LIABILITIES AND STOCKHOLDERS EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 2,175 | \$ 7,194 |
| Accrued compensation | 11,760 | 9,252 |
| Accrued expenses | 11,777 | 8,540 |
| Accrued clinical trial expenses | 13,612 | 12,144 |
| Deferred revenue, current portion | 19,982 | 20,584 |
| Convertible subordinated notes, current portion | 214,955 | |
| Other current liabilities | 4,781 | 6,394 |
| Total current liabilities | 279,042 | 64,108 |
| Convertible subordinated notes | | 214,955 |
| Capital lease obligations, less current portion | 15,250 | 17,014 |
| Deferred revenue, less current portion | 113,045 | 124,763 |
| Deferred gain | 3,497 | 4,152 |
| Other long-term liabilities | 6,462 | 5,571 |
| Total liabilities | 417,296 | 430,563 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock, 10,000 shares authorized Series A, \$0.0001 par value; 3,100 shares designated; no shares issued or outstanding at September 30, 2011 and December 31, 2010 | | |

Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

| | | |
|---|----------------|----------------|
| Common stock, \$0.0001 par value; 300,000 authorized; 114,426 shares and 94,517 shares issued and outstanding at September 30, 2011 and December 31, 2010, respectively | 11 | 9 |
| Capital in excess of par value | 1,592,803 | 1,354,232 |
| Accumulated other comprehensive (loss) income | (987) | 968 |
| Accumulated deficit | (1,361,030) | (1,264,547) |
| Total stockholders' equity | 230,797 | 90,662 |
| Total liabilities and stockholders' equity | \$ 648,093 | \$ 521,225 |

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

Table of Contents

NEKTAR THERAPEUTICS
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share information)

(Unaudited)

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|-------------------------------------|-------------------|------------------------------------|--------------------|
| | 2011 | 2010 | 2011 | 2010 |
| Revenue: | | | | |
| Product sales and royalties | \$ 10,222 | \$ 7,230 | \$ 26,023 | \$ 21,968 |
| License, collaboration and other | 16,846 | 30,695 | 29,675 | 91,757 |
| Total revenue | 27,068 | 37,925 | 55,698 | 113,725 |
| Operating costs and expenses: | | | | |
| Cost of goods sold | 5,038 | 6,245 | 16,441 | 15,430 |
| Research and development | 31,018 | 27,724 | 93,464 | 76,610 |
| General and administrative | 12,350 | 10,181 | 35,262 | 29,401 |
| Total operating costs and expenses | 48,406 | 44,150 | 145,167 | 121,441 |
| Loss from operations | (21,338) | (6,225) | (89,469) | (7,716) |
| Non-operating income (expense): | | | | |
| Interest income | 622 | 369 | 1,583 | 1,225 |
| Interest expense | (2,543) | (2,826) | (7,698) | (8,686) |
| Other income (expense), net | (717) | 249 | (599) | 436 |
| Total non-operating expense | (2,638) | (2,208) | (6,714) | (7,025) |
| Loss before provision for income taxes | (23,976) | (8,433) | (96,183) | (14,741) |
| Provision for income taxes | 92 | 278 | 300 | 617 |
| Net loss | \$ (24,068) | \$ (8,711) | \$ (96,483) | \$ (15,358) |
| Basic and diluted net loss per share | \$ (0.21) | \$ (0.09) | \$ (0.86) | \$ (0.16) |
| Weighted average shares outstanding used in computing basic and diluted net loss per share | 114,413 | 94,213 | 112,435 | 93,972 |

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

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

| | Nine months ended September 30, | |
|---|--|------------------|
| | 2011 | 2010 |
| Cash flows from operating activities: | | |
| Net loss | \$ (96,483) | \$ (15,358) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 11,424 | 12,499 |
| Stock-based compensation | 14,501 | 12,716 |
| Other non-cash transactions | 967 | (176) |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 12,188 | (752) |
| Inventory | (3,388) | (4,989) |
| Other assets | (1,750) | 1 |
| Accounts payable | (4,200) | 1,755 |
| Accrued compensation | 2,508 | 500 |
| Accrued expenses | 6,238 | 4,090 |
| Accrued clinical trial expenses | 1,468 | (1,408) |
| Deferred revenue | (12,320) | (83,107) |
| Other liabilities | (2,681) | (2,049) |
| Net cash used in operating activities | (71,528) | (76,278) |
| Cash flows from investing activities: | | |
| Purchases of investments | (627,529) | (315,160) |
| Sales of investments | 218,660 | 10,290 |
| Maturities of investments | 290,810 | 360,906 |
| Purchases of property and equipment | (8,294) | (22,160) |
| Net cash (used in) provided by investing activities | (126,353) | 33,876 |
| Cash flows from financing activities: | | |
| Payments of loan and capital lease obligations | (1,431) | (1,119) |
| Issuance of common stock, net of issuance costs | 224,072 | 7,142 |
| Net cash provided by financing activities | 222,641 | 6,023 |
| Effect of exchange rates on cash and cash equivalents | 493 | (312) |
| Net increase (decrease) in cash and cash equivalents | 25,253 | (36,691) |
| Cash and cash equivalents at beginning of period | 17,755 | 49,597 |
| Cash and cash equivalents at end of period | \$ 43,008 | \$ 12,906 |

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

Table of Contents

NEKTAR THERAPEUTICS

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2011

(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 designed to improve the benefits of drugs for patients.

Our 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. Historically, we have financed our operations primarily through cash from licensing, collaboration and manufacturing agreements and public and private placements of debt and equity securities. At September 30, 2011, we had approximately \$458.0 million in cash, cash equivalents, and investments in marketable securities and \$239.8 million in indebtedness, including \$215.0 million in outstanding convertible subordinated notes due September 2012. We are exploring a number of alternatives to provide for the repayment of the convertible notes.

Basis of Presentation and Principles of Consolidation

Our consolidated financial statements include the financial position, results of operations and cash flows of our wholly-owned subsidiaries: Nektar Therapeutics (India) Private Limited (Nektar India) and Nektar Therapeutics UK Limited and Aerogen, Inc. All intercompany accounts and transactions have been eliminated in consolidation. On December 2, 2010, we completed the dissolution of Aerogen, Inc. and all remaining assets were transferred to Nektar Therapeutics.

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 income 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.

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

The accompanying Condensed Consolidated Balance Sheet as of September 30, 2011, the Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2011 and 2010, and the Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2011 and 2010 are unaudited. The Condensed Consolidated Balance Sheet data as of December 31, 2010 was derived from the audited consolidated financial statements which are included in our Annual Report on Form 10-K filed with the SEC on March 1, 2011. 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, 2010.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions

Table of Contents

that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ materially from these estimates. On an ongoing basis, we evaluate our estimates, including those related to deferred revenue recognition periods, inventories, the impairment of investments and long-lived assets, contingencies, stock-based compensation, and litigation, amongst others. 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 impact previously reported revenue, operating loss or net loss or 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 medicines. 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, royalties, and other amounts due under collaborative research, development and commercialization 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 regularly review our customers' payment histories and associated credit risk. We have not experienced significant credit losses from our accounts receivable and therefore recorded no allowance for doubtful accounts at either September 30, 2011 or December 31, 2010.

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 regulatory requirements. In certain cases, we rely on single sources of supply. Consequently, in the event that supplies are delayed or interrupted for any reason, our ability to develop and produce our products could be impaired, which could have a material adverse effect on our business, financial condition and results of operations.

Revenue

We enter into license and manufacturing agreements and collaborative research, development and commercialization arrangements with pharmaceutical and biotechnology 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, 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 for each element.

On January 1, 2011, we adopted on a prospective basis Accounting Standards Update (ASU) 2009-13, which amends the criteria to identify separate units of accounting within Subtopic 605-25, Revenue Recognition-Multiple-Element Arrangements. The adoption of the standard did not impact our financial position or results of operations as of and for the three and nine months ended September 30, 2011 as we did not enter into or materially modify any multiple-element arrangements during that period. However, the adoption of this standard may result in revenue recognition patterns for future agreements that are materially different from those recognized for our existing multiple-element arrangements.

Product sales and royalties

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.

Generally, we are entitled to royalties from our partners based on their net sales of approved drugs. We recognize royalty revenue when the cash is received or when the royalty amount to be received is estimable and collection is reasonably assured.

Table of Contents

License, collaboration and other

Upfront fees received for license and collaborative agreements entered into prior to January 1, 2011 are recognized ratably over our expected performance period under the arrangement. Management makes its best estimate of the period over which we expect to fulfill our performance obligations, which may include technology transfer assistance, clinical development activities, and manufacturing activities from development through the commercialization of the product. Given the uncertainties of these collaborative arrangements, significant judgment is required to determine the duration of the performance period.

On January 1, 2011, we elected to prospectively adopt ASU 2010-17, *Milestone Method of Revenue Recognition*. Under the milestone method, 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 more 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 on either 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 and approvals for drug candidates. As of January 1, 2011, our agreements with partners included potential future payments for development milestones totaling approximately \$183.8 million. In addition, we are entitled to receive up to \$235.0 million and \$75.0 million of contingent payments related to NKTR-118 and NKTR-119, respectively, based on development events to be pursued and completed solely by AstraZeneca. Given the challenges inherent in developing and obtaining approval for pharmaceutical and biologic products, there was substantial uncertainty whether any such milestones would be achieved at the time these licensing and collaboration agreements were entered into. In addition, we evaluated whether the development milestones met the remaining criteria to be considered substantive. As a result of our analysis, we consider our development milestones to be substantive and, accordingly, we expect to recognize as revenue future payments received from such milestones as each milestone is achieved. This policy election may result in revenue recognition patterns for future milestones that are materially different from those recognized for milestones received prior to adoption. During the three and nine months ended September 30, 2011, we achieved two development milestones totaling \$4.5 million from two of our collaboration agreements. Under the milestone method of revenue recognition, these substantive milestones were recognized in their entirety upon achievement in the three months ended September 30, 2011, whereas under our previous milestone revenue recognition policy, we would have recognized approximately \$0.4 million related to such amounts during this period. As a result, in each of the three months and nine months ended September 30, 2011, this change in accounting policy results in increased revenues and a corresponding decrease to net loss of approximately \$4.1 million and an increase of \$0.04 per share.

Milestone payments received prior to January 1, 2011 have been deferred and are recognized as revenue ratably over the period of time from the achievement of the milestone to our estimated date on which the next milestone will be achieved. Management makes its best estimate of the period of time until the next milestone is expected to be reached. Final milestone payments were recorded and recognized upon achieving the respective milestone. The Company will continue to recognize milestone payments received prior to January 1, 2011 in this manner. As of September 30, 2011, deferred revenue from milestone payments received prior to January 1, 2011 is not significant.

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, 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

We account for income taxes under the liability method, in which deferred tax assets and liabilities are determined based on

Table of Contents

differences between the financial reporting and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain. We record a valuation allowance against deferred tax assets to reduce their carrying value to an amount that is more likely than not to be realized.

For the three months and nine months ended September 30, 2011 and 2010, we recorded an income tax provision for our Nektar India operations at an effective tax rate of approximately 33% and 34%, respectively. 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, Cash Equivalents, and Available-For-Sale Investments

Cash, cash equivalents, and available-for-sale investments are as follows (in thousands):

| | Estimated Fair Value at | |
|--|-------------------------|----------------------|
| | September 30, 2011 | December 31, 2010 |
| Cash and cash equivalents | \$ 43,008 | \$ 17,755 |
| Short-term investments | 223,479 | 298,177 |
| Long-term investments | 191,478 | |
| Total cash, cash equivalents, and available-for-sale investments | \$ 457,965 | \$ 315,932 |

Our portfolio of cash, cash equivalents, and available-for-sale investments includes (in thousands):

| | Estimated Fair Value at | |
|--|-------------------------|----------------------|
| | September 30, 2011 | December 31, 2010 |
| Corporate notes and bonds | \$ 342,278 | \$ 190,527 |
| U.S. corporate commercial paper | 49,941 | 82,361 |
| Obligations of U.S. government agencies | 22,738 | 25,289 |
| Cash and money market funds | 43,008 | 17,755 |
| Total cash, cash equivalents, and available-for-sale investments | \$ 457,965 | \$ 315,932 |

The following table summarizes our portfolio of available-for-sale investments reported as short-term and long-term investments by contractual maturity (in thousands):

| | Estimated Fair Value at | |
|---|-------------------------|----------------------|
| | September 30, 2011 | December 31, 2010 |
| Less than one year | \$ 223,479 | \$ 298,177 |
| Greater than one year but less than two years | 191,478 | |
| Total available-for-sale investments | \$ 414,957 | \$ 298,177 |

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 maturities of less than one year are classified as short-term investments.

During the nine months ended September 30, 2011 and 2010, realized gains and losses from sales of available-for-sale securities were not significant in each of the periods. The cost of securities sold is based on the specific identification method.

Gross unrealized gains and losses were not significant at September 30, 2011 and December 31, 2010. The gross unrealized losses were primarily due to changes in interest rates on fixed income securities. Based on our available cash and our expected operating cash requirements, we do not intend to sell these securities and it is more likely than not that we will not be required to sell these securities before we recover the

Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

amortized cost basis. Accordingly, we believe there are no other-than-temporary impairments on these securities and have not recorded a provision for impairment.

We use a market approach to value our Level 2 investments as described in the table below. The disclosed fair value related to our investments is based primarily on the reported fair values in our period-end brokerage statements. We independently validate these fair values using available market quotes and other information.

Table of Contents

The following table represents the fair value hierarchy for our financial assets measured at fair value on a recurring basis as of September 30, 2011 and December 31, 2010 (in thousands):

| | Level 1 | Level 2 | Level 3 | Total |
|--|-----------|------------|---------|------------|
| As of September 30, 2011: | | | | |
| Money market funds | \$ 42,276 | \$ | \$ | \$ 42,276 |
| U.S. corporate commercial paper | | 49,941 | | 49,941 |
| Corporate notes and bonds | | 342,278 | | 342,278 |
| Obligations of U.S. government agencies | | 22,738 | | 22,738 |
| Cash equivalents and available-for-sale investments | \$ 42,276 | \$ 414,957 | \$ | \$ 457,233 |
| Cash | | | | 732 |
| Cash, cash equivalents, and available-for-sale investments | | | | \$ 457,965 |
| As of December 31, 2010: | | | | |
| Money market funds | \$ 16,028 | \$ | \$ | \$ 16,028 |
| U.S. corporate commercial paper | | 82,361 | | 82,361 |
| Corporate notes and bonds | | 190,527 | | 190,527 |
| Obligations of U.S. government agencies | | 25,289 | | 25,289 |
| Cash equivalents and available-for-sale investments | \$ 16,028 | \$ 298,177 | \$ | \$ 314,205 |
| Cash | | | | 1,727 |
| Cash, cash equivalents, and available-for-sale investments | | | | \$ 315,932 |

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.

Note 3 Inventory

Inventory consists of the following (in thousands):

| | September 30, 2011 | December 31, 2010 |
|-----------------|-----------------------|----------------------|
| Raw materials | \$ 9,305 | \$ 6,101 |
| Work-in-process | 1,349 | |
| Finished goods | | 1,165 |
| Total | \$ 10,654 | \$ 7,266 |

Inventory is manufactured upon receipt of firm orders from our collaboration partners. Inventory includes direct materials, direct labor, and manufacturing overhead and is determined on a first-in, first-out basis. Inventory is stated at the lower of cost or market and is net of reserves of \$3.2 million and \$4.0 million as of September 30, 2011 and December 31, 2010, respectively. Reserves are determined using specific identification plus an estimated reserve for potential defective or excess inventory based on historical experience or projected usage.

Note 4 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, if necessary, are reviewed at least quarterly and adjusted to reflect the impact of settlement negotiations, judicial and administrative rulings, advice of legal counsel, and other information and events pertaining to a particular case. Litigation is inherently unpredictable. If any unfavorable ruling were to occur in any specific period, there exists the possibility of a material adverse impact on the results of operations of that period or on our cash flows and liquidity.

Table of Contents

In October 2011, we entered into a settlement agreement with a third party in order to resolve a trade secret and breach of contract litigation matter. While we believe the claims made in this litigation matter were without merit, we determined that it was in our best interests to settle this matter to avoid the substantial cost and uncertainty of further litigation. The terms of this settlement included an upfront payment of \$2.7 million by us to the third party and a contingent payment of \$3.0 million by us to the third party in the event that a certain drug candidate in our pipeline receives the approval of the United States Food and Drug Administration. As of September 30, 2011, we have accrued the \$2.7 million settlement payment to general and administrative expense. However, we have not accrued any amounts related to the \$3.0 million contingent payment as that payment is contingent upon a future event that, given the challenges inherent in developing and obtaining approval for any early stage drug candidate, is not considered by management to be probable at this time.

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 our pulmonary asset sale to Novartis that was effective as of December 31, 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 were determined that we breached certain of the representations and warranties or covenants and agreements made by us in the transaction documents, we could incur an indemnification liability 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 obligated amount under these agreements is not explicitly stated, the overall maximum amount of any such obligations cannot be reasonably estimated. No liabilities have been recorded for these obligations on our Condensed Consolidated Balance Sheets at either September 30, 2011 or December 31, 2010.

Note 5 Stockholders Equity

On January 24, 2011, we completed the issuance and sale of 19,000,000 shares of our common stock for gross proceeds to the Company of approximately \$220.4 million. Additionally, we incurred approximately \$0.6 million in legal and accounting fees, filing fees, and other offering expenses.

Note 6 License and Collaboration Agreements

We have entered into various license and manufacturing agreements and collaborative research, development and commercialization agreements with pharmaceutical and biotechnology companies. Under these arrangements, we are entitled to receive license fees, upfront payments, milestone payments when and if certain development or regulatory milestones are achieved, royalties, sales milestones when and if certain annual sales levels are achieved, payment for the manufacture and supply of certain drug materials, and/or reimbursement for research and development activities. All of our research, development and commercialization agreements are generally cancelable by our partners without significant financial penalty. Our costs of performing these services are included in research and development expense in the accompanying Condensed Consolidated Statements of Operations.

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

| Partner | Drug or Drug Candidate | Three months ended September 30, | | Nine months ended September 30, | |
|----------------------|---------------------------------|-------------------------------------|----------|------------------------------------|----------|
| | | 2011 | 2010 | 2011 | 2010 |
| F. Hoffmann- LaRoche | PEGASYS® | \$ 1,283 | \$ 1,283 | \$ 3,849 | \$ 3,849 |
| Amgen, Inc. | Neulasta® | 1,250 | | 3,750 | |
| AstraZeneca AB | NKTR-118 and NKTR-119 | 1,395 | 26,788 | 2,481 | 80,094 |
| Bayer Healthcare LLC | BAY41-6551 (Amikacin Inhale) | 750 | 818 | 2,250 | 2,523 |
| Other | | 12,168 | 1,806 | 17,345 | 5,291 |

Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

| | | | | |
|---|-----------|-----------|-----------|-----------|
| License, collaboration, and other revenue | \$ 16,846 | \$ 30,695 | \$ 29,675 | \$ 91,757 |
|---|-----------|-----------|-----------|-----------|

Table of Contents***F. Hoffmann-LaRoche Ltd and Hoffmann-LaRoche Inc.******PEGASYS®***

In February 1997, we entered into a license, manufacturing and supply agreement with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (Roche), under which we granted Roche a worldwide, exclusive license to use certain PEGylation materials in the manufacture of PEGASYS. As a result of Roche exercising a license extension option in December 2009, Roche has the right to manufacture all of its requirements for our proprietary PEGylation materials for PEGASYS and we will perform additional manufacturing, if any, only on an as-requested basis. In connection with Roche's exercise of the license option extension in December 2009, we received a payment of \$31.0 million. As of September 30, 2011, we have deferred revenue of approximately \$21.8 million related to this agreement, which we expect to amortize through December 2015, the period through which we are required to provide back-up manufacturing and supply services on an as-requested basis.

Amgen, Inc.***Neulasta®***

On October 29, 2010, we amended and restated an existing supply and license agreement by entering into a supply, dedicated suite and manufacturing guarantee agreement (the amended and restated agreement) and a license agreement with Amgen Inc. and Amgen Manufacturing, Limited (together referred to as Amgen). Under the terms of the amended and restated agreement, we guarantee the manufacture and supply of our proprietary PEGylation materials (Polymer Materials) to Amgen in an existing manufacturing suite to be used exclusively for the manufacture of Polymer Materials for Amgen (the Manufacturing Suite) in our manufacturing facility in Huntsville, Alabama (Facility). This supply arrangement is on a non-exclusive basis (other than the use of the Manufacturing Suite and certain equipment) whereby Nektar is free to manufacture and supply the Polymer Materials to any other third party and Amgen is free to procure the Polymer Materials from any other third party. Under the terms of the amended and restated agreement, we received a \$50.0 million payment in the fourth quarter of 2010 in return for our guaranteeing the supply of certain quantities of Polymer Materials to Amgen including without limitation the Additional Rights described below and manufacturing fees that are calculated based on fixed and variable components applicable to the Polymer Materials ordered by Amgen and delivered by us. Amgen has no minimum purchase commitments. If quantities of the Polymer Materials ordered by Amgen exceed specified quantities, significant additional payments become payable to us in return for our guaranteeing the supply of additional quantities of the Polymer Materials.

The term of the amended and restated agreement ends on October 29, 2020. In the event we become subject to a bankruptcy or insolvency proceeding, we cease to own or control the Facility, we fail to manufacture and supply or certain other events, Amgen or its designated third party will have the right to elect, among certain other options, to take title to the dedicated equipment and access the Facility to operate the Manufacturing Suite solely for the purpose of manufacturing the Polymer Materials (the Additional Rights). Amgen may terminate the amended and restated agreement for convenience or due to an uncured material default by us.

As of September 30, 2011, we have deferred revenue of approximately \$45.4 million related to this agreement, which we expect to amortize through October 2020, the estimated end of our obligations under the amended and restated agreement.

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

On August 1, 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. Bayer is responsible for most future clinical development and commercialization costs, all activities to support worldwide regulatory filings, approvals and related activities, further development of Amikacin Inhale and final product packaging and distribution. We received an upfront payment of \$40.0 million in 2007 and performance milestone payments of \$20.0 million, of which \$10.0 million will be used to reimburse Bayer for Phase 3 clinical trial costs. We are entitled to up to \$60.0 million of development milestones upon achievement of certain development objectives, sales milestones upon achievement of annual sales targets, and royalties based on annual worldwide net sales of Amikacin Inhale. As of September 30, 2011, we have deferred revenue of approximately \$28.1 million related to this agreement, which we expect to amortize through July 2021, the estimated end of our obligations under this agreement.

Table of Contents**AstraZeneca AB***NKTR-118 and NKTR-119*

On September 20, 2009, we entered into a License Agreement with AstraZeneca AB, a Swedish corporation (AstraZeneca), under which we granted AstraZeneca a worldwide, exclusive, perpetual, royalty-bearing, and sublicensable license under our patents and other intellectual property to develop, market, sell and otherwise commercially exploit NKTR-118 and NKTR-119. AstraZeneca is responsible for all costs associated with research, development and commercialization and will control drug development and commercialization decisions for NKTR-118 and NKTR-119. Under the terms of the agreement, AstraZeneca paid us an upfront payment of \$125.0 million, which we received in the fourth quarter of 2009. As of December 31, 2010, we completed our obligations under the license agreement and related manufacturing technology transfer agreement. The upfront payment was amortized over approximately 15 months beginning in October 2009 in accordance with our performance obligation period and was fully recognized as of December 31, 2010. We are entitled to receive up to \$235.0 million and \$75.0 million of contingent payments related to NKTR-118 and NKTR-119, respectively, based on development and commercial events to be pursued and completed solely by AstraZeneca. We are also entitled to sales milestones and royalties based on annual worldwide net sales of NKTR-118 and NKTR-119 products.

Other

In addition to the revenues recognized from the collaboration agreements discussed above, during the three months and nine months ended September 30, 2011, we recorded license, collaboration and other revenue of approximately \$12.2 million and \$17.3 million, which primarily consisted of the following license and development milestone revenues.

In September 2011, we entered into a license agreement with a third party under which we granted a worldwide, exclusive, and sublicensable license under certain of our patents and other intellectual property for a limited field that is unrelated to any of the therapeutic areas where we or our existing collaboration partners are currently developing drug candidates. Under the terms of the agreement, we are due total license fee payments of \$10 million, of which \$5.0 million was receivable at September 30, 2011 and collected in October 2011. We are due the remaining license fee payments of \$3.0 million and \$2.0 million in 2013 and 2015, respectively. We completed our contractual performance obligations upon the execution of the agreement and recognized the initial \$5.0 million payment into revenue in the three months ended September 30, 2011.

During the three months ended September 30, 2011, we achieved two development milestones totaling \$4.5 million from two of our collaboration agreements. Under our milestone method revenue recognition policy, these substantive milestones were recognized in their entirety upon achievement.

Note 7 Stock-Based Compensation

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

| | Three months ended | | Nine months ended | |
|------------------------------------|--------------------|----------|-------------------|-----------|
| | September 30, | | September 30, | |
| | 2011 | 2010 | 2011 | 2010 |
| Cost of goods sold | \$ 295 | \$ 258 | \$ 957 | \$ 693 |
| Research and development expense | 2,020 | 1,967 | 6,109 | 5,268 |
| General and administrative expense | 2,504 | 2,386 | 7,435 | 6,755 |
| Total stock-based compensation | \$ 4,819 | \$ 4,611 | \$ 14,501 | \$ 12,716 |

During the three months ended September 30, 2011 and 2010, we granted 331,480 and 560,320 stock options, respectively. The weighted average grant-date fair value of options granted during the three months ended September 30, 2011 and 2010 was \$2.79 per share and \$6.75 per share, respectively.

During the nine months ended September 30, 2011 and 2010, we granted 2,723,445 and 5,035,475 stock options, respectively. The weighted average grant-date fair value of options granted during the nine months ended September 30, 2011 and 2010 was \$5.30 per share and \$6.24 per share, respectively.

Table of Contents

As a result of stock issuances under our equity compensation plans, during the three months ended September 30, 2011 and 2010, we issued 121,705 and 142,257 common shares, respectively, and during the nine months ended September 30, 2011 and 2010, we issued 909,181 and 992,680 common shares, respectively.

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 | | Nine months ended | |
|--------------------------------|---------------------------|---------------|--------------------------|---------------|
| | September 30, | | September 30, | |
| | 2011 | 2010 | 2011 | 2010 |
| Convertible subordinated notes | 9,989 | 9,989 | 9,989 | 9,989 |
| Stock options | 14,471 | 9,142 | 11,423 | 9,273 |
| Total | 24,460 | 19,131 | 21,412 | 19,262 |

Table of Contents**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 improve the benefits of drugs for patients. Our current pipeline is comprised of drug candidates across a number of therapeutic areas, including oncology, pain, anti-infectives, anti-viral and immunology. Our research and development activities involve small molecule drugs, peptides and other potential biologic drug candidates. We create our innovative drug candidates by using our proprietary PEGylation and advanced polymer conjugate technologies and expertise to modify the chemical structure of drugs 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 the 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 pharmacokinetics, pharmacodynamics, half-life, bioavailability, metabolism or distribution of drugs in order to increase the overall benefits and use of a drug for the patient. Our objective is to apply our PEGylation and advanced polymer conjugate technology platforms to create new drugs in multiple therapeutic areas.

We have a number of existing license and collaboration agreements with third parties in which we have an economic interest and which could have a material impact on our business, results of operations and financial condition. In particular, the future clinical and commercial success or failure of our collaborations, described below, with AstraZeneca AB for NKTR-118 and NKTR-119 and Bayer Healthcare LLC (Bayer) for BAY41-6551 (Amikacin Inhale) will have a material impact on our business and financial condition over the next several years. In addition, the amount of revenue that we derive from UCB's CIMZIA, Roche's MIRCERA, Map's Levadex and Affymax's peginesatide, among other of our collaboration agreements, could together have a material impact on our business, financial results and cash position. Because drug development and commercialization is subject to numerous risks and uncertainties, there is a substantial risk that our future revenue from one or more of these agreements will be less than our projections.

Our most advanced proprietary product candidate, NKTR-118 (oral PEG-naloxol), is a peripheral opioid antagonist that is currently being evaluated for the treatment of opioid-induced constipation. We are a party to an exclusive worldwide license agreement with AstraZeneca for the global development and commercialization of NKTR-118 and NKTR-119. NKTR-119 is an early stage research and development program that is designed to combine various opioids with NKTR-118. On March 15, 2011, AstraZeneca announced enrollment of the first patient in the Phase 3 clinical study for NKTR-118. This Phase 3 clinical program is designed to investigate the safety and efficacy of NKTR-118 as a medicine to relieve opioid-induced constipation, a common side effect of prescription opioids when used for chronic pain management.

We have a collaboration with Bayer for Amikacin Inhale, an inhaled solution of amikacin, an aminoglycoside antibiotic, that has completed Phase 2 development. Preparations for a Phase 3 clinical study, which we currently expect to start in the second half of 2012, are continuing. The program is significantly behind schedule due to our plan with Bayer to finalize the design of the nebulizer device for commercial manufacturing prior to initiating Phase 3 clinical development, with the objective of commencing Phase 3 clinical trials as soon as possible following completion of this work.

We continue to make substantial investments in our drug candidate pipeline from early stage discovery research through clinical development. We continue to advance Phase 2 clinical trials for NKTR-102 (topoisomerase I inhibitor-polymer conjugate) in metastatic breast cancer, platinum resistant/refractory ovarian cancer and metastatic colorectal cancer. The Phase 2 clinical trial for metastatic breast cancer was fully enrolled in 2010, with patients continuing in the study into 2011. In June 2010, we expanded the Phase 2 clinical trial in platinum resistant/refractory ovarian cancer by 50 patients and, in March 2011, we announced that we expanded the clinical study in platinum resistant/refractory ovarian cancer by up to 60 additional patients. Ovarian cancer patients eligible for our Phase 2 expansion study are required to have received prior Doxil® therapy. Due to an ongoing supply shortage of Doxil®, we anticipate future enrollment in this study to be very limited. On November 2, 2011, we announced that we would start compiling, reviewing and analyzing the data from the patients enrolled in the study to date. Following our review and analysis of the data, we will determine our future regulatory and development options for NKTR-102 in ovarian cancer. The Phase 2 clinical study in metastatic colorectal cancer patients is still enrolling. Enrollment in the colorectal cancer study has been challenging due to the fact that the comparator arm of this study, single-agent irinotecan, is not the standard of care for second line metastatic colorectal therapy in the United States or Europe.

Table of Contents

We expect to start a Phase 3 clinical study for NKTR-102 in metastatic breast cancer prior to the end of 2011. In platinum resistant/refractory ovarian cancer, we also plan to evaluate NKTR-102 in combination with DOXIL[®] in a Phase 1 clinical study in 2012 as well as continue to develop plans for a potential Phase 3 clinical study in this indication. The size, scope and timing of our investment in comparative Phase 3 clinical studies in platinum resistant/refractory ovarian cancer will depend upon a number of important variables, including our evaluation of the expanded Phase 2 study results, discussions with health authorities and key opinion leaders, evolving regulatory standards and requirements, the estimated cost of these studies, and our prioritization of research and development opportunities. We anticipate our Phase 3 development plans for NKTR-102 to require substantial investment over the next several years.

Our focus on research and clinical development requires substantial investments that continue to increase as we advance each drug candidate through each phase of the development cycle. In addition to advancing our proprietary programs that are currently in clinical development, we are committed to continuing to make significant investments to advance new opportunities from our earlier stage research discovery pipeline. For example, we started a Phase 1 clinical study for NKTR-181 on March 21, 2011 and on September 8, 2011, we initiated a second Phase 1 clinical study for this drug candidate. 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 demonstrates positive clinical results and/or receives 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 is extremely difficult to predict. In addition, we continually prioritize our programs. For example, as a result of prioritization of our drug candidate pipeline opportunities, we do not currently intend to advance NKTR-105 (PEGylated docetaxel) into Phase 2 clinical studies. 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

On January 24, 2011, we completed a public offering of our common stock with gross proceeds of approximately \$220.4 million. As part of the public offering, we incurred approximately \$0.6 million in legal and accounting fees, filing fees, and other offering expenses. At September 30, 2011, we had approximately \$458.0 million in cash, cash equivalents, and investments in marketable securities and \$239.8 million in indebtedness. We have \$215.0 million in outstanding convertible subordinated notes due September 2012. We have no material credit facility or other material committed sources of capital. We expect the Phase 3 clinical studies of NKTR-102 to require significant resources as we anticipate bearing a majority or all of the development costs for that drug candidate. We do not currently have sufficient resources to fund our current research and development plans and repay these convertible notes. We are exploring a number of alternatives to provide for the repayment of the convertible notes.

Historically, we have financed our operations primarily through cash from licensing, collaboration and manufacturing agreements and public and private placements of debt and equity securities. 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 future. In addition, we have substantial debt in the form of our outstanding convertible subordinated notes. Our substantial debt, the market price of our securities, and the general economic climate, among other factors, could have material consequences for our financial condition and could affect our sources of short-term and long-term funding. Our ability to meet our ongoing operating expenses and repay our outstanding indebtedness is dependent upon our and our partners' ability to successfully complete clinical development of, obtain regulatory approvals for and successfully commercialize drug candidates. Even if we or our partners are successful, we may require additional capital to continue to fund our operations and repay our debt obligations as they become due. There can be no assurance that additional funds, if and when required, will be available to us on favorable terms, if at all.

Table of Contents**Results of Operations**

Three Months and Nine Months Ended September 30, 2011 and 2010

Revenue (in thousands, except percentages)

| | Three months ended September 30, 2011 | Three months ended September 30, 2010 | Increase / (Decrease) 2011 vs. 2010 | Percentage Increase / (Decrease) 2011 vs. 2010 |
|----------------------------------|---|---|---|---|
| Product sales and royalties | \$ 10,222 | \$ 7,230 | \$ 2,992 | 41% |
| License, collaboration and other | 16,846 | 30,695 | (13,849) | (45)% |
| Total revenue | \$ 27,068 | \$ 37,925 | \$ (10,857) | (29)% |

| | Nine months ended September 30, 2011 | Nine months ended September 30, 2010 | Increase / (Decrease) 2011 vs. 2010 | Percentage Increase / (Decrease) 2011 vs. 2010 |
|----------------------------------|---|---|---|---|
| Product sales and royalties | \$ 26,023 | \$ 21,968 | \$ 4,055 | 18% |
| License, collaboration and other | 29,675 | 91,757 | (62,082) | (68)% |
| Total revenue | \$ 55,698 | \$ 113,725 | \$ (58,027) | (51)% |

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. Upfront fees received for license and collaborative agreements 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. Management makes its 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 management to determine the performance periods.

Product Sales and Royalties

Product sales include cost-plus and fixed price manufacturing and supply agreements with our collaboration partners. We also receive royalty revenue from certain of our collaboration partners based on their net sales of approved products.

Product sales and royalties in the three months and nine months ended September 30, 2011 increased compared to the three and nine months ended September 30, 2010 as a result of increased product sales volume and increased royalties. The timing of product shipments is based on the demand and requirements of our collaboration partners and is generally not ratable throughout the year.

License, Collaboration and Other

License, collaboration and other revenue includes amortization of upfront payments and milestone payments received in connection with our license and collaboration agreements and reimbursed research and development expenses. The level of license, collaboration and other revenue depends in part upon the estimated amortization period of the upfront payments, the achievement of milestones, the continuation of existing collaborations, the amount of reimbursed research and development work, and the signing of new collaboration agreements, if any.

Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

For the three months and nine months ended September 30, 2011, the decrease in license, collaboration and other revenue compared to the three months and nine months ended September 30, 2010 is primarily attributable to the complete amortization as of December 31, 2010 of the \$125.0 million upfront payment received in 2009 from AstraZeneca in connection with the NKTR-118 and NKTR-119 license agreement. Under our license agreement with AstraZeneca, we recognized \$25.3 million and \$76.0 million of the \$125.0 million upfront payment in the three months and nine months ended September 30, 2010, respectively, compared to nil in the three months and nine months ended September 30, 2011. These decreases were partially offset by a \$5.0 million license fee from a new license agreement signed in September 2011 and \$4.5 million in development milestone payments received under two existing collaboration agreements and earned in the three months ended September 30, 2011.

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

| | Three months ended September 30, 2011 | Three months ended September 30, 2010 | Increase / (Decrease) 2011 vs. 2010 | Percentage Increase / (Decrease) 2011 vs. 2010 |
|----------------------|---|---|---|---|
| Cost of goods sold | \$ 5,038 | \$ 6,245 | \$ (1,207) | (19)% |
| Product gross profit | \$ 5,184 | \$ 985 | \$ 4,199 | >100% |
| Product gross margin | 51% | 14% | | |

| | Nine months ended September 30, 2011 | Nine months ended September 30, 2010 | Increase / (Decrease) 2011 vs. 2010 | Percentage Increase / (Decrease) 2011 vs. 2010 |
|----------------------|--|--|---|--|
| Cost of goods sold | \$ 16,441 | \$ 15,430 | \$ 1,011 | 7% |
| Product gross profit | \$ 9,582 | \$ 6,538 | \$ 3,044 | 47% |
| Product gross margin | 37% | 30% | | |

For the three months and nine months ended September 30, 2011 compared to the three months and nine months ended September 30, 2010, the increase in product gross profit and product gross margin is primarily attributable to increases in royalties and the different mix of products sold.

As a result of the fixed cost base associated with our manufacturing activities, we expect product gross margin to fluctuate in future periods depending on the level of our manufacturing requirements.

Research and Development Expense (in thousands, except percentages)

| | Three months ended September 30, 2011 | Three months ended September 30, 2010 | Increase / (Decrease) 2011 vs. 2010 | Percentage Increase / (Decrease) 2011 vs. 2010 |
|----------------------------------|---|---|---|---|
| Research and development expense | \$ 31,018 | \$ 27,724 | \$ 3,294 | 12% |

| | Nine months ended September 30, 2011 | Nine months ended September 30, 2010 | Increase / (Decrease) 2011 vs. 2010 | Percentage Increase / (Decrease) 2011 vs. 2010 |
|----------------------------------|---|---|---|---|
| Research and development expense | \$ 93,464 | \$ 76,610 | \$ 16,854 | 22% |

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 and supplies, licenses and fees, and overhead allocations consisting of various support and facilities related costs. Research and development expense is not expected to be ratable over the four quarters of the year, however we expect research and development expense to increase throughout 2011 compared to 2010 as we continue to advance our pipeline of drug candidates, including our plan to advance NKTR-102 into Phase 3 clinical development in metastatic breast cancer by the end of the year.

For the three months and nine months ended September 30, 2011 compared to the three months and nine months ended September 30, 2010, research and development expense increased by approximately \$0.9 million and \$6.7 million, respectively, due to increased direct research and development program costs and related materials, primarily due to our NKTR-181 single and multiple dose Phase I clinical studies initiated in

Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

2011, by \$0.8 million and \$3.9 million, respectively, due to increased salaries and employee benefits resulting from increased headcount to support our expanded clinical efforts, and by \$1.6 million and \$4.9 million, respectively, due to increased support and facilities-related costs, which includes increased non-cash depreciation and rent expenses related to our new facility in San Francisco. The remaining increases to research and development expense in the three months and nine months ended September 30, 2011 compared to the three months and nine months ended September 30, 2010 consist primarily of increases to non-cash stock based compensation and other non-program outside services.

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 three and nine months ended September 30, 2011 from the activities discussed in our Annual Report on Form 10-K for the year ended December 31, 2010 on file with the Securities and Exchange Commission.

General and Administrative Expense (in thousands, except percentages)

| | Three months ended September 30, 2011 | Three months ended September 30, 2010 | Increase / (Decrease) 2011 vs. 2010 | Percentage Increase / (Decrease) 2011 vs. 2010 |
|------------------------------------|---|---|---|---|
| General and administrative expense | \$ 12,350 | \$ 10,181 | \$ 2,169 | 21% |

| | Nine months ended September 30, 2011 | Nine months ended September 30, 2010 | Increase / (Decrease) 2011 vs. 2010 | Percentage Increase / (Decrease) 2011 vs. 2010 |
|------------------------------------|---|---|---|---|
| General and administrative expense | \$ 35,262 | \$ 29,401 | \$ 5,861 | 20% |

General and administrative expense includes the cost of administrative staffing, business development, marketing, finance and legal. For the three months and nine months ended September 30, 2011 compared to the three months and nine months ended September 30, 2010, general and administrative expense increased by \$2.2 million and \$2.7 million, respectively, due to a payment obligation related to the settlement of a commercial litigation matter. In addition, during the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010, general and administrative expense increased due to personnel-related costs, support and facilities-related costs, and professional and other administrative costs.

Interest Income and Interest Expense (in thousands, except percentages)

| | Three months ended September 30, 2011 | Three months ended September 30, 2010 | Increase / (Decrease) 2011 vs. 2010 | Percentage Increase / (Decrease) 2011 vs. 2010 |
|------------------|---|---|---|---|
| Interest Income | \$ 622 | \$ 369 | \$ 253 | 69% |
| Interest Expense | \$ 2,543 | \$ 2,826 | \$ (283) | (10)% |

| | Nine months ended September 30, 2011 | Nine months ended September 30, 2010 | Increase / (Decrease) 2011 vs. 2010 | Percentage Increase / (Decrease) 2011 vs. 2010 |
|------------------|--|--|---|---|
| Interest Income | \$ 1,583 | \$ 1,225 | \$ 358 | 29% |
| Interest Expense | \$ 7,698 | \$ 8,686 | \$ (988) | (11)% |

The increase in interest income for the three months and nine months ended September 30, 2011 compared to the three months and nine months ended September 30, 2010 is a result of higher average cash and investment balances partially offset by the impact of decreased market interest rates.

The decrease in interest expense for the three months and nine months ended September 30, 2011 compared to the three months and nine months ended September 30, 2010 is primarily attributable to the complete amortization of deferred financing costs during 2010 from our 3.25% convertible subordinated notes due September 2012.

Liquidity and Capital Resources

We have financed our operations primarily through cash from licensing, collaboration and manufacturing agreements and public and private placements of debt and equity securities.

We had cash, cash equivalents and investments in marketable securities of \$458.0 million and indebtedness of \$239.8 million, including \$215.0 million of 3.25% convertible subordinated notes due September 2012, \$17.5 million in capital lease obligations, and \$7.3 million in other liabilities as of September 30, 2011.

Table of Contents

Due to the potential for continued uncertainty in the credit markets in 2011, we may experience reduced liquidity with respect to some of our investments in marketable securities. These investments are generally held to maturity, which is less than two years. However, if the need arose to liquidate such securities before maturity, we may experience losses on liquidation. At September 30, 2011, the average time to maturity of the investments held in our portfolio was approximately eight months and the maturity of any single investment did not exceed twenty-four months. To date we have not experienced any liquidity issues with respect to these securities, but should 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, cash equivalents, and investments will be sufficient to meet our anticipated cash needs for at least the next twelve months. Based on our available cash and our expected operating cash requirements, we do not intend to sell these securities prior to maturity and it is more likely than not that we will not be required to sell these securities before we recover the amortized cost basis. Accordingly, we believe there are no other-than-temporary impairments on these securities and have not recorded any provisions for impairment.

Cash flows from operating activities

Cash flows used in operating activities for the nine months ended September 30, 2011 totaled \$71.5 million, which includes \$7.0 million for semi-annual interest payments on our convertible subordinated notes, and \$89.0 million of other net operating cash uses, partially offset by the receipt of \$24.5 million from collaboration agreements, of which \$16.5 million was included in accounts receivable at December 31, 2010 resulting from an upfront payment obligation arising from an amendment to one of our manufacturing and supply agreements to extend the supply term and provide for a manufacturing transition. 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.

Cash flows used in operating activities for the nine months ended September 30, 2010 totaled \$76.3 million, which includes \$7.0 million for semi-annual interest payments on our convertible subordinated notes and \$69.3 million of other net operating cash uses.

We expect cash flows used in operating activities, excluding upfront payments received, if any, will increase throughout the remainder of 2011 compared to the same period in 2010 as a result of increased spending on our research and development programs.

Cash flows from investing activities

We purchased \$8.3 million and \$22.2 million of property and equipment in the nine months ended September 30, 2011 and 2010, respectively. The decrease in 2011 compared to 2010 is primarily due to the completion of the San Francisco facilities in 2010.

Cash flows from financing activities

On January 24, 2011, we completed a public offering of our common stock with gross proceeds of approximately \$220.4 million. As part of the public offering, we incurred approximately \$0.6 million in legal and accounting fees, filing fees, and other offering expenses.

We received \$4.3 million and \$7.1 million, respectively, from issuances of common stock to employees during the nine months ended September 30, 2011 and 2010. Cash used in financing activities was not significant for the nine months ended September 30, 2011 and 2010.

Contractual Obligations

There were no material changes during the nine months ended September 30, 2011 to the summary of contractual obligations included in our Annual Report on Form 10-K for the year ended December 31, 2010 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.

Table of Contents

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. With the exception of the updates to the following critical accounting policies and estimates, 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, 2010.

On January 1, 2011, we adopted on a prospective basis Accounting Standards Update (ASU) 2009-13, which amends the criteria to identify separate units of accounting within Subtopic 605-25, Revenue Recognition-Multiple-Element Arrangements and we also elected to prospectively adopt ASU 2010-17, Milestone Method of Revenue Recognition. The adoption of these standards may result in revenue recognition patterns for future agreements and milestones that are materially different from those recognized for our existing multiple-element arrangements and for milestones received prior to adoption. The adoption of the multiple-element arrangement standard did not impact our financial position or results of operations as of and for the three month and nine month periods ended September 30, 2011. However, under the milestone method of revenue recognition, in the three and nine month periods ended September 30, 2011, we recognized \$4.5 million from substantive milestones upon achievement in the three months ended September 30, 2011, whereas under our previous milestone revenue recognition policy, we would have recognized approximately \$0.4 million during this period.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Our market risks at September 30, 2011 have not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2010 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 financial disclosure.

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

Changes in Internal Control Over Financial Reporting

We continuously seek to improve the efficiency and effectiveness of our internal controls. This results in refinements to processes throughout the Company. However, there was no change in our internal control over financial reporting that occurred in the three months ended September 30, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how

Table of Contents

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

Table of Contents**PART II: OTHER INFORMATION****Item 1. Legal Proceedings**

Reference is hereby made to our disclosures in **Legal Matters** under Note 4 of the Notes to 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, 2010. 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 convertible 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, 2010, 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 product candidates and partnered product candidates in research and development ranging from the early discovery research phase through preclinical testing and clinical trials. Preclinical testing and clinical trials are long, expensive and highly uncertain processes. It will take us, or our collaborative partners, several years to complete clinical trials. The start or end of clinical trials may be delayed or halted due to regulatory delays, manufacturing challenges, required clinical trial administrative actions (e.g., clinical research organization contracting matters, institutional review board approvals at study sites etc.), slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparator drug or required prior therapy, clinical outcomes (e.g. adverse safety events), or financial constraints.

Drug development is an uncertain scientific and medical endeavor, and failure can unexpectedly occur at any stage of clinical development even after early preclinical or mid-stage clinical results suggest that the drug candidate has potential as a new therapy that may benefit patients and that health authority approval would be anticipated. Typically, there is a high rate of attrition for product candidates in preclinical and clinical trials due to scientific feasibility, safety, efficacy, changing standards of medical care and other variables. We or our partners have a number of important product candidates in mid- to late-stage development, such as Amikacin Inhale which we partnered with Bayer, NKTR-118 (oral PEGylated naloxol) and NKTR-119, which we partnered with AstraZeneca, and NKTR-102 (topoisomerase I inhibitor-polymer conjugate). Any one of these trials could fail at any time, as clinical development of drug candidates presents numerous unpredictable and significant risks and is very uncertain at all times prior to regulatory approval by one or more health authorities in major markets.

Even with success in preclinical testing and clinical trials, the risk of clinical failure remains high prior to regulatory approval.

A number of companies in the pharmaceutical and biotechnology industries have suffered significant unforeseen setbacks in later stage clinical trials (i.e., Phase 2 or Phase 3 trials) due to factors such as inconclusive efficacy results and adverse medical events, even after achieving positive results in earlier trials that were satisfactory both to them and to reviewing regulatory agencies. Although we announced positive Phase 2 clinical results for NKTR-118 in 2009, there are still substantial risks and uncertainties associated with the outcomes of Phase 3 clinical trials and the regulatory review process even following our partnership with AstraZeneca. While NKTR-102 continues in Phase 2 clinical development for multiple cancer indications, it is possible this product candidate could fail in one or all of the cancer indications in which it is currently being studied due to efficacy, safety or other commercial or regulatory factors. In 2010 and in the first half of 2011, we have announced preliminary positive results from our Phase 2 trials for NKTR-102 in ovarian and breast cancer. These results were based on preliminary data only, and such results could change based on final audit and verification procedures. In addition, the preliminary results from the NKTR-102 clinical studies for ovarian and breast cancer are not necessarily indicative or predictive of the future results from the completed ovarian or breast cancer trials, anticipated Phase 3 trials in these indications or clinical trials in the other cancer indications for which we are studying NKTR-102. There remains a significant uncertainty as to the success or failure of NKTR-102 and whether this drug candidate will

Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

eventually receive regulatory approval or be a commercial success even if approved by one or more health authorities in any of the cancer indications for which it is being studied. The risk of failure is increased for our product candidates that are based on new technologies, such as the application of our advanced polymer conjugate technology to small molecules, including NKTR-118, NKTR-119, NKTR-102, NKTR-181 and other drug candidates currently in the discovery research or preclinical development phases.

Table of Contents

The results from the expanded Phase 2 clinical trial for NKTR-102 in women with platinum-resistant/refractory ovarian cancer are unlikely to result in a review or an approval of an NDA by the United States Food and Drug Administration (FDA), and the future results from this trial are difficult to predict.

In 2010, we expanded the NKTR-102 Phase 2 study by 50 patients in women with platinum-resistant/refractory ovarian cancer with the potential for us to consider an early NDA submission after we evaluate these expanded study results. On March 1, 2011, we announced that we intended to further expand this Phase 2 study by up to an additional 60 patients. 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 and therefore we are not expecting the FDA to accept or approve an accelerated NDA based on our Phase 2 clinical study in platinum resistant/refractory ovarian cancer. 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 used 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 Nektar's ability to submit an accelerated NDA for platinum resistant/refractory ovarian cancer patients, and even if submitted, whether the FDA would accept it for review and/or approve the NDA.

Further, this expansion of our Phase 2 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. If the clinical studies for NKTR-102 in women with platinum-resistant/refractory ovarian cancer are not successful, it could significantly harm our business, results of operations and financial condition.

We may not be able to obtain intellectual property licenses related to the development of our technology 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, medical devices and equipment and methods for preparation, packaging and delivery of pharmaceutical compositions. We cannot predict with any certainty which, if any, patent references will be considered relevant to our or our collaborative 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, our business, results of operations, and financial condition could be significantly harmed and we may be prevented from developing and selling the product.

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, medical device and biotechnology companies, such as ours, are uncertain and involve complex legal and factual issues. We own greater than 100 U.S. and 380 foreign patents and a number of pending patent applications that cover various aspects of our technologies. 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 patents that have issued will be valid and enforceable or that patents for which we apply will issue with broad coverage, if at all. The coverage claimed in a patent application can be significantly reduced before the patent is issued and, as a consequence, our patent applications may result in patents with narrow coverage that may not prevent competition from similar products or generics. 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. As part of the patent application process, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office, which could result in substantial cost to us, even if the eventual outcome is favorable. Further, an issued patent may undergo further proceedings to limit its scope so as not to provide meaningful protection and any claims that have issued, or that eventually issue, may be circumvented or otherwise invalidated. Any attempt to enforce our patents or patent application rights could be time consuming and costly. An adverse outcome 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. 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 commercialization of related products.

Table of Contents

There are many laws, regulations and judicial decisions that dictate and otherwise influence the manner in which patent applications are filed and prosecuted and in which patents are granted and enforced. Changes to these laws, regulations and judicial decisions are subject to influences outside of our control and may negatively affect our business, including our ability to obtain meaningful patent coverage or enforcement rights to any of our issued patents. New laws, regulations and judicial decisions may be retroactive in effect, potentially reducing or eliminating our ability to implement our patent-related strategies. Changes to laws, regulations and judicial decisions that affect our business are often difficult or impossible to foresee, which limits our ability to adequately adapt our patent strategies to these changes.

If we or our partners are not able to manufacture drugs or drug substances in quantities and at costs that are commercially feasible, we may fail to meet our contractual obligations or our proprietary and partnered product candidates may experience clinical delays or constrained commercial supply which could significantly harm our business.

If we are not able to scale-up manufacturing to meet the drug quantities required to support large clinical trials or commercial manufacturing in a timely manner or at a commercially reasonable cost, we risk delaying our clinical trials or those of our partners and may breach contractual obligations and incur associated damages and costs, and reduce or even eliminate associated revenues. In some cases, we may subcontract manufacturing or other services. Pharmaceutical manufacturing 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 validation, and challenges in controlling for all of these factors during manufacturing scale-up for large clinical trials and commercial manufacturing and supply. In addition, we have faced and may in the future face significant difficulties, delays and unexpected expenses as we validate third party contract manufacturers required for scale-up to clinical or commercial quantities. Failure to manufacture products in quantities or at costs that are commercially feasible could cause us not to meet our supply requirements, contractual obligations or other requirements for our proprietary product candidates and, as a result, would significantly harm our business, results of operations and financial condition.

For instance, we entered a service agreement with Novartis pursuant to which we subcontract to Novartis certain important services to be performed in relation to our partnered program for Amikacin Inhale with Bayer Healthcare LLC. If our subcontractors do not dedicate adequate resources to our programs, we risk breach of our obligations to our partners. 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. Further, our drug and device combination products, such as Amikacin Inhale and the Cipro Inhale program, require significant device design, formulation development work and manufacturing scale-up activities. We have experienced repeated significant delays in starting the Phase 3 clinical development program for Amikacin Inhale as we seek to finalize the device design with a demonstrated capability to be manufactured at commercial scale. This work is ongoing and there remains significant risk in finalizing the device until those activities are completed. 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/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.

We will need to restructure our convertible notes or raise substantial additional capital to repay the notes and fund operations, and we may be unable to restructure the notes or raise such capital when needed and on acceptable terms.

We have \$215.0 million in outstanding convertible subordinated notes due September 2012. We do not have sufficient resources to fund the development of the drug candidates in our current research and development pipeline, complete late stage clinical development of NKTR-102 and repay these convertible notes. We have no material credit facility or other material committed sources of capital. We expect the Phase 3 clinical trials of NKTR-102 to require particularly significant resources because we anticipate bearing a majority or all of the development costs for that drug candidate. We are exploring a number of alternatives to provide for the repayment of the notes. Despite these efforts, we may be unable to find a commercially acceptable alternative or any alternative to repaying the notes by September 2012. Our future capital requirements will depend upon numerous factors, including:

the progress, timing, cost and results of our clinical development programs, including our clinical development of NKTR-102;

patient enrollment in our current and future clinical studies, including clinical development of NKTR-102;

Table of Contents

whether and when we receive potential milestone payments and royalties, particularly from the product candidates that are subject to our collaboration agreements with AstraZeneca for NKTR-118 and Bayer for Amikacin Inhale;

the success, progress, timing and costs of our business development efforts to implement new business collaborations, licenses and other strategic transactions;

the cost, timing and outcomes of regulatory reviews of our product candidates (e.g., NKTR-102) and those of our collaboration partners (e.g., NKTR-118, Amikacin Inhale);

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

disputes concerning patents, proprietary rights, or license and collaboration agreements;

the availability and scope of coverage from government and private insurance payment or reimbursement for our drug candidates partnered with collaboration partners and any future drug candidates that may receive regulatory approval in the future; and

the size, design (i.e., primary and secondary endpoints) and number of clinical studies required by the government health authorities in order to consider for approval our product candidates and those of our collaboration partners.

Although we believe that our cash, cash equivalents and investments in marketable securities of \$458.0 million as of September 30, 2011 will be sufficient to meet our liquidity requirements through at least the next 12 months, we will likely need to restructure our notes or obtain additional funds through one or more financing, strategic or collaboration partnership transactions. If adequate funds are not available or are not available on acceptable terms when we need them, we may need to delay or reduce one or more of our programs in research and development including one or more ongoing or planned clinical trials for NKTR-102.

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 products that receive regulatory approval for commercialization, we must either develop internal sales, marketing and distribution capabilities, which would be expensive and time consuming, or enter into collaboration arrangements with third parties to perform these services. If we decide to market our products directly, we must commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and with supporting distribution, administration and compliance capabilities. Factors that may inhibit our efforts to commercialize our products directly or indirectly with our partners include:

our inability to recruit and retain adequate numbers of effective sales and marketing personnel;

the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to use or prescribe our products;

the lack of complementary products or multiple product pricing arrangements may put us at a competitive disadvantage relative to companies with more extensive product lines; and

unforeseen costs and expenses associated with creating and sustaining an independent sales and marketing organization.

If we, or our partners through our collaboration, 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.

Table of Contents

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

We intend to continue to seek partnerships with pharmaceutical and biotechnology partners to fund a portion of our research and development expenses and develop and commercialize certain of our product candidates. In September 2009, we entered into a license agreement with AstraZeneca for NKTR-118 and NKTR-119 which included an upfront payment of \$125.0 million, which upfront payment was completely amortized as of December 13, 2010. The timing of new collaboration partnerships is difficult to predict due to availability of clinical data, 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 collaborative arrangements with favorable commercial terms with respect to our existing and future product candidates or the licensing of our technology, or if any arrangements we negotiate, or have negotiated, are terminated, our business, results of operations and financial condition could suffer.

The commercial potential of a drug candidate in development is difficult to predict and 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 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, patient and physician preferences, 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 health authorities based on the expiration of regulatory exclusivity or our inability to prevent generic versions from coming to market in one or more geographies by the assertion of one or more patents covering such approved drug. If due to one or more of these risks the market potential for a product candidate is lower than we anticipated, it could significantly and negatively impact the commercial terms of any collaboration partnership potential for such product 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 revenue, results of operations and financial condition.

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 with partners, under which we may receive contract research payments, milestone payments based on clinical progress, regulatory progress or net sales achievements, royalties or manufacturing revenue. Significant variations in the timing of receipt of cash payments and our recognition of revenue can result from the nature of significant milestone payments based on the execution of new collaboration agreements, the timing of clinical, regulatory or sales events which result in single milestone payments and the timing and success of the commercial launch of new drugs by our collaboration partners. 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 partner achieve clinical and sales milestones, whether the partnership is exclusive or whether we can seek other partners, the timing of regulatory approvals in one or more major markets 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 products, are not successful, or if such collaborations fail, the development or commercialization of our partnered products may be delayed or unsuccessful.

When we sign a collaborative development agreement or license agreement to develop a product 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 product candidate; and/or

market and sell our products when and if they are approved.

Table of Contents

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

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

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

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

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

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

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

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

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

partners may be unable to pay us as expected; and

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

Given these risks, the success of our current and future partnerships is highly unpredictable and can have a substantial negative or positive impact on our business. We have entered into 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 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. Product candidates must undergo rigorous

Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

animal and human testing and an extensive FDA mandated or equivalent foreign authorities review process for safety and efficacy. This process generally takes a number of years and requires the expenditure of substantial resources. The time required for completing testing and obtaining approvals is uncertain, and the FDA and other U.S. and foreign regulatory agencies have substantial discretion, at any phase of development, to terminate clinical trials, require additional clinical development or other testing, delay or withhold registration and marketing approval and mandate product withdrawals, including recalls. 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.

Table of Contents

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.

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 performance;

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

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

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

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

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

On September 20, 2009, we entered into a worldwide exclusive license agreement with AstraZeneca for the further development and commercialization of NKTR-118 and NKTR-119. In addition, we have also entered into complex commercial agreements with Novartis in connection with the sale of certain assets related to our pulmonary business, associated technology and intellectual property to Novartis (the Novartis Pulmonary Asset Sale), which was completed on December 31, 2008. As part of the Novartis Pulmonary Asset Sale, we entered an exclusive license agreement with Novartis Pharma pursuant to which Novartis Pharma grants back to us an exclusive, irrevocable, perpetual, royalty-free and worldwide license under certain specific patent rights and other related intellectual property rights necessary for us to satisfy certain continuing contractual obligations to third parties, including in connection with development, manufacture, sale and commercialization activities related to our partnered program for Amikacin Inhale with Bayer. We also entered into a service agreement pursuant to which we have subcontracted to Novartis certain services to be performed related to our partner program for Amikacin Inhale. Our agreements with AstraZeneca and Novartis contain 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 AstraZeneca or Novartis 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 impact on our business, results of operations or financial condition.

Table of Contents

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 year ended December 31, 2010 and the nine months ended September 30, 2011, we reported net losses of \$37.9 million and \$96.5 million, respectively. If and when we achieve profitability depends upon a number of factors, including the timing and recognition of milestone payments and royalties received, the timing of revenue under our collaboration agreements, the amount of investments we make in our proprietary product candidates and the regulatory approval and market success of our product candidates. We may not be able to achieve and sustain profitability.

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

develop products 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 NKTR-102 since we expect to bear a majority or all of such costs;

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.

Table of Contents

If we do not generate sufficient cash through raising additional capital, we may be unable to meet our substantial debt obligations and continue our substantial investment in research and development.

As of September 30, 2011, we had cash, cash equivalents, and investments in marketable securities valued at approximately \$458.0 million and indebtedness of approximately \$239.8 million, including approximately \$215.0 million in convertible subordinated notes due September 2012, \$17.5 million in capital lease obligations, and \$7.3 million of other liabilities.

Our substantial indebtedness has and will continue to impact us by:

making it more difficult to obtain additional financing;

constraining our ability to react quickly in an unfavorable economic climate;

constraining our stock price; and

constraining our ability to invest in our research and development programs.

Currently, we are not generating positive cash flow. If we are unable to satisfy our debt service requirements, substantial liquidity problems could result. In relation to our convertible notes, since the market price of our common stock is significantly below the conversion price, the holders of our outstanding convertible notes are unlikely to convert the notes to common stock in accordance with the existing terms of the notes. If we do not generate sufficient cash from operations to repay principal or interest on our remaining convertible notes, or satisfy any of our other debt obligations, when due, we may have to raise additional funds through one or more financing, strategic, or collaboration partnership transactions. Any such financing or restructuring may not be available to us on commercially acceptable terms, if at all.

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 trial, 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.

Table of Contents

Our manufacturing operations and those of our contract manufacturers are subject to 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 are subject to inspections by the FDA 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 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 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.

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 Dr. Reddy's Laboratories Ltd., Enzon Pharmaceuticals, Inc., SunBio Corporation, Mountain View Pharmaceuticals, Inc., Novo Nordisk A/S (formerly assets held by Neose Technologies, Inc.), and NOF Corporation. Several other chemical, biotechnology and pharmaceutical companies may also be developing PEGylation technologies or technologies that have similar impact on target drug molecules. Some of these companies license or provide the technology to other companies, while others are developing the technology for internal use.

There are several competitors for our proprietary product candidates currently in development. For Amikacin Inhale, the current standard of care includes several approved intravenous antibiotics for the treatment of either hospital-acquired pneumonia or ventilator-associated pneumonia in patients on mechanical ventilators. For NKTR-118 (oral PEGylated naloxol), 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 Adolor Corporation, Progenics Pharmaceuticals, Inc. in collaboration with Salix Pharmaceuticals, Ltd., Mundipharma Int. Limited, Sucampo Pharmaceuticals, Alkermes, Inc. and Takeda Pharmaceutical Company Limited. For NKTR-102 (topoisomerase I inhibitor-polymer conjugate), there are a number of chemotherapies and cancer therapies approved today and in various stages of clinical development for ovarian and breast cancers including but not limited to: Avastin® (bevacizumab), Camptosar® (irinotecan), Doxil® (doxorubicin HCl), Ellence® (epirubicin), Gemzar® (gemcitabine), Herceptin® (trastuzumab), Hycamtin® (topotecan), Iniparib, Paraplatin® (carboplatin), and Taxol® (paclitaxel). Major pharmaceutical or biotechnology companies with approved drugs or drugs in development for these cancers include Bristol-Myers Squibb, Eli Lilly & Co., Roche, GlaxoSmithKline plc, Johnson and Johnson, Pfizer, Inc., Sanofi Aventis, and many others. There are approved therapies for the treatment of colorectal cancer, including Eloxatin® (oxaliplatin), Camptosar® (irinotecan), Avastin® (bevacizumab), Erbitux® (cetuximab), Vectibix® (panitumumab), Xeloda® (capecitabine), Adrucil® (fluorouracil), and Wellcovorin® (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., Mediatech Research Ltd, Alchemia Limited, Enzon Pharmaceuticals, Inc. and others.

Table of Contents

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.

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

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 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 partners from intellectual property infringement, product liability and certain other claims, which could cause us to incur substantial costs 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 products or product candidates in the U.S. and abroad. For instance, F. Hoffmann-La Roche Ltd, to which we license our proprietary PEGylation reagent for use in the MIRCERA product, was a party to a significant patent infringement lawsuit brought by Amgen Inc. related to Roche's proposed marketing and sale of MIRCERA to treat chemotherapy anemia in the U.S. In October 2008, a federal court ruled in favor of Amgen, issuing a permanent injunction preventing Roche from marketing or selling MIRCERA in the U.S. In December 2009, the U.S. District court for the District of Massachusetts entered a final judgment and permanent injunction, and Roche and Amgen entered into a settlement and limited license agreement which allows Roche to begin selling MIRCERA in the U.S. in July 2014.

Third-party claims involving proprietary rights or other matters could also result in the award of substantial damages to be paid by us or a settlement resulting in significant payments to be made by us. For instance, a settlement might require us to enter a license agreement under which we pay substantial royalties or other compensation to a third party, diminishing our future economic returns from the related product. In 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. 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, results of operations and financial condition.

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 product 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 expenses generated by these activities. Our decision to bear a majority or all of the clinical development costs of NKTR-102 substantially increases our expenses. 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 further reductions in our workforce, which could harm our operations, employee morale and impair our ability to retain and recruit talent. Furthermore, if

Table of Contents

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, regulatory, finance, marketing and distribution and develop additional expertise in our existing personnel. In particular, additional highly qualified personnel will be required for late stage development of NKTR-102. We face intense competition from other biopharmaceutical companies, research and academic institutions and other organizations for qualified personnel. Many of the organizations with which we compete for qualified personnel have greater resources than we have. Because competition for skilled personnel in our industry is intense, companies such as ours sometimes experience high attrition rates with regard to their skilled employees. Further, in making employment decisions, job candidates often consider the value of the stock options they are to receive in connection with their employment. Our equity incentive plan and employee benefit plans may not be effective in motivating or retaining our employees or attracting new employees, and significant volatility in the price of our stock may adversely affect our ability to attract or retain qualified personnel. If we fail to attract new personnel or to retain and motivate our current personnel, our business and future growth prospects could be severely harmed.

If earthquakes and 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 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;

Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

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;

Table of Contents

the ability of our board to authorize the issuance of blank check preferred stock to increase the number of outstanding shares and thwart a takeover attempt;

prohibition on stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of stockholders;

establishment of advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon by stockholders at stockholder meetings; and

limitations on who may call a special meeting of stockholders.

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

Risks Related to Our Securities

The price of our common stock and convertible debt are expected to remain volatile.

Our stock price is volatile. During the quarter ended September 30, 2011, based on closing bid prices on The NASDAQ Global Select Market, our stock price ranged from \$4.85 to \$7.65 per share. We expect our stock price to remain volatile. In addition, as our convertible notes are convertible into shares of our common stock, volatility or depressed prices of our common stock could have a similar effect on the trading price of our notes. Also, interest rate fluctuations can affect the price of our convertible notes. A variety of factors may have a significant effect on the market price of our common stock or notes, including:

announcements of data from, or material developments in, our clinical trials or those of our competitors, including delays in clinical development, approval or launch;

announcements by collaboration partners as to their plans or expectations related to products using our technologies;

announcements or terminations of collaboration agreements by us or our competitors;

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;

Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

announcements of changes in governmental regulation affecting us or our competitors;

hedging activities by purchasers of our convertible notes;

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.

Table of Contents

Our stockholders may be diluted, and the price of our common stock may decrease, as a result of the exercise of outstanding stock options and warrants, the restructuring of our convertible notes, or the future issuances of securities.

We may restructure our convertible notes or issue additional common stock, preferred stock, restricted stock units or securities convertible into or exchangeable for our common stock. Furthermore, substantially all shares of common stock for which our outstanding stock options or warrants are exercisable are, once they have been purchased, eligible for immediate sale in the public market. The issuance of additional common stock, preferred stock, restricted stock units or securities convertible into or exchangeable for our common stock or the exercise of stock options or warrants would dilute existing investors and could lower the price of our common stock.

Restructuring of our convertible notes or raising additional funds by issuing equity securities could cause significant dilution to existing stockholders; restructured or additional debt financing may restrict our operations.

If we raise additional funds through the restructuring of our convertible notes or issuance of equity or convertible debt securities, the percentage ownership of our stockholders could be diluted significantly, and these restructured or newly issued securities may have rights, preferences or privileges senior to those of our existing stockholders. If we restructure our notes or incur additional debt financing, the payment of principal and interest on such indebtedness may limit funds available for our business activities, and we could be subject to covenants that restrict our ability to operate our business and make distributions to our stockholders. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on the ability of us to create liens, pay dividends, redeem our stock or make investments.

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

None, including no purchases of any class of our equity securities by us or any affiliate pursuant to any publicly announced repurchase plan in the three months ended September 30, 2011.

Item 3. Defaults Upon Senior Securities

None.

Item 4. (Removed and Reserved)**Item 5. Other Information**

None.

Item 6. Exhibits

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

Exhibit

| Number | Description of Documents |
|---------------|--|
| 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). |

Edgar Filing: NEKTAR THERAPEUTICS - Form 10-Q

- 32.1(1)* Section 1350 Certifications.
- 101** The following materials from Nektar Therapeutics Quarterly Report on Form 10-Q for the quarter ended September 30, 2011, 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 Cash Flows, and (iv) 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.
- ** Exhibit 101 is being furnished and, in accordance with Rule 406T of Regulation S-T, 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 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.

Table of Contents

SIGNATURES

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

By: /s/ JOHN NICHOLSON

John Nicholson

Senior Vice President and Chief Financial Officer

Date: November 3, 2011

By: /s/ JILLIAN B. THOMSEN

Jillian B. Thomsen

Senior Vice President, Finance and Chief Accounting Officer

Date: November 3, 2011

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.

Exhibit

| Number | Description of Documents |
|---------------|---|
| 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(1)* | Section 1350 Certifications. |
| 101** | The following materials from Nektar Therapeutics Quarterly Report on Form 10-Q for the quarter ended September 30, 2011, 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 Cash Flows, and (iv) 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.

** Exhibit 101 is being furnished and, in accordance with Rule 406T of Regulation S-T, 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 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.