NEKTAR THERAPEUTICS
Form 10-Q
May 08, 2014

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 March 31, 2014

or

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

For the transition period from to

Commission File Number: 0-24006

NEKTAR THERAPEUTICS

(Exact name of registrant as specified in its charter)

Delaware	**94-3134940**
(State or other jurisdiction of incorporation or organization)	**(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 x 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 x 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 x	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 x

The number of outstanding shares of the registrant s Common Stock, $0.0001 par value, was 126,977,001 on April 30, 2014.

NEKTAR THERAPEUTICS

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PART I: FINANCIAL INFORMATION

PART II: OTHER INFORMATION

Forward-Looking Statements

This report includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act). All statements other than statements of historical fact are forward-looking statements for purposes of this quarterly report on Form 10-Q, including any projections of earnings, revenue, milestone payments, royalties, sales or other financial items, any statements of the plans and objectives of management for future operations (including, but not limited to, preclinical development, clinical trials and manufacturing), any statements related to our financial condition and future working capital needs, any statements regarding potential future financing alternatives, any statements concerning proposed drug candidates, any statements regarding the timing for the start or end of clinical trials or submission of regulatory approval filings, any statements regarding future economic conditions or performance, any statements regarding the success of our collaboration arrangements or future payments that may come due to us under these arrangements, any statements regarding our plans and objectives to initiate or continue clinical trials, and any statements of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as may, will, expects, plans, anticipates, estimates, potential or 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, a our refer to Nektar Therapeutics, a Delaware corporation, and, where appropriate, its subsidiaries.

Trademarks

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

PART I: FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements Unaudited:

NEKTAR THERAPEUTICS

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except par value)

(Unaudited)

	March 31, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 32,443	$ 39,067
Short-term investments	251,628	197,959
Accounts receivable, net	1,855	2,229
Inventory	12,872	13,452
Other current assets	5,972	5,175
Total current assets	304,770	257,882
Restricted cash	25,000	25,000
Property and equipment, net	72,968	66,974
Goodwill	76,501	76,501
Other assets	7,774	8,170
Total assets	$ 487,013	$ 434,527
LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 3,064	$ 9,115
Accrued compensation	9,427	14,254
Accrued expenses	6,821	6,243
Accrued clinical trial expenses	13,726	16,905
Interest payable	3,167	6,917
Deferred revenue, current portion	23,542	23,664
Liability related to the sales of future royalties, current portion		7,000
Other current liabilities	19,566	14,123
Total current liabilities	79,313	98,221
Senior secured notes	125,000	125,000
Capital lease obligations, less current portion	7,050	8,049
Liability related to receipt of refundable milestone payment	70,000	70,000
Liability related to sale of future royalties, less current portion	121,134	121,520
Deferred revenue, less current portion	76,549	82,384

Other long-term liabilities	17,776	19,256
Total liabilities	496,822	524,430
Commitments and contingencies		
Stockholders equity (deficit):		
Preferred stock, $0.0001 par value, 10,000 shares authorized, no shares designated, issued or outstanding at March 31, 2014 or December 31, 2013, respectively		
Common stock, $0.0001 par value, 300,000 authorized, 126,936 shares and 116,494 shares issued and outstanding at March 31, 2014 and December 31, 2013, respectively	12	11
Capital in excess of par value	1,769,713	1,643,660
Accumulated other comprehensive loss	(940)	(1,181)
Accumulated deficit	(1,778,594)	(1,732,393)
Total stockholders equity (deficit)	(9,809)	(89,903)
Total liabilities and stockholders equity (deficit)	$ 487,013	$ 434,527

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

NEKTAR THERAPEUTICS

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share information)

(Unaudited)

	Three months ended March 31,	
	2014	**2013**
Revenue:		
Product sales and royalty revenue	$ 5,917	$ 12,135
Non-cash royalty revenue related to sale of future royalties	5,773	4,393
License, collaboration and other revenue	8,081	6,476
Total revenue	19,771	23,004
Operating costs and expenses:		
Cost of goods sold	7,907	11,661
Research and development	38,338	45,618
General and administrative	9,928	10,829
Total operating costs and expenses	56,173	68,108
Loss from operations	(36,402)	(45,104)
Non-operating income (expense):		
Interest income	134	314
Interest expense	(4,533)	(4,645)
Non-cash interest expense on liability related to sale of future royalties	(5,387)	(5,543)
Other income (expense), net	178	127
Total non-operating expense, net	(9,608)	(9,747)
Loss before provision for income taxes	(46,010)	(54,851)
Provision for income taxes	191	212
Net loss	$ (46,201)	$ (55,063)
Basic and diluted net loss per share	$ (0.37)	$ (0.48)
Weighted average shares outstanding used in computing basic and diluted net loss per share	123,543	115,309

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

(Unaudited)

	Three months ended March 31,	
	2014	2013
Comprehensive loss	$ (45,960)	$ (55,101)

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

NEKTAR THERAPEUTICS

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Three months ended March 31,	
	2014	**2013**
Cash flows from operating activities:		
Net loss	$ (46,201)	$ (55,063)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash royalty revenue related to sale of future royalties	(5,773)	(4,393)
Non-cash interest expense on liability related to sale of future royalties	5,387	5,543
Stock-based compensation	4,361	4,245
Depreciation and amortization	3,264	3,628
Other non-cash transactions	777	139
Changes in operating assets and liabilities:		
Accounts receivable, net	374	2,158
Inventory	580	(112)
Other assets	(718)	3,844
Accounts payable	(6,126)	1,355
Accrued compensation	(4,827)	179
Accrued expenses	693	(1,130)
Accrued clinical trial expenses	(3,179)	6,532
Interest payable	(3,750)	(3,916)
Deferred revenue	(5,957)	2,710
Other liabilities	(1,195)	(3,830)
Net cash used in operating activities	(62,290)	(38,111)
Cash flows from investing activities:		
Maturities of investments	56,972	100,338
Purchases of investments	(110,661)	(56,336)
Purchases of property and equipment	(4,524)	(316)
Net cash (used in) provided by investing activities	(58,213)	43,686
Cash flows from financing activities:		
Payment of capital lease obligations	(825)	(692)
Repayment of proceeds from sale of future royalties	(7,000)	(3,000)
Issuance of common stock, net of issuance costs	116,619	
Proceeds from shares issued under equity compensation plans	5,074	1,218
Net cash provided by (used in) financing activities	113,868	(2,474)

Effect of exchange rates on cash and cash equivalents	11	(7)
Net (decrease) increase in cash and cash equivalents	(6,624)	3,094
Cash and cash equivalents at beginning of period	39,067	25,437
Cash and cash equivalents at end of period	$ 32,443	$ 28,531
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 7,961	$ 8,250

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

NEKTAR THERAPEUTICS

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2014

(Unaudited)

Note 1 Organization and Summary of Significant Accounting Policies

Organization

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

Our research and development activities have required significant resources to date and are expected to continue to require significant resources. As a result, we expect to continue to incur substantial losses and negative cash flows from operations in the future. We have financed our operations primarily through cash generated from licensing, collaboration and manufacturing agreements and financing transactions. At March 31, 2014, we had approximately $309.1 million in cash and investments in marketable securities, of which $25.0 million was restricted in relation to our 12% senior secured notes, and $164.2 million in indebtedness. The indebtedness includes $125.0 million in aggregate principal amount of 12.0% senior secured notes due July 15, 2017, but excludes our long-term liability relating to the sale of future royalties. As is further described in Note 4, this royalty obligation liability will not be settled in cash.

Basis of Presentation and Principles of Consolidation

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

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

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

Our comprehensive loss consists of our net loss plus our foreign currency translation gains and losses and unrealized holding gains and losses on available-for-sale securities, neither of which were significant during the three months ended March 31, 2014 and 2013. In addition, there were no significant reclassifications out of accumulated other comprehensive loss to the statements of operations during the three months ended March 31, 2014 and 2013.

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

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

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ materially from those estimates and assumptions. On an ongoing basis, we evaluate our estimates, including those related to deferred revenue recognition periods, inventory, the impairment of investments, the impairment of goodwill and long-lived assets, contingencies, accrued clinical trial expenses, estimated interest expense from our liability related to our sale of future royalties, stock-based compensation, and ongoing litigation, among other estimates. We base our estimates on historical experience and on other assumptions that management believes are reasonable under the circumstances. These estimates form the basis for making judgments about the carrying values of assets and liabilities when these values are not readily apparent from other sources.

Reclassifications

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

Segment Information

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

Significant Concentrations

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

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

Revenue Recognition

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

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

Product sales

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

Royalty revenue

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

License, collaboration and other revenue

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

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

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

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

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

Research and Development Expense

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

We record accruals for the estimated costs of our clinical trial activities performed by third parties. We generally accrue costs associated with the start-up and reporting phases of the clinical trials ratably over the estimated duration

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

Income Taxes

For the three months ended March 31, 2014 and 2013, we recorded an income tax provision for our Nektar India operations at effective tax rates of approximately 34%. The U.S. federal deferred tax assets generated from our net operating losses have been fully reserved, as we believe it is not more likely than not that the benefit will be realized.

Note 2 Cash and Investments in Marketable Securities

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

	Estimated Fair Value at	
	March 31, 2014	December 31, 2013
Cash and cash equivalents	$ 32,443	$ 39,067
Short-term investments	251,628	197,959