NEKTAR THERAPEUTICS
Form 8-K
July 31, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): July 31, 2014

NEKTAR THERAPEUTICS

(Exact Name of Registrant as Specified in Charter)

Delaware	**0-24006**	**94-3134940**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

455 Mission Bay Boulevard South

San Francisco, California 94158

(Address of Principal Executive Offices and Zip Code)

Registrant’s telephone number, including area code: (415) 482-5300

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

¨Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02 Results of Operations and Financial Condition.

On July 31, 2014, Nektar Therapeutics, a Delaware corporation ("Nektar"), issued a press release (the "Press Release") announcing its financial results for the quarter ended June 30, 2014. A copy of the Press Release is furnished herewith as Exhibit 99.1.

On July 22, 2014, Nektar announced that it would hold a Webcast conference call on July 31, 2014 to review its financial results for the quarter ended June 30, 2014. This conference call is accessible through a link that is posted on the home page and Investor Relations section of the Nektar website: http://www.nektar.com.

On this conference call, management expects to provide information regarding Nektar's business and to make forward-looking statements, including statements regarding the potential approval and commercial launch of MOVANTIK™ (naloxegol) in the United States and European Union, the timing and availability of Phase 3 data for BAX 855 from our collaboration partner Baxter International Inc., the timing and availability of topline median overall survival results for the BEACON Phase 3 clinical study for NKTR-102 and the target date for regulatory filings if this study is successful, the timing of Phase 3 clinical study results for CIPRO DPI and Amikacin Inhale with our collaboration partner Bayer, the potential market size for certain drug candidates, financial guidance for 2014, and certain other future events. These forward-looking statements involve substantial risks and uncertainties including but not limited to:

- Nektar's proprietary drug candidates, including NKTR-102, NKTR-181, NKTR-171, CIPRO DPI, and Amikacin Inhale are in clinical development and the risk of failure remains high and can unexpectedly occur at any time due to lack of efficacy, frequency and severity of adverse safety events, manufacturing challenges, regulatory delays, changes in regulatory requirements (e.g., additional or expanded clinical studies), changing standards of care, or other factors that can negatively impact drug development.

- On June 11-12, 2014, the United States Food and Drug Administration (FDA) held an Anesthetic and Analgesic Drug Products Advisory Committee (the "Advisory Committee") meeting to review cardiovascular safety assessment requirements for the class of peripherally acting opioid receptor antagonists (PAMORAs), which includes MOVANTIK™. The meeting was convened to assess the necessity, timing, design and size of cardiovascular outcomes trials to support approval of products in PAMORA class, for the proposed indication of OIC in patients taking opioids for chronic non-cancer pain. A majority of the Advisory Committee members voted in favor of a recommendation that the FDA should not require cardiovascular outcomes trials for PAMORAs. However, the FDA is not bound by the Advisory Committee's recommendation and there can be no certainty until the FDA's regulatory review process is complete. If the FDA were to require a CV Safety Study prior to an approval of the NDA filed by AstraZeneca for MOVANTIK™ and AstraZeneca terminates the license agreement with us in its entirety or only with respect to its rights in the United States, it would have a material adverse effect on our business, financial condition, results of operations and prospects.

- The scheduled Prescription Drug User Fee Act (PDUFA) date for MOVANTIK™ is September 16, 2014. The FDA endeavors to complete its review of NDAs by the PDUFA date but does not always do so.

If approved by the FDA and European Medicines Agency, the commercial launch of MOVANTIK™ will depend upon the timing of the United States Drug Enforcement Agency's completion of the decontrol process for MOVANTIK™.

The timing and/or success of the commencement or end of clinical trials, including without limitation the anticipated Phase 3 commencement for NKTR-181 in early 2015, may be delayed or unsuccessful due to regulatory delays, clinical trial design and the need to obtain regulatory concurrence for such designs, manufacturing challenges, required clinical trial administrative actions (e.g. clinical research organization contracting matters and institutional review board approvals at study sites), slower than anticipated patient enrollment, changing standards of care, clinical outcomes, or financial constraints.

- It is very difficult to estimate the commercial potential of drug candidates due to important factors such as safety and efficacy compared to other available therapies, including potential generic drug alternatives with similar efficacy profiles, changing standards of care, third party payer reimbursement standards, patient and physician preferences, drug scheduling status, the availability of competitive alternatives that may emerge either during the long drug development process or after commercial introduction, and the availability of generic versions of our successful product candidates following approval by government health authorities based on the expiration of regulatory exclusivity or our inability to prevent generic versions from coming to market.

- Scientific discovery of new medical breakthroughs is an inherently uncertain process, and the future success of the application of Nektar's technology platforms to potential new drug candidates is therefore very uncertain and unpredictable and one or more research and development programs could fail.

- Nektar's patent applications for its proprietary or partner product candidates may not issue, patents that have issued may be unenforceable, or additional intellectual property licenses from third parties may be required in the future.

- The outcome of any intellectual property or other litigation related to Nektar's proprietary drug candidates (or partnered drug candidates where Nektar has indemnification responsibility) is unpredictable and could have a material adverse effect on Nektar's business, results of operations and financial condition.

- Management's financial projections for 2014 annual revenue, certain annual expense category estimates, and year-end cash position are subject to the significant risk of unplanned cash receipt short-falls, unplanned or increased expenses, any of which could significantly and adversely affect Nektar's actual 2014 annual financial results and end of year cash position.

- Other important risks and uncertainties set forth in Nektar's Quarterly Report on Form 10-Q filed with the SEC on May 8, 2014.

Actual results could differ materially from the forward-looking statements and Nektar undertakes no obligation to update forward-looking statements, whether as a result of new information, future events or otherwise.

The information in this report, including the exhibit hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing with the Securities and Exchange Commission made by Nektar Therapeutics, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press release titled “Nektar Therapeutics Reports Second Quarter 2014 Financial Results” issued by Nektar Therapeutics on July 31, 2014.

SIGNATURES

Pursuant to the requirement 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/ Gil M. Labrucherie
Gil M. Labrucherie
General Counsel and Secretary

Date: July 31, 2014

EXHIBIT INDEX

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