NEKTAR THERAPEUTICS
Form 8-K
November 02, 2011

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): November 2, 2011

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 November 2, 2011, Nektar Therapeutics, a Delaware corporation ("Nektar"), issued a press release (the "Press Release") announcing its financial results for the quarter ended September 30, 2011. A copy of the Press Release is furnished herewith as Exhibit 99.1.

On October 26, 2011, Nektar announced that it would hold a Webcast conference call on November 2, 2011 to review its financial results for the quarter ended September 30, 2011. 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 pre-clinical and clinical development plans, the medical and commercial potential for certain of Nektar's drug candidates, the value and potential of Nektar's technology, the projected Phase 3 clinical trial start date for NKTR-102 in metastatic breast cancer and Amikacin Inhale (partnered with Bayer), the future regulatory and development strategy for NKTR-102 in platinum resistant/refractory ovarian cancer, the timing and availability of clinical results, the timing of future events related to the advancement of our drug candidate pipeline including potential future regulatory filings and submissions with health authorities, financial guidance for 2011, and certain other future events. This information and these forward-looking statements involve substantial risks and uncertainties including but not limited to:

- Nektar's proprietary drug candidates, including NKTR-118, NKTR-102, NKTR-181 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), or other factors that can negatively impact drug development.

- The preliminary Phase 2 results for NKTR-102 in ovarian and breast cancer previously announced or presented by Nektar remain subject to final data gathering and audit confirmation procedures. Therefore, the final results for the ovarian and breast cancer trials may differ materially and adversely from previously reported data after these audit and verification procedures are completed.

- The expanded Phase 2 study in women with platinum-resistant/refractory ovarian cancer could change the efficacy results (e.g. overall response rates, progression-free survival, overall survival etc.) and safety observations (e.g., frequency and severity of serious adverse events). As such, the overall results from the Phase 2 study for platinum-resistant/refractory ovarian cancer remain subject to change and the final results could be materially and adversely different from results previously announced.

- Acceptance and approval of a new drug application (NDA) by the United States Food and Drug Administration (FDA) almost always requires the sponsor to conduct comparative Phase 3 clinical studies prior to acceptance, review and/or approval of an NDA. As a result, acceptance for review and/or approval of an NDA submitted to the FDA based on overall response rate from our single-arm Phase 2 study in platinum-resistant/refractory ovarian cancer would be unusual and is highly unlikely—therefore we are not expecting the FDA to accept and/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.

- The timing and/or success of the commencement or end of clinical trials, including without limitation the anticipated Phase 3 commencement for NKTR-102 in metastatic breast cancer by the end of 2011 and Amikacin Inhale by mid-2012, 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 (i.e. clinical research organization contracting matters, institutional review board approvals at study sites etc.), slower than anticipated patient enrollment, changing standards of care, clinical outcomes, or financial constraints. For example, Nektar has experienced several significant delays in finalizing the commercial device design for Amikacin Inhale and successful completion of this device design and the commercial scale-up effort is an essential element to enabling the future start of the planned Phase 3 trial—these activities are ongoing and remain subject to a substantial risk of failure until such activities are successfully completed.

- The discussion of NKTR-181 by management on the conference call is based on preclinical and data from the first Phase 1 clinical study and there is a risk that future clinical results may not confirm one or more of these results and observations. In addition, although Nektar has conducted various experiments using laboratory and home-based chemistry techniques that so far have been unable to convert NKTR-181 into a rapidly-acting, more abusable opioid, in the future, an alternative chemistry technique, process or method of administration may be discovered to enable the conversion of NKTR-181 into a more abusable opioid which would significantly and negatively impact the potential of NKTR-181.

- 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 not be enforceable, 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.

- The market sizes for Nektar's proprietary and partnered product programs are based on management's current estimates (and in some cases estimates communicated to us by our collaboration partners or published by financial analysis) only and actual market sizes may differ materially and adversely.

- Management's financial projections for Nektar's 2011 annual revenue, certain annual expense category estimates, and year-end cash position are subject to the significant risk of unplanned revenue short-falls, unplanned expenses, and expenses being higher than planned, any of which could significantly and adversely affect Nektar's actual 2011 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 August 4, 2011.

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 Third Quarter 2011 Financial Results" issued by Nektar Therapeutics on November 2, 2011.

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: November 2, 2011

EXHIBIT INDEX

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