NEKTAR THERAPEUTICS
Form 8-K
August 09, 2012

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): August 9, 2012

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 August 9, 2012, Nektar Therapeutics, a Delaware corporation ("Nektar"), issued a press release (the "Press Release") announcing its financial results for the quarter ended June 30, 2012. A copy of the Press Release is furnished herewith as Exhibit 99.1.

On August 2, 2012, Nektar announced that it would hold a Webcast conference call on August 9, 2012 to review its financial results for the quarter ended June 30, 2012. 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 make certain forward-looking statements regarding Nektar's business including but not limited to statements regarding future pre-clinical and clinical development plans, the potential medical benefit and commercial potential for certain of Nektar's drug candidates and those of its collaboration partners, the value and potential of Nektar's PEGylation technology platform, the potential timing of the high level Phase 3 clinical study results and regulatory filings for naloxegol, or NKTR-118 (partnered with AstraZeneca), the potential timing of the planned start of Phase 3 clinical studies for BAX 855 (partnered with Baxter Healthcare) and Amikacin Inhale (partnered with Bayer Healthcare), the future regulatory and clinical development plans for NKTR-102, the timing and availability of future clinical results for one or more of our drug candidates, the timing of future events related to the advancement of our drug candidate pipeline including potential future regulatory filings and submissions with governmental health authorities, financial guidance for 2012, the planned repayment of indebtedness and certain other future events. These forward-looking statements involve substantial risks and uncertainties including but not limited to:

- Nektar's drug candidates, including naloxegol (NKTR-118), BAX 855, NKTR-102, NKTR-181, Amikacin Inhale, and NKTR-192 are in clinical development and the risk of failure remains high and can unexpectedly occur at any time due to lack of efficacy, frequency or 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 timing of, or the ability to commence, clinical trials, including without limitation the potential start of the Phase 3 clinical studies for Amikacin Inhale and BAX 855, may be delayed, and ongoing clinical trials may be canceled, due to negative findings from ongoing preclinical or clinical trials, clinical trial design requirements or the need to obtain regulatory concurrence for such study designs, the availability of study drugs or comparator drugs, and manufacturing challenges, required clinical trial administrative actions (e.g. clinical research organization contracting matters and institutional review board approvals at study sites), changing standards of care, results from other clinical studies in the same therapeutic area, financial constraints, or other factors that can significantly and negatively impact the drug development process. For example, Nektar has experienced several significant delays in finalizing the commercial device design for Amikacin Inhale and successful completion of the manufacturing of clinical study devices and related stability testing 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.

- Although AstraZeneca has stated that it expects to have high level Phase 3 clinical study results for naloxegol (NKTR-118) by the end of 2012, Nektar does not have any access or knowledge of data from these Phase 3 clinical studies and therefore the outcome remains unknown and uncertain until such data becomes available.

- 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 or approval of an NDA. As a result, acceptance for review 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 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 and overall survival), and the number of patients required to be studied to demonstrate sufficient therapeutic benefit and safety profile. One or more of such 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 or approve the NDA.

- While we have conducted numerous experiments using laboratory and home-based chemistry techniques that have not been able to convert NKTR-181 or NKTR-192 into rapid-acting and more abusable opioids, there is a risk that in the future a technique could be discovered to convert NKTR-181 or NKTR-192 into rapid-acting and more abusable opioids which would significantly diminish the value of these drug candidates.

- 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 2012 are subject to the significant risk of unplanned revenue shortfalls, unplanned expenses or liabilities, and expenses being higher than planned, any of which could significantly and adversely affect Nektar's actual 2012 annual financial results.

- Other important risks and uncertainties set forth in Nektar's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2012.

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 Financial Results for the Second Quarter 2012"** issued by Nektar Therapeutics on August 9, 2012.

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: August 9, 2012

EXHIBIT INDEX

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