NEKTAR THERAPEUTICS
Form 8-K
September 19, 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): September 19, 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 8.01 Other Events

On September 13, 2012, Nektar Therapeutics, a Delaware corporation ("Nektar"), announced that its President and Chief Executive Officer, Howard W. Robin, is scheduled to present at the UBS 2012 Global Life Sciences Conference in New York at the Grand Hyatt Hotel on Wednesday, September 19, 2012 at 10:30 a.m. Eastern time. This presentation will be accessible via a Webcast through a link posted on the Investor Relations, Events Calendar section of the Nektar website http://www.nektar.com. This webcast will be available for replay until October 20, 2012.

During this presentation Nektar expects Mr. Robin to make certain forward-looking statements regarding Nektar's business including but not limited to the following: (i) statements regarding the commercial and financial potential of certain of Nektar's drug candidates and those of its collaboration partners (e.g. estimates of peak market revenue and potential royalty revenue to Nektar); (ii) Nektar's 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; (iii) the value and potential of Nektar's technology platform; (iv) the potential timing of clinical study plans and regulatory filings for naloxegol or NKTR-118 (partnered with AstraZeneca), Amikacin Inhale (partnered with Bayer Healthcare), BAX 855 (partnered with Baxter Healthcare), NKTR-102, NKTR-181 and NKTR-192; (v) the timing and availability of future clinical results for one or more of our drug candidates and those of Nektar's collaboration partners; (vi) financial guidance for 2012; (vii) and certain other future events and opportunities related to Nektar's business. These forward-looking statements involve substantial risks and uncertainties including but not limited to:

- Nektar's drug candidates and those of its collaboration partners, including nolexegol (or NKTR-118), BAX 855, Amikacin Inhale, NKTR-102, NKTR-181, 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, drug shortages, regulatory delays, changes in regulatory requirements (e.g., additional or expanded clinical studies), or other factors that can negatively impact drug development.

- The timing or success of the commencement or end of clinical trials, including without limitation the potential start of the Phase 3 clinical study for Amikacin Inhale or the Phase 3 clinical study for BAX 855, may be delayed or unsuccessful due to regulatory delays, clinical trial design or the need to obtain regulatory concurrence for such designs, manufacturing challenges, required clinical trial administrative actions (e.g. clinical research organization contracting matters or institutional review board approvals at study sites), 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 the manufacturing of clinical study devices and related stability testing is an essential element to enabling the future start of the planned Phase 3 clinical trial — these activities are ongoing and remain subject to a substantial risk of failure until such activities are successfully completed.

- 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.

- Estimates of Nektar's potential future royalty revenue opportunity are based on peak market estimates and are not discounted for risks associated with such programs, including important risks such as clinical failure, failure to obtain regulatory approval, or failure of the product to achieve market sales equivalent to current peak market estimates.

- 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 (an 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 for NKTR-102 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 for NKTR-102 based on our expanded 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.

- 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 or may issue with narrow coverage, our 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.

- Nektar has conducted various experiments using laboratory and home-based chemistry techniques that to date have been unable to convert NKTR-181 or NKTR-192 into more rapidly-acting, more abusable opioids. In the future, an alternative chemistry technique, process or method of administration may be discovered to enable the conversion of NKTR-181 or NKTR-192 into more abusable opioids which would significantly and negatively impact the potential of NKTR-181 or NKTR-192.

- 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 Securities and Exchange Commission 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.

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: September 19, 2012