

NEKTAR THERAPEUTICS
Form 8-K
January 11, 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): January 11, 2012

NEKTAR THERAPEUTICS
(Exact Name of Registrant as Specified in Charter)

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| Delaware (State or Other Jurisdiction of Incorporation) | 0-24006 (Commission File Number) | 94-3134940 (IRS Employer Identification No.) |
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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 January 4, 2012, Nektar Therapeutics, a Delaware corporation (“Nektar”), announced that President and Chief Executive Officer, Howard W. Robin, will make a presentation at the upcoming 30th Annual J.P. Morgan Healthcare Conference in San Francisco at the Westin St. Francis Hotel on Wednesday, January 11, 2012 at 8:30 a.m. Pacific Time. The 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>.

During Mr. Robin’s presentation, he expects to make certain forward-looking statements regarding Nektar’s business, including without limitation, forward-looking statements regarding pre-clinical and clinical development plans, the medical and commercial potential for certain of Nektar’s drug candidates and those of its partners, the value and potential of Nektar’s technology, the projected clinical trial start dates for Nektar’s drug development programs and those of its partners, the future regulatory and development strategy for Nektar’s drug candidates and those of its partners, the economic potential of certain collaboration partnerships, the timing of the end of clinical trials and availability of future clinical results, and certain other future events. These forward-looking statements involve substantial risks and uncertainties including but not limited to:

- Nektar’s proprietary drug candidates and those of its collaboration partners including NKTR-118 (partnered with AstraZeneca), NKTR-102, NKTR-181, Amikacin Inhale (partnered with Bayer Healthcare), and BAX 855 (partnered with Baxter Healthcare) are in clinical development and the risk of failure remains very high and can unexpectedly occur at any time due to lack of efficacy, frequency and 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 expanded NKTR-102 Phase 2 clinical study in women with platinum-resistant/refractory ovarian cancer could change the efficacy results (i.e. overall response rates, progression-free survival, overall survival) and safety observations (i.e. frequency and severity of serious adverse events). As such, the overall results from the expanded 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 reported by Nektar.
- 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 a NDA. As a result, acceptance for review and/or approval of a NDA submitted to the FDA based on overall response rate from our single-arm NKTR-102 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 a sufficient efficacy 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 and/or approve the NDA.
- The timing and/or success of the commencement or end of clinical trials, including without limitation (i) the anticipated start of the Phase 1 study for NKTR-192 (following projected submission and effectiveness of the investigational new drug application with the FDA), (ii) the start of the Phase 2 study for NKTR-181, (iii) the start of the Phase 3 study for Amikacin Inhale, (iv) the estimates for the end of the Phase 3 studies for NKTR-118, and (v) the estimated end date of the Phase 1 study for BAX 855 and the start of late stage studies for this drug candidate, may be

delayed or unsuccessful due to health authority review issues and delays, clinical trial design and the need to obtain concurrence for such designs with health authorities, manufacturing challenges, drug supply shortages (including shortages in comparator drugs if applicable), required clinical trial administrative actions (e.g. clinical research organization contracting matters, institutional review board approvals at study sites etc.), slower than anticipated patient enrollment, changing standards of care, patient outcomes, and 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 is an essential element to enabling the future start of the planned Phase 3 study—these activities are ongoing and remain subject to a substantial risk of failure until such activities are successfully completed.

- The information regarding NKTR-181 referred to by Mr. Robin is based on preclinical data and Phase 1 clinical study results and there is a substantial risk that future clinical results may not confirm one or more of these results, observations or important elements of the NKTR-181 target product profile (e.g. the potential benefits of a slow rate of entry into the central nervous system such as a potential reduction in euphoria, drowsiness and respiratory depression). To date, 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.
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- 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 only (and in some cases based on third party data that has not been independently verified by Nektar) and actual market sizes may differ materially and adversely.
- Nektar is a party to numerous collaboration agreements and other significant agreements that contain complex commercial terms that could result in disputes, litigation or indemnification liability that could materially and adversely affect Nektar's business, results of operations and financial condition.
- Other important risks and uncertainties set forth in Nektar's Quarterly Report on Form 10-Q filed with the SEC on November 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.

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: January 11, 2012