

NEKTAR THERAPEUTICS
Form 8-K
June 07, 2010

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): June 6, 2010

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

Delaware
(State or Other Jurisdiction
of Incorporation)

0-24006
(Commission
File Number)

94-3134940
(IRS Employer
Identification No.)

201 Industrial Road
San Carlos, California 94070
(Address of Principal Executive Offices and Zip Code)

Registrant's telephone number, including area code: (650) 631-3100

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))
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Item 2.02

Results of Operations and Financial Condition

On June 6, 2010, Nektar Therapeutics, a Delaware corporation (“Nektar”), issued a press release (the “Press Release”) announcing results from a Phase 2 clinical study evaluating NKTR-102 in women with platinum-resistant/refractory ovarian cancer. A copy of the Press Release is furnished herewith as Exhibit 99.1.

On May 20, 2010, Nektar announced that it would host an investor and analyst breakfast on Monday, June 7, 2010, in conjunction with the 2010 ASCO Annual Meeting to discuss results from the Phase 2 clinical trial in ovarian cancer and perspective from clinical investigators and thought leaders in the ovarian cancer field. This breakfast event is being webcast, and as previously announced by Nektar, may be accessed in the Events Calendar section on the homepage of Nektar’s website at www.nektar.com. At this breakfast event Nektar management expects to make certain forward-looking statements regarding the potential therapeutic benefit of NKTR-102 for ovarian cancer patients, the future clinical development and regulatory plans for NKTR-102, and the potential and timing for a collaboration partnership for NKTR-102, the market potential of NKTR-102, and certain other statements regarding the prospects and potential of Nektar’s business, technology platform and drug candidate pipeline. These forward-looking statements involve substantial risks and uncertainties including but not limited to: (i) NKTR-102 is in early stage clinical development and the risk of failure remains high and failure can unexpectedly occur at any stage for one or more of the cancer indications being studied (i.e. ovarian cancer, breast cancer, and colorectal cancer) prior to regulatory approval due to lack of sufficient efficacy, safety considerations or other important factors that impact drug development; (ii) the data package required and the timing for regulatory approval of a new drug application (NDA) is very uncertain and difficult to predict due to the broad regulatory discretion of health authorities, changing standards of care, available approved therapies, the size of the completed clinical trials and the statistical significance of the results, the potential need for comparative clinical studies against approved therapies, and other important factors that are not very unpredictable and not within the control of Nektar; (iii) approval of a NDA by the Food and Drug Administration (FDA) almost always requires the sponsor to conduct Phase 3 clinical studies prior to consideration and approval of an NDA and, as a result, approval of an NDA by the FDA based on Phase 2 results prior to completion of Phase 3 clinical studies is highly unlikely; (iv) the expansion of the Phase 2 study in women with platinum-resistant/refractory ovarian cancer in the Q21 dose group will necessarily change the final efficacy (e.g. overall response rates, progression-free survival etc.) and safety (i.e. frequency of serious adverse events) final results for the Phase 2 clinical trial and, as such, the final results in the Q21 dose group remain subject to change and could be materially and adversely different from the current results; (v) the Phase 2 results for NKTR-102 in ovarian cancer described in the Press Release remain subject to final data gathering and analysis review and confirmation procedures and the final results for the ovarian cancer trial may differ materially and adversely; (vi) the results from the NKTR-102 clinical study for ovarian cancer are not necessarily indicative or predictive of the results for future clinical trial for NKTR-102 in ovarian cancer study or the results of NKTR-102 in any other cancer indications for which it is currently being studied (i.e., breast and colorectal cancers); (vii) the timing or success of the commencement or end of clinical trials and commercial launch of new drugs may be delayed or unsuccessful due to regulatory delays, clinical trial design, slower than anticipated patient enrollment, drug manufacturing challenges, changing standards of care, clinical outcomes, or delay or failure in obtaining regulatory approval in one or more important markets; (viii) scientific discovery of new medical breakthroughs is an inherently uncertain process and the future success of the application of Nektar’s technology platform to potential new drug candidates is therefore very uncertain and unpredictable and one or more research and development programs could fail; (ix) 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; (x) the outcome of any existing or future intellectual property or other litigation related to Nektar’s proprietary product candidates, including without limitation NKTR-102, is unpredictable and could have a material adverse effect on our business, results of operations and financial condition and the prospects for commercialization of NKTR-102; (xi) the market potential for NKTR-102 is based on management’s current estimates only and actual market size may differ materially and adversely; (xii) if Nektar is unable to establish and maintain collaboration partnerships or appropriate

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transaction structures relating to its drug candidates (such as for NKTR-102) on attractive commercial terms, our business, results of operations and financial condition could suffer; (xiii) the timing of any new collaboration partnerships is difficult to predict due to availability of clinical data, the number of potential partners that need to complete due diligence and approval processes, and numerous other unpredictable factors that can delay, impede or prevent partnering transactions; and (xiv) certain other important risks and uncertainties set forth in Nektar's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010 filed on May 6, 2010, and the Annual Report on Form 10-K for the year ended December 31, 2009, filed on March 3, 2010. Actual results could differ materially from the forward-looking statements contained in this press release. Nektar undertakes no obligation to update forward-looking statements, including but not limited to any clinical, health authority communications or other regulatory information, 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 “NKTR-102 Has High Response Rate and Sustained Clinical Benefit in 48 Percent of Women with Platinum-Resistant/Refractory Ovarian Cancer” issued by Nektar Therapeutics on June 6, 2010.

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: June 7, 2010

EXHIBIT INDEX

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