NEKTAR THERAPEUTICS
Form 8-K
June 09, 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 9, 2010

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.) |

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))

Item 2.02 Results of Operations and Financial Condition

On June 9, 2010, Nektar Therapeutics, a Delaware corporation ("Nektar"), issued a press release (the "Press Release") announcing initial results from a Phase 2 clinical study evaluating NKTR-102 in women with metastatic breast cancer. A copy of the Press Release is furnished herewith as Exhibit 99.1.

On June 3, 2010, Nektar announced that Howard W. Robin, President and Chief Executive Officer of Nektar, would present at the Jefferies 2010 Global Life Sciences Conference at The Grand Hyatt New York on Wednesday, June 9, 2010 at 10:00 a.m. Eastern Time. This presentation is being webcast and may be accessed in the Events Calendar section on the homepage of Nektar's website at www.nektar.com. At this presentation Nektar expects to make certain forward-looking statements regarding the potential therapeutic benefit of NKTR-102, the future clinical development and regulatory plans for NKTR-102, NKTR-105, NKTR-118 and certain other of Nektar's drug candidates in research and development, the potential and timing for a collaboration partnership for NKTR-102, the market potential of NKTR-102 and other of Nektar's drug candidates, 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 the following:

(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) due to lack of sufficient efficacy, safety concerns or other important factors that impact drug development and regulatory approval;

(ii) the Phase 2 results for NKTR-102 in breast cancer described in the Press Release and presented by Nektar management at the Jefferies conference remain subject to data audit confirmation procedures, and the reported results may change materially and adversely after such review is completed;

(iii) the initial preliminary RECIST response data for the NKTR-102 clinical trial in breast cancer reported in the Press Release and to be discussed at the Jefferies conference is subject to substantial change and such substantial change could be material and adverse—in particular, there is no way to predict whether unconfirmed responses will become confirmed responses as the clinical trial progresses;

(iv) additional important data will be reported by Nektar in the future regarding the NKTR-102 clinical study in breast cancer including but not limited to confirmed/unconfirmed RECIST response rates, progression-free survival, overall survival and further safety information regarding the frequency and severity of adverse events observed, and therefore the complete and final results for the Phase 2 breast cancer trial may differ materially and adversely from the results reported in the Press Release and at the Jefferies conference;

(v) the initial results from the NKTR-102 clinical study in breast cancer are not necessarily indicative or predictive of the future results of NKTR-102 in any other cancer indications for which it is currently being studied (i.e., ovarian and colorectal cancers);

(vi) the data package required and the timing for regulatory approval of a new drug application (NDA) by the Food and Drug Administration (FDA) is very uncertain and difficult to predict due to broad regulatory discretion, changing standards of care, available approved therapies, the size of 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 very unpredictable and not within Nektar's control;

(vii)

approval of an NDA by the 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;

(viii) the expansion of the Phase 2 study in women with platinum-resistant/refractory ovarian cancer in the Q21 dose group, which Nektar announced on Monday, June 7, 2010 at a webcast breakfast meeting, will necessarily result in changes to the final efficacy (e.g., overall response rates, progression-free survival, overall survival) and safety (i.e., frequency and severity of adverse events) results for the Phase 2 clinical trial in ovarian cancer, and, as such, the complete and final results in the Q21 dose group remain subject to change and could be materially and adversely different from the results previously announced by Nektar in a press release furnished on Exhibit 99.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on June 7, 2010;

(ix) 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;

(x) 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;

(xi) 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;

(xii) the outcome of any existing or future intellectual property or other litigation related to Nektar's proprietary product candidates, including without limitation NKTR-102, NKTR-118, NKTR-105 and other of Nektar's drug candidates, is unpredictable and could have a material adverse effect on our business, results of operations and financial condition and the prospects for commercialization of one or more of Nektar's drug candidates;

(xiii) the market potential for NKTR-102, NKTR-118, NKTR-105 and other of Nektar's drug candidates is based on management's current estimates only, and actual market size may differ materially and adversely;

(xiv) if Nektar is unable to establish and maintain collaboration partnerships or appropriate transaction structures relating to its drug candidates (e.g., NKTR-102) on attractive commercial terms, our business, results of operations and financial condition could suffer;

(xv) 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 from being consummated; and

(xvi) 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 the Press Release and those made by Nektar management at the Jefferies conference. Nektar undertakes no obligation to update forward-looking statements whether as a result of new information, future events or otherwise, including without limitation updated clinical trial results or regulatory communications.

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 Announces Positive Initial Results from Phase 2 Study of NKTR-102 in Metastatic Breast Cancer" issued by Nektar Therapeutics on June 9, 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.

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|---|---|
| By: | /s/ Gil M. Labrucherie<br>Gil M. Labrucherie<br>General Counsel and Secretary |
| Date: | June 9, 2010 |

EXHIBIT INDEX

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Press release titled “Nektar Therapeutics Announces Positive Initial Results from Phase 2 Study of NKTR-102 in Metastatic Breast Cancer” issued by Nektar Therapeutics on June 9, 2010. |

Exhibit 99.1