

NEKTAR THERAPEUTICS
Form 8-K
March 01, 2011

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): March 1, 2011

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.)

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 March 1, 2011, Nektar Therapeutics, a Delaware corporation (“Nektar”), issued a press release (the “Press Release”) announcing its financial results for the quarter and year ended December 31, 2010. A copy of the Press Release is furnished herewith as Exhibit 99.1.

On February 17, 2011, Nektar announced that its management would hold a Webcast conference call on March 1, 2011 to review its financial results for the quarter and year ended December 31, 2010. This conference call will be accessible through a link posted on the Investor Relations, Events Calendar section of the Nektar website: <http://www.nektar.com>.

On this conference call, management expects to make certain forward-looking statements, including statements regarding pre-clinical and clinical development plans and the potential for certain of Nektar’s proprietary drug development programs, the value and potential of Nektar’s advanced polymer chemistry technology platform, the expected start dates for clinical trials to be conducted by Nektar and its partners including NKTR-102, NKTR-118 partnered with AstraZeneca AB, and Amikacin Inhale partnered with Bayer AG, the timing and availability of future clinical results, the potential for submitting a New Drug Application (“NDA”) on an accelerated basis to the Food and Drug Administration (“FDA”) pending the outcome of future results from an expanded Phase 2 clinical study which is currently in progress for NKTR-102 in platinum-resistant/refractory ovarian cancer, the estimated market potential for our drug candidates, management’s financial guidance for 2011, and certain other future events. This information and these forward-looking statements involve substantial risks and uncertainties including but not limited to:

1. Nektar’s proprietary drug candidates, including NKTR-118, NKTR-102, Amikacin Inhale, and NKTR-105, are in early to mid-stage clinical development and the risk of failure remains high and can unexpectedly occur at any time prior to regulatory approval due to lack of efficacy, safety issues, manufacturing challenges or other factors that can impact drug development.
2. The preliminary Phase 2 results for NKTR-102 in ovarian and breast cancer announced or presented by Nektar to date remain subject to final data gathering and audit confirmation procedures. Therefore, the final results for the ovarian and breast cancer trials may differ materially and adversely from previously reported data after these audit and verification procedures are completed. In addition, there are patients still enrolled in both of these studies and as these studies progress, final results may change and new data will become available, and the final results could be materially and adversely different from results previously announced.
3. The expanded Phase 2 study in women with platinum-resistant/refractory ovarian cancer could change the efficacy results (e.g. overall response rates, progression-free survival, overall survival etc.) and safety observations (e.g., frequency and severity of serious adverse events). As such, the overall results from the 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 announced.
4. 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, review and/or approval of an NDA by the FDA based on Phase 2 results for NKTR-102 in platinum-resistant/refractory ovarian cancer prior to completion of Phase 3 clinical studies would be unusual and is highly unlikely.
5. The timing and/or success of the commencement or end of clinical trials, including without limitation the anticipated Phase 3 commencement for NKTR-118, NKTR-102 and Amikacin Inhale, may be delayed or unsuccessful due to regulatory delays, clinical trial design (and the need to obtain regulatory concurrence for such designs), slower than anticipated patient enrollment, manufacturing challenges, changing standards of care or

clinical outcomes. For example, Nektar has experienced significant delays in finalizing the commercial device design for Amikacin Inhale and successful completion of this device design and commercial scale-up effort is an essential element to meeting the targeted start of the Phase 3 trial in the second half of 2011 and these activities are ongoing and remain subject to a substantial risk of failure until such activities are successfully completed.

6. 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.
 7. 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.
 8. The outcome of any intellectual property or other litigation related to Nektar's proprietary product candidates or partner product candidates where Nektar has indemnification responsibility is unpredictable and could have a material adverse effect on our business, results of operations and financial condition.
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9. The market sizes for Nektar's proprietary and partnered product programs are based on management's (and in some cases estimates of our collaboration partners) current estimates only and actual market sizes may differ materially and adversely.
10. Management's financial projections for Nektar's 2011 annual revenue, certain annual expense category estimates, and year-end cash position are subject to the significant risk of unplanned revenue short-fall, unplanned expenses, and expenses being higher than planned which could adversely affect Nektar's actual 2011 annual financial results and end of year cash position.
11. Other important risks and uncertainties set forth in Nektar's Annual Report on Form 10-K filed with the SEC on March 1, 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.

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 Fourth Quarter and Year End 2010 Financial Results" issued by Nektar Therapeutics on March 1, 2011.

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: March 1, 2011

EXHIBIT INDEX

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