NEKTAR THERAPEUTICS
Form 8-K
June 04, 2018

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 2, 2018

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events

On June 2, 2018, Nektar Therapeutics, a Delaware corporation ("Nektar"), issued a press release announcing interim data from the dose-escalation phase of the PIVOT-02 Phase 1/2 study, which is designed to evaluate the combination of Nektar's CD122-biased agonist, NKTR-214, with nivolumab across several tumor types. A copy of the press release announcing these interim data is attached as Exhibit 99.1 to this Current Report on Form 8-K.

On May 16, 2018, Nektar announced that it would host a webcast analyst and investor event with clinical investigators during the 2018 American Society of Clinical Oncology Annual Meeting. The event was held on Saturday, June 2, 2018, at 6:45 p.m. Central Daylight Time and included a presentation and discussion of updated clinical data for NKTR-214. Data from the PIVOT-02 Phase 1/2 study and plans for future clinical trials were reviewed at the event. Presenters included Dr. Adi Diab, Assistant Professor, Melanoma Medical Oncology at the University of Texas MD Anderson Cancer Center, Dr. Scott N. Gettinger, Associate Professor, Medical Oncology at the Yale Cancer Center and Dr. Nizar M. Tannir, Professor, Genitourinary Medical Oncology at the University of Texas MD Anderson Cancer Center. A recording of this analyst and investor event is available for replay for two weeks on Nektar's website, www.nektar.com.

At the analyst and investor event, Nektar made certain forward-looking statements regarding the potential therapeutic benefit of NKTR-214 for cancer patients, the future clinical development plans for NKTR-214, the potential of NKTR-214 in combination with other immunotherapy agents including Bristol-Myers Squibb's Opdivo (nivolumab), 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) our statements regarding the therapeutic potential of NKTR-214 in combination with Opdivo are based on findings and observations from ongoing clinical studies and these findings and observations will evolve over time as more data emerges from the studies; (ii) NKTR-214 is in early stage clinical development and the risk of failure remains high and failure can unexpectedly occur due to efficacy, safety or other unpredictable factors; (iii) the initial preliminary RECIST response data presented at the event is subject to change—in particular, there is no way to predict whether unconfirmed responses will become confirmed responses as the clinical studies progress; (iv) the preliminary clinical results from the NKTR-214 clinical studies presented at the event remain subject to change as a result of final data audit confirmation procedures to be conducted following completion of the studies; (v) the timing of the commencement or end of clinical studies and the availability of clinical data may be delayed or unsuccessful due to regulatory delays, slower than anticipated patient enrollment, manufacturing challenges, changing standards of care, evolving regulatory requirements, clinical trial design, clinical outcomes, competitive factors, or delay or failure in ultimately obtaining regulatory approval in one or more important markets; (vi) scientific discovery of new medical breakthroughs is an inherently uncertain process and the future success of applying our technology platform to potential new drug candidates (such as NKTR-214) is therefore highly uncertain and unpredictable and one or more research and development programs could fail; (vii) patents may not issue from our patent applications for our drug candidates including NKTR-214, patents that have issued may not be enforceable, or additional intellectual property licenses from third parties may be required; and (viii) certain other important risks and uncertainties set forth in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 10, 2018. Any forward-looking statement made by Nektar at the investor and analyst event will be based only on information currently available to Nektar and speaks only as of the date on which it is made. Actual results could differ materially from the forward-looking statements made at the investor and analyst event. Nektar undertakes no obligation to update forward-looking statements whether as a result of new information, future events or otherwise.

Exhibit No.	Description
99.1	Press release titled "Preliminary Data for NKTR-214 in Combination with Opdivo (nivolumab) for Patients with Stage IV Metastatic Melanoma, Renal Cell Carcinoma, and Urothelial Cancers Presented at ASCO 2018" issued by Nektar Therapeutics on June 2, 2018.

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/ Mark A. Wilson
Mark A. Wilson
General Counsel and Secretary

Date: June 4, 2018