

NEKTAR THERAPEUTICS
Form 8-K
November 13, 2017

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): November 13, 2017

NEKTAR THERAPEUTICS

(Exact Name of Registrant as Specified in Charter)

Delaware	0-24006	94-3134940
(State or Other Jurisdiction	(Commission	(IRS Employer
of Incorporation)	File	Identification No.)
	Number)	

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

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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 November 11, 2017, 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 November 7, 2017, Nektar, announced that it would host an analyst and investor event at the 2017 Society for Immunotherapy of Cancer Annual Meeting. The event was held on Saturday, November 11, 2017 at 6:15 p.m. Eastern Time, and included a presentation and discussion of updated clinical data for the company’s CD122-biased agonist, NKTR-214. Data from the PIVOT-02 Phase 1/2 study was reviewed at the event, as well as data from the Phase 1 dose-escalation study of NKTR-214 in combination with nivolumab in patients with melanoma, renal cell carcinoma and non-small cell lung cancer. Presenters included Dr. Patrick Hwu of MD Anderson Cancer Center, Dr. Adi Diab of MD Anderson Cancer Center, Dr. Michael E. Hurwitz of Yale Cancer Center, Dr. Antoni Ribas of UCLA Medical Center and Dr. Nizar M. Tannir of 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 November 8, 2017. Any forward-looking statement made by Nektar at the investor and analyst event will be based only on information

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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
<u>99.1</u>	<u>Press release titled “First Data for NKTR-214 in Combination with OPDIVO® (nivolumab) for Patients with Stage IV Melanoma, Renal Cell Carcinoma and Non-Small Cell Lung Cancers, Including Patients with PD-L1 Negative Status, Revealed at SITC 2017” issued by Nektar Therapeutics on November 11, 2017.</u>

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: November 13, 2017