

NEKTAR THERAPEUTICS
Form 8-K
March 01, 2019

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, 2019

NEKTAR THERAPEUTICS

(Exact Name of Registrant as Specified in Charter)

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

455 Mission Bay Boulevard South

San Francisco, California 94158

(Address of Principal Executive Offices and Zip Code)

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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 March 1, 2019, Nektar Therapeutics, a Delaware corporation (“Nektar”), issued a press release announcing early results from the ongoing dose-escalation stage of the REVEAL Phase 1/2 clinical study evaluating the safety and efficacy of NKTR-262, a novel toll-like receptor (TLR) 7/8 agonist, in combination with bempedaldesleukin (NKTR-214 or bempeg), a CD122-preferential IL-2 pathway agonist. A copy of the press release announcing these preliminary data is attached as Exhibit 99.1 to this Current Report on Form 8-K.

On February 25, 2019, Nektar announced that it would host a webcast conference call with Dr. Adi Diab, Assistant Professor of Melanoma Medical Oncology at The University of Texas MD Anderson Cancer Center, and company management for analysts and investors during the 2019 ASCO-SITC Clinical Immuno-Oncology Symposium. The conference call will be held on Friday, March 1, 2019, at 3:00 p.m. Pacific Time and is expected to include a presentation and discussion of safety and clinical data from the ongoing dose-escalation stage of the REVEAL Phase 1/2 clinical study evaluating NKTR-262 in combination with bempedaldesleukin, as well as initial pharmacokinetic and biomarker data from the study. A recording of this analyst and investor conference call will be available for replay through April 1, 2019, on Nektar’s website, <https://ir.nektar.com/events-and-presentations/events>.

At the analyst and investor conference call, Nektar expects to make certain forward-looking statements regarding the potential therapeutic benefit of NKTR-262 in combination with bempedaldesleukin, future clinical development plans, the timing for the conclusion of the dose-escalation stage of the REVEAL Phase 1/2 clinical study, the timing for the availability of clinical and other data from clinical studies, 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 the combination of NKTR-262 in combination with bempedaldesleukin 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 (which data may include negative safety and efficacy results); (ii) both NKTR-262 and bempedaldesleukin are in the early stages of clinical development and the risk of failure for each drug candidate remains high and failure can unexpectedly occur at any time due to efficacy, safety or other unpredictable factors; (iii) preliminary clinical results from clinical studies, including results reported in case studies, remain subject to change as a result of final data audit confirmation procedures to be conducted following completion of the studies and interim data are also subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available; (iv) the timing of the commencement and end of clinical studies and the availability of clinical data may be delayed due to regulatory delays, slower than anticipated patient enrollment, manufacturing challenges, changing standards of care, evolving regulatory requirements, clinical trial design, or clinical outcomes; (v) 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-262 and bempedaldesleukin) is therefore highly uncertain and unpredictable and one or more research and development programs could fail; (vi) patents may not issue from our patent applications for our drug candidates (including NKTR-262 and bempedaldesleukin), patents that have issued may not be held enforceable by a court of law, or additional intellectual property licenses from third parties may be required; and (vii) certain other important risks and uncertainties set forth in Nektar’s Annual Report on Form 10-K for the year ended December 31, 2018 filed with the Securities and Exchange Commission on March 1, 2019. Any forward-looking statement made by Nektar at the

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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.

Item 9.01

Financial Statements and Exhibits

**Exhibit
No. Description**

99.1 Press release titled “Nektar Therapeutics Presents Preliminary Immune Activation, Safety and Clinical Activity Data from the Ongoing Dose-Escalation Stage of the REVEAL Study at 2019 ASCO-SITC Meeting” issued by Nektar Therapeutics on March 1, 2019.

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: March 1, 2019