

NEKTAR THERAPEUTICS
Form 8-K
February 15, 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): February 15, 2019

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 Number) | 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 February 15, 2019, Nektar Therapeutics, a Delaware corporation (“Nektar”), issued a press release announcing new efficacy, safety and biomarker data for metastatic urothelial carcinoma patients in the PIVOT-02 study of Nektar’s CD122-preferential IL-2 pathway agonist, bempegaldesleukin (NKTR-214), with Bristol-Myers Squibb’s Opdivo (nivolumab). 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 February 11, 2019, Nektar announced that it would host a webcast conference call with a urothelial cancer specialist and company management for analysts and investors during the 2019 American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium (GU). The conference call will be held on Friday, February 15, 2019, at 2:00 p.m. Pacific Time and is expected to include a presentation and discussion of updated clinical data of bempegaldesleukin plus nivolumab in metastatic urothelial carcinoma patients. Biomarker and translational medicine results for the combination of bempegaldesleukin and nivolumab in melanoma and urothelial cancers, as well as plans for future clinical trials involving bempegaldesleukin are also expected to be reviewed at the event. Presenters include Dr. Arlene O. Siefker-Radtke, M.D., Professor, Department of Genitourinary Medical Oncology, Division of Cancer Medicine at The University of Texas MD Anderson Cancer Center and Clinical Co-Leader of the Bladder Cancer SPORE Executive Committee. A recording of this analyst and investor conference call will be available for replay through March 15, 2019, on Nektar’s website, <https://ir.nektar.com>.

At the analyst and investor conference call, Nektar expects to make certain forward-looking statements regarding the potential therapeutic benefit of bempegaldesleukin for cancer patients, future clinical development plans for bempegaldesleukin, the potential of bempegaldesleukin in combination with other pharmacological agents including Opdivo, the timing for the initiation of new clinical studies, 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 bempegaldesleukin 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) bempegaldesleukin is in the early stages of clinical development and the risk of failure remains high and failure can unexpectedly occur due to efficacy, safety or other unpredictable factors; (iii) the preliminary clinical results from the clinical studies presented on the conference call, 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 (including whether reported unconfirmed objective responses are subsequently confirmed); (iv) 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; (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 bempegaldesleukin) 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 bempegaldesleukin), 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 our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 8, 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 |
|------------------------|--------------------|
|------------------------|--------------------|

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| <u>99.1</u> | <u>Press release titled “Clinical Data Presented from Pivot-02 Study of Bempegaldesleukin (NKTR-214) with Nivolumab in Metastatic Urothelial Carcinoma Patients at the 2019 ASCO Genitourinary Cancers Symposium” issued by Nektar Therapeutics on February 15, 2019.</u> |
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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: February 15, 2019