

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
(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))

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 bempegaldesleukin (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 bempegaldesleukin, 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 bempegaldesleukin, 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 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 (which data may include negative safety and efficacy results); (ii) both NKTR-262 and bempegaldesleukin 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 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 NKTR-262 and 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 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 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 Financial Statements and Exhibits

9.01

Exhibit

Exhibit No.	Description
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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.
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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: March 1, 2019



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

SAN FRANCISCO, March 1, 2019 /PRNewswire/ – Nektar Therapeutics (Nasdaq: NKTR) today announced early results from the ongoing dose-escalation stage of the first-in-human 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 bempedalsleukin* (NKTR-214 or bempreg), a CD122-preferential IL-2 pathway agonist. The results were presented today in an oral session at the 2019 ASCO-SITC Clinical Immuno-Oncology Symposium by Dr. Adi Diab, Assistant Professor of Melanoma Medical Oncology at The University of Texas MD Anderson Cancer Center (Oral Abstract Session B, Abstract #28, 1:00 p.m. – 2:15 p.m. PT).

NKTR-262 is designed to induce the body's innate immune response to prime antigen-specific cytotoxic T cells to fight cancer. Bempedalsleukin is designed to activate the adaptive immune system to expand and proliferate these specific cancer-fighting T cells in the tumor microenvironment.

“We’re excited by the preliminary data from the REVEAL study which demonstrate desirable changes in the tumor micro-environment consistent with the activation of both the innate and adaptive immune responses induced by NKTR-262 and bempreg,” said Dr. Jonathan Zalevsky, Chief Scientific Officer at Nektar. “The early data from REVEAL demonstrate that a comprehensive approach to activating the body’s immune system can drive abscopal anti-tumor responses even in the absence of a checkpoint inhibitor. We are looking forward to the ongoing dose-escalation and planned expansion of the study.”

The dose-escalation phase of REVEAL is ongoing. As of January 23, 2019, 13 patients were enrolled that were refractory to all prior therapies known to confer clinical benefit. Key highlights of the data presentation are:

- Maximum tolerated dose has not been reached and the dose escalation stage of the study is continuing.
 - Initial dose cohorts of NKTR-262 intra-tumoral injection combined with fixed dose of bempreg IV Q3W were well tolerated. Treatment-related adverse events were transient, characterized by Grade 1-2 flu-like symptoms (69.2%), rash (46.2%), fatigue (46.2%), pruritus (46.2%) and nausea (30.8%). There were no immune-mediated adverse events or study discontinuations due to TRAEs.
 - Local gene expression analysis of the injected tumor along with analysis of blood cells in system circulation demonstrated comprehensive activation of the immune system, including increases in the Type I interferon pathway and induction of CD4+, CD8+ and NK cell proliferation.
 - Early evidence of clinical benefit including abscopal responses in non-injected lesions was observed in the dose-escalation cohort. 11 of 13 patients in dose-escalation were evaluable for efficacy with at least one on treatment scan. 2 out of 5 evaluable patients with relapsed/refractory (R/R) melanoma who progressed on more than one prior checkpoint or I-O therapy experienced confirmed partial responses with 100% and 50% reductions in target lesions per RECIST 1.1, respectively. 2 out of 2 heavily pre-treated Stage IV leiomyosarcoma patients and 1 heavily pre-treated triple negative breast cancer patient experienced stable disease as best response.
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A copy of the full data presentation made by Dr. Diab is available on Nektar's corporate website at https://www.nektar.com/download_file/663/0.

Analyst Call

Nektar will host an analyst conference call featuring Dr. Adi Diab and company management on Friday, March 1, 2019 at 3:00 p.m. PT during the 2019 ASCO-SITC Clinical Immuno-Oncology Symposium. The conference call may be accessed by dialing 877-881-2183 (toll-free) or 970-315-0453 (international) with the conference call passcode 6970019. The webcast and slides for the conference call can be accessed through a link posted on the Investors section of the Nektar website at <https://ir.nektar.com/events-and-presentations/events>. The webcast of the conference call will be available for replay through April 1, 2019.

About Nektar Phase 1/2 REVEAL Study

REVEAL is a Nektar-sponsored, open-label, multicenter, dose escalation and dose expansion study evaluating the combination of NKTR-262 administered as an initial intratumoral injection followed by bempeg administered as an IV infusion systemically (doublet). In the Phase 2 expansion, the study also may evaluate the doublet combination with nivolumab (triplet). During the dose escalation phases, recommended Phase 2 dose (RP2D) regimens of the doublet and/or triplet combinations will be established. Following dose escalation, the dose expansion phase will evaluate the doublet and/or triplet combinations in up to 350 patients who have been diagnosed with a range of locally advanced or metastatic cancers including: melanoma, Merkel cell carcinoma, triple-negative breast cancer, ovarian cancer, renal cell carcinoma, colorectal cancer, urothelial carcinoma, or sarcoma. For more information, please visit <https://clinicaltrials.gov/> and search NCT03435640.

About Bempegaldesleukin (NKTR-214)

Bempegaldesleukin is an investigational, first-in-class, CD122-preferential IL-2 pathway agonist designed to provide rapid activation and proliferation of cancer-killing immune cells, known as CD8+ effector T cells and natural killer (NK) cells, without over activating the immune system. Bempegaldesleukin stimulates these cancer-killing immune cells in the body by targeting CD122 specific receptors found on the surface of these immune cells. CD122, which is also known as the Interleukin-2 receptor beta subunit, is a key signaling receptor that is known to increase proliferation of these effector T cells.¹ In clinical and preclinical studies, treatment with bempegaldesleukin resulted in expansion of these cells and mobilization into the tumor micro-environment.^{2,3} Bempegaldesleukin has an antibody-like dosing regimen similar to the existing checkpoint inhibitor class of approved medicines.

About NKTR-262

Cancer treatments that couple pharmacological activation of tumor antigen presentation with activation and expansion of CD8+ T and natural killer (NK) cells in the tumor environment have the potential to induce an effective anti-tumor immune response in patients. NKTR-262 is a novel small molecule agonist designed to activate toll-like receptors (TLRs). Intratumoral delivery of NKTR-262 promotes TLR activation to induce the development of antigen-specific immunity by initiating the process by which the immune system generates antigen-specific cytotoxic T cells to the patient's specific tumor.⁴ Bempeg targets CD122 specific receptors found on the surface of these cancer-killing immune cells, known as CD8+ effector T cells. By first generating antigen-specific cytotoxic T cells with NKTR-262 and then growing these CD8+ effector T cells with bempeg, the patient's entire immunity cycle can potentially be engaged to fight cancer. In preclinical studies, a single intratumoral dose of NKTR-262, administered in combination with bempeg, resulted in complete abscopal tumor regressions in multiple mouse syngeneic tumor models.⁵

About Nektar

Nektar Therapeutics is a research-based, development stage biopharmaceutical company whose mission is to discover and develop innovative medicines to address the unmet medical needs of patients. Our R&D pipeline of new investigational medicines includes treatments for cancer, auto-immune disease and chronic pain. We leverage our proprietary and proven chemistry platform in the discovery and design of our new therapeutic candidates. Nektar is headquartered in San Francisco, California, with additional operations in Huntsville, Alabama and Hyderabad, India. Further information about Nektar and its drug development programs and capabilities may be found online at <http://www.nektar.com>.

Forward-Looking Statements

This press release contains forward-looking statements which can be identified by words such as: "will," "may," "can," "planned," "designed" and similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding the therapeutic potential of NKTR-262 in combination with bempegaldesleukin, the anticipated initiation and completion of clinical studies, and the timing of the availability of results and outcomes from our clinical studies. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, anticipated events and trends, and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results to differ materially from those indicated in the forward-looking statements include, among others: (i) our statements regarding the therapeutic potential of the combination of NKTR-262 in combination with 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 (which data may include negative safety and efficacy results); (ii) both NKTR-262 and bempegaldesleukin 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 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 NKTR-262 and 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 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 us in this press release is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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¹ Boyman, J., et al., Nature Reviews Immunology, 2012, 12, 180-190.

² Charych, D., et al., Clin Can Res; 22(3) February 1, 2016

³ Diab, A., et al., Journal for ImmunoTherapy of Cancer 2016, 4(Suppl 1): P369

⁴ Adams S. Toll-like receptor agonists in cancer therapy. Immunotherapy. 2009;1(6):949-964. doi:10.2217/imt.09.70.

⁵ Kivimae, S., et al., Journal for ImmunoTherapy of Cancer 2017, 5(Suppl 2):P275

* rINN (recommended International Nonproprietary Name)
