**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**WASHINGTON, DC 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 20, 2017**

# 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 (*see* General Instruction A.2. below):

☐ 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))

**Item 7.01 Regulation FD Disclosure.**

On March 20, 2017, Nektar Therapeutics, a Delaware corporation ("Nektar"), issued a press release (the "Press Release") announcing the results from the SUMMIT-07 Phase 3 efficacy study for NKTR-181 in the treatment of patients with moderate to severe chronic low back pain. A copy of the Press Release reporting results from the Phase 3 Study is furnished herewith as Exhibit 99.1.

In the Press Release, Nektar announced that it would hold a Webcast conference call on March 20, 2017 at 5:45 a.m. (Pacific Time)/8:45 a.m. (Eastern Time) on March 20, 2017 to review the results from the Phase 3 SUMMIT-07 study. This conference call is accessible through a link that is posted on the home page and Investor section of the Nektar website: http://www.nektar.com.

The information in this report, including the exhibit hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing with the Securities and Exchange Commission made by Nektar Therapeutics, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**Item 9.01 Financial Statements and Exhibits.**

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release titled "NKTR-181 Meets Primary and Secondary Endpoints in Phase 3 SUMMIT-07 Study in Chronic Pain" issued by Nektar Therapeutics on March 20, 2017. |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**NEKTAR THERAPEUTICS**

March 20, 2017

By: */s/ Mark A. Wilson*
Mark A. Wilson
General Counsel and Secretary

**EXHIBIT INDEX**

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|---|---|
| 99.1 | Press Release titled "NKTR-181 Meets Primary and Secondary Endpoints in Phase 3 SUMMIT-07 Study in Chronic Pain" issued by Nektar Therapeutics on March 20, 2017. |

**NKTR-181 Meets Primary and Secondary Endpoints in Phase 3 SUMMIT-07 Study in Chronic Pain**

***NKTR-181 Significantly Reduced Pain in Patients with Moderate to Severe Chronic Low Back Pain***

***Primary Efficacy Endpoint Achieved (p=0.0019)***

***Analyst Conference Call and Webcast***
***Today at 5:45 a.m. PDT/8:45 a.m. EDT***

**San Francisco, March 20, 2017** – Nektar Therapeutics (Nasdaq: NKTR) today announced positive results from the SUMMIT-07 Phase 3 efficacy study of NKTR-181, a first-in-class opioid analgesic. NKTR-181 is a new chemical entity (NCE) that is the first full mu-opioid agonist molecule designed to provide potent pain relief without the high levels of euphoria that can lead to abuse and addiction with standard opioids.[1] The U.S. Food and Drug Administration (FDA) has granted the investigational medicine NKTR-181 Fast Track designation for the treatment of moderate to severe chronic pain.

“The data from this efficacy study are extremely important because they demonstrate that NKTR-181 produces strong analgesia in patients suffering from chronic pain while NKTR-181 has also demonstrated significantly lower abuse potential than oxycodone in a human abuse potential study," said clinical investigator Martin Hale, M.D., medical director of Gold Coast Research. "While standard opioid analgesics, including abuse-deterrent formulations, have been the most effective way to treat chronic pain, they are associated with serious safety concerns and many opioid-naïve patients fear taking them because of the potential for abuse and addiction. The data for NKTR-181 suggest that it is a transformational pain medicine that could fundamentally change how we treat patients with chronic pain conditions."

The SUMMIT-07 study compared twice-daily dosing of NKTR-181 tablets to placebo in the treatment of over 600 patients with moderate to severe chronic low back pain who were new to opioid therapy (opioid-naïve). The clinical trial met the primary efficacy endpoint of the study in demonstrating significantly improved chronic back pain relief with NKTR-181 compared to placebo (p=0.0019). Key secondary endpoints of the study were also met with high statistical significance.

Pain is one of the most common reasons people seek medical treatment.[2] Low back pain is the second most common cause of disability for adults in the U.S.[3] Approximately 149 million work days are lost every year because of low back pain, with total costs estimated to be $100 to 200 billion a year (of which two-thirds is due to lost wages and lower productivity).[4] A study published in the American Pain Society's *The Journal of Pain* in October 2014 estimated that 19 percent of the U.S. population, or 39 million people, suffer from some type of persistent pain.[5]

The Phase 3 SUMMIT-07 study used an enriched-enrollment randomized withdrawal (EERW) trial design in patients with moderate to severe chronic low back pain. The trial included an open-label titration period in which patients were titrated to a tolerated, effective dose of NKTR-181 (100 mg to 400 mg twice-daily). Following this open-label titration period, patients entered a double-blind, placebo-controlled treatment period in which they were randomized 1:1 to either continue to receive the tolerated, effective dose of NKTR-181 or to receive matching placebo (i.e. active drug was withdrawn) for a period of 12 weeks.

During the open-label titration period of the trial in which patients were titrated to a tolerated, effective dose of NKTR-181, average pain scores dropped by 65% (from 6.73 at screening to 2.32 at randomization, n=610).

The primary endpoint of the study was mean change in the weekly average pain score in the double-blind randomized treatment period from baseline (end of open-label titration period) to week 12 (end of double-blind randomized treatment period).

Primary and key sensitivity analyses:

- During the double-blind randomized treatment period of the trial, average pain scores increased more in the placebo arm versus NKTR-181 at week 12 from randomization baseline (1.46, placebo versus 0.92, NKTR-181, p=0.0019, n=610).
- 83% of patients completed the 12-week double-blind randomized treatment period and for these study completers, average pain scores increased more in the placebo arm versus NKTR-181 at week 12 from baseline (1.25, placebo versus 0.56, NKTR-181, p<0.0001, n=504).

Key secondary endpoints:

- A statistically significant proportion of patients on NKTR-181 experienced pain reductions greater than 30% compared to placebo (71.2% versus 57.1%; p=0.0003).
- A statistically significant proportion of patients on NKTR-181 experienced pain reductions greater than 50% compared to placebo (51.1% versus 37.9%; p=0.001).
- A statistically significant proportion of patients on NKTR-181 reported their general overall status and quality of life as “improved” or “very much improved” compared to placebo as assessed by the Patient’s Global Impression of Change (PGIC) of pain medication questionnaire (51.5% versus 33.2%; p<0.0001).

The study also demonstrated that NKTR-181 had a favorable safety profile and was well tolerated. During the double-blind randomized treatment period, the most commonly reported adverse events for patients (>5%) were nausea (10.4%) and constipation (8.7%) in the NKTR-181 arm as compared to nausea (6.0%) and constipation (3.0%) in the placebo arm.

Patients randomized to NKTR-181 as compared to placebo reported more favorable sleep outcomes as measured by the validated Medical Outcomes Study (MOS) Sleep Scale, which captures debilitating aspects of sleep most strongly associated with chronic pain. Patients reported better overall quality of sleep with less sleep problems on NKTR-181 versus placebo. There were no differences in daytime sleepiness on NKTR-181 versus placebo.

Full data from the SUMMIT-07 study will be presented at a medical meeting in the second half of 2017.

“As a new molecule, NKTR-181 has a highly differentiated profile with the potential to be one of the most important advancements in pain medicine,” said Howard W. Robin, President and CEO of Nektar Therapeutics. “Given the seriousness of the current opioid epidemic in the U.S. and the significant number of people battling chronic pain, we are committed to bringing this new molecule to patients and physicians as quickly as possible.”

In March 2017, results from a separate human abuse potential trial of NKTR-181 were published in the American Academy of Pain Medicine's journal of ***Pain Medicine***. The human abuse potential study assessed the relative abuse potential of a range of therapeutic doses of NKTR-181 (100 mg to 400 mg), the same dose range evaluated in the Phase 3 SUMMIT-07 efficacy trial. All doses of NKTR-181 tested for abuse potential were rated similarly to placebo in "drug liking" and "feeling high" scores and had highly statistically significant lower "drug liking" scores and reduced "feeling high" scores as compared to 40 mg oxycodone ($p < 0.0001$). In addition, all doses of NKTR-181 also scored lower on sleepiness when compared to 40 mg oxycodone ($p < 0.0001$).

"It is clear that there is a pressing societal need for better and safer analgesics," said Dr. Jack Henningfield, Ph.D., Adjunct Professor of Behavioral Biology in the Department of Psychiatry and Behavioral Sciences at the Johns Hopkins University School of Medicine and Head of Health Policy and Abuse Liability at Pinney & Associates in Bethesda, MD. "In the human abuse potential study, even the highest analgesic dose of NKTR-181 was barely distinguishable from placebo with respect to both drug-liking and feeling high and these effects were modest compared to those produced by oxycodone. Drug-liking and feeling high are two of the most important metrics that help us understand the abuse potential of a medicine. Importantly, as NKTR-181 is a new chemical entity, the properties of NKTR-181 are inherent to its molecular structure and independent of any abuse-deterrent formulation. Today's reported efficacy and safety results, along with the human abuse potential data published this past week in Pain Medicine, suggest NKTR-181 may be a major advance towards safer opioid therapy for the treatment of moderate to severe chronic pain."

**Conference Call and Webcast Information**
Nektar will host a conference call and webcast presentation today, March 20, 2017, at 8:45 a.m. Eastern Daylight Time to discuss the study results. The call can be accessed by dialing (877) 881-2183 (U.S.) or (970) 315-0453 (international), and entering passcode 89288091. To access the live webcast, or the subsequent archived recording, visit the Investors section of the Nektar website at www.nektar.com. The webcast will be available for replay on Nektar's website for two weeks following the call.

**About NKTR-181**
NKTR-181 is the first long-acting, selective mu-opioid agonist designed to provide potent pain relief without the inherent high levels of euphoria which lead to abuse and addiction with standard opioids. The novel molecular structure of NKTR-181 is designed to have low permeability across the blood-brain barrier in order to slow its rate of entry into the brain and attenuate the dopamine release that underlies euphoria. NKTR-181 is the first opioid molecule to exhibit reduction in specific CNS-mediated side effects, like euphoria, through the strategic alteration of brain-entry kinetics. NKTR-181 is an investigational medicine and has not been approved by the FDA or any other regulatory agencies.

Current strategies of abuse deterrence to address the addictive qualities of standard opioids rely on formulations alone. All abuse-deterrent formulations are limited in that once the opioid within the formulation is liberated through tampering, it can rapidly enter the brain and is highly euphorigenic. Preclinical data show that the inherent properties of NKTR-181 reduce its rate of entry into the brain compared to standard mu opioids, regardless of route of administration.[12]

**About the SUMMIT-07 Study Design**
SUMMIT-07 used an enriched-enrollment, randomized withdrawal (EERW) design and enrolled opioid-naïve patients ages 18 to 75 years who had moderate to severe non-neuropathic chronic low back pain for at least six months. The study included an open-label, dose-titration period followed by a randomized, double-blind, placebo-controlled 12-week treatment period.

During the open-label titration phase, study participants with pain scores of between 5 and 9 were titrated on NKTR-181 tablets administered orally twice daily until they experienced an adequate and sustained pain response (a drop of at least 2 points and a pain score below 4 on the numeric rating scale (NRS) of 0-10).

Patients who achieved this were then randomized on a 1:1 basis to either continue receiving their analgesic dose of NKTR-181 or to receive placebo (i.e. the active drug was withdrawn) during the double-blind 12-week treatment period. A total of 610 patients were randomized into the double-blind treatment period. The primary outcome was based on assessing worsening of pain in the placebo arm relative to the active arm for patients who achieved substantial analgesic responses with NKTR-181. The primary efficacy endpoint was a change in pain as measured by the change in a patient's weekly pain score from baseline to week 12 of the randomized, double-blind, treatment period.

**About Opioids and Abuse**

Pain is one of the most common reasons people seek medical treatment.[2] A study published in the American Pain Society's *The Journal of Pain* in October 2014 estimated that 19 percent of the U.S. population, or 39 million people, suffer from persistent pain.[5]

Opioids are considered the most effective therapeutic option for pain. In 2016, 230 million opioid prescriptions were written in the U.S.[6] However, these painkillers can cause serious side effects such as respiratory depression and sedation, and they have the potential for addiction, abuse and misuse.[7] In 2014, nearly 2 million Americans either abused or were dependent on prescription opioid pain relievers.[8] One in five Americans say they have a family member who has been addicted to prescription painkillers.[9] In 2015, there were nearly 22,000 deaths involving prescription opioids in the U.S.[10]

According to a 2011 Institute of Medicine Report, pain is a significant public health problem that costs society at least $560 to 635 billion annually. [2] In the U.S., prescription opioid abuse costs were about $78.5 billion in 2013.[11]

**About Nektar Therapeutics**

Nektar Therapeutics is a research-based 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 Nektar's 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 the company and its drug development programs and capabilities may be found online at http://www.nektar.com.

Cautionary Note Regarding Forward-Looking Statements

*This press release contains forward-looking statements which can be identified by words such as: "plan," "expect," "may," "will" and similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding the potential therapeutic benefit of NKTR-181 for treating patients with pain, the potential importance of NKTR-181's development in the area of new pain medicines, the risks of opioid abuse resulting from new and existing pain medicines, future development plans for NKTR-181 (including, but not limited to, future clinical development plans and future regulatory filings seeking regulatory approval for NKTR-181), the potential timeframe for commercial availability of NKTR-181, and certain other statements regarding the prospects and potential of NKTR-181 specifically, and Nektar's business and technology platform generally. 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, the economy 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) challenges and uncertainties inherent in pharmaceutical research and development, including the uncertainty of future clinical and regulatory success, where the risk of failure remains high and failure can unexpectedly occur at any stage prior to regulatory approval due to lack of sufficient efficacy, safety considerations or other factors; (ii) the regulatory pathway to review and approve NKTR-181 for use in patients, even with a Fast Track designation by the FDA, is subject to substantial uncertainty; (iii) regulations concerning and controlling the access to opioid-based pharmaceuticals are strict and there is no guarantee which scheduling category will apply to NKTR-181 if regulatory approval is achieved; (iv) the partnering process for NKTR-181 is at a very early stage and there is therefore substantial uncertainty as to the timing and terms of a potential partnership, or the success of our partnering efforts; (v) drug manufacturing challenges which can delay or render unavailable sufficient supplies of NKTR-181; (vi) changing standards of care and new regulations (including, but not limited to, standards and regulations related to health care cost containment) can affect the use NKTR-181 and commercial success following a regulatory approval; (vii) Nektar's patent applications for NKTR-181 may not issue in one or more jurisdictions, patents that have issued may not be enforceable, or additional intellectual property licenses from third parties may be required in the future; (viii) the outcome of any existing or future intellectual property or other litigation related to Nektar's proprietary product candidates, including, without limitation, NKTR-181, is unpredictable and could have a material adverse effect on our business; and (ix) certain other important risks and uncertainties set forth in Nektar's Annual Report on Form 10-K for the year ended December 31, 2016 filed with the Securities and Exchange Commission on March 1, 2017. 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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