

NEKTAR THERAPEUTICS
Form 8-K
October 17, 2016

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): October 17, 2016

NEKTAR THERAPEUTICS

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction

of Incorporation)

0-24006
(Commission

File Number)
455 Mission Bay Boulevard South

94-3134940
(IRS Employer

Identification No.)

Edgar Filing: NEKTAR THERAPEUTICS - Form 8-K

San Francisco, California 95128

(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))

Item 2.02 Results of Operations and Financial Condition.

Please see the disclosure set forth under Item 7.01 Regulation FD Disclosure, which is incorporated by reference into this Item 2.02.

Item 7.01 Regulation FD Disclosure.

On October 17, 2016, Nektar Therapeutics, a Delaware corporation (Nektar), issued a press release announcing that it has commenced an underwritten public offering of \$175 million of shares of its common stock. In connection with this offering, Nektar will also grant to the underwriters a 30-day option to purchase up to an additional \$26.25 million of shares of common stock. J.P. Morgan is acting as the sole book-running manager in the offering. A copy of the press release is furnished herewith as Exhibit 99.1 to this Current Report.

Based upon preliminary estimates, Nektar had cash and investments in marketable securities of approximately \$253.5 million as of September 30, 2016. This financial information has been prepared by and is the responsibility of Nektar's management and has not been reviewed by Nektar's independent registered public accounting firm, and, accordingly, Nektar's independent registered public accounting firm does not express an opinion on, or provide any other form of assurance with respect to, this preliminary data. This financial information is subject to completion of Nektar's quarterly financial closing procedures, the preparation of Nektar's consolidated financial statements, and the performance of a review of Nektar's consolidated financial statements by Nektar's independent registered public accounting firm as of and for the three- and nine-month periods ended September 30, 2016. Nektar's actual results may differ from these estimates.

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, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 8.01 Other Information.

This Current Report on Form 8-K updates the Annual Report on Form 10-K of Nektar for the year ended December 31, 2015 and Nektar's most recent Quarterly Report on Form 10-Q for the quarter ended June 30, 2016 to reflect the following:

Company Overview

We are a biopharmaceutical company developing a pipeline of drug candidates that utilize our PEGylation and advanced polymer conjugate technology platforms, which are designed to enable the development of new molecular entities that target known mechanisms of action. Our current proprietary pipeline is comprised of drug candidates across a number of therapeutic areas including oncology, pain, anti-infectives, and immunology. Our research and development activities involve small molecule drugs, peptides and protein biologic drug candidates. We create innovative drug candidates by using our proprietary advanced polymer conjugate technologies and expertise to modify the chemical structure of pharmacophores to create new molecular entities. Polymer chemistry is a science focused on the synthesis or bonding of polymer architectures with drug molecules to alter the properties of a molecule. Additionally, we may utilize established pharmacologic targets to engineer a new drug candidate relying on a combination of the known properties of these targets and our proprietary polymer chemistry technology and expertise. Our drug candidates are designed to improve the overall benefits and use of a drug for patients by improving the

Edgar Filing: NEKTAR THERAPEUTICS - Form 8-K

metabolism, distribution, pharmacokinetics, pharmacodynamics, half-life and/or bioavailability of drugs. Our objective is to apply our advanced polymer conjugate technology platform to create new drug candidates in multiple therapeutic areas that address large potential markets.

Commercial Stage Partnered Portfolio

In 2014, we achieved the first approval of one of our proprietary drug candidates based on our polymer conjugation technology, MOVANTIK™ (naloxegol), under a global license agreement with AstraZeneca AB (AstraZeneca). MOVANTIK™ is an oral peripherally-acting opioid antagonist, for the treatment of opioid-induced constipation, or OIC, a side effect caused by chronic administration of prescription opioid pain medicines. AstraZeneca markets and sells MOVANTIK™ in the United States in collaboration with Daiichi Sankyo, Inc. (Daiichi). On March 31, 2015, AstraZeneca and Daiichi launched MOVANTIK™ in the United States. On March 1, 2016, AstraZeneca entered into an agreement with ProStrakan Group plc (ProStrakan), a subsidiary of Kyowa Hakko Kirin Co. Ltd., granting ProStrakan exclusive marketing rights to MOVENTIG® (the naloxegol brand name in the EU) in the EU, Iceland, Liechtenstein, Norway and Switzerland. Under the terms of that agreement, ProStrakan made a \$70 million upfront payment to AstraZeneca and will make future payments based on achieving market access milestones, tiered net sales royalties, as well as sales milestones. Under our license agreement, AstraZeneca and Nektar shared the upfront payment and will share the market access milestones, royalties and sales milestones from ProStrakan with AstraZeneca receiving 60% and Nektar receiving 40%.

We have a collaboration with Baxalta Incorporated (Baxalta) to develop and commercialize PEGylated drug candidates with the objective of providing new long-acting therapies for hemophilia patients. Under this collaboration, we worked with Baxalta to develop ADYNOVATE™, an extended half-life recombinant factor VIII (rFVIII) treatment for Hemophilia A based on ADVATE®. In November 2015, ADYNOVATE™ was approved by the U.S. Food and Drug Administration (FDA) for use in adults and adolescents, aged 12 years and older, who have Hemophilia A. Baxalta announced the launch and first shipments of ADYNOVATE™ on November 30, 2015. On April 4, 2016, Baxalta announced that the Ministry of Health, Labour and Welfare in Japan approved ADYNOVATE™ for patients aged 12 years and older with Hemophilia A. ADYNOVATE™ is also under regulatory review in Europe, Switzerland and Canada.

Development Stage Partnered Portfolio

We have two significant drug development programs with Bayer. The first is a collaboration to develop BAY41-6551 (Amikacin Inhale, formerly known as NKTR-061), which is an inhaled solution of amikacin, an aminoglycoside antibiotic. We originally developed the liquid aerosol inhalation platform and the NKTR-061 drug candidate and entered into a collaboration agreement with Bayer to further advance the drug candidate's development and potential commercialization. Bayer is currently enrolling patients in a Phase 3 clinical study for Amikacin Inhale. Bayer is conducting this study under a Special Protocol Assessment process agreed to with the FDA and topline data is anticipated in the first quarter of 2017. The second is the Cipro DPI (Cipro Dry Powder Inhaler, previously called Cipro Inhale) program with Bayer. We retained significant royalty rights in this pulmonary program, but otherwise transferred development responsibility to Novartis as part of the 2008 pulmonary asset divestiture transaction. In August 2012, Bayer initiated a global Phase 3 program called RESPIRE for the Cipro DPI product candidate in patients with non-cystic fibrosis bronchiectasis. These programs represent a significant future economic opportunity for us.

We have a license, manufacturing and supply agreement with Ophthotech Corporation (Ophthotech) for Fovista®, an anti-platelet-derived growth factor (anti-PDGF) agent, currently in Phase 3 development for the treatment of wet age-related macular degeneration. Data for the Phase 3 program of Fovista® is anticipated in the fourth quarter of 2016. Ophthotech expected that, if the FDA grants priority review, Fovista® could be launched in U.S. as early as in the fourth quarter of 2017.

We have a license, manufacturing and supply agreement with Halozyme Therapeutics, Inc. for PEG-PH20, which is entering Phase 3 development for the treatment of pancreatic cancer. We have a license, manufacturing and supply agreement with UCB Pharma for dapirolizumab pegol, a monovalent pegylated Fab antibody fragment against the

Edgar Filing: NEKTAR THERAPEUTICS - Form 8-K

CD40 ligand (CD40L), being developed for the treatment of autoimmune diseases, including systemic lupus erythematosus for which the candidate is entering Phase 2 development with UCB partner Biogen. We also have a number of license, manufacturing and supply agreements with other leading biotechnology and pharmaceutical companies, including Amgen Inc., Allergan, Inc., Merck & Co., Inc., Pfizer, Inc. and F. Hoffmann-La Roche Ltd. A total of ten products using our PEGylation technology have received regulatory approval in the U.S. or EU. There are also a number of other products in clinical development that incorporate our advanced PEGylation and advanced polymer conjugate technologies.

Nektar Proprietary Portfolio

ONZEALD for metastatic breast cancer

NKTR-102 (etirinotecan pegol, also known as ONZEALD™) is our next-generation topoisomerase I inhibitor proprietary drug candidate. In 2015, we announced topline data from a Phase 3 clinical study for NKTR-102, which we call the BEACON study (BrEAst Cancer Outcomes with NKTR-102), as a single-agent therapy for women with advanced metastatic breast cancer. The BEACON study compared NKTR-102 to an active control arm comprised of a single chemotherapy agent of physician's choice (TPC) in patients who were heavily pre-treated with a median of three prior therapies for metastatic disease. In a topline analysis of 852 patients from the trial, NKTR-102 provided a 2.1 month improvement in median overall survival over TPC (12.4 months for patients receiving NKTR-102 compared to 10.3 months for patients receiving TPC). Based on a stratified log-rank analysis, the primary endpoint measuring the hazard ratio for survival in the NKTR-102 group compared to the active control arm was 0.87 with a p-value of 0.08, which did not achieve statistical significance. Secondary endpoints in the BEACON study included objective response rate and progression-free survival, which did not achieve statistical significance in the study. We also announced that we observed a significant overall survival benefit in two pre-specified subgroups: patients with a history of brain metastases and patients with baseline liver metastases at study entry.

We have explored future regulatory and development paths forward for ONZEALD™ with the EU and U.S. health authorities. In Europe, we met with the National Authorities in Sweden and the United Kingdom to discuss the BEACON data. On May 26, 2016, the Committee for Medicinal Products for Human Use granted an accelerated assessment procedure for the planned ONZEALD™ filing, which provides for an accelerated marketing authorization application (MAA) review timeline. In June 2016, we also met with the European Medicines Agency (EMA) and filed an MAA for conditional approval of ONZEALD™ for adult patients with advanced breast cancer who have brain metastases. On July 14, 2016, we received a letter from the EMA notifying us that the ONZEALD™ application successfully passed validation to be accepted for review. As contemplated by our recently announced European commercialization collaboration with Daiichi and in connection with our MAA filing for ONZEALD™, in 2016 we plan to initiate a randomized Phase 3 confirmatory study to evaluate ONZEALD™ as compared to a single-agent chemotherapy of physician's choice in approximately 350 adult patients with advanced breast cancer who have brain metastases (Confirmatory Study). The primary endpoint of the Confirmatory Study will be overall survival and the Confirmatory Study will include a pre-specified interim analysis for overall survival which is to be conducted after 130 events have occurred in the study. In addition, based on our meetings with the FDA's Oncology Division, the FDA staff has indicated that positive results from the Confirmatory Study could also support an NDA filing in the U.S. where Nektar has retained all rights to ONZEALD™.

NKTR-181 for chronic pain

NKTR-181 is a novel mu-opioid analgesic drug candidate for chronic pain conditions and is currently in Phase 3 clinical development. We enrolled the first patient in the first Phase 3 efficacy study in February 2015 and we recently completed enrollment in the study. In this study, we are randomizing patients with chronic low back pain in an enriched enrollment randomized withdrawal design which will include a qualifying screening period, an open-label titration period where NKTR-181 is given to all patients, followed by a 12 week double-blind randomized period where subjects will be randomized on a 1:1 basis to receive either NKTR-181 or placebo. On February 29, 2016, we increased the sample size of this trial by 200 patients following a prespecified sample size assessment by an independent analysis center after approximately fifty percent of the initially planned 416 patients completed the study. We anticipate topline data from the Phase 3 efficacy portion of this trial in the first quarter of 2017.

Nektar 214 Immuno-oncology program

Edgar Filing: NEKTAR THERAPEUTICS - Form 8-K

In December 2015, we dosed the first patient in a Phase 1/2 clinical study for NKTR-214, which is our engineered immunostimulatory CD122-biased cytokine designed to preferentially activate the beta and gamma sub-units of the IL-2 receptor with the objective to induce proliferation of tumor-killing T cells within the body (CD8-positive effector T cells and natural killer T cells) without stimulating regulatory T cells (CD4-positive T cells). The study is being conducted at two primary investigator sites: the University of Texas MD Anderson Cancer Center and Yale Cancer Center. The dose-escalation stage of the Phase 1/2 study is designed to evaluate safety and efficacy, and define the recommended Phase 2 dose of NKTR-214 in patients with solid tumors. In addition to a

determination of the recommended Phase 2 dose, the study will assess preliminary anti-tumor activity, including objective response rate. The immunologic effect of NKTR-214 on tumor-infiltrating lymphocytes and other immune infiltrating cells in both blood and tumor tissue will also be assessed.

On September 27, 2016, we entered into a Clinical Trial Collaboration Agreement with Bristol-Myers Squibb Company (BMS) to conduct Phase 1/2 clinical trials evaluating NKTR-214, and BMS' s human monoclonal antibody that binds PD-1, known as Opdivo (nivolumab), as a potential combination treatment regimen in five tumor types and seven potential indications. Under the Agreement, BMS will be responsible for 50% of all out-of-pocket costs reasonably incurred in connection with third party contract research organizations, laboratories, clinical sites and institutional review boards. Each party will otherwise be responsible for its own internal costs.

Ownership of, and global commercial rights to, NKTR-214 remain solely with us under the Agreement. If we wish to license the right to commercialize NKTR-214 in one of certain major market territories prior to September 30, 2018 (the Exclusivity Expiration Date), we must first negotiate with BMS, for a period of three months (the Negotiation Period) to grant an exclusive license to develop and commercialize NKTR-214 in any of these major market territories. If BMS and we do not reach an agreement for an exclusive license within the Negotiation Period, we will be free to license any right to NKTR-214 to other parties in any territory worldwide except that in the event that we receive a license offer from a third party during a period of 90 calendar days after the end of the Negotiation Period, we will provide BMS ten business days to match the terms of such third-party offer. After the Exclusivity Expiration Date, we are free to license NKTR-214 without any further obligation to BMS.

NKTR-358 for autoimmune diseases

We are developing NKTR-358, a drug candidate currently being studied pre-clinically for use in autoimmune diseases. NKTR-358 is an immune-regulatory cytokine targeting the IL-2 pathway to stimulate growth of regulatory T cells (T-reg). In healthy people, T-regs regulate protective immune responses by suppressing auto-reactive effector T cells and engaging the natural capability of the immune system to return itself to homeostasis. In people with autoimmune diseases, T-regs fail to suppress auto-reactive T cells due to impaired function or low frequency and this imbalance can cause the immune system to attack healthy tissue. Current systemic treatments for autoimmune diseases, including corticosteroids and anti-TNF agents, suppress the immune system broadly and come with severe side effects. NKTR-358 is designed to selectively bind to the IL-2Rag receptor to proliferate T-regs without stimulating effector T cells and restoring balance to the immune system. We currently plan to submit an Investigational New Drug application for NKTR-358 in the first quarter of 2017.

NKTR-255 Immuno-oncology program

We are developing NKTR-255, one of our immune-oncology product candidates that is currently being studied pre-clinically. NKTR-255 is a memory T cell stimulating cytokine designed to engage the IL-15 pathway to induce long-term T cell activation and improve the quality of T cell memory response to treat cancer. Through enhanced engagement of the IL-15Ra/IL-2Rg receptor complex, NKTR-255 stimulates proliferation and survival of CD8+ T cells, natural killer cells and enhances formation of long-term immunological memory which may lead to sustained anti-tumor immune response. Native rhIL-15 is rapidly cleared from the body and must be administered frequently and in high doses limiting its utility due to toxicity. NKTR-255 is designed with IL-15 receptor alpha specificity to enhance biological activity and improve safety profile.

Forward-Looking Statements

This report includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact are forward-looking statements for purposes of this current report on Form 8-K, including statements

Edgar Filing: NEKTAR THERAPEUTICS - Form 8-K

concerning the completion, timing and size of the offering, any projections of market size, earnings, revenue, milestone payments, royalties, sales or other financial items, any statements of the plans and objectives of management for future operations (including, but not limited to, preclinical development, clinical trials and manufacturing), any statements related to our financial condition and future working capital needs, any statements regarding potential future financing alternatives, any statements concerning proposed drug candidates, any statements

regarding the timing for the start or end of clinical trials or submission of regulatory approval filings, any statements regarding future economic conditions or performance, any statements regarding the success of our collaboration arrangements, timing of commercial launches and product sales levels by our collaboration partners and future payments that may come due to us under these arrangements, any statements regarding our plans and objectives to initiate or continue clinical trials, and any statements of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as *may*, *will*, *expects*, *plans*, *anticipates*, *estimates*, *potential* or *continue*, or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, such expectations or any of the forward-looking statements may prove to be incorrect and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including, but not limited to, the risk factors set forth in Part II, Item 1A *Risk Factors* in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2016 and for the reasons described elsewhere therein. All forward-looking statements and reasons why results may differ included in this report are made as of the date hereof and we do not intend to update any forward-looking statements except as required by law or applicable regulations. Except where the context otherwise requires, in this current report on Form 8-K, the *Company*, *Nektar*, *we*, *us*, and *our* refer to Nektar Therapeutics, Delaware corporation, and, where appropriate, its subsidiaries.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit

No.	Description
99.1	Press release titled <i>Nektar Therapeutics Announces Public Offering of Shares of Common Stock</i> issued by Nektar Therapeutics on October 17, 2016.

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 thereunto duly authorized.

Nektar Therapeutics

Date: October 17, 2016

By: /s/ Gil M. Labrucherie
Gil M. Labrucherie
Senior Vice President and Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release titled Nektar Therapeutics Announces Public Offering of Shares of Common Stock issued by Nektar Therapeutics on October 17, 2016.