NEKTAR THERAPEUTICS
Form 8-K
September 27, 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): September 21, 2016

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 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 1.01 Entry into a Material Definitive Agreement.

On September 21, 2016, Nektar Therapeutics, a Delaware corporation ("Nektar"), entered into a Clinical Trial Collaboration Agreement (the "Agreement") with Bristol-Myers Squibb Company, a Delaware corporation ("BMS"), pursuant to which Nektar and BMS will collaborate to conduct Phase 1/2 clinical trials evaluating Nektar's IL-2-based CD122-biased agonist, known as NKTR-214, and BMS's human monoclonal antibody that binds PD-1, known as Nivolumab, as a potential combination treatment regimen in five tumor types and seven potential indications, and such other clinical trials evaluating the combined therapy as may be mutually agreed upon by the parties (each, a "Combined Therapy Trial").

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, including internal personnel costs, incurred in connection with each Combined Therapy Trial. Nektar and BMS will use commercially reasonable efforts to manufacture and supply its compound for each Combined Therapy Trial and will bear the costs related thereto. The parties will form a joint development committee to oversee clinical trial design, regulatory strategy, and other activities necessary to conduct and support the Combined Therapy Trials. Nektar will act as sponsor of each Combined Therapy Trial.

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

Each party grants to the other party a non-exclusive, worldwide (subject to certain exceptions in the case of the license granted by BMS), non-transferable and royalty-free research and development license to such licensing party's patent rights, technology and regulatory documentation to use its compound solely to the extent necessary to discharge its obligations under the Agreement with respect to the conduct of the Combined Therapy Trials.

The Agreement also contains certain reciprocal exclusivity provisions that run until the Exclusivity Expiration Date. Nektar agrees not to conduct any preclinical or clinical research with, or grant rights under its proprietary intellectual property or relevant investigational new drug applications to, certain restricted third parties regarding an anti-PD-1 antagonist or anti-PD-L1 antagonist together with the NKTR-214 (a "Restricted NKTR-214 Combination"), and BMS agrees not to conduct any preclinical or clinical research with certain restricted third parties regarding Nivolumab

together with an IL2-based CD122 agonist (a "Restricted Nivolumab Combination"). Nektar and BMS remain free to conduct any preclinical or clinical research—involving a Restricted NKTR-214 Combination in the case of Nektar and a Restricted Nivolumab Combination in the case of BMS—on their own or in collaboration with academic or other non-profit entities.

Subject to termination rights for breach, bankruptcy or a material safety issue/clinical hold, the term of the Agreement will continue in effect until completion by all centers or institutions participating in the Combined Therapy Trials, the delivery of study data to both parties and the completion of any then agreed upon protocol, statistical analysis and bioanalysis plan. In the event a third party merges with or acquires Nektar, Nektar is free to assign or transfer the Agreement without the consent of BMS.

The foregoing summary does not purport to be complete and is qualified in its entirety by reference to the Agreement, a copy of which will be filed as an exhibit to Nektar's Quarterly Report on Form 10-Q for the period ended September 30, 2016.

Item 7.01 Regulation FD Disclosure.

On September 27, 2016, BMS and Nektar jointly issued a press release attached hereto as Exhibit 99.1 ("Press Release"), announcing the entry into the Agreement.

The information in this Item 7.01, including Exhibit 99.1, is being furnished and shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall such information be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as otherwise stated in such filing.

Item 8.01 Other Events.

On September 27, 2016, Nektar announced that it would hold a Webcast conference call on September 27, 2016, at 9:00 a.m. Eastern Time to review the collaboration with BMS and give an update on the NKTR-214 development program. This conference call is accessible through a link that is posted on the home page and Investor Relations section of the Nektar website: http://www.nektar.com. On this conference call, management expects to make certain forward-looking statements regarding the therapeutic potential of NKTR-214 both as a single agent and in combination with other cancer therapies such as Nivolumab, the potential benefits of the BMS collaboration, plans and expectations for the conduct and completion of future clinical studies, and certain other forward looking statements regarding Nektar's business. These forward-looking statements involve substantial risks and uncertainties including but not limited to:

· NKTR-214 is in early-stage clinical development and there are substantial risks that can unexpectedly occur for numerous reasons, including negative safety and efficacy findings in the ongoing Phase 1/2 clinical study notwithstanding positive findings from interim clinical results and preclinical studies;

· The clinical observations from the ongoing Phase 1/2 clinical trial of NKTR-214 are based on preliminary data from an ongoing clinical trial that is still actively enrolling patients and these preliminary data may not be representative of final results after all patients complete the trial and all data are collected and analyzed. Further, this preliminary data is subject to continuing audit and verification procedures that will not be complete until the conclusion of the trial and therefore the interim data is subject to change;

· The timing of the commencement or end of clinical trials 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;

· 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-214) is therefore highly uncertain and unpredictable and one or more research and development programs could fail;

· Patents may not issue from our patent applications for our drug candidates including NKTR-214, patents that have issued may not be enforceable, or additional intellectual property licenses from third parties may be required; and

· Other important risks and uncertainties set forth in Nektar's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 4, 2016 and available at www.sec.gov.

Actual results could differ materially from the forward-looking statements made by management during the conference call and in the Press Release. 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.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release titled “Bristol-Myers Squibb and Nektar Therapeutics Form Oncology Clinical Collaboration to Evaluate the Combination of Opdivo (nivolumab) and NKTR-214” issued on September 27, 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: September 27, 2016 By: /s/ Gil M. Labrucherie
Gil M. Labrucherie
Senior Vice President and Chief Financial Officer

EXHIBIT INDEX

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