

NEKTAR THERAPEUTICS

FORM 8-K (Current report filing)

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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): July 23, 2017

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 1.01. Entry into a Material Definitive Agreement

On July 23, 2017, Nektar Therapeutics, a Delaware corporation (“Nektar”), entered into a License Agreement (the “Agreement”) with Eli Lilly and Company, an Indiana corporation (“Lilly”). The Agreement is subject to review by the U. S. Government under the Hart-Scott-Rodino Act (the “HSR Act”) and will not become effective until the expiration or earlier termination of the waiting period (or any extension thereof). Either party may terminate the Agreement 120 days after the date of filing under the HSR Act, if the transaction is not effective by that date.

Under the terms of the Agreement, Nektar and Lilly agree to co-develop Nektar’s proprietary product candidate NKTR-358, which is an investigational compound that is a potential immunological therapeutic targeting the interleukin receptor complex, and certain other pharmacologically related compounds (the “Licensed Compounds”) that selectively stimulate the growth and activation of regulatory T cells designed to suppress an immune response (the “Field”). Pursuant to the Agreement, Nektar granted Lilly a worldwide, exclusive, perpetual, royalty-bearing, sub-licensable license to the Licensed Compounds solely in the Field. Neither Lilly nor Nektar may develop the Licensed Compounds outside the Field.

Under the terms of the Agreement, Lilly agreed to pay Nektar a non-refundable up-front payment of \$150 million. Nektar and Lilly agreed to co-develop the NKTR-358 with Nektar responsible for completing Phase 1 clinical development, and Lilly paying 75% and Nektar paying 25% of the costs of Phase 2 development. Lilly will pay the costs of Phase 3 development; provided that Nektar shall have the option to pay up to 25% of the costs of global Phase 3 development on an indication-by-indication basis. Nektar is eligible to receive up to \$250 million in development and regulatory milestones.

Nektar is also eligible to receive royalty payments. If Nektar elects during the initiation of a global Phase 3 development program to contribute up to its maximum share of 25% (“Full Share Contribution”) of the Phase 3 development costs (the “Phase 3 Costs”), then Nektar will be entitled to a two tier royalty rate on global net sales with the first tier in the mid-teens and the second tier in the low twenties (“Full Share Rates”). If Nektar elects to make no contribution to Phase 3 Costs, then Nektar will be entitled to a two tier royalty on global net sales with the first tier in the high single digits and the second tier in the low double digits (“No Share Rates”). If Nektar elects to contribute between 0 to 25% of the Phase 3 Costs, then the royalty rates fluctuate between the Full Share Rates and the No Share Rates proportionally based on Nektar’s actual contribution to the Phase 3 Costs and the amount of the Full Share Contribution. Nektar’s right to receive royalties (subject to certain adjustments) in any particular country will expire upon the later of (a) specified period of time after the first commercial sale of the product in that country, (b) the expiration of regulatory exclusivity in that particular country, or (c) the expiration of patent rights in that particular country.

Nektar and Lilly agreed to enter into supply agreements. Lilly will have exclusive pre-clinical, clinical and commercial manufacturing rights, subject to Nektar’s limited, specified manufacturing rights. Lilly will bear all costs associated with commercialization and will control commercialization decisions; provided that Nektar will have the option to co-promote in the U.S. if it elects to do so during a period prior to commercial launch. Each party retains rights to its own intellectual property and an equal interest in jointly-developed intellectual property in connection with the work conducted under or in connection with the Agreement.

Pursuant to the terms of the Agreement, each of Nektar and Lilly agrees, until the first commercial sale of a product, not to develop, license, or commercialize, certain competing products relating to interleukin-2 or aldesleukin that have activity primarily targeted in the Field.

The Agreement includes various representations, warranties, covenants, indemnities and other provisions customary for transactions of this nature. Lilly may terminate the Agreement at any time without cause following a specified notice period, subject to delay if commercial sales have commenced. Either party may terminate the Agreement in the event of an uncured material breach.

The foregoing summary is qualified in its entirety by reference to the Agreement. Nektar will seek from the Securities and Exchange Commission confidential treatment for portions of the Agreement, which Agreement, subject to such confidential treatment, will be filed as an exhibit to Nektar’s Quarterly Report on Form 10-Q for the period ended September 30, 2017.

Item 7.01. Regulation FD Disclosure

On July 24, 2017, Nektar and Lilly issued a joint press release announcing entry into the Agreement, which is filed herewith as Exhibit 99.1 to this Current Report. 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.

FORWARD LOOKING STATEMENTS

In this Form 8-K Nektar makes certain forward-looking statements regarding the collaboration with Lilly. These forward-looking statements involve substantial risks and uncertainties including but not limited to: (i) laboratory research and clinical trials are long, expensive and uncertain processes and the successful completion of future development and regulatory milestones will be required in order for Nektar to realize future milestone payments under the Agreement, (ii) the risk of failure of any product that is in pre-clinical and clinical development and prior to regulatory approval is high and can occur at any stage due to efficacy, safety or other factors, (iii) any failure would likely result in reduced or no further payments to Nektar from Lilly, (iv) competing alternative therapies that are currently on the market or under development could reduce the commercial potential of the products which could materially reduce Nektar's royalty revenue and sales milestones under the Agreement, (v) the Agreement could be terminated by Lilly at any time without cause, subject to limitation only after commercial sales have commenced, (vi) Lilly and Nektar may not be successful in obtaining regulatory approval of the products, (vii) the products may not achieve a minimally acceptable commercial profile based on results of clinical trials or competing therapies that target one or more of the same indications, (viii) Nektar's patent applications for the products which have not already issued may not issue, or even if such patents issue, the claims contained in such pending patents and patents that have already been issued to Nektar may not provide sufficient market exclusivity, (ix) current patents and future patents that may issue may not be valid or enforceable and (x) potential future third-party intellectual property disputes. Other important risks and uncertainties are detailed in Nektar's reports and other filings with the SEC including its most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q. Actual results could differ materially from the forward-looking statements. Nektar undertakes no obligation to update forward-looking statements, whether as a result of new information, future events or otherwise.

(d) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release issued on July 24, 2017 by Nektar Therapeutics and Eli Lilly and Company announcing their collaboration for development of NKTR-358.

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.

Date: July 24, 2017

Nektar Therapeutics

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

EXHIBIT INDEX

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99.1	Press Release issued on July 24, 2017 by Nektar Therapeutics and Eli Lilly and Company announcing their collaboration for development of NKTR-358.



**Lilly and Nektar Therapeutics Announce Alliance to Develop and Commercialize
NKTR-358, A Novel Autoimmune Therapy**

INDIANAPOLIS & SAN FRANCISCO — Eli Lilly and Company (NYSE: LLY) and Nektar Therapeutics (NASDAQ: NKTR) have announced a strategic collaboration to co-develop NKTR-358, a novel immunological therapy discovered by Nektar. NKTR-358, which achieved first human dose in Phase 1 clinical development in March of 2017, has the potential to treat a number of autoimmune and other chronic inflammatory conditions.

NKTR-358 is a potential first-in-class resolution therapeutic that may address an underlying immune system imbalance in patients with many autoimmune conditions. It targets the interleukin (IL-2) receptor complex in the body in order to stimulate proliferation of powerful inhibitory immune cells known as regulatory T cells. By activating these cells, NKTR-358 may act to bring the immune system back into balance. This could lead to a profound clinical impact and healthy organ function in autoimmune conditions.

“We look forward to working with Nektar to study this novel approach to treating a number of autoimmune conditions,” said Thomas F. Bumol, Ph.D., Senior Vice President of Biotechnology and Immunology Research at Lilly. “NKTR-358 is an exciting addition to our immunology portfolio and reinforces Lilly’s commitment to sustain a flow of innovative medicines in our pipeline.”

Under the terms of the agreement, Nektar will receive an initial payment of \$150 million and is eligible for up to \$250 million in additional development and regulatory milestones. Lilly and Nektar will co-develop NKTR-358 with Nektar responsible for completing Phase 1 clinical development. The parties will share Phase 2 development costs 75 percent Lilly and 25 percent Nektar. Nektar will have the option to participate in Phase 3 development on an indication-by-indication basis. Nektar has the opportunity to receive double-digit royalties that increase commensurate with their Phase 3 investment and product sales. Lilly will be responsible for all costs of global commercialization. Nektar will have an option to co-promote in the U.S. under certain conditions.

“We are very pleased to enter into this collaboration with Lilly as they have strong expertise in immunology and a successful track record in bringing novel therapies to market,” said Howard W. Robin, Nektar’s President and Chief Executive Officer. “Importantly, this agreement enables the broad development of NKTR-358 in multiple autoimmune conditions in order to achieve its full potential as a first-in-class resolution therapeutic.”

This transaction is subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act and other customary closing conditions. Subject to the closing of this transaction, Lilly expects to incur an acquired in-process research and development charge to earnings in 2017 of approximately \$0.09 per share. The company’s reported earnings per share guidance in 2017 is expected to be reduced by the amount of the charge. There will be no change to the company’s non-GAAP earnings per share guidance as a result of this transaction.

About Eli Lilly and Company

Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com and <http://newsroom.lilly.com/social-channels>.

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>.

Lilly Forward-Looking Statement

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about the benefits of a strategic alliance between Lilly and Nektar Therapeutics, and the potential benefits of NKTR-358, and reflects Lilly's current beliefs. However, as with any such undertaking, there are substantial risks and uncertainties in the process of drug development and commercialization. Among other things, there can be no guarantee that Lilly will realize the expected benefits of the collaboration, or that NKTR-358 will yield commercially successful products. For a further discussion of these and other risks and uncertainties that could cause actual results to differ from Lilly's expectations, please see Lilly's most recent Forms 10-K and 10-Q filed with the U.S. Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.

Nektar Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements which can be identified by words such as: "potential," "plan," "expect," "should," "will" and similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding: (i) the therapeutic and commercial potential of NKTR-358; (ii) development plans related to NKTR-358; and (iii) the potential of our technology and drug candidates in our research and development pipeline. 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. 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) NKTR-358 is in early-stage clinical development and the risk of failure remains high and failure can unexpectedly occur; (ii) the timing of the commencement or end of clinical trials and the availability of clinical data may be delayed or unsuccessful due to many factors; (iii) patents may not issue from our patent applications for NKTR-358, patents that have issued may not be enforceable, or additional intellectual property licenses from third parties may be required; and (iv) certain other important risks and uncertainties set forth in our Quarterly Report on Form 10-Q with the Securities and Exchange Commission on May 10, 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.
