

NEKTAR THERAPEUTICS
Form 8-K
August 06, 2007

**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): 08/01/2007

Nektar Therapeutics

(Exact name of registrant as specified in its charter)

Commission File Number: 0-24006

Delaware
(State or other jurisdiction of
incorporation)

94-3134940
(IRS Employer
Identification No.)

201 Industrial Road, San Carlos, CA 94070
(Address of principal executive offices, including zip code)

(650) 631-3100
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

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))
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Information to be included in the report

Item 1.01. Entry into a Material Definitive Agreement

On August 1, 2007, Nektar Therapeutics entered into a Co-Development, License and Co-Promotion Agreement with Bayer Healthcare LLC with regard to the further development and commercialization of Nektar's Amikacin product candidate currently under development consisting of a liquid formulation of Amikacin that is delivered to the lungs using a nebulizer device based on Nektar's proprietary pulmonary delivery platform. Under the terms of this agreement, Bayer and Nektar will co-promote and share profits (or losses) on sales of the Amikacin product in the United States. In all other countries, Nektar has granted Bayer an exclusive, royalty-bearing license for the development and commercialization of the Amikacin product.

Under the agreement, Bayer has agreed to pay Nektar up to \$175 million in development and sales milestones. This amount includes \$50 million as an up-front payment for reimbursement of prior research and development costs incurred by Nektar related to the Amikacin product. If all development milestone events are achieved, development milestone payments due to Nektar under the agreement will total \$120 million (including the \$50 million up-front payment). In the event that the first post-signing development milestone is achieved, Bayer will pay to Nektar a \$10 million development milestone payment, and thereafter Nektar will be responsible for reimbursement of up to \$10 million in Phase III development costs for the Amikacin product as such costs are incurred by Bayer. If all sales milestone events are achieved, additional lump sum royalty payments due to Nektar will total \$55 million.

Bayer will fund all clinical development of the Amikacin product following the completion of the ongoing Phase II clinical studies currently being conducted by Nektar (other than \$10 million of Phase III clinical trial costs to be reimbursed by Nektar as described above), all activities to support world-wide regulatory filings, approvals and related activities, further development of formulated Amikacin, and final product packaging. Nektar will fund the ongoing clinical development of the Amikacin product through the completion of ongoing Phase II clinical studies and the further development of the nebulizer device included in the Amikacin product through the completion of the Phase III clinical trials and scale-up for commercialization.

Bayer and Nektar will share profits (or losses) on sales of the Amikacin product in the United States such that Bayer receives 52% of product profits (or losses) and Nektar receives 48% of product profits (or losses), subject to certain adjustments. This profit sharing and co-promotion arrangement in the United States will include, among other things, Bayer and Nektar collaborating on the commercial plan, commercial launch, and the shared deployment of sales and marketing personnel and related support activities. In addition, Bayer will pay Nektar a royalty based on annual net sales of the Amikacin product made in any country outside the United States. The royalty rate varies based on the level of annual net sales of the Amikacin product, ranging from a minimum of 14% to a maximum of 30%. Nektar's right to receive the foregoing royalties will expire on a country by country basis upon the later of (a) ten years after the date of first commercial sale of the Amikacin product in that country and (b) the expiration of the last-to-expire of certain patent rights related to the Amikacin product in that country, subject to certain exceptions. Nektar retains responsibility for paying third-party royalties under intellectual property that is practiced in the development, manufacture or commercialization of the Amikacin product as of the date of the agreement.

Nektar will perform clinical manufacturing and supply Bayer with the nebulizer device and formulated Amikacin for use in clinical trials at Nektar's fully burdened manufacturing cost. For commercial manufacturing and supply of the Amikacin product, the parties will enter into a manufacturing and commercial supply agreement pursuant to which Nektar will supply Bayer with all of its requirements for the nebulizer device for the Amikacin product at 130% of Nektar's fully burdened manufacturing cost.

The term of the agreement continues on a country-by-country basis until all royalty and payment obligations expire between the parties. Bayer has termination for convenience rights upon payment of a termination fee and has a termination right that could trigger certain reimbursement obligations by Nektar. In addition, each party has certain termination rights in circumstances where product safety is a concern, the product's failure to meet certain minimum commercial profile requirements, or uncured material breach of terms and conditions of the agreement.

Item 7.01. Regulation FD Disclosure

On August 6, 2007, Nektar issued a press release titled "Bayer HealthCare and Nektar Therapeutics Launch Global Development and Commercialization Agreement To Fight Gram-Negative Pneumonias" a copy of which is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

The information in Item 7.01 of this report, including the Exhibit 99.1 hereto, 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.

This Current Report on Form 8-K contains forward-looking statements regarding the Amikacin product and Nektar's agreement with Bayer. These forward-looking statements involve risks and uncertainties, including but not limited to: (i) clinical trials are long, expensive and uncertain processes and the successful completion of future clinical development milestones will be required in order for Nektar to realize future development milestone payments under the agreement with Bayer, (ii) the risk of failure of any product that is in clinical development and prior to regulatory approval such as the Amikacin product remains high and can occur at any stage due to efficacy, safety or other factors, (iii) any such failure would likely result in reduced or no further payments to Nektar from Bayer, (iv) competing alternative therapies that are currently on the market or under development could impact the commercial potential of the Amikacin product which could materially and negatively impact Nektar's profit (or loss) share, royalty revenue, and sales milestones under the agreement with Bayer, (v) the agreement could be terminated by Bayer at any time with 90 days notice by Bayer and its payment of a specified termination fee, or under certain circumstances, by Bayer with a termination fee due to Bayer from Nektar, (vi) Bayer and Nektar may not be successful in obtaining regulatory approval of the Amikacin product, (vii) the Amikacin product 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 Amikacin product may not issue, or even if such patents issue, the claims contained in such patents may not provide sufficient market exclusivity, (ix) current patents and future patents that may issue may not be valid or enforceable, (x) intellectual property licenses from third parties may be required in the future and such licensing fees may be borne solely by Nektar in certain circumstances, and (xi) potential future disputes with current or future licensees of intellectual property required for the commercialization of the Amikacin product. 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 contained in this press release. Nektar undertakes no obligation to update forward-looking statements, whether as a result of new information, future events, or otherwise.

Signature(s)

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

Date: August 06, 2007

By: /s/ Gil M. Labrucherie

Gil M. Labrucherie
Senior Vice President and General Counsel

Exhibit Index

Exhibit No.	Description
EX-99.1	Press Release Titled "Bayer HealthCare and Nektar Therapeutics Launch Global Development and Commercialization Agreement to Fight Gram-Negative Pneumonias."