NEKTAR THERAPEUTICS
Form 8-K
August 08, 2013

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): August 8, 2013

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:

¨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 August 8, 2013, Nektar Therapeutics ("Nektar") and AstraZeneca AB ("AstraZeneca") entered into Amendment No. 1 (the "Amendment") to the License Agreement dated September 20, 2009 (together with the Amendment, the "Agreement") related to the licensing, development and commercialization of naloxegol (formerly known as NKTR-118) and naloxegol fixed-dose combination products. Under the terms of the Amendment, AstraZeneca has agreed to (i) submit the new drug application ("NDA") to the United States Food and Drug Administration ("FDA") in September 2013, and (ii) submit a marketing authorization application ("MAA") to the European Medicines Agency ("EMA") in September 2013. If the NDA is accepted by the FDA, AstraZeneca will pay Nektar a $70 million milestone payment payable within 5 business days of such acceptance, and if the MAA is accepted by the EMA, AstraZeneca will pay Nektar a $25 million milestone payment within 5 business days of such acceptance.

In addition, the terms of the Amendment also provide that in the event that the FDA does not require a future clinical trial or other studies or activities (which individually or in the aggregate are financially significant) in each case for the primary purpose of assessing the cardiovascular safety of naloxegol prior to an approval decision on the NDA (a "Pre-Approval CV Study"), AstraZeneca would pay Nektar an additional $35 million milestone payment. In the event that the FDA does require a Pre-Approval CV Study, AstraZeneca may terminate the Agreement in its entirety or only in respect of its License Agreement rights in the United States ("U.S."). If AstraZeneca elects to terminate the Agreement in its entirety due to a Pre-Approval CV Study, then Nektar would be required to pay AstraZeneca $70 million plus accrued interest in four installments in accordance with the following schedule: $10 million plus accrued interest on January 15, 2015, $10 million plus accrued interest on January 15, 2016, $20 million plus accrued interest on January 15, 2017, and a final payment of $30 million plus accrued interest on January 15, 2018. If AstraZeneca elects to terminate the Agreement only with respect to the U.S. due to a Pre-Approval CV Study, then such amount would be paid through reduction of the royalty amounts otherwise payable to Nektar for the remaining non-U.S. territories by 50% until such time as the aggregate accumulated amount of such royalty reduction offsets the total principal amount of $70 million plus annual interest at a rate of 4.5% per annum on the remaining unpaid principal amount. Interest would accrue commencing on the effective date of termination at the rate of 4.5% per annum. The repayment obligation is secured by Nektar's right to receive royalty payments under the Agreement. If the FDA requires a post-approval cardiovascular safety study as a condition to approval of the naloxegol NDA, then the royalty rate payable to Nektar from net sales of naloxegol in the U.S. by AstraZeneca would be reduced by two percentage points until such time as the corresponding aggregate accumulated amount of such royalty payment reduction is equal to a maximum of $35 million provided that in no event shall the aggregate accumulated amount of such royalty payment reduction exceed 33% of the external costs actually incurred by AstraZeneca to conduct the post-approval studies.

Other than as described herein regarding the Amendment, all material terms and conditions of the Agreement remain in full force and effect. The foregoing summary is qualified in its entirety by reference to the Amendment, which will be filed as an exhibit to Nektar's Quarterly Report on Form 10-Q for the period ended September 30, 2013.

SIGNATURES

Pursuant to the requirement 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.

By: /s/ Gil M. Labrucherie
Gil M. Labrucherie
General Counsel and Secretary

Date: August 8, 2013