NEKTAR THERAPEUTICS
Form 8-K
April 05, 2017

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): April 5, 2017

NEKTAR THERAPEUTICS

(Exact Name of Registrant as Specified in Charter)

Delaware	**0-24006**	**94-3134940**
(State or Other Jurisdiction	**(Commission**	**(IRS Employer**
of Incorporation)	**File Number)**	**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 8.01 Other Events.

Nektar Therapeutics, a Delaware corporation ("Nektar"), has royalty rights to Bayer AG's ("Bayer") Ciprofloxacin Dry Powder for Inhalation (DPI) drug candidate. Bayer has sole responsibility for all aspects of the development and commercialization of Ciprofloxacin DPI.

The Phase III clinical trial program for Ciprofloxacin DPI, called RESPIRE, was designed and conducted solely by Bayer and was comprised of two pivotal trials with identical study designs to evaluate the efficacy and safety of Ciprofloxacin DPI in adult patients with non-cystic fibrosis bronchiectasis (NCFB). The data from RESPIRE 1 were presented at the 26th International Congress of European Respiratory Society in September 2016. In the 14 days on/off regimen, the RESPIRE 1 trial met its primary endpoints of significantly prolonged time to first exacerbation and significantly reduced frequency of exacerbations versus placebo. On April 5, 2017, an abstract with data from the RESPIRE 2 trial was published by the American Thoracic Society in connection with the American Thoracic Society 2017 International Conference. The abstract had been previously submitted by Bayer in accordance with ATS submission guidelines. The RESPIRE 2 trial showed a positive trend of Ciprofloxacin DPI efficacy for both the 14 and the 28 days on/off regimens, but did not reach statistical significance. A pooled analysis of the primary efficacy results of RESPIRE 1 and RESPIRE 2 is positive. The data of both RESPIRE 1 and RESPIRE 2 indicated that Ciprofloxacin DPI has a positive safety profile. Top-line results of RESPIRE 2 will be presented at the upcoming American Thoracic Society 2017 International Conference.

Patients with NCFB suffer from frequent and severe exacerbations of their disease, so there is a significant unmet medical need for long-term treatment options. Bayer has informed us that they plan to discuss next steps with regulatory authorities on the basis of the findings from RESPIRE 1 and RESPIRE 2.

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/ Mark A. Wilson
Mark A. Wilson
General Counsel and Secretary
April 5, 2017