VIVUS INC
Form 8-K
January 09, 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)

January 3, 2017

VIVUS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-33389**	**94-3136179**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

900 E. HAMILTON AVENUE, SUITE 550

CAMPBELL, CA 95008

(Address of principal executive offices, including zip code)

(650) 934-5200

(Registrant s telephone number, including area code)

N/A

(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 (see General Instruction A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01. Other Events

On January 3, 2017, VIVUS, Inc., or the Company, entered into a Settlement Agreement with Hetero USA, Inc., Hetero Labs Limited Unit III and Hetero Labs Limited, collectively referred to as Hetero. The Settlement Agreement resolves the lawsuit, brought by the Company in the U.S. District Court for the District of New Jersey (Case No. 16-4560 (KSH)(CLW)) on July 27, 2016, in response to Hetero s filing of an Abbreviated New Drug Application, or ANDA, seeking to market and sell generic versions of the currently approved doses of STENDRA® (avanafil) tablets prior to the expiration of U.S. Patents 6,656,935 and 7,501,409, collectively referred to as the Asserted Patents. Under the Settlement Agreement, Hetero was granted a license to manufacture and commercialize the generic version of STENDRA described in its ANDA filing in the United States as of the date that is the later of (a) 180 days prior to the expiration of the last to expire of the Asserted Patents or (b) the date that Hetero obtains final approval from the FDA of the Hetero ANDA. The Settlement Agreement provides for a full settlement of all claims that were asserted in the suit, subject to the Court s acceptance of the stipulation of dismissal. As required by law, the Settlement Agreement will be submitted to the U.S. Federal Trade Commission and U.S. Department of Justice.

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 hereunto duly authorized.

VIVUS, INC.

/s/ John L. Slebir
John L. Slebir
Senior Vice President, Business Development and General Counsel

Date: January 9, 2017