

VIVUS INC
Form 8-K
March 10, 2015

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)

March 5, 2015

VIVUS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-33389
(Commission File Number)

94-3136179
(IRS Employer
Identification No.)

351 EAST EVELYN AVENUE

MOUNTAIN VIEW, CA 94041

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(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):

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

On March 5, 2015, VIVUS, Inc., or the Company, received notice from Teva Pharmaceuticals USA, Inc., or Teva, that it has filed with the U.S. Food and Drug Administration, or the FDA, an Abbreviated New Drug Application, or ANDA, for generic versions of all strengths of Qsymia® (phentermine and topiramate extended release) capsules CIV. The notice from Teva included a paragraph IV certification with respect to eight of the Company's patents listed in the FDA's Orange Book on the date of the Company's receipt of the notice. A paragraph IV certification is a certification by a generic applicant that patents covering the branded product are invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the generic product.

The Company is currently reviewing the details of Teva's notice. Under the Hatch-Waxman Act, the Company has 45 days from receipt of the notice to determine if it will file a patent infringement suit. If the Company brings such a suit, a stay of approval of up to 30 months will be imposed by the FDA on Teva's ANDA. The Company intends to vigorously enforce its intellectual property rights, but cannot predict the outcome of this matter.

Certain statements in this Current Report on Form 8-K are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as anticipate, believe, forecast, estimate, expect, intend, likely, may, plan, potential, predict, opportunity and should, among others. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. The Company does not undertake an obligation to update or revise any forward-looking statements. Investors should read the risk factors set forth in the Company's Form 10-K for the year ended December 31, 2014, and periodic reports filed with the Securities and Exchange Commission.

SIGNATURE

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.

Date: March 10, 2015

By:

/s/ John L. Slebir
John L. Slebir

Senior Vice President, Business Development and
General Counsel