VIVUS INC
Form 8-K
May 09, 2014

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)

May 7, 2014

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.)

351 EAST EVELYN AVENUE

MOUNTAIN VIEW, CA 94041

(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 May 7, 2014, VIVUS, Inc., or the Company, received notice from Actavis Laboratories FL, Inc., or Actavis, 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 Actavis included a paragraph IV certification with respect to all 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 Actavis 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 Actavis 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, int likely, may, plan, potential, predict, opportunity and should, among others. There are a number of factors that could cause actual event 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, 2013, as amended by the Form 10-K/A filed on April 30, 2014, and periodic reports filed with the Securities and Exchange Commission.

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: May 9, 2014