VIVUS INC
Form 8-K
March 09, 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 4, 2015

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 March 4, 2015, VIVUS, Inc., or the Company or VIVUS, filed a lawsuit (Case No. 15-1636 (FSH)(MAH)) in the U.S. District Court for the District of New Jersey against Actavis Laboratories FL, Inc., Actavis, Inc. and Actavis PLC, collectively referred to as Actavis, in response to a second Paragraph IV certification notice from Actavis contending that the claims of two additional patents (U.S. Patents 8,895,057 and 8,895,058, collectively referred to as patents-in-suit) listed in the FDA s Approved Drug Products with Therapeutic Equivalence Evaluations, or Orange Book, are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale or offer for sale of a generic form of Qsymia® (phentermine and topiramate extended release) capsules CIV. The lawsuit was filed on the basis that Actavis submission of their Abbreviated New Drug Application, or ANDA, constitutes infringement of one or more claims of the patents-in-suit.

VIVUS filed an earlier lawsuit against Actavis in the U.S. District Court for the District of New Jersey (Case No. 14-3786 (FSH)(MAH)) asserting additional patents held by VIVUS and listed in the Orange Book. In accordance with the Hatch-Waxman Act, as a result of having filed the earlier lawsuit, FDA approval of Actavis ANDA will be stayed until the earlier of (i) November 7, 2016 or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. The Company intends to vigorously enforce its intellectual property rights relating to Qsymia, but the Company 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, 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 9, 2015

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