
**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 9, 2012

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.)

**1172 CASTRO STREET
MOUNTAIN VIEW, CA 94040**
(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 7.01. Regulation FD Disclosure

On January 9, 2012, VIVUS, Inc. issued a press release titled "VIVUS Provides Qnexa Regulatory Update." A copy of the press release is attached hereto as Exhibit 99.1.

By filing this information, the Company makes no admission as to the materiality of any information in this report. The information contained in this report is intended to be considered in the context of the Company's filings with the Securities and Exchange Commission and other public announcements that the Company makes, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the Securities and Exchange Commission, through press releases or through other public disclosure.

The information in this Form 8-K and the exhibit attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference into any of the Registrant's filings under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
-------------	-------------

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.

By: /s/ Lee B. Perry

Lee B. Perry

Vice President and Chief Accounting Officer

Date: January 9, 2012

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated January 9, 2012.


CONTACT:
VIVUS, Inc.

Timothy E. Morris
Chief Financial Officer
650-934-5200

Investor Relations:
The Trout Group

Brian Korb
bkorb@troutgroup.com
646-378-2923

VIVUS PROVIDES QNEXA REGULATORY UPDATE
FDA Requests Removal of Contraindication for Women of Childbearing Potential

MOUNTAIN VIEW, Calif., January 9, 2012 - VIVUS, Inc. (NASDAQ: VVUS) today announced that following recent discussions with Food and Drug Administration (FDA) officials, the company has been asked to remove the Qnexa® contraindication for women of childbearing potential contained in the proposed label. Qnexa would remain contraindicated for women who are pregnant. A contraindication typically indicates that a drug should not be used because the risk of use clearly outweighs any possible therapeutic benefit.

Included with the resubmission of the Qnexa New Drug Application (NDA) was a proposed Risk Evaluation and Mitigation Strategy, or REMS. The company is currently revising its proposed REMS based on this change in the contraindication and plans to discuss the details of the Qnexa REMS during the upcoming Endocrinologic and Metabolic Drugs Advisory Committee.

“Based on our discussions with the FDA, we will modify the contraindication and develop an appropriate REMS with FDA’s guidance. It is important for patients seeking treatment to understand and be reminded of the potential risks associated with Qnexa. In addition to other elements, the proposed REMS program will focus on the education of patients and healthcare providers through frequent communications that will outline the safety aspects and appropriate use of Qnexa,” commented Peter Tam, president of VIVUS, Inc. “The company’s disclosure of this regulatory update should not be interpreted to mean that the potential for FDA approval of Qnexa has improved or that, if approved, that the final Qnexa label would not include contraindications or warnings for specific populations, including women of childbearing potential.”

In September 2011, the company announced that it reached agreement with the FDA on a plan that allowed for an early resubmission of the Qnexa NDA. The resubmission plan allowed VIVUS to seek approval for an initial indication that included obese men and women of non-childbearing potential which contained a contraindication for women of childbearing potential.

VIVUS, Inc. 1172 Castro Street, Mountain View, CA 94040 Tel 650-934-5200 Fax 650-934-5389 www.vivus.com

Based on this agreement, VIVUS resubmitted the Qnexa NDA in October 2011. The FDA accepted the NDA for review on November 3, 2011.

The Endocrinologic and Metabolic Drugs Advisory Committee of the FDA is scheduled to review the Qnexa NDA on February 22, 2012. The target date for the FDA to complete its review of the Qnexa NDA is April 17, 2012.

About Qnexa

Qnexa [kyoo-nek-suh] is an investigational drug candidate being developed to address weight loss, type 2 diabetes and obstructive sleep apnea. Qnexa is a once-a-day, proprietary, oral, controlled-release formulation of low-dose phentermine and topiramate, which is designed to decrease appetite and increase satiety (the sense of feeling full), the two main mechanisms that impact eating behavior. In phase 2 and 3 clinical data to date, patients taking Qnexa have demonstrated statistically significant weight loss, glycemic control, and improvement in cardiovascular risk factors, when used in combination with a diet and lifestyle modification program.

About VIVUS

VIVUS is a biopharmaceutical company developing therapies to address obesity, sleep apnea, diabetes and male sexual health. The company’s lead investigational product in clinical development, Qnexa, has completed phase 3 clinical trials for the treatment of obesity and is currently being considered for approval by US and EU regulators. VIVUS received a Complete Response Letter, or CRL, to the initial Qnexa NDA on October 28, 2010. We resubmitted the Qnexa NDA in October 2011, with an FDA action date of April 17, 2012. Qnexa is also in phase 2 clinical development for the treatment of type 2 diabetes and obstructive sleep apnea. In the area of sexual health, VIVUS has submitted an NDA for avanafil, a PDE5 inhibitor being studied for the treatment of erectile dysfunction, with an FDA action date of April 29, 2012. For more information about the company, please visit www.vivus.com.

Certain statements in this press release 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. These factors include, but are not limited to, the response from the United States Food and Drug Administration, or FDA, to our resubmission of the New Drug Application, or NDA, for Qnexa for the treatment of obesity, including weight loss and maintenance of weight loss, recommended for obese patients (BMI ≥ 30 kg/m²), or overweight patients (BMI ≥ 27 kg/m²) with weight-related co-morbidities such as hypertension, type 2 diabetes, dyslipidemia, or central adiposity (abdominal obesity), with a contraindication that excludes the use of Qnexa by women who are pregnant; the timing and results of the retrospective observational study of fetal outcomes in infants born to mothers exposed to topiramate during pregnancy, or the FORTRESS study; the reliability of the electronic medical claims healthcare databases used in the FORTRESS study; the FDA’s

interpretation of and agreement with the information VIVUS submitted relating to teratogenicity and cardiovascular safety; the FDA's interpretation of the data from our SEQUEL study (OB-305) and Sleep Apnea study (OB-204); that we may be required to provide further analysis of

clinical trial data; our response to questions and requests for additional information including additional pre-clinical or clinical studies from the European Medicines Agency, or EMA, and the Committee for Medicinal Products for Human Use, or CHMP, of the Marketing Authorization Application, or MAA, for Qnexa; the results of external studies to assess the teratogenic risk of topiramate; results of the REMS or cardiovascular outcomes for obesity advisory meetings; the outcome of the second advisory committee meeting for Qnexa; the impact, if any, of the agreement by one of our competitors with an obesity compound to conduct or complete a cardiovascular outcomes study pre-approval; impact on future sales based on specific indication and contraindications contained in the label and extent of the REMS, distribution and patient access program; the FDA's response to the NDA filed for avanafil; our ability to successfully commercialize or establish a marketing partnership for avanafil or our partner's ability to obtain regulatory approval to manufacture and adequately supply avanafil for commercial use; our history of losses and variable quarterly results; substantial competition; risks related to the failure to protect our intellectual property and litigation in which we may become involved; uncertainties of government or third party payer reimbursement; our reliance on sole source suppliers; our limited sales and marketing efforts and our reliance on third parties; failure to continue to develop innovative investigational drug candidates and drugs; risks related to the failure to obtain FDA or foreign authority clearances or approvals and noncompliance with FDA regulations; our ability to demonstrate through clinical testing the safety and effectiveness of our investigational drug candidates; our dependence on the performance of our collaborative partners; the timing of initiation and completion of clinical trials and submissions to the FDA or foreign authorities; the volatility and liquidity of the financial markets; our liquidity and capital resources; and our expected future revenues, operations and expenditures. As with any pharmaceutical in development, there are significant risks in the development, the regulatory approval, and commercialization of new products. There are no guarantees that our response to the FDA's CRL or CHMP's 120-day questions, the FDA's requests stemming from the end-of-review meeting or the results of the FORTRESS study and subsequent meetings and communications will be sufficient to satisfy the FDA or CHMP's safety concerns, that the FDA or foreign authorities will not require us to conduct any additional prospective studies or retrospective observational studies, or that any product will receive regulatory approval for any indication or prove to be commercially successful. VIVUS does not undertake an obligation to update or revise any forward-looking statements. Investors should read the risk factors set forth in VIVUS' Form 10-K for the year ending December 31, 2010, and periodic reports filed with the Securities and Exchange Commission.

###
