## 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) December 12, 2007

## VIVUS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

000-23490 (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):

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 December 12, 2007, VIVUS, Inc. issued a press release titled "VIVUS Initiates Third Qnexa Phase 3 Trial in Obese Patients." A copy of the press release is attached hereto as Exhibit 99.1.

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.

99.1

Press Release dated December 12, 2007

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: December 13, 2007

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## CONTACT:

VIVUS, Inc. Timothy E. Morris Chief Financial Officer 650-934-5200

## FOR IMMEDIATE RELEASE

**Trout Group** Ian Clements (SF) 415-392-3385 Brian Korb (NYC) 646-378-2923

## VIVUS INITIATES THIRD QNEXA PHASE 3 TRIAL IN OBESE PATIENTS

EQUATE trial to study impact of Qnexa in obese patients over 28 weeks

Mountain View, Calif, December 12, 2007 — VIVUS, Inc. (NASDAQ: VVUS), a pharmaceutical company dedicated to the development and commercialization of novel therapeutic products, today announced that it has initiated the third phase 3 study of Qnexa in obese patients with co-morbidities. The EQUATE study (OB-301) will enroll 700 patients with Body Mass Index ("BMI") ranging from 30 to 45. The co-primary endpoints for these studies will evaluate the differences between treatments in mean percent weight loss and in the percentage of subjects achieving weight loss of 5% or more. Patients will be studied over 28 weeks.

"The initiation of the EQUATE study completes our plans for phase 3 studies of Qnexa. The EQUATE study will evaluate two doses of Qnexa over 6 months and should give us an early look at the outcomes of the larger pivotal phase 3 studies," commented Wesley Day, Ph.D., vice president of Clinical Development for VIVUS. "EQUATE will evaluate the safety and efficacy of two dose levels of Qnexa compared to both placebo and the individual phentermine and topiramate constituents in order to satisfy the combination guidelines set forth by the FDA. We will also measure the impact of weight loss and Qnexa on quality of life using the same tools utilized in the phase 2 study. This study should provide necessary data to support the hypothesis that the combination of both agents leads to synergistic weight loss with enhanced tolerability."

## About the EQUATE Study

The EQUATE study will enroll approximately 700 subjects in up to 35 centers. Patients will undergo a 4-week dose escalation period followed by 24 weeks of treatment. The study is a randomized, double-blind, placebo-controlled, 7-arm, prospective trial with subjects randomized to receive once-a-day treatment with mid-dose Qnexa (7.5 mg phentermine/46 mg topiramate), full strength Qnexa (15 mg phentermine/92 mg topiramate), the respective phentermine and topiramate constituents, or placebo. At randomization, subjects will be instructed to follow a hypocaloric diet representing a 500-calorie/day deficit and advised to implement a simple lifestyle modification program throughout the study period. VIVUS has completed the Special Protocol Assessment ("SPA") process for this trial with the U.S. Food and Drug Administration (FDA). Under the SPA process, the company and the FDA have reached agreement on study design features that will be employed throughout the entire phase 3 program including the co-primary endpoints of the study, scope and size of the patient population, specific safety assessments, inclusion/exclusion criteria, duration of the trials and the statistical method for analyzing the co-primary study endpoints. More information about the trial can be found at http://www.clinicaltrials.gov.

## About a Special Protocol Assessment

A Special Protocol Assessment is a regulatory procedure by which the FDA can provide advice on the current thinking at the FDA regarding the evaluation of issues related to the adequacy (e.g., design, conduct, analysis) of certain proposed studies associated with the development of products in human drug applications as defined in section 735(1) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 379g(1)) (PDUFA products). The advice given by the FDA is not binding. For more information about the Agency's Special Protocol Assessment process see http://www.fda.gov/cder/guidance/3764fnl.htm.

## About VIVUS

VIVUS, Inc. is a pharmaceutical company dedicated to the development and commercialization of novel therapeutic products. The current portfolio includes investigational products addressing obesity and sexual health. The pipeline includes: Qnexa<sup>TM</sup>, which is in phase 3 for the treatment of obesity; Luramist, for which a phase 2 study has been completed for the treatment of Hypoactive Sexual Desire Disorder (HSDD); and avanafil, for which a phase 2 study has been completed for the treatment of ED. MUSE® is approved and currently on the market for the treatment of ED. For more information on clinical trials and products, please visit the company's web site at http://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," "estimated" and "intend," among others. These forwardlooking statements are based on VIVUS' current expectations and actual results could differ materially. 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, substantial competition; uncertainties of patent protection and litigation; uncertainties of government or third party payer reimbursement; reliance on sole source suppliers; limited sales and marketing efforts and dependence upon third parties; risks related to the development of innovative products; and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. There are no guarantees that future clinical studies discussed in this press release will be completed or successful 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 statement. Investors should read the risk factors set forth in VIVUS' Form 10-K for the year ended December 31, 2006 and periodic reports filed with the Securities and Exchange Commission.