

**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)

October 6, 2008

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 8.01. Other Events

On October 6, 2008, VIVUS, Inc. issued a press release titled "VIVUS Announces the Weight Loss Effects of Qnexa in Type 2 Diabetes." 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. | Description |
|--------------------|-------------------------------------|
| 99.1 | Press Release dated October 6, 2008 |

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: October 7, 2008

3

EXHIBIT INDEX

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|-------------------------------------|
| 99.1 | Press Release dated October 6, 2008 |

4


CONTACT:
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FOR IMMEDIATE RELEASE
VIVUS ANNOUNCES THE WEIGHT LOSS EFFECTS OF QNEXA IN TYPE 2 DIABETES
Presentation at the Obesity Society Annual Scientific Meeting Shows Weight Loss of 17 Pounds in 28 Weeks

MOUNTAIN VIEW, Calif., October 6, 2008 VIVUS, Inc. (NASDAQ: VVUS), a pharmaceutical company dedicated to the development and commercialization of novel therapeutic products, today announced the weight loss effects of Qnexa in subjects with type 2 diabetes at The Obesity Society Annual Scientific Meeting in Phoenix, Arizona. Dr. Barbara Troupin, Senior Director of Clinical Development, announced the data in a poster presentation titled "The Weight Loss Effects of VI-0521 in Type 2 Diabetes." On an intent-to-treat basis, subjects treated with Qnexa, an investigational drug, for 28 weeks had a mean weight loss of approximately 17 pounds or 8 percent of their starting body weight, as compared to subjects treated with placebo who had weight loss of approximately 2.9 pounds or 1.2 percent ($p < 0.0001$). In the study, 61 percent of the patients treated with Qnexa had weight loss of 5 percent as compared to 14 percent of the patients in the placebo group ($p < 0.0001$).

VIVUS had previously reported the positive results of this study, OB-202, at the American Diabetes Association Scientific Meeting in June 2008. Subjects treated with Qnexa had a mean reduction in HbA1c, a common measure of glycemic control, of 1.2 percent, from 8.7 percent to 7.5 percent, as compared with a reduction of 0.6 percent, from 8.6 percent to 8.0 percent, in subjects in the placebo group ($p < 0.001$). Patients on placebo required a three-fold increase in the number and dose of additional anti-diabetic medications during the study than those receiving Qnexa. Fasting plasma glucose levels were reduced in the Qnexa arm from 174.7 mg/dL to 141.9 mg/dL, and decreased from 174 mg/dL to 166.6 mg/dL in the placebo group ($p < 0.001$). The change in HbA1c was correlated with weight loss. Qnexa patients also had significant improvement in cardiovascular risk factors including blood pressure, triglycerides levels and waist circumference. Specifically, patients in the Qnexa group reduced systolic blood pressure from 122.8 mmHg to 118.9 mmHg, as compared to a neutral effect in the placebo group from 124.4 mmHg to 124.5 mmHg ($p < 0.005$). Patients in the Qnexa group reduced diastolic blood pressure from 74.7 mmHg to 73.7 mmHg, as compared to a marginal increase in the placebo group from 75.7 mmHg to 76.6 mmHg ($p < 0.018$). Patients in the Qnexa group also had a significant reduction in triglycerides from 162 mg/dL to 143 mg/dL, as compared to subjects in

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the placebo group that had a slight reduction from 172.2 mg/dL to 171.6 mg/dL ($p < 0.016$). The trial randomized 206 subjects at 10 sites. The Qnexa treatment group had a study completion rate of 85 percent, as compared to 72 percent in the placebo arm. Qnexa subjects reported an overall improvement when evaluated for quality of life, including physical function, self-esteem and distress.

"The weight loss of 17 pounds in 28 weeks is an outstanding result for these diabetic patients. The reduction in blood sugar levels of 1.2% coupled with improvement in the cardiovascular risk factors may make Qnexa an ideal treatment for diabetics," commented Leland Wilson, president and chief executive officer at VIVUS. "Thought leaders in the diabetes community now recognize that treating diabetes through weight loss should be the fundamental approach to managing glycemic and cardiovascular risk. We are pleased with the results and look forward to moving ahead with our plans for the phase 3 development of Qnexa in diabetes."

Subjects completing the OB-202 study were allowed to enroll in a placebo-controlled extension study, DM-230. Subjects continued their current treatment for an additional 28 weeks. Results from the DM-230 study are expected before the end of 2008.

About the OB-202 Study

In the OB-202 study, subjects underwent a 4-week dose escalation period followed by 24 weeks of treatment. The study was a randomized, double-blind, placebo-controlled prospective trial, with subjects randomized to receive Qnexa (15 mg phentermine/100 mg topiramate) or placebo. The study included 206 subjects (141 females, 65 males) with an average age of 49 years. Baseline BMIs were greater than 35 in both groups, and baseline body weight was 94.7 kg in the Qnexa group and 98.6 kg in the placebo group. At baseline, subjects had glycosylated hemoglobin (HbA1c) of 8.7 percent. Most of the subjects had been diagnosed with diabetes for more than 5 years (59 percent). Sixty percent of subjects were on two or more oral diabetic medications. Patients on antidepressant medications such as SSRIs and SNRIs were allowed to participate in the study. Subjects were instructed to follow a simple diet and lifestyle modification program throughout the study. The primary endpoint was change in glycemic control as reflected by measurements of HbA1c. Secondary endpoints included weight loss and change in various cardiovascular risk factors. Investigators were allowed to intervene and add/adjust anti-diabetic and anti-hypertensive medications during the study based on predetermined rescue criteria and nationally recognized standards of care. Subjects completing the study were allowed to enroll in an extension study, DM-230. The extension study will continue to monitor HbA1c levels, body weight, other metabolic endpoints, and patient safety over an additional six months. Despite a mean baseline HbA1c level of 8.7 percent, 41 percent of the subjects treated with Qnexa were able to achieve the American Diabetes Association (ADA) recommended goal of 7 percent or lower, versus 26 percent of the subjects in the placebo arm ($p = 0.008$). The incidence of hypoglycemia in the treatment and placebo arms were comparable (6 percent versus 5 percent, respectively). Qnexa was well-tolerated, with no treatment-related serious adverse events (SAEs). The most common treatment-related adverse events were nausea, paresthesias, constipation, dry mouth and dizziness.

About Diabetes

Diabetes affects more than 24 million people in the United States and an estimated 246 million adults worldwide. Common measures of blood sugar include the percent of glycosylated hemoglobin (also referred to as HbA1c) present in the blood and fasting plasma glucose (FPG),

which is a measure of blood sugar at a specific point in time. Diabetes is diagnosed when FPG exceeds 125 mg/dL. According to the Centers for Disease Control and Prevention's National Health and Nutrition Examination Survey, approximately 60 percent of people with diabetes do not achieve their target blood sugar levels with their current treatment regimen.

About the Qnexa Phase 3 Obesity Program

Qnexa is currently under development for obesity. A phase 2 study in obese patients with controlled co-morbidities (no type 2 diabetes) previously reported weight loss of 10.7 percent over 24 weeks. The phase 3 Qnexa program includes two pivotal, double-blind, placebo-controlled, multi-center studies that will compare the efficacy and safety of Qnexa to placebo during a 56-week treatment period. The first study, known as EQUIP (OB-302), has enrolled approximately 1,250 morbidly obese adult subjects with a Body Mass Index (BMI) of 35 or greater with or without controlled co-morbidities. The second trial, known as CONQUER (OB-303), has enrolled overweight and obese adult subjects with BMIs from 27 to 45 and at least two co-morbid conditions, such as hypertension, dyslipidemia and type 2 diabetes. The co-primary endpoints for these studies are the mean percent weight loss and the percentage of subjects achieving a weight loss of 5 percent or more.

The phase 3 program also includes a six-month confirmatory factorial study, known as EQUATE (OB-301), in obese subjects with BMIs from 30 to 45. This trial is designed to evaluate two dose levels of Qnexa compared to placebo and to the individual components in Qnexa. The primary endpoints will be similar to those evaluated in the pivotal studies. Safety and tolerability of Qnexa will be determined by reports of adverse events, physical exam, clinical laboratory data, electrocardiogram, cognitive function tests, psychological assessments, and clinical assessment of clinical laboratory variables. The phase 3 program has enrolled a total of approximately 4,500 subjects.

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(TM), which is in phase 3 for obesity and phase 2 for diabetes; avanafil, for which a phase 2 study has been completed for the treatment of erectile dysfunction (ED) and Testosterone MDTs(R), for which a phase 2 study has been completed for the treatment of Hypoactive Sexual Desire Disorder (HSDD). MUSE(R) 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 forward-looking 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, 2007 and periodic reports filed with the Securities and Exchange Commission.
