

**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)
July 17, 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 8.01. Other Events

On July 17, 2012, VIVUS, Inc. issued a press release titled, "VIVUS Announces FDA Approval of Once Daily Qsymia™ (Phentermine and Topiramate Extended-Release) Capsules CIV." 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 July 17, 2012. |

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: July 18, 2012

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EXHIBIT INDEX

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|------------------------------------|
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**CONTACT:****VIVUS, Inc.**

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VIVUS ANNOUNCES FDA APPROVAL OF ONCE DAILY QSYMIA™ (PHENTERMINE AND TOPIRAMATE EXTENDED-RELEASE) CAPSULES CIV

THE FIRST ONCE DAILY COMBINATION TREATMENT FOR CHRONIC WEIGHT MANAGEMENT IN ADULTS WHO ARE OBESE OR OVERWEIGHT WITH A WEIGHT-RELATED COMORBIDITY

MOUNTAIN VIEW, Calif., July 17, 2012 — VIVUS, Inc. (NASDAQ: VVUS) today announced that the U.S. Food and Drug Administration (FDA) has approved Qsymia™ (pronounced Kyoo sim ee' uh) as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of 30 or greater (obese), or 27 or greater (overweight) in the presence of at least one weight-related comorbidity, such as hypertension, type 2 diabetes mellitus or high cholesterol (dyslipidemia).

"Qsymia is the first FDA-approved once daily combination treatment for patients struggling with obesity," said Peter Tam, President of VIVUS. "The degree and severity of obesity and the lack of effective pharmacological interventions that we face as a society were two primary reasons for the development of Qsymia. We are pleased with FDA's decision today because patients and physicians now have another treatment option available to them. It is expected that Qsymia will be available in the fourth quarter of 2012."

The safety and efficacy of Qsymia were evaluated in two multicenter, phase 3 trials that included severely obese patients (the EQUIP study), and overweight or obese patients with at least two weight-related comorbidities, such as hypertension, hypertriglyceridemia, type 2 diabetes, or central adiposity (the CONQUER study). The average weight loss in EQUIP was 10.9% on Qsymia 15 mg/92 mg and 1.6% for placebo (ITT-LOCF, $p < 0.0001$). The average weight loss in CONQUER was 9.8% on Qsymia 15 mg/92 mg, 7.8% on Qsymia 7.5 mg/46 mg and 1.2% for placebo (ITT-LOCF, $p < 0.0001$).

The most common adverse reactions for patients treated with Qsymia included tingling sensation of hands and feet, dizziness, altered taste, insomnia, constipation and dry mouth.

Qsymia was approved with a Risk Evaluation and Mitigation Strategy (REMS) with a goal of informing prescribers and female patients of reproductive potential about an increased risk of orofacial clefts in infants exposed to Qsymia during the first trimester of pregnancy, the importance of pregnancy prevention for females of reproductive potential receiving Qsymia and the need to discontinue Qsymia immediately if pregnancy occurs. The Qsymia REMS program includes a Medication Guide, Healthcare Provider training, distribution through certified pharmacies, implementation system and a time table for assessments.

As part of the approval of Qsymia, VIVUS is committed to conduct post-marketing studies. The company will conduct a study to assess the long-term treatment effect of Qsymia on the incidence of major adverse cardiovascular events in overweight and obese subjects with confirmed cardiovascular disease, studies to assess the safety and efficacy of Qsymia for weight management in obese pediatric and adolescent subjects, studies to assess drug utilization and pregnancy exposure, a study to assess renal function, as well as animal and in vitro studies.

For more information about Qsymia, go to www.Qsymia.com or for full prescribing information go to <http://vivus.com/docs/QsymiaPI.pdf>.

Note to Investors

VIVUS will hold a conference call to discuss this update tomorrow, July 18, 2012, beginning at 5:30 a.m. Pacific Time / 8:30 a.m. Eastern Time. You can listen to this call by dialing toll free 877-359-2916 or outside the U.S. at 224-357-2386. A 30-day archive of the call can be accessed at <http://ir.vivus.com/>.

Qsymia Phase 3 Clinical Program

The safety and efficacy of Qsymia were evaluated in two randomized, double-blind, placebo-controlled, phase 3 studies that randomized more than 3,700 patients who were obese (EQUIP) or obese and overweight with two or more weight-related co-morbidities (CONQUER). There were two co-primary efficacy outcomes measured after one year of treatment: 1) the percent weight loss from baseline; and 2) treatment response defined as achieving at least 5% weight loss from baseline.

In the EQUIP study, obese patients (BMI greater than or equal to 35 kg/m²) were randomized to receive one year of treatment with placebo (N=514), Qsymia 3.75 mg/23 mg (N=241), or Qsymia 15 mg/92 mg (N=512).

In the CONQUER study, overweight and obese patients were randomized to receive one year of treatment with placebo (N=994), Qsymia 7.5 mg/46 mg (N=498), or Qsymia 15 mg/92 mg (N=995). Eligible patients had to have a BMI greater than or equal to 27 kg/m² and less than or equal to 45 kg/m² (no lower limit on BMI for patients with type 2 diabetes) and two or more obesity-related comorbid conditions.

Important Safety Information

Qsymia (phentermine and topiramate extended-release) capsules CIV must not be used by women who are pregnant; by patients with eye problems (glaucoma); by patients who have been told they have an overactive thyroid; by patients taking a type of anti-depressant called MAOI; or by patients who are allergic to phentermine, topiramate, or any of the ingredients in Qsymia.

Qsymia may harm your unborn baby. If you take Qsymia while you are pregnant, your baby has a higher risk for birth defects called cleft lip and cleft palate. These defects can begin early in pregnancy, even before you know you are pregnant. You should have a negative pregnancy test before taking Qsymia and every month while taking Qsymia. Use effective birth control (contraception) consistently while taking Qsymia. Talk to your healthcare provider about how to prevent pregnancy. If you become pregnant while taking Qsymia, you should stop taking Qsymia immediately and contact your healthcare provider right away.

Qsymia can increase your heart rate at rest. Tell your healthcare provider if you experience, while at rest, a racing or pounding feeling in your chest lasting several minutes when taking Qsymia.

Topiramate, a component of Qsymia, increases the risk of suicidal thoughts or behavior in patients. Pay attention to any changes and call your healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you: thoughts about suicide or dying, attempts to commit suicide, new or worse depression, or other unusual changes in behavior or mood.

Eye problems, such as glaucoma (an increased pressure in the eye due to fluid blockage), may develop while you are taking Qsymia. You should call your healthcare provider if you experience any sudden decrease in vision, with or without eye pain and redness, and stop taking Qsymia immediately. These problems can lead to permanent vision loss if not treated.

Qsymia may affect how you think and is associated with difficulty with attention and concentration, memory and word-finding. Therefore, use caution when operating hazardous machinery, including automobiles.

Weight loss may increase the risk of low blood sugar in patients with type 2 diabetes mellitus treated with insulin. Your healthcare provider may adjust your antidiabetic medicines while you are taking Qsymia.

The most common side effects seen in Qsymia clinical studies were tingling in the hands and feet, dizziness, change in taste, trouble sleeping, constipation, and dry mouth.

To report negative side effects, contact VIVUS, Inc., at 1-888-998-4887 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

About VIVUS

VIVUS is a biopharmaceutical company commercializing and developing innovative, next-generation therapies to address unmet needs in obesity, sleep apnea, diabetes and sexual health for U.S., Europe and other world markets. Qsymia is also in phase 2 clinical development for the treatment of type 2 diabetes and obstructive sleep apnea. 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, our lack of commercial experience with Qsymia in the U.S.; the timing of initiation and completion of the clinical studies required as part of the approval of Qsymia by the United States Food and Drug Administration, or FDA; the response from the FDA to the data that VIVUS will submit relating to post-approval clinical studies; the impact of the indicated uses and contraindications contained in the Qsymia label and the REMS requirements; the impact of distribution of Qsymia through a certified pharmacy network; that we may be required to provide further analysis of previously submitted 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 Qsymia; our ability to successfully commercialize or establish a marketing partnership for avanafil, which will be marketed in the U.S. under the name Stendra, or our partner’s ability to obtain and maintain 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 and manufacturing experience; our reliance on third parties and our collaborative partners; our 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 or foreign authority regulations; our ability to demonstrate through clinical testing the safety and effectiveness of our investigational drug candidates; the timing of initiation and completion of clinical trials and submissions to 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 CHMP’s 180-day list of outstanding issues and subsequent meetings and communications will be sufficient to satisfy the CHMP’s safety concerns, that the foreign authorities will not require us to conduct any additional prospective studies or retrospective observational studies, or that any product will receive foreign 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, 2011, and periodic reports filed with the Securities and Exchange Commission.
