

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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 2, 2020**

VIVUS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-33389
(Commission
File Number)

94-3136179
(I.R.S. Employer
Identification No.)

**900 E. Hamilton Avenue, Suite 550
Campbell, CA 95008**
(Address of Principal Executive Offices, and Zip Code)

(650) 934-5200
Registrant's Telephone Number, Including Area Code

N/A
(Former Name or Former Address, if Changed Since Last Report)

Securities registered pursuant to Section 12(b) of the Act:

| <u>Title of each class</u> | <u>Trading Symbol(s)</u> | <u>Name of each exchange on which registered</u> |
|---------------------------------|--------------------------|--|
| Common Stock | VVUS | The Nasdaq Global Select Market |
| Preferred Share Purchase Rights | | |

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01. Other Events

On March 2, 2020, VIVUS, Inc. issued a press release titled “VIVUS Completes Enrollment in Phase 4 Safety and Efficacy Study of Qsymia® in Adolescents.” A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

| Exhibit No. | Description |
|----------------------|--|
| 99.1 | Press Release dated March 2, 2020. |

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.

/s/ John L. Slebir

John L. Slebir

Senior Vice President, Business Development and General Counsel

Date: March 2, 2020



VIVUS Completes Enrollment in Phase 4 Safety and Efficacy Study of Qsymia® in Adolescents

-Post-marketing study designed to evaluate Qsymia as an approach to weight management in a growing patient population with significant unmet medical need-

CAMPBELL, CA., March 2, 2020 – VIVUS, Inc. (Nasdaq: VVUS; the “Company”), a biopharmaceutical company, today announced the completion of patient enrollment in a Phase 4 clinical study designed to evaluate the safety and efficacy of Qsymia® (phentermine and topiramate extended-release) capsules CIV in adolescents between the ages of 12 and 17 years who are obese (NCT# 03922945).

“Completing enrollment in this study is an important milestone in our ongoing efforts to expand the clinical use of Qsymia based on robust safety and efficacy data,” said Santosh T. Varghese, MD, Senior Vice President, Chief Medical Officer at VIVUS. “The enthusiasm among clinicians, adolescent patients and their parents for participating in this study reflects the unmet need for new medical treatments that safely and effectively address the challenges of obesity in this patient population.”

The Centers for Disease Control and Prevention estimates that nearly 21 percent of adolescents ages 12 to 19 years in the United States are obese.¹ A study conducted by the World Health Organization found that obesity in children ages five to 19 years has risen ten-fold in the past four decades and estimates that more children globally will be overweight rather than underweight by 2022.²

“We believe that Qsymia has significant clinical and commercial potential, and we are committed to capturing a larger share of the global market for anti-obesity medications,” said John Amos, Chief Executive Officer at VIVUS. “Expanding the body of clinical evidence supporting the safety and efficacy of Qsymia in diverse patient populations and clinical settings is an essential component of our strategy to demonstrate the clinical value of Qsymia and to make this product the leading global anti-obesity medication.”

In December 2019, VIVUS reported that data from a pharmacokinetic (PK) and pharmacodynamic (PD) study (NCT# 02714062) conducted in order to establish dosing levels for the ongoing Phase 4 post-marketing study demonstrated that Qsymia has favorable PK, efficacy, and safety/tolerability profiles when used for eight weeks to treat adolescents with obesity.

About the Phase 4 Post-Marketing Study

The Phase 4 post-marketing study, which the U.S. Food and Drug Administration (FDA) required as part of the approval of Qsymia in 2012, enrolled approximately 200 patients at 26 clinical sites in the United States. The primary endpoint of the randomized, double blind, placebo-controlled, parallel-design study is the mean percentage change in body-mass index (BMI) in patients randomized 1:2:1 to daily mid- or top-dose Qsymia compared with placebo over 56 weeks of treatment. Participants will also be instructed to follow a reduced-calorie diet and to implement a family-based lifestyle modification program that includes physical activity, behavioral change and family support. Safety and tolerability of Qsymia will also be assessed.

About Qsymia

Qsymia is approved in the United States and South Korea and is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of 30 kg/m² or greater (obese) or 27 kg/m² or greater (overweight) in the presence of at least one weight-related medical condition such as high blood pressure, type 2 diabetes, or high cholesterol.

The effect of Qsymia on cardiovascular morbidity and mortality has not been established. The safety and effectiveness of Qsymia in combination with other products intended for weight loss, including prescription and over-the-counter drugs, and herbal preparations, have not been established.

Important Safety Information

Qsymia (phentermine and topiramate extended-release) capsules CIV is contraindicated in pregnancy; in patients with glaucoma; in hyperthyroidism; in patients receiving treatment or within 14 days following treatment with monoamine oxidase inhibitors; or in patients with hypersensitivity to sympathomimetic amines, topiramate, or any of the inactive ingredients in Qsymia.

Qsymia can cause fetal harm. Females of reproductive potential should have a negative pregnancy test before treatment and monthly thereafter and use effective contraception consistently during Qsymia therapy. If a patient becomes pregnant while taking Qsymia, treatment should be discontinued immediately, and the patient should be informed of the potential hazard to the fetus.

The most commonly observed side effects in controlled clinical studies, 5% or greater and at least 1.5 times placebo, include paraesthesia, dizziness, dysgeusia, insomnia, constipation, and dry mouth.

About VIVUS

VIVUS is a biopharmaceutical company committed to the development and commercialization of innovative therapies that focus on advancing treatments for patients with serious unmet medical needs. For more information about VIVUS, please visit www.vivus.com.

Forward-Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995 and are subject to risks, uncertainties and other factors, including risks and uncertainties related to our ability to execute on our business strategy to enhance long-term stockholder value; risks and uncertainties related to our ability to address our outstanding balance of the convertible notes due in May 2020; risk and uncertainties related to the timing, strategy, structure and success of our capital raising efforts; risks and uncertainties related to our expected future revenues, operations and expenditures; risks and uncertainties related to the impact of the indicated uses and contraindications contained in the Qsymia label and the Risk Evaluation and Mitigation Strategy requirements; risks and uncertainties related to the timing of initiation and completion of the post-approval clinical studies required as part of the approval of Qsymia by the U.S. Food and Drug Administration ("FDA"), including the Phase 4 post-marketing study of Qsymia in obese adolescents; risks and uncertainties related to the response from FDA to any data and/or information relating to post-approval clinical studies required for Qsymia; risks and uncertainties related to the impact of any possible future requirement to provide further analysis of previously submitted clinical trial data; risks and uncertainties related to the design and outcome of any clinical study required by FDA to expand the Qsymia label; risks and uncertainties related to our, or our current or potential partners', ability to successfully commercialize Qsymia in their respective territories, including our partner in South Korea; and risks and uncertainties related to our ability to sell through the Qsymia retail pharmacy network and the Qsymia Advantage Program. These risks and uncertainties could cause actual results to differ materially from those referred to in these forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. Investors should read the risk factors set forth in VIVUS' Form 10-K for the year ended December 31, 2018 as filed on February 26, 2019, and periodic reports filed with the Securities and Exchange Commission. VIVUS does not undertake an obligation to update or revise any forward-looking statements.

VIVUS, Inc.

Mark Oki
Chief Financial Officer
oki@vivus.com
650-934-5200

Investor Relations: Lazar FINN Partners

David Carey
Senior Partner
david.carey@finnpartners.com
212-867-1768

¹ Centers for Disease Control and Prevention. Childhood Obesity Facts. Prevalence of Childhood Obesity in the United States. Available at: <https://www.cdc.gov/obesity/data/childhood.html>

² NCD Risk Factor Collaboration (NCD-RisC). Worldwide trends in body-mass index, underweight, overweight, and obesity from 1975 to 2016: a pooled analysis of 2416 population-based measurement studies in 128.9 million children, adolescents, and adults. *Lancet* 2017;390:2627-42.
