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): **May 28, 2019**

VIVUS, INC.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-33389**	**94-3136179**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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:

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

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 communication 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 communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communication 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 May 28, 2019, VIVUS, Inc. issued a press release titled "VIVUS Initiates Phase Four Safety and Efficacy Study of Qsymia® in Obese 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 issued by VIVUS, Inc. dated May 28, 2019.

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: May 28, 2019

Exhibit 99.1

VIVUS Initiates Phase Four Safety and Efficacy Study of Qsymia® in Obese 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., May 28, 2019 — VIVUS, Inc. (NASDAQ: VVUS; the "Company"), a biopharmaceutical company, today announced that the first patient has been enrolled in a Phase four clinical study designed to evaluate the safety and efficacy of Qsymia® (phentermine and topiramate extended-release) capsules CIV in obese adolescents between the ages of 12 and 17 years (NCT# 03922945). The Centers for Disease Control and Prevention estimates that nearly 21 percent of adolescents ages 12 to 19 years 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]

"Adolescent obesity represents one of the most critical medical and public health issues not only because one out of five teenagers is affected, but also due to the fact that medical treatment options are limited," said Aaron Kelly, PhD, Associate Professor of Pediatrics, Co-Director of the Center for Pediatric Obesity Medicine at the University of Minnesota, and an investigator on the trial. "Currently only one obesity medication for long-term use is approved for adolescents, and it is rarely prescribed because of its modest effectiveness and often intolerable side effects. More options are needed, and a new clinical trial evaluating the safety and effectiveness of Qsymia in adolescents with obesity is very important for the field of pediatric obesity medicine."

"Childhood and adolescent obesity is known to impact both physical and psychological health, and increases the risks of adult obesity, type 2 diabetes and lipid disorders," said Santosh T. Varghese, MD, Chief Medical Officer at VIVUS. "If this trial is successful, Qsymia could play an important role in helping obese adolescents achieve healthier weight goals."

The Phase four post-marketing study, which the U.S. Food and Drug Administration (FDA) required as part of the approval of Qsymia in 2012, is expected to enroll 200 patients at approximately 20 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 1:1:2 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.

“A previously completed pharmacokinetic (PK) study of Qsymia in obese adolescents showed PK parameters consistent with those observed in the clinical trials conducted in obese adults,” said John Amos, Chief Executive Officer at VIVUS. “These findings provide a strong rationale for evaluating the safety and efficacy of Qsymia in this patient population. Qsymia has demonstrated significant clinical benefits in the treatment of obese and overweight adults. If successful, this Phase four study could position Qsymia as an important new treatment option for millions of adolescents struggling with the near- and long-term challenges of obesity.”

The Company expects to report top-line results from this Phase four trial in the second half of 2020.

About Qsymia

Qsymia is approved in the United States 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/m^2 or greater (obese) or 27 kg/m^2 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 the Company, 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, or our current or potential partners', ability to successfully commercialize Qsymia; 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, or FDA; 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 our ability to work with FDA to significantly reduce or remove the requirements of the clinical post-approval cardiovascular outcomes trial, or CVOT; 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, or REMS, requirements; risks and uncertainties related to the impact of any possible future requirement to provide further analysis of previously submitted clinical trial data; and risks and uncertainties related to our dialog with the European Medicines Agency, or EMA, relating to the U.S.-based CVOT for Qsymia, and the resubmission of an application for the grant of a marketing authorization to EMA, the timing and scope of such resubmission, if any, the results of any required CVOT, the assessment by EMA of the application for marketing authorization, and their agreement with the data from any required CVOT and ultimately the decision of the European Commission whether to grant marketing authorization for Qsymia in the EU. 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.

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[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.