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): **December 18, 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 December 18, 2019, VIVUS, Inc. issued a press release titled "VIVUS Announces New Data Supporting the Safety and Efficacy of Qsymia® in Adolescents with Obesity." 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 December 18, 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: December 18, 2019

Exhibit 99.1

VIVUS Announces New Data Supporting the Safety and Efficacy of Qsymia® in Adolescents with Obesity

-Data published in Diabetes, Obesity and Metabolism demonstrate that Qsymia provides statistically significant weight loss compared with placebo over an 8 week period, provide basis for ongoing 56 week phase 4 study in obese adolescents-

CAMPBELL, Calif., December 18, 2019 — VIVUS, Inc. (Nasdaq: VVUS) (the "Company"), a biopharmaceutical company, today announced the results of a pharmacokinetic (PK) and pharmacodynamic (PD) study (NCT02714062) demonstrating that Qsymia® (phentermine and topiramate extended-release) capsules CIV has favorable pharmacokinetic, efficacy, and safety/tolerability profiles when used for eight weeks to treat adolescents with obesity. The study was conducted in order to establish dosing levels for the ongoing Phase 4 post-marketing study of Qsymia in obese adolescents. The results have been published online in *Diabetes, Obesity and Metabolism.*[1]

"Over the past 30 years, childhood obesity has become an epidemic and continues to be a major public health concern, with obesity rates currently over 18% for those between the ages of 12 and 19 years based on U.S. government data[2]," said Daniel Hsia, MD, an adult/pediatric endocrinologist, Associate Professor at Pennington Biomedical Research Center and lead author on the publication. "Lifestyle-based interventions alone often show only a modest effect on long-term weight loss, and overweight and obese children have more comorbidities compared with children with normal weight. Importantly, they are also five times more likely to become overweight or obese adults and have a higher risk of developing diabetes, hypertension, dyslipidemia, and coronary heart disease later in adulthood. More effective treatment modalities are urgently needed to address childhood obesity."

This randomized, double blind, placebo-controlled, study was conducted at four U.S. sites and enrolled 42 participants ages 12-17 years with a body-mass index (BMI) greater than or equal to the 95th percentile for age and sex. The study consisted of a 14-day (maximum) screening period followed by a 56-day treatment period. Eligible participants were randomly assigned in a 1:1:1 ratio to placebo, mid-dose Qsymia or top-dose Qsymia. Within each active treatment arm, doses were titrated at two-week intervals starting with low dose Qsymia and increasing until the randomized dose was achieved. Participants assigned to placebo underwent a sham titration to ensure that both participants and site personnel remained blinded to treatment assignment. The primary objective of the study was to describe the PK profiles of Qsymia after administration in adolescents with obesity.

Key findings from the study include:

- The study authors conclude that both the mid- and top-doses of Qsymia evaluated in this study are appropriate for longer-term safety and efficacy study in adolescents.
- PK analyses were conducted in 26 patients in the Qsymia groups (14 mid-dose and 12 top-dose), and results show that exposure to the mid- and top-dose Qsymia groups was comparable to that observed in prior studies of Qsymia in overweight and obese adults.
- Significant differences from baseline to Day 56 were observed with respect to mean percentage change in weight for both Qsymia groups compared with placebo (-3.72%, -4.96% and +1.06% for the mid- and top-dose Qsymia groups and placebo group, respectively); and for mean change in waist circumference and hunger scores for the top-dose Qsymia group compared with placebo (-2.8 cm, -4.9 cm, and +0.3 cm for the mid- and top-dose Qsymia groups and placebo group, respectively).
- Treatment emergent adverse events were reported in 54.8% of the 42 patients who entered the trial; specific events reported by two or more subjects included headache, paresthesia, hypoesthesia, dry mouth, decreased appetite, and insomnia. All of these have been observed in previous studies with Qsymia.
- Of the 42 patients enrolled, 37 (88.1%) completed the study, indicating tolerability of Qsymia.

“These findings add to the growing body of data supporting the safety and clinical benefit of Qsymia in diverse patient populations,” said John Amos, Chief Executive Officer at VIVUS. “Currently, there is only one approved weight loss drug for patients age 12 years and older and, while it effectively lowers BMI, its side effect profile of gastrointestinal distress has limited its clinical use. The data reported today suggest that Qsymia could be an important treatment option in this patient population, and our ongoing Phase 4 trial of Qsymia, if successful, could support label expansion to include adolescents who are overweight or obese.”

In May 2019, VIVUS initiated a Phase 4 post-marketing study, which the U.S. Food and Drug Administration (FDA) required as part of the approval of Qsymia in 2012. The study is expected to enroll 200 participants 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. To date, 98 patients have been enrolled and randomized.

References

[1] Hsia DS, Gosselin N, Williams J, Farhat N, Marier JF, Shih W, et al. A randomized, double-blind, placebo-controlled, pharmacokinetic and pharmacodynamic study of a fixed-dose combination of phentermine/topiramate in adolescents with obesity. Diabetes, Obesity and Metabolism. doi: 10.1111/dom.13910.

[2] Hales CM, Fryar CD, Carroll MD, Freedman DS and Ogden CL. Trends in obesity and severe obesity prevalence in US youth and adults by sex and age, 2007-2008 to 2015-2016. JAMA. 2018;319(16):1723-1725.

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 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 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; 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.

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