
**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): **November 20, 2019**

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 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 November 20, 2019, VIVUS, Inc. issued a press release titled “New Clinical Data Demonstrate VIVUS’ Qsymia® is Effective at Reducing Binge Eating in Patients with Binge-Eating Disorder or Bulimia Nervosa.” 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated November 20, 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: November 20, 2019



New Clinical Data Demonstrate VIVUS' Qsymia® is Effective at Reducing Binge Eating in Patients with Binge-Eating Disorder or Bulimia Nervosa

-Data published in International Journal of Eating Disorders show patients in the Qsymia group had 75% decrease in binge day frequency compared with 19% for placebo-

CAMPBELL, Calif., November 20, 2019 — VIVUS, Inc. (Nasdaq: VVUS) (the “Company”), a biopharmaceutical company, today announced the results of a clinical study (NCT02553824) demonstrating that patients with binge-eating disorder (BED) or bulimia nervosa (BN) receiving Qsymia (phentermine and topiramate extended-release (ER)) capsules CIV had a significant reduction in binge day frequency compared with placebo over four weeks. Additionally, Qsymia was well tolerated in these patient populations. The study results appear online in the *International Journal of Eating Disorders*.

“Dropout rates for the two pharmacologic therapies approved for BED and BN range from 20 to 30 percent and many patients using these medications remain symptomatic, underscoring the need for alternative therapeutic approaches,” said Santosh T. Varghese, MD, Chief Medical Officer at VIVUS. “The promising results announced today, along with previously reported data from another study evaluating Qsymia in BED, suggest that Qsymia could address an unmet treatment need in BED and BN and support further investigation of Qsymia as a treatment option for these serious medical conditions.”

The randomized, double blind, placebo-controlled, crossover study enrolled 22 patients (BED=18 and BN=4) who were randomized to Qsymia (n=12, 3.75/23 mg phentermine [PHEN]/topiramate [TPM]-ER — 15 mg PHEN/92 mg TPM-ER) or placebo (n=10) for 12 weeks. The mean baseline body mass index for the 22 was 31.1 kg/m². Following a two-week washout, patients crossed over to the other arm for 12 weeks. The primary outcome was the number of objective binge-eating (OBE) days over four weeks; secondary outcomes included binge abstinence. Demographics, vital signs, eating disorder behaviors, mood and side effect data were also collected.

Key findings from the study include:

- Mean OBE days over four weeks was 16.2 at baseline and decreased to 4.2 days and 13.2 days following Qsymia treatment and placebo, respectively (p < .0001).
 - Abstinence rates were 63.6% with Qsymia and 9.1% with placebo (p < .0001).
 - Qsymia was associated with a mean decrease in weight of 5.8 kg, compared with a mean gain of 0.4 kg on placebo.
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- There was a significant improvement in secondary measures assessing eating disordered related pathologies and comorbid mood symptoms and marked improvements in depressive symptoms were also observed in patients receiving Qsymia compared to placebo.
- No serious adverse events were reported. Patient-reported adverse events while on Qsymia were dry mouth (52.4% of patients), insomnia (28.6%), paresthesia (28.6%), dysgeusia (23.8%), anxiety (14.3%), nausea, cold intolerance, decreased appetite, dizziness, fatigue, hair loss and difficulty finding words (9.5% each).
- Dropout rates were the same between the Qsymia and placebo groups (9%).
- Blood pressure and heart rate changes with Qsymia were minimal and similar to placebo.
- Responses were not significantly different for BED versus BN.
- Binge eating returned and abstinence rates decreased during the eight-week post-treatment follow-up period, suggesting that additional approaches to improved maintenance are needed.

“These data further validate the clinical utility of Qsymia in helping patients with a variety of weight-related health conditions to achieve healthier eating behaviors,” said John Amos, Chief Executive Officer at VIVUS. “A growing body of data demonstrates that Qsymia has an excellent safety profile in diverse patient populations and that it may offer clinical benefit across a wide spectrum of weight- and eating-related health conditions.”

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/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 design and outcome of any clinical study required by the U.S. Food and Drug Administration to expand the Qsymia label for a binge eating indication; 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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