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): **August 20, 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):

- o Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o 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 o

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. o

Item 8.01. Other Events

On August 20, 2019, VIVUS, Inc. issued a press release titled "New Pilot Clinical Study Results Demonstrate that Addition of VIVUS' Qsymia® to Gastric Sleeve Surgery Significantly Improves Weight Loss Compared with Surgery Alone." 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 August 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: August 20, 2019

Exhibit 99.1

New Pilot Clinical Study Results Demonstrate that Addition of VIVUS' Qsymia® to Gastric Sleeve Surgery Significantly Improves Weight Loss Compared with Surgery Alone

-Data published in Surgery for Obesity and Related Diseases also show that patients in the Qsymia group lost more than twice as much weight during preoperative treatment compared with control group-

CAMPBELL, CA., August 20, 2019 — VIVUS, Inc. (NASDAQ: VVUS; the "Company") today announced the results of a pilot clinical study demonstrating that patients receiving Qsymia (phentermine and topiramate extended-release (ER)) capsules CIV before and after laparoscopic sleeve gastrectomy (LSG) surgery lost more weight and had a greater probability of achieving a body mass index (BMI) of less than 40 compared with patients undergoing surgery alone without anti-obesity medication (AOM). The study was conducted at the Wake Forest School of Medicine and the results appear in the current issue of *Surgery for Obesity and Related Diseases.*

"Patients with a BMI of 50 or greater generally benefit from bariatric surgery but have higher surgical risk and increased perioperative morbidity compared with patients with lower BMI," said Jamy Ard, MD, Professor, Epidemiology and Prevention at Wake Forest School of Medicine and lead author on the publication. "In an effort to reduce these risks, we undertook a pilot study to assess the feasibility and impact of using the drug before and after LSG surgery. Study results show that patients taking it lost significantly more weight before surgery and had improved outcomes with respect to weight loss and BMI than those not on AOM. This may allow more patients to avoid a secondary surgical procedure and its attendant risks. These results should be further evaluated in larger studies."

In addition to increased surgical risk, patients with a BMI of 50 or greater are likely to have a BMI of 40 or greater even after successful surgery. Physicians often address this issue by offering patients a two-stage weight loss process that involves an initial LSG followed by a second surgical procedure after initial post-LSG weight loss. Treatments that allow patients to achieve BMI of less than 40 after the initial LSG could reduce the need for a second surgical procedure, decreasing health risks and costs. "Though there is no consensus from a guidelines perspective, the use of the AOM Qsymia with a low-calorie diet prior to LSG has the potential to decrease weight and reduce surgical risk, while post-LSG Qsymia use could increase and maintain the total amount of weight lost with the potential to eliminate the need for a second surgical procedure," said Santosh T. Varghese, MD, Chief Medical Officer at VIVUS.

The pilot study recruited 25 participants with a BMI of 50 or more who were planning to undergo LSG. Patients in the control group had a BMI of 50 or more and underwent LSG in the same timeframe (June 2014 — July 2016) but were not included in the study protocol. Patients in the experimental arm received Qsymia at a dose of 3.75/23 mg once daily for two weeks, which was then increased to 7.5/46 mg or 15/92 mg daily in order to achieve the greatest weight loss with the fewest side effects. Patients tapered off the medication beginning two weeks prior to surgery in order to avoid potential interactions between phentermine and anesthesia and resumed dosing at 7.5/46 mg daily one month following LSG, with dose adjustments made monthly over the next two months. Patients then continued to utilize Qsymia for a 24-month period.

Key findings from the study include:

- The experimental group had a baseline BMI of 61.2 ± 7.1 kg/m2 compared with 57.0 ± 5.6 kg/m2 for control participants. At 24 months, the mean BMI was 33.8 kg/m2 for the experimental group vs. 42 kg/m2 for control participants.
- Of the 25 patients recruited, 13 completed LSG. Patients who did not complete LSG were due to: medical complications unrelated to Qsymia (n=2), decision not to pursue surgery (n=1), Qsymia-related adverse events (n=3), because they were lost to follow-up and withdrawn from the study (n=4) or opted to undergo a surgical procedure other than LSG (n=2).
- Patients in the experimental arm lost more than twice the weight with an average of 28.1 kg during the pre-operative period compared with an average of 12.3 kg for those in the control group.
- At two years post-LSG, the experimental group lost 11.2% more of initial body weight compared with controls (p=0.007), which translates to a -18.2% difference in percent excess weight loss (%EWL) of favoring the experimental group.
- A higher proportion of patients in the experimental group compared with controls achieved a BMI less than 40 at 3, 6, 12 and 24 months post-LSG (61.5% vs. 47.5% at 24 months, respectively).
- There was a significant increase in the odds of achieving BMI less than 40 for the experimental group compared with controls at 6 months post-LSG (odds ratio = 4.1); at 24 months the odds ratio remained 4.1 but was no longer statistically significant.

The study authors conclude that for patients with a BMI of 50 or more the combination of LSG and phentermine/topiramate ER (Qsymia) had a robust impact on patients both before and for up to two years after LSG surgery.

“This pilot study adds to the growing body of data supporting the use of Qsymia in a variety of therapeutic strategies for helping adults with obesity improve their BMI and achieve more healthy weight goals,” said John Amos, Chief Executive Officer at VIVUS. “The potential to help these patients achieve a BMI less than 40 and potentially avoid the need for a second surgical procedure would be an important advance in improving outcomes while reducing risk. Additionally, the enhanced pre-LSG weight loss in the experimental group compared with controls further underscores the clinical benefit that Qsymia can provide even in patients with a BMI of 50 or more.”

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 ability to execute on our business strategy to enhance long-term stockholder value; risks and uncertainties related to our expected future revenues, operations and expenditures; 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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