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): **January 7, 2020**

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 January 7, 2020, VIVUS, Inc. issued a press release titled “New Data Further Demonstrate Effectiveness of VIVUS’ Qsymia as a Weight Management Tool.” 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 January 7, 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: January 7, 2020

Exhibit 99.1

New Data Further Demonstrate Effectiveness of VIVUS' Qsymia as a Weight Management Tool

*-Data published in **Journal of General Internal Medicine** show that patients using Qsymia and other weight loss tools, lost at least 5% of body weight loss compared with those not using Qsymia-*

CAMPBELL, Calif., January 7, 2020 – VIVUS, Inc. (Nasdaq: VVUS), a biopharmaceutical company, today announced the publication of a new study from the Toolbox Trial (NCT01922934), a real-world clinical trial conducted in urban safety-net primary care clinics offering patients a "toolbox" of cost-effective weight management tools. The study, published in the *Journal of General Internal Medicine*[1] (JGIM), found that a higher proportion of subjects who initially selected Qsymia from the toolbox or added it to their weight management plans during the study period achieved at least a 5% weight loss compared with subjects who never used Qsymia.

"Despite the known health benefits of maintaining a healthy weight, many patients do not receive ongoing counsel and access to cost-effective weight management tools," said Daniel Bessesen, MD, Professor of Medicine, Division of Endocrinology, Metabolism and Diabetes, University of Colorado, School of Medicine and the principle investigator and senior author on the study. "The Toolbox Trial was designed to provide insight into treatment choices and outcomes when patients are offered a variety of low out-of-pocket cost weight management options. The finding that more patients who included a weight loss medication in their weight management plans (almost all of whom chose Qsymia as their medication option compared with phentermine) achieved at least 5% weight loss provides additional support for the use of pharmacotherapy in helping patients achieve and maintain a healthy weight in real-world settings."

About the Toolbox Trial

The Toolbox Trial was a 12-month real-world, open-label, single institution intervention study with a registry-based comparator group that offered patients with obesity a toolbox of weight management services for $5 or $10 per month. The services included partial meal replacement, recreation center membership, phentermine, Qsymia, Weight Watchers vouchers and group behavioral weight loss program. At the start of the trial, each patient selected one tool. At each monthly visit, patients had the option of continuing with the initial tool selected or switching to a different tool. After six months, patients could pay an additional $5 per month to add recreation center vouchers or a behavioral weight loss program. The trial was conducted in primary care clinics at Denver Health, an urban safety-net healthcare organization serving a low-income, ethnically diverse population. The primary outcome was at least 5% weight loss at 12 months. There were 305 intervention-eligible participants, of which 119 selected and paid for a tool.

Key findings from the study include:

- Significantly more intervention-eligible patients than comparators achieved the primary endpoint (23.3% vs. 15.7%, $p<0.001$).
- Of the 113 patients who were on treatment, 34.5% achieved the primary endpoint.
- Of the 119 patients who selected and paid for a tool, initial selections were meal replacements (35.3%), weight loss medication (28.6%, including 33 subjects, or 27.7%, who chose Qsymia), recreation center membership (21.8%), Weight Watchers vouchers (6.7%), group behavioral weight loss program (5.9%) and ongoing contact (1.7%).
- More than half (56.3%) of patients switched tools at least once and 29.4% added a second tool at six months.
- The proportion of patients selecting Qsymia increased over time, while the proportion of patients using meal replacements or recreation center passes declined.
- A higher proportion of patients who added a second tool or ever used Qsymia during the study achieved the primary endpoint compared with those who never used Qsymia.
- The proportion of intervention-eligible and on-treatment patients who achieved the primary endpoint was higher than the comparator group who received usual care.

These findings build on an earlier study from the Toolbox Trial published in 2018 in *Obesity Journal*[2], which found that education about the relative effectiveness of the weight-loss tools within the primary care setting as well as direct experience with patients using these medications, resulted in physicians giving higher effectiveness ratings to weight loss medications. In this study, PCPs from the four intervention clinics (PCP-I) as well as PCPs from the five control clinics (PCP-C) who were part of the Toolbox Trial completed pre- and post-trial surveys on weight-loss counseling, comfort discussing obesity treatments and perceived effectiveness of weight loss interventions. PCP-I received updates on their patients who were participating in the trial and education about weight loss medication, while PCP-C did not receive this information. The key finding from this study was that providers initially overvalued exercise and undervalued weight-loss medications in the treatment of obesity, and that providers who were exposed to education and patient experience gave higher comfort and effectiveness ratings to weight loss medications.

“These two studies highlight the significant market opportunity for Qsymia and provide important insight into the types of physician education and patient outreach initiatives required to educate stakeholders about Qsymia’s role in helping individuals who are overweight or obese achieve and maintain a healthy weight,” said John Amos, Chief Executive Officer at VIVUS. “We are evaluating how to incorporate these insights into the VIVUS Health Platform and the Qsymia Advantage Program. Our goal is to provide individuals who are overweight or obese with an integrated weight management strategy that integrates nutrition science, pharmaceutical science and technology and is optimized for long-term success in achieving and maintaining a healthy weight.”

References

[1] Saxon DR, Chaussee EL, Juarez-Colunga E, Tsai AG, Iwamoto SJ, Speer RB, et al. A toolbox approach to obesity treatment in urban safety-net primary care clinics: a pragmatic clinical trial. J Gen Intern Med. 2019;34(11):2405-2413.

[2] Iwamoto S, Saxon D, Tsai A, Leister E, Speer R, Heyn H, et al. Effects of education and experience on primary care providers' perspectives of obesity treatments during a pragmatic trial. Obesity Journal. 2019;26(10):1532-1538.

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 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; 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