UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 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 14, 2019

VIVUS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-33389**	**94-3136179**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

900 E. HAMILTON AVENUE, SUITE 550
CAMPBELL, CA 95008
(Address of principal executive offices, including zip code)

(650) 934-5200
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

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 communications 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 communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications 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 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 January 14, 2019, VIVUS, Inc. issued a press release titled "Data Supporting the Cardiovascular Safety of VIVUS' Qsymia® Published in *The Journal of Clinical Endocrinology & Metabolism*." 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 January 14, 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: January 14, 2019

Data Supporting the Cardiovascular Safety of VIVUS' Qsymia® Published in *The Journal of Clinical Endocrinology & Metabolism*

-Study finds no increase in risk for major adverse cardiovascular events for individuals currently using phentermine in combination with topiramate; study adds to robust data supporting the safety and efficacy of Qsymia-

CAMPBELL, CA., January 14, 2019 — VIVUS, Inc. (NASDAQ: VVUS; the "Company"), a biopharmaceutical company, today announced that results from a new study evaluating the cardiovascular safety of Qsymia® (phentermine and topiramate extended-release) capsules CIV will be published in the February 1, 2019 issue of *The Journal of Clinical Endocrinology & Metabolism* and are currently available online.[1] This retrospective study, conducted using medical claims databases, was prompted by the observation in clinical trials that participants taking Qsymia had higher heart rates than those taking placebo. The new findings indicate that the combined risk of major adverse cardiovascular events (MACE) was not elevated in patients currently taking Qsymia, or concurrently taking both phentermine and topiramate, compared with former users of these medications. The number of MACE events (3 events during 3,245 person-years of follow-up) was too few to draw a definitive conclusion from the data. Results from the study were previously presented in a poster at the 34th International Conference on Pharmacoepidemiology & Therapeutic Risk Management in August 2018.

"The results of this study provide some assurance that, despite the increase in heart rate seen in the clinical trials, current use of phentermine in combination with topiramate did not appear to be associated with a higher cardiovascular risk. We note that the confidence intervals for this observation were broad, indicating that the data were imprecise and compatible with a considerable range of possible effects," said Peter R. Kowey, MD, Emeritus Chief, Cardiology at Lankenau Heart Institute, Professor of Medicine and Pharmacology at Jefferson Medical College in Philadelphia, and an author on the publication.

"Obesity is a significant and growing problem in the United States. Safe and effective tools for managing body weight and body mass index are critical for helping patients reduce the risks of overall cardiovascular and diabetes-related mortality, which are increased in obese individuals. Qsymia provides a safe and efficacious option for patients seeking to manage body weight and body mass index," said Santosh T. Varghese, MD, Chief Medical Officer at VIVUS.

More than 500,000 patients were included in this retrospective study, which evaluated risk of MACE among current users of Qsymia, phentermine and topiramate in combination (PHEN/TPM), phentermine (PHEN), and topiramate (TPM), compared to the risk among patients who were former users who had discontinued these medications. MACE was defined as hospitalization for acute myocardial infarction (AMI) or stroke or in-hospital cardiovascular-related death, as determined via discharge status and ICD-9-CM diagnoses.

“Qsymia is an effective tool as a component of body mass index management regimens. These study results provide additional evidence that its use does not increase MACE risk,” said John Amos, Chief Executive Officer at VIVUS. “We intend to include these findings in our ongoing discussions with the U.S. Food and Drug Administration related to our requested label modification for Qsymia. The requested modification would allow for the safe and effective short-term use of Qsymia and could potentially reduce or modify the need for a cardiovascular outcomes study.”

The efficacy and safety of Qsymia have been demonstrated in multiple clinical trials and peer-reviewed publications, including:

- A Phase 3 randomized, placebo-controlled Phase 3 trial conducted in 1,267 obese adults with body-mass index (BMI) $\geq$ 35 kg/m^2 (EQUIP).[2] Patients were randomized to placebo, phentermine/topiramate controlled release (PHEN/TPM CR) 3.75/23 mg, or PHEN/TPM CR 15/92 mg, added to a reduced-energy diet. At 56 weeks, patients lost 1.6%, 5.1% and 10.9%, respectively, of baseline body weight ($p<0.0001$). A significantly higher proportion of patients achieved at least 5% weight loss in the PHEN/TPM CR groups compared with placebo ($p<0.0001$). Study authors suggest that the beneficial effects of PHEN/TPM CR on weight, blood pressure, lipids, and glycemic measures mitigate any adverse effects on heart rate.

- A Phase 3 randomized, placebo-controlled 56-week trial conducted in 2,487 adults with BMI 27—45 kg/m^2 and two or more comorbidities (hypertension, dyslipidaemia, diabetes or prediabetes, or abdominal obesity) (CONQUER).[3] Patients were randomly assigned to receive PHEN/TPM CR 7.5/46.0 mg (n = 498), PHEN/TPM CR 15.0/92.0 mg (n = 995) or placebo (n = 994). At 56 weeks, change in bodyweight in the 2,448 patients available for analysis was —1.4 kg, —8.1 kg, and —10.2 kg ($p<0.0001$) in the patients assigned to placebo, PHEN/TPM CR 7.5/46.0 mg, and PHEN/TPM CR 15.0/92.0 mg, respectively. A significantly higher proportion of patients achieved at least 5% or at least 10% weight loss in the PHEN/TPM CR groups compared with placebo ($p<0.0001$) for all comparisons. Study authors also noted significant improvements in blood pressure, waist circumference, lipid concentrations, glycaemia and inflammatory biomarkers (high sensitivity C-reactive protein and adiponectin) in the PHEN/TPM CR group compared with placebo.

- A two-year Phase 3 randomized, placebo-controlled study (SEQUEL)[4], which was a 52-week extension study of CONQUER. A total of 866 patients from CONQUER were eligible for the extension study, of which 676 elected to participate in SEQUEL. At week 108, PHEN/TPM CR was associated with significant, sustained weight loss (intent-to-treat with last observation carried forward; $p < 0.0001$ compared with placebo). Percentage changes from baseline in body weight were —1.8%, —9.3%, and —10.5% for placebo, 7.5/46, and 15/92, respectively. Significantly more PHEN/TPM CR—treated subjects at each dose achieved $\geq$ 5%, $\geq$ 10%, $\geq$ 15%, and $\geq$ 20% weight loss compared with placebo ($p < 0.001$). No cardiovascular safety signals were detected.

    - A sub-analysis of SEQUEL conducted in 475 patients with prediabetes and/or metabolic syndrome (MetS).[5] After 108 weeks, subjects with prediabetes and/or MetS in the placebo, 7.5/46, and 15/92 groups experienced mean percent weight loss of 2.5%, 10.9%, and 12.1%, respectively ($p < 0.0001$ vs. placebo). These losses were associated with reductions of 70.5% and 78.7% in the annualized incidence rate of type 2 diabetes for those receiving 7.5/46 and 15/92, respectively ($p < 0.05$), versus placebo. No cardiovascular safety signals were observed in this patient subset.

- A Phase 2 randomized, double-blind, placebo-controlled study of PHEN/TPM CR 15/92 for the treatment of moderate to severe obstructive sleep apnea (OSA) in obese adults.[6] A total of 45 patients were randomized to placebo (n = 23) or PHEN/TPM CR (n = 22) for 28-week treatment periods in addition to lifestyle-modification counseling. At 28 weeks, changes in the apnea-hypopnea index (AHI), significantly favored PHEN/TPM CR over placebo (-31.5 events/h vs. 16.6 events/h, $p = 0.0084$). At week 28 there was also a positive, significant ($p = 0.0003$) correlation between percent change in weight and change in AHI. Authors also noted significant improvements in overnight oxygen saturation and reduction in blood pressure compared to placebo.

- A subset analysis of health-related quality of life (HRQOL) conducted in 2,374 patients who had participated in EQUIP (n = 751) or CONQUER (n = 1,623) and completed HRQOL questionnaires at weeks 28 and 56. Significant improvements in both obesity-specific and physical HRQOL were observed at 56 weeks in both trials ($p < 0.0001$). Although reduction in BMI accounted for the majority of improvements in obesity-specific and physical HRQOL, decrease in depressive symptoms was also a significant mediator.

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 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 fact that we may be required to provide further analysis of previously submitted clinical trial data; and risks and uncertainties related to our discussions with the European Medicines Agency, or EMA, relating to the resubmission of the marketing authorization application for Qsymia, and the assessment by the EMA of the marketing authorization application. 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, 2017 as filed on March 14, 2018, and as amended by the Form 10-K/A filed on April 26, 2018, 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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