# 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)
**August 27, 2018**

# 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 August 27, 2018, VIVUS, Inc. issued a press release titled "VIVUS Reports Data Supporting the Cardiovascular Safety of Qsymia®." 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 August 27, 2018. |

**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 27, 2018

**VIVUS Reports Data Supporting the Cardiovascular Safety of Qsymia®**

*-Retrospective analysis presented at the 34th International Conference on Pharmacoepidemiology & Therapeutic Risk Management-*

CAMPBELL, CA., August 27, 2018 — VIVUS, Inc. (NASDAQ: VVUS; the "Company"), a biopharmaceutical company, has reported encouraging data from a retrospective analysis evaluating the cardiovascular safety of Qsymia® (phentermine and topiramate extended-release) capsules CIV. Results show that the risk of major adverse cardiovascular events (MACE) trended lower in patients taking Qsymia compared with similar patients who were not taking Qsymia. The results were presented yesterday in a poster at the 34th International Conference on Pharmacoepidemiology & Therapeutic Risk Management, which took place in Prague, Czech Republic, August 22-26.

"The results of this retrospective analysis add to the body of data demonstrating that Qsymia does not increase the risk of MACE," said John Amos, Chief Executive Officer at VIVUS. "We continue to believe that Qsymia provides patients with significant benefits as a platform for managing body mass index, and our ongoing dialogue with the U.S. Food and Drug Administration includes a label modification request to allow for the safe and effective short-term utilization of Qsymia while significantly reducing or eliminating the requirement for conducting a cardiovascular outcomes study."

Results of the study were presented in a poster titled "Cardiovascular Safety of Phentermine and Topiramate in a United States Claims Database," (Abstract 983/118). The study was a retrospective cohort analysis conducted in MarketScan Commercial Claims and Medicare Supplemental data. The study evaluated MACE rates during periods of exposure to Qsymia, generic phentermine and topiramate combinations (PHEN/TPM) and phentermine (PHEN) or topiramate (TPM) alone, and compared each of these to MACE rates during unexposed periods in former users of these drugs. MACE was defined as a composite of hospitalization for acute myocardial infarction (AMI), stroke, or in-hospital cardiovascular-related death as determined via discharge status and ICD-9-CM diagnoses.

Propensity scores were calculated to adjust for differences in cardiovascular risk factors among the cohorts. Propensity score-adjusted analyses showed that MACE risk trended lower with current Qsymia and PHEN/TPM use compared with the unexposed cohort. Compared to the unexposed cohort, MACE risk was also lower with current PHEN use and higher with current TPM use. The study authors note that the small number of events that occurred during exposure to Qsymia and PHEN/TPM produced considerable statistical uncertainty in the analysis of these cohorts.

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***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.

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***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 dialog with the European Medicines Agency, or EMA, relating to real world safety data for Qsymia and the resubmission of the marketing authorization application, and the assessment by the EMA of the marketing authorization application and the real world safety data. 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.*

**VIVUS, Inc.**
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