

**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): **October 7, 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:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
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 October 7, 2019, VIVUS, Inc. issued a press release titled “VIVUS Announces Acceptance of Qsymia Decentralized Marketing Authorization Application in Europe.” 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 October 7, 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: October 7, 2019



VIVUS Announces Acceptance of Qsymia Decentralized Marketing Authorization Application in Europe

CAMPBELL, Calif., Oct. 7, 2019 — VIVUS, Inc. (Nasdaq: VVUS) (the “Company”), a biopharmaceutical company, announced today that European regulatory agencies in Sweden, Denmark, Finland, Iceland, Norway, and Poland (the “Concerned Member States”) have accepted the Marketing Authorization Application (the “MAA”) for Qsymia (phentermine and topiramate extended-release) on a decentralized basis, with Sweden acting as the lead Concerned Member State, also known as the Reference Member State, for purposes of assessing the MAA. Under the decentralized MAA procedure, the regulatory authorities in each of the Concerned Member States may simultaneously provide Marketing Authorization for use of a product within those specific countries.

“With the growing body of real world evidence supporting the safety and efficacy of Qsymia and its recent approval in the Republic of Korea, we believe that there is growing recognition of the benefit that this therapy can provide to patients seeking to achieve and maintain a healthy body mass index,” said John Amos, Chief Executive Officer of VIVUS. “As we gain traction in capturing a growing share of the market for weight management therapies in the United States, we continue to work with international regulators and current or potential commercial partners to expand Qsymia into additional countries. We believe that Qsymia has an important role to play in addressing the growing challenge of obesity in the United States, Europe, and other markets.”

Based on the decentralized MAA procedure timelines, the Company anticipates the completion of the MAA assessment and, if approved, Marketing Authorizations to begin in the second half of 2020.

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, 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 dialog with certain concerned member states in Europe relating to the pending decentralized Marketing Authorization Application, the timing and scope of the assessment by such Concerned Member State health authorities of our Marketing Authorization Application, and ultimately the decision of such Concerned Member State health authorities whether to grant Marketing Authorization for Qsymia in such EU countries; risks and uncertainties related to our, or our current or potential partners', ability to successfully seek and gain approval for Qsymia in territories outside the U.S.; 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.

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