

**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 30, 2017

VIVUS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-33389
(Commission File Number)

94-3136179
(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):

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

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 September 6, 2017, VIVUS, Inc. issued a press release titled "VIVUS Announces Tacrolimus Receives Orphan Drug Designation in the European Union for the Treatment of Pulmonary Arterial Hypertension." 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
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99.1	Press Release issued by VIVUS, Inc. dated September 6, 2017.
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EXHIBIT INDEX

Number	Description
99.1	Press Release issued by VIVUS, Inc. dated September 6, 2017.

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: September 6, 2017



VIVUS Announces Tacrolimus Receives Orphan Drug Designation in the European Union for the Treatment of Pulmonary Arterial Hypertension

CAMPBELL, CA., September 6, 2017 — VIVUS, Inc. (Nasdaq:VVUS) (the “Company”), a biopharmaceutical company committed to the development and commercialization of innovative therapies focusing on treatments for patients with serious unmet medical needs, today announced that the European Medicines Agency (EMA) has granted Orphan Drug Designation to the Company’s lead clinical candidate tacrolimus, for the treatment of pulmonary arterial hypertension (PAH).

“Receiving Orphan Drug Designation from the EMA is an important milestone in our long-term development and commercialization strategy for tacrolimus,” said Seth H. Z. Fisher, VIVUS’ Chief Executive Officer. “There is an urgent need for new therapies that have the potential to address the underlying cause of PAH, and we are committed to advancing tacrolimus as a novel approach to treating this debilitating disease.”

Orphan Drug Designation is awarded for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition that is rare (affecting not more than five in 10,000 people in the European Union) or where the medicine is unlikely to generate sufficient profit to justify research and development costs. This designation provides VIVUS with a number of potential incentives in the EU. Tacrolimus was granted Orphan Drug Designation by the U.S. Food & Drug Administration (FDA) for the treatment of PAH in March 2015.

VIVUS remains on track to hold a pre-IND meeting with the FDA by the end of 2017.

About Pulmonary Arterial Hypertension (PAH)

PAH is a chronic life-threatening disease characterized by elevated blood pressure in the pulmonary arteries (arteries between the heart and lungs) due to severe constriction of these blood vessels. These high pressures make it difficult for the heart to pump blood through the lungs to be oxygenated. The symptoms of PAH are non-specific and can range from mild shortness of breath and fatigue during normal daily activity to symptoms of right heart failure and severe restrictions on exercise capacity and ultimately reduced life expectancy. PAH includes patients with idiopathic PAH, familial PAH, and associated PAH, which is related to certain conditions including connective tissue diseases, congenital systemic-to-pulmonary-shunts, portal hypertension, HIV infection, drugs and toxins. The current treatments for PAH involve calcium channel antagonists, prostacyclins, prostacyclin receptor (IP receptor) agonist, endothelin receptor antagonists, phosphodiesterase-5 (PDE5) inhibitors, and long-term anticoagulant therapy, with the aim to reduce symptoms and improve quality of life.

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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.

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 potential change in our business strategy to enhance long-term stockholder value; risks and uncertainties related to our ability to successfully develop or acquire a proprietary formulation of tacrolimus as a precursor to the clinical development process; risks and uncertainties related to our ability to continue to identify, acquire and develop innovative investigational drug candidates and drugs; risks and uncertainties related to the failure to obtain FDA or foreign authority clearances or approvals and noncompliance with FDA or foreign authority regulations; risks and uncertainties related to our ability to develop a proprietary formulation and to demonstrate through clinical testing the quality, safety, and efficacy of our current or future investigational drug candidates; and risks and uncertainties related to the timing of initiation and completion of clinical trials and submissions to U.S. and foreign authorities. 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, 2016 as filed on March 8, 2017 and as amended by the Form 10-K/A filed on April 26, 2017, and periodic reports filed with the Securities and Exchange Commission. VIVUS does not undertake an obligation to update or revise any forward-looking statements.

CONTACT:

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