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)
July 10, 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):

☐ 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 July 10, 2018, VIVUS, Inc. issued a press release titled "VIVUS Announces Positive Results from a Phase 1 Clinical Trial of VI-0106." 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 July 10, 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: July 10, 2018

Exhibit 99.1

VIVUS Announces Positive Results from a Phase 1 Clinical Trial of VI-0106

-Favorable pharmacokinetic results add to body of data supporting continued development in the treatment of pulmonary arterial hypertension-

CAMPBELL, CA., July 10, 2018 — VIVUS, Inc. (NASDAQ: VVUS; the "Company"), a biopharmaceutical company, today announced positive preliminary results from a Phase 1 clinical study evaluating the pharmacokinetic (PK) profile of its VI-0106 in healthy volunteers. VIVUS is developing VI-0106, a proprietary soft capsule formulation of tacrolimus for the treatment of pulmonary arterial hypertension (PAH), a degenerative disease that makes it difficult for the heart to pump blood through the lungs to be oxygenated and may ultimately lead to heart failure.

Current PAH treatment options only address the symptoms, slowing but not preventing disease progression. New therapies that address the underlying cause of disease are urgently needed. The U.S. Food and Drug Administration (FDA) approved tacrolimus in 1994 for use in lowering the risk of organ rejection in patients undergoing kidney transplant, and the drug is currently indicated for use in additional organ transplant settings and to treat atopic dermatitis. Tacrolimus has been shown to increase signaling through the bone morphogenetic protein receptor 2 (BMPR2) pathway, which is down-regulated in PAH patients.

"The positive Phase 1 data from this study of VI-0106 in healthy volunteers support continued evaluation of this investigational candidate in PAH patients," said John Amos, Chief Executive Officer at VIVUS. "The worldwide and U.S. markets for PAH therapies were approximately $4.5 billion and $2.7 billion, respectively, in 2015, and we believe that VI-0106 has the potential to capture significant market share as a first-in-class therapy with a novel mechanism of action. We are exploring a variety of strategies for leveraging this collection of data to advance this program consistent with our goals of working toward profitability and reducing our corporate debt."

The single-center, UK-based Phase 1 PK study was conducted in two parts. Sixteen healthy volunteers were enrolled in Part 1 and each patient sequentially received single doses of three different tacrolimus prototype regimens administered at least 10 days apart. An interim analysis was conducted following the third dosing period to select a formulation prototype with the most desirable PK profile. Three subsequent periods assessed the selected formulation at different doses, or under different fed/fasted conditions. The second part of the study evaluated steady-state PK parameters in 12 healthy volunteers receiving daily doses of the selected prototype formulation.

Dr. Santosh T. Varghese, MD Chief Medical Officer at VIVUS stated, “The key findings from the Phase 1 PK study show that prototype formulations had PK profiles consistent with earlier in-vitro evaluations, namely an extended Tmax, a lowered Cmax, and an increased AUC compared to available immediate release tacrolimus. Moreover, data from this study demonstrate that once-daily dosing of VI-0106 may facilitate maintenance of the low tacrolimus concentrations required for the treatment of PAH with minimal monitoring of drug levels.” Dr. Varghese further added, “Based on the ongoing COMPERA registry study, the five-year survival rate for high risk PAH patients is 22.8%. We are hopeful that VI-0106 can be added to the therapeutic options for patients and their treating physicians.”

VIVUS is developing VI-0106 under the FDA’s 505(B)(2) regulatory pathway, which will allow the Company to leverage the FDA’s finding of safety and effectiveness for tacrolimus as well as a significant body of previously published tacrolimus safety and efficacy data. This is expected to reduce the time and cost to develop VI-0106 as a potential breakthrough therapy for the treatment of PAH.

In September 2017, results of a university-run Phase 2a clinical study of tacrolimus in patients with PAH were published in the *European Respiratory Journal*. Study results demonstrate the safety of tacrolimus in patients with PAH.

The currently approved formulation of VI-0106 tacrolimus was also provided for compassionate use in three class 3 or 4 PAH patients. The compassionate use demonstrated dramatically reduced rates of hospitalizations and functional class improvements were observed.

VIVUS believes that VI-0106 could become an important new treatment option for PAH patients and intends to request both Fast Track and Breakthrough Therapy Designation from the FDA for VI-0106 in this indication. Breakthrough therapy designation is intended to expedite the development and review of drugs for serious or life-threatening conditions. The criteria for breakthrough therapy designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy.

About Pulmonary Arterial Hypertension (PAH)

PAH is a chronic life-threatening disease characterized by endothelial dysfunction in the pulmonary vasculature, resulting in excess smooth muscle proliferation, elevated blood pressure in the pulmonary arteries (arteries between the heart and lungs), and ultimately right-sided heart failure. 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, soluble guanylate cyclase stimulators, and long-term anticoagulant therapy, with the aim to reduce symptoms and improve quality of life.

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 potential change in our business strategy to enhance long-term stockholder value, including the acquisition of revenue generating products and the strengthening of our balance sheet; risks and uncertainties related to our ability to address or reduce our outstanding balance of the convertible notes due in 2020; risks and uncertainties related to our expected future revenues, operations and expenditures; 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 identify, acquire and develop new product pipeline candidates; 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 failure to obtain FDA or foreign authority clearances or approvals and noncompliance with FDA or foreign authority regulations. 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.
Mark Oki
Chief Financial Officer
oki@vivus.com
650-934-5200

Investor Relations: Lazar Partners
David Carey
Managing Director
dcarey@lazarpartners.com
212-867-1768