
**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)
March 14, 2019

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 March 14, 2019, VIVUS, Inc. issued a press release titled “VIVUS Announces Marketing Approval of Avanafil in the Russian Federation for the Treatment of Erectile Dysfunction.” 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 issued by VIVUS, Inc. dated March 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: March 14, 2019



VIVUS Announces Marketing Approval of Avanafil in the Russian Federation for the Treatment of Erectile Dysfunction

CAMPBELL, CA., March 14, 2019 — VIVUS, Inc. (NASDAQ: VVUS; the “Company”), a biopharmaceutical company, today announced that the Ministry of Health of the Russian Federation has approved 50 mg, 100 mg and 200 mg tablets of avanafil for the treatment of erectile dysfunction (ED). The product will be marketed in the Russian Federation under the brand name RAZATUS.

“The approval of avanafil in the Russian Federation adds to the growing list of territories in which the product is now available for the treatment of ED and demonstrates the high quality capabilities of our Regulatory Affairs team, in close collaboration with our partners Sanofi and Menarini, to obtain drug approvals in multiple jurisdictions,” said John Amos, Chief Executive Officer at VIVUS. “Following recent approvals of avanafil in Jordan, Saudi Arabia, Turkey and the United Arab Emirates, approval in the Russian Federation further demonstrates the potential of the product in multiple global markets. We will continue to drive licensing opportunities for avanafil and effectively manage our existing avanafil license agreements for optimal royalties.”

VIVUS has licensed the rights to avanafil in a variety of global territories. These include an exclusive license to Menarini to commercialize and promote avanafil as SPEDRA for the treatment of ED in over 40 European countries, including the EU Member States, plus Australia and New Zealand, and an exclusive license to Metuchen to market STENDRA in the United States, Canada, South America and India. The Company is currently in discussions with potential partners to develop, market and sell avanafil for territories in which it does not currently have a commercial collaboration, including the Middle East and Africa, Russia and certain former CIS countries, and Central America and Mexico.

About Avanafil

Avanafil is an oral phosphodiesterase type 5 (PDE5) inhibitor indicated for the treatment of erectile dysfunction. The product received U.S. Food and Drug Administration approval for the treatment of erectile dysfunction in April 2012 under the approved trade name STENDRA. In June 2013, the EC adopted a decision granting marketing authorization for SPEDRA, the approved trade name for avanafil in the EU, for the treatment of ED in the EU.

Important Safety Information for Avanafil

Avanafil is prescribed to treat erectile dysfunction (ED).

Do not take avanafil if you take nitrates, often prescribed for chest pain, as this may cause a sudden, unsafe drop in blood pressure.

Discuss your general health status with your healthcare provider to ensure that you are healthy enough to engage in sexual activity. If you experience chest pain, nausea, or any other discomforts during sex, seek immediate medical help.

Avanafil may affect the way other medicines work. Tell your healthcare provider if you take any of the following; medicines called HIV protease inhibitors, such as ritonavir (Norvir[®]), indinavir (Crixivan[®]), saquinavir (Fortavase[®] or Invirase[®]) or atazanavir (Reyataz[®]); some types of oral antifungal medicines, such as ketoconazole (Nizoral[®]), and itraconazole (Sporanox[®]); or some types of antibiotics, such as clarithromycin (Biaxin[®]), telithromycin (Ketek[®]), or erythromycin.

In the rare event of an erection lasting more than 4 hours, seek immediate medical help to avoid long-term injury.

In rare instances, men taking PDE5 inhibitors (oral erectile dysfunction medicines, including avanafil) reported a sudden decrease or loss of vision. It is not possible to determine whether these events are related directly to these medicines or to other factors. If you experience sudden decrease or loss of vision, stop taking PDE5 inhibitors, including STENDRA, and call a doctor right away.

Sudden decrease or loss of hearing has been rarely reported in people taking PDE5 inhibitors, including STENDRA. It is not possible to determine whether these events are related directly to the PDE5 inhibitors or to other factors. If you experience sudden decrease or loss of hearing, stop taking STENDRA and contact a doctor right away. If you have prostate problems or high blood pressure for which you take medicines called alpha blockers or other anti-hypertensives, your doctor may start you on a lower dose of avanafil.

Drinking too much alcohol when taking avanafil may lead to headache, dizziness, and lower blood pressure.

Avanafil in combination with other treatments for ED is not recommended.

Avanafil does not protect against sexually transmitted diseases, including HIV.

The most common side effects of avanafil are headache, flushing, runny nose and congestion.

Please see full patient prescribing information for avanafil (50 mg, 100 mg, 200 mg) tablets.

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 our ability to execute on our business strategy to enhance long-term stockholder value; risks and uncertainties related to our ability to manage the supply chain for STENDRA/SPEDRA (avanafil) for our current or potential collaborators; risks and uncertainties related to the timing, strategy, tactics and success of the launches and commercialization of STENDRA/SPEDRA (avanafil) by our current or potential collaborators; risks and uncertainties related to our ability to successfully complete on acceptable terms, and on a timely basis, avanafil partnering discussions for territories under our license with Mitsubishi Tanabe Pharma Corporation in which we do not have a commercial collaboration; and the ability of our partners to maintain regulatory approvals to manufacture and adequately supply our products to meet demand. 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.
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
