
**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 23, 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))
-
-

Item 1.01. Entry into a Material Definitive Agreement.

The information contained in Item 1.02 below is hereby incorporated by reference.

Item 1.02. Termination of a Material Definitive Agreement.

On December 11, 2013, VIVUS, Inc., or VIVUS or the Company, entered into a license and commercialization agreement, or the License Agreement, with Sanofi, and a supply agreement, or the Supply Agreement, with Sanofi Winthrop Industrie, a wholly owned subsidiary of Sanofi. The Supply Agreement terminated in accordance with its terms on June 30, 2015. On March 23, 2017, the Company and Sanofi entered into the Termination, Rights Reversion and Transition Services Agreement, or the Transition Agreement, effective February 28, 2017. Under the Transition Agreement, effective upon the thirtieth (30th) day following February 28, 2017, the License Agreement will terminate for all countries in the Sanofi Territory (as defined below) as a termination by Sanofi for convenience notwithstanding any notice requirements contained in the License Agreement. In addition, under the Transition Agreement, Sanofi will provide the Company with certain transition services in support of ongoing regulatory approval efforts while the Company seeks to obtain a new commercial partner or partners for the Sanofi Territory. The Company will pay certain transition service fees to Sanofi as part of the Transition Agreement.

Under the terms of the License Agreement, Sanofi received an exclusive license to commercialize and promote VIVUS' drug avanafil for therapeutic use in humans in Africa, the Middle East, Turkey and the Commonwealth of Independent States, including Russia, or the Sanofi Territory. Under the terms of the Supply Agreement, VIVUS agreed to supply Sanofi Winthrop Industrie with avanafil tablets until June 30, 2015, or in the event the obligations of Mitsubishi Tanabe Pharma Corporation, or MTPC, to supply avanafil tablets to VIVUS were amended to extend beyond June 30, 2015 then until the expiration of the MTPC supply obligations as amended.

As previously reported on Form 8-K, on July 31, 2013, VIVUS entered into a Commercial Supply Agreement with Sanofi Chimie, a wholly owned subsidiary of Sanofi, pursuant to which Sanofi Chimie will manufacture and supply the active pharmaceutical ingredient for VIVUS’ drug avanafil. Further, as previously reported on Form 8-K, on November 18, 2013, VIVUS entered into a Manufacturing and Supply Agreement with Sanofi Winthrop Industrie, a wholly owned subsidiary of Sanofi, pursuant to which Sanofi Winthrop Industrie will manufacture and supply the tablets for VIVUS’ drug avanafil. The Transition Agreement does not affect the terms of these manufacturing and supply agreements.

Certain statements in this Current Report on Form 8-K are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as “anticipate,” “believe,” “forecast,” “estimate,” “expect,” “intend,” “likely,” “may,” “plan,” “potential,” “predict,” “opportunity” and “should,” among others. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. The Company does not undertake an obligation to update or revise any forward-looking statements. Investors should read the risk factors set forth in the Company’s Form 10-K for the year ended December 31, 2016 as filed on March 8, 2017, and periodic reports filed with the Securities and Exchange Commission.

Item 7.01. Regulation FD Disclosure.

In a press release issued on March 27, 2017, VIVUS announced the termination of the License Agreement with Sanofi and the entry into the Transition Agreement with Sanofi. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information in Item 7.01 of this Form 8-K and the exhibit attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section, or incorporated by reference into any of the Company’s filings under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release issued by VIVUS, Inc. dated March 27, 2017.

2

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.

Date: March 27, 2017

By: /s/ John L. Slebir
John L. Slebir
Senior Vice President, Business Development and General Counsel

3

EXHIBIT INDEX

<u>Number</u>	<u>Description</u>
99.1	Press Release issued by VIVUS, Inc. dated March 27, 2017.

4



VIVUS, Inc. Reacquires STENDRA® (Avanafil) Commercial Rights from Sanofi

VIVUS to Receive Commercial Rights to Africa, the Middle East, Turkey and the Commonwealth of Independent States, Including Russia

CAMPBELL, CA — (Marketwired) — March 27, 2017 — VIVUS, Inc. (NASDAQ: VVUS) (the “Company”), announced today that it reached an agreement with Sanofi to return the commercial rights for STENDRA in Africa, the Middle East, Turkey and the Commonwealth of Independent States, including Russia, to VIVUS. As part of the agreement, Sanofi will provide transition services to avoid adverse impacts to the regulatory approval applications in process, specifically in Russia and certain Middle East countries.

“The return of STENDRA from Sanofi provides us with the opportunity to find a commercial partner in the former Sanofi territories and continue our efforts to build long-term stockholder value,” said Seth H. Z. Fischer, VIVUS Chief Executive Officer. “We have begun the process of finding a commercial partner to take advantage of Sanofi’s efforts to obtain regulatory approvals in Russia and the Middle East. We look forward to continuing our relationship with Sanofi as the manufacturer of STENDRA.”

About Avanafil

STENDRA® (avanafil) is approved in the U.S. by the FDA for the treatment of erectile dysfunction. Metuchen Pharmaceuticals LLC has exclusive marketing rights to STENDRA in the U.S., Canada, South America and India.

STENDRA is available through retail and mail order pharmacies.

SPEDRA™, the trade name for avanafil in the EU, is approved by the EMA for the treatment of erectile dysfunction in the EU. VIVUS has granted an exclusive license to the Menarini Group through its subsidiary Berlin-Chemie AG to commercialize and promote SPEDRA for the treatment of erectile dysfunction in over 40 European countries plus Australia and New Zealand.

Avanafil is licensed from Mitsubishi Tanabe Pharma Corporation (MTPC). VIVUS owns worldwide development and commercial rights to avanafil for the treatment of sexual dysfunction, with the exception of certain Asian-Pacific Rim countries. VIVUS is in discussions with other parties for the commercialization rights to its remaining territories.

For more information about STENDRA, please visit www.STENDRA.com.

Important Safety Information

STENDRA® (avanafil) is prescribed to treat erectile dysfunction (ED).

Do not take STENDRA 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.

STENDRA 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 STENDRA) 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 STENDRA.

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

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

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

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

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

About VIVUS

VIVUS is a biopharmaceutical company developing and commercializing innovative, next-generation therapies to address unmet medical needs in human health. 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 the timing, strategy, tactics and success of the commercialization of STENDRA (avanafil) by our sublicensees in the U.S., Canada, South America, India, the EU, Australia and New Zealand; 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 MTPC in which we do not have a commercial collaboration, including the former Sanofi territories; risks and uncertainties related to Sanofi Chimie's ability to undertake manufacturing of the avanafil active pharmaceutical ingredient and Sanofi Winthrop Industrie's ability to undertake manufacturing of the tablets for avanafil; risks and uncertainties related to our ability to manage the supply chain for STENDRA/SPEDRA for our collaborators; the ability of our partners to maintain regulatory approvals to manufacture and adequately supply our products to meet demand; risks related to the failure to obtain foreign authority clearances or approvals and noncompliance with foreign authority regulations; and risks and uncertainties related to our ability to protect our intellectual property and litigation in which we are involved or may become involved. 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 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

VIVUS Investor Relations: The Trout Group

Brian Korb
Managing Director
bkorb@troutgroup.com
646-378-2923
