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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**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)  
**December 11, 2013**

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**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.)

**351 EAST EVELYN AVENUE  
MOUNTAIN VIEW, CA 94041**  
(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))
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**Item 1.01. Entry into a Material Definitive Agreement.**

***License and Commercialization Agreement and Supply Agreement***

On December 11, 2013, VIVUS, Inc., or VIVUS, entered into a license and commercialization agreement, or the License Agreement, with Sanofi, and a supply agreement, or the Supply Agreement, with sanofi-aventis U.S., LLC, or sanofi-aventis, a wholly-owned subsidiary of Sanofi.

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 Eurasia, or the Territory. During the term of the License Agreement, each party agreed not to develop, commercialize, or in-license any other product that operates as a phosphodiesterase type-5 inhibitor for therapeutic use in humans in the Territory for a limited time period, subject to certain exceptions.

VIVUS will receive an upfront license fee, manufacturing milestone payments, regulatory milestone payments and sales milestone payments, plus royalties on avanafil sales. No later than December 26, 2013, Sanofi will pay VIVUS an upfront license fee of \$5 million. VIVUS is eligible to receive up to \$5 million in manufacturing milestone payments, up to \$6 million in regulatory milestone payments and up to \$45 million in sales milestone payments, plus royalties on avanafil sales based on tiered percentages of the aggregate annual net sales in the Territory. Sanofi will also reimburse VIVUS for a portion of any sales milestone paid by VIVUS to Mitsubishi Tanabe Pharma Corporation, or MTPC, based on the share of Sanofi's net sales in the total worldwide net sales amount triggering the payment of such sales milestone.

Royalty payment obligations under the License Agreement will be payable for avanafil in each country in the Territory until the later to occur of (i) the expiration of the last to expire valid claim within the VIVUS patents that, absent the licenses granted to Sanofi under the License Agreement, would be

infringed by the sale of avanafil in such country, and (ii) December 11, 2029, or the Royalty Payment Term. The License Agreement will terminate as follows: (i) as to avanafil in each country in the Territory, upon the expiration of the Royalty Payment Term with respect to avanafil in such country, provided however, that Sanofi's obligation to reimburse VIVUS for Sanofi's pro-rata share of any sales milestone paid by VIVUS to MTPC will survive if such sales milestone has not yet come due; and (ii) in its entirety, upon the expiration of all royalty payment obligations arising under the License Agreement in all countries in the Territory.

In addition, VIVUS may terminate the License Agreement immediately upon written notice to Sanofi on a country by country basis if Sanofi becomes subject to certain regulatory actions or legal restrictions. VIVUS may also terminate the License Agreement in its entirety upon written notice to Sanofi if Sanofi or any affiliate commences any action or proceeding that challenges the validity, enforceability or scope of any VIVUS patent in the Territory or any country outside of the Territory, or if a similar action is instituted by a sublicensee and Sanofi does not terminate the sublicense after being aware of such action for a specified period. Further, Sanofi may terminate the License Agreement in whole or on a country by country basis for convenience at any time upon advance prior notice to VIVUS. Either party may terminate the License Agreement for the other party's uncured material breach, or bankruptcy or related actions or proceedings. In the event of an uncured material breach by VIVUS, Sanofi may, in lieu of terminating the License Agreement in its entirety, elect to continue the License Agreement in full force and effect except (i) VIVUS will have no further rights to receive certain commercialization reports, and (ii) Sanofi may set off any payments or amounts due by Sanofi but not yet paid to VIVUS against all direct and undisputed damages suffered by Sanofi as a result of the breach.

Under the terms of the Supply Agreement, VIVUS will supply sanofi-aventis with avanafil tablets until June 30, 2015, or in the event the obligations of MTPC to supply avanafil tablets to VIVUS are amended to extend beyond June 30, 2015 then until the expiration of the MTPC supply obligations as amended. Either party may terminate the Supply Agreement for (i) the other party's uncured material breach or (ii) bankruptcy, insolvency, liquidation or certain receivership proceedings, or certain proceedings for reorganization under bankruptcy or comparable laws. In addition, the Supply Agreement will automatically terminate upon the termination of the License Agreement.

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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.

#### **Item 7.01. Regulation FD Disclosure.**

In a press release issued on December 12, 2013, VIVUS announced its entry into the License Agreement. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information in 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 Registrant'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 December 12, 2013.

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#### **SIGNATURE**

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 thereunto duly authorized.

VIVUS, Inc.

Date: December 12, 2013

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

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#### **EXHIBIT INDEX**

<u>Number</u>	<u>Description</u>
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99.1	Press Release issued by VIVUS, Inc. dated December 12, 2013.
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## **VIVUS ANNOUNCES LICENSE AND COMMERCIALIZATION AGREEMENT WITH SANOFI FOR AVANAFIL IN AFRICA, MIDDLE EAST, TURKEY AND CIS/RUSSIA**

MOUNTAIN VIEW, Calif., December 12, 2013 — VIVUS, Inc. (NASDAQ: VVUS) today announced that it has entered into a License and Commercialization Agreement with Sanofi to commercialize avanafil on an exclusive basis in Africa, the Middle East, Turkey, and the Commonwealth of Independent States (CIS) including Russia. Sanofi will be responsible for obtaining regulatory approval in its territories. Sanofi intends to market avanafil under the tradename SPEDRA™ or STENDRA™.

Under the terms of the agreement, VIVUS is eligible to receive up to \$61 million in upfront payments, regulatory and sales milestones. VIVUS will also receive escalating royalties based on net sales over the life of the agreement.

“Sanofi is an established leader in emerging markets and a valued partner for VIVUS,” said Seth H. Z. Fischer, CEO of VIVUS, Inc.

In July 2013, VIVUS announced an exclusive license with the Menarini Group to commercialize avanafil in Europe, Australia and New Zealand. In October 2013, VIVUS announced an exclusive license with Auxilium Pharmaceuticals, Inc. to commercialize avanafil in the United States and Canada. Under the Menarini, Auxilium and Sanofi agreements, avanafil is expected to be commercialized in over 100 countries worldwide.

“We are pleased with the alliance we have forged with our partners at Sanofi,” stated John L. Slebir, vice president, business development and general counsel of VIVUS, Inc. “This agreement is another key accomplishment for VIVUS in the monetization of avanafil.”

Aquilo Partners, L.P. acted as the exclusive advisor to VIVUS on the transaction.

### **About Avanafil**

SPEDRA™, the trade name for avanafil in the EU and certain other territories outside of the U.S., has been approved by the EMA for the treatment of erectile dysfunction in the EU.

STENDRA™, the trade name for avanafil in the U.S. and certain other territories, is approved by the FDA for the treatment of erectile dysfunction in the U.S. 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.

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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. VIVUS has granted an exclusive license to Auxilium Pharmaceuticals, Inc. to market STENDRA in the United States and Canada. VIVUS has granted an exclusive license to Sanofi to commercialize avanafil in Africa, the Middle East, Turkey, and the Commonwealth of Independent States (CIS) including Russia. VIVUS is currently in discussions with potential partners to commercialize STENDRA in its remaining territories.

For more information about STENDRA, please visit [www.Stendra.com](http://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.

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## **About VIVUS**

VIVUS is a biopharmaceutical company commercializing and developing innovative, next-generation therapies to address unmet needs in obesity, sleep apnea, diabetes and sexual health. For more information about the company, please visit [www.vivus.com](http://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 regulatory approval of avanafil within the Sanofi territories; risks and uncertainties related to the timing and success of avanafil commercialization by Sanofi in Africa, the Middle East, Turkey, and the Commonwealth of Independent States (CIS) including Russia; and risks and uncertainties related to the timing and success of avanafil commercialization by the Menarini Group and Auxilium Pharmaceuticals, Inc. in their respective territories. 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's Form 10-K for the year ending December 31, 2012, as amended by the Form 10-K/A filed on April 30, 2013, and as amended by the Form 10-K/A filed on June 12, 2013, and periodic reports filed with the Securities and Exchange Commission. VIVUS does not undertake an obligation to update or revise any forward-looking statements.

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