VIVUS INC
Form 8-K
December 12, 2013

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)

December 11, 2013

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.)

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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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.

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.

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.

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

EXHIBIT INDEX

Number	Description
99.1	Press Release issued by VIVUS, Inc. dated December 12, 2013.