VIVUS INC
Form 8-K
July 09, 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)

July 9, 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.)

1172 CASTRO STREET

MOUNTAIN VIEW, CA 94040

(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

On July 5, 2013, VIVUS, Inc. (the Company) entered into a license and commercialization agreement (the License Agreement) and a supply agreement (the Supply Agreement) with the Menarini Group through its subsidiary Berlin-Chemie AG (Menarini).

Under the terms of the License Agreement, Menarini received an exclusive license to commercialize and promote VIVUS s drug SPEDRA (avanafil) for the treatment of erectile dysfunction in over 40 European countries plus Australia and New Zealand. Additionally, VIVUS has agreed to transfer to Menarini ownership of the European Union marketing authorization for SPEDRA for the treatment of erectile dysfunction, which was granted by the European Commission in June 2013. Each party agreed not to develop, commercialize, or in-license any other product that operates as phosphodiesterase type-5 inhibitor for the treatment of erectile dysfunction for a limited time period, subject to certain exceptions.

VIVUS will receive upfront payments and various approval and sales milestones, plus royalties on SPEDRA sales. Within the first year, VIVUS expects to receive approximately 39 million (or approximately $51 million at current exchange rates) including upfront payments totaling 16 million (or approximately $21 million at current exchange rates). Menarini will also reimburse VIVUS for payments made to cover various obligations to Mitsubishi-Tanabe Pharmaceutical Corporation during the term of the License Agreement. The License Agreement will terminate on a country-by-country basis in the relevant territories upon the latest to occur of the following: the expiration of the last-to-expire valid VIVUS patent covering SPEDRA; the expiration of data protection covering SPEDRA; or ten (10) years after the SPEDRA product launch. In addition, Menarini may terminate the License Agreement if certain additional regulatory obligations are imposed on SPEDRA, the Company may terminate the License Agreement if Menarini challenges the VIVUS patents covering SPEDRA or if Menarini commits certain legal violations. Either party may terminate the License Agreement for the other party s uncured material breach or bankruptcy.

Under the terms of the Supply Agreement, VIVUS will supply Menarini with STENDRA drug product until December 31, 2018 at the latest. Menarini also has the right to manufacture STENDRA independently, provided that it continues to satisfy certain minimum purchase obligations to VIVUS. Following the expiration of the Supply Agreement, Menarini will be responsible for its own supply of STENDRA. Either party may terminate the Supply Agreement for the other party s uncured material breach or bankruptcy, or upon the termination of the License Agreement.

Item 7.01. Regulation FD Disclosure

In a press release issued on July 9, 2013, the Company announced its entry into the License Agreement and the Supply 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 exhibits 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, dated July 9, 2013, announcing entry into the License Agreement and Supply Agreement.

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: July 9, 2013

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

EXHIBIT INDEX

Number	Description
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