VIVUS INC
Form 8-K
October 03, 2016

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)

September 30, 2016

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 Commercial Supply Agreement

On September 30, 2016, VIVUS, Inc., or VIVUS, entered into a license and commercialization agreement, or the License Agreement, and a commercial supply agreement, or the Supply Agreement, with Metuchen Pharmaceuticals LLC, or Metuchen. The License Agreement and Supply Agreement were entered into to replace the (i) license and commercialization agreement and (ii) commercial supply agreement, entered into between VIVUS and Auxilium Pharmaceuticals, Inc., or Auxilium (acquired by Endo International plc in January 2015), on October 10, 2013, following the receipt by VIVUS from Auxilium of a notice of termination.

Under the terms of the License Agreement, Metuchen received an exclusive license to commercialize and promote VIVUS drug STENDRA® (avanafil) for therapeutic use in humans in the United States and its respective territories and possessions, Canada, South America and India, or the Territory. Additionally, following the completion of certain events, VIVUS has agreed to transfer to Metuchen ownership of the product marketing authorization for STENDRA, which was granted by the U.S. Food and Drug Administration, or the FDA, in April 2012. Further, VIVUS has agreed to transfer to Metuchen ownership of all other regulatory filings previously made with any governmental authorities in any country within the Territory that remain pending approval as of the date of the License Agreement. Each party agreed not to develop, commercialize, or in-license any other product that operates as a PDE-5 inhibitor in the Territory for a limited time period, subject to certain exceptions. A PDE-5 inhibitor means any product that operates as a phosphodiesterase type-5 inhibitor.

VIVUS will receive an upfront license fee of $70 million. Metuchen will also reimburse VIVUS for payments made to cover royalty and milestone obligations to Mitsubishi Tanabe Pharmaceutical Corporation, or MTPC, during the term of the License Agreement.

Metuchen will receive an exclusive license, with a right to sublicense, subject to certain limitations, under VIVUS STENDRA related patents and know-how (i) to use, distribute, import, promote, market, sell, offer for sale and otherwise commercialize STENDRA for therapeutic use in humans in the Territory, (ii) to make and have made STENDRA, subject to VIVUS exclusive manufacturing rights, anywhere in the world, with certain exceptions, where STENDRA is solely for use or sale for therapeutic use in humans in the Territory, and (iii) to conduct certain development activities on STENDRA for therapeutic use in humans solely in support of regulatory approval in the Territory. At its sole discretion and at its sole cost unless the parties mutually agree to otherwise, Metuchen shall have the sole right to conduct any further development work related to regulatory approval, including clinical trials, on STENDRA for therapeutic use in humans in the Territory. Subject to the terms and conditions of the License Agreement, VIVUS agreed to sell, assign, convey, transfer and deliver to Metuchen, and Metuchen agreed to receive and accept from VIVUS, all of its right, title and interest in and to certain of VIVUS trademarks and any and all goodwill associated therewith.

Metuchen will obtain STENDRA exclusively from VIVUS for a mutually agreed term pursuant to the Supply Agreement, as further described below. Metuchen may elect to transfer the control of the supply chain for STENDRA for the Territory to itself or its designee by assigning to Metuchen VIVUS agreements with the contract manufacturer, which is referred to below as the Supply Chain Transfer.

Metuchen shall be responsible for conducting any post-regulatory studies of STENDRA that are required by the FDA in the Territory or that Metuchen determines to conduct with respect to STENDRA for therapeutic use in humans in the Territory. Any and all such post-regulatory studies shall be conducted by Metuchen at its sole expense, but Metuchen shall be under no obligation to conduct any post-regulatory studies other than the FDA required studies.

The License Agreement will terminate upon the expiration of the last-to-expire payment obligations under the License Agreement; upon expiration of the term of the License Agreement, the exclusive license granted under the License Agreement and the covenant not to sue on VIVUS STENDRA related patents and know-how given by VIVUS to Metuchen in regards to certain actions under the License Agreement shall become fully paid-up, royalty-free, perpetual and irrevocable as to VIVUS but not certain trademark royalties due to MTPC. Metuchen may terminate the License Agreement (i) for any reason upon one hundred eighty (180) days written notice, and (ii) upon a generic entry into the market upon thirty (30) days written notice. VIVUS may terminate the License Agreement (i) immediately upon written notice to Metuchen if Metuchen is excluded from participation in the U.S. federal healthcare programs and fails to cure such exclusion within one hundred twenty (120) days, and (ii) if Metuchen or any affiliate challenges certain VIVUS patents covering STENDRA upon written notice to Metuchen. Subject to certain exceptions and cure periods, either party may terminate the License Agreement for the other party s uncured material breach. Upon termination of the License Agreement (other than the expiration of the term under the License Agreement), the exclusive license granted under the License Agreement shall terminate, subject to such license remaining in effect on a non-exclusive basis to allow the sell through of STENDRA inventory.

Under the terms of the Supply Agreement, VIVUS will supply Metuchen with STENDRA drug product. For 2016 and each subsequent calendar year during the term of the Supply Agreement, if Metuchen fails to purchase an agreed minimum purchase amount of STENDRA from VIVUS, it will reimburse VIVUS for the shortfall as it relates to VIVUS out of pocket costs to acquire certain raw materials needed to manufacture STENDRA. Upon the termination of the Supply Agreement (other than by Metuchen for VIVUS uncured material breach or upon completion of the Supply Chain Transfer, as described above), Metuchen s agreed minimum purchase amount of STENDRA from VIVUS shall accelerate for the entire then current initial term or renewal term, as applicable. The initial term under the Supply Agreement will be for a period of five years, with automatic renewal for successive two year periods unless either party provides a termination notice to the other party at least two years in advance of the expiration of the then current term. Either party may terminate the Supply Agreement for the other party s uncured material breach (subject to certain exceptions) or upon the termination of the License Agreement. The Supply Agreement will automatically terminate upon completion of the Supply Chain Transfer, as described above.

Item 7.01. Regulation FD Disclosure.

In a press release issued on October 3, 2016, VIVUS 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 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 October 3, 2016.

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 thereunto duly authorized.

VIVUS, Inc.

Date: October 3, 2016

By: /s/ John L. Slebir
John L. Slebir

Senior Vice President, Business Development and General Counsel

EXHIBIT INDEX

Number	Description
99.1	Press Release issued by VIVUS, Inc. dated October 3, 2016.