

VIVUS INC
Form 8-K
January 09, 2017

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)

January 6, 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

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(Address of principal executive offices, including zip code)

(650) 934-5200

(Registrant's telephone number, including area code)

351 EAST EVELYN AVENUE

MOUNTAIN VIEW, CA 94041

(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))
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Item 1.01. Entry into a Material Definitive Agreement.

Patent Assignment Agreement and License Assignment Agreement

On January 6, 2017, VIVUS, Inc., or the Company, entered into a Patent Assignment Agreement, or the Patent Agreement, with Selten Pharma, Inc., or Selten. Under the terms of the Patent Agreement, Selten will receive a one-time upfront fee from the Company, and Selten will transfer and assign, and cause its applicable affiliates to transfer and assign, to the Company all of Selten's and its affiliates' rights, title and interest in and to (i) certain patent rights directed to methods of using tacrolimus and ascomycin to treat pulmonary arterial hypertension and related vascular diseases and (ii) any orphan-drug designation in each of the compounds tacrolimus and ascomycin. Also, under the terms of the Patent Agreement, Selten will grant to the Company an exclusive license under the Selten know-how (i) to use, distribute, import, promote, market, sell, offer for sale and otherwise commercialize certain pharmaceutical compositions containing tacrolimus and/or ascomycin in the treatment, diagnosis and/or prevention of pulmonary arterial hypertension and related vascular diseases worldwide, (ii) to conduct development activities in support of regulatory approval of pharmaceutical compositions containing tacrolimus and/or ascomycin worldwide and (iii) to otherwise exploit the patent rights under the Patent Agreement. The one-time upfront fee was due upon execution of the Patent Agreement and payable within ten (10) days thereafter.

Under the Patent Agreement, Selten agreed not to begin a phase II study on a Competing Product (as defined below) earlier than a certain amount of time from January 6, 2017. A Competing Product is a product with an application in the treatment, diagnosis and/or prevention of pulmonary arterial hypertension and related vascular diseases, or a product comprising of tacrolimus and/or ascomycin. Further, during the term of the Patent Agreement, the Company will have a right of first refusal with respect to any license, sale, assignment, transfer or other disposition by Selten of any material portion of intellectual property related to any Competing Product (as defined above) conceived or developed by Selten either alone or in collaboration with a third party.

In the event the Company is unable to develop a formulation for tacrolimus that is suitable for phase II studies, as determined by the Company at its sole discretion, by a certain date, the Company will terminate the Patent Agreement, subject to the Company providing thirty (30) days written notice to Selten and such termination shall be effective upon assignment of the patent rights remaining as of the date of such termination back to Selten. In the event the Company terminates the Patent Agreement because it is unable to develop a formulation for tacrolimus that is suitable for phase II studies as described above or for any reason at any time by providing thirty (30) days written notice to Selten, the Company covenants that neither it nor its affiliates will, directly or indirectly, begin a phase II study on a Competing Product (as defined above) earlier than a certain amount of time from the date at which such termination becomes effective.

The Company shall make certain milestone payments to Selten based upon the achievement of certain regulatory/development and sales milestone events; the Company may satisfy certain milestone payments, at its sole option, in the Company's common stock, subject to certain limitations. In addition, the Company will pay quarterly royalty payments to Selten based on a percentage of aggregate net sales of certain pharmaceutical compositions containing tacrolimus and/or ascomycin in the treatment, diagnosis and/or prevention of pulmonary arterial hypertension and related vascular diseases worldwide. Such royalties shall be payable, on a

country-by-country and product-by-product basis, beginning on the first commercial sale of a Company product in a particular country and ending on the later of (i) ten (10) years after the first commercial sale in such country, or (ii) the date of expiration of the last-to-expire patent right having an issued claim covering the Company product in such country. The Company has an option during the term of the Patent Agreement to terminate the Company's milestone and royalty payment obligations by paying Selten a predetermined amount.

The Patent Agreement has a term commencing on January 6, 2017 and, unless earlier terminated, will continue until the expiration of (i) all patent rights under the Patent Agreement or (ii) that certain Exclusive Agreement between The Board of Trustees of the Leland Stanford Junior University and Selten, or the Stanford Exclusive Agreement. The Company may terminate the Patent Agreement at any time by providing thirty (30) days written notice to Selten, and such termination shall be effective upon assignment of the patent rights remaining as of the date of such termination back to Selten.

On January 6, 2017, the Company entered into a License Assignment Agreement, or the License Agreement, with Selten. Under the terms of the License Agreement, Selten will receive a one-time upfront fee from the Company, and Selten will transfer, assign and novate the Stanford Exclusive Agreement in which Selten is the exclusive licensee of certain patents directed to methods of using tacrolimus to treat pulmonary arterial hypertension and certain patent applications directed to additional compounds and methods for the treatment of pulmonary arterial hypertension and formulations for tacrolimus. The one-time upfront fee was due upon execution of the License Agreement and payable within ten (10) days thereafter. The License Agreement has a term commencing on January 6, 2017 and, unless earlier terminated, will extend until expiration of the Stanford Exclusive Agreement. In the event the Company terminates the Patent Agreement prior to the expiration of the term of the License Agreement, then the License Agreement will also terminate. In the event of the termination of the License Agreement, the Company shall reassign the Stanford Exclusive Agreement to Selten.

Item 7.01. Regulation FD Disclosure.

In a press release issued on January 9, 2017, the Company announced the entry into certain agreements with Selten. 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 dated January 9, 2017.

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: January 9, 2017

By:

/s/ John L. Slebir

John L. Slebir

Senior Vice President, Business Development and
General Counsel

EXHIBIT INDEX

Number	Description
99.1	Press Release dated January 9, 2017.