
**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**
(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):

- ☐ 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.

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.

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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.

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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

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EXHIBIT INDEX

Number

Description



VIVUS AND SELTEN PHARMA ANNOUNCE AGREEMENT FOR THE DEVELOPMENT AND COMMERCIALIZATION RIGHTS TO TREATMENTS FOR PULMONARY ARTERIAL HYPERTENSION (PAH)

CAMPBELL, CA, and SAN CARLOS, CA, January 9, 2017 - VIVUS, Inc. (NASDAQ: VVUS) and Selten Pharma, Inc., announced VIVUS' acquisition from Selten of exclusive, worldwide rights for the development and commercialization of tacrolimus and ascomycin for the treatment of Pulmonary Arterial Hypertension (PAH) and related vascular diseases. VIVUS assumes all development and commercialization responsibilities.

Selten has assigned VIVUS its license to a family of patents owned by the Board of Trustees of the Leland Stanford Junior University (Stanford) and all rights under a collection of patent applications owned by Selten. The licensed patent family includes U.S. Patent No. 9,474,745 and is directed to methods of using tacrolimus to treat PAH. The assigned patent applications are directed to additional compounds and methods for the treatment of PAH and formulations for tacrolimus. In March 2015, Selten received orphan drug designation for tacrolimus for the treatment of PAH.

VIVUS is responsible for all future financial obligations to Stanford under the Stanford license. Selten will receive an upfront payment, and development and sales milestone payments, as well as tiered royalties on future sales of these compounds.

"Pulmonary Arterial Hypertension is a degenerative disease with current treatment options that only address the symptoms to slow the progression of the disease. We are excited about the potential of tacrolimus and ascomycin to significantly improve the quality of life and life expectancy of PAH patients," said Seth H. Z. Fischer, VIVUS' Chief Executive Officer. "The move into PAH is the latest announcement in our efforts to reshape VIVUS to build long-term stockholder value, and we look forward to additional announcements in the future."

"We are excited to partner with VIVUS to strive to bring new therapies to PAH patients who have limited treatment options," said Leo Gu, Ph.D., President and Co-CEO of Selten. "Early compassionate use of the licensed compounds demonstrate potential to go beyond symptom management and impact the progression of disease," he added.

"It has been a pleasure to collaborate with VIVUS on this strategic deal, and we are looking forward to these important therapies being developed and making a difference in patients' lives," said Narinder S. Banait, Ph.D., J.D. General Counsel, and Co-CEO of Selten. "Selten will continue to focus on rare diseases," he added.

About Pulmonary Arterial Hypertension (PAH)

PAH is a chronic life-threatening disease characterized by elevated blood pressure in the pulmonary arteries (arteries between the heart and lungs) due to severe constriction of these blood vessels. These high pressures make it difficult for the heart to pump blood through the lungs to be oxygenated. The symptoms of PAH are non-specific and can range from mild shortness of breath and fatigue during normal daily activity to symptoms of right heart failure and severe restrictions on exercise capacity and ultimately reduced life expectancy. PAH includes patients with idiopathic PAH, familial PAH, and associated PAH, which is related to certain conditions including connective tissue diseases, congenital systemic-to-pulmonary-shunts, portal hypertension, HIV infection, drugs and toxins. The current treatments for PAH involve calcium channel antagonists, prostacyclins, prostacyclin receptor (IP receptor) agonist, endothelin receptor antagonists, phosphodiesterase-5 (PDE5) inhibitors, and long-term anticoagulant therapy, with the aim to reduce symptoms and improve quality of life.

About VIVUS

VIVUS is a biopharmaceutical company commercializing Qsymia® (phentermine and topiramate extended-release) capsules CIV for the treatment of obesity. For more information about the company, please visit 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 potential change in our business strategy to enhance long-term stockholder value; risks and uncertainties related to the timing, strategy and success of the development and commercialization of tacrolimus and ascomycin for the treatment of Pulmonary Arterial Hypertension and related vascular diseases; and risks and uncertainties related to our ability to continue to identify, acquire and develop innovative investigational drug candidates and drugs. 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' Form 10-K for the year ended December 31, 2015 as filed on March 9, 2016 and as amended by the Form 10-K/A filed on April 22, 2016, and periodic reports filed with the Securities and Exchange Commission. VIVUS does not undertake an obligation to update or revise any forward-looking statements.

About Selten Pharma, Inc.

Selten Pharma, Inc. is a privately held clinical-stage biopharmaceutical company focused on the development and commercialization of therapies for the treatment of rare diseases. The company has drug candidates in various stages of clinical and preclinical development. Selten's pipeline and product development strategy offers the possibility of rapid commercialization with lower risks than typical new chemical entities.

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