

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): **May 21, 2019**

VIVUS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-33389
(Commission
File Number)

94-3136179
(I.R.S. Employer
Identification No.)

**900 E. Hamilton Avenue, Suite 550
Campbell, CA 95008**
(Address of Principal Executive Offices, and Zip Code)

(650) 934-5200
Registrant's Telephone Number, Including Area Code

N/A
(Former Name or Former Address, if Changed Since Last Report)

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---------------------------------|-------------------|---|
| Common Stock | VVUS | The Nasdaq Global Select Market |
| Preferred Share Purchase Rights | | |

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 communication 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 communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01. Entry into a Material Definitive Agreement

As previously reported on Form 8-K, on July 5, 2013, VIVUS, Inc. (“VIVUS”) entered into a License and Commercialization Agreement and a Commercial Supply Agreement with the Menarini Group through its subsidiary Berlin-Chemie AG (“Menarini”). On May 21, 2019, VIVUS entered into Amendment No. 1 to License and Commercialization Agreement and Commercial Supply Agreement with Menarini effective as of January 1, 2019, pursuant to which certain amendments were made to the License and Commercialization Agreement and the Commercial Supply Agreement, which include: (i) under the License and Commercialization Agreement, Menarini’s exclusive license to commercialize and promote VIVUS’ drug avanafil for the treatment of erectile dysfunction will be limited to over 40 European countries and will no longer include Australia and New Zealand; (ii) under the License and Commercialization Agreement, the timing requirements of the product launches by Menarini have been adjusted; (iii) under the License and Commercialization Agreement, the milestone payments have been adjusted to reflect the removal of Australia and New Zealand and will continue to be non-refundable and non-creditable, with one exception added for certain costs and expenses incurred by Menarini for development work related to an avanafil development opportunity in the Menarini territory (“Menarini Development”); (iv) under the License and Commercialization Agreement, the royalties on avanafil sales payable by Menarini to VIVUS will be adjusted to allow Menarini to recoup certain Menarini Development costs and expenses but only as to sales of the Menarini Development product unless the Menarini Development product is commercialized by VIVUS or its sublicensees outside the Menarini territory; (v) under the Commercial Supply Agreement, the minimum purchase obligations for Menarini will be modified and extended, including the ability of Menarini to satisfy its minimum purchase obligations with the purchase of avanafil active pharmaceutical ingredient (“API”) and the addition of minimum purchase obligations for the calendar years for the extended term; and (vi) under the Commercial Supply Agreement, the term will be extended to December 31, 2023, unless otherwise agreed by the parties in writing. VIVUS and Menarini intend to enter into standalone agreements relating to Australia and New Zealand, including a license with royalties and milestone payments and a supply agreement.

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. On May 22, 2019, VIVUS entered into Amendment N°1 to the Manufacturing and Supply Agreement with Sanofi Winthrop Industrie effective as of March 18, 2019, pursuant to which certain amendments were made to the Manufacturing and Supply Agreement, which include: (i) Sanofi Winthrop Industrie will manufacture and supply the tablets for VIVUS’ drug avanafil on an exclusive basis in all countries where VIVUS or its sublicensees and/or Menarini have the right to sell avanafil; (ii) the yearly minimum quantities of tablets that VIVUS must purchase from Sanofi Winthrop Industrie and the price of such tablets will be adjusted; and (iii) with the initial term of the Manufacturing and Supply Agreement expiring on January 16, 2021, VIVUS and Sanofi Winthrop Industrie have agreed to extend the term of the Manufacturing and Supply Agreement until December 31, 2023 unless either party makes a timely election to terminate the agreement and that thereafter the Manufacturing and Supply Agreement will auto-renew for successive one year terms unless either party makes a timely election not to renew.

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 API for VIVUS’ drug avanafil. Also, as previously reported on Form 8-K, on December 7, 2018, VIVUS entered into Amendment N°1 to the Commercial Supply Agreement with Sanofi Chimie, pursuant to which certain amendments were made to the Commercial Supply Agreement.

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.

/s/ John L. Slebir

John L. Slebir

Senior Vice President, Business Development and General Counsel

Date: May 28, 2019