
**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): **June 26, 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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 April 30, 2018, VIVUS, Inc. (“VIVUS”) entered into an Asset Purchase Agreement (the “Asset Purchase Agreement”) with Janssen Pharmaceuticals, Inc., a Pennsylvania corporation (“Janssen”), pursuant to which VIVUS acquired the rights, title and interest in and to, and assumed certain liabilities with respect to products currently commercialized in the United States and Canada as PANCREAZE® and PANCREAZE® MT (together, the “Product”), including certain related data and intellectual property, from Janssen for a purchase price of \$135,000,000 in cash. In conjunction with the Asset Purchase Agreement and upon the terms and subject to the conditions set forth in the Asset Purchase Agreement, Janssen assigned to VIVUS the Amended and Restated Know-How License and Supply Agreement (the “Supply Agreement”) effective as of November 7, 2017 by and between Nordmark Arzneimittel GmbH & Co. KG (“Nordmark”) and Janssen.

In order to extend the term of the Supply Agreement and ensure a stable and predictable price of the Product, VIVUS entered into the First Amendment to the Supply Agreement on June 26, 2019 (the “Amended Supply Agreement”). The material terms of the Amended Supply Agreement are: (i) VIVUS shall purchase certain minimum order quantities at the applicable supply prices for the calendar years under the Amended Supply Agreement; (ii) in exchange for Nordmark’s obligations under the Amended Supply Agreement, VIVUS shall pay an annual fee to Nordmark; (iii) Nordmark and VIVUS have agreed to undertake joint efforts to develop new formulations of the Product; (iv) the term of the Amended Supply Agreement shall begin on June 26, 2019 and continue through December 31, 2029, unless earlier terminated pursuant to the Amended Supply Agreement, and the Amended Supply Agreement may be renewed for additional five year periods unless earlier terminated pursuant to the Amended Supply Agreement; and (v) Nordmark shall have the option to terminate the Amended Supply Agreement upon certain circumstances related to the launch date in the United States if VIVUS assigns any or all of its rights under the Amended Supply Agreement to certain parties and/or enters into a transaction or series of transactions resulting in a Change of Control, as defined in the Amended Supply Agreement.

Item 8.01. Other Events

On June 26, 2019, VIVUS issued a press release titled “VIVUS and Nordmark Amend Contract Manufacturing Agreement to Supply Current and Future Demand for PANCREAZE®.” A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated June 26, 2019.

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: June 26, 2019



VIVUS and Nordmark Amend Contract Manufacturing Agreement to Supply Current and Future Demand for PANCREAZE®

-Companies will also collaborate to develop additional PANCREAZE dose formulations and an advanced formulation with an extended shelf life-

CAMPBELL, Calif. — June 26, 2019 — VIVUS, Inc. (Nasdaq: VVUS) (“VIVUS”), a biopharmaceutical company, today announced an amendment to its manufacturing and supply agreement with Nordmark Arzneimittel GmbH & Co. KG (“Nordmark”) for PANCREAZE® (pancrelipase) Delayed Release Capsules. The amended agreement covers a ten-year initial term and may be renewed for additional five-year periods, the first at VIVUS’ option and by mutual agreement thereafter. Financial terms of the agreement were not disclosed.

“As VIVUS continues its 10-quarter turnaround, ensuring PANCREAZE supply to meet the current and future demand for PANCREAZE at a stable and predictable price was a key step in our strategy, and we are pleased to have achieved this important milestone,” said John Amos, Chief Executive Officer at VIVUS. “We believe that there is a significant opportunity to grow the PANCREAZE market with our current product formulations and expect to create additional clinical and commercial value with the future introduction of advanced formulations of the product. We view our manufacturing partner, Nordmark, as a world class partner and we are fortunate to work with them.”

Under the terms of the agreement, VIVUS and Nordmark will jointly develop an advanced formulation of PANCREAZE with the objective of extending the shelf life of the product. VIVUS expects that the advanced formulation will be available in 2021.

“Nordmark has established expertise in manufacturing PANCREAZE Delayed Release Capsules, and we are pleased to extend our agreement with VIVUS for at least another ten years,” said Jörn Tonne, Chief Executive Officer at Nordmark. “We have a track record of success in developing new products and are committed to meeting the needs of our customers and the patients they serve. We look forward to working with VIVUS to develop new formulations of PANCREAZE that make treatment more convenient for patients with exocrine pancreatic insufficiency.”

About Nordmark Arzneimittel GmbH & Co. KG

Nordmark Arzneimittel GmbH & Co. KG is a privately owned biopharmaceutical company specialized in the development and manufacture of biological drug substances and drug products. For more information about the company, please visit www.nordmark-pharma.de.

About PANCREAZE

PANCREAZE is a prescription medicine used to treat people who cannot digest food normally because their pancreas does not make enough enzymes due to cystic fibrosis or other conditions. PANCREAZE may help your body use fats, proteins, and sugars from food. PANCREAZE contains a mixture of digestive enzymes including lipases, proteases, and amylases from pig pancreas. PANCREAZE is safe and effective in children when taken as prescribed by your doctor.

Important Safety Information for PANCREAZE

What is the most important information I should know about PANCREAZE?

- PANCREAZE may increase your chance of having a serious, rare bowel disorder called fibrosing colonopathy that may require surgery.
- The risk of having this condition may be reduced by following the dosing instructions that your healthcare provider gave you.

Call your doctor right away if you have any unusual or severe stomach area (abdominal) pain, bloating, trouble passing stool (having bowel movements), nausea, vomiting, or diarrhea.

Take PANCREAZE exactly as prescribed by your doctor. Do not take more or less PANCREAZE than directed by your doctor.

What are the possible side effects of PANCREAZE?

PANCREAZE may cause serious side effects, including:

- **A rare bowel disorder** called fibrosing colonopathy.
- **Irritation of the inside of your mouth.** This can happen if PANCREAZE is not swallowed completely.
- **Increase in blood uric acid levels.** This may cause worsening of swollen, painful joints (gout) caused by an increase in your blood uric acid levels.
- **Allergic reactions** including trouble with breathing, skin rashes, or swollen lips.

Call your doctor right away if you have any of these symptoms.

The most common side effects include pain in your stomach (abdominal pain) and gas.

Other possible side effects: PANCREAZE and other pancreatic enzyme products are made from the pancreas of pigs, the same pigs people eat as pork. These pigs may carry viruses. Although it has never been reported, it may be possible for a person to get a viral infection from taking pancreatic enzyme products that come from pigs.

These are not all the side effects of PANCREAZE. Talk to your doctor about any side effect that bothers you or does not go away.

You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

What should I tell my doctor before taking PANCREAZE?

Tell your doctor if you:

- are allergic to pork (pig) products.
- have a history of blockage of your intestines, or scarring or thickening of your bowel wall (fibrosing colonopathy).
- have gout, kidney disease, or high blood uric acid (hyperuricemia).
- have trouble swallowing capsules.
- have any other medical condition.
- are pregnant or plan to become pregnant.
- are breast-feeding or plan to breast-feed.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

The Product Information and Medication Guide for PANCREAZE is available at www.pancreaze.com.

About VIVUS

VIVUS is a biopharmaceutical company committed to the development and commercialization of innovative therapies that focus on advancing treatments for patients with serious unmet medical needs. For more information about VIVUS, please visit www.vivus.com.

Forward-Looking Statements

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 our ability to execute on our business strategy to enhance long-term stockholder value; risks and uncertainties related to our expected future revenues, operations and expenditures; risks and uncertainties related to our ability to maintain the relationship with the sole manufacturer for PANCREAZE; risks and uncertainties related to our ability to accurately forecast PANCREAZE demand; risks and uncertainties related to our ability to maintain a satisfactory level of PANCREAZE inventory; risks and uncertainties related to the timing, strategy, tactics and success of the marketing and sales of PANCREAZE; risks and uncertainties related to our ability to successfully maintain and increase market share against current competing products and potential competitors that may develop alternative formulations of the drug; and risks and uncertainties related to the ability of our partners to maintain regulatory approvals to manufacture and adequately supply our products to meet demand. 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, 2018 as filed on February 26, 2019, and periodic reports filed with the Securities and Exchange Commission. VIVUS does not undertake an obligation to update or revise any forward-looking statements.

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