

**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): **February 5, 2020**

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 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))

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 8.01. Other Events

On February 5, 2020, VIVUS, Inc. issued a press release titled “VIVUS Receives U.S. Food and Drug Administration Approval for Improved Formulation of PANCREAZE® with a 36-Month Shelf Life.” 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 February 5, 2020.

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: February 5, 2020



VIVUS Receives U.S. Food and Drug Administration Approval for Improved Formulation of PANCREAZE® with a 36-Month Shelf Life

CAMPBELL, Calif. – February 5, 2020 – VIVUS, Inc. (Nasdaq: VVUS) (“VIVUS”), a biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has approved the supplemental New Drug Application (sNDA) for an improved formulation of PANCREAZE® (pancrelipase) Delayed Release Capsules that extends the shelf life to 36 months across all PANCREAZE dosages. VIVUS worked closely with Nordmark Arzneimittel GmbH & Co. KG, its manufacturing partner for PANCREAZE, on the FDA approval pursuant to the terms of the amended contract manufacturing agreement announced in June 2019. PANCREAZE is indicated for the treatment of exocrine pancreatic insufficiency (EPI) due to cystic fibrosis or other conditions.

“The approval of this sNDA is an important milestone for VIVUS and for the patients with EPI we seek to treat,” said John Amos, Chief Executive Officer at VIVUS. “It highlights our ability to derive additional value from our marketed products and allows patients to store PANCREAZE for longer periods of time, which may help to reduce their out-of-pocket expenses. We also expect that the 36-month shelf life will limit the amount of returned product and, over time, will lower our overall supply chain costs. We look forward to working with Nordmark and our supply chain and commercial partners on the transition to the improved formulation.”

Approved in 2010, PANCREAZE is a pancreatic enzyme preparation consisting of pancrelipase, an extract derived from porcine pancreatic glands, as well as other enzyme classes, including porcine-derived lipases, proteases and amylases. The pancreatic enzymes in PANCREAZE act like digestive enzymes physiologically secreted by the pancreas.

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 transition to the improved formulation 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.

VIVUS, Inc.

Mark Oki
Chief Financial Officer
oki@vivus.com
650-934-5200

Investor Relations: Lazar FINN Partners

David Carey
Senior Partner
david.carey@finnpartners.com
212-867-1768
