

**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 15, 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 8.01. Other Events

On May 15, 2019, VIVUS, Inc. issued a press release titled “VIVUS Partners with HarborPath Direct to Facilitate Access to PANCREAZE® for Patients Without Health Insurance.” 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated May 15, 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: May 15, 2019



VIVUS Partners with HarborPath Direct to Facilitate Access to PANCREAZE® for Patients Without Health Insurance

CAMPBELL, CA and CHARLOTTE, NC — May 15, 2019 — VIVUS, Inc. (Nasdaq: VVUS; the “Company”), a biopharmaceutical company, and HarborPath Direct, Inc., today announced a partnership to facilitate access to PANCREAZE® (pancrelipase) Delayed Release Capsules for uninsured or underinsured patients with exocrine pancreatic insufficiency (EPI) that meet applicable eligibility criteria. The Company intends to make PANCREAZE available to eligible patients through the VIVUS Health Platform and the PANCREAZE Advantage Program integrated with HarborPath Direct’s SuccorRx™ Patient Assistance Program (PAP) platform. Financial terms of the partnership were not disclosed.

“Following the launch of PANCREAZE under the VIVUS brand in the first quarter of 2019, we are now working to ensure access to this important therapy for as many eligible EPI patients as possible, regardless of their health insurance status,” said John Amos, Chief Executive Officer at VIVUS. “HarborPath Direct’s focus on leveraging technology and innovative approaches to maximize program benefits is very well aligned with our plans for the VIVUS Health Platform and the PANCREAZE Advantage Program. We believe that HarborPath Direct is a critical partner in helping VIVUS to meet its goal of making the PANCREAZE Advantage Program the most user-friendly and efficient patient support program in the United States.”

VIVUS is continuing the development of the VIVUS Health Platform with the goal of enabling the Company to partner with medical doctors, dieticians, nutritionists, self-insured employers, private and public insurers and, most importantly, patients, to achieve healthy patient weight goals. The developing VIVUS Health Platform is expected to continue expanding VIVUS’ integration of medical, pharmaceutical, nutritional and information technology into its sales, marketing and patient access programs. The PANCREAZE Advantage Program is a component of the developing VIVUS Health Platform and, as planned, comprises a physician sampling program, Patient Assistance Program (PAP), co-pay card and integration with the VIVUS Health store front powered by Amazon for vitamins and nutritional supplements.

SuccorRx is an easy-to-use, single-page PAP web application developed to meet the growing need of ensuring that eligible uninsured and underinsured patients have access to life-changing therapies. The platform features benefits for patients, healthcare providers and participating pharmaceutical companies, including streamlining the process of enrollment and approval, ordering, and tracking shipments of pharmaceutical products for delivery to a patient’s home or healthcare facility.

“Our partnership with VIVUS on their PANCREAZE PAP provides further validation of the value that HarborPath Direct’s programs, services and technologies provide to patients and leading pharmaceutical companies,” said Trond Waerness, VP of Strategy and BD at HarborPath Direct. “We are committed to innovating PAPs that truly address the critical and growing needs of uninsured and underinsured patients. We welcome the opportunity to work with VIVUS, a company that shares our commitment to taking innovative approaches to improving patient access to important therapies.”



About HarborPath Direct

HarborPath Direct is a subsidiary of HarborPath Inc., which was established to manage the front and back end of Patient Assistance Programs (PAPs) for small to medium-sized pharmaceutical companies in all disease areas. HarborPath Direct offers clients a suite of cost-effective and efficient services ranging from managing the eligibility process, providing call center services, to expediting shipment of prescription products through its innovative trademarked SuccorRx™ platform.

For more information, visit www.harborpathdirect.com.

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.
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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 the Company, 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 the timing, strategy, tactics and success of the marketing and sales of PANCRAZE; and risks and uncertainties related to our commercialization of PANCRAZE as a new product and our recently changed management team initiating the commercialization of PANCRAZE. 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.

HarborPath Media Contact

Ken Trogdon Jr.
President
HarborPath
980-859-3483
Ken.trogdon@harborpath.org

VIVUS Contacts

VIVUS, Inc.

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

Investor Relations: Lazar Partners

David Carey
Managing Director
dcarey@lazarpartners.com
212-867-1768
