# 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)
**December 6, 2010**

# VIVUS, INC.

(Exact name of registrant as specified in its charter)

| **Delaware** | **001-33389** | **94-3136179** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

**1172 CASTRO STREET**
**MOUNTAIN VIEW, CA 94040**
(Address of principal executive offices, including zip code)

**(650) 934-5200**
(Registrant's telephone number, including area code)

**N/A**
(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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Item 8.01. Other Events**

On December 6, 2010, VIVUS, Inc. issued a press release titled "VIVUS Announces Positive Results From Long-Term Phase 3 Study of Avanafil in Erectile Dysfunction." A copy of the press release is attached hereto as Exhibit 99.1.

The information in 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 incorporated by reference into any of the Registrant'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.**

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release dated December 6, 2010, titled "VIVUS Announces Positive Results From Long-Term Phase 3 Study of Avanafil in Erectile Dysfunction." |

**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.**

By: /s/ John L. Slebir
**John L. Slebir**
**General Counsel**

Date: December 6, 2010



**EXHIBIT INDEX**

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release dated December 6, 2010, titled "VIVUS Announces Positive Results From Long-Term Phase 3 Study of Avanafil in Erectile Dysfunction." |

**CONTACT:**

**VIVUS, Inc.**
Timothy E. Morris
Chief Financial Officer
650-934-5200

**Investor Relations:** **The Trout Group**
Brian Korb
646-378-2923

**VIVUS ANNOUNCES POSITIVE RESULTS FROM LONG-TERM PHASE 3 STUDY OF AVANAFIL IN ERECTILE DYSFUNCTION**

***Results Confirm Avanafil Efficacy; NDA Filing Expected Q2 2011***

**MOUNTAIN VIEW, Calif., December 6, 2010** — VIVUS, Inc. (NASDAQ: VVUS) today announced positive results from TA-314, a phase 3 pivotal open-label safety study of avanafil, an investigational drug for the treatment of erectile dysfunction (ED). The study met all primary endpoints by demonstrating improvement from baseline in erectile function as measured by the Sexual Encounter Profile (both SEP2 and SEP3) and improvements in the International Index of Erectile Function (IIEF). In the study, patients treated with avanafil who attempted sexual intercourse (SEP3) within the first 15 minutes of dosing had success rates of 80%.

"TA-314 confirms the longer term safety and efficacy results observed in the previously reported placebo-controlled phase 3 studies of avanafil in patients with ED. The open label design allowed the over 700 enrolled patients to use avanafil as needed and at a dose of their choosing," stated Leland Wilson, chief executive officer of VIVUS. "With the completion of this study, we continue to anticipate the completion of the NDA filing for avanafil in the second quarter of 2011."

Highlights of the study include:

- Eighty percent (80%) of sexual attempts among patients on avanafil had erections sufficient for intercourse (SEP2)
- Sixty-seven percent (67%) of patients taking avanafil experienced successful intercourse (SEP3)
- Successful intercourse was achieved as early as 15 minutes after dosing
- Avanafil was well tolerated as evidenced by a low rate of discontinuations due to adverse events (2.8%)



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- The most common side effects reported were headache (5.6%), flushing (3.5%), nasopharyngitis (3.4%) and nasal congestion (2.1%)
- There were no drug-related serious adverse events reported in the study

Patients achieved an overall improvement in erectile function, as measured by the erectile function (EF) domain score of the International Index of Erectile Function (IIEF). EF domain scores range from 0-30 and measure erectile function as follows: severe dysfunction is less than or equal to 10; moderate dysfunction is 11-16; mild/minimal dysfunction is 17-25; with normal function in the range of 26-30. At baseline, patients in the study had a mean EF domain score of 12.3 (high moderate). At the end of treatment, patients in the study had a mean EF domain score of 22.6, representing a change from baseline of 10.3.

**About the avanafil phase 3 program**

The avanafil phase 3 program consists of four pivotal studies: TA-301 (REVIVE), TA-302 (REVIVE-Diabetes), TA-303 and TA-314.

TA-301 (REVIVE) was a randomized, double-blind, placebo-controlled phase 3 study of avanafil in 646 men with a history of generalized ED for at least six months. Seventy-two percent (72%) of study participants had tried at least one other ED treatment. This phase 3 study was conducted under a Special Protocol Assessment with the FDA. The study met the primary endpoints with the 200 mg dose, which were: successful penetration (SEP2), 77%; successful intercourse (SEP3) 57%; and IIEF, 22.2.

TA-302 (REVIVE-Diabetes) was a randomized, double-blind, placebo-controlled phase 3 study of avanafil in 390 diabetic males with ED. Seventy-six percent (76%) of study participants had tried at least one other ED treatment. The study met the primary endpoints with the 200 mg dose, which were: successful penetration (SEP2), 42%; successful intercourse (SEP3), 40%; and IIEF 17.3.

TA-303 is a randomized, double-blind, placebo-controlled phase 3 study of avanafil in approximately 300 males with ED following bilateral nerve-sparing radical prostatectomy. Enrollment is expected to be complete by the end of the year. Study results are expected in the second half of 2011. The completion of this study is not required as part of the avanafil NDA submission. TA-303 results will be submitted to the FDA as a supplement to the NDA.

Except for the patient population under review, TA-301, TA-302 and TA-303 all have similar trial designs with patients undergoing a four-week, non-treatment run-in period followed by 12 weeks of treatment. Primary endpoints of the studies are improvement in erectile function as measured by the Sexual

Encounter Profile (SEP) and improvements in the EF domain of the International Index of Erectile Function (IIEF) score; secondary endpoints included patient satisfaction with erections and with sexual experience.

The TA-314 study was an open-label, long-term extension study conducted in 40 centers throughout the U.S. that evaluated avanafil in 712 men, 486 with a history of general ED and 226 diabetic men with ED. Patients completing REVIVE (TA-301) or REVIVE-Diabetes (TA-302) were eligible for rollover into TA-314.

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VIVUS has also held a pre-NDA meeting with the FDA to confirm that the preclinical and clinical requirements necessary for the filing of an NDA have been met.

**About Avanafil**

Avanafil is a highly selective oral phosphodiesterase type 5 (PDE5) inhibitor therapy being investigated for the treatment of ED. Studies to date have demonstrated that avanafil has a fast onset of action, with activity demonstrated in 15 minutes or less after administration. The unique profile of avanafil suggests that the compound may be more selective than other PDE5 inhibitors, potentially resulting in lower incidence of the side effects most commonly associated with PDE5 inhibitor therapies.

**About Erectile Dysfunction (ED)**

Erectile Dysfunction (ED) is defined as the inability to attain and maintain an erection sufficient for sexual intercourse. According to the Massachusetts Male Aging Study (MMAS), ED affects an estimated 52% of men between the ages of 40 and 70. The prevalence of ED increases with age and can be affected by a variety of factors, including certain medications such as anti-hypertensives and histamine receptor antagonists; lifestyle, such as tobacco or alcohol use; diseases, including diabetes and cardiovascular conditions; and spinal cord injuries. Internal market research reveals that approximately half of ED patients try more than one drug with 80% of those who switch citing efficacy as the dominant reason for switching.

**About VIVUS**

VIVUS is a biopharmaceutical company developing therapies to address obesity, sleep apnea, diabetes and male sexual health. The company's lead product in clinical development is QNEXA®, which also is in phase 2 clinical development for the treatment of type 2 diabetes and obstructive sleep apnea. In the area of sexual health, VIVUS is in phase 3 development with avanafil, a PDE5 inhibitor being studied for the treatment of erectile dysfunction. 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. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimated" and "intend," among others. These forward-looking statements are based on VIVUS' current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, substantial competition; uncertainties of patent protection and litigation; uncertainties of government or third party payer reimbursement; reliance on sole source suppliers; limited sales and marketing efforts and dependence upon third parties; risks related to the development of innovative products; and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. There are no guarantees that future clinical studies discussed in this press release will be completed or successful or that any product will receive regulatory approval for any indication or prove to be commercially successful. VIVUS does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in VIVUS' Form 10-K for the year ended December 31, 2009 and periodic reports filed with the Securities and Exchange Commission.

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