
**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)

February 10, 2009

VIVUS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-33389
(Commission File Number)

94-3136179
(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):

- ☐ 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))
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Item 8.01. Other Events

On February 10, 2009, VIVUS, Inc. issued a press release titled "VIVUS Initiates Second Pivotal Phase 3 Trial of Avanafil for Treatment of 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated February 10, 2009

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/ Lee B. Perry

Lee B. Perry

Vice President and Chief Accounting Officer

Date: February 11, 2009

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EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated February 10, 2009

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CONTACT:

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FOR IMMEDIATE RELEASE

VIVUS INITIATES SECOND PIVOTAL PHASE 3 TRIAL OF AVANAFIL FOR TREATMENT OF ERECTILE DYSFUNCTION

REVIVE-Diabetes (TA-302) Study to Evaluate Avanafil for Treatment of Erectile Dysfunction (ED) in Men with Diabetes, One of the Most Common Causes of Erectile Dysfunction

MOUNTAIN VIEW, Calif., February 10, 2009 VIVUS, Inc. (NASDAQ: VVUS), a pharmaceutical company dedicated to the development and commercialization of novel therapeutic products, today announced it has initiated a second pivotal Phase 3 study of avanafil, its investigational new drug for the treatment of erectile dysfunction (ED). Avanafil is a next-generation, fast-acting, selective, investigational oral phosphodiesterase type 5 (PDE5) inhibitor.

The study, REVIVE-Diabetes (TA-302), is a multicenter, randomized, double-blind, placebo-controlled trial and will evaluate the safety and efficacy of avanafil in the treatment of ED in men with type 1 or type 2 diabetes. Subjects who meet the inclusion criteria will undergo a four-week non-treatment run-in period followed by 12 weeks of treatment. The co-primary endpoints of the study will be improvement in erectile function as measured by changes in the sexual encounter profile (SEP) questions 2 and 3, and improvement in erectile function as measured by the erectile function domain score of the International Index of Erectile Function (IIEF). The SEP is a self-administered patient diary and the IIEF is a patient questionnaire; both are used as standard diagnostic tools to assess erectile dysfunction. REVIVE-Diabetes is the second of three planned pivotal studies in the avanafil Phase 3 development program.

“There has not been a new treatment option for men with ED in more than five years,” stated Andrew McCullough, MD, associate professor of clinical urology, NYU School of Medicine and REVIVE-Diabetes clinical investigator. Early data suggest that avanafil may provide a fast-acting therapy with a short half-life, which, if approved, may represent a noteworthy advance for the millions of men living with ED and searching for new options.”

Diabetes is one of the most common causes of ED; clinical data suggest that at least 50 percent of diabetic men will experience difficulties with erectile function. Men with diabetes are up to three times more likely to have ED than non-diabetic men and appear to experience it earlier in life. The significance of ED increases with the severity and duration of diabetes as well as with advanced age.

“Evidence suggests that there is room for significant improvement in the current treatment of ED,” Charles Bowden, MD, senior director, clinical development for VIVUS. “We’re pleased with the promising results demonstrated thus far with avanafil, and with the momentum behind our Phase 3 program. Enrollment in our first pivotal study, REVIVE, initiated in December to evaluate avanafil in ED, is ongoing. REVIVE-Diabetes will be conducted at many of the same sites as REVIVE.”

It is expected that this study will enroll approximately 375 patients at about 30 sites in the United States. Subjects are instructed to attempt sexual intercourse 30 minutes after taking avanafil, with no restrictions on food or alcohol consumption. REVIVE-Diabetes will study two doses of avanafil. More information about the trial can be found at <http://www.clinicaltrials.gov>.

As previously disclosed, VIVUS has entered into a \$30 million funding collaboration with Deerfield Management to fund the Phase 3 program.

About Erectile Dysfunction

Erectile dysfunction, or ED, the inability to attain or maintain an erection sufficient for intercourse, was reported by 35% of men between the ages of 40 to 70 in the United States, according to an independent study, with the incidence increasing with age. ED, frequently associated with vascular problems, is particularly common in men with diabetes and in those who have had a radical prostatectomy for prostate cancer. PDE5 inhibitors such as sildenafil citrate (Viagra®), vardenafil (Levitra®) and tadalafil (Cialis®), which inhibit the breakdown of cyclic guanosine monophosphate, have been shown to be effective treatments for ED.

Worldwide sales in 2008 of PDE5 inhibitor products for ED were estimated, based on reports from the companies that market these products, to be in excess of \$3.7 billion, including approximately \$1.9 billion in reported sales of Viagra, approximately \$1.5 billion in reported sales of Cialis and approximately \$300 million in reported sales of Levitra. VIVUS believes that based on the aging baby boomer population and the desire to maintain an active sexual lifestyle, the market for PDE5 inhibitors will continue to grow.

Avanafil Phase 2 Data

VIVUS previously reported positive results from the Phase 2 studies of avanafil. Following a four-week, non-treatment, run-in period, 284 patients were treated for 12 weeks with placebo or avanafil at various doses. The primary endpoints used to assess treatment efficacy included the percentage of erections sufficient for vaginal penetration and the percentage of erections lasting long enough for successful intercourse. Avanafil produced erections sufficient for vaginal penetration on 76, 79, 80 and 84 percent of sexual attempts on the 50, 100, 200 and 300 mg doses, respectively (p<0.05). Erections lasting long

enough for successful intercourse were achieved on 54, 59, 62 and 64 percent of attempts, respectively ($p < 0.0001$). Patients were instructed to attempt sexual intercourse 30 minutes after taking avanafil, with no restrictions on food or alcohol consumption. Avanafil was well tolerated at all doses, with headache being the most commonly recorded adverse event. There were no reports of visual disturbances. Previous studies have suggested that avanafil may be taken twice a day for those patients that desire sexual intercourse more frequently than once per day.

About VIVUS

VIVUS is a biopharmaceutical company developing innovative, next-generation therapies to address unmet needs in obesity, diabetes and sexual health. The company's lead product in clinical development, Qnexa™, is expected to complete Phase 3 clinical trials for the treatment of obesity in 2009. Qnexa is also in Phase 2 clinical development for the treatment of type 2 diabetes. In the area of sexual health, VIVUS is in Phase 3 development with avanafil, a potentially best-in-class PDE5 inhibitor, and in Phase 2 development of Luramist™ for the treatment of hypoactive sexual desire disorder (HSDD) in women. MUSE® (alprostadil), a first generation therapy for the treatment of ED, is already on the market and generating revenue for VIVUS. 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, 2007 and periodic reports filed with the Securities and Exchange Commission.

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