

**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)

**May 10, 2006**

**VIVUS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation)

**000-23490**  
(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))

**Item 8.01. Other Events**

On May 10, 2006, VIVUS, Inc. issued two press releases titled "VIVUS Announces Positive Phase 2 Clinical Trial Results with Qnexa, a Novel Therapy to Treat Obesity" and "VIVUS to Raise \$12 Million in Registered Direct Offering of Common Stock." Copies of the press releases are attached hereto as Exhibits 99.1 and 99.2, respectively.

The information in this Form 8-K and the exhibits 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>
<b>99.1</b>	Press Release dated May 10, 2006 titled "VIVUS Announces Positive Phase 2 Clinical Trial Results with Qnexa, a Novel Therapy to Treat Obesity"
<b>99.2</b>	Press Release dated May 10, 2006 titled "VIVUS to Raise \$12 Million in Registered Direct Offering of Common Stock"

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**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/ Timothy E. Morris

**Timothy E. Morris**

**Vice President and Chief Financial Officer**

Date: **May 10, 2006**

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**EXHIBIT INDEX**

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**CONTACT:**

**VIVUS, Inc.**

Timothy E. Morris  
Chief Financial Officer  
650-934-5200

**Investor Relations**

**Vida Communication**  
Stephanie Diaz & Tim Brons  
415-675-7400

**Public Relations**

Kevin Knight  
214-739-0353

**FOR IMMEDIATE RELEASE**

**VIVUS ANNOUNCES POSITIVE PHASE 2 CLINICAL TRIAL RESULTS WITH QNEXA, A NOVEL THERAPY TO TREAT OBESITY**

*Over 50% of Obese Patients Experienced 10% or More Total Body Weight Loss in a 24-Week Study*

Mountain View, CA, May 10, 2006 – VIVUS, Inc. (Nasdaq:VVUS) today announced positive results from a 200-patient, double-blind, placebo-controlled clinical trial of Qnexa<sup>®</sup>, an investigational oral treatment for obesity. In the study conducted by Duke University Medical Center, more than 50% of obese patients in the Qnexa treatment group experienced 10% or more total body weight loss during the 24-week study period. Mean weight loss on an intent-to-treat (ITT) basis in the Qnexa group was 25.1 lbs., compared to 4.8 lbs in the placebo group (p<0.0001). Importantly, the rate of weight loss for patients in the Qnexa group had not plateaued by the end of the study. Qnexa was well-tolerated with a study completion rate of 92% versus a completion rate of 62% for the placebo group.

**Qnexa<sup>®</sup> Phase 2 Trial Results**

Qnexa is a proprietary pharmaceutical treatment containing low doses of the active ingredients phentermine and topiramate. This phase 2 study was a 4-arm, double-blind, randomized, placebo-controlled study comparing Qnexa to placebo, phentermine and topiramate. Primary and secondary efficacy measurements in the study all showed that Qnexa was significantly better than placebo and the active single-agent control groups. Findings from the study included:

- Qnexa achieved significantly greater weight loss as compared to placebo and each of the active single-agent control groups. Moreover, the proportion of patients achieving 10% or more total body weight loss with Qnexa was greater than the sum of both active comparator agents.
- Qnexa achieved a placebo-adjusted weight loss of 20.3 pounds at week 24.
- Weight loss with Qnexa had not plateaued by 24 weeks.
- Qnexa was well-tolerated as evidenced by the fact that only four patients (8%) dropped out of the Qnexa study arm, versus 19 patients (38%) on placebo.

This trial involved 200 subjects, 159 women and 41 men with an average age of 40 and a mean body mass index (BMI) of 38. (A BMI of >30.0 is classified as obese per guidelines from the U.S. Department of Health and Human Services). Each subject in the study received daily doses, consisting of Qnexa, placebo, or each one of the active ingredients separately. The most frequent adverse event reported was paresthesia, which was mild and transient in nature. Subjects were asked to reduce caloric intake by 500 calories per day.

“The prevalence of obesity and related illnesses such as type 2 diabetes has increased at an alarming rate in the U.S. in the recent years. There is considerable need for effective treatments for weight control. The weight loss observed in this trial is quite impressive,” said Kishore M. Gadde, M.D., Director, Obesity Clinical Trials Program, Duke University Medical Center and Principal Investigator of the phase 2 trial. “Qnexa was well-tolerated and it will be exciting to follow this investigational product as it advances through clinical development.”

“These results are consistent with the research data that I have generated using this treatment,” stated Dr. Thomas Najarian, Principal Scientist and inventor of Qnexa. “Qnexa provides synergistic weight loss over the two active agents and is well tolerated.”

“Qnexa is being developed as a proprietary pharmaceutical treatment that incorporates the active ingredients from two previously approved products with demonstrated weight loss properties. We believe that by combining the activity of each of these compounds, Qnexa simultaneously addresses the two main mechanisms that impact eating behavior,” stated Wesley W. Day, Ph.D., Vice President, Clinical Development. “Qnexa could be the first product to significantly affect both excessive hunger and the inability to feel satisfied. Based on the results from the Duke study, Qnexa appears to induce significantly greater weight loss than either component individually. Importantly, the weight loss had not plateaued in the Qnexa group at week 24.”

“The announcement of this program represents the natural expansion of our pipeline outside of our focus on sexual health. Obesity is a serious medical condition that leads to major co-morbidities including diabetes, hypertension and dyslipidemia. Qnexa fits well with our strategy of developing proprietary compounds, with proven safety records for

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large market opportunities,” said Leland Wilson, President and Chief Executive Officer of VIVUS.

### **About Qnexa**

Qnexa is a proprietary pharmaceutical treatment that incorporates low doses of active ingredients from two previously approved products. By combining the activity of each of these compounds, Qnexa simultaneously addresses excessive appetite and high threshold for satiety, the two main mechanisms that impact eating behavior. In a recent clinical trial conducted at Duke University, over 50% of obese patients experienced 10% or more total body weight loss in a 24-week study. Qnexa is subject to U.S. and International patents.

### **About Obesity**

In 2004, the U.S. Centers for Disease Control and Prevention ranked obesity as the number one health threat in America. Obesity is a chronic condition that affects millions of people and often requires long-term or invasive treatment to promote and sustain weight loss. Obesity is the second leading cause of preventable death in the United States. The American Obesity Association estimates that approximately 127 million, or 64.5 percent, of adults in the U.S. are overweight, and an estimated 60 million, or 30.5 percent, are obese. An estimated 400,000 deaths a year in the U.S. may be attributable to poor diet and physical inactivity. The total direct and indirect costs attributed to overweight and obesity amounted to \$117 billion in 2000. Additionally, Americans spend more than \$33 billion annually on weight-loss products and services.

### **About VIVUS**

VIVUS Inc. is a pharmaceutical company dedicated to the development and commercialization of next-generation therapeutic products addressing obesity and sexual health. VIVUS has four products that are positioned to enter Phase 3 clinical trials, and one product has completed Phase 3 evaluation, for which an NDA is anticipated to be submitted to the U.S. Food and Drug Administration (FDA) in late 2006. The pipeline includes: Qnexa, for which a phase 2 study has been completed; ALISTA, for which a phase 2B program ongoing for the treatment of Female Sexual Arousal Disorder (FSAD); Testosterone MDTs, for which a phase 2 program has been completed for the treatment of Hypoactive Sexual Desire Disorder (HSDD); Evamist, for which a phase 3 program has been completed for the treatment of menopausal symptoms; avanafil, for which a phase 2 program has been completed for the treatment of erectile dysfunction (ED); and MUSE, which is approved and currently on the market for the treatment of ED. For more information on clinical trials and products, please visit the company's web site at [www.vivus.com](http://www.vivus.com).

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### **Note to Investors**

#### **Conference Call & Webcast**

As previously announced, VIVUS will hold a conference call to discuss Qnexa today, May 10, 2006, beginning at 10:30 a.m. Eastern time. You can listen to this call by dialing (877) 660-0983 and entering reservation number 9107678. A live webcast and 30-day archive of the call can be accessed at [www.vivus.com](http://www.vivus.com).

A telephone replay of the conference call will be available for 24 hours beginning May 10<sup>th</sup> at approximately 1:30 p.m. (EDT) by dialing (800) 642-1687 and entering reservation number 9107678.

#### **Analyst Day**

VIVUS will hold an Analyst Day in New York City on Thursday, May 18, 2006, from 12:00 p.m. to 2:30 p.m. EDT. The event will be held at the Four Seasons Hotel, 57 East 57<sup>th</sup> Street, New York, New York. VIVUS management and certain principal investigators will be on hand to discuss the results from the phase 2 clinical trial of Qnexa, and the pivotal phase 3 studies of Evamist. A detailed update on all other development programs will be included. Seating is limited and participants can confirm their attendance by contacting Stephanie Diaz at Vida Communication, 415-675-7401 or [sdiaz@vidacommunication.com](mailto:sdiaz@vidacommunication.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, 2005 and periodic reports filed with the Securities and Exchange Commission.*

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**FOR IMMEDIATE RELEASE**

**VIVUS to Raise \$12 Million in Registered Direct Offering of Common Stock**

***Proceeds to Fund Clinical Advancement of the Qnexa Program for the Treatment of Obesity***

**MOUNTAIN VIEW, Calif., May 10, 2006** – VIVUS, Inc. (NASDAQ: VVUS), a pharmaceutical company dedicated to the development and commercialization of next-generation therapeutic products addressing obesity and sexual health, today announced that it has entered into a purchase agreement with two institutional investors for the sale of \$12 million of its common stock in a registered direct offering. Under the terms of the financing, VIVUS will sell 3,669,725 shares of VIVUS common stock at a price of \$3.27 per share. The transaction is expected to close on May 10, 2006, subject to customary closing conditions. All of the shares of common stock are being offered pursuant to an effective Registration Statement previously filed with the Securities and Exchange Commission.

A new investor, OrbiMed Advisors, LLC, led the financing in addition to an existing VIVUS investor. The shares were priced at market, based on a five-day average close ending on May 9, 2006. VIVUS intends to use the proceeds from the financing to fund clinical trials, including certain studies required prior to the initiation of a Phase 3 clinical trial of VIVUS' recently announced Qnexa™ program for the treatment of obesity, as well as for general corporate purposes.

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