

**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)

**October 23, 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 October 23, 2006, VIVUS, Inc. issued a press release titled "VIVUS' Qnexa Phase 2 Study Results Demonstrate Significant Weight Loss, Reduction in Waist Circumference and Positive Effect on Factors Contributing to Metabolic Syndrome." 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 October 23, 2006

## 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: **October 24, 2006**

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## EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated October 23, 2006

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## **CONTACT:**

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

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

## **FOR IMMEDIATE RELEASE**

### **VIVUS' Qnexa Phase 2 Study Results Demonstrate Significant Weight Loss, Reduction in Waist Circumference and Positive Effect on Factors Contributing to Metabolic Syndrome**

#### ***Data Presented in Oral Presentation at the North American Association for the Study of Obesity (NAASO) 2006 Annual Scientific Meeting***

**MOUNTAIN VIEW, Calif., October 23, 2006** — VIVUS, Inc. (NASDAQ: VVUS), a pharmaceutical company dedicated to the development and commercialization of novel therapeutic products addressing obesity and sexual health, today announced that Dr. Kishore Gadde, principal investigator in the study and the Director of Obesity Clinical Trials at Duke University, presented positive results from a Phase 2 clinical trial of Qnexa™ (formerly VI-0521), an investigational oral treatment for obesity, at the North American Association for the Study of Obesity (NAASO) 2006 Annual Scientific Meeting. The NAASO Meeting is being held this week in Boston. When compared to those on placebo, patients treated with Qnexa experienced a statistically significant average weight loss and a reduction in waist circumference. Significant reductions were also seen in lipid levels despite normal mean baseline values. The dropout rate for the trial was 8% in the Qnexa arm, as compared to 38% for the placebo arm.

“Qnexa demonstrated significant weight loss and reduction in waist circumference in this study, coupled with excellent tolerability and a positive impact on certain factors pertaining to metabolic syndrome in obese patients,” commented Leland Wilson, president and chief executive officer of VIVUS. “This is the first time the Qnexa Phase 2 data has been presented in a medical forum and represents the beginning of our education process with practicing physicians on the potential of Qnexa.”

Dr. Gadde's presentation, entitled ***A 24-week Randomized Controlled Trial of VI-0521, a Combination Weight Loss Therapy, in Obese Adults***, provided data on average weight-loss, percent of weight loss from baseline, waist circumference and the observed benefit of Qnexa

VIVUS, Inc. 1172 Castro Street, Mountain View, CA 94040 Tel 650-934-5200 Fax 650-934-5389 [www.vivus.com](http://www.vivus.com)

with respect to certain risk factors contributing to metabolic syndrome. Metabolic syndrome is a condition characterized by multiple metabolic risk factors, including obesity as well as elevated triglyceride levels, blood pressure and cholesterol. Dr. Gadde also detailed the primary findings from this study, which have been previously reported.

### **Presentation Highlights**

Qnexa is a proprietary oral investigational pharmaceutical treatment for obesity. The Phase 2 study was a double-blind, randomized, placebo-controlled trial conducted at Duke University. This trial involved 200 subjects, 159 women and 41 men with an average age of 40 and a mean body mass index (BMI) of 38.6. (A BMI of >30.0 is classified as obese per guidelines from the U.S. Department of Health and Human Services.)

Patients completing the twenty-four week treated period achieved a highly significant average weight loss of 26.0 pounds, as compared to 7.0 pounds for the placebo group ( $p < 0.0001$ ). Using an intent-to-treat, last observation-carried forward (ITT-LOCF) analysis, treatment with Qnexa had a highly significant average weight loss of 25.1 pounds, compared to 4.8 pounds for the placebo group ( $p < 0.0001$ ).

The study completion rate for patients on Qnexa over the 24-week treatment period was 92%, as compared to 62% for patients in the placebo group.

### **Additional Findings on Weight Loss**

Patients completing the twenty-four week treatment period lost on average 11.1% of baseline body weight, as compared to an average 2.8% in the placebo group. The difference between the Qnexa arm and the placebo arm was highly significant ( $p < 0.0001$ ). Using an ITT-LOCF analysis, patients on Qnexa lost 10.7% of baseline body weight, as compared to 2.1% for the placebo arm ( $p < 0.0001$ ). The primary efficacy endpoint for weight loss trials as required by the U.S. Food and Drug Administration is demonstration of a mean placebo-subtracted 1 year weight loss of 35%. In Europe, The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended that demonstration of significant weight loss of at least 10% of baseline weight is considered to be a valid primary endpoint for anti-obesity drugs.

Using an ITT-LOCF analysis, the percentage of patients achieving 5%, 10% and 15% weight loss from baseline was 82% ( $p < 0.0001$ ), 50% ( $p < 0.0001$ ) and 20% ( $p = 0.0007$ ), respectively, as compared to 14%, 8% and 0% for the placebo group.

### **Findings for Secondary Endpoints**

On an ITT-LOCF basis, patients in the Qnexa group had a significant reduction of waist circumference of 12.6 cm, as compared to 6.4 cm for the placebo group (p<0.0001). Waistline is an indicator of central adiposity, which has been shown to be positively correlated with the risk factors for diabetes, cardiovascular disease and certain types of cancer.

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Patients treated with Qnexa had a mean reduction of 10% for cholesterol and 16.2% for triglycerides, as compared to a reduction of 3.5% and an increase of 6.7%, respectively, for the placebo group. Baseline cholesterol and triglycerides were considered normal. Decreases in blood pressure as measured by the mean change from baseline at week 24 were also observed in the Qnexa group as compared to the placebo group. These findings suggest that Qnexa may improve certain metabolic risk factors in obese patients. Qnexa was well tolerated in this trial. Adverse events occurring in greater than 10% in the Qnexa arm as compared to placebo included paresthesia (mild tingling of the extremities), altered taste and increased urinary frequency. There were no dropouts in the Qnexa arm due to serious or severe adverse events.

### **About Qnexa**

Qnexa is a proprietary pharmaceutical treatment that incorporates low doses of active ingredients from two previously approved products (phentermine and topiramate). 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. We believe Qnexa is the first product to treat obesity in this manner. 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. The total direct and indirect costs attributed to those who are overweight and obese amounted to \$117 billion in 2000. Additionally, Americans spend more than \$33 billion annually on weight-loss products and services.

### **About Metabolic Syndrome**

According to the American Heart Association, “The metabolic syndrome is characterized by a group of metabolic risk factors in one person.” Such factors include but are not limited to:

- Abdominal obesity
- Blood fat disorders that foster plaque buildup in artery walls including:
  - high triglycerides
  - low HDL cholesterol
  - high LDL cholesterol
- Elevated blood pressure

People with metabolic syndrome have an increased risk of coronary heart disease and other conditions that result from the buildup of plaque in artery walls (e.g., stroke and peripheral

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vascular disease) and type 2 diabetes. It is currently estimated that more than 50 million Americans are living with metabolic syndrome.

### **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 three products that are positioned to enter Phase 3 clinical trials, and one product currently under NDA review by the FDA. The pipeline includes: Qnexa™, for which a Phase 2 study has been completed for the treatment of obesity; Testosterone MDTs®, for which a Phase 2 study has been completed for the treatment of Hypoactive Sexual Desire Disorder (HSDD); EvaMist™, for which a Phase 3 study has been completed and an NDA submitted for the treatment of menopausal symptoms; and avanafil, for which a Phase 2 study has been completed for the treatment of erectile dysfunction (ED). MUSE® 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).

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.

