# 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): **July 15, 2004**

# VIVUS, INC

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

COMMISSION FILE NUMBER: 0–23490

| **DELAWARE** | **94–3136179** |
|---|---|
| (STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION) | (I.R.S. EMPLOYER IDENTIFICATION NO.) |
| **1172 CASTRO STREET**<br>**MOUNTAIN VIEW, CA**<br>(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES | **94040**<br>(ZIP CODE) |

**(650) 934–5200**
(REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE)

**N/A**
(FORMER NAME, FORMER ADDRESS AND FORMER FISCAL YEAR, IF CHANGED SINCE LAST REPORT)

**Item 5. Other Events and Regulation FD Disclosure.**

On July 14, 2004, the Registrant issued a press release announcing that data from a recently completed Phase 2 clinical trial demonstrated that ALISTA, our topical formulation of alprostadil for the treatment of female sexual arousal disorder (FSAD), significantly increased the percentage of satisfying sexual events in pre-menopausal women with FSAD when compared with placebo. The press release is attached as exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 7. Exhibits.**

**(c)**

| **Exhibit Number** | **Description** |
|---|---|
| 99.1 | Press Release dated July 14, 2004. |



**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 thereunto duly authorized.

Date: July 15, 2004

VIVUS, INC.

/s/ LARRY J. STRAUSS

Larry J. Strauss
Vice President and Chief Financial Officer



VIVUS, INC.

INDEX TO EXHIBITS
The following exhibits are filed herewith:

| **Exhibit** | **Description** |
|---|---|
| 99.1 | Press Release dated July 14, 2004. |

[VIVUS LETTERHEAD]

For More Information:

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**FOR RELEASE JULY 14, 2004, 8:00AM EST**

# VIVUS ANNOUNCES POSITIVE PHASE 2 RESULTS FOR ALISTA IN PREMENOPAUSAL WOMEN WITH FEMALE SEXUAL AROUSAL DISORDER

***— Study Shows 64 Percent of ALISTA Doses Resulted in Satisfying Sexual Events —***

**MOUNTAIN VIEW, Calif. July 14, 2004) — VIVUS, Inc. (Nasdaq NM: VVUS)** today announced that data from a recently completed Phase 2 clinical trial demonstrated that ALISTA™ significantly increased the percentage of satisfying sexual events in premenopausal women with female sexual arousal disorder (FSAD) when compared with placebo. Sixty-four percent of ALISTA doses resulted in satisfying sexual events ($p<0.05$). The study also showed patients experienced an increase in the total number of satisfying sexual encounters when compared to placebo ($p=0.05$).

This double-blind, randomized, placebo-controlled, crossover study evaluated the efficacy and safety of ALISTA for premenopausal women in the home setting. In this study, involving six different sites, 36 women received at least one dose each of the placebo and active drug.

Women rated ALISTA as providing an increase in their level of sexual arousal ($p<0.01$) and a decrease in level of distress ($p<0.05$) when compared to placebo. Sexual arousal was evaluated through the use of a daily diary and level of distress was evaluated through the use of an industry standard questionnaire.

“This is the third Phase 2 study of ALISTA showing clinically significant improvements in sexual satisfaction among participants,” said Leland Wilson, VIVUS’ president and chief executive officer. “These results in premenopausal women are consistent with previous results from studies in postmenopausal women. Success in this study has greatly increased the potential market for ALISTA. VIVUS plans to include clinical trials in premenopausal women in the ALISTA Phase 3 development program.”

The full results from this Phase 2 study will be presented at a scientific forum later this year.

## About ALISTA

VIVUS is entering Phase 3 clinical development with ALISTA, a topical formulation of alprostadil, for the treatment of female sexual arousal disorder (FSAD). Alprostadil is thought to increase blood flow to the genital tissues in females, which could improve sexual function. ALISTA Phase 2 clinical data in postmenopausal women using the product at home demonstrated improved arousal. These data were presented at the International Society of the Study of Women’s Health (ISSWSH) in 2003 and were consistent with an in-clinic study of the same dose range concluded in 2002. VIVUS owns the method-of-use patents for the topical and local application of vasoactive agents, including alprostadil, for the treatment of female sexual dysfunction.

## About VIVUS

VIVUS is a specialty pharmaceutical company focused on research, development and commercialization of products to restore sexual function. In addition to currently marketed therapies, VIVUS has a strong pipeline that includes both new and existing chemical compounds that can be developed to address unmet medical needs. VIVUS’ business strategy applies the Company’s scientific and medical expertise to identify, develop and commercialize therapies that restore sexual function. For more information, please visit the Company's Web site at: 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; 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 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, 2003 and periodic reports filed with the Securities and Exchange Commission.