

**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 9, 2005**

VIVUS, INC.

(Exact name of Registrant as specified in its charter)

DELAWARE
(State or other jurisdiction of
incorporation)

0-23490
(Commission File Number)

94-3136179
(I.R.S. 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 February 9, 2005, the Registrant issued a press release announcing that data from a recently completed Phase 2 clinical trial demonstrated that Testosterone MDTs®, the Company's investigational transdermal testosterone spray for the treatment of females with hypoactive sexual desire disorder (HSDD), significantly increased the number of satisfactory sexual events in premenopausal women with HSDD 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 9.01. Financial Statements and Exhibits

(c) Exhibits.

Exhibit No.	Description
99.1	Press Release dated February 9, 2005.

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, Finance and Chief Financial Officer

Date: February 9, 2005

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated February 9, 2005.



For more information:
VIVUS Inc.
Christina Weisgerber
650-934-5240

FOR IMMEDIATE RELEASE

Clinical Trial Demonstrates Improved Sexual Desire in Women with Low Libido After Treatment with VIVUS' Testosterone Spray

Phase 2 Study Shows Number of Satisfactory Sexual Events more than Doubled

Mountain View, Calif. (February 9, 2005) – VIVUS Inc. (**Nasdaq:VIVUS**) today announced that clinical data from a Phase 2 study showed treatment with the Company's Testosterone MDTs®, an investigational transdermal testosterone spray, significantly increased the number of satisfactory sexual events in premenopausal women with Hypoactive Sexual Desire Disorder (HSDD).

The 28-week, double-blind, randomized, placebo controlled, dose-ranging study consisted of 261 premenopausal women with low serum testosterone and low libido that caused distress. Patients were randomized to receive a once daily administration of Testosterone MDTs or placebo spray to the abdomen over a 16-week treatment period. The primary endpoint of the study was the number of satisfactory sexual events reported by women over a 4-week period at week 16. The study was conducted at 6 sites across Australia by Acrux Limited (ASX: ACR), under an Investigational New Drug (IND) Application on file with the United States Food and Drug Administration (FDA).

Study results showed a statistically significant ($p < 0.05$) increase in the number of satisfactory sexual events at week 16 for the second highest dose of testosterone MDTs compared to placebo. A positive trend was observed in all treatment groups from week four compared with baseline. In the most effective treatment group, the number of satisfactory sexual events more than doubled at week 16 compared with baseline. No serious adverse events resulting in discontinuation of the study occurred in any subject receiving testosterone MDTs. The most common side effect was a mild increase in hair growth, resulting in only two patients withdrawing from the study, both in the highest dose group. The incidence of skin irritation was very low and reported as mild.

"Earlier studies have demonstrated the efficacy of transdermal testosterone delivery for the treatment of naturally and surgically menopausal women. This new study supports the findings of our earlier study that premenopausal women with low libido can also enjoy an increase in satisfactory sexual events following treatment with transdermal testosterone," said Susan Davis Professor of Women's Health at Monash University and Principal Investigator.

"This is the first double-blind, placebo controlled study conducted under an IND Application evaluating the safety and efficacy of transdermal testosterone in premenopausal women with low testosterone," said Peter Tam, Senior Vice President of Product and Corporate Development. "This is also the first at-home clinical trial to validate the ability of the MDTs technology to effectively deliver an adequate amount of testosterone to improve sexual response."

"Testosterone MDTs is an important component of our entire development pipeline, which includes ALISTA™ for the treatment of Female Sexual Arousal Disorder and Evamist™ for the treatment of menopausal symptoms, both currently in Phase 3 development," commented Leland Wilson, President and CEO for VIVUS.

Testosterone MDTs®

Testosterone (Metered Dose Transdermal Spray) is a patented new-generation transdermal spray. MDTs features a small, discrete, hand-held applicator that delivers a pre-set dose of a proprietary formulation of testosterone to the skin where it is released into the blood stream on a sustained basis over 24 hours. The MDTs spray is fast drying, non-irritating and invisible after application.

About Acrux

Acrux Limited's group of companies is engaged in the development and commercialization of a range of patented, patient-preferred healthcare products for global markets. Acrux has completed sixteen human clinical trials with six different drugs using its proprietary drug delivery technology, comprising ACROSS® penetration enhancers, Metered Dose Transdermal System (MDTs®) applicators for transdermal administration, and Patchless Patch® delivery method. Acrux's portfolio includes treatments of hormonal deficiencies, pain, central nervous system disorders and urinary incontinence, as well as a contraceptive. Acrux has licensed USA rights to its two lead products, Estradiol MDTs® and Testosterone MDTs®, to VIVUS and AUS/NZ distribution rights for Testosterone MDTs® to CSL Limited. Acrux has also licensed its technology for commercial development to Eli Lilly for veterinary healthcare products, and to Connetics Australia, a subsidiary of the US Company Connetics, for anti-psoriatics and local anaesthetics. For more information please visit the Company's web site at www.acrux.com.au.

About VIVUS

VIVUS Inc. is a pioneer in the research and development of proprietary products to restore sexual function for men and women. VIVUS' current product pipeline includes four investigational products in late stage clinical development. For women, VIVUS has initiated its Phase 3 programs with ALISTA™ for female sexual arousal disorder, and Evamist™ for the alleviation of menopausal symptoms. Testosterone MDTs® for the treatment of HSDD has completed Phase 2 development. The MDTs system is a patented new-generation, transdermal drug delivery technology that delivers drugs through the skin. For men, VIVUS is developing avanafil for erectile dysfunction, which is currently in a Phase 2 program. VIVUS currently markets MUSE® (alprostadil) suppository in the U.S. and internationally through distributors for the treatment of erectile dysfunction. For more information on clinical trials and products, 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.

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