FORM 8-K

Current report filing

Filing Date: **2004-02-12** | Period of Report: **2004-02-12**
SEC Accession No. 0001072613-04-000270

FILER

VIVUS INC

CIK:**881524**| IRS No.: **943136179** | State of Incorp.:**CA** | Fiscal Year End: **1231**
Type: **8-K** | Act: **34** | File No.: **000-23490** | Film No.: **04588513**
SIC: **3841** Surgical & medical instruments & apparatus

Mailing Address
1172 CASTRO STREET
MOUNTAIN VIEW CA 94040

Business Address
1172 CASTRO ST
STE 200
MOUNTAIN VIEW CA 94040
6509345265

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 12, 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 **MOUNTAIN VIEW, CA** (ADDRESS OF PRINCIPAL EXECUTIVE OFFICES	**94040** (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 February 12, 2004, the Registrant issued a press release announcing the execution of exclusive licensing agreements with Acrux Limited, a pharmaceutical company based in Melbourne, Australia, under which VIVUS has the rights and responsibilities to develop and commercialize Testosterone MDTS® and Estradiol MDTS® in the United States for treatment of low sexual desire and menopausal symptoms, respectively. The press release is attached as exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

On February 12, 2004, the Registrant issued a second press release announcing that the Company will hold a conference call to dicuss the licensing agreements with ACRUX. The press release is attached as exhibit 99.2 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 February 12, 2004.
99.2	Press Release dated February 12, 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: February 12, 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 February 12, 2004.
99.2	Press Release dated February 12, 2004.

Exhibit 99.1

[VIVUS LETTERHEAD]

For More Information:

Investors: Christina Weisgerber
(650) 934-5240 or
weisgerber@vivus.com

Media: Nathan Kaiser
(415) 318-4235 or
kaisern@fleishman.com

FOR RELEASE: FEBRUARY 12, 2004, 8:00AM EST

VIVUS EXPANDS SEXUAL HEALTH PRODUCTS PIPELINE THROUGH DEAL WITH ACRUX

–Phase 2 Testosterone and Phase 3 Estradiol Products for Diminished Sexual Desire and Menopause Symptoms Employ Next Generation Transdermal Drug Delivery Spray –

Mountain View, Calif. – February 12, 2004 –VIVUS, Inc. (Nasdaq NM: VVUS), today announced the execution of exclusive licensing agreements with Melbourne, Australia-based specialty pharmaceutical company Acrux under which VIVUS will develop and commercialize Testosterone MDTS® and Estradiol MDTS® in the United States for treatment of low sexual desire and menopausal symptoms, respectively. Acrux' s Metered-Dose Transdermal System (MDTS®) technology is a patented, simple to use spray that is being developed to deliver testosterone and estradiol effectively to women when applied to the skin. This technology was pioneered by Acrux working with leading drug-delivery scientists from Monash University in Melbourne, Australia.

Under the terms of the agreements, VIVUS will pay to Acrux combined licensing fees of $3.0 million to be paid over the next 17 months, payments up to $4.3 million for achievement of certain clinical development milestones, product approval milestones payments of $6.0 million, and royalties on net sales in the United States upon commercialization of each product.

"The MDTS technology is the next generation of transdermal drug delivery. Using this spray is as easy as taking a pill with all the safety advantages of transdermal delivery," said Leland Wilson president and CEO of VIVUS. "Testosterone has been used effectively in clinical trials for treating women with low sexual desire and we now have a patient-preferred, patented delivery system. With the addition of these products, VIVUS is well-positioned with therapies in its pipeline to address women' s health issues including the two most prevalent conditions related to female sexual dysfunction (FSD) – decreased desire and arousal. These strategic agreements underscore VIVUS' commitment to developing innovative treatments for sexual dysfunction."

Acrux has conducted clinical trials for both products under Investigational New Drug Applications on file with the United States Food and Drug Administration (FDA). Acrux is currently conducting a 200-patient Phase 2 study in Australia for Testosterone MDTS. This study is expected to be completed in early 2005. With the exception of this Phase 2 study, VIVUS will conduct all future development work for Testosterone MDTS. Current plans anticipate beginning Phase 3 clinical

development in 2005. VIVUS will take Estradiol MDTS into Phase 3 clinical development in late 2004 for short-term therapy for women experiencing symptoms associated with menopause and anticipates filing a New Drug Application with the FDA in 2006.

"After years of concerns being expressed by a vast number of women, the issue of low sexual desire has finally gained increased visibility and the attention of the medical community," said Professor Susan Davis, Director of Research, Jean Hailes Foundation, Melbourne and primary investigator in the on-going Phase 2 clinical trial. "The development of this simple method of delivering testosterone in a range of doses appropriate for the treatment of low sexual desire in women is a considerable step forward in this field of women' s health research."

A study published in the *Journal of the American Medical Association* in 1999 estimated that more than 40 percent of women report some form of sexual dysfunction, including both organic and psychogenic causes, with the incidence increasing after menopause. Data published in the *New England Journal of Medicine* in 2000 suggest that testosterone is effective in treating surgically menopausal women with low sexual desire.

"We are extremely pleased to partner these two products with VIVUS, a leading developer of treatments for sexual health. VIVUS' commitment and ability to commercialize innovative treatments addressing unmet sexual health needs make it a very attractive partner," said Igor Gonda, Ph.D., Acrux managing director and CEO. "We look forward to bringing these innovative therapies to large patient populations with significant unmet needs."

Testosterone MDTS is a small, hand-held transdermal spray which delivers testosterone via Acrux' s proprietary ACROSS® skin penetration enhancers. It provides a simple way of delivering a pre-set dose of testosterone to the skin. The MDTS is placed gently against the skin and the actuator is depressed releasing a light spray, which quickly dries on the skin to form an invisible drug depot. The enhancers allow testosterone to pass through the top layers of the skin. A once daily application delivers drug through the skin where it is released into the blood stream on a sustained basis over 24 hours.

The licensed MDTS patent covers the use of specific skin penetration enhancers commonly found in sunscreens for delivering testosterone and estradiol to the skin. The safety profile of these skin penetration enhancers has been well established in humans. Therefore, no further non-clinical safety testing is anticipated.

Estradiol MDTS is currently entering Phase 3 clinical trials as a therapy for women with symptoms associated with menopause such as hot flashes and vaginal dryness. Acrux completed Phase 1 and 2 studies showing comparable pharmacokinetic profiles to the marketed transdermal estradiol patches. VIVUS' Phase 3 clinical trial in approximately 200 patients, will be a three-month efficacy study to demonstrate reduction of vasomotor symptoms, i.e., hot flashes, in menopausal women with moderate to severe symptoms.

A study published in *The Lancet* in 2003 suggests that transdermal estrogen replacement treatments may be safer as compared to oral estrogen with respect to thrombotic risk. According to recent FDA industry guidance, estrogens are the most effective approved products for hot flashes and symptoms of vulvar and vaginal atrophy.

About Acrux

Acrux Limited' s group of companies is engaged in the development of proprietary transdermal and cosmeceutic products using technology licensed from Monash University, Melbourne, Australia. The company has completed eleven human clinical trials with 6 different drugs using the proprietary ACROSS® enhancers and Metered Dose Transdermal System (MDTS®) for transdermal administration. Acrux portfolio includes treatments of hormonal deficiencies, pain, anxiety, Alzheimer' s and Parkinson' s disease, nausea and urinary incontinence. In addition to the projects funded internally, Acrux has sub-licensed its technology for commercial development to Eli Lilly for Veterinary healthcare products, and to Connectics Australia, Pty Ltd, a subsidiary of the U.S. Company Connetics, for anti-psoriatics and local anesthetics. For more information, please visit the Company' s web site at: www.acrux.com.au.

About VIVUS

VIVUS is a specialty pharmaceutical company focused on research, development and commercialization of products proven to restore sexual function. In addition to currently marketed therapies, VIVUS has a strong pipeline that includes both new chemical entities and existing

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, 2002 and periodic reports filed with the Securities and Exchange Commission.

# # #

Exhibit 99.2

[VIVUS LETTERHEAD]

For More Information:

Investors: Christina Weisgerber
(650) 934-5240 or
weisgerber@vivus.com

Media: Nathan Kaiser
(415) 318-4235 or
kaisern@fleishman.com

FOR RELEASE: February 12, 2004, 8:00AM EST

VIVUS TO HOLD CONFERENCE CALL TO DISCUSS LICENSING AGREEMENTS WITH ACRUX

MOUNTAIN VIEW, Calif. (February 12, 2004) − VIVUS, Inc. **(Nasdaq: VVUS)** today announced that the Company will hold a conference call to discuss the licensing agreements with Acrux, a specialty pharmaceutical company in Melbourne, Australia, under which VIVUS will exclusively develop and commercialize Testosterone MDTS® and Estradiol MDTS® in the United States.

The conference call will be held today, Thursday, February 12, 2004, at 11:30 a.m. EST. Investors can participate in the call by telephone: domestic callers should dial (877)-660-0983, and international callers should dial (706)-679-5921. The conference call can be heard live via audio webcast at the Company' s Web site, www.vivus.com, and a replay will be available for 7 days.

A telephone replay of the conference call will be available for 24 hours beginning February 12 at approximately 12:30 p.m. Eastern Time by dialing (800) 642-1687 domestically, or (706) 645-9291 Internationally and entering reservation number 5478847.

About VIVUS
VIVUS is a specialty pharmaceutical company focused on research, development and commercialization of products proven to restore sexual function. In addition to currently marketed therapies, VIVUS has a strong pipeline that includes both new chemical entities and existing 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.

# # #