

**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): **April 28, 2005**

**VIVUS, INC.**

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

COMMISSION FILE NUMBER: **0-23490**

**DELAWARE**

(STATE OR OTHER JURISDICTION OF  
INCORPORATION OR ORGANIZATION)

**94-3136179**

(I.R.S. EMPLOYER  
IDENTIFICATION NUMBER)

**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)

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:

- ☐ 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 2.02 Results of Operations and Financial Condition.**

On April 28, 2005, VIVUS, Inc. issued a press release announcing its financial results for the fiscal quarter ended March 31, 2005. The full text of the April 28, 2005 press release is included as Exhibit 99.1 hereto.

The information in this Form 8-K and the exhibit attached hereto shall not be deemed to be "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.**

(c) Exhibits.

**Exhibit  
Number**

**Description**

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: April 28, 2005

VIVUS, Inc.

/s/ Leland F. Wilson

Leland F. Wilson

President and Chief Executive Officer

VIVUS, INC.

INDEX TO EXHIBITS  
The following exhibits are filed herewith:

EXHIBIT	DESCRIPTION
99.1	Text of Press Release, dated April 28, 2005, titled “VIVUS Reports First Quarter Financial Results.”



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

## FOR IMMEDIATE RELEASE

### VIVUS REPORTS FIRST QUARTER FINANCIAL RESULTS

**Mountain View, Calif. (April 28, 2005)** — VIVUS, Inc. (**Nasdaq:VIVUS**), a specialty pharmaceutical company focused on the research, development and commercialization of products to restore sexual function in women and men, today announced its accomplishments and financial results for the three months ended March 31, 2005.

#### First Quarter 2005 Accomplishments

The quarter ended March 31, 2005 was marked by several achievements including:

- **Completion of avanafil Phase 2 patient enrollment** - Avanafil is an investigational drug being studied for the treatment of erectile dysfunction. Avanafil is a highly selective, orally administered phosphodiesterase type 5 (PDE5) inhibitor. This multi-center, double-blind, randomized, placebo-controlled, parallel-design clinical study enrolled 298 patients. The purpose of this study is to evaluate the safety and efficacy of a number of different doses of avanafil, with the goal of selecting the appropriate doses for Phase 3 clinical trials. VIVUS intends to announce results upon completion of this Phase 2 trial later this year.
- **Positive Phase 2 data for Testosterone MDTs® for the treatment of HSDD** - The results of the 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 pre-menopausal 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 with associated distress. The primary endpoint of the study was the number of satisfactory sexual events reported by women over a 4-week period at week 16. In the most effective treatment group, the number of satisfactory sexual events more than doubled at week 16 compared with baseline.
- **Raising \$19.6 million through the sale of common stock** - VIVUS sold 6,250,000 shares of its common stock at \$3.40 per share in an underwritten public offering. The shares were sold to the public at a price per share of \$3.40. SG Cowen & Co., LLC acted as the lead manager for the offering and Wachovia Capital Markets, LLC acted as co-manager.
- **Initiation of research coverage from SG Cowen & Co. and Wachovia Capital Markets, LLC** - The research departments of the investment banking firms SG Cowen & Co. and Wachovia Capital Markets LLC both initiated coverage of the company and have issued their initial reports. The SG Cowen & Co. report was authored by the Pharmaceutical Research Team, headed by Ian Sanderson. Mr. Sanderson is a Senior Research Analyst covering emerging and midcap pharmaceutical companies for SG Cowen & Co., including specialty pharmaceutical, drug delivery, and generic pharmaceutical companies. The Wachovia Capital Markets LLC report was authored by Michael Tong, Vice President Equity Research, who follows the specialty pharmaceutical industry.

---

"In the first quarter of 2005, VIVUS continued to make progress in each of its late stage clinical candidates," commented Leland Wilson, President and CEO of VIVUS. "We strengthened the balance sheet by completing a financing in a difficult market that resulted in \$19.6 million in net proceeds to the company. The proceeds from the financing combined with the cash and investment balances on hand should allow us to continue to fund development of our late stage clinical development programs into 2006."

#### Financial Results for the First Quarter of 2005

For the three months ended March 31, 2005, VIVUS reported a net loss of \$8.8 million, or \$0.22 per share, as compared to a net loss of \$10.9 million, or \$0.29 per share, in the first quarter of 2004. The decrease in net loss was primarily due to lower research and development expenses in the first quarter of 2005 as compared to the first quarter of 2004. In the first quarter of 2004, the company's research and development expenses included \$2.9 million in licensing fees under the agreements with Acrux Limited for the rights to estradiol and testosterone MDTs and \$1.8 million to Tanabe Seiyaku Co., LTD for the rights to avanafil.

Total revenue for the first quarter of 2005 was \$629,000, as compared to \$1.9 million for the first quarter of 2004. The decrease in total revenue was primarily due to a decrease in international revenue resulting from lower shipments of MUSE to our international distribution partners. In the first quarter of 2004 our international distributors purchased quantities of MUSE in anticipation of a multi-country promotion effort. A similar purchasing pattern did not occur in the first quarter of 2005. Domestic sales of MUSE were also lower in the first quarter of 2005 due to the lack of growth in the demand for approved PDE5 inhibitors, the large volume of purchases made by the wholesalers in the fourth quarter of 2004 and new US government pricing. We expect this trend to continue in 2005.

#### Cash, Cash Equivalents and Available-for-Sale Securities

At March 31, 2005, VIVUS had cash, cash equivalents and available-for-sale securities of \$50.4 million, as compared to \$29.8 million at December 31, 2004. The increase in cash, cash equivalents and available-for-sale securities of \$20.6 million is due to receipt of net proceeds from the sale of common stock of \$19.6 million, the collection of amounts owed at December 31, 2004 from customers as measured by a decrease in accounts receivable of \$9.2 million offset by cash used in operations, financing and investment activities for the quarter. Exclusive of the proceeds from the public offering and the decrease in accounts receivable, the decrease in cash, cash equivalents and available-for-sale securities was \$8.2 million.

### **First Quarter Investigational Product Pipeline Update**

We continued the development of our late stage clinical candidates. Highlights for each of the major programs in the first quarter are as follows:

- **ALISTA**- Continued recruitment of patients and enrollment in the Phase 3 clinical trial of ALISTA for the treatment of Female Sexual Arousal Disorder (FSAD). Our goal is to complete enrollment in this study by the end of 2005.
- **Testosterone-MDTS**- In addition to the announcement of the positive results from the Phase 2 study in pre-menopausal women with HSDD, we submitted a written proposal for a Phase 3 development program for testosterone MDTS to the Food and Drug Administration (FDA) for review and comment. Our goal is to finalize the Phase 3 protocol for the testosterone MDTS trials in 2005.
- **Evamist**<sup>TM</sup>- Enrollment in the Phase 3 trials is progressing as expected. Our goal is to complete enrollment in this pivotal trial by the end of 2005. The trial is being conducted under a previously granted Special Protocol Assessment (SPA) from the FDA.

- **Avanafil**- As discussed above we have completed patient enrollment in a Phase 2 study with avanafil. We anticipate that results from this study will be available later this year.

### **About VIVUS**

VIVUS, Inc. is a pioneer in the research and development of proprietary products to restore sexual function for women and men. VIVUS' current product pipeline includes four investigational products in late stage clinical development. For women, VIVUS has initiated its Phase 3 programs with ALISTA<sup>TM</sup> for female sexual arousal disorder, and Evamist<sup>TM</sup> for the alleviation of menopausal symptoms. Testosterone MDTS<sup>®</sup> for the treatment of hypoactive sexual desire disorder 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<sup>®</sup> (alprostadil) suppository for the treatment of erectile dysfunction in the U.S. and internationally through distributors. For more information on clinical trials and products, please visit the Company's web site at [www.vivus.com](http://www.vivus.com).

### **Conference Call Information**

As previously announced, VIVUS will hold a conference call to discuss the first quarter accomplishments and financial results today, April 28, 2005, beginning at 4:30 p.m. Eastern Time. You can listen to this call by dialing 877-660-0983 domestically or 706-634-7206 internationally (live or 30-day replay) via the Internet 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; 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, 2004 and periodic reports filed with the Securities and Exchange Commission.*

Financial Tables Follow

### **VIVUS, Inc. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS** (in thousands, except per share amounts)

	<b>Three Months Ended</b>	
	<b>March 31 2005 (unaudited)</b>	<b>March 31 2004 (unaudited)</b>
Revenue		
US product, net	\$ 396	\$ 572
International product	192	1,332
Other revenue	41	38

Total revenue	629	1,942
Operating expenses:		
Cost of goods sold and manufacturing	2,090	2,280
Research and development	4,265	7,721
Selling, general and administrative	3,189	3,008
Total operating expenses	9,544	13,009
Loss from operations	(8,915)	(11,067)
Interest and other income, net	91	171
Loss before income taxes	(8,824)	(10,896)
Provision for income taxes	(13)	(3)
Net loss	<u>\$ (8,837)</u>	<u>\$ (10,899)</u>
Net loss per share		
Basic and diluted	\$ (0.22)	\$ (0.29)
Shares used in per share computation		
Basic and diluted	39,380	37,881

**VIVUS, Inc.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(in thousands, except per share amount)

	March 31 2005 (unaudited)	December 31 2004*
Current assets:		
Cash and cash equivalents	\$ 41,942	\$ 8,304
Available-for-sale securities	5,077	16,739
Accounts receivable	323	9,544
Inventories	4,571	3,855
Prepaid expenses and other assets	1,465	1,459
Total current assets	53,378	39,901
Property and equipment	5,901	6,394
Restricted cash	3,324	3,324
Available-for-sale securities, non-current	3,356	4,770
Total assets	<u>\$ 65,959</u>	<u>\$ 54,389</u>
Current liabilities:		
Accounts payable	\$ 3,259	\$ 3,120
Accrued and other liabilities	12,924	11,315
Total current liabilities	16,183	14,435
Notes payable	3,939	3,239
Accrued and other long-term liabilities	4,091	5,993
Total liabilities	24,213	23,667
Stockholders' equity:		
Common stock; \$.001 par value; shares authorized 200,000; shares outstanding - March 31, 2005 44,473; December 31, 2004 38,127;	44	38
Additional paid-in capital	173,147	153,275
Accumulated other comprehensive loss	(65)	(48)
Accumulated deficit	(131,380)	(122,543)
Total stockholders' equity	41,746	30,722
Total liabilities and stockholder's equity	<u>\$ 65,959</u>	<u>\$ 54,389</u>

\* The Condensed Consolidated Balance Sheet at December 31, 2004 has been derived from the Company's audited financial statements at that date.