
**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 26, 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

(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)

Not Applicable

(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:

- ☐ 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))
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Item 2.02. Results of Operations and Financial Condition

On October 26, 2005, Vivus, Inc. issued a press release regarding its financial results for the third quarter ended September 30, 2005 and certain other information. The full text of the press release concerning the foregoing is furnished herewith 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 Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(c) Exhibits.

Exhibit Number	Description
99.1	Text of press release issued by Vivus, Inc., dated October 26, 2005, reporting the results of operations for the third quarter ended September 30, 2005 and certain other information (furnished herewith)

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.

/s/ Timothy E. Morris

Timothy E. Morris

Vice President and Chief Financial Officer

Date: October 26, 2005

EXHIBIT INDEX

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For more information:
VIVUS, Inc.
Timothy E. Morris
650-934-5200

FOR IMMEDIATE RELEASE

VIVUS REPORTS THIRD QUARTER 2005 FINANCIAL RESULTS AND PRODUCT DEVELOPMENT HIGHLIGHTS

Mountain View, Calif. (October 26, 2005) – VIVUS, Inc. (**Nasdaq:VVUS**), 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 for the third quarter 2005 and financial results for the three and nine months ended September 30, 2005.

“The third quarter was marked by significant progress with the clinical development of Evamist and obtaining FDA input on the continued clinical development of Testosterone MDTs,” commented Leland Wilson, President and Chief Executive Officer of VIVUS. “In addition, the details of the Phase 2 study for Testosterone MDTs for the treatment of Hypoactive Sexual Desire Disorder in premenopausal women were presented by the lead investigator at the North American Menopause Society meeting. Furthermore, five abstracts have been accepted for presentation at the Sexual Medicine Society of North America 2005 fall meeting. These abstracts detail much of the development work completed through Phase 2 for avanafil, our investigational PDE5 inhibitor for male erectile dysfunction.”

Third Quarter 2005 Highlights

The quarter ended September 30, 2005 highlights included:

- Completion of enrollment in a pivotal Phase 3 clinical study of the investigational drug Evamist[®] (Estradiol MDTs[®]), an estradiol spray being developed for the treatment of vasomotor symptoms associated with menopause. This Phase 3 trial is a multi-center, randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of Evamist. The primary endpoint is the reduction in the frequency and severity of moderate-to-severe vasomotor symptoms associated with menopause at weeks 4 and 12 of the study. Over 400 patients were enrolled at 43 centers throughout the United States. The study was initiated in December 2004 under a Special Protocol Assessment (“SPA”) with the Food and Drug Administration (“FDA”).
- Presentation of positive results from a Phase 2 study evaluating the safety and efficacy of Testosterone MDTs[®] (Metered Dose Transdermal Spray), an

investigational transdermal testosterone spray for the treatment of low libido in premenopausal women. The presentation was made by Susan R. Davis, M.D., Ph.D., Professor of Women’s Health at Monash University and Principal Investigator for the study, at The North American Menopause Society’s 16th Annual Meeting. The study found that patients treated with the Testosterone MDTs more than doubled their number of satisfactory sexual events as compared to baseline and placebo.

- An End of Phase 2 meeting was held with the FDA regarding Testosterone MDTs, which is being developed for the treatment of Hypoactive Sexual Desire Disorder (“HSDD”). On September 12, 2005, we met with the FDA and although final Phase 3 protocols have not been agreed upon, the FDA was able to give us guidance on the size and duration requirements that would be necessary to support regulatory approval for the use of testosterone to treat HSDD.
- Acceptance of five abstract presentations at the Sexual Medicine Society of North America’s (SMSNA) 2005 fall meeting for avanafil. These abstracts summarize the important attributes of avanafil based on its unique pharmacokinetic and high-selectivity profile. These abstracts will be presented during the meeting, which will be held in New York November 17th through 20th.

Financial Results for the Third Quarter

For the three months ended September 30, 2005, total revenue was \$3.3 million, compared to \$4.3 million for the three months ended September 30, 2004. Domestic sales of MUSE were lower in the third quarter of 2005 due to the decline in the demand for MUSE and a reduction in inventory at the wholesale level. We estimate that the inventory at the wholesale level has continued to decrease since the beginning of 2005.

The net loss for the third quarter of 2005 was \$6.0 million, or \$0.13 per share, compared to \$4.9 million, or \$0.13 per share, in the third quarter of 2004. The increased loss was principally due to decreased revenues and increased expenses from continuing clinical activities related to the company’s development programs.

For the nine months ended September 30, 2005, total revenue was \$5.6 million, compared to \$9.5 million for the nine months ended September 30, 2004. The net loss for the first nine months of 2005 was \$23.4 million, or \$0.55 per share, compared to \$20.7 million, or \$0.54 per share in the same prior year nine-month period. The decreased revenue and increased net loss in the first nine months of 2005 resulted primarily from lower product sales.

Cash, Cash Equivalents and Available-for-Sale Securities

At September 30, 2005, VIVUS had cash, cash equivalents and available-for-sale securities of \$33.5 million, as compared to \$39.5 million at June 30, 2005.

Exclusive of the \$19.6 million in net proceeds from the sale of common stock in the first quarter of 2005, the decrease in cash, cash equivalents and available-for-sale securities since December 31, 2004 was \$16.0 million.

Third Quarter Investigational Product Pipeline Update

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

- ALISTA - Recruitment of patients and enrollment continues in the current clinical trial of ALISTA, an investigational drug being developed for the treatment of Female Sexual Arousal Disorder ("FSAD"). Our goal is to complete enrollment in this trial by the end of 2005.
- Testosterone MDTs - Based on the recent meeting and discussion with the FDA, we obtained guidance on the size and duration of the clinical trials necessary to complete the development of this product. We will continue to work with the FDA to finalize the Phase 3 safety and efficacy studies for Testosterone MDTs to treat HSDD.
- Evamist - We completed the enrollment in the pivotal Phase 3 trial. We intend to complete the current trial and prepare the New Drug Application by mid 2006.
- Avanafil - We have requested an End of Phase 2 meeting with the FDA to discuss the details of our Phase 3 development program. The meeting is planned for November 2005. We also completed an independent research report that reveals the market potential for avanafil. This report may serve as a key component for the partnering effort for this product candidate.

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 a Phase 2B program with ALISTA for female sexual arousal disorder and a Phase 3 program for Evamist for the alleviation of menopausal symptoms. Testosterone MDTs® 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 has completed Phase 2 development. VIVUS currently markets MUSE®(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.

Conference Call Information

As previously announced, VIVUS will hold a conference call to discuss the third quarter accomplishments and financial results today, October 26, 2005, beginning at 4:00 p.m. Eastern Time. You can listen to this call by dialing 877-660-0983 and entering conference ID #1836976. The call will be available for replay through November 25, 2005, by calling 800-642-1687, conference ID #1836976.

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; litigation and legislation; 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, 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)

	Three Months Ended		Nine Months Ended	
	September 30, 2005	September 30, 2004	September 30, 2005	September 30, 2004
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Revenue:				
US product, net	\$ 2,538	\$ 3,665	\$ 4,255	\$ 6,697
International product	688	629	1,235	2,666
Other revenue	41	37	122	112

Total revenue	3,267	4,331	5,612	9,475
Operating expenses:				
Cost of goods sold and manufacturing	2,477	2,634	6,616	7,238
Research and development	4,154	3,856	14,080	14,629
Selling, general and administrative	2,826	2,863	8,941	8,685
Total operating expenses	9,457	9,353	29,637	30,552
Loss from operations	(6,190)	(5,022)	(24,025)	(21,077)
Interest and other income, net	232	105	601	386
Loss before provision for income taxes	(5,958)	(4,917)	(23,424)	(20,691)
Provision for income taxes	(2)	—	(23)	(5)
Net loss	<u>\$ (5,960)</u>	<u>\$ (4,917)</u>	<u>\$ (23,447)</u>	<u>\$ (20,696)</u>
Net loss per share:				
Basic and diluted	\$ (0.13)	\$ (0.13)	\$ (0.55)	\$ (0.54)
Shares used in per share computation:				
Basic and diluted	44,526	38,048	42,824	37,986

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

	September 30 2005 (unaudited)	December 31 2004*
Current assets:		
Cash and cash equivalents	\$ 15,725	\$ 8,304
Available-for-sale securities	17,725	16,739
Accounts receivable	1,822	9,544
Inventories	5,126	3,855
Prepaid expenses and other assets	1,576	1,459
Total current assets	41,974	39,901
Property and equipment	5,348	6,394
Restricted cash	3,324	3,324
Available-for-sale securities, non-current	—	4,770
Total assets	<u>\$ 50,646</u>	<u>\$ 54,389</u>
Current liabilities:		
Accounts payable	\$ 2,476	\$ 3,120
Accrued and other liabilities	11,911	11,315
Total current liabilities	14,387	14,435
Notes payable	4,929	3,239
Accrued and other long-term liabilities	4,009	5,993
Total liabilities	23,325	23,667
Stockholders' equity:		
Common stock; \$.001 par value; shares authorized 200,000; shares outstanding - 44,527 at September 30, 2005; 38,127 at December 31, 2004	44	38
Additional paid-in capital	173,306	153,275
Accumulated other comprehensive loss	(39)	(48)
Accumulated deficit	(145,990)	(122,543)
Total stockholders' equity	27,321	30,722
Total liabilities and stockholder's equity	<u>\$ 50,646</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.