

**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 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 July 28, 2005, VIVUS, Inc. issued a press release announcing its financial results for the fiscal six months and quarter ended June 30, 2005. The full text of the July 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
99.1	Text of Press Release, dated July 28, 2005, titled "VIVUS Reports Second Quarter Financial Results."

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 28, 2005

VIVUS, Inc.

/s/ Timothy E. Morris

Timothy E. Morris

Vice President and Chief Financial Officer

3

VIVUS, INC.

INDEX TO EXHIBITS

The following exhibits are filed herewith:

EXHIBIT	DESCRIPTION
99.1	Text of Press Release, dated July 28, 2005, titled "VIVUS Reports Second Quarter Financial Results."

4



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

FOR IMMEDIATE RELEASE

**VIVUS REPORTS SECOND QUARTER 2005
FINANCIAL RESULTS AND PRODUCT DEVELOPMENT HIGHLIGHTS**

Mountain View, Calif. (July 28, 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 second quarter 2005 and financial results for the three and six months ended June 30, 2005.

“The second quarter was marked by significant clinical milestones for avanafil relating to the announcement of the positive results from the Phase 2 dose ranging study and positive data from the twice-daily dosing and nitrate interaction studies,” commented Leland Wilson, President and CEO of VIVUS. “In addition our other investigational products received important exposure to medical professionals through presentations made in conjunction with the American College of Obstetricians and Gynecologists (ACOG) Annual Meeting and at the American Urological Association (AUA) Annual Meeting.”

Second Quarter 2005 Highlights

The quarter ended June 30, 2005 highlights included:

- **Positive Phase 2 data for avanafil at-home study** — Avanafil, our next-generation, fast-acting, highly-selective, investigational oral phosphodiesterase type 5 (PDE5) inhibitor was studied in men with erectile dysfunction (ED). This was a multicenter, double-blind, randomized, parallel-design study conducted to assess the safety and efficacy of different doses of avanafil for the treatment of ED. Patients were instructed to attempt sexual intercourse 30 minutes after taking avanafil, with no restrictions on food or alcohol consumption. Results showed that up to 84 percent of avanafil doses resulted in erections sufficient for vaginal penetration, as compared to placebo ($p < 0.001$). No serious adverse events were reported during this study.
- **Positive data from avanafil twice-daily dosing study** — This open-label, pharmacokinetic study compared blood levels of avanafil in healthy volunteer subjects after taking a single dose of avanafil with blood levels after taking avanafil twice daily (every 12 hours) for seven days. The results showed no

significant plasma accumulation of avanafil after the twice-a-day treatment regimen when compared to the single dose.

- **Positive data from avanafil nitrate interaction study** — This study was conducted to evaluate the hemodynamic responses (blood pressure and heart rate) to glyceryl trinitrate (GTN) in subjects pretreated with placebo, avanafil and sildenafil citrate (VIAGRA®). Results revealed that avanafil had less impact on blood pressure and heart rate than Viagra.
- **Positive ALISTA™ data presented at the Annual Meeting of the American Urological Association** — Dr. Raymond A. Costabile, from the University of Virginia Health System Charlottesville, VA, presented a detailed analysis of previously announced results of a study in premenopausal women diagnosed with female sexual arousal disorder (FSAD) treated with ALISTA (topical alprostadil) to the urology community at the AUA's annual meeting. The double blind, placebo-controlled, crossover-design trial evaluated the response to ALISTA administered at home by 51 women. The study showed that 64 percent of ALISTA doses resulted in satisfactory sexual events and the use of ALISTA also resulted in significant improvement in orgasm. This was the first trial that evaluated the use of ALISTA in premenopausal women in the home setting. No serious adverse events were reported during this study.
- **Positive clinical data demonstrates early MUSE® therapy following radical prostatectomy enhances penile recovery and improves penile function** — Rupesh Raina, MD of the Center for Advanced Research in Human Reproduction, Infertility and Sexual Function at the Cleveland Clinic presented results from the study at the AUA Annual Meeting. The study, conducted by the Cleveland Clinic, focused on an individual's ability to recover sexual function following radical prostatectomy, a common treatment for prostate cancer. The study showed that 74 percent of patients who completed six months of MUSE treatment were able to resume sexual activity and 39 percent were able to achieve natural erections sufficient for intercourse without the use of erectogenic agents.
- **VIVUS was added to the Russell Microcap™ Index** — The Russell Microcap Index measures performance of the microcap segment and includes the smallest 1,000 securities in the small-cap Russell 2000 Index plus the next 1,000 securities based on descending market capitalization. As of the latest reconstitution, the average market capitalization in the Microcap Index was approximately \$217.0 million. Russell indexes are widely used by investment managers and institutional investors for index funds and as benchmarks for both passive and active investment strategies. Investment managers who oversee these funds purchase shares of member stocks according to that company's weighting in the particular index.

For the three months ended June 30, 2005, VIVUS revenue totaled \$1.7 million compared to \$3.2 million reported for the three months ended June 30, 2004. Domestic sales of MUSE were lower in the second quarter of 2005 due to the decline in the demand for MUSE and a reduction in inventory levels at the wholesale level. We estimate that the inventory at the wholesale level has decreased significantly since the beginning of 2005. International revenue also decreased as a result of lower shipments of MUSE to our international distribution partners in the second quarter of 2005.

The net loss for the second quarter of 2005 was \$8.7 million, or \$0.19 per share, compared to \$4.9 million, or \$0.13 per share, in the prior year period. The increased loss was principally due to decreased revenues and increased expenses from continuing clinical activities related to the company's four primary development programs.

For the six months ended June 30, 2005, VIVUS revenue totaled \$2.3 million compared to \$5.1 million reported for the six months ended June 30, 2004. The net loss for the first six months of 2005 was \$17.5 million, or \$0.42 per share compared to \$15.8 million, or \$0.42 per share in the same prior year six-month period. The decreased revenue and increased net loss in the first half of 2005 resulted primarily from lower product sales in addition to increased research and development expenses in support of VIVUS' on-going clinical development programs in the six months ended June 30, 2005.

Cash, Cash Equivalents and Available-for-Sale Securities

At June 30, 2005, VIVUS had cash, cash equivalents and available-for-sale securities of \$39.5 million, as compared to \$50.4 million at March 31, 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 \$10.0 million.

Second Quarter Investigational Product Pipeline Update

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

- **ALISTA**- Recruitment of patients and enrollment continues in the current clinical trial of ALISTA for the treatment of Female Sexual Arousal Disorder (FSAD). To date we have enrolled more than half of our target number of patients. We will continue to enroll patients in this trial throughout the remainder of 2005. The FDA has recently provided guidance to us for approval of drugs for treating Female Sexual Arousal Disorder (FSAD). In this regard, the FDA now requires co-primary endpoints including both the number of Satisfactory Sexual Events (SSEs) and improvement in the self-assessed level of sexual arousal using validated questionnaires. Due to this new guidance, we believe it is more appropriate to recategorize the current study from a Phase 3 to a Phase 2B trial. This recategorization does not alter our previously stated development plan for ALISTA, which calls for subsequent confirmatory studies following completion of the current clinical trial.
-
- **Testosterone-MDTS®**- We previously submitted a written proposal for a Phase 3 development program for testosterone-MDTS to the Food and Drug Administration (FDA) for review and comment. The FDA has acknowledged receipt and is currently reviewing the proposal. Our goal is to establish with the FDA the size and scope of the Phase 3 protocol for the testosterone-MDTS trials in 2005.
 - **Evamist™** - Enrollment in the Phase 3 trials is progressing as expected. We remain on target 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**- In addition to the announcement of the positive results from the Phase 2 study in men with ED and the positive twice-daily dosing study and nitrate interaction study, we will be requesting an end of Phase 2 meeting with the FDA to discuss the Phase 3 protocol before the end of the 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 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 second quarter accomplishments and financial results today, July 28, 2005, beginning at 11:00 a.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.

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.

Financial Tables Follow

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

	Three Months Ended		Six Months Ended	
	June 30, 2005	June 30, 2004	June 30, 2005	June 30, 2004
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Revenue:				
US product, net	\$ 1,321	\$ 2,460	\$ 1,717	\$ 3,032
International product	355	705	547	2,037
Other revenue	40	37	81	75
Total revenue	1,716	3,202	2,345	5,144
Operating expenses:				
Cost of goods sold and manufacturing	2,049	2,324	4,139	4,604
Research and development	5,661	3,052	9,926	10,773
Selling, general and administrative	2,894	2,814	6,115	5,822
Total operating expenses	10,604	8,190	20,180	21,199
Loss from operations	(8,888)	(4,988)	(17,835)	(16,055)
Interest and other income, net	246	110	369	281
Loss before provision for income taxes	(8,642)	(4,878)	(17,466)	(15,774)
Provision for income taxes	(8)	(2)	(21)	(5)
Net loss	<u>\$ (8,650)</u>	<u>\$ (4,880)</u>	<u>\$ (17,487)</u>	<u>\$ (15,779)</u>
Net loss per share:				
Basic and diluted	\$ (0.19)	\$ (0.13)	\$ (0.42)	\$ (0.42)
Shares used in per share computation:				
Basic and diluted	44,508	38,028	41,958	37,954

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

	June 30 2005	December 31 2004*
	(unaudited)	
Current assets:		
Cash and cash equivalents	\$ 26,126	\$ 8,304
Available-for-sale securities	13,344	16,739
Accounts receivable	1,158	9,544
Inventories	5,031	3,855
Prepaid expenses and other assets	1,620	1,459
Total current assets	47,279	39,901
Property and equipment	5,564	6,394
Restricted cash	3,324	3,324
Available-for-sale securities, non-current	—	4,770
Total assets	<u>\$ 56,167</u>	<u>\$ 54,389</u>
Current liabilities:		
Accounts payable	\$ 2,123	\$ 3,120
Accrued and other liabilities	12,376	11,315
Total current liabilities	14,499	14,435
Notes payable	4,356	3,239

Accrued and other long-term liabilities	4,050	5,993
Total liabilities	22,905	23,667
Stockholders' equity:		
Common stock; \$.001 par value; shares authorized 200,000; shares outstanding - 44,526 at June 30, 2005; 38,127 at December 31, 2004	45	38
Additional paid-in capital	173,293	153,275
Accumulated other comprehensive loss	(46)	(48)
Accumulated deficit	(140,030)	(122,543)
Total stockholders' equity	33,262	30,722
Total liabilities and stockholder's equity	\$ 56,167	\$ 54,389

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