
**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): **January 27, 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 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)

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

The information in this section, including the information contained in the press release included as Exhibit 99.1 hereto, is being furnished pursuant to this Item 2.02 and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. In addition, this information shall not be deemed to be incorporated by reference into any of the Registrant's filings with the Securities and Exchange Commission, except as shall be expressly set forth by specific reference in any such filing.

On January 27, 2005, VIVUS, Inc. issued a press release regarding its financial results for the fiscal quarter and twelve month period ended December 31, 2004. The full text of the January 27, 2005 press release is included as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(c) Exhibits.

Exhibit Number	Description
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99.1	Press Release dated January 27, 2005 regarding financial results for the three and twelve months ended December 31, 2004.
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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: January 27, 2005

VIVUS, INC.

/s/ TIMOTHY E. MORRIS

Timothy E. Morris
Vice President, Finance and Chief Financial Officer

/s/ LELAND F. WILSON

Leland F. Wilson
President and Chief Executive Officer

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VIVUS, INC.

INDEX TO EXHIBITS

The following exhibits are filed herewith:

<u>Exhibit</u>	<u>Description</u>
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99.1	Press Release dated January 27, 2005 regarding financial results for the three and twelve months ended December 31, 2004 and certain other information.
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For more information:
 VIVUS, Inc.
 Christina Weisgerber
 650-934-5240

FOR IMMEDIATE RELEASE

VIVUS REPORTS 2004 FOURTH QUARTER AND FULL-YEAR FINANCIAL RESULTS

Late-stage product pipeline made significant progress in 2004

Mountain View, Calif. (January 27, 2005) – VIVUS Inc. (**Nasdaq:VVUS**), a pioneer in the research and development of proprietary products to restore sexual function for women and men, today announced its financial results for the fourth quarter and year ended December 31, 2004. Total revenues for the fourth quarter of 2004 were \$10.1 million, an increase of 13% over total revenues of \$9.0 million in the fourth quarter of 2003.

Fiscal Year 2004 Accomplishments

The year ended December 31, 2004 was marked by a number of significant achievements by VIVUS. Some of the accomplishments included:

First Quarter

- Announced data from a Phase 2 head-to-head study comparing Viagra[®] (sildenafil) and avanafil, the Company's next generation investigational oral phosphodiesterase type 5 (PDE5) inhibitor for the treatment of erectile dysfunction (ED). Both products demonstrated comparable results, with an average onset of action of approximately 20 minutes.
- Expanded the product portfolio by acquiring two late-stage products for women's health, Testosterone MDTs[®] to treat hypoactive sexual desire disorder (HSDD) and Evamist[™] to treat symptoms associated with menopause.

Second Quarter

- Secured an \$8.5 million line of credit from Tanabe Seiyaku Co., Ltd. for the development of avanafil, for the treatment of ED.
- Initiated a Phase 2 at-home, dose ranging study with avanafil for the treatment of ED.

Third Quarter

- Completed the Phase 2 development for ALISTA[™], topical alprostadil, for the treatment of female sexual arousal disorder (FSAD). VIVUS reported positive results from a clinical trial in pre-menopausal women diagnosed with FSAD, which demonstrated that ALISTA significantly increased the percentage of satisfying sexual encounters when compared to placebo.
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- Initiated a Phase 3 clinical trial for ALISTA for the treatment of FSAD in surgically menopausal women in the third quarter. The study aims to enroll patients at approximately 40 sites in the U.S.

Fourth Quarter

- Completed treatment of patients in a Phase 2 clinical study for Testosterone MDTs for the treatment of HSDD in pre-menopausal women.
- A key patent for the MDTs delivery system was granted by the United States Patent and Trademark Office. The MDTs delivery system is currently in clinical trials as Evamist, estradiol spray for the treatment of menopause symptoms and testosterone spray for HSDD.
- Received a Special Protocol Assessment (SPA) from the FDA for Evamist.
- Initiated the pivotal Phase 3 program for Evamist for the treatment of menopausal symptoms.

"In 2004, we made significant progress in advancing our late stage investigational product pipeline in the clinic," stated Leland Wilson, President and CEO of VIVUS. "Our goal in 2005 will be to continue to make progress in the clinic for each of these important products."

Financial Results for the Quarter Ended December 31, 2004

Total revenues for the fourth quarter of 2004 were \$10.1 million, compared to \$9.0 million in the fourth quarter of 2003. Net loss for the fourth quarter of 2004 was \$887,000 or \$0.02 per share, compared to net income of \$2.2 million or \$0.06 per share for the same period last year. The increase in revenues over the fourth quarter last year can be attributed to higher sales of MUSE resulted from wholesalers purchasing ahead of a price increase late in the fourth quarter. Although a similar pattern was seen in the fourth quarter of 2003, the purchases of MUSE in the fourth quarter of 2004 were greater than the strategic buying seen in the fourth

quarter of 2003. The loss in the fourth quarter of 2004 as compared to net income in the fourth quarter of 2003 is attributable to increased expenses, mainly research and development, for clinical trials and development of ALISTA, Evamist, Testosterone MDTs, and avanafil.

Financial results for the Year Ended December 31, 2004

For 2004, total revenues were \$19.6 million, compared to \$27.4 million for 2003. Total revenues for 2003 at December 31, 2003 included \$5.0 million of other revenue from the settlement of the Janssen arbitration claim. Net loss for 2004 was \$21.6 million or \$0.57 per share, compared to a net loss of \$26,000 or \$0.00 per share, for 2003. The increase in the net loss in 2004 is due primarily to lower product revenue, due to decreased demand for MUSE and increased clinical activities related to the Company's four primary clinical development programs.

VIVUS had cash, cash equivalents and available-for-sale securities of \$29.8 million, a decrease of \$18.5 million from December 31, 2003.

MUSE Performance

Worldwide product revenues from the sales of MUSE were \$19.4 million in 2004, a decrease of \$2.8 million or 13% from the worldwide sales of MUSE in 2003. The change in revenues is mainly due to decreased demand for MUSE. The market for erectile dysfunction treatments is highly competitive. The launch of new PDE5 inhibitors and the associated direct-to-consumer advertising and aggressive sampling programs for all PDE5 inhibitors contributed to the decline in demand for MUSE. In addition,

based on the current demand for MUSE, as measured by independent third party prescription data, we estimate purchases made by wholesalers in the fourth quarter of 2004 represent approximately 6 to 7 months of demand. As a result of the decrease in demand and the strategic buying in the fourth quarter of 2004, combined with the promotional efforts of all PDE5 inhibitors, we anticipate worldwide revenues of MUSE will decline in 2005.

Outlook for 2005

Our goal for 2005 will be to continue to make progress in the clinic for each of our development programs. Specific goals include:

- *ALISTA* — complete enrollment in the ongoing Phase 3 clinical trial for the treatment of FSAD.
- *Evamist* — complete Phase 3 study enrollment for the treatment of menopausal symptoms.
- *Testosterone MDTs* — announce results from the Phase 2 clinical trial in pre-menopausal women for the treatment of HSDD and continue to work with the FDA on refinement of the Phase 3 development program.
- *Avanafil* — complete Phase 2 at-home clinical trial and announce results.

“Our efforts in 2005 will be focused on the clinical development of each of our products,” commented Peter Tam, Senior Vice President of Product and Corporate Development. “There are currently no approved products to treat female sexual dysfunction (FSD). VIVUS has two late-stage products for FSD and a third for menopausal symptoms. We believe VIVUS is well positioned to take advantage of a potentially very large market opportunity.”

Changes in Management

The Company also announced that it is changing its clinical and regulatory organization. Peter Tam, Senior Vice President of Product and Corporate Development, who was previously promoted to this position in August 2004, will continue to have responsibility of providing day-to-day strategic direction and management for clinical research, R&D, regulatory and corporate development. As a result, effective January 31, 2005, James R. Nickel, M.D. Vice President of Clinical Medicine will be leaving the Company to attend to family medical matters. In addition, Carol Zoltowski V.M.D., Vice President of Regulatory Affairs, will be resigning as an officer of the Company and remain as a consultant.

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 is in 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.

Note to Investors

As previously announced, VIVUS will hold a conference call to discuss the fourth quarter and full-year financial results today, January 27, 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.

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.

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

	Three Months Ended		Twelve Months Ended	
	December 31 2004	December 31 2003	December 31 2004	December 31 2003
	(unaudited)	(unaudited)	(unaudited)	
Revenue				
US product, net	\$ 9,722	\$ 8,803	\$ 16,419	\$ 18,953
International product	404	188	3,182	3,452
Other Revenue	—	—	—	5,033
Total revenue	10,126	8,991	19,601	27,438
Cost of goods sold	4,045	2,783	11,283	10,993
Gross profit	6,081	6,208	8,318	16,445
Operating expenses:				
Research and development	4,047	1,773	18,676	7,724
Selling, general and administrative	3,045	2,520	11,730	9,839
Total operating expenses	7,092	4,293	30,406	17,563
(Loss) income from operations	(1,011)	1,915	(22,088)	(1,118)
Interest and other income	125	202	511	773
(Loss) income before income taxes	(886)	2,117	(21,577)	(345)
(Provision) benefit for income taxes	(1)	100	(6)	319
Net (loss) income	\$ (887)	\$ 2,217	\$ (21,583)	\$ (26)
Net (loss) income per share:				
Basic	\$ (0.02)	\$ 0.06	\$ (0.57)	\$ —
Diluted	\$ (0.02)	\$ 0.06	\$ (0.57)	\$ —
Shares used in per share computation				
Basic	38,080	37,728	38,010	35,884
Diluted	38,080	38,040	38,010	35,884

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

	DECEMBER 31 2004	DECEMBER 31 2003*
	(unaudited)	
Current assets:		
Cash and cash equivalents	\$ 8,304	\$ 13,097
Available-for-sale securities	16,739	21,488
Accounts receivable	9,544	2,623
Inventories	3,855	3,109
Prepaid expenses and other assets	1,459	1,108

Total current assets	39,901	41,425
Property and equipment	6,394	8,220
Restricted cash	3,324	3,324
Available-for-sale securities, non-current	4,770	13,763
	<hr/>	<hr/>
Total assets	\$ 54,389	\$ 66,732
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Current liabilities:		
Accounts payable	\$ 3,120	\$ 2,917
Accrued and other liabilities	11,315	8,409
	<hr/>	<hr/>
Total current liabilities	14,435	11,326
Notes payable	3,239	--
Accrued and other long-term liabilities	5,993	4,171
	<hr/>	<hr/>
Total liabilities	23,667	15,497
	<hr/>	<hr/>
Stockholders' equity:		
Common stock; \$.001 par value; shares authorized 200,000; shares outstanding - December 31, 2004 38,123; December 31, 2003 37,788;	38	38
Additional paid-in capital	153,275	152,093
Accumulated other comprehensive (loss) income	(48)	64
Accumulated deficit	(122,543)	(100,960)
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Total stockholders' equity	30,722	51,235
	<hr/>	<hr/>
Total liabilities and stockholder's equity	\$ 54,389	\$ 66,732
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*The Condensed Consolidated Balance Sheet at December 31, 2003 has been derived from the Company's audited financial statements at that date.