## 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 22, 2004

## 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)

#### 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 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 October 20, 2004, VIVUS, Inc. issued a press release announcing its financial results for the fiscal quarter and nine month period ended September 30, 2004. A copy of the October 20, 2004 press release is included as Exhibit 99.1 hereto.

#### Item 9.01. Financial Statements and Exhibits.

(c) Exhibits.

Exhibit

Number	Description

99.1 Press Release dated October 20, 2004 regarding financial results for the three and nine months ended September 30, 2004.

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: October 22, 2004
VIVUS, INC.
/s/ LELAND F. WILSON

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Leland F. Wilson President and Chief Executive Officer

### VIVUS, INC.

# INDEX TO EXHIBITS The following exhibits are filed herewith:

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release dated October 20, 2004 regarding financial results for the three and nine months ended September 30, 2004 and certain other information.
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For more information: Investors Fleishman-Hillard Nina Ferrari 415/318-4286 or Marie Villalba 415/318-4254

#### FOR IMMEDIATE RELEASE

#### **VIVUS Reports Third Quarter and Nine Month Financial Results**

MOUNTAIN VIEW, Calif. (October 20, 2004) — VIVUS, Inc. (Nasdaq NM: VVUS), today announced third quarter and nine months ended September 30, 2004 financial results.

For the three months ended September 30, 2004, VIVUS' total revenues increased to \$4.3 million from the \$3.2 million reported in the three months ended June 30, 2004. Total revenues for last year's third quarter were \$5.5 million (not including \$5.0 million in other revenue due to the settlement of the Janssen arbitration claim). The net loss for the 2004 third quarter was (\$4.9) million, or (\$0.13) per share, compared to net income of \$3.9 million, or \$0.10 per share, in the same prior year period. Net income in the third quarter of 2003 was principally due to \$5.0 million in other revenue due to the settlement of the Janssen arbitration claim. Clinical activities related to the Company's four primary development programs increased during the third quarter of 2004 as compared to the same period last year.

At September 30, 2004, VIVUS had cash, cash equivalents and available-for-sale securities of \$34.1 million, as compared to \$48.3 million at December 31, 2003. Net cash used during the quarter was \$4.1 million. During the first quarter of 2004, the Company signed an agreement for a line of credit with Tanabe Seiyaku Co., Ltd. This facility allows VIVUS to borrow up to \$8.5 million to be used for development of avanafil, a treatment for erectile dysfunction. As of the end of the third quarter, borrowing against this facility totaled \$2.2 million.

"The third quarter was a positive one for VIVUS. All of VIVUS' clinical programs advanced as expected during the third quarter and we were pleased to initiate the Phase 3 study of ALISTA for Female Sexual Arousal Disorder in early September. We continue to expect to initiate Phase 3 studies with Estradiol MDTS® during the fourth quarter of this year," said Leland Wilson, president and CEO of VIVUS. "Phase 3 studies with avanafil and Testosterone MDTS® are expected to be initiated during the first half of 2005."

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VIVUS Third Quarter Financial Results October 20, 2004

For the nine months ended September 30, 2004, VIVUS sales totaled \$9.5 million compared to \$13.4 million reported for the nine months ended September 30, 2003 (not including \$5.0 million in other revenue due to the settlement of the Janssen arbitration claim). The net loss for the first nine months of 2004 was (\$20.7) million, or (\$0.54) per share compared to (\$2.2) million, or (\$0.06) per share in the same prior year nine-month period.

#### **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 products in late stage clinical development. For women, VIVUS has initiated its Phase 3 program with ALISTA<sup>TM</sup> for sexual arousal disorder, and will enter Phase 3 studies with testosterone and estradiol for the treatment of sexual desire disorder and menopausal syndrome via its novel Metered Dose Transdermal Spray (MDTS®). The MDTS system is a next generation, patient-preferred transdermal drug delivery technology that delivers drugs through the skin safely and non-invasively. For men, VIVUS is developing avanafil for erectile dysfunction in a Phase 2 program. VIVUS currently markets MUSE® in the US for the treatment of erectile dysfunction. For more information on clinical trials, products and corporate goals, 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, 2003 and periodic reports filed with the Securities and Exchange Commission.

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# CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (In thousands, except per share data)

	THREE MONTHS ENDED			NINE MONTHS ENDED				
	SEPTEMBER         SEPTEMBER           30         30           2004         2003		SEPTEMBER 30 2004		SEPTEMBER 30 2003			
	(UNA	UDITED)	(UNAUDITED)		(UNAUDITED)		(UNAUDITED)	
Revenue United States product International product Other Returns provision	\$	4,017 666 — (352)	\$	4,443 1,426 5,033 (372)	\$	7,357 2,778 — (660)	\$	11,212 3,264 5,033 (1,062)
Total revenue Cost of goods sold		4,331 2,634		10,530 3,002		9,475 7,238		18,447 8,210
Gross profit		1,697		7,528		2,237		10,237
Operating expenses: Research and development		1,697 3,856		7,528 1,821		2,237		10,237 5,951
Selling, general and administrative  Total operating expenses		6,719		2,255 4,076		23,314		7,319
(Loss) income from operations Interest and other income: Interest income Gain on disposal of property and equipment Foreign exchange (loss) gain		(5,022) 155 — (2)		3,452 177 20 5		(21,077) 471 1 5		(3,033) 537 19 15
Interest expense		(48)				(91)		
(Loss) income before benefit (provision) for income taxes Benefit (Provision) for income taxes		(4,917)		3,654 219		(20,691) (5)		(2,462) 219
Net (loss) income	\$	(4,917)	\$	3,873	\$	(20,696)	\$	(2,243)
Net (loss) income per share: Basic Diluted Shares used in per share computation: Basic Diluted	\$ \$	(0.13) (0.13) 38,048 38,048	\$ \$	0.10 0.10 37,653 38,064	\$ \$	(0.54) (0.54) 37,986 37,986	\$ \$	(0.06) (0.06) 35,263 35,263

### VIVUS, INC.

# CONDENSED CONSOLIDATED BALANCE SHEETS (In thousands, except par value)

### ASSETS

	SEPTEMBER 30 2004		DECEMBER 31 2003 *	
	(UNAUDITED)			
Current assets:				
Cash and cash equivalents	\$	5,960	\$	13,097
Available-for-sale securities		23,362		21,488
Accounts receivable, net		3,053		2,623
Inventories, net		3,316		3,109
Prepaid expenses and other assets		1,707		1,108
Total current assets		37,398	<u></u>	41,425
Property and equipment, net		6,863		8,220
Restricted cash		3,324		3,324
Available-for-sale securities, non-current		4,797		13,763
Total assets	\$	52,382	\$	66,732

Current liabilities:		
Accounts payable	\$ 2,483	\$ 2,917
Accrued and other liabilities	10,458	8,409
Total current liabilities	12,941	11,326
Notes payable	2,205	_
Accrued and other long-term liabilities	5,894	4,171
Total liabilities	21,040	 15,497
Stockholders' equity:		_
Preferred stock; \$1.00 par value; shares authorized 5,000; shares issued and		
outstanding - 0 at September 30, 2004 and December 31, 2003	_	_
Common stock; \$.001 par value; shares authorized 200,000; shares issued		
and outstanding - 38,048 at September 30, 2004, and 37,788 at		
December 31, 2003	38	38
Additional paid-in capital	152,980	152,093
Accumulated other comprehensive (loss) income	(20)	64
Accumulated deficit	(121,656)	(100,960)
Total stockholders' equity	31,342	51,235
Total liabilities and stockholders' equity	\$ 52,382	\$ 66,732

• The Condensed Consolidated Balance Sheet at December 31, 2003 has been derived from the Company's audited financial statements at that date.