# 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 16, 2003

### **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 7. Financial Statements and Exhibits.

(c) Exhibits

Exhibit

Number

99.1

**Description** 

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Press Release dated April 16, 2003 regarding financial results for the first quarter ended March 31, 2003 and certain other information

#### Item 9. Regulation FD Disclosure.

The information in this item is being furnished to, but not filed with, the Securities and Exchange Commission solely under Item 12 of Form 8-K, "Results of Operations and Financial Condition," pursuant to interim procedures promulgated by the Commission in Release No. 33-8216 issued March 27, 2003.

On April 16, 2003, VIVUS, Inc. announced its financial results for the fiscal quarter ended March 31, 2003 and certain other information. A copy of the April 16, 2003 press release announcing these financial results and certain other information is included as Exhibit 99.1 hereto. This exhibit is not filed, but is furnished pursuant to Item 12. (a) of Form 8-K.

This Current Report on Form 8-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The forward-looking statements contained herein are based on VIVUS' current expectations and they involve risks and uncertainties that could cause actual results to differ materially from those referred to in the forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for such forward-looking statements. In order to comply with the terms of the safe harbor, VIVUS notes that a variety of factors could cause actual results and experiences to differ materially from the anticipated results or other expectations expressed in

such forward-looking statements. The risks and uncertainties that may affect the operations, performance, development, and results of VIVUS' business include but are not limited to: (1) substantial competition; (2) uncertainties of patent protection and litigation; (3) reliance on sole source suppliers; (4) limited sales and marketing efforts and dependence upon third parties; (5) failure to continue to develop innovative products; (6) risks related to noncompliance with FDA regulations; and (7) other factors that are described from time to time in VIVUS' periodic filings with the Securities and Exchange Commission, including those set forth in VIVUS' annual report on Form 10-K for fiscal year ended December 31, 2002. VIVUS does not undertake an obligation to update forward-looking statements.					
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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: April 16, 2003					
VIVUS, INC.					
/s/ RICHARD WALLISER					
Richard Walliser Vice President and Chief Financial Officer					
/s/ LELAND F. WILSON					
Leland F. Wilson					

#### VIVUS, INC. INDEX TO EXHIBITS

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Press Release dated April 16, 2003 regarding financial results for the first quarter ended March 31, 2003 and certain other information.

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#### [VIVUS LOGO]

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#### FOR IMMEDIATE RELEASE

#### VIVUS REPORTS FIRST QUARTER FINANCIAL RESULTS

**MOUNTAIN VIEW, Calif. (April 16, 2003)** — **VIVUS, Inc. (Nasdaq NM: VVUS)**, a pharmaceutical company developing innovative products to improve quality of life, today reported financial results for the three months ended March 31, 2003.

For the first quarter of 2003, VIVUS reported a net loss of (\$3.2) million, or (\$0.10) net loss per share, compared with a net loss of (\$1.9) million, or (\$0.06) net loss per share, during the same quarter in 2002. Lower U.S. product revenue contributed to the change from the same period last year.

U.S. net product revenue was \$3.4 million in the first quarter of 2003 as compared to \$5.8 million in the first quarter of 2002. We believe the decrease in revenues in the quarter ended March 31, 2003 is primarily due to wholesaler buying patterns. Based on information from our third party data resource providers, total unit demand for MUSE in the U.S. in the first quarter of 2003 decreased by only 5% as compared to the first quarter of 2002. We believe 2003 product revenues will be consistent with 2002 levels.

International product revenue was \$878 thousand for the first quarter of 2003, an increase of \$253 thousand compared to the same period in the previous year. The increase in international revenue in the first quarter of 2003 is a result of our new distributor Meda building their inventories to levels that are sufficient to support MUSE sales in the European marketplace. Based on current forecasts from Meda, we anticipate that 2003 international product revenue will continue to increase over 2002 levels.

Cost of goods sold in the first quarter of 2003 was \$2.8 million, as compared to \$3.4 million for the same period in the previous year. Lower sales volumes in the first quarter of 2003 resulted in lower manufacturing costs of \$379 thousand. We also used certain raw material inventory, the cost basis of which had been reduced to zero in prior years. This had a favorable impact on our gross profit in the first quarter of 2003 of \$190 thousand.

Research and development expenses for the first quarter of 2003 were \$2.3 million, as compared to \$2.8 million for the first quarter of 2002. The decrease is due to heavier clinical trial activity in the first quarter of 2002 as compared to the first quarter of 2003.

Selling, general and administrative expenses in the first quarter of 2003 of \$2.6 million were comparable to the same period last year.

The Company recorded a tax benefit of \$300 thousand in the first quarter of 2002 based on an updated estimate of our tax liabilities. There was no such benefit in 2003.

Unrestricted cash, cash equivalents and available—for—sale securities at March 31, 2003 totaled \$29.8 million, down \$50 thousand from December 31, 2002.

#### **Product Pipeline Update**

As previously announced, VIVUS' recently completed study to evaluate ALISTA<sup>TM</sup> (topical alprostadil) for the treatment of women with female sexual arousal disorder (FSAD) demonstrated a significantly greater improvement over baseline in the primary endpoint of sexual arousal and/or orgasm with a 400 mcg dose of ALISTA than with placebo. Improvements over baseline in secondary endpoints were not significantly different from those observed with placebo. The positive effect observed at 400 mcg corroborates results obtained in an earlier in–clinic study. There was a dose–related incidence of discomfort at the site of application, but this was in general mild and transient.

The Company also initiated a Phase II clinical trial to evaluate the safety and efficacy of ALISTA in premenopausal women. This at-home, double-blinded, placebo controlled study is being conducted at multiple sites throughout the United States.

In November of 2002, VIVUS initiated a proof–of–principal clinical trial to evaluate the safety and efficacy of VI–0162, a proprietary, oral, on–demand treatment for premature ejaculation (PE). This ongoing double–blinded crossover study will provide data for the future development of VI–0162. Results are anticipated by the end of the second quarter 2003.

A multidose pharmacokinetic trial with TA-1790, our oral on-demand therapy for erectile dysfunction, has been completed and data is being analyzed.

#### **About VIVUS**

VIVUS, Inc. is a pharmaceutical company engaged in the development of innovative therapies for the treatment of quality–of–life disorders in men and women, with a focus on sexual dysfunction. Current development programs target Female Sexual Dysfunction (FSD), Erectile Dysfunction (ED) and Premature Ejaculation (PE). The Company developed and markets in the U.S. MUSE<sup>®</sup> (alprostadil) and ACTIS<sup>®</sup>, two innovations in the treatment of erectile dysfunction, and has partnered with Meda AB (Stockholm: MEDAa.ST) for the international marketing and distribution of its male transurethral ED products. In Canada, VIVUS has partnered exclusively with Paladin Labs (TSE: PLB) to market and distribute MUSE.

NOTE TO INVESTORS: VIVUS will hold a conference call to discuss first quarter financial results today, April 16, 2003, beginning at 4:30 p.m. Eastern Time. You are invited to listen to this call (live or 14-day replay) via the Internet at the VIVUS website, <a href="https://www.vivus.com">www.vivus.com</a>.

Note to editors and investors: Additional written materials, recent releases and Company information are available through a variety of sources, including the VIVUS website <a href="https://www.vivus.com">www.vivus.com</a> and the VIVUS Fax-On-Demand Service (1-888-329-5719).

This news release contains forward-looking statements about the potential commercialization of products in treating male and female sexual dysfunction and reflects management's current beliefs. However, as with any pharmaceutical under development, there are significant risks in development, regulatory approval and commercialization of new products. There are no guarantees that future clinical studies discussed in this news release will be successful or that any product will receive regulatory approval for any indication. Further, even if the Company were to receive regulatory approval for a product, there could be no assurance that such a product would prove to be commercially successful. Please see the Company's filings with the Securities and Exchange Commission including, without limitation, the Company's Form 10-K and Forms 10-Q, which identify these and other risks and uncertainties that may cause actual results or events to differ materially from those described in this news release.

Financial Tables Follow

## VIVUS, Inc. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amount)

Three Months Ended

		THICE MIDI	iuis Ended	
March 31, 2003			March 31, 2002 (unaudited)	
D.	(unaudited)			
Revenue United States product International product Returns provision	\$	3,808 878 (417)	\$	6,595 625 (837)
Total revenue Cost of goods sold		4,269 2,784		6,383 3,354
Gross profit		1,485		3,029
Operating expenses: Research and development Selling, general and administrative		2,284 2,572		2,773 2,688
Total operating expenses		4,856		5,461
Loss from operations Interest and other income:		(3,371)		(2,432)
Interest Income Loss on disposal equipment Foreign exchange loss		187 (1) (6)		313 (1) (5)
Loss before benefit for income taxes Benefit for income taxes		(3,191)	(2,125) 268	
Net loss	\$	(3,191)	\$	(1,857)
Net loss per share:  Basic  Diluted  Shares used in per share computation  Basic  Diluted	\$	(0.10) (0.10) 33,011 33,011	\$ \$	(0.06) (0.06) 32,781 32,781

## VIVUS, Inc. CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except per share amount)

	M	March 31, 2003			
	(u	(unaudited)		(unaudited)	
Current assets: Cash and cash equivalents Available-for-sale securities Accounts receivable, net Inventories, net Prepaid expenses and other assets	\$	10,187 12,917 1,267 1,581 972	\$	12,296 11,206 3,592 1,358 1,497	
Total current assets Property and equipment, net Restricted cash Available-for-sale securities, non-current		26,924 9,562 3,324 6,672		29,949 10,084 3,324 6,324	
Total assets	\$	46,482	\$	49,681	
Current Liabilities:     Accounts payable     Accrued and other liabilities  Total current liabilities     Accrued and other long-term liabilities	\$	2,270 8,768 11,038 4,283	\$	1,866 9,109 10,975 4,321	
Total liabilities		15,321		15,296	
Stockholders' equity: Preferred stock; \$1.00 par value; shares authorized 5,000; shares issued and outstanding - March 31, 2003 and December 31, 2002, 0 Common stock; \$.001 par value; shares authorized 200,000; shares issued and outstanding - March 31, 2003, 33,013; December 31, 2002 32,999 Paid-in-capital Accumulated other comprehensive income Accumulated deficit		 33 135,044 209 (104,125)		 33 135,005 281 (100,934)	
Total stockholders' equity		31,161		34,385	
Total liabilites and stockholder's equity	\$	46,482	\$	49,681	

<sup>\*</sup> The Condensed Consolidated Balance Sheet at December 31, 2002 has been derived from the Company's audited financial statements at that date.