# 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 22, 2004**

# VIVUS, INC

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

COMMISSION FILE NUMBER: 0–23490

| **DELAWARE** | **94–3136179** |
|---|---|
| (STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION) | (I.R.S. EMPLOYER IDENTIFICATION NO.) |
| **1172 CASTRO STREET MOUNTAIN VIEW, CA** | **94040** |
| (ADDRESS OF PRINCIPAL EXECUTIVE OFFICES | (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)**

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release dated July 21, 2004 regarding the financial results for the three and six months ended June 30, 2004. |

**Item 12. 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 12 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 July 21, 2004, VIVUS, Inc. announced its financial results for the fiscal quarter and six month period ended June 30, 2004. A copy of the July 21, 2004 press release announcing these financial results is included as Exhibit 99.1 hereto.



**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 22, 2004

VIVUS, INC.

/s/ LARRY J. STRAUSS

Larry J. Strauss
Vice President and Chief Financial Officer

/s/ LELAND F. WILSON

Leland F. Wilson
President and Chief Executive Officer



VIVUS, INC.

INDEX TO EXHIBITS
The following exhibits are filed herewith:

| Exhibit | Description |
|---|---|
| 99.1 | Press Release dated July 21, 2004 regarding the financial results for the three and six months ended June 30, 2004 and certain other information. |

Exhibit 99.1

[VIVUS LETTERHEAD]

For More Information:

Investors contact: Matt Clawson
(949) 474-4300 or matt@allencaron.com

Media: Nathan Kaiser
(415) 318-4235 or kaisern@fleishman.com

**FOR RELEASE JULY 21, 2004, 8:00AM EST**

**VIVUS Reports Second Quarter and Six Months Financial Results**

MOUNTAIN VIEW, Calif. (July 21, 2004) — VIVUS, Inc. (Nasdaq NM: VVUS), today announced second quarter financial results and an update on operational progress in its four development programs.

For the three months ended June 30, 2004, VIVUS sales increased from first quarter levels growing to $3.2 million from the $1.9 million reported in the quarter ended March 31, 2004. Revenues for last year's second quarter were $3.6 million. Gross profit for the 2004 second quarter was 27.4 percent compared to 33.6 percent in the prior year period. The net loss for the 2004 second quarter was ($4.9) million, or ($0.13) per share, compared to ($2.9) million, or ($0.08) per share, in the prior year period. The increased loss was principally due to initiation of clinical activities related to the company's four primary development programs.

At June 30, 2004, VIVUS had cash, cash equivalents and available-for-sale securities of $38.2 million, as compared to $48.3 million at December 31, 2003. Net cash used during the quarter was $6.2 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. As of the end of the second quarter, borrowing against this facility totaled $1.2 million.

For the six months ended June 30, 2004, VIVUS sales totaled $5.1 million compared to $7.9 million reported for the six months ended June 30, 2003. The net loss for the first six months of 2004 was ($15.8) million, or ($0.42) per share compared to ($6.1) million, or ($0.18) per share in the same prior year six-month period.

"MUSE® sales are expected to rebound in the third and fourth quarter as wholesale inventories built in the fourth quarter of 2003 have declined. The launches of the two new oral products, along with heavy physician sampling has had an impact on sales of all erectile dysfunction (ED) products. However, we continue to believe we will meet our sales goals for the current year consistent with historical wholesale ordering patterns. During the second quarter clinical development activity increased significantly with new trials beginning and others being successfully completed" said Larry J. Strauss, VIVUS' chief financial officer.

Clinical and operational highlights, achievements in the second quarter and goals include:

- ALISTA: Data from the recently completed Phase 2 clinical trial in premenopausal women demonstrated ALISTA significantly increased the percentage of satisfying sexual events in women with females sexual arousal disorder when compared to placebo. The first Phase 3 clinical trial will be initiated in September 2004.

- Avanafil: VIVUS initiated a multi-center Phase 2 study evaluating the safety and efficacy of avanafil in the first quarter of 2004. Approximately 50 percent of the patients needed for this study have been enrolled. Top line results from this trial are expected to be available during the first half of 2005. VIVUS anticipates initiating Phase 3 clinical trials during the second half of 2005.

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- Testosterone MDTS®: The Phase 2 development of Testosterone MDTS is on schedule to be completed in the fourth quarter of 2004. VIVUS anticipates meeting with the FDA during Q1 2005 to present the Phase 2 results and discuss the Phase 3 development program. Phase 3 clinical trials are currently expected to begin during the second half of 2005.

- Estradiol MDTS®: VIVUS has contracted with a U.S. manufacturer for Estradiol MDTS. In addition, Phase 3 trials are expected to start during the fourth quarter of 2004. This trial is planned to be completed during the second half of 2005 and the NDA submitted by mid 2006.

**About VIVUS**

VIVUS is a specialty pharmaceutical company focused on research, development and commercialization of products to restore sexual function. In addition to currently marketed therapies, VIVUS has a strong pipeline that includes both new and existing chemical compounds that can be developed to address unmet medical needs. VIVUS' business strategy applies the Company's scientific and medical expertise to identify, develop and commercialize therapies that restore sexual function. For more information, 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.

Financial Tables Follow



**VIVUS, Inc.**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(in thousands, except per share amount)

| | Three Months Ended | | Six Months Ended | |
|---|---|---|---|---|
| | June 30 2004 | June 30 2003 | June 30 2004 | June 30 2003 |
| | (unaudited) | (unaudited) | (unaudited) | (unaudited) |
| Revenue | | | | |
| US product | $ 2,677 | $ 2,961 | $ 3,340 | $ 6,769 |
| International product | 742 | 960 | 2,112 | 1,838 |
| Returns | (217) | (273) | (308) | (690) |
| Total revenue | 3,202 | 3,648 | 5,144 | 7,917 |
| Cost of goods sold | 2,324 | 2,424 | 4,604 | 5,208 |
| Gross profit | 878 | 1,224 | 540 | 2,709 |
| Operating expenses: | | | | |
| Research and development | 3,052 | 1,846 | 10,773 | 4,130 |
| Selling, general and administrative | 2,814 | 2,492 | 5,822 | 5,064 |
| Total operating expenses | 5,866 | 4,338 | 16,595 | 9,194 |
| Loss from operations | (4,988) | (3,114) | (16,055) | (6,485) |
| Interest and other income | | | | |
| Interest Income | 156 | 173 | 316 | 360 |
| Loss on dispsosal of equipment | — | — | 1 | (1) |
| Foreign exchange gain (loss) | (3) | 16 | 7 | 10 |
| Interest expense | (43) | — | (43) | — |
| Loss before provision for income taxes | (4,878) | (2,925) | (15,774) | (6,116) |
| Provision for income taxes | (2) | — | (5) | — |
| Net loss | $ (4,880) | $ (2,925) | $ (15,779) | $ (6,116) |

| | | | | |
|---|---|---|---|---|
| Net loss per share: | | | | |
| Basic | $ (0.13) | $ (0.08) | $ (0.42) | $ (0.18) |
| Diluted | $ (0.13) | $ (0.08) | $ (0.42) | $ (0.18) |
| Shares used in per share computation | | | | |
| Basic | 38,028 | 35,073 | 37,954 | 34,048 |
| Diluted | 38,028 | 35,073 | 37,954 | 34,048 |



**VIVUS, Inc.**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

(in thousands, except per share amount)

| | June 30 2004 | December 31 2003 * |
|---|---|---|
| | (unaudited) | |
| Current assets: | | |
| Cash and cash equivalents | $ 3,965 | $ 13,097 |
| Available-for-sale securities | 27,467 | 21,488 |
| Accounts receivable, net | 1,929 | 2,623 |
| Inventories, net | 3,861 | 3,109 |
| Prepaid expenses and other assets | 1,540 | 1,108 |
| Total current assets | 38,762 | 41,425 |
| Property and equipment, net | 7,313 | 8,220 |
| Restricted cash | 3,324 | 3,324 |
| Available-for-sale securities, non-current | 6,760 | 13,763 |
| Total assets | $ 56,159 | $ 66,732 |
| Current Liabilities: | | |
| Accounts payable | $ 2,973 | $ 2,917 |
| Accrued and other liabilities | 8,922 | 8,409 |
| Total current liabilities | 11,895 | 11,326 |
| Notes payable | 1,198 | |
| Accrued and other long–term liabilities | 6,847 | 4,171 |
| Total liabilities | 19,940 | 15,497 |
| Stockholders' equity: | | |
| Preferred stock; $1.00 par value; shares authorized – 5,000; shares issued and outstanding – June 30, 2004 and December 31, 2003, 0 | — | — |
| Common stock; $.001 par value; shares authorized 200,000; shares issues and outstanding – June 30, 2004, 38,046; December 31, 2003, 37,788 | 38 | 38 |
| Paid in capital | 152,963 | 152,093 |
| Accumulated other comprehensive income | (43) | 64 |
| Accumulated deficit | (116,739) | (100,960) |
| Total stockholders' equity | 36,219 | 51,235 |
| Total liabilites and stockholder's equity | $ 56,159 | $ 66,732 |

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