

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2003

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE TRANSITION PERIOD FROM _____ TO _____.

Commission File Number: 0-23490

VIVUS, INC.
(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

DELAWARE
(STATE OR OTHER JURISDICTION OF
INCORPORATION OR ORGANIZATION)

94-3136179
(I.R.S. EMPLOYER
IDENTIFICATION NUMBER)

1172 Castro Street
Mountain View, California 94040
(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES AND 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)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether Registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act.) Yes ☒ No ☐

At November 7, 2003, 37,704,549 shares of common stock were outstanding.

PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

VIVUS, INC.

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

ASSETS

	SEPTEMBER 30 2003	DECEMBER 31 2002
	(UNAUDITED)	
Current assets:		
Cash and cash equivalents	\$ 7,671	\$ 12,296
Available-for-sale securities	13,626	11,206
Accounts receivable, net	1,941	3,592
Other receivables	3,994	—
Inventories, net	1,320	1,358
Prepaid expenses and other assets	1,624	1,497

Total current assets	30,176	29,949
Property and equipment, net	8,637	10,084
Restricted cash	3,324	3,324
Available-for-sale securities, non-current	19,670	6,324

Total assets	\$ 61,807	\$ 49,681
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LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:

Accounts payable	\$ 1,636	\$ 1,866
Accrued and other liabilities	7,207	9,109

Total current liabilities	8,843	10,975
Accrued and other long-term liabilities	4,208	4,321

Total liabilities	13,051	15,296
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Stockholders' equity:

Preferred stock; \$.001 par value; shares authorized 5,000; shares issued and outstanding — September 30, 2003, 0; December 31, 2002, 0	—	—
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Common stock; \$.001 par value; shares authorized 200,000; shares issued and outstanding — September 30, 2003, 37,653; December 31, 2002, 32,999	38	33
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Additional paid-in capital	151,791	135,005
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Accumulated other comprehensive income	104	281
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Accumulated deficit	(103,177)	(100,934)
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Total stockholders' equity	48,756	34,385
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Total liabilities and stockholders' equity	\$ 61,807	\$ 49,681
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See accompanying notes to Condensed Consolidated Financial Statements.

VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

	THREE MONTHS ENDED		NINE MONTHS ENDED	
	SEPTEMBER 30 2003	SEPTEMBER 30 2002	SEPTEMBER 30 2003	SEPTEMBER 30 2002
	(UNAUDITED)	(UNAUDITED)	(UNAUDITED)	(UNAUDITED)
Revenue				
United States product	\$ 4,443	\$ 3,683	\$ 11,212	\$ 14,920
International product	1,426	155	3,264	1,024
Other	5,033	—	5,033	—
Returns provision	(372)	(308)	(1,062)	(1,484)
Total revenue	10,530	3,530	18,447	14,460
Cost of goods sold	3,002	2,292	8,210	7,196
Gross profit	7,528	1,238	10,237	7,264
Operating expenses:				
Research and development	1,821	2,707	5,951	9,460
Selling, general and administrative	2,255	2,607	7,319	8,007
Total operating expenses	4,076	5,314	13,270	17,467
Income (loss) from operations	3,452	(4,076)	(3,033)	(10,203)
Interest and other income:				
Interest income	177	341	537	986
Gain on disposal of property and equipment	20	6	19	4
Foreign exchange gain	5	7	15	25
Income (loss) before benefit for income taxes	3,654	(3,722)	(2,462)	(9,188)
Benefit for income taxes	219	—	219	268
Net income (loss)	\$ 3,873	\$ (3,722)	\$ (2,243)	\$ (8,920)

Net income (loss) per share:

Basic	\$	0.10	\$	(0.11)	\$	(0.06)	\$	(0.27)
Diluted	\$	0.10	\$	(0.11)	\$	(0.06)	\$	(0.27)

Shares used in per share computation:

Basic	37,653	32,950	35,263	32,882
Diluted	38,064	32,950	35,263	32,882

See accompanying notes to Condensed Consolidated Financial Statements.

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VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(In thousands)

	THREE MONTHS ENDED		NINE MONTHS ENDED	
	SEPTEMBER 30 2003	SEPTEMBER 30 2002	SEPTEMBER 30 2003	SEPTEMBER 30 2002
	(UNAUDITED)	(UNAUDITED)	(UNAUDITED)	(UNAUDITED)
Net income (loss)	\$ 3,873	\$ (3,722)	\$ (2,243)	\$ (8,920)
Other comprehensive income (loss):				
Unrealized gain (loss) on securities	(54)	33	(177)	81
Comprehensive income (loss)	\$ 3,819	\$ (3,689)	\$ (2,420)	\$ (8,839)

See accompanying notes to Condensed Consolidated Financial Statements.

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VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	NINE MONTHS ENDED SEPTEMBER 30	
	2003	2002
	(UNAUDITED)	(UNAUDITED)
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (2,243)	\$ (8,920)
Adjustments to reconcile net loss to net cash used for operating activities:		
Provision for doubtful accounts	(81)	(110)
Depreciation and amortization	1,581	1,648
Stock compensation costs	29	78
(Gain) loss on disposal of property and equipment	(19)	32
Changes in assets and liabilities:		
Accounts receivable	1,732	(675)
Other receivables	(3,994)	—
Inventories	38	367
Prepaid expenses and other assets	(127)	(491)
Accounts payable	(230)	(399)
Accrued and other liabilities	(2,015)	868
Net cash used for operating activities	(5,329)	(7,602)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Property and equipment purchases	(135)	(25)
Proceeds from sale of property and equipment	20	5
Investment purchases	(34,559)	(8,432)
Proceeds from sale/maturity of securities	18,616	9,911
Net cash (used for) provided by investing activities	(16,058)	1,459
CASH FLOWS FROM FINANCING ACTIVITIES:		
Exercise of common stock options	186	624
Sale of common stock through employee stock purchase plan	162	154
Proceeds from issuance of common stock	17,500	—
Common stock issuance costs	(1,086)	—

Net cash provided by financing activities	16,762	778
NET DECREASE IN CASH	(4,625)	(5,365)
CASH:		
Beginning of period	12,296	11,545
End of period	\$ 7,671	\$ 6,180
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Unrealized gain (loss) on securities	\$ (177)	\$ 81
SUPPLEMENTAL CASH FLOW DISCLOSURE:		
Income taxes paid	\$ 18	\$ 32

See accompanying notes to Condensed Consolidated Financial Statements.

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VIVUS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS SEPTEMBER 30, 2003

1. BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulations S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the nine-month period ended September 30, 2003 are not necessarily indicative of the results that may be expected for the year ending December 31, 2003. For further information, refer to the financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2002.

2. SIGNIFICANT ACCOUNTING POLICIES

Stock Options

The Company applies the intrinsic-value-based method of accounting prescribed by Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations including Financial Accounting Standards Board, or FASB, Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation*, an Interpretation of APB Opinion No. 25, issued in March 2000, to account for its fixed-plan stock options. Under this method, compensation expense is recorded on the date of the grant only if the current market price of the underlying stock exceeds the exercise price. SFAS No. 123, *Accounting for Stock Based Compensation*, establishes accounting and disclosure requirements using a fair-value-based method of accounting for stock-based employee compensation plans. As allowed by SFAS No. 123, the Company has elected to continue to apply the intrinsic-value-based method of accounting described above, and has adopted only the disclosure requirements of SFAS No. 123. The following table illustrates the effect on net income if the fair-value-based method has been applied to all outstanding and unvested awards during the three and nine months ended September 30, 2003 and 2002.

	THREE MONTHS ENDED		NINE MONTHS ENDED	
	SEPTEMBER 30 2003	SEPTEMBER 30 2002	SEPTEMBER 30 2003	SEPTEMBER 30 2002
Net income (loss), as reported	\$ 3,873	\$ (3,722)	\$ (2,243)	\$ (8,920)
Deduct total stock-based employee compensation expense determined under fair-value-based method for all rewards, net of tax	(442)	(495)	(1,307)	(1,373)
Pro forma net income (loss)	\$ 3,431	\$ (4,217)	\$ (3,550)	\$ (10,293)
Pro forma net income (loss) per share:				
Basic	\$ 0.09	\$ (0.13)	\$ (0.10)	\$ (0.31)
Diluted	\$ 0.09	\$ (0.13)	\$ (0.10)	\$ (0.31)

The Company updated the following significant accounting policy from its previously filed Form 10-K for the year ended December 31, 2002:

Revenue Recognition

The Company recognizes revenue when the following four criteria are met:

- persuasive evidence of an arrangement exists;
- delivery has occurred;
- the sales price is fixed or determinable; and
- collectibility is reasonably assured.

The Company recognizes revenue upon shipment when title passes to the customer and risk of loss is transferred to the customer. The Company does not have any post shipment obligations.

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The Company primarily sells its products through the wholesale channel in the United States. The Company provides for discounts, rebates, returns and other adjustments in the same period the related product sales are recorded. Provisions for discounts, rebates, returns and other adjustments are based upon analysis of historical data. Each period the Company reviews its reserves for discounts, rebates, returns and other adjustments based on data available at that time. Any adjustment to these reserves results in changes to the amount of product sales revenue recognized in the period.

International

The Company has supply agreements with Meda AB to market and distribute MUSE[®] and ACTIS[®] internationally in all Member States of the European Union, the Baltic States, the Czech Republic, Hungary, Iceland, Norway, Poland, Switzerland and Turkey. In Canada, we have entered into a license and supply agreement with Paladin Labs, Inc. for the marketing and distribution of MUSE. Sales to our distribution partner, who supplies MUSE in the European marketplace, for the nine months ended September 30, 2003 and 2002 were 95.0% and 81.4% of international sales, respectively. The balance of international sales was made to our Canadian distribution partner.

The Company invoices its international distributors based on an agreed transfer price per unit, which is subject to revision based on contractual formulas upon quarterly reconciliations. Final pricing for product shipments to international distributors is subject to contractual formulas based on the distributor's net realized price to its customers. The Company recognizes revenue at the lowest possible price, upon shipment, in accordance with contractual formulas. The Company recognizes additional revenue, if any, upon finalization of pricing with its international distributors. International distributors generally do not have the right to return products unless the products are damaged or defective.

The Company initially recorded \$1.5 million of unearned revenue related to an upfront payment in accordance with the international supply agreement signed with Meda AB in September 2002. This amount is being recognized as income ratably over the term of the supply agreement. As of September 30, 2003, \$163 thousand had been recognized as revenue. Another \$1.3 million of previously deferred revenue was recognized in the third quarter of 2003 due to the outcome of the Janssen Pharmaceutica arbitration as discussed below and on page 9 of this report. As of September 30, 2003, the Company had also recorded deferred revenue of \$100 thousand representing amounts billed and received in excess of revenue recognized, related to sales to the Company's previous international distributor.

3. ARBITRATION AWARD

On October 24, 2003, VIVUS received notification of the resolution of its arbitration claim against Janssen Pharmaceutica International related to payments owing to VIVUS under a previously terminated distribution agreement between the companies. The arbitration panel awarded VIVUS \$4.0 million, consisting of \$3.4 million for inventory manufactured in 1998 in reliance on contractual forecasts and orders submitted by Janssen Pharmaceutica, \$0.3 million for lost profits on forecasted units not purchased by Janssen, and \$0.3 million for legal fees and other expenses related to the arbitration. The Company had been awarded the \$0.3 million for legal fees and other expenses in an earlier phase of the arbitration, but had not recorded the amount pending the final outcome of the arbitration.

Although the arbitration award was not received until after the end of the third quarter, it provided additional evidence with respect to conditions that existed as of September 30, 2003 and it affected the estimates inherent in the process of preparing the third quarter financial statements. Therefore, the third quarter financial statements have been adjusted for the changes in estimates resulting from the arbitration award.

Other revenue in the third quarter includes \$5.0 million related to the award: the \$3.4 million for units previously manufactured, the \$0.3 million for lost profits on forecasted units not purchased, and \$1.3 million from recognizing Janssen Pharmaceutica related revenue that was previously deferred pending the outcome of the arbitration. Third quarter general and administrative expenses include an offset of \$0.3 million related to recognizing the award for legal fees and other expenses related to the arbitration.

4. INVENTORIES

Inventories are recorded net of reserves of \$6.0 million and \$7.2 million as of September 30, 2003 and December 31, 2002, respectively, and consist of (in thousands):

	SEPTEMBER 30, 2003	DECEMBER 31, 2002
Raw materials	\$ 646	\$ 393
Work in process	177	32
Finished goods	497	933
Inventory, net	\$ 1,320	\$ 1,358

As noted above, the Company has recorded significant reserves against the carrying value of its inventories. The reserves relate primarily to raw materials inventory that the Company previously estimated would not be used. The Company now estimates that at least some portion of the fully reserved inventory will now be used in production. The Company includes in cost of goods sold the standard cost of raw materials inventory. In the first nine months of 2003, the Company used \$799 thousand of its fully reserved raw materials inventory. The fully reserved used raw materials were charged to cost of goods sold at a zero basis, which had a favorable impact on gross profit.

5. ACCRUED AND OTHER LIABILITIES

Accrued and other liabilities as of September 30, 2003 and December 31, 2002 consist of:

Short-term accrued and other liabilities	SEPTEMBER 30, 2003	DECEMBER 31, 2002

Product returns	\$	2,606	\$	2,280
Income taxes		1,315		1,554
Research and clinical expenses		662		1,363
Royalties		523		539
Deferred revenue		281		1,644
Employee compensation and benefits		1,331		1,129
Other		489		600
Total short-term accrued and other liabilities	\$	7,207	\$	9,109
Long-term accrued and other liabilities		SEPTEMBER 30, 2003		DECEMBER 31, 2002
		(000'S)		
Restructuring	\$	3,021	\$	3,021
Deferred revenue		1,187		1,300
Total long-term accrued and other liabilities	\$	4,208	\$	4,321

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6. RESTRUCTURING RESERVE

During 1998, VIVUS, Inc. experienced a significant decline in market demand for MUSE due to the market launch of sildenafil, the first oral treatment for erectile dysfunction. During the second and third quarters of 1998, the Company took significant steps to restructure its operations in an attempt to bring the cost structure in line with current and projected revenues. (See Notes 1 and 6 to the Consolidated Financial Statements for the year ended December 31, 2002 included in the Company's Annual Report on Form 10-K.) The restructuring reserve balance at September 30, 2003 was \$3.0 million, remaining the same as at December 31, 2002.

	PROPERTY AND RELATED COMMITMENTS
	(000'S)
Balance at December 31, 2002	\$ 3,021
Activity in first quarter 2003	—
Activity in second quarter 2003	—
Activity in third quarter 2003	—
Balance at September 30, 2003	\$ 3,021

The remaining balance in the restructuring reserve is related to the restoration liability for our leased manufacturing facilities. This liability will remain in effect through the end of the lease term, including any renewals. The Company has exercised its first option to renew the original lease, thereby extending any cash payments to be made for this liability to 2007. The second renewal term, if exercised, would then extend the liability an additional five years, to 2012.

7. NET INCOME PER SHARE

Net income per share is calculated in accordance with Statement of Financial Accounting Standards No. 128, *Earnings per Share*, which requires a dual presentation of basic and diluted earnings per share. Basic income per share is based on the weighted average number of common shares outstanding during the period. Diluted income per share is based on the weighted average number of common and common equivalent shares, which represent shares that may be issued in the future upon the exercise of outstanding stock options. Certain options are excluded from the diluted income per share for the period presented because they are anti-dilutive.

8. CONCENTRATION OF CUSTOMERS AND SUPPLIERS

During the first nine months of 2003 and 2002, sales to significant customers as a percentage of total revenues were as follows:

	2003	2002
Customer A	26%	19%
Customer B	19%	19%
Customer C	18%	0%
Customer D	17%	22%

The Company did not have any suppliers making up more than 10% of operating costs.

9. LEGAL MATTERS

On November 3, 1999, the Company filed a demand for arbitration against Janssen Pharmaceutica International with the American Arbitration Association pursuant to the terms of the Distribution Agreement entered into on January 22, 1997. The Company sought compensation for inventory manufactured in 1998 in reliance on contractual forecasts and orders submitted by Janssen Pharmaceutica. The Company also sought compensation for forecasts and order shortfalls attributed to Janssen Pharmaceutica in 1998, pursuant to the terms of the Distribution Agreement. The Company amended its arbitration demand in August 2000 to include claims for lost profits due to Janssen Pharmaceutica's failure to use the requisite diligence and reasonable efforts to gain regulatory approval for and to launch MUSE in China. A full hearing on the merits was conducted before a three-member arbitration panel in Chicago on March 18 – 20, 2002.

On October 24, 2003 a final award was issued awarding the Company \$3,358,881 for 332,880 units manufactured and \$311,708 for lost profits from order shortfalls. In addition, the Company was awarded \$231,711 for reimbursement of legal fees and \$91,738 for reimbursement of other expenses related to the arbitration, but was denied any relief on claims related to diligence in China. The Company received payment from Janssen Pharmaceutica on November 10, 2003.

The Company is not aware of any asserted or unasserted claims against it where an unfavorable resolution would have an adverse material impact on the operations, liquidity or financial position of the Company.

ITEM 2. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Management’s Discussion and Analysis of Financial Conditions and Results of Operations and other parts of this Form 10-Q contain “forward-looking” statements that involve risks and uncertainties. These statements typically may be identified by the use of forward-looking words or phrases such as “believe,” “expect,” “intend,” “anticipate,” “should,” “planned,” “estimated,” and “potential,” among others. All forward-looking statements included in this document are based on our current expectations, and we assume no obligation to update any such 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, we note 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 our business include but are not limited to: (1) our history of losses and variable quarterly results; (2) substantial competition; (3) risks related to the failure to protect our intellectual property and litigation in which we may become involved; (4) our reliance on sole source suppliers; (5) our limited sales and marketing efforts and our reliance on third parties; (6) failure to continue to develop innovative products; (7) risks related to noncompliance with United States Food and Drug Administration regulations; and (8) other factors that are described from time to time in our periodic filings with the Securities and Exchange Commission, including those set forth in this filing as “Risk Factors Affecting Operations and Future Results.”

All percentage amounts and ratios were calculated using the underlying data in thousands. Operating results for the nine-month period ended September 30, 2003 are not necessarily indicative of the results that may be expected for the full fiscal year or any future period.

OVERVIEW

VIVUS, Inc. is a pharmaceutical company developing innovative products to improve quality of life disorders in men and women, with a focus on sexual dysfunction. VIVUS develops and markets MUSE® (alprostadil) and ACTIS®, two innovations in the treatment of erectile dysfunction, in the United States. We have entered into supply agreements with Meda AB (Stockholm:MEDAa.ST) to market and distribute MUSE and ACTIS internationally in all Member States of the European Union, the Baltic States, the Czech Republic, Hungary, Iceland, Norway, Poland, Switzerland and Turkey. In Canada, we have entered into a license and supply agreement with Paladin Labs, Inc. (TSE:PLB) for the marketing and distribution of MUSE. We have ongoing research and development programs, including projects in erectile dysfunction, female sexual dysfunction and premature ejaculation.

In recent years we have invested in a number of research and development projects. The current status of our most advanced research and development projects is depicted in the table below.

Indication	Product Candidate	Progress
Erectile Dysfunction	TA-1790 (oral) TA-1790 (transurethral) ALIBRA	At-Home Efficacy and Safety—Ongoing Pre-clinical No further developemnt planned
Female Sexual Dysfunction	ALISTA (topical alprostadil) TA-1790	Phase II–postmenopausal–Completed Phase II–pre-menopausal–Ongoing Pre-clinical

We anticipate that our research and development expenses will continue to increase as we focus our efforts on clinical development of our current research and development pipeline, targeted acquisitions of new technologies and the development of patentable uses of known pharmacologic agents for which significant safety data already exists.

Recent progress and current plans in our research and development projects include:

- **ALISTA** — A proprietary formulation of alprostadil applied locally to the female genitalia to treat female sexual arousal disorder.

- Our first Phase II clinical study, which was an in-clinic, single dose, multi-center trial designed to evaluate the safety of and response to ALISTA in postmenopausal subjects with female sexual arousal disorder, was completed in 2001. The study demonstrated a significant increase in ALISTA-treated women versus placebo and baseline in sexual response associated with visual sexual stimulation. ALISTA was associated with a rapid and sustained improvement in sexual response.
- An expanded Phase II study, designed to evaluate the efficacy and safety of ALISTA when used by postmenopausal women with female sexual arousal disorder at-home with their partner, was completed in the first quarter of 2003. The study demonstrated a statistically significant improvement in satisfactory sexual arousal or orgasm in postmenopausal women who were treated with the 400 mcg dose of ALISTA. On October 18, 2003, this data was podium presented at the International Society for the Study of Women's Sexual Health (ISSWSH) meeting in Amsterdam.
- A second at-home Phase II study to assess the efficacy and safety of ALISTA when used by pre-menopausal women with female sexual arousal disorder began at the end of the first quarter of 2003. The results of this study are currently expected in the first quarter of 2004.
- The Company recently announced that it will pursue Phase III clinical development of ALISTA and is currently designing a clinical development program that will meet the Phase III requirements set out by the United States Food and Drug Administration.
- **TA-1790** — A fast-acting, highly selective, potent phosphodiesterase type 5 (PDE5) inhibitor for the oral and local treatments of male and female sexual dysfunction.
 - We filed an Investigational New Drug application with the United States Food & Drug Administration in December 2001 to initiate a clinical study to evaluate the safety of and erectile response to oral TA-1790 in men with erectile dysfunction. This in-clinic single-dose trial began in the first quarter of 2002. Subjects with mild-to-moderate erectile dysfunction were treated with placebo, TA-1790, and Viagra® prior to visual sexual stimulation, and their penile rigidity response was measured over a two-hour period. Dosing was completed during the third quarter 2002. The trial results demonstrated that TA-1790 caused a rapid increase in penile rigidity that was statistically significantly greater than placebo. TA-1790 was safe and well tolerated in this trial. Thus, clinical data from this study demonstrated that TA-1790 is capable of restoring penile function in men with erectile dysfunction.
 - A single and multiple dose pharmacokinetic study with oral TA-1790 was completed in the first quarter of 2003 and results demonstrated that TA-1790 was rapidly absorbed after ingestion. The rapid absorption supports the efficacy data generated in the in-clinic trial as described above.
 - In July 2003, we began enrolling patients in an at-home, prospective, randomized, double-blind clinical trial to evaluate the safety and efficacy of oral TA-1790 in men with erectile dysfunction. The results of this trial are currently expected in the first quarter of 2004.
- **Premature Ejaculation**
 - We are currently evaluating strategic options and are considering alternative formulations.
- **ALIBRA**
 - In October 2000, we withdrew the New Drug Application, or NDA, previously submitted to the United States Food and Drug Administration to market ALIBRA®, our second-generation product for the treatment of erectile dysfunction. We met with the United States Food and Drug Administration in December 2000 addressing additional data required to obtain marketing clearance for ALIBRA. At this time, we have no plans to continue developing nor to file an NDA for ALIBRA.

We continue to place significant emphasis on securing global intellectual property rights and aggressively pursuing new patents to expand upon our foundation for commercializing products in development. In the United States, patents and patent applications licensed to or developed by VIVUS currently include 20 in erectile dysfunction, 14 in female sexual dysfunction and 5 in premature ejaculation.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to product returns, doubtful accounts, income taxes, restructuring, inventories and contingencies and litigation. (See Critical Accounting Policies and Estimates on page 25 of the Company's Annual Report on Form 10-K for the year ended December 31, 2002.) We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

The Company updated the following critical accounting policy from its previously filed Form 10-K for the year ended December 31, 2002:

- **Available-for-Sale Securities:** Available-for-sale securities represents investments in debt securities that are stated at fair value. We restrict our cash investments to:

- 1) Direct obligations of the United States Treasury;
- 2) Federal Agency securities that carry the direct or implied guarantee of the United States government; and
- 3) Corporate securities, including commercial paper, rated A1/P1 or better.

The difference between amortized cost (cost adjusted for amortization of premiums and accretion of discounts that are recognized as adjustments to interest income) and fair value, representing unrealized holding gains or losses, is recorded in "Accumulated Other Comprehensive Income (Loss)," a separate component of stockholders' equity until realized.

The Company's policy is to record investments in debt securities as available-for-sale because the sale of such securities may be required prior to maturity. Any gains and losses on the sale of debt securities are determined on a specific identification basis and are included in interest and other income in the accompanying consolidated statements of operations. Available-for-sale securities with maturities beyond one year from the balance sheet date are classified as non-current.

2003 HIGHLIGHTS

FIRST QUARTER

The Company reported a net loss of \$3.2 million, for a \$0.10 net loss per share. Lower United States product revenue contributed to the loss.

Our expanded Phase II study, designed to evaluate the efficacy and safety of ALISTA when used by postmenopausal women with female sexual arousal disorder at-home with their partner, was completed in the first quarter of 2003. The study demonstrated a statistically significant improvement in satisfactory sexual arousal or orgasm in postmenopausal women who were treated with the 400 mcg dose of ALISTA.

We initiated a second at-home clinical study for ALISTA designed to evaluate the efficacy and safety of ALISTA when used by pre-menopausal women with female sexual arousal disorder.

SECOND QUARTER

The Company reported a net loss of \$2.9 million, for a \$0.08 net loss per share. Lower United States product revenue contributed to the loss.

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VIVUS completed a private placement of 4,375,000 shares of common stock for aggregate net proceeds of \$16.4 million on May 23, 2003. The shares of common stock were sold at \$4.00 per share, an approximate 9% discount to the five-day trailing average ended May 21, 2003.

We were awarded a new patent by the United States Patent and Trademark Office for the transmucosal use of PDE inhibitors to treat erectile dysfunction. This allows us to develop PDE inhibitors that could be administered by routes other than oral or transurethral, including buccal (between the cheek and gum) and sublingual (underneath the tongue).

The Swedish Pharmaceutical Benefits Board approved the reimbursement of transurethral therapy for the treatment of male erectile dysfunction.

A single and multiple dose pharmacokinetic study with oral TA-1790 demonstrated that TA-1790 was rapidly absorbed after ingestion. The rapid absorption supports the efficacy data generated in the in-clinic trial, completed in the third quarter of 2002, where RigiScan was used to measure penile rigidity in conjunction with visual sexual stimulation.

Our clinical trial to evaluate the safety and efficacy of VI-0162, a proprietary, oral, on-demand treatment for premature ejaculation did not demonstrate an increase in the time to ejaculation.

THIRD QUARTER

On October 28, 2003, the Company announced the resolution of its arbitration claim against Janssen Pharmaceutica International with the American Arbitration Association related to payments owing to VIVUS under a previously terminated distribution agreement between the companies. The arbitration panel awarded VIVUS \$4.0 million, as discussed on pages 7 and 9 of this report.

The Company reported net income of \$3.9 million, for \$0.10 net income per basic and diluted share. Total revenue included other revenue of \$5.0 million of which \$3.7 million represents amounts due from Janssen Pharmaceutica under the award as discussed above and the remaining \$1.3 million results from recognizing Janssen Pharmaceutica related revenue that was previously deferred pending the outcome of the arbitration.

We were awarded two new patents by the United States Patent and Trademark Office relating to the treatment of female sexual dysfunction. The patents cover the usage of various therapeutic agents and combinations of agents, as well as their application.

We announced the appointment of Larry J. Strauss as vice president, finance and chief financial officer, who will have overall responsibilities for the Company's finance, accounting, investor relations, corporate communications, facilities and information systems functions.

RESULTS OF OPERATIONS

Three Months Ended September 30, 2003 and 2002

For the three months ended September 30, 2003, the Company reported net income of \$3.9 million, for \$0.10 net income per basic and diluted share as compared to a net loss of \$3.7 million, or an \$0.11 net loss per share, during the same quarter in 2002. Higher product revenue, lower research and development expenses and \$5.0 million in other revenue resulting from the settlement of the Janssen Pharmaceutica arbitration claim contributed to the change from the same period last year.

The Company anticipates continued losses over the next several quarters. The Company expects MUSE sales in 2003 and future years to approximate total MUSE sales in 2002. The Company will continue to invest in clinical development of its current research and development pipeline in an attempt to bring those potential products to market.

Revenue. United States net product revenue for the quarter ended September 30, 2003 was \$4.1 million, compared to \$3.4 million for the quarter ended September 30, 2002. We believe the increase in revenues for the quarter ended September 30, 2003 is primarily due to wholesaler buying patterns.

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We believe that wholesalers will continue the historical buying pattern of building their inventories in the fourth quarter, and as such, we anticipate that fourth quarter 2003 United States product revenues will outpace third quarter 2003 sales levels.

International product revenue was \$1.4 million for the third quarter of 2003, an increase of \$1.3 million compared to the same period last year. Lower international product revenue in 2002 was due to a decrease in product demand by our previous international distributor in anticipation of the transition to our new distribution partner, Meda. That transition occurred in September 2002.

Other revenue was \$5.0 million due to the resolution of the Company's arbitration claim against Janssen Pharmaceutica with the American Arbitration Association related to payments owing to VIVUS under a previously terminated distribution agreement between the companies. \$3.7 million represents amounts due from Janssen Pharmaceutica under the award. The remaining \$1.3 million results from recognizing Janssen Pharmaceutica related revenue that was previously deferred pending the outcome of the arbitration.

Cost of Goods Sold. Cost of goods sold was \$3.0 million (54.6% of total revenue, excluding the \$5.0 million in other revenue) for the third quarter of 2003, compared to \$2.3 million (64.9% of total revenue) for the third quarter of 2002. The decrease in cost of goods sold as a percentage of revenue is due to increased unit sales in the third quarter of 2003.

Research and development expenses. Research and development expenses for the third quarter of 2003 were \$1.8 million, as compared to \$2.7 million for the three months ended September 30, 2002. The decrease is due to greater clinical trial activity in the third quarter of 2002 as compared to the third quarter of 2003. The Company currently does not expect to recognize revenues from sales of any new products being developed through research and development efforts until 2007 at the earliest.

Selling, general and administrative expenses. Selling, general and administrative expenses in the third quarter of 2003 of \$2.3 million are \$352 thousand lower than last year due to the reimbursement of legal fees and other expenses related to the arbitration as discussed on pages 7 and 9 of this report.

Interest income. Interest for the three months ended September 30, 2003 was \$177 thousand, as compared to \$341 thousand for the three months ended September 30, 2002. The decrease is primarily due to declining interest rates.

Benefit for income taxes. During the third quarter of 2003, the Company recorded a tax benefit based on an updated estimate of our tax liabilities. No such benefit was recorded in the third quarter of 2002.

Nine Months Ended September 30, 2003 and 2002

For the nine months ended September 30, 2003, the Company reported a net loss of \$2.2 million, for a \$0.06 net loss per share as compared to a net loss of \$8.9 million, or a \$0.27 net loss per share, during the same period in 2002. The improvement in the net loss is primarily due to \$5.0 million in other revenue resulting from the settlement of the Janssen Pharmaceutica arbitration claim, as discussed on pages 7 and 9 of this report, and lower research and development expenses.

The Company anticipates continued losses over the next several quarters. The Company expects MUSE sales in 2003 and future years to approximate total MUSE sales in 2002. The Company will continue to invest in clinical development of its current research and development pipeline in an attempt to bring those potential products to market.

Revenue. United States net product revenue for the nine months ended September 30, 2003 was \$10.2 million, compared to \$13.4 million for the nine months ended September 30, 2002.

We sell our product primarily through the wholesale channel, which in turn supports the following three sectors:

- United States government healthcare organizations;
- Private healthcare organizations; and
- General retail pharmacies.

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We believe the decrease in revenue for the nine months ended September 30, 2003 is primarily due to wholesaler buying patterns. Based on data acquired from third party providers, total unit demand for MUSE, from the three sectors listed above, through the first nine months of 2003, decreased by 3.5% as compared to the same period in 2002. We believe the decrease is primarily due to the availability of competitive oral PDE5 inhibitors and to the care of men with erectile dysfunction shifting to the general practice physician from the urologist.

We believe that wholesalers will continue the historical buying pattern of building their inventories in the fourth quarter, and as such, we anticipate that fourth quarter 2003 United States product revenues will outpace third quarter 2003 sales levels.

International product revenue was \$3.3 million for the nine months ended September 30, 2003, an increase of \$2.2 million compared to the same period last year. Lower international product revenue in 2002 was due to a decrease in product demand by our previous international distributor in anticipation of the

transition to our new distribution partner, Meda AB. That transition occurred in September 2002.

Other revenue was \$5.0 million due to the resolution of the Company's arbitration claim against Janssen Pharmaceutica with the American Arbitration Association related to payments owing to VIVUS under a previously terminated distribution agreement between the companies. \$3.7 million represents amounts due from Janssen Pharmaceutica under the award. The remaining \$1.3 million results from recognizing Janssen Pharmaceutica related revenue that was previously deferred pending the outcome of the arbitration.

Cost of Goods Sold. Cost of goods sold was \$8.2 million for the nine months ended September 30, 2003, compared to \$7.2 million for the same period in 2002. The cost of goods sold for the nine months ended September 30, 2002 was favorably impacted by an \$802 thousand reduction against accruals made in 1998 for inventory purchase commitments that were no longer needed based on the outcome of negotiations with a supplier. We also increased our production of finished goods during the second quarter of 2002. The increase in production of inventory led to a significant incremental reduction in the cost of goods sold for the second quarter of 2002 of \$790 thousand. The Company began using certain raw material inventory in the third quarter of 2002, which had been reduced to a zero cost basis in prior years. This had a favorable impact on our gross profit in the nine months ended September 30, 2003 and 2002 of \$799 thousand and \$144 thousand, respectively. The remaining net decrease in margins was largely attributable to the revenue/cost mix with United States sales decreasing and international sales increasing.

Research and development expenses. Research and development expenses for the nine months ended September 30, 2003 were \$6.0 million, as compared to \$9.5 million for the nine months ended September 30, 2002. The decrease is due to greater clinical trial activity in 2002 as compared to 2003. The Company currently does not expect to recognize revenues from sales of any new products being developed through research and development efforts until 2007 at the earliest.

Selling, general and administrative expenses. Selling, general and administrative expenses in the first nine months of 2003 of \$7.3 million are \$688 thousand less than the same period in 2002 due to the legal fees that were expended in 2002 and subsequently reimbursed in 2003 related to the Janssen arbitration hearing that was held in mid-March 2002, as discussed on pages 7 and 9 of this report.

Interest income. Interest for the nine months ended September 30, 2003 was \$537 thousand as compared to \$986 thousand for the nine months ended September 30, 2002. Declining interest rates and declining balances of cash, cash equivalents and available-for-sale securities from January 1, 2002 until May 23, 2003, the completion date of the private placement in which we raised aggregate net proceeds of \$16.4 million, contributed to the decrease in interest income.

Benefit for income taxes. The Company recorded tax benefits of \$219 thousand and \$268 thousand for the nine months ended September 30, 2003 and 2002, respectively. These benefits are based on updated estimates of our tax liabilities.

LIQUIDITY AND CAPITAL RESOURCES

Cash. Unrestricted cash, cash equivalents and available-for-sale securities totaled \$41.0 million at September 30, 2003, an increase of \$11.1 million from December 31, 2002. The increase is due primarily to the private placement on May 23, 2003 of 4,375,000 shares of common stock for aggregate net proceeds of \$16.4 million.

Since inception, we have financed operations primarily from the issuance of equity securities. Through September 30, 2003, VIVUS raised \$172.8 million from financing activities and had an accumulated deficit of \$103.2 million at September 30, 2003.

Available-for-sale securities. The Company focuses on liquidity and capital preservation in its investments in available-for-sale securities. The Company restricts its cash investments to:

- Direct obligations of the United States Treasury;
- Federal Agency securities which carry the direct or implied guarantee of the United States government; and
- Corporate securities, including commercial paper, rated A1/P1 or better.

The Company sequences the maturities of its investments consistent with its cash forecasts. The weighted average maturity of the portfolio is not to exceed 18 months. As investments mature, the Company re-invests the money by purchasing additional securities. As the Company needs cash for its operating expenses, it sells such investment securities. Because the Company sequences maturities consistent with its cash forecasts, realized gains and losses on sales of securities are typically insignificant.

Accounts Receivable. Accounts receivable (net of allowance for doubtful accounts) at September 30, 2003 was \$1.9 million, as compared to \$3.6 million at December 31, 2002. The 47.2% decrease in the accounts receivable balance at September 30, 2003 is due to a 58.4% decrease in the number of units sold in September 2003 as compared to December 2002. Currently, the Company does not have any significant concerns related to accounts receivable or collections.

Other Receivables. The other receivables balance at September 30, 2003 is the \$4.0 million the Company was awarded by the arbitration panel from Janssen Pharmaceutica, as discussed on pages 7 and 9 of this report.

Liabilities. Total liabilities were \$13.1 million at September 30, 2003, as compared to \$15.3 million at December 31, 2002. Current accrued liabilities decreased \$1.3 million due to recognizing Janssen Pharmaceutica related revenue that was previously deferred pending the outcome of the arbitration as discussed on pages 7 and 9 of this report, and by \$700 thousand due to a decrease in research and clinical activities during 2003.

Operating Activities. Our operating activities used \$5.3 million and \$7.6 million of cash during the nine months ended September 30, 2003 and 2002, respectively. The decrease in cash used was primarily due to the nine months revenues and operating expenses in 2003 being less than those in 2002.

Investing Activities. Net cash used for investing activities was \$16.1 million and \$1.5 million during the nine months ended September 30, 2003 and 2002, respectively. The fluctuations from period to period are due primarily to the timing of purchases, sales and maturity of investment securities, including the investment of \$16.4 million in net proceeds from the private placement of 4,375,000 shares of common stock that took place in the second quarter of 2003.

Financing Activities. Financing activities provided cash of \$16.8 million and \$778 thousand during the nine months ended September 30, 2003 and 2002, respectively. These amounts include the proceeds from the exercise of stock options and the sale of common stock through our employee stock purchase plan in both the first nine months of 2003 and 2002. Additionally, during the second quarter of 2003, VIVUS completed a private placement of 4,375,000 shares of common stock for aggregate net proceeds of \$16.4 million. The shares of common stock were sold at \$4.00 per share, an approximate 9% discount to the five-day trailing average ended May 21, 2003.

We anticipate that our existing capital resources combined with anticipated future cash flows will be sufficient to support our operating needs for at least the coming year. However, we anticipate that we will be required to obtain additional financing to fund the development of our research and development pipeline in future periods as well as to support the possible launch of any future products. In particular, substantial payments for certain development, regulatory and sales milestones will be made in accordance with the agreement for licensing TA-1790. In addition, royalty payments would be required on any future product sales.

We expect to evaluate potential financing sources, including, but not limited to, the issuance of additional equity or debt securities, corporate alliances, joint ventures, and licensing agreements to fund the development and possible commercial launch of any future products. The sale of additional equity securities would result in additional dilution to VIVUS' stockholders.

Our working capital and additional funding requirements will depend upon numerous factors, including:

- the progress of our research and development programs;
- the timing and results of pre-clinical testing and clinical trials;
- results of operations;
- demand for MUSE;
- technological advances;
- the level of resources that we devote to our sales and marketing capabilities; and
- the activities of competitors.

RISK FACTORS AFFECTING OPERATIONS AND FUTURE RESULTS

If we are unable to continue to develop, market and obtain regulatory approval for our products, our business would be harmed.

Our future operating results may be adversely affected if we are unable to continue to develop, manufacture and bring to market new drug products in a timely manner. The process of developing new drugs and/or therapeutic products is inherently complex and uncertain. We must make long-term investments and commit significant resources before knowing whether our development programs will eventually result in products that will receive regulatory approval and achieve market acceptance. As with any pharmaceutical product under development, there are significant risks in development, regulatory approval and commercialization of new compounds. During the product development phase, there is no assurance that the United States Food and Drug Administration will approve our clinical trial protocols. There is no guarantee that future clinical studies, if performed, will demonstrate the safety and efficacy of any product in development or that we will receive regulatory approval for such products. Further, the United States Food and Drug Administration can suspend clinical studies at any time if the agency believes that the subjects participating in such studies are being exposed to unacceptable health risks.

We cannot predict with certainty if or when we might submit for regulatory review those product candidates currently under development. Once we submit our potential products for review, we cannot assure you that the United States Food and Drug Administration or other regulatory agencies will grant approvals for any of our proposed products on a timely basis or at all. Further, even if we receive regulatory approval for a product, there can be no assurance that such product will prove to be commercially successful or profitable.

Sales of our products both inside and outside the United States will be subject to regulatory requirements governing marketing approval. These requirements vary widely from country to country and could delay the introduction of our proposed products in those countries. After the United States Food and Drug Administration and international regulatory authorities approve a product, we must manufacture sufficient volumes to meet market demand. This is a process that requires accurate forecasting of market demand. There is no guarantee that there will be market demand for any future products or that we will be able to successfully manufacture or adequately support sales of any future products.

We are developing TA-1790 as potential oral and local treatments for male and female sexual dysfunction. In January 2001, we licensed TA-1790, a proprietary phosphodiesterase type 5 (PDE5) inhibitor compound, from Tanabe Seiyaku, a Japanese pharmaceutical company. Tanabe Seiyaku completed a Phase I clinical trial evaluating the safety of orally administered TA-1790 for male erectile dysfunction. We are currently conducting additional pre-clinical safety studies and have recently completed one efficacy study in patients with erectile dysfunction. A second efficacy study was initiated in the beginning of July 2003. Based on the results of these studies, we intend to initiate additional clinical studies that would be required to obtain regulatory approval. However, there are no guarantees that TA-1790 will prove to be safe and effective or receive regulatory approval for any indication. Further, even if we were to receive regulatory approval for a product, there can be no assurance that such a product will prove to be commercially successful or profitable.

We are developing ALISTA for the potential treatment of female sexual arousal disorder. After successful completion of our first two Phase II ALISTA clinical trials, a third study was begun at the end of the first quarter of 2003. There are no guarantees that ALISTA will prove to be safe and effective or that we will receive regulatory approval for the treatment of female sexual arousal disorder or any other indication. Even if ALISTA eventually becomes an approved product, there can be no assurance that this treatment for female sexual arousal disorder will be successful in the marketplace.

The markets in which we operate are highly competitive and we may be unable to compete successfully against new entrants or established companies with greater resources.

Competition in the pharmaceutical and medical products industries is intense and is characterized by extensive research efforts and rapid technological progress. The most significant competitive therapy is an oral medication marketed by Pfizer under the name Viagra®, which received regulatory approvals in the United States in March 1998 and in the European Union in September 1998. The commercial launch of Viagra in the United States in April 1998 significantly decreased demand for MUSE. Another oral medication under the name Uprima® was approved and launched in Europe by Abbott Laboratories and Takeda in May 2001. In February 2003, a new oral medication under the name Cialis® was launched in Europe by Lilly ICOS LLC and in Australia and New Zealand by Eli Lilly and Company. Bayer AG and GlaxoSmithKline plc launched Levitra® in the European Union and the United States in March and September 2003, respectively.

Other treatments for erectile dysfunction exist, such as needle injection therapy, vacuum constriction devices and penile implants, and the manufacturers of these products will continue to improve these therapies. Additional competitive products in the erectile dysfunction market include needle injection therapy products from Pfizer (formerly Pharmacia) and Schwartz Pharma, which were approved by the United States Food and Drug Administration in July 1995 and June 1997, respectively.

Several large pharmaceutical companies are also actively engaged in the development of therapies for the treatment of erectile dysfunction. These companies have substantially greater research and development capabilities as well as substantially greater marketing, financial and human resources abilities than VIVUS. In addition, many of these companies have significantly greater experience than us in undertaking pre-clinical testing, human clinical trials and other regulatory approval procedures. Our competitors may develop technologies and products that are more effective than those we are currently marketing or developing. Such developments could render our products less competitive or possibly obsolete. We are also competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have limited experience.

We have limited sales and marketing capabilities in the United States.

We support MUSE sales in the United States through a small sales support group targeting major accounts that include the top prescribers of MUSE. Additionally, telephone marketers focus on additional urologists who prescribe MUSE. Physician and patient information/help telephone lines are available to answer additional questions that may arise after reading the inserts or after actual use of the product. The sales force actively participates in national urologic and sexual dysfunction forums and conferences, such as the

American Urological Association annual and regional meetings and the International Society for Impotence Research. There can be no assurance that our sales programs will effectively maintain or potentially increase current sales levels. There can be no assurance that demand for MUSE will continue or that we will be able to adequately support sales of MUSE in the United States in the future.

We rely on third parties to manufacture sufficient quantities of compounds for use in our pre-clinical and clinical trials and an interruption to this service may harm our business.

We do not have the ability to independently manufacture the materials we use in our pre-clinical and clinical trials, and we rely on various third parties to perform this function. There can be no assurance that we will be able to identify and qualify additional sources for clinical materials. If interruptions in this supply occur for any reason, including a decision by the third parties to discontinue manufacturing, labor disputes or a failure of the third parties to follow regulations, we may not be able to obtain regulatory approvals for our proposed products and may not be able to successfully commercialize these proposed products.

We rely on third parties to conduct clinical trials for our products in development and those third parties may not perform satisfactorily.

We do not have the ability to independently conduct clinical studies for any of our products currently in development, and we rely on third parties to perform this function. If third parties do not successfully carry out their contractual duties or meet expected timelines, we may not be able to obtain regulatory approvals for our proposed products and may not be able to successfully commercialize these proposed products. If third parties do not perform satisfactorily, we may not be able to locate acceptable replacements or enter into favorable agreements with them, if at all.

If the results of future clinical testing indicate that our proposed products are not safe or effective for human use, our business will suffer.

All of the drug candidates that we are currently developing require extensive pre-clinical and clinical testing before we can submit any application for regulatory approval. Before obtaining regulatory approvals for the commercial sale of any of our proposed drug products, we must demonstrate through pre-clinical testing and clinical trials that our product candidates are safe and effective in humans. Conducting clinical trials is a lengthy, expensive and uncertain process. Completion of clinical trials may take several years or more. Our commencement and rate of completion of clinical trials may be delayed by many factors, including:

- ineffectiveness of the study compound, or perceptions by physicians that the compound is not effective for a particular indication;
- inability to manufacture sufficient quantities of compounds for use in clinical trials;
- failure of the United States Food and Drug Administration to approve our clinical trial protocols;
- slower than expected rate of patient recruitment;
- inability to adequately follow patients after treatment;
- unforeseen safety issues; or
- government or regulatory delays.

The clinical results we have obtained to date do not necessarily predict that the results of further testing, including later stage controlled human clinical testing, will be successful. If our trials are not successful or are perceived as not successful by the United States Food and Drug Administration or physicians, our business, financial condition and results of operations will be materially harmed.

If we require additional capital for our future operating plans, we may not be able to secure the requisite additional funding on acceptable terms, if at all.

Our capital resources from operating activities are expected to continue to decline over the next several quarters as the result of increased spending for research and development projects, including clinical trials. We expect that our existing capital resources combined with future cash flows will be sufficient to support operating needs for at least the coming year. Financing in future periods will most likely be required to fund development of our research and development pipeline and the possible launch of any future products. Our future capital requirements will depend upon numerous factors, including:

- the progress of our research and development programs;

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- the scope, timing and results of pre-clinical testing and clinical trials;
 - the results of operations;
 - the cost, timing and outcome of regulatory reviews;
 - the rate of technological advances;
 - ongoing determinations of the potential commercial success of our products under development;
 - the level of resources devoted to sales and marketing capabilities; and
 - the activities of competitors.

To obtain additional capital when needed, we will evaluate alternative financing sources, including, but not limited to, the issuance of equity or debt securities, corporate alliances, joint ventures, and licensing agreements. However, there can be no assurance that funding will be available on favorable terms, if at all. If we are unable to obtain additional capital, management may be required to explore alternatives to reduce cash used by operating activities, including the termination of research and development efforts that may appear to be promising to the Company.

If we, or our suppliers, fail to comply with United States Food and Drug Administration and other government regulations, our manufacturing operations could be interrupted, and our product sales and profitability could suffer.

All new drugs, including our products under development, are subject to extensive and rigorous regulation by the United States Food and Drug Administration and comparable foreign authorities. These regulations govern, among other things, the development, pre-clinical and clinical testing, manufacturing, labeling, storage, pre-market approval, advertising, promotion, sale and distribution of our products. To date, MUSE has received marketing approval in more than 40 countries worldwide.

After regulatory approval is obtained, our products are subject to continual review. Manufacturing, labeling and promotional activities are continually regulated by the United States Food and Drug Administration and equivalent foreign regulatory agencies, and we must also report certain adverse events involving our products to these agencies. Previously unidentified adverse events or an increased frequency of adverse events that occur post-approval could result in labeling modifications of approved products, which could adversely affect future marketing. Finally, approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing. The restriction, suspension or revocation of regulatory approvals or any other failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

Failure to comply with the applicable regulatory requirements can result in, among other things, civil penalties, suspensions of regulatory approvals, product recalls, operating restrictions and criminal prosecution. The marketing and manufacturing of pharmaceutical products are subject to continuing United States Food and Drug Administration and other regulatory review, and later discovery of previously unknown problems with a product, manufacturer or facility may result in the United States Food and Drug Administration and/or other regulatory agencies requiring further clinical research or restrictions on the product or the manufacturer, including withdrawal of the product from the market. The restriction, suspension or revocation of regulatory approvals or any other failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

Failure of our third-party manufacturers to maintain satisfactory compliance with cGMPs could have a material adverse effect on our ability to continue to market and distribute our products and, in the most serious cases, could result in the issuance of warning letters, seizure or recall of products, civil penalties or closure of our manufacturing facility until such cGMP compliance is achieved. We obtain the necessary raw materials and components for the manufacture of MUSE as well as certain services, such as testing and sterilization, from third parties. We currently contract with suppliers and service providers, including foreign manufacturers that are required to comply with strict standards established by us. Certain suppliers and service providers are required to follow cGMP requirements and are subject to routine unannounced periodic inspections by the United States Food and Drug Administration and by certain state and foreign regulatory agencies for compliance with cGMP requirements and other applicable regulations. Certain of our suppliers were inspected for cGMP compliance as part of the approval process. However, upon routine re-inspection of these facilities, there can be no assurance that the United States Food and Drug Administration and other regulatory agencies will find the manufacturing process or facilities to be in compliance with cGMP requirements and other regulations.

Failure to achieve satisfactory cGMP compliance as confirmed by routine unannounced inspections could have a material adverse effect on our ability to continue to manufacture and distribute our products and, in the most serious case, result in the issuance of a regulatory warning letter or seizure or recall of products, injunction and/or civil penalties or closure of our manufacturing facility until cGMP compliance is achieved.

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Our success depends in large part on the strength of our current and future patent positions for the treatment of sexual dysfunction.

VIVUS holds various patents and patent applications in the following three major areas of sexual dysfunction:

- male erectile dysfunction,
- female sexual dysfunction, and
- premature ejaculation.

We are the exclusive licensee of United States and Canadian patents originally filed in the name of Dr. Gene Voss. These patents claim methods of treating erectile dysfunction with a vasodilator-containing ointment that is administered either topically or transurethraly.

We are also the exclusive licensee of patents and patent applications filed in the name of Dr. Nils G. Kock, in numerous countries. Four United States patents have been issued directed to methods and compositions for treating erectile dysfunction by transurethral administration of an active agent. Patents have also been granted in Australia, Austria, Belgium, Canada, Finland, France, Germany, Great Britain, Greece, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Romania, Spain, Sweden and South Africa. A patent application is pending in Denmark. The foreign patents and applications, like the United States patents, are directed to the treatment of erectile dysfunction by transurethral administration of certain active substances including alpha-receptor blockers, vasoactive polypeptides, prostaglandins or nitroglycerin dispersed in a hydrophilic vehicle.

VIVUS' license and assignment agreements for the patents and patent applications identified above are royalty-bearing and do not expire until the licensed and assigned patents expire. These license and assignment agreements generally provide that we assume responsibility for the maintenance and prosecution of the patents and patent applications and may bring infringement actions.

We are the sole assignee of five United States patents deriving from patent applications originally filed by ALZA Corporation, covering inventions Dr. Virgil Place made while he was an employee of ALZA. The patents are directed to dosage forms for administering a therapeutic agent to the urethra, methods for treating erectile dysfunction, and specific drug formulations that can be delivered transurethral for the treatment of erectile dysfunction. With one exception, the patents derive from patent applications that were filed in the United States prior to June 8, 1995, and therefore have a seventeen-year patent term calculated from the date of patent grant. Foreign patents have been granted in Australia, Canada, Europe (including Austria, Belgium, Denmark, France, Germany, Great Britain, Greece, Italy, Luxembourg, the Netherlands, Spain, Sweden and Switzerland), Finland, Ireland, Mexico, New Zealand, Norway, Portugal, South Africa and South Korea, and foreign applications are pending in Canada and Japan.

We are the sole assignee of patent applications filed in the name of Dr. Gary W. Neal and AndroSolutions, Inc. that are complementary to our patents and applications directed to the treatment of female sexual dysfunction.

In addition to the Voss, Kock, Place and Neal patents and applications identified above, we have numerous issued and pending United States and foreign patents. Many of these patents and applications further address the prevention, treatment and diagnosis of erectile dysfunction, while others are directed to prevention and/or treatment of other types of sexual dysfunction, including premature ejaculation and female sexual dysfunction. One of our issued patents covers VIVUS' venous flow control device, ACTIS.

Our strategy is to expand our existing patent portfolio through internal development of new intellectual property as well as through licensing and acquiring patents and patent applications that would increase our ability to succeed in the fields of erectile dysfunction, female sexual dysfunction and premature ejaculation. Our success will depend in large part on the strength of our current and future patent position for the treatments of these therapeutic indications. Our patent position, like that of other pharmaceutical companies, is highly uncertain and involves complex legal and factual questions. The claims of a United States or foreign patent application may be denied or significantly narrowed, and patents that are ultimately issued may not provide significant commercial protection to us. We could incur substantial costs in proceedings before the United States Patent and Trademark Office, including interference proceedings. These proceedings could also result in adverse decisions as to the priority of our licensed or assigned inventions. There can be no assurance that our patents will not be successfully challenged or designed around by others.

If our raw material supplier fails to supply us with alprostadil, for which availability is limited, we may experience delays in our product development and commercialization.

We are required to initially receive regulatory approval for suppliers and we obtained our current supply of alprostadil from two approved sources. The first is Nera Pharm, formerly Spolana Chemical Works a.s. in Neratovice, Czech Republic. The second is ChinoIn Pharmaceutical and Chemical Works Co., Ltd. In the second quarter of 2002, we ended our contractual relationship with Nera Pharm, which left ChinoIn Pharmaceutical as our sole qualified supplier of alprostadil. We are currently in the process of investigating additional sources for our future alprostadil supplies. However, there can be no assurance that we will be able to identify and qualify additional suppliers of alprostadil, in a timely manner, if at all.

Furthermore, alprostadil is subject to periodic re-testing to ensure it continues to meet specifications. There can be no guarantees the material will pass these re-testing procedures and continue to be usable material. There is a long lead-time for manufacturing alprostadil. A short supply of alprostadil to be used in the manufacture of MUSE would have a material adverse effect on our business, financial condition and results of operations.

We outsource several key parts of our operations and any interruption in the services provided could harm our business.

We entered into a distribution agreement with Cardinal Health (formerly CORD Logistics, Inc.). Under this agreement, Cardinal Health

- warehouses our finished goods for United States distribution;
- takes customer orders; picks, packs and ships our products;
- invoices customers; and
- collects related receivables.

As a result of this distribution agreement, we are heavily dependent on Cardinal Health's efforts to fulfill orders and warehouse our products effectively in the United States. There can be no assurance that such efforts will continue to be successful.

Gibraltar Laboratories performs sterility testing on finished product manufactured by us to ensure that it complies with product specifications. Gibraltar Laboratories also performs microbial testing on water and compressed gases used in the manufacturing process and microbial testing on environmental samples to ensure that the manufacturing environment meets appropriate current Good Manufacturing Practice, or cGMP, regulations and cleanliness standards. As a result of this testing agreement, we are dependent on Gibraltar Laboratories to perform testing and issue reports on finished product and the manufacturing environment in a manner that meets cGMP regulations. There can be no assurance that such efforts will be successful.

We have an agreement with WRB Communications to handle patient and healthcare professional hotlines for us. WRB Communications maintains a staff of healthcare professionals to answer questions and inquiries about MUSE and ACTIS. These calls may include complaints about our products due to efficacy or quality, as well as the reporting of adverse events. As a result of this agreement, we are dependent on WRB Communications to effectively handle these calls and inquiries. There can be no assurance that such efforts will be successful.

We entered into a distribution agreement with Integrated Commercialization Services, or ICS, a subsidiary of Bergen Brunswig Corporation. ICS provides “direct-to-physician” distribution capabilities in support of United States marketing and sales efforts. As a result of this distribution agreement, we are dependent on ICS’s efforts to distribute product samples effectively. There can be no assurance that such efforts will be successful.

We currently depend on a single source for the supply of plastic applicator components, and an interruption to this supply source could harm our business.

We rely on a single injection molding company, Medegen (formerly Porex Medical Products, Inc.), for our supply of plastic applicator components. In turn, Medegen obtains its supply of resin, a key ingredient of the applicator, from a single source, Huntsman Corporation. There can be no assurance that we will be able to identify and qualify additional sources of plastic components. We are required to initially receive United States Food and Drug Administration approval for suppliers. Until we secure and qualify additional sources of plastic components, we are entirely dependent upon Medegen. If interruptions in this supply occur for any reason, including a decision by Medegen to discontinue manufacturing, labor disputes or a failure of Medegen to follow regulations, the development and commercial marketing of MUSE and other potential products could be delayed or prevented. An extended interruption in the supply of plastic components could have a material adverse effect on our business, financial condition and results of operations.

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We currently depend on a single source to sterilize MUSE, and an interruption to this source could harm our business.

We rely on a single source, E-Beam Services, Inc., for the sterilization of MUSE. There can be no assurance that we will be able to identify and qualify additional sterilization facilities. We are required to receive prior United States Food and Drug Administration approval for any sterilization facility. Until we secure and qualify an additional sterilization facility, we are entirely dependent upon E-Beam Services. If interruptions in these services occur for any reason, including a decision by E-Beam Services to discontinue manufacturing or services, labor disputes or a failure of E-Beam Services to follow regulations, the development and commercial marketing of MUSE and other potential products could be delayed or prevented. An extended interruption in sterilization services would have a material adverse effect on our business, financial condition and results of operations.

All of our manufacturing operations are currently conducted at a single location, and a prolonged interruption to our manufacturing operations could harm our business.

We lease 90,000 square feet of space in Lakewood, New Jersey, in which we constructed manufacturing, warehousing and testing facilities. The United States Food and Drug Administration and the Medicines Control Agency, the regulatory authority in the United Kingdom, authorized us to begin commercial production and shipment of MUSE from this facility in June and March 1998, respectively. MUSE is manufactured in this facility and we have no immediate plans to construct another manufacturing site. Since MUSE is produced with custom-made equipment under specific manufacturing conditions, the inability of our manufacturing facility to produce MUSE for whatever reason could have a material adverse effect on our business, financial condition and results of operations.

We depend exclusively on third-party distributors outside of the United States and we have very limited control over their activities.

We entered into agreements granting Meda AB exclusive marketing and distribution rights for MUSE and ACTIS in all Member States of the European Union, the Baltic States, the Czech Republic, Hungary, Iceland, Norway, Poland, Switzerland and Turkey. These agreements do not have minimum purchase commitments and we are entirely dependent on Meda AB’s efforts to distribute and sell our products effectively in all these markets. There can be no assurance that such efforts will be successful or that Meda AB will continue to support the products.

We entered into an agreement granting Paladin Labs exclusive marketing and distribution rights for MUSE in Canada. This agreement does not have minimum purchase commitments and we are entirely dependent on Paladin Labs’ efforts to distribute and sell our product effectively in Canada. There can be no assurance that such efforts will be successful or that Paladin Labs will continue to support the product.

We have an accumulated deficit of \$103.2 million at September 30, 2003 and expect to continue to incur substantial operating losses for the foreseeable future.

We have generated a cumulative net loss of \$103.2 million for the period from our inception through September 30, 2003 and we anticipate losses for the next several quarters due to increased investment in our research and development programs and limited revenues. We are subject to a number of risks, including our ability to develop and successfully commercialize products in our research and development pipeline, our ability to market, distribute and sell our products in the United States, our reliance on others to market and distribute MUSE in countries other than the United States, intense competition, and our reliance on a single therapeutic approach to erectile dysfunction. There can be no assurance that we will be able to achieve profitability on a sustained basis. Accordingly, there can be no assurance of our future success.

We are dependent upon a single approved therapeutic approach to treat erectile dysfunction.

MUSE relies on a single approved therapeutic approach to treat erectile dysfunction, a transurethral system. The existence of side effects or dissatisfaction with this product may impact a patient’s decision to use or continue to use, or a physician’s decision to recommend, this therapeutic approach as a therapy for the treatment of erectile dysfunction, thereby affecting the commercial viability of MUSE. In addition, technological changes or medical advancements could diminish or eliminate the commercial viability of our product, the results of which could have a material effect on our business operations and results.

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We may be sued for infringing on the intellectual property rights of others.

There can be no assurance that our products do not or will not infringe on the patent or proprietary rights of others. Third parties may assert that we are employing their proprietary technology without authorization. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes these patents. We could incur substantial costs and diversion of the time and attention of management and technical personnel in defending ourselves against any such claims. Furthermore, parties making claims against us may be able to obtain injunctive or other equitable relief that could effectively block our ability to further develop, commercialize and sell products, and such claims could result in the award of substantial damages against us. In the event of a successful claim of infringement against us, we may be required to pay damages and obtain one or more licenses from third parties. We may not be able to obtain

these licenses at a reasonable cost, if at all. In that event, we could encounter delays in product introductions while we attempt to develop alternative methods or products or be required to cease commercializing affected products and our operating results would be harmed.

Our inability to adequately protect our proprietary technologies could harm our competitive position and have a material adverse effect on our business.

The success of our business depends, in part, on our ability to obtain patents and maintain adequate protection of our intellectual property for our proprietary technology and products in the United States and other countries. The laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting their proprietary rights in these foreign countries. These problems can be caused by, for example, a lack of rules and processes allowing for meaningful defense of intellectual property rights. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode our competitive advantage, and our business and operating results could be harmed.

The patent positions of pharmaceutical companies, including our patent position, are often uncertain and involve complex legal and factual questions. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. We apply for patents covering our technologies and products, as we deem appropriate. However, we may not obtain patents on all inventions for which we seek patents, and any patents we obtain may be challenged and may be narrowed in scope or extinguished as a result of such challenges. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Others may independently develop similar or alternative technologies or design around our patented technologies or products. These companies would then be able to develop, manufacture and sell products that compete directly with our products. In that case, our revenues and operating results would decline.

We seek to protect our confidential information by entering into confidentiality agreements with employees, collaborators and consultants. Nevertheless, employees, collaborators or consultants may still disclose or misuse our confidential information, and we may not be able to meaningfully protect our trade secrets. In addition, others may independently develop substantially equivalent information or techniques or otherwise gain access to our trade secrets. Disclosure or misuse of our confidential information would harm our competitive position and could cause our revenues and operating results to decline.

If we fail to retain our key personnel and hire, train and retain qualified employees, we may not be able to compete effectively, which could result in reduced revenues.

Our success is highly dependent upon the skills of a limited number of key management personnel. To reach our business objectives, we will need to retain and hire qualified personnel in the areas of manufacturing, research and development, regulatory affairs, clinical trial management and pre-clinical testing. There can be no assurance that we will be able to hire or retain such personnel, as we must compete with other companies, academic institutions, government entities and other agencies. The loss of any of our key personnel or the failure to attract or retain necessary new employees could have an adverse effect on our research, product development and business operations.

We are subject to additional risks associated with our international operations.

MUSE is currently marketed internationally. Changes in overseas economic and political conditions, terrorism, currency exchange rates, foreign tax laws or tariffs or other trade regulations could have an adverse effect on our business, financial condition and results of operations. The international nature of our business is also expected to subject us and our representatives, agents and distributors to laws and regulations of the foreign jurisdictions in which we operate or where our products are sold. The regulation of drug therapies in a number of such jurisdictions, particularly in the European Union, continues to develop, and there can be no assurance that new laws or regulations will not have a material adverse effect on our business, financial condition and results of operations. In addition, the laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the United States.

Any adverse changes in reimbursement procedures by Medicare and other third-party payors may limit our ability to market and sell our products.

In the United States and elsewhere, sales of pharmaceutical products are dependent, in part, on the availability of reimbursement to the consumer from third-party payors, such as government and private insurance plans. Third party payors are increasingly challenging the prices charged for medical products and services. While a large percentage of prescriptions in the United States for MUSE have been reimbursed by third party payors since our commercial launch in January 1997, there can be no assurance that our products will be considered cost effective and that reimbursement to the consumer will continue to be available or sufficient to allow us to sell our products on a competitive basis.

In addition, certain healthcare providers are moving towards a managed care system in which such providers contract to provide comprehensive healthcare services, including prescription drugs, for a fixed cost per person. We hope to further qualify MUSE for reimbursement in the managed care environment. However, we are unable to predict the reimbursement policies employed by third party healthcare payors. Furthermore, reimbursement for MUSE could be adversely affected by changes in reimbursement policies of governmental or private healthcare payors.

The healthcare industry is undergoing fundamental changes that are the result of political, economic and regulatory influences. The levels of revenue and profitability of pharmaceutical companies may be affected by the continuing efforts of governmental and third party payors to contain or reduce healthcare costs through various means. Reforms that have been and may be considered include mandated basic healthcare benefits, controls on healthcare spending through limitations on the increase in private health insurance premiums and Medicare and Medicaid spending, the creation of large insurance purchasing groups and fundamental changes to the healthcare delivery system. Due to uncertainties regarding the outcome of healthcare reform initiatives and their enactment and implementation, we cannot predict which, if any, of the reform proposals will be adopted or the effect such adoption may have on us. There can be no assurance that future healthcare legislation or other changes in the administration or interpretation of government healthcare or third party reimbursement programs will not have a material adverse effect on us. Healthcare reform is also under consideration in some other countries.

If we become subject to product liability claims, we may be required to pay damages that exceed our insurance coverage.

The commercial sale of MUSE exposes us to a significant risk of product liability claims due to its availability to a large population of patients. In addition, pharmaceutical products are subject to heightened risk for product liability claims due to inherent side effects. We detail potential side effects in the patient package insert and the physician package insert, both of which are distributed with MUSE. While we believe that we are reasonably insured against these risks, we may not be able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. A product liability

claim in excess of our insurance coverage would have to be paid out of cash reserves and could have a material adverse effect upon our business, financial condition and results of operations. Product liability insurance is expensive, difficult to maintain, and current or increased coverage may not be available on acceptable terms, if at all.

Our stock price has been and may continue to be volatile.

The market price of our common stock has been volatile and is likely to continue to be so. The market price of our common stock may fluctuate due to factors including, but not limited to:

- announcements of technological innovations or new products by us or our competitors;
- our ability to increase demand for our products in the United States;
- our ability to successfully sell our products in the United States and internationally;
- actual or anticipated fluctuations in our financial results;
- our ability to obtain needed financing;
- economic conditions in the United States and abroad;
- comments by or changes in Company assessments or financial estimates by security analysts;

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- adverse regulatory actions or decisions;
- any loss of key management;
- the results of our clinical trials or those of our competitors;
- developments or disputes concerning patents or other proprietary rights;
- product or patent litigation; or
- public concern as to the safety of products developed by us.

These factors and fluctuations, as well as political and market conditions, may materially adversely affect the market price of our common stock. Securities class action litigation is often brought against a company following periods of volatility in the market price of its securities. We may be the target of similar litigation. Securities litigation, whether with or without merit, could result in substantial costs and divert management's attention and resources, which could harm our business and financial condition, as well as the market price of our common stock.

Additionally, volatility or a lack of positive performance in our stock price may adversely affect our ability to retain key employees, all of whom have been granted stock options.

Our charter documents and Delaware law could make an acquisition of our company difficult, even if an acquisition may benefit our stockholders.

Our Board of Directors has adopted a Preferred Shares Rights Plan. The Preferred Shares Rights Plan has the anti-takeover effect of causing substantial dilution to a person or group that attempts to acquire us on terms not approved by our Board of Directors. The existence of the Preferred Shares Rights Plan could limit the price that certain investors might be willing to pay in the future for shares of our common stock and could discourage, delay or prevent a merger or acquisition that a stockholder may consider favorable.

Certain provisions of our Amended and Restated Certificate of Incorporation and Bylaws could also delay or prevent a change in control of our company. Some of these provisions:

- authorize the issuance of preferred stock by the Board of Directors without prior stockholder approval, commonly referred to as "blank check" preferred stock, with rights senior to those of common stock;
- prohibit stockholder actions by written consent;
- specify procedures for director nominations by stockholders and submission of other proposals for consideration at stockholder meetings; and
- eliminate cumulative voting in the election of directors.

In addition, we are governed by the provisions of Section 203 of Delaware General Corporate Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us. These and other provisions in our charter documents could reduce the price that investors might be willing to pay for shares of our common stock in the future and result in the market price being lower than it would be without these provisions.

Changes in accounting standards regarding stock option plans could limit the desirability of granting stock options, which could harm our ability to attract and retain employees, and could also reduce our profitability.

The Financial Accounting Standards Board is considering whether to require all companies to treat the value of stock options granted to employees as an expense. The United States Congress and other governmental and regulatory authorities have also considered requiring companies to expense stock options. If this change were to become mandatory, we and other companies would be required to record a compensation expense equal to the fair market value of each stock option granted. This expense would be spread over the vesting period of the stock option. Currently, we are generally not required to record compensation expenses in connection with stock options granted to our employees. If we were required to expense stock option grants, it would reduce the attractiveness of granting stock options because of the additional expense associated with these grants, which would reduce our profitability. However, stock options are an important employee recruitment and retention tool, and we may not be able to attract and retain key personnel if we reduce the scope of our employee stock option program. Accordingly, in the event we are required to expense stock option grants, our profitability would be reduced, as would our ability to use stock options as an employee recruitment and retention tool.

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The Securities and Exchange Commission's rule related to market risk disclosure requires that we describe and quantify our potential losses from market risk sensitive instruments attributable to reasonably possible market changes. Market risk sensitive instruments include all financial or commodity instruments and other financial instruments that are sensitive to future changes in interest rates, currency exchange rates, commodity prices or other market factors. VIVUS is not exposed to market risks from changes in foreign currency exchange rates or commodity prices. We do not hold derivative financial instruments nor do we hold securities for trading or speculative purposes. At September 30, 2003 and December 31, 2002, we had no debt outstanding, and consequently VIVUS currently has no risk exposure associated with increasing interest rates. VIVUS, however, is exposed to changes in interest rates on our investments in cash equivalents and available-for-sale securities. A significant portion of all of our investments in cash equivalents and available-for-sale securities are in money market funds that hold short-term investment grade commercial paper, treasury bills or other United States government obligations. Currently, this reduces our exposure to long-term interest rate changes.

ITEM 4. CONTROLS AND PROCEDURES

(a.) Evaluation of disclosure controls and procedures. Our management evaluated, with the participation of our Chief Executive Officer and our Chief Financial Officer, the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

(b.) Changes in internal controls. There was no change in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On November 3, 1999, the Company filed a demand for arbitration against Janssen Pharmaceutica International with the American Arbitration Association pursuant to the terms of the Distribution Agreement entered into on January 22, 1997. The Company sought compensation for inventory manufactured in 1998 in reliance on contractual forecasts and orders submitted by Janssen Pharmaceutica. The Company also sought compensation for forecasts and order shortfalls attributed to Janssen Pharmaceutica in 1998, pursuant to the terms of the Distribution Agreement. The Company amended its arbitration demand in August 2000 to include claims for lost profits due to Janssen Pharmaceutica's failure to use the requisite diligence and reasonable efforts to gain regulatory approval for and to launch MUSE in China. A full hearing on the merits was conducted before a three-member arbitration panel in Chicago on March 18 – 20, 2002.

On October 24, 2003, a final award was issued awarding the Company \$3,358,881 for 332,880 units manufactured and \$311,708 for lost profits from order shortfalls. In addition, the Company was awarded \$231,711 for reimbursement of legal fees and \$91,738 for reimbursement of other expenses related to the arbitration, but was denied any relief on claims related to diligence in China. The Company received payment from Janssen Pharmaceutica on November 10, 2003.

In the normal course of business, the Company receives and makes inquiries regarding patent infringement and other legal matters. The Company believes that it has meritorious claims and defenses and intends to pursue any such matters vigorously. The Company is not aware of any asserted or unasserted claims against it where the resolution would have an adverse material impact on the operations, liquidity or financial position of the Company.

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

None

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None

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ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None

ITEM 5. OTHER INFORMATION

None

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) EXHIBITS (IN ACCORDANCE WITH ITEM 601 OF REGULATION S-K)

EXHIBIT NUMBER	DESCRIPTION
3.2(7)	Amended and Restated Certificate of Incorporation of the Company
3.3(4)	Bylaws of the Registrant, as amended
3.4(8)	Certificate of Designations of Rights, Preferences and Privileges of Series A Participating Preferred Stock
4.1(7)	Specimen Common Stock Certificate of the Registrant
4.2(7)	Registration Rights, as amended
4.4(1)	Form of Preferred Stock Purchase Warrant issued by the Registrant to Invemed Associates, Inc., Frazier Investment Securities, L.P., and Cristina H. Kepner
4.5(8)	Second Amended and Restated Preferred Shares Rights Agreement, dated as of April 15, 1997 by and between the

	Registrant and Harris Trust Company of California, including the Certificate of Determination, the form of Rights Certificate and the Summary of Rights attached thereto as Exhibits A, B, and C, respectively
10.1(1)+	Assignment Agreement by and between Alza Corporation and the Registrant dated December 31, 1993
10.2(1)+	Memorandum of Understanding by and between Ortho Pharmaceutical Corporation and the Registrant dated February 25, 1992
10.3(1)+	Assignment Agreement by and between Ortho Pharmaceutical Corporation and the Registrant dated June 9, 1992
10.4(1)+	License Agreement by and between Gene A. Voss, MD, Allen C. Eichler, MD, and the Registrant dated December 28, 1992
10.5A(1)+	License Agreement by and between Ortho Pharmaceutical Corporation and Kjell Holmquist AB dated June 23, 1989
10.5B(1)+	Amendment by and between Kjell Holmquist AB and the Registrant dated July 3, 1992
10.5C(1)	Amendment by and between Kjell Holmquist AB and the Registrant dated April 22, 1992
10.5D(1)+	Stock Purchase Agreement by and between Kjell Holmquist AB and the Registrant dated April 22, 1992
10.6A(1)+	License Agreement by and between Amsu, Ltd., and Ortho Pharmaceutical Corporation dated June 23, 1989
10.6B(1)+	Amendment by and between Amsu, Ltd., and the Registrant dated July 3, 1992
10.6C(1)	Amendment by and between Amsu, Ltd., and the Registrant dated April 22, 1992
10.6D(1)+	Stock Purchase Agreement by and between Amsu, Ltd., and the Registrant dated July 10, 1992
10.11(4)	Form of Indemnification Agreements by and among the Registrant and the Directors and Officers of the Registrant
10.12(2)	1991 Incentive Stock Plan and Form of Agreement, as amended
10.13(1)	1994 Director Option Plan and Form of Agreement
10.14(1)	Form of 1994 Employee Stock Purchase Plan and Form of Subscription Agreement
10.17(1)	Letter Agreement between the Registrant and Leland F. Wilson dated June 14, 1991 concerning severance pay
10.21(3)+	Distribution Services Agreement between the Registrant and Synergy Logistics, Inc. (a wholly-owned subsidiary of Cardinal Health, Inc.)+ dated February 9, 1996

<u>EXHIBIT NUMBER</u>	<u>DESCRIPTION</u>
10.22(3)+	Manufacturing Agreement between the Registrant and CHINOIN Pharmaceutical and Chemical Works Co., Ltd. dated December 20, 1995
10.22A(11)+	Amendment One, dated as of December 11, 1997, to the Manufacturing Agreement by and between VIVUS and CHINOIN Pharmaceutical and Chemical Works Co., Ltd. dated December 20, 1995
10.23(6)+	Distribution and Services Agreement between the Registrant and Alternate Site Distributors, Inc. dated July 17, 1996
10.24(5)+	Distribution Agreement made as of May 29, 1996 between the Registrant and ASTRAZ AB
10.24A(14)+	Amended Distribution Agreement dated December 22, 1999 between AstraZeneca and the Registrant
10.27(11)+	Distribution Agreement made as of January 22, 1997 between the Registrant and Janssen Pharmaceutica International, a division of Cilag AG International
10.27A(11)+	Amended and Restated Addendum 1091, dated as of October 29, 1997, between VIVUS International Limited and Janssen Pharmaceutica International
10.28(7)	Lease Agreement made as of January 1, 1997 between the Registrant and Airport Associates
10.29(7)	Lease Amendment No. 1 as of February 15, 1997 between Registrant and Airport Associates
10.29A(10)	Lease Amendment No. 2 dated July 24, 1997 by and between the Registrant and Airport Associates
10.29B(10)	Lease Amendment No. 3 dated July 24, 1997 by and between the Registrant and Airport Associates
10.31(9)+	Manufacture and Supply Agreement between Registrant and Spolana Chemical Works, A.S. dated May 30, 1997
10.32A(11)	Agreement between ADP Marshall, Inc. and the Registrant dated December 19, 1997
10.32B(11)	General Conditions of the Contract for Construction
10.32C(11)	Addendum to General Conditions of the Contract for Construction
10.34(12)+	Agreement dated as of June 30, 1998 between Registrant and Alza Corporation
10.35(12)+	Sales Force Transition Agreement dated July 6, 1998 between Registrant and Alza Corporation
10.36(13)	Form of, "Change of Control Agreements," dated July 8, 1998 by and between the Registrant and certain Executive Officers of the Company.
10.30A(13)	Amendment of lease agreement made as of October 19, 1998 by and between Registrant and 605 East Fairchild Associates, L.P.
10.37(13)	Sublease agreement made as of November 17, 1998 between Caliper Technologies, Inc. and Registrant
10.22B(13)+	Amendment Two, dated as of December 18, 1998 by and between VIVUS, Inc. and CHINOIN Pharmaceutical and Chemical Works Co.
10.31A(13)+	Amendment One, dated as of December 12, 1998 by and between VIVUS, Inc. and Spolana Chemical Works, A.S.
10.38(14)+	License Agreement by and between ASIVI, LLC, AndroSolutions, Inc., and the Registrant dated February 29, 2000
10.38A(14)+	Operating Agreement of ASIVI, LLC, between AndroSolutions, Inc. and the Registrant dated February 29, 2000
10.39(14)	Sublease agreement between KVO Public Relations, Inc. and the Registrant dated December 21, 1999
10.40(15)+	License and Supply Agreement made as of May 23, 2000 between the Registrant and Abbott Laboratories, Inc.
10.41(16)+	License and Supply Agreement made as of November 20, 2000 between the Registrant and Paladin Labs, Inc.
10.42(16)+	Development, License and Supply Agreement made as of January 22, 2001 between the Registrant and TANABE SEIYAKU CO., LTD.
10.43(17)+	Settlement and Modification Agreement made as of July 12, 2001 between ASIVI, LLC, AndroSolutions, Inc. Gary W. Neal and the Registrant.
10.44(18)	2001 Stock Option Plan and Form of Agreement
10.45(19)+	Supply Agreement made as of September 3, 2002 between the Registrant and Meda AB.
10.46(20)+	Amendment Three, dated November 21, 2002 by and between VIVUS, Inc. and CHINOIN Pharmaceutical and Chemical Works, Ltd.

**EXHIBIT
NUMBER****DESCRIPTION**

10.47(20)	Lease Amendment No. 4 and Settlement Agreement dated October 25, 2000 by and between the Registrant and Airport Associates
10.48(20)+	Exclusive Distribution Agreement dated October 1, 2002 between the Registrant and Cord Logistics
10.49(20)+	Distribution and Supply Agreement made as of February 18, 2003 between the Registrant and Meda AB.
31.1	Certification of Chief Executive Officer, dated November 13, 2003, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer, dated November 13, 2003, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended.
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

+ Confidential treatment granted.

- (1) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Registration Statement on Form S-1 No. 33-75698, as amended.
- (2) Incorporated by reference to the same numbered exhibit filed with the Registrant's Registration Statement on Form S-1 No. 33-90390, as amended.
- (3) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1995, as amended.
- (4) Incorporated by reference to the same numbered exhibit filed with the Registrant's Form 8-B filed with the Commission on June 24, 1996.
- (5) Incorporated by reference to the same numbered exhibit filed with the Registrant's Current Report on Form 8-K/A filed with the Commission on June 21, 1996.
- (6) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1996.
- (7) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1996, as amended.
- (8) Incorporated by reference to exhibit 99.1 filed with Registrant's Amendment Number 2 to the Registration Statement of Form 8-A (File No. 0-23490) filed with the Commission on April 23, 1997.
- (9) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1997.
- (10) Incorporated by reference to the same numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1997.
- (11) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1997.
- (12) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1998.
- (13) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1998.

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- (14) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1999.
 - (15) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2000.
 - (16) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 2000.
 - (17) Incorporated by reference to the same numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.
 - (18) Incorporated by reference to the same numbered exhibit filed with the Registrant's Registration Statement on Form S-8 filed with the Commission on November 15, 2001.
 - (19) Incorporated by reference to the same numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.
 - (20) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002.

(b) REPORTS ON FORM 8-K

On July 16, 2003, we furnished a current report on Form 8-K that disclosed our financial results for the second quarter ended June 30, 2003 and certain other information. The Form 8-K included our unaudited financial statements for the second quarter ended June 30, 2003.

On September 22, 2003, we filed a current report on Form 8-K that disclosed the appointment of Larry J. Strauss as our Vice President, Finance and Chief Financial Officer, and the resignation of Richard Walliser as Vice President, Finance and Chief Financial Officer.

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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: November 13, 2003

VIVUS, Inc.

/s/ LARRY J. STRAUSS

Larry J. Strauss
Vice President, Finance and Chief Financial Officer
(Principal Financial and Accounting Officer)

/s/ LELAND F. WILSON

Leland F. Wilson
President and Chief Executive Officer
(Principal Executive Officer)

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VIVUS, INC.

INDEX TO EXHIBITS*

<u>EXHIBIT</u>	<u>DESCRIPTION</u>
31.1	Certification of Chief Executive Officer, dated November 13, 2003, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer, dated November 13, 2003, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended.
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002



CERTIFICATION

I, Leland F. Wilson, certify that:

1. I have reviewed this quarterly report on Form 10-Q of VIVUS, Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2003

By: /s/ LELAND F. WILSON

Name: Leland F. Wilson

Title: President and Chief Executive Officer

CERTIFICATION

I, Larry J. Strauss, certify that:

1. I have reviewed this quarterly report on Form 10-Q of VIVUS, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2003

By: /s/ LARRY J. STRAUSS

Name: Larry J. Strauss

Title: Vice President, Finance and Chief Financial Officer

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Leland F. Wilson, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of VIVUS, Inc. on Form 10-Q for the period ending September 30, 2003 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of VIVUS, Inc.

November 13, 2003

By: /s/ LELAND F. WILSON

Leland F. Wilson
President and Chief Executive Officer

I, Larry J. Strauss, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of VIVUS, Inc. on Form 10-Q for the period ending September 30, 2003 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of VIVUS, Inc.

November 13, 2003

By: /s/ LARRY J. STRAUSS

Larry J. Strauss
Vice President and Chief Financial Officer