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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549  
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FORM 10-Q  
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☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 1999

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)

605 EAST FAIRCHILD DRIVE  
(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES)

MOUNTAIN VIEW, CA 94043  
(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

At JUNE 30, 1999, 32,137,458 shares of common stock were outstanding.

EXHIBIT INDEX ON PAGE 25

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## PART I: FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

## VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS  
(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)  
(Unaudited)

	THREE MONTHS ENDED			SIX MONTHS ENDED	
	JUNE 30, 1999	MARCH 31, 1999	JUNE 30, 1998	JUNE 30, 1999	JUNE 30, 1998
Revenue					
US Product	\$ 5,239	\$ 4,538	\$ 6,142	\$ 9,777	\$ 30,693
International Product	1,572	1,716	9,841	3,288	11,812
Milestone	--	4,000	--	4,000	1,000
Total revenue	6,811	10,254	15,983	17,065	43,505
Operating Expenses					
Cost of goods sold	3,072	3,603	10,704	6,675	21,186
Research and development	1,762	1,786	5,359	3,548	9,239
Selling, general and administrative	1,554	1,352	17,576	2,906	34,634
Settlement of shareholder lawsuits	600	--	--	600	--
Other restructuring costs	--	--	6,522	--	6,522
Total operating expenses	6,988	6,741	40,161	13,729	71,581
Income (loss) from operations	(177)	3,513	(24,178)	3,336	(28,076)
Interest and other income	484	479	597	963	1,508
Income (loss) before taxes	307	3,992	(23,581)	4,299	(26,568)
Income tax provision	(15)	(200)	(597)	(215)	--
Net income (loss)	\$ 292	\$ 3,792	\$(24,178)	\$ 4,084	\$(26,568)
Net income (loss) per share:					
Basic	\$ 0.01	\$ 0.12	\$ (0.76)	\$ 0.13	\$ (0.83)
Diluted	\$ 0.01	\$ 0.12	\$ (0.76)	\$ 0.13	\$ (0.83)
Shares used in the computation of net income (loss) per share:					
Basic	32,066	31,934	31,752	32,000	31,938
Diluted	32,889	32,211	31,752	32,600	31,938

## VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)  
 (IN THOUSANDS)  
 (Unaudited)

	THREE MONTHS ENDED			SIX MONTHS ENDED	
	JUNE 30, 1999	MARCH 31, 1999	JUNE 30, 1998	JUNE 30, 1999	JUNE 30, 1998
Net Income (loss)	\$ 292	\$ 3,792	\$(24,178)	\$ 4,084	\$(26,568)
Other comprehensive income (loss):					
Unrealized gain (loss) on securities	231	(65)	31	166	(91)
Income tax benefit (provision)	(12)	3	--	(9)	--
	219	(62)	31	157	(91)
Comprehensive income (loss)	\$ 511	\$ 3,730	\$(24,147)	\$ 4,241	\$(26,659)
	=====	=====	=====	=====	=====

## VIVUS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS  
(IN THOUSANDS, EXCEPT PER SHARE AMOUNT)

	JUNE 30, 1999 ----- (unaudited)	MARCH 31, 1999 ----- (unaudited)	DECEMBER 31, 1998 -----
Current assets:			
Cash	\$ 5,152	\$ 4,428	\$ 2,989
Available-for-sale securities	33,542	31,950	20,903
Accounts receivable	2,518	3,514	5,197
Inventories	4,093	4,337	5,272
Prepaid expenses and other assets	1,155	673	534
	-----	-----	-----
Total current assets	46,460	44,902	34,895
Property and equipment	17,633	18,424	19,213
	-----	-----	-----
Total	\$ 64,093 =====	\$ 63,326 =====	\$ 54,108 =====
Current Liabilities:			
Accounts payables	\$ 1,804	\$ 2,194	\$ 3,277
Accrued and other liabilities	29,295	29,014	21,294
	-----	-----	-----
Total current liabilities	31,099	31,208	24,571
Accrued and other long-term liabilities	6,052	6,555	7,860
	-----	-----	-----
Total liabilities	37,151	37,763	32,431
Stockholders' equity:			
Common stock; \$.001 par value; shares authorized 200,000; shares outstanding - June 30, 1999, 32,137; March 31, 1999, 31,947; December 31, 1998, 31,890	32	32	32
Paid in capital	132,481	131,625	131,466
Accumulated other comprehensive income	135	(96)	(31)
Accumulated deficit	(105,706)	(105,998)	(109,790)
	-----	-----	-----
Total stockholders' equity	26,942	25,563	21,677
	-----	-----	-----
Total	\$ 64,093 =====	\$ 63,326 =====	\$ 54,108 =====

## VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
(IN THOUSANDS)  
(Unaudited)

	SIX MONTHS ENDED JUNE 30,	
	1999	1998
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	\$ 4,084	\$ (26,568)
Adjustments to reconcile net income (loss) to net cash provided by (used for) operating activities:		
Depreciation and amortization	1,654	1,656
Stock compensation costs	182	256
Issuance of common stock for lawsuit settlement	600	--
Changes in assets and liabilities:		
Accounts receivable	2,679	3,621
Inventories	1,179	(7,688)
Prepaid expenses and other assets	(621)	(822)
Accounts payable	(1,473)	796
Accrued and other liabilities	6,193	(2,484)
Net cash provided by (used for) operating activities	14,477	(31,233)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Property and equipment purchases	(75)	(12,072)
Investment purchases	(52,817)	(67,743)
Proceeds from sale/maturity of securities	40,345	129,201
Net cash provided by (used for) investing activities	(12,547)	49,386
CASH FLOWS FROM FINANCING ACTIVITIES:		
Exercise of common stock options	133	277
Sale of common stock through employee stock purchase plan	100	413
Repurchase of common stock	--	(23,584)
Net cash provided by (used for) financing activities	233	(22,894)
NET INCREASE (DECREASE) IN CASH	2,163	(4,741)
CASH:		
Beginning of period	2,989	6,161
End of period	\$ 5,152	\$ 1,420
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Unrealized gain on securities	\$ 166	\$ (91)
SUPPLEMENTAL CASH FLOW DISCLOSURE:		
Income taxes paid	\$ 36	\$ 71

## VIVUS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
JUNE 30, 1999

## 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 three-month and six-month periods ended June 30, 1999 are not necessarily indicative of the results that may be expected for the year ending December 31, 1999. 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, 1998.

## 2. RESTRUCTURING RESERVE

During 1998, the Company experienced a significant decline in market demand as the result of the introduction of a competitor's product. As a result, 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, 1998 included in the Company's Annual Report on Form 10-K). The reserve balance at June 30, 1999 was \$10.1 million, a decrease of \$2.8 million from \$12.9 million at March 31, 1999. The decrease was primarily related to payments made for employee retention obligations (\$1.5 million), the return of expired product from wholesalers (\$1.0 million), and lease commitments (\$158,000) as follows (in thousands):

	SEVERANCE AND EMPLOYEE COSTS	INVENTORY AND RELATED COMMITMENTS	PROPERTY AND RELATED COMMITMENTS	MARKETING PROGRAMS	OTHER	TOTAL
	-----	-----	-----	-----	-----	-----
Balance at December, 1998 .....	\$ 1,910	\$ 5,384	\$ 4,664	\$ 1,307	\$ 1,793	\$ 15,058
Incurred in first quarter 1999 .....	(108)	(128)	(309)	(1,076)	(500)	(2,121)
	-----	-----	-----	-----	-----	-----
Balance at March 31, 1999 .....	1,802	5,256	4,355	231	1,293	12,937
Incurred in second quarter 1999 ....	(1,502)	(48)	(158)	(131)	(1,000)	(2,839)
	-----	-----	-----	-----	-----	-----
Balance at June 30, 1999 .....	\$ 300	\$ 5,208	\$ 4,197	\$ 100	\$ 293	\$ 10,098
	=====	=====	=====	=====	=====	=====

The Company expects that over the next twelve months, it will make cash payments of approximately \$4.0 million related to the restructuring, with the remaining \$6.1 million in cash payments to occur after this period.

## 3. DEFERRED REVENUE

The Company invoices its international partners based on an agreed billing price per unit, that is subject to revision based on contractual formulas either up or down upon periodic reconciliation's. Final pricing for product shipments to international partners is subject to contractual formulas based on the partners' net realizable price to their customers and the Company's cost of goods among other things. At the time of product shipment, the Company recognizes revenue at the lowest possible price in accordance with contractual formulas and will recognize additional revenue, if any, upon finalization of pricing with its international partners. As of June 30, 1999, the Company had deferred revenue of \$5.3 million representing amounts billed in excess of revenue recognized, unchanged from March 31, 1999.

During the second quarter of 1999, the Company received \$2.5 million from an international partner representing pre-payment for product shipments to occur in future periods, bringing total pre-payments at June 30, 1999 to \$10.4 million. The Company recorded these payments as unearned revenue and will record revenue from product shipments in future periods as they occur.

## VIVUS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)  
JUNE 30, 1999

## 4. ACCRUED AND OTHER LIABILITIES

Accrued and other liabilities as of June 30, 1999, March 31, 1999, and December 31, 1998 consist of :

(in thousands)	June 31, 1999	March 31, 1999	December 31, 1998
Unearned revenue	15,677	13,158	5,040
Restructuring	10,098	12,937	15,058
Research and clinical expenses	2,549	2,429	2,337
Income taxes	2,263	2,247	2,082
Royalties	2,100	2,014	2,133
Employee compensation and benefits	1,132	1,006	902
Manufacturing expenses	615	251	368
Sales and marketing expenses	301	941	664
Other	612	585	570
	-----	-----	-----
	\$35,347	\$35,569	\$29,154
	=====	=====	=====

## 5. NET INCOME (LOSS) PER SHARE

Net income (loss) 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 (loss) per share is based on the weighted average number of common shares outstanding during the periods. 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 and warrants. Certain options and warrants are excluded from the diluted income per share for income periods presented because they are anti-dilutive. All options and warrants are excluded from the diluted loss per share for all loss periods because they are anti-dilutive.

## 6. SETTLEMENT OF SHAREHOLDER LAWSUITS

On February 18, 1998, a purported shareholder class action entitled Crain et al. v. Vivus, Inc. et al., was filed in Superior Court of the State of California for the County of San Mateo. Five identical complaints were subsequently filed in the same court. These complaints were filed on behalf of a purported class of persons who purchased stock between May 15, 1997 and December 9, 1997. The complaints allege that the Company and certain current and former officers or directors artificially inflated the Company's stock price by issuing false and misleading statements concerning the Company's prospects and issuing false financial statements. On March 16, 1998, a purported shareholder class action entitled Cramblit et al. v. Vivus, Inc. et al. was filed in the United States District Court for the Northern District of California. Five additional complaints were subsequently filed in the same court. The federal complaints were filed on behalf of a purported class of persons who purchased stock between May 2, 1997 and December 9, 1997. The federal complaints asserted the same factual allegations as the state court complaints, but assert legal claims under the Federal Securities Laws. The federal court cases were consolidated, and a lead plaintiff had been appointed and the plaintiff filed a consolidated and amended complaint in 1998.

On May 4, 1999 the Company reached a settlement with plaintiffs of the shareholder class action lawsuits described above. The aggregate settlement amount is \$6 million. The settlement will be funded by insurance proceeds of \$5.4 million and by the Company contributing 120,000 shares of VIVUS Common Stock, with a market value of \$0.6 million on the date of settlement, to the settlement fund. The settlement is subject to approval by the Court. This settlement was recorded in the Company's income statement for the three months ended June 30, 1999.

## 7. SEGMENT INFORMATION

During 1998, the Company adopted Statement of Financial Accounting Statement SFAS No. 131, "Disclosure About Segments of an Enterprise and Related Information." SFAS 131 requires a new basis of determining reportable business segments, i.e. the management approach. This approach requires that business segment information used by management to assess performance and manage company resources for information disclosure. On this basis, the Company primarily sells its product through wholesale channels in the United States. International sales are made only to the Company's two international partners. All transactions are denominated in U.S. dollars, therefore, the Company considers the arrangement as operating in a single segment.

During the first six months of 1999, five customers accounted for 24%, 20%, 13%, 13%, and 10% of total product revenue, as compared to five customers accounted for 35%, 13%, 11%, 11% and 10% of total product revenue for fiscal year 1998.



This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. The Company's actual results could differ from those set forth in such forward-looking statements as a result of certain factors, including those set forth in this Risk Factors section starting on page 13 of this document.

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

### OVERVIEW

VIVUS, Inc. ("VIVUS" or the "Company") is the developer and manufacturer of MUSE(R) (alprostadil) and ACTIS(TM), two advancements in the treatment of men with erectile dysfunction ("ED"), also known as impotence. The Company's objective is to become a global leader in the development and commercialization of innovative therapies for the treatment of sexual dysfunction and urologic disorders in men and women. To this end, the Company utilizes its expertise and patent portfolio by focusing its R&D activities on male and female sexual dysfunction, incontinence and premature ejaculation. VIVUS focuses on the development of new indications or delivery systems for pharmacological agents that have pre-existing data. The Company believes that such agents present a lower development risk profile and may progress more rapidly through the clinical development and regulatory process than agents without pre-existing data.

The Company intends to market and sell its products worldwide through distribution, co-promotion or license agreements with corporate partners. To date, the Company has entered into licensing and distribution agreements with ASTRA AB, now ("AstraZeneca") and Janssen Pharmaceutica ("Janssen") for certain international markets. The Company is currently seeking a major pharmaceutical partner(s) to market, distribute and sell its products in the U.S. and Japan. (SEE RISK FACTORS ON PAGE 13)

The Company supports MUSE sales in the U.S. through physician and patient information/help lines, sales support for major accounts, product education newsletters and participation 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. In addition, the Company supports ongoing research and clinical investigation of MUSE and the publication of data in peer-reviewed journals.

In November 1996, the Company obtained marketing clearance by the U.S. Food and Drug Administration (the "FDA") to manufacture and market its first product, MUSE and commercially introduced MUSE in the United States beginning in January 1997. The launch of MUSE went on to become one of the top 25 most successful drug launches in the U.S. and the Company recorded a net profit of \$36.6 million and product revenue of \$129.3 million for the year ended December 31, 1997.

During 1998, the Company experienced a significant decline in market demand for MUSE as the result of the introduction of a competitor's product in April 1998. Since the launch of this competitive product, MUSE prescriptions have declined approximately 80% in the US. 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. As a result, the Company incurred a net loss of \$80 million and had negative operating cash flow of \$26 million for the year ended December 31, 1998. 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, 1998.

During the first quarter of 1999, the Company received approval to market MUSE in Germany and France. To date, MUSE has been approved by regulatory agencies in 44 countries, including all of European Union countries except Spain and Italy. The Company expects to receive regulatory approval to market in Spain and Italy in the second half of 1999.

On May 17, 1999, the Company signed an agreement with Bio-Medic Institute, Inc. ("BMI"). The agreement would have given BMI exclusive rights to act as VIVUS' agent to establish an agreement with a Japanese pharmaceutical company for the registration and commercialization of MUSE in Japan. On July 9, 1999, the Company terminated its agreement with BMI due to BMI's failure to make a \$5 million up-front payment as required by the agreement. The Company continues to seek major pharmaceutical partners to market, distribute and sell its products in the U.S. and Japan.

During the second quarter of 1999, the Company has conducted a Phase III clinical trial for ALIBRA, the Company's second generation transurethral approach to treat ED. ALIBRA is expected to submit the New Drug Application ("NDA") in the latter part of 1999. The Company expects to initiate a Phase II, proof of concept, clinical study for a premature

ejaculation product this year. In addition, the company is developing a product for female sexual dysfunction and expects to enter clinical testing next year.

The Company has seen the domestic demand for MUSE stabilize at current levels during the first half of 1999. The Company anticipates that demand will remain at current levels and may increase modestly as the Company's investments in marketing programs begin to produce results.

## RESULTS OF OPERATIONS

### THREE MONTHS ENDED JUNE 30, 1999 AND MARCH 31, 1999

Product revenues for the quarter ended June 30, 1999 were \$5.2 million in the United States and \$1.6 million internationally compared to \$4.5 million in the United States and \$1.7 million internationally for the quarter ended March 31, 1999. U.S. revenues increased 16% in second quarter 1999 compared to the first quarter 1999. Demand for the first six months of 1999 has remained relatively flat as measured by retail prescriptions. Lower shipments in the first quarter of 1999 were primarily the results of balancing of inventory levels in the wholesale channel. As of June 30, 1999, wholesale inventory levels represent approximately one months sales. International product revenue decreased by \$144,000 from first quarter 1999 as a result of the Company's international marketing partners, Janssen and AstraZeneca, having sufficient inventory for their markets. The Company anticipates that international revenues will decline further in the third quarter of 1999, as our partners continue to deplete existing inventories. International product revenues are expected to increase significantly in the fourth quarter of 1999 over the second quarter 1999 as reordering begins to occur.

Total revenues during the first quarter of 1999 also included milestone revenue of \$4.0 million from AstraZeneca related to regulatory approval of MUSE in Germany and France. The Company anticipates that regulatory approval in Spain and Italy will occur in the second half of 1999. These approvals will trigger milestone revenue of \$2.0 million for each country approved from AstraZeneca.

Cost of goods sold was \$3.1 million for the second quarter 1999 compared to \$3.6 million for the first quarter 1999. This decrease was primarily the result of improving yields and continued cost conservation efforts.

Research and development ("R&D") expenses for the second quarter 1999 were \$1.8 million consistent with the spending in the first quarter 1999. The Company anticipates that R&D expenses will increase in the second half of 1999 from the first half levels, as the Company progresses in the development of its R&D pipeline.

Selling, general and administrative expenses for the second quarter 1999 were \$1.6 million compared to \$1.4 million in the first quarter of 1999. Higher expenses in second quarter of 1999 were primarily the result of increased investment in U.S. marketing in the second quarter. The Company anticipates that US marketing and sales expenses will increase in the second half from the first half levels, as the Company continues to invest in sales and marketing programs.

During second quarter 1999, the Company reached a settlement of the shareholder class action lawsuits, in which the company incurred a non-cash expense of \$600,000 for the issuance of 120,000 shares of Vivus, Inc. common stock.

Interest and other income for the second quarter 1999 were \$484,000 compared with \$479,000 in the first quarter 1999. The increase was primarily the result of higher interest resulting from higher average invested cash balances in the second quarter 1999.

The Company recorded a tax provision of \$15,000 or five percent of income before taxes for the second quarter 1999. This five percent rate is consistent with the rate recorded in first quarter of 1999, and includes the effect of net operating loss ("NOL") carried forward from prior periods. The tax rate would have been substantially higher if the NOLs were not available to offset current income.

### THREE AND SIX MONTHS ENDED JUNE 30, 1999 AND 1998

Product revenues for the quarter ended June 30, 1999 were \$5.2 million in the United States and \$1.6 million internationally compared to \$6.1 million in the United States and \$9.8 million internationally for the quarter ended June 30, 1998. Product revenues for the six months ended June 30, 1999 were \$9.8 million in the U.S. and \$3.3 million internationally compared to \$30.7 million in

the U.S. and \$11.8 million internationally for the same periods in 1998. Underlying demand for MUSE domestically, as measured by retail prescriptions, has declined approximately 80% since the commercial launch of a competitive product in April 1998. Internationally, the decrease in product revenue for the three and six month periods is attributed to the Company's partners, Janssen and AstraZeneca, having accumulated sufficient inventory in 1998 for their respective markets.

Total revenues for the six month ended June 30, 1999 include milestone revenue of \$4.0 million received in the first quarter 1999 related to regulatory approval of MUSE in Germany and France, compared with milestone revenue of \$1.0 million in the first quarter of 1998 related to regulatory approval of MUSE in South Korea.

Cost of goods sold was \$3.1 million for the second quarter 1999 compared to \$10.7 million for the second quarter 1998. For the six months ended June 30, 1999, cost of goods sold was \$6.7 million compared to \$21.2 million for the first six months of 1998. The Company's has made significant progress in manufacturing projects improving yields and continued cost conservation in the first half of 1999. As a result, the higher unit cost caused by lower economies of scale has been partially offset by the ongoing improvements.

Research and development expenses for the second quarter 1999 were \$1.8 million compared to \$5.4 million in the second quarter 1998. For the six months ended June 30, 1999 and 1998, research and development expenses were \$3.5 million and \$9.2 million, respectively. Lower spending for three and six month periods ended June 30, 1999 was primarily the result of the Company's efforts to bring its cost structure in line with current and projected revenues. Higher spending in 1998 was mainly associated with a significantly larger R&D organization.

Selling, general and administrative expenses for the second quarter 1999 were \$1.6 million compared to \$17.6 million in the second quarter 1998. For the six months ended June 30, 1999, expenses were \$2.9 million compared to \$34.6 million for the same period in 1998. The lower expenses in three and six month periods ended June 30, 1999 were primarily a result of Company's effort to bring overall cost levels in line with the Company's projected future demand for MUSE. Included in the three and six month periods ended June 30, 1998 were significant expenses for a direct-to-consumer advertising campaign as well as a direct sales force, which are not included in 1999.

In the second quarter 1999, the Company reached a settlement of shareholders class action lawsuits, in which the company recorded a non-cash expense of \$600,000 for the issuance of 120,000 shares of Vivus, Inc. common stock. In the second quarter of 1998, the company incurred a restructuring charge of \$6.5 million, primarily associated with the Company's agreement to facilitate the transition of its direct U.S. sales force to ALZA Corporation, as well as terminating the contract sales agreement with Innovex, and personnel reductions.

Interest and other income for the three and six month periods ended June 30, 1999 were \$479,000 and \$963,000, respectively, compared with \$597,000 and \$1.5 million in the three and six month periods ended June 30, 1998. The decrease was primarily the result of lower average invested cash balances in 1999.

The Company recorded a tax provision of five percent of net income before taxes for the six month ended June 30, 1999. This compares to no tax provision recorded during the first six-months period 1998. The zero tax provision recorded in the first half of 1998 was calculated based on an expected loss for the fiscal year ended 1998. The 1999 effective tax rate calculation includes the effect of NOLs carried forward from prior periods. The tax rate would have been substantially higher if the NOLs were not available to offset current income.

#### LIQUIDITY AND CAPITAL RESOURCES

Since inception, the Company has financed operations primarily from the sale of preferred and common stock. Through June 30, 1999, VIVUS has raised \$153.6 million from financing activities and has an accumulated deficit of \$105.7 million at June 30, 1999.

Cash, cash equivalents and available-for-sale securities totaled \$38.7 million at June 30, 1999 compared with \$36.4 million at March 31, 1999 and \$23.9 million at December 31, 1998. The \$14.8 million increase in cash from December 31, 1998 primarily resulted from the prepayments received for product shipments to occur in future periods, collection of accounts receivable and the receipt of milestone payments related to approval of MUSE in Germany and France. These increases were partially offset by payments made related to the restructuring reserve established in 1998 (See Note 2 to the Condensed Consolidated Financial Statements on page 6).

Accounts receivable at June 30, 1999 were \$2.5 million compared with \$5.2 million at December 31, 1998, a decrease of \$2.7 million due primarily to lower sales and improved collection of accounts receivable.

Total liabilities were \$37.2 million at June 30, 1998, compared with \$32.4 million at December 31, 1998, an increase of \$4.8 million. The increase primarily relates to the prepayment for product shipments, included in deferred revenue, partially offset by payments made related to the restructuring reserve established in 1998 (See Notes 2, 3 and 4 of the Condensed Consolidated Financial Statements on page 6 and 7).

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. The Company's actual results could differ from those set forth in such forward-looking statements as a result of certain factors, including those set forth in this Risk Factors section.

## RISK FACTORS

### LIMITED SALES AND MARKETING EXPERIENCE; DEPENDENCE ON THIRD PARTIES

The Company intends to market and sell its products through distribution, co-promotion or license agreements with corporate partners. To date, the Company has entered into marketing agreements with AstraZeneca and Janssen for certain international markets. The Company is currently seeking a major pharmaceutical partner(s) to market, distribute and sell its products in the United States and Japan. There can be no assurance that the Company will be able to successfully enter into additional agreements with corporate partners upon reasonable terms, if at all. To the extent that the Company enters into distribution, co-promotion or license agreements for the sale of its products, the Company will be dependent upon the efforts of third parties. These third parties may have other commitments, and there can be no assurance that they will commit the necessary resources to effectively market, distribute and sell the Company's product.

In 1996, the Company entered into a distribution agreement with CORD Logistics, Inc. ("CORD"), a wholly owned subsidiary of Cardinal Health, Inc. Under this agreement, CORD warehouses the Company's finished goods for U.S. distribution, takes customer orders, picks, and packs and ships its product, invoices customers and collects related receivables. The Company also has access to CORD's information systems that support these functions. As a result of this distribution agreement with CORD, the Company is heavily dependent on CORD's efforts to fulfill orders and warehouse its products effectively in the U.S. There can be no assurance that such efforts will be successful.

In 1996, the Company entered into an international marketing agreement with AstraZeneca to purchase the Company's products for resale in Europe, South America, Central America, Australia and New Zealand. The marketing agreement does not have minimum purchase commitments, and AstraZeneca may take up to twelve months to introduce a product in a given country following regulatory approval in such country. As a result, the Company is dependent on AstraZeneca's efforts to market, distribute and sell the Company's products effectively in the above mentioned markets. There can be no assurance that such efforts will be successful, or that AstraZeneca will continue to support the product.

In 1996, the Company entered into a distribution agreement with Integrated Commercialization Services ("ICS") a subsidiary of Bergen Brunswig Corporation. ICS provides "direct-to-physician" distribution, telemarketing and customer service capabilities in support of U.S. marketing and sales efforts. As a result of this distribution agreement with ICS, the Company is dependent on ICS's efforts to distribute, telemarket, and provide customer service effectively. There can be no assurance that such efforts will be successful.

In 1997, the Company entered into an international marketing agreement with Janssen to purchase the Company's products for resale in China, multiple Pacific Rim countries (excluding Japan), Canada, Mexico, South Africa, the Middle East, Russia, the Indian sub-continent, and Africa. The marketing agreement does not have minimum purchase commitments and the Company is dependent on Janssen's efforts to distribute and sell the Company's products effectively in the above mentioned markets. Janssen may take up to twelve months to introduce a product in a given country following regulatory approval in such country. There can be no assurance that such efforts will be successful or that Janssen will continue to support the product.

### INTENSE COMPETITION

Competition in the pharmaceutical and medical products industries is intense and is characterized by extensive research efforts and rapid technological progress. Certain treatments for ED exist, such as oral medications, needle injection therapy, vacuum constriction devices and penile implants, and the manufacturers of these products will continue to improve these therapies. The most significant competitive therapy is sildenafil, an oral medication marketed by Pfizer, which received regulatory approvals in the U.S. in March 1998 and in the European Union in September 1998. The commercial launch of sildenafil in the U.S. in April 1998 dramatically increased the number of men seeking treatment for impotence and significantly decreased demand for MUSE. Since the launch of sildenafil, MUSE prescriptions have declined approximately 80% in the U.S.

Additional competitive products in the erectile dysfunction market include needle injection therapy products from Pharmacia Upjohn and Schwartz Pharma, which were approved by the FDA in July 1995 and June 1997, respectively. Other large pharmaceutical companies are also actively engaged in the development of therapies for the treatment of ED. These companies have substantially greater research and development capabilities as well as substantially greater marketing, financial and human resources than the Company. In addition, many of these companies have significantly greater experience than the Company in undertaking pre-clinical testing, human clinical trials and other regulatory approval procedures. There are also small companies, academic institutions, governmental agencies and other research organizations that are conducting research in the area of ED. For instance, Zonagen, Inc. has filed for FDA approval of its oral treatment and has received approval in Mexico; TAP Pharmaceuticals, Inc. has submitted an application to the FDA for approval of its oral treatment; ICOS Corporation has an oral medication in clinical testing; and Senetek has a needle injection therapy product approved recently in Denmark and has filed for approval in other countries. These entities may market commercial products either on their own or through collaborative efforts. For example, Zonagen, Inc. announced a worldwide marketing agreement with Schering-Plough in November 1997; and ICOS Corporation formed a joint venture with Eli Lilly in October 1998 to jointly develop and market its oral treatment. The Company's competitors may develop technologies and products that are more effective than those currently marketed or being developed by the Company. Such developments would render the Company's products less competitive or possibly obsolete. The Company is also competing with respect to marketing capabilities and manufacturing efficiency, areas in which it has limited experience.

#### HISTORY OF LOSSES AND LIMITED OPERATING HISTORY

The Company has generated a cumulative net loss of \$105.7 million for the period from its inception through June 30, 1999. In order to sustain profitable operations, the Company must successfully manufacture and market MUSE and adjust its expenditures in conjunction with lower product revenues. The Company is subject to a number of risks including its ability to successfully market, distribute and sell its product, intense competition, and its reliance on a single therapeutic approach to erectile dysfunction and its ability to secure additional operating capital. There can be no assurance that the Company will be able to achieve profitability on a sustained basis. Accordingly, there can be no assurance of the Company's future success.

During 1998, the Company took significant steps to restructure its operations in an attempt to bring the cost structure of the business in line with current demand for MUSE. These steps included significant reductions in personnel, closing the contract-manufacturing site located in PACO Pharmaceutical Services, Inc., the termination of the lease for the Company's leased corporate offices, and recorded significant write-down of property, equipment and inventory. As a result of these and other factors the Company experienced an operating loss of \$80.3 million, or \$2.52 per share, in the year ended December 31, 1998.

In September 1998, the Company significantly scaled back its manufacturing operations as a result of lower demand domestically and internationally for MUSE. Current production is significantly below capacity for the plant resulting in a higher unit cost, and the Company expects that the gross margin from the sale of MUSE will be less predictable in future periods, which may cause greater volatility in the Company's results of operations and financial condition.

Management believes that these restructuring measures are adequate to bring the cost structure in line with current and projected revenues, however, there can be no assurance that product demand will not weaken further or that these measures will result in sustained profitability in future periods.

#### FUTURE CAPITAL NEEDS AND UNCERTAINTY OF ADDITIONAL FINANCING

Cash, cash equivalents and available-for-sale securities totaled \$38.7 million at June 30, 1999 compared with \$23.9 million at December 31, 1998. The Company anticipates that its existing capital resources combined with anticipated future revenues might not be sufficient to support the commercial introduction of any additional future products. The Company is currently seeking other sources of financing to support the development of its R&D pipeline.

On October 5, 1998, the Company's lessor ("plaintiff") named the Company in a civil action in connection with the Company's leased manufacturing facilities, located in Lakewood, New Jersey. The Company's lease requires that the Company provide a removal security deposit in the form of cash or letter of credit. The Company and the plaintiff have not been able to agree on the amount of the deposit, and the plaintiff filed suit asking for specific performance in the amount of \$3.3 million. The Company believes the \$3.3 million security deposit is excessive and not mandated by the terms of the lease. However, if the Company is required to post a certificate of deposit of \$3.3 million, this will have a material adverse effect on the Company's financial condition.

The Company expects that it will be required to issue additional equity or debt securities or use other financing sources including, but not limited to corporate alliances and lease financing to fund the development and possible commercial launch of its future products. The sale of additional equity securities would result in additional dilution to the Company's stockholders. The Company's working capital and additional funding requirements will depend upon numerous factors, including: (i) results of operations; (ii) demand for MUSE; (iii) the outcome of litigation; (iv) the activities of competitors; (v) the progress of the Company's research and development programs; (vi) the timing and results of pre-clinical testing and clinical trials; (vii) technological advances; and (viii) the level of resources that the Company devotes to sales and marketing capabilities.

#### DEPENDENCE ON KEY PERSONNEL

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

#### DEPENDENCE ON SINGLE SOURCE OF SUPPLY

The Company relies on a single source, E-Beam Services, Inc., for sterilization of its product. There can be no assurance that the Company will be able to identify and qualify additional sterilization sources. The Company is required to receive FDA approval for suppliers. The FDA may require additional clinical studies or other testing prior to accepting a new supplier. Unless the Company secures and qualifies additional sources of sterilization facilities, it will be entirely dependent on E-Beam. If interruption in this services were to occur for any reason, including a decision by E-Beam to discontinue service, political unrest, labor disputes or a failure of E-Beam to follow regulatory guidelines, the development and commercial marketing of MUSE and other potential products could be delayed or prevented. An interruption in sterilization services would have a material adverse effect on the Company's business, financial condition and results of operations.

#### LIMITED MANUFACTURING EXPERIENCE

The Company has limited experience in manufacturing and selling MUSE in commercial quantities. The Company initially experienced product shortages due to higher than expected demand and difficulties encountered in scaling up production of MUSE. The Company leased 90,000 square feet of space in New Jersey in which it has constructed manufacturing and testing facilities. The FDA and MCA authorized the Company to begin commercial production and shipment of MUSE from its new facility in June and March 1998, respectively. In September 1998, the Company closed its contract manufacturing site within PACO Pharmaceutical Services, Inc. and significantly scaled back its manufacturing operations in the New Jersey facility, as a result of lower domestic and international demand for MUSE. Production is currently significantly below capacity for the plant.

#### DEPENDENCE ON THE COMPANY'S TRANSURETHRAL SYSTEM FOR ERECTION

The Company currently relies on a single therapeutic approach to treat ED, its transurethral system for erection. Certain side effects have been found to occur with the use of MUSE. MUSE is applied into the urinary opening and is not for men with sickle cell trait, disease, or other blood disorders. One third of men reported genital pain, causing some to stop use. A few men reported dizziness and, less commonly, fainting. To date, the incidence of post-launch adverse side effects is consistent with that experienced in clinical trials. As a result of the Company's single therapeutic approach, the failure to successfully commercialize the product will have a material adverse effect to the Company's business.

The existence of side effects or dissatisfaction with product results may impact a patient's decision to use or continue to use, or a physician's decision to recommend, MUSE as a therapy for the treatment of ED thereby affecting the commercial viability of MUSE. In addition, technological changes or medical advancements could diminish or eliminate the commercial viability of the Company's product.

## RISKS RELATING TO INTERNATIONAL OPERATIONS

The Company's product is currently marketed internationally. Changes in overseas economic and political conditions, currency exchange rates, foreign tax laws or tariffs or other trade regulations could have a material adverse effect on the Company's business, financial condition and results of operations. The international nature of the Company's business is also expected to subject it and its representatives, agents and distributors to laws and regulations of the foreign jurisdictions in which they operate or the Company's product is 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 the Company's business, financial condition and results of operations. In addition, the laws of certain foreign countries do not protect the Company's intellectual property rights to the same extent, as do the laws of the United States.

## GOVERNMENT REGULATION AND UNCERTAINTY OF PRODUCT APPROVALS

The Company's research, preclinical development, clinical studies, manufacturing and marketing of its products are subject to extensive regulation, rigorous testing and approval processes of the Food and Drug Administration ("FDA") and equivalent foreign regulatory agencies. In November 1996, the Company received final marketing clearance from the FDA for MUSE. In November 1997, the Company obtained regulatory marketing clearance by the European Medicine Controls Agency ("MCA") to market MUSE in the United Kingdom. To date, MUSE has been approved in 44 countries.

After regulatory approval is obtained, the Company's products are subject to continual review. Manufacturing, labeling and promotional activities are continually regulated by the FDA and equivalent foreign regulatory agencies, and the Company must also report certain adverse events involving its drugs 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 effect future marketing of a drug. 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 would have a material adverse effect on the Company's business, financial condition and results of operations.

The Company has submitted applications for approval of MUSE in several other countries. These applications will be subject to rigorous approval processes. There can be no assurance that approval in these or other countries will be granted or that these approvals if granted, will not contain significant limitations in the form of warnings, precautions or contraindications with respect to condition of use. Any delay in obtaining, or failure to obtain such approval would adversely affect the Company's ability to generate product revenue.

The Company's clinical studies for future products will generate safety data as well as efficacy data and will require substantial time and significant funding. There is no assurance that clinical studies related to future products would be completed successfully within any specified time period, if at all. Furthermore, the FDA could suspend clinical studies at any time if it is believed that the subjects participating in such studies are being exposed to unacceptable health risks.

Failure to comply with the applicable regulatory requirements can, among other things, result in fines, suspensions of regulatory approvals, product recalls, operating restrictions and criminal prosecution. In addition, the marketing and manufacturing of pharmaceutical products are subject to continuing FDA and other regulatory review, and later discovery of previously unknown problems with a product, manufacturer or facility may result in the FDA and 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 would have a material adverse effect on the Company's business, financial condition and results of operations.

The Company obtains the necessary raw materials and components for the manufacture of MUSE as well as certain services, such as testing and sterilization, from third parties. The Company currently contracts with suppliers and service providers, including foreign manufacturers that are required to comply with strict standards established by the Company. Certain suppliers and service providers are required by the Federal Food, Drug, and Cosmetic Act, as amended, and by FDA regulations to follow current good manufacturing practice ("cGMP") requirements and are subject to routine periodic inspections by the FDA and certain state and foreign regulatory agencies for compliance with cGMP and other applicable regulations. Certain of the Company's 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 FDA and other regulatory agencies will find the manufacturing process or facilities to be in compliance with





cGMP and other regulations. Failure to achieve satisfactory cGMP compliance as confirmed by routine inspections could have a material adverse effect on the Company's ability to continue to manufacture and distribute its 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 fines or closure of the Company's manufacturing facility until cGMP compliance is achieved.

#### PATENTS AND PROPRIETARY RIGHTS

The Company's policy is to aggressively maintain its patent position and to enforce all of its intellectual property rights.

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

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

The Company is also the exclusive licensee of two United States patent applications and one PCT application filed in the names of Jan Geliebter, Arnold Melman, George Christ and Jamil Rehman. The patent applications are directed to the use of gene therapy in the treatment of erectile dysfunction and in the regulation of bladder smooth muscle tone. All three patent applications are currently pending.

The Company is the sole assignee of three United States patents, one divisional patent application and two continuation applications all deriving from patent applications originally filed by Alza, covering inventions of Dr. Virgil Place made while he was an employee of Alza. The patents and patent applications 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 transurethraly for the treatment of erectile dysfunction. The divisional and continuation applications were filed in the United States on June 7, 1995. All patents issuing on applications filed before June 8, 1995 will automatically have a term that is the greater of twenty years from the patent's effective filing date or seventeen years from the date of patent grant. Foreign patents have been granted in Australia, Europe (including Austria, Belgium, Denmark, France, Germany, Great Britain, Greece, Italy, Luxembourg, Norway, the Netherlands, Portugal, Spain, Sweden and Switzerland), New Zealand, South Africa and South Korea, and foreign applications are pending in Canada, Finland, Ireland, Mexico, and Japan.

The Company's license and assignment agreements for these patents and patent applications are royalty bearing and do not expire until the licensed patents expire. These license and assignment agreements provide that the Company may assume responsibility for the maintenance and prosecution of the patents and bring infringement actions.

In addition to the Voss, Kock, Geliebter et al. and Place patents and applications identified above, the Company has ten issued United States patents, seven pending United States patent applications, three Patent Cooperation Treaty ("PCT") applications, two granted foreign patents, and ten pending foreign patent applications. Several of these patents and applications further address the prevention, treatment and diagnosis of ED, while others are directed to prevention and/or treatment of other types of sexual dysfunction, including premature ejaculation in men, and female sexual dysfunction. One of the Company's issued patents covers the Company's ACTIS(R) venous flow control device. Other issued patents and pending patent applications focus on prevention and/or treatment of conditions other than sexual dysfunction, including vascular disorders such as peripheral vascular disease ("PVD"), prostate disorders such as benign prostate hyperplasia ("BPH"), hormone replacement therapy, and contraception.

One of the Company's issued United States patents is directed to a method for treating female sexual dysfunction with a topical or intravaginal formulation containing a vasoactive prostaglandin. Since issuance of that patent, another U.S. patent has been issued that

claims a similar method wherein an "E-series" prostaglandin is administered topically. That patent, U.S. Patent No. 5,891,915 to Wysor et al., derives from a U.S. patent application that was filed after the Company's patent application was filed. The Company believes that its patent is dominant, and that the Wysor et al. patent will not have an impact on the Company's plans to develop and market a prostaglandin formulation for treating female sexual dysfunction. At this time, however, the issue has not been determined with certainty, and there can be no assurance that the Company's patent is in fact dominant.

The Company's success will depend in large part on the strength of its current and future patent position relating to the transurethral delivery of pharmacologic agents for the treatment of erectile dysfunction. The Company's patent position, like that of other pharmaceutical companies, is highly uncertain and involves complex legal and factual questions. The claims of a U.S. or foreign patent application may be denied or significantly narrowed and patents that ultimately issue may not provide significant commercial protection to the Company. The Company 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 the Company's licensed or assigned inventions. There is no assurance that the Company's patents will not be successfully challenged or designed around by others.

The Company is presently involved in an opposition proceeding that was instigated by the Pharmedic Company against a European patent, inventors Nils G. Kock et al., that is exclusively licensed to VIVUS. As a result of the opposition proceeding, certain pharmaceutical composition claims in the European patent were held unpatentable by the Opposition Division of the EPO. The patentability of all other claims in the patent was confirmed, i.e., those claims directed to the use of active agents in the treatment of ED, and to a pharmaceutical composition claim for prazosin. The Company appealed the EPO's decision with respect to the pharmaceutical composition claims that were held unpatentable. The Pharmedic Company appealed the EPO's decision with respect to the claims that were held patentable, but has since withdrawn the appeal. Despite the withdrawal of the Pharmedic Company from the appeal process, the Company has continued with its own appeal in an attempt to reinstate the composition claims. The EPO Appeals Board must make its own finding whether the claims that were deemed unpatentable by the Opposition Division are indeed patentable before it can reverse the Opposition Division's decision. There can be no assurance that the appeal will be successful or that further challenges to the Company's European patent will not occur should the Company try to enforce the patent in the various European courts.

The Company was also the first to file a Notice of Opposition to Pfizer's European patent application claiming the use of phosphodiesterase inhibitors to treat erectile dysfunction. Numerous other companies have also opposed the patent, and the Company will support these other entities in their oppositions as necessary.

There can be no assurance that the Company's products do not or will not infringe on the patent or proprietary rights of others. The Company may be required to obtain additional licenses to the patents, patent applications or other proprietary rights of others. There can be no assurance that any such licenses would be made available on terms acceptable to the Company, if at all. If the Company does not obtain such licenses, it could encounter delays in product introductions while it attempts to design around such patents, or the development, manufacture or sale of products requiring such licenses could be precluded. The Company believes there will continue to be significant litigation in the pharmaceutical industry regarding patent and other intellectual property rights.

In addition to its patent portfolio, the Company also relies on trade secrets and other unpatented proprietary technology. No assurance can be given that the Company can meaningfully protect its rights in such unpatented proprietary technology or that others will not independently develop substantially equivalent proprietary products and processes or otherwise gain access to the Company's proprietary technology. The Company seeks to protect its trade secrets and proprietary know-how, in part, with confidentiality agreements with employees and consultants. There can be no assurance that the agreements will not be breached or that the Company will have adequate remedies for any breach or that the Company's trade secrets will not otherwise become known or be independently developed by competitors. In addition, protracted and costly litigation may be necessary to enforce and determine the scope and validity of the Company's proprietary rights.

#### UNCERTAINTY OF PHARMACEUTICAL PRICING AND REIMBURSEMENT

In the U.S. 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. With the introduction of sildenafil, third party payors have begun to restrict or eliminate reimbursement for erectile dysfunction treatments. While more than 70 percent of prescriptions in the U.S. for MUSE have been reimbursed by third party payors since its commercial launch in January 1997, there can be no assurance that the Company's



products will be considered cost effective and that reimbursement to the consumer will continue to be available or sufficient to allow the Company to sell its products on a competitive basis.

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

#### PRODUCT LIABILITY AND AVAILABILITY OF INSURANCE

The commercial launch of MUSE exposes the Company 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. The Company details potential side effects in the patient package insert and the physician package insert, both of which are distributed with MUSE, and the Company maintains product liability insurance coverage. However, the Company's product liability coverage is limited and may not be adequate to cover potential product liability exposure. Product liability insurance is expensive, difficult to maintain and current or increased coverage may not be available on acceptable terms, if at all. Product liability claims brought against the Company in excess of its insurance coverage, if any, could have a material adverse effect upon the Company's business, financial condition and results of operations.

#### UNCERTAINTY AND POSSIBLE NEGATIVE EFFECTS OF HEALTHCARE REFORM

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, the Company cannot predict which, if any, of the reform proposals will be adopted or the effect such adoption may have on the Company. 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 the Company. Healthcare reform is also under consideration in some other countries.

#### POTENTIAL VOLATILITY OF STOCK PRICE

The stock market has experienced significant price and volume fluctuations unrelated to the operating performance of particular companies. In addition, the market price of the Company's Common Stock has been highly volatile and is likely to continue to be so. Factors such as the Company's ability to increase demand for its product in the U.S., the Company's ability to successfully sell its product in the U.S. and internationally, variations in the Company's financial results and its ability to obtain needed financing, announcements of technological innovations or new products by the Company or its competition, comments by security analysts, adverse regulatory actions or decisions, any loss of key management, the results of the Company's clinical trials or those of its competition, changing governmental regulations, patents or other proprietary rights, product or patent litigation or public concern as to the safety of products developed by the Company, may have a significant effect on the market price of the Company's Common Stock.

#### ANTI-TAKEOVER EFFECT OF PREFERRED SHARES RIGHTS PLAN AND CERTAIN CHARTER AND BYLAW PROVISIONS

In February 1996, the Company's Board of Directors authorized its reincorporation in the State of Delaware (the "Reincorporation") and adopted a Preferred Shares Rights Plan. The Company's Reincorporation into the State of Delaware was approved by its stockholders and became effective in May 1996. The Preferred Shares Rights Plan provides for a dividend distribution of one Preferred Shares Purchase Right (a "Right") on each outstanding share of the Company's Common Stock. The Rights will become exercisable following the tenth day after a person or group announces acquisition of 20 percent or more of the Company's Common Stock, or announces commencement of a tender offer, the consummation of which would result in ownership by the person or group of 20 percent or more of the Company's common stock. The Company will be entitled to redeem the Rights at \$0.01 per

Right at any time on or before the tenth day following acquisition by a person or group of 20 percent or more of the Company's common stock.

The Preferred Shares Rights Plan and certain provisions of the Company's Certificate of Incorporation and Bylaws may have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, control of the Company. The Company's Certificate of Incorporation allows the Company to issue Preferred Stock without any vote or further action by the stockholders, and certain provisions of the Company's Certificate of Incorporation and Bylaws eliminate the right of stockholders to act by written consent without a meeting, 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. Certain provisions of Delaware law could also delay or make more difficult a merger, tender offer or proxy contest involving the Company, including Section 203, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years unless certain conditions are met. The Preferred Shares Rights Plan, the possible issuance of Preferred Stock, the procedures required for director nominations and stockholder proposals and Delaware law could have the effect of delaying, deferring or preventing a change in control of the Company, including without limitation, discouraging a proxy contest or making more difficult the acquisition of a substantial block of the Company's common stock. These provisions could also limit the price that investors might be willing to pay in the future for shares of the Company's Common Stock.

## PART II: OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

On October 5, 1998, the Company was named in a civil action filed in the Superior Court of New Jersey. This complaint seeks specific performance and other relief in connection with the Company's leased manufacturing facilities, located in Lakewood, New Jersey. The Company's lease agreement requires that the Company provide a removal security deposit in the form of cash or a letter of credit. The Company and lessor ("plaintiff") have not been able to agree on the amount of such deposit and the plaintiff filed suit asking for specific performance in the amount of \$3.3 million. The Company believes that the amount sought by the plaintiff is excessive and not mandated by the terms of the lease. However, if the Company is required to post a certificate of deposit of \$3.3 million, this will have a material adverse effect on the company's financial condition.

On February 18, 1998, a purported shareholder class action entitled *Crain et al. v. Vivus, Inc. et al.*, was filed in Superior Court of the State of California for the County of San Mateo. Five identical complaints were subsequently filed in the same court. These complaints were filed on behalf of a purported class of persons who purchased stock between May 15, 1997 and December 9, 1997. The complaints alleged that the Company and certain current and former officers or directors artificially inflated the Company's stock price by issuing false and misleading statements concerning the Company's prospects and issuing false financial statements. On March 16, 1998, a purported shareholder class action entitled *Cramblit et al. v. Vivus, Inc. et al.* was filed in the United States District Court for the Northern District of California. Five additional complaints were subsequently filed in the same court. The federal complaints were filed on behalf of a purported class of persons who purchased stock between May 2, 1997 and December 9, 1997. The federal complaints asserted the same factual allegations as the state court complaints, but asserted legal claims under the Federal Securities Laws. The federal court cases were consolidated, and a lead plaintiff has been appointed and the plaintiff filed a consolidated and amended complaint in 1998.

On May 4, 1999 the Company reached a settlement with plaintiffs of the shareholder class action lawsuits described above. The aggregate settlement amount is \$6 million. The settlement will be funded by insurance proceeds of \$5.4 million and by the Company contributing 120,000 shares of VIVUS Common Stock to the settlement fund. The settlement is subject to approval by the Court.

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 or financial position of the Company.

### ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

None

## ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None

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

The annual meeting of stockholders was held June 8, 1999. Matters voted on at that meeting were: (i) the election of six directors and (ii) the confirmation of the appointment of Arthur Andersen LLP as independent public accountants for the fiscal year ended December 31, 1999. Tabulation for each proposal and individual director were as follows:

## Proposal I. Election of Directors

Director -----	For ---	Withheld -----
Virgil A. Place, MD	28,476,586	287,932
Leland F. Wilson	28,345,348	419,170
Mark B. Logan	28,514,046	250,472
Linda M. Shortliffe, MD	28,512,938	251,580
Mario M. Rosati	28,519,746	244,772
Joseph E. Smith	28,521,746	243,472

## Proposal II. Confirmation of the Appointment of Arthur Andersen LLP

For ---	Against -----	Abstain -----	No Vote -----
28,584,682	141,203	38,633	--

## 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





EXHIBIT NUMBER -----	DESCRIPTION -----
	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
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
10.27(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.

EXHIBIT  
NUMBER

## DESCRIPTION

EXHIBIT NUMBER -----	DESCRIPTION -----
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.
27.1	Financial Data Schedule

- -----
- \* Confidential treatment requested.
- + 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.

(b) REPORTS ON FORM 8-K

(c) None.

## 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.

VIVUS, Inc. Date:

August 11, 1999

/s/ RICHARD WALLISER

Richard Walliser  
Vice President and Chief Financial Officer

/s/ LELAND F. WILSON

Leland F. Wilson  
President and Chief Executive Officer

## VIVUS, INC.

## INDEX TO EXHIBITS\*

EXHIBIT -----	DESCRIPTION -----
27.1	Financial Data Schedule

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\* Only exhibits actually filed are listed. Exhibits incorporated by reference are set forth in the exhibit listing included in Item 6 of the Quarterly Report on Form 10-Q.

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DEC-31-1999  
APR-01-1999  
JUN-30-1999  
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33,542  
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(188)  
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292  
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0.01

For Purposes of this Exhibit, Primary means Basic