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

FORM 10-Q

☒ [X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2000

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, CA
(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES)

94040
(ZIP CODE)

(650) 934-5200
(REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE)

N/A
(FORMER NAME, FORMER ADDRESS AND FORMER FISCAL YEAR,
IF CHANGED SINCE LAST REPORT)

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. ☒ [X] Yes ☐ [] No

At September 30, 2000, 32,400,158 shares of common stock were outstanding.

Exhibit Index on Page 24

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PART 1: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

	THREE MONTHS ENDED		NINE MONTHS ENDED	
	SEPTEMBER 30, 2000	SEPTEMBER 30, 1999	SEPTEMBER 30, 2000	SEPTEMBER 30, 1999
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Revenue				
US product	\$ 5,016	\$ 5,640	\$ 16,719	\$ 15,417
International product	256	1,105	3,434	4,393
Milestone	--	2,000	--	6,000
Returns Allowance	(294)	(2,618)	(961)	(4,118)
	-----	-----	-----	-----
Total revenue	4,978	6,127	19,192	21,692
Operating Expenses				
Cost of goods sold	2,942	2,840	8,733	9,514
Research and development	1,289	1,416	3,702	4,965
Selling, general and administrative	2,100	1,719	6,599	4,625
Settlement of shareholder lawsuits	--	--	--	600
Other restructuring costs	(903)	(293)	(903)	(1,793)
	-----	-----	-----	-----
Total operating expenses	5,428	5,682	18,131	17,911
	-----	-----	-----	-----
Income (loss) from operations	(450)	445	1,061	3,781
Interest and other income	681	499	1,877	1,462
	-----	-----	-----	-----
Income before taxes	231	944	2,938	5,243
Income tax provision	(23)	(47)	(294)	(262)
	-----	-----	-----	-----
Net income	\$ 208	\$ 897	\$ 2,644	\$ 4,981
	=====	=====	=====	=====
Net income per share:				
Basic	\$ 0.01	\$ 0.03	\$ 0.08	\$ 0.16
Diluted	\$ 0.01	\$ 0.03	\$ 0.08	\$ 0.15
Shares used in the computation of net income per share:				
Basic	32,371	32,143	32,290	32,048
Diluted	33,530	32,546	33,621	32,585

VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(IN THOUSANDS)

	THREE MONTHS ENDED		NINE MONTHS ENDED	
	SEPTEMBER 30, 2000	SEPTEMBER 30, 1999	SEPTEMBER 30, 2000	SEPTEMBER 30, 1999
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Net Income	\$ 208	\$ 897	\$ 2,644	\$ 4,981
Other comprehensive income:				
Unrealized gain (loss) on securities	118	(309)	192	(143)
Income tax benefit (provision)	(12)	15	(19)	7
	-----	-----	-----	-----
	106	(294)	173	(136)
	-----	-----	-----	-----
Comprehensive income	\$ 314	\$ 603	\$ 2,817	\$ 4,845
	=====	=====	=====	=====

VIVUS, INC.

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

	SEPTEMBER 30, 2000 ----- (unaudited)	DECEMBER 31, 1999 -----
Current assets:		
Cash	\$ 27,012	\$ 8,785
Available-for-sale securities	11,069	27,049
Accounts receivable	2,362	4,432
Inventories	3,320	3,527
Prepaid expenses and other assets	1,101	4,338
	-----	-----
Total current assets	44,864	48,131
Property and equipment	14,710	16,071
Available-for-sale securities, non-current	6,071	4,558
	-----	-----
Total	\$ 65,645 =====	\$ 68,760 =====
Current Liabilities:		
Accounts payable	\$ 1,359	\$ 2,453
Accrued and other liabilities	15,503	19,062
	-----	-----
Current liabilities	16,862	21,515
Accrued and other long-term liabilities	4,026	5,749
	-----	-----
Total liabilities	20,888 -----	27,264 -----
Stockholders' equity:		
Common stock; \$.001 par value; shares authorized 200,000; shares outstanding - September 30, 2000 32,400; December 31, 1999 32,211;	32	32
Paid in capital	133,068	132,643
Accumulated other comprehensive income	2	(190)
Accumulated deficit	(88,345)	(90,989)
	-----	-----
Total stockholders' equity	44,757 -----	41,496 -----
Total	\$ 65,645 =====	\$ 68,760 =====

VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(IN THOUSANDS)

	NINE MONTHS ENDED SEPT 30,	
	2000	1999
	(unaudited)	(unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	\$ 2,644	\$ 4,981
Adjustments to reconcile net income to net cash provided by (used for) operating activities:		
Depreciation and amortization	1,816	2,482
Stock compensation costs	--	182
Issuance of common stock for lawsuit settlement	--	600
Changes in assets and liabilities:		
Accounts receivable	2,071	3,147
Inventories	207	1,241
Prepaid expenses and other assets	3,237	(542)
Accounts payable	(1,094)	(1,556)
Accrued and other liabilities	(5,281)	7,815
Net cash provided by operating activities	3,600	18,350
CASH FLOWS FROM INVESTING ACTIVITIES:		
Property and equipment purchases	(455)	(111)
Investment purchases	(117,965)	(103,509)
Proceeds from sale/maturity of securities	132,624	87,547
Net cash provided by (used for) investing activities	14,204	(16,073)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Exercise of common stock options	293	187
Sale of common stock through employee stock purchase plan	131	100
Net cash provided by financing activities	424	287
NET INCREASE IN CASH	18,228	2,564
CASH:		
Beginning of period	8,785	2,989
End of period	\$ 27,013	\$ 5,553
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Unrealized gain (loss) on securities	\$ 192	\$ (143)
SUPPLEMENTAL CASH FLOW DISCLOSURE:		
Income taxes paid	\$ 535	\$ 36

VIVUS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2000

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 Regulation 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 nine-month periods ended September 30, 2000 are not necessarily indicative of the results that may be expected for the year ending December 31, 2000. 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, 1999.

2. RESTRUCTURING RESERVE

During 1998, the Company experienced a significant decline in market demand for MUSE(R) due to the introduction of Viagra. As a result, the Company took steps to restructure its operations 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, 1999 included in the Company's Annual Report on Form 10-K.) The restructuring reserve balance at September 30, 2000 was \$5.1 million.

	SEVERANCE AND EMPLOYEE COSTS	INVENTORY AND RELATED COMMITMENTS	PROPERTY AND RELATED COMMITMENTS	MARKETING COMMITMENTS	OTHER	TOTAL
	-----	-----	-----	-----	-----	-----
	(IN THOUSANDS)					
Restructuring Provision.....	\$ 3,069	\$ 16,083	\$ 34,684	\$ 3,191	\$ 3,708	\$ 60,735
Incurred in 1998.....	(1,159)	(10,699)	(30,020)	(1,884)	(1,915)	(45,677)
Incurred in 1999.....	(1,610)	(1,379)	(784)	(1,307)	(1,793)	(6,873)
	-----	-----	-----	-----	-----	-----
Balance at December 31, 1999.....	300	4,005	3,880	--	--	8,185
Incurred in first quarter 2000....	(229)	(500)	(158)	--	--	(887)
Incurred in second quarter 2000....	0	(1,015)	(149)	--	--	(1,164)
Incurred in third quarter 2000.....*	(71)	(823)	(155)	--	--	(1,049)
	-----	-----	-----	-----	-----	-----
Balance at September 30, 2000.....	\$ 0	\$ 1,667	\$ 3,418	\$ --	\$ --	\$ 5,085
	=====	=====	=====	=====	=====	=====

* During the third quarter of 2000, VIVUS reversed \$903 thousand of the restructuring reserve related primarily to inventory commitments and other manufacturing expenses that were not required as of September 30, 2000.

The Company expects that over the next twelve months, it will make cash payments of approximately \$1.1 million related to the restructuring, with the remaining \$4.0 million to occur in later years.

3. ACCRUED AND OTHER LIABILITIES

Accrued and other liabilities as of September 30, 2000 and December 31, 1999, in thousands, consist of:

	SEPTEMBER 30, 2000	DECEMBER 31, 1999
	-----	-----
Restructuring.....	\$ 5,085	\$ 8,185
Product returns*.....	2,339	4,300
Income taxes.....	2,770	3,016
Research and clinical expenses.....	2,327	2,803
Royalties.....	2,365	2,312
Unearned revenue.....	1,501	1,930
Employee compensation and benefits.....	1,945	1,287
Other.....	1,197	978
	-----	-----
	\$ 19,529	\$ 24,811
	=====	=====

- * During the first nine months of 2000, the Company recorded a provision for returns of \$961 thousand that was more than offset by actual returns of expired product of \$2.9 million.

4. 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 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. Certain options are excluded from the diluted income per share for periods presented because they are anti-dilutive.

5. SEGMENT INFORMATION

The Company has 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 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 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 nine months of 2000 and 1999, five customers accounted for the following percentages of revenue:

	2000	1999
	----	----
Customer A.....	21%	19%
Customer B.....	20%	15%
Customer C.....	19%	16%
Customer D.....	12%	12%
Customer E.....	10%	24%

6. SUBSEQUENT EVENTS

On October 25, 2000, the Company issued an irrevocable standby letter of credit for \$3.3 million in connection with its leased manufacturing facilities. The Company purchased a certificate of deposit as collateral for this letter of credit, which is restricted and not available for use in operations. This restriction will remain through the end of the lease term, including any renewals. The original lease term expires in 2002 and the Company has the option to extend the lease for two renewal terms of five years each.

On October 20, 2000, VIVUS withdrew its U.S. New Drug Application for its second-generation product, ALIBRA(R), a urethral microsuppository containing alprostadil and prazosin hydrochloride for the treatment of male erectile dysfunction. The Company expects to meet with the FDA in the near future to determine the next steps in the development of ALIBRA. (See Risk Factors "New Product Development" on page 12.)

The Management's Discussion and Analysis of Financial Condition and Results of Operations section contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Actual results could differ materially from those projected in the forward-looking statements as a result of the factors set forth in the Liquidity and Capital Resources section, the Risk Factors section, the Results of Operations section and the Description of Business section. The discussion of those factors is incorporated herein by this reference as if said discussion was fully set forth at this point.

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 the Risk Factors section starting on page 12 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 a specialty pharmaceutical company engaged in the development of innovative therapies for the treatment of quality-of-life disorders in men and women, with a focus on sexual dysfunction. The Company developed and manufactures the drug MUSE(R) and the medical device ACTIS(R), two innovations for the treatment of erectile dysfunction ("ED"), also known as impotence. The Company has filed an Investigational New Drug ("IND") application with the U.S. Food and Drug Administration ("FDA") for its female sexual dysfunction ("FSD") product, ALISTA(TM), and began enrollment for its first clinical study in October 2000. The Company also has ongoing research and development ("R&D") programs in ED and premature ejaculation ("PE"), and intends to pursue targeted technology acquisitions to expand its R&D pipeline.

In November 1996, the Company obtained marketing clearance by the FDA to manufacture and market its first product and commercially introduced MUSE in the U.S. 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. During 1998, the Company experienced a significant decline (more than 80%) in market demand for MUSE as a result of the introduction of Viagra in April 1998. During the second and third quarters of 1998, the Company took significant steps to restructure its operations 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.

During 1999, the Company continued to align its operations more closely with the Company's current and expected revenues. The Company achieved profitability for all quarters in 1999, earning \$0.58 per share for the year. Cash, cash equivalents and available-for-sale securities at December 31, 1999 increased \$16.5 million from December 31, 1998 to \$40.4 million, while total liabilities decreased \$5.1 million during the same period, resulting in a stronger balance sheet for investing in the future. The Company was awarded five patents in the areas of FSD, ED and PE to further build and strengthen its patent portfolio. The company established a targeted sales force in the U.S. to support its product, MUSE, in the marketplace. The Company submitted a New Drug Application ("NDA") for ALIBRA, its second-generation treatment for ED, to the FDA in December 1999.

During 2000, the Company continued to strengthen its balance sheet to enable investment in its R&D projects and to pursue targeted technology acquisitions to expand its pipeline. The Company solidified its FSD intellectual property position through an agreement with AndroSolutions, Inc. during the first quarter. Patient enrollment for the initial clinical study for ALISTA, the Company's FSD product, began in October 2000. The Company signed an agreement for distribution of MUSE internationally with Abbott in June 2000 and began shipping product in September 2000 in support of Abbott's launch activities in Europe and other countries worldwide. The U.S. Patent and Trademark Office awarded patents to VIVUS, providing broad protection for commercializing locally delivered PDE5 and PDE4 inhibitors, including combinations with other active agents, for the treatment of ED. The Company withdrew its NDA application for ALIBRA in October 2000 and plans to meet with the FDA in the near future to determine the next steps in the development of ALIBRA. The Company also filed a 510(k) notification with the FDA in October 2000, to provide over-the-counter (OTC) marketing of ACTIS, an adjustable constriction band used to enhance the erection process in men with ED.

FISCAL 2000

FIRST QUARTER

The Company reported net income of \$1.5 million, for \$0.05 per diluted share. The Company continued to strengthen its balance sheet, increasing cash by \$2 million to \$42.4 million while reducing total liabilities by \$5.2 million.

The Company further solidified its FSD intellectual property position through an agreement with AndroSolutions, Inc., whereby VIVUS has exclusive global rights to develop and commercialize FSD technologies based on the combined intellectual property pool.

The Company was awarded two new patents by the U.S. Patent & Trademark Office. The first provides the Company with broad patent protection for commercializing locally delivered PDE5 inhibitors, including combinations with other active agents, for the treatment of ED. The second provides VIVUS with broad patent protection for oral, topical, transdermal and transurethral administration of serotonin antagonists, specifically 5-HT3 antagonists, to treat PE in men.

SECOND QUARTER

The Company reported net income of \$890 thousand, for \$0.03 per diluted share. Cash and available-for-sale securities increased \$1.1 million to \$43.5 million from March 31, 2000.

The Company and Janssen Pharmaceutica International ("Janssen") agreed to terminate the distribution agreement for MUSE that was entered into in 1997.

The Company signed a distribution and marketing agreement granting Abbott Laboratories ("Abbott") exclusive rights for MUSE and ALIBRA, pending regulatory approval, covering all international markets outside the U.S. This agreement also provides Abbott with the option to co-develop and license future VIVUS transurethral products for the treatment of ED in this territory.

The Company was added to the list of companies included in the Russell 2000(R) Small-Cap U.S. Equity Index, which is widely used as a benchmark for both passive and active investment strategies.

THIRD QUARTER

The Company reported net income of \$208 thousand, for \$0.01 per diluted share. Cash and available-for-sale securities at September 30, 2000 increased \$700 thousand to \$44.2 million from June 30, 2000.

The Company filed an IND application with the FDA for its female sexual dysfunction (FSD) product, ALISTA(TM), and began enrollment for the initial clinical study in October 2000.

The Company manufactured and shipped product to Abbott, its new international partner, within three months of the distribution agreement being signed. Abbott began marketing and distributing MUSE in the United Kingdom in September, with distribution in Sweden and Germany occurring in mid-October. The Company continues to ship MUSE to Abbott in support of their launch activities in Europe and other countries worldwide.

The Company was awarded a new patent by the U.S. Patent & Trademark Office. This patent provides VIVUS with broad patent protection for commercializing local delivery of PDE4 inhibitors, including combinations with other active agents, for the treatment of ED.

The Company announced the promotion of Guy Marsh to the position of Vice President of Operations and General Manager. Mr. Marsh joined VIVUS in May 1998 as Senior Director of Operations, and has been instrumental in streamlining the Company's operations and in cost-cutting efforts.

John W. Dietrich, Ph.D. was appointed to the position of Vice President of Research and Development. Dr. Dietrich brings 20 years of experience in the pharmaceutical industry to VIVUS. During his career, he has coordinated and directed the discovery and development efforts for a variety of drug candidates. Most recently, Dr. Dietrich was Vice President of Research and Development at Cellegy Pharmaceuticals.

RESULTS OF OPERATIONS

THREE MONTHS ENDED SEPTEMBER 30, 2000 AND 1999

Gross product revenues for the quarter ended September 30, 2000 were \$5.0 million in the United States and \$256 thousand internationally, compared to \$5.6 million in the United States and \$1.1 million internationally for the quarter ended September 30, 1999. U.S. product revenue decreased 11% in the third quarter of 2000, compared to the same period last year. The Company believes that the decline is mainly attributed to Viagra being approved for the Veteran's Administration's (VA) formulary. The Company began shipping MUSE to its international partner, Abbott, during the third quarter of 2000 for distribution in certain European markets.

Total revenues in the third quarter of 2000 were reduced by a returns provision of \$294 thousand for U.S. shipments, compared to \$2.6 million in the third quarter of 1999. Higher returns in 1999 were attributable to excess inventories at wholesalers and in retail pharmacies throughout most of 1998 and the first half of 1999, resulting from the sharp decline in demand for MUSE in April 1998. During 2000, the provision for returns reflects management's estimate, based on historical experience, of returns in the U.S. expected to occur in the future related to shipments during this period. Total revenues in the third quarter 1999 also included \$2.0 million in milestone revenue related to marketing approval of MUSE in Spain.

Cost of goods sold was \$2.9 million for the third quarter of 2000, compared to \$2.8 million for the third quarter 1999. Gross margin for product sales increased by 10% to 41% in the third quarter of 2000 compared to the same period last year. This increase is due to lower returns in 2000 that were partially offset by lower sales volumes both in the U.S. and internationally.

Research and development ("R&D") expenses for the third quarter of 2000 were \$1.3 million, compared to \$1.4 million in the third quarter of 1999. The Company anticipates that R&D expenses will increase from the current levels as the Company begins clinical trials for its FSD product, ALISTA. Enrollment for the initial clinical trial for ALISTA began in October 2000.

Selling, general and administrative expenses were \$2.1 million for the third quarter 2000, compared to \$1.7 million in the third quarter of 1999. This increase is mainly attributed to increased investment in U.S. sales and marketing efforts.

During the third quarter, the Company reversed \$903 thousand of the restructuring reserve that was established in 1998. This reversal is related primarily to inventory commitments and other manufacturing expenses that are not required as of September 30, 2000.

The Company recorded a tax provision of ten percent (10%) of income before taxes for the third quarter of 2000, compared with five percent (5%) recorded in the same period of 1999. Both periods include the effect of net operating loss ("NOL") carried forward from prior periods. The tax rate would have been substantially higher if the NOLs had not been available to offset current income.

NINE MONTHS ENDED SEPTEMBER 30, 2000 AND 1999

Gross product revenues for the nine months ended September 30, 2000 were \$16.7 million in the U.S. and \$3.4 million internationally, compared to \$15.4 million in the U.S. and \$4.4 million internationally for the same period last year. The increase in U.S. product revenue is due to higher shipments in the first six months of 2000 as compared to the same time period in 1999 when wholesale inventory levels were significantly higher. This increase is partially offset by the decrease in U.S. revenue for the third quarter of 2000 as discussed above. Lower international product revenue for the nine-month period ended September 30, 2000 is attributable to the transition of marketing and distribution of MUSE to the Company's new partner, Abbott.

Total revenue for the nine months ended September 30, 1999 included \$6.0 million in milestone revenue related to marketing approval of MUSE in Germany, France and Spain. The returns provision in the first nine months of 2000 of \$961 thousand reflects management's estimate, based on historical experience, of returns expected to occur in the future related to shipments during this period. In 1999, the returns provision of \$4.1 million was higher mainly due to the excess inventories at wholesalers and retailers discussed above.

Cost of goods sold was \$8.7 million for the nine months ended September 30, 2000, compared to \$9.5 million for the same period of 1999. Gross margin for product sales increased by 16.3%, to 54%, in the first nine months of 2000 compared to the same period last year. Lower returns, higher U.S. sales volumes and greater production efficiencies were slightly offset by lower international sales to account for the overall increase in margin.

R&D expenses for the nine months ended September 30, 2000 were \$3.7 million, compared to \$5.0 million in the same period of 1999 when the Company was completing its Phase III clinical studies for ALIBRA.

Selling, general and administrative expenses were \$6.6 million for the nine months ended September 30, 2000, compared to \$4.6 million in the same period of 1999. This increase is mainly attributed to increased investments in U.S. sales and marketing efforts.

The Company recorded a tax provision of ten percent (10%) of income before taxes for the first nine-month period of 2000, compared with five percent (5%) recorded in the same period of 1999. Both periods include the effect of net operating loss ("NOL") carried forward from prior periods. The tax rate would have been substantially higher if the NOLs had not been 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 September 30, 2000, VIVUS has raised \$154.2 million from financing activities and has an accumulated deficit of \$88.3 million at September 30, 2000.

Cash, cash equivalents and available-for-sale securities totaled \$44.2 million at September 30, 2000, compared with \$40.4 million at December 31, 1999. This \$3.8 million increase is primarily the result of net cash provided by operating activities of \$3.6 million. On October 25, 2000, the Company issued an irrevocable standby letter of credit for \$3.3 million in connection with its leased manufacturing facilities. The Company purchased a certificate of deposit as collateral for this letter of credit, which is restricted and not available for use in operations. This restriction will remain through the end of the lease term, including any renewals. The original lease term expires in 2002 and the Company has the option to extend the lease for two renewal terms of five years each.

Accounts receivable at September 30, 2000 was \$2.4 million, compared with \$4.4 million at December 31, 1999, a decrease of \$2.0 million. The decrease is primarily the result of the receipt of a \$2 million milestone payment in the first quarter of 2000 from AstraZeneca for approval of MUSE in Italy.

Total liabilities were \$20.9 million at September 30, 2000, compared with \$27.3 million at December 31, 1999, a decrease of \$6.4 million. This reduction in liabilities is primarily the result of a reduction in the restructuring reserve of \$3.1 million, actual returns of expired product of \$2.9 million, and the recognition of unearned revenue of \$500 thousand. These decreases are partially offset by an increase in the returns provision of \$961 thousand.

RISK FACTORS

NEW PRODUCT DEVELOPMENT

The Company's future operating results may be adversely affected if the Company is unable to continue to develop, manufacture and bring to market new drug products rapidly. The process of developing new drugs and/or therapeutic products is inherently complex and uncertain. The Company must make long-term investments and commit significant resources before knowing whether its development programs will eventually result in products that will receive regulatory approval and achieve market acceptance. After the FDA and international regulatory authorities approve a product, the Company must manufacture sufficient volumes to meet market demand. This is a process that requires accurate forecasting of market demand. Given existing alternative treatments and the number of products introduced in the market each year, the drug development process becomes increasingly difficult, expensive and risky.

In December 1999, the Company submitted an NDA to the FDA to market ALIBRA, which it subsequently withdrew in October 2000. The Company plans to meet with the FDA in the near future to determine the next steps in the development of ALIBRA. There can be no assurance that the Company will re-file an NDA for ALIBRA. Even if the Company does re-file an NDA for ALIBRA, there can be no assurance that it would be approved or that it would be successful in the marketplace.

In May 2000, the Company filed for marketing authorization for ALIBRA with the European Agency for the Evaluation of Medicinal Products (EMA) under the Centralized Process in Europe. The Company plans to meet with the EMA to discuss its pending European application. Based on these discussions, the EMA may (1) ask the Company to provide more data; (2) ask the Company to perform additional clinical trials; or (3) not grant approval of the application. Even if ALIBRA is approved, there can be no assurances that this transurethral system to treat ED will be successful in the marketplace.

In September 2000, the Company submitted an IND to the FDA to begin clinical studies with its female sexual dysfunction product, ALISTA. Clinical studies will be focused on the treatment of female sexual arousal disorder ("FSAD"), a subcategory of FSD. Patient enrollment in the Company's initial study began in October 2000. There can be no assurances that the clinical studies will be successful. Even if the trials are successful, and the Company eventually files an NDA for ALISTA with the FDA, there are no assurances that it would be approved. Even if ALISTA eventually becomes an approved product, there can be no assurances that this treatment for FSD will be successful in the marketplace.

LIMITED SALES AND MARKETING EXPERIENCE

The Company supports MUSE sales in the U.S. through physician and patient information/help lines, targeted 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. After the launch of Viagra in April 1998, demand for MUSE declined more than eighty percent (80%) in the U.S. There can be no assurance that demand for the Company's product MUSE will not continue to decline further or that the Company will be able to adequately support sales of MUSE in the U.S.

In June 2000, the Company entered into an agreement granting Abbott exclusive marketing and distribution rights for MUSE in all countries outside the U.S. This agreement does not have minimum purchase commitments and the Company is entirely dependent on Abbott's efforts to distribute and sell the Company's product effectively in all markets except the U.S. There can be no assurance that such efforts will be successful or that Abbott 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 Viagra, 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 Viagra in the U.S. in April 1998 significantly decreased demand for MUSE.

Additional competitive products in the ED 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 abilities than VIVUS. 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, 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, 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.

DEPENDENCE ON SINGLE SOURCE OF SUPPLY

The Company relies on a single injection molding company, The Kipp Group ("Kipp"), for its supply of plastic applicator components. In turn, Kipp obtains its supply of resin, a key ingredient of the applicator, from a single source, Huntsman Corporation. The Company also relies on a single source, E-Beam Services, Inc. ("E-Beam"), for sterilization of its product. There can be no assurance that the Company will be able to identify and qualify additional sources of plastic components or an additional sterilization facility. The Company is required to receive FDA approval for suppliers. The FDA may require additional clinical trials or other studies prior to accepting a new supplier. Until the Company secures and qualifies additional sources of plastic components or an additional sterilization facility, it is entirely dependent upon Kipp and E-Beam. If interruptions in these supplies or services were to occur for any reason, including a decision by Kipp and/or E-Beam to discontinue manufacturing or services, political unrest, labor disputes or a failure of Kipp and/or E-Beam to follow regulatory guidelines, the development and commercial marketing of MUSE and other potential products could be delayed or prevented. An extended interruption in sterilization services or the Company's supply of plastic components would have a material adverse effect on the Company's business, financial condition and results of operations.

DEPENDENCE ON THIRD PARTIES

In June 2000, the Company entered into an international marketing and distribution agreement with Abbott to purchase the Company's products for distribution in all countries of the world except the U.S. This agreement does not have minimum purchase commitments and the Company is dependent on Abbott's efforts to distribute and sell the Company's product effectively. There can be no assurance that such efforts will be successful.

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, packs and ships its product; invoices customers, and collects related receivables. 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 agreement with WRB Communications ("WRB") to handle patient and healthcare professional hotlines for the Company. WRB maintains a staff of healthcare professionals to handle questions and inquiries about MUSE and ACTIS. These calls may include complaints about the Company's product due to efficacy or quality, as well as the reporting of adverse events. As a result of this agreement, the Company is dependent on WRB to effectively handle these hotline calls. There can be no assurance that such effort will be successful.

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 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 product samples effectively. There can be no assurance that such efforts will be successful.

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 pre-clinical 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.

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. Four U.S. patents have issued directed to methods and compositions for treating ED by transurethraly administering 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, Spain, Sweden and South Africa. Patent applications are pending in Denmark and Romania. The foreign patents and applications, like the U.S. patents, 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 the sole assignee of five U.S. patents deriving from patent applications originally filed by Alza, 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 transurethraly for the treatment of erectile dysfunction. With one exception, the patents derive from patent applications that were filed in the U.S. prior to June 8, 1995, and will therefore have a seventeen-year patent term calculated 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, the Netherlands, Spain, Sweden and Switzerland), Finland, Ireland, New Zealand, Norway, Portugal, South Africa and South Korea, and foreign applications are pending in Canada, 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 and Place patents and applications identified above, the Company has thirteen issued U.S. patents, twelve pending U.S. patent applications, three granted foreign patents, and twenty-three 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 PE in men, and FSD. One of the Company's issued patents covers the Company's ACTIS venous flow control device.

The Company has entered into an agreement with AndroSolutions, Inc., a privately held biomedical corporation based in Knoxville, Tennessee that owns patents and applications complementary to the Company's patents and applications directed to the treatment of FSD. Both the Company and AndroSolutions have contributed their FSD patents and applications into a jointly formed Limited Liability Company, ASIVI, LLC, which exclusively licenses to VIVUS worldwide rights to the common patents and applications.

The Company's success will depend in large part on the strength of its current and future patent position for the treatment of ED, PE and FSD. 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, through confidentiality agreements with employees and consultants. There can be no assurance that the agreements will not be breached, 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.

HISTORY OF LOSSES AND LIMITED OPERATING HISTORY

The Company has generated a cumulative net loss of \$88.3 million for the period from its inception through September 30, 2000. The Company must successfully manufacture and market MUSE and keep its expenditures in line with lower product revenues. The Company is subject to a number of risks including its ability to market, distribute and sell its product in the U.S., its reliance on Abbott to market and distribute MUSE internationally, intense competition, and its reliance on a single therapeutic approach to erectile dysfunction. There can be no assurance that the Company will be able to continue 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. The Company expects the gross margin from sales of MUSE to be less predictable in future periods, which may cause greater volatility in the Company's results of operations and financial condition.

RISKS RELATING TO INTERNATIONAL OPERATIONS

The Company's product MUSE 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 where 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.

DEPENDENCE ON THE COMPANY'S TRANSURETHRAL SYSTEM FOR ERECTION

MUSE, a drug product developed by the Company to treat ED, relies on a single therapeutic approach, a transurethral system for erection. 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 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 products, the results of which could have a material affect on the business operations and results of the Company.

FUTURE CAPITAL NEEDS AND UNCERTAINTY OF ADDITIONAL FINANCING

The Company anticipates that its existing capital resources combined with anticipated future revenues may not be sufficient to support the commercial introduction of any new products and as such, it continually evaluates alternative financing opportunities that may include joint ventures, co-development, or licensing agreements to support the development of its R&D pipeline.

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 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 activities of competitors; (iv) the progress of the Company's R&D programs; (v) the timing and results of pre-clinical testing and clinical trials; (vi) technological advances; and (vii) the level of resources that the Company devotes to sales and marketing capabilities.

GOVERNMENT REGULATION AND UNCERTAINTY OF PRODUCT APPROVALS

The Company's research, preclinical development, clinical studies, manufacturing and marketing of its products are subject to rigorous testing and extensive regulation processes of the FDA and equivalent foreign regulatory agencies. To date, the Company's product MUSE has received marketing clearance in 53 countries.

The Company submitted a New Drug Application ("NDA") for ALIBRA to the FDA in December 1999 and with the EMEA in May 2000. In October 2000, the Company withdrew its application from the FDA. The Company plans to meet with the FDA and the EMEA to determine the next steps in the development of ALIBRA. There is no guarantee, however, that the company will be successful in obtaining approvals for ALIBRA.

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 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 would have a material adverse effect on the Company's business, financial condition and results of operations.

In October 2000, the Company began enrolling patients in the initial study of its FSD product, ALISTA. The Company's clinical studies for ALISTA and future products will require safety and efficacy data that will entail 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 result in fines, suspensions of regulatory approvals, product recalls, operating restrictions and criminal prosecution, among other things. 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.

Failure to maintain satisfactory cGMP compliance would have a material adverse effect on the Company's ability to continue to market and distribute its products and, in the most serious cases, could result in the issuance of additional Warning Letters, seizure or recall of products, civil fines or closure of the Company's manufacturing facility until such cGMP compliance is achieved.

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 cGMP requirements and are subject to routine periodic inspections by the FDA and by certain state and foreign regulatory agencies for compliance with cGMP requirements 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 requirements 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.

LIMITED MANUFACTURING EXPERIENCE

The Company has limited experience in manufacturing and selling MUSE in commercial quantities. The Company leases 90,000 square feet of space in New Jersey, in which it constructed manufacturing and testing facilities. The FDA and European Medicine Controls Agency ("MCA") authorized the Company to begin commercial production and shipment of MUSE from this 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.

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 Viagra, third party payors have begun to restrict or eliminate reimbursement for erectile dysfunction treatments. While a large percentage 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 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. 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 healthcare payors. Furthermore, reimbursement for MUSE could be adversely affected by changes in reimbursement policies of governmental or private healthcare 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 September 11, 2000, the Company filed a Notice and Demand for Arbitration with the American Arbitration Association ("AAA") against AndroSolutions, Inc. ("ASI") in connection with certain contractual provisions governing the parties' joint venture, ASIVI, LLC ("ASIVI"). The Company seeks an award declaring that it is not liable to ASI for a \$625,000 milestone payment that ASI claims is due under the parties' Memorandum of Understanding dated October 14, 1999 (the "MOU"). The Company also seeks an award directing ASI's specific performance of other non-monetary contractual obligations. On October 5, 2000, ASI responded to the arbitration Demand, denying all claims and asserting its entitlement to the \$625,000 milestone payment. ASI also asserted counterclaims seeking an award directing VIVUS' specific performance of other non-monetary contractual obligations. The Company believes ASI's counterclaims are without merit and, on October 16, 2000, it filed its response to the counterclaims, denying all liability. The proceedings are being administered under the AAA's Expedited Procedures, and the parties anticipate a hearing on the merits before the end of the calendar year.

On May 19, 2000, the Company was named, along with other defendants, in a civil action filed in the Superior Court of New Jersey. The Complaint in this action alleges that plaintiff was the victim of sexual harassment during the second quarter of 1998, while she was working as a temporary worker for the Company at a facility operated by PACO Pharmaceutical Services, Inc. At the time, the Company was leasing space and workers from PACO to assist it with the manufacture of the Company's product, MUSE. The complaint alleges hostile work environment and quid pro quo sexual harassment, and seeks compensatory and punitive damages. The Company denies liability, and intends to defend the case vigorously. At this early stage in the litigation, it is not possible to predict the outcome of the suit with any degree of certainty. In addition, plaintiff has not yet provided the Company with information concerning the extent of her alleged damages, so it is not possible to estimate the extent of any loss in the event plaintiff prevails against the Company. Nevertheless, an adverse judgment in this litigation is not expected to have a material impact on the Company's financial position.

On November 3, 1999, the Company filed a demand for arbitration against Janssen Pharmaceutica International ("Janssen") with the American Arbitration Association pursuant to the terms of the Distribution Agreement entered into on January 22, 1997. The Company seeks compensation for inventory manufactured in 1998 in reliance on contractual forecasts and orders submitted by Janssen. The Company also seeks compensation for forecasts and order shortfalls attributed to Janssen 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's failure to use the requisite diligence and reasonable efforts to gain regulatory approval for and launch MUSE in each country of the Territory. This amendment also includes claims based on Janssen's development of a competing product intended for use in the treatment of male ED, in violation of the Distribution Agreement. The Company's amended demand seeks an award of \$7.9 million plus costs and interest. On October 20, 2000, Janssen submitted its response to the Company's amended arbitration demand denying liability on all claims, and asserting counterclaims against the Company for \$1.8 million based on the Company's alleged improper calculation of its Cost of Goods charged to Janssen pursuant to the Distribution Agreement. Although the Company has yet to file its response to the counterclaims, the Company believes they are without merit and intends to defend against them vigorously. Administration of the arbitration has been transferred to JAMS and a three-member arbitration panel has been selected. The parties are currently in the process of conducting discovery and anticipate a hearing sometime in the first half of 2001.

On October 5, 1998, the Company was named in a civil action filed in the Superior Court of New Jersey by its landlord. This Complaint sought 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 litigation was dismissed on the Company's motion for summary judgment, and the parties were directed to proceed to arbitration to determine the amount of removal security to be posted. The Company and its landlord have reached agreement whereby the Company issued in October 2000 an irrevocable standby letter of credit for \$3.3 million for this security deposit.

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

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
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 the Registrant 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.
- 27.1 Financial Data Schedule

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+ 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.
- (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.

(b) REPORTS ON FORM 8-K

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.

Date: November 13, 2000

VIVUS, Inc.

/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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3-MOS
DEC-31-2000
JUL-01-2000
SEP-30-2000
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(227)
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4,978
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5,428
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0
0
231
(23)
208
0
0
0
208
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0.01