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, 2001

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, 2001, 32,630,544 shares of common stock were outstanding.

Exhibit Index on Page 25

TABLE OF CONTENTS

PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

VIVUS, INC.

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

ASSETS

	SEPTEMBER 30, 2001	DECEMBER 31, 2000
	(UNAUDITED)	
Current assets:		
Cash and cash equivalents	$ 13,910	$ 29,236
Available-for-sale securities	10,252	9,187
Accounts receivable, net	2,583	3,434
Inventories, net	3,454	5,045
Prepaid expenses and other assets	1,351	1,143
Total current assets	31,550	48,045
Property and equipment, net	12,915	14,294
Restricted cash	3,324	3,324
Available-for-sale securities, non-current	12,658	3,511
Total assets	$ 60,447	$ 69,174
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,436	$ 1,775
Accrued and other liabilities	11,093	13,289
Total current liabilities	12,529	15,064
Accrued and other long-term liabilities	3,923	3,923
Total liabilities	16,452	18,987
Stockholders' equity:		
Common stock; $.001 par value; shares authorized 200,000; shares outstanding — September 30, 2001, 32,631; December 31, 2000, 32,461	33	32
Paid in capital	133,762	133,288
Accumulated other comprehensive income	418	165
Accumulated deficit	(90,218)	(83,298)
Total stockholders' equity	43,995	50,187
Total liabilities and stockholders' equity	$ 60,447	$ 69,174

VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data)

	THREE MONTHS ENDED		NINE MONTHS ENDED	
	SEPTEMBER 30, 2001	SEPTEMBER 30, 2000	SEPTEMBER 30, 2001	SEPTEMBER 30, 2000
	(UNAUDITED)	(UNAUDITED)	(UNAUDITED)	(UNAUDITED)
Revenue				
US product	$ 5,146	$ 5,016	$15,415	$16,719
International product	708	256	3,759	3,434
Returns	(301)	(294)	(892)	(961)
Total revenue	5,553	4,978	18,282	19,192
Cost of goods sold	3,286	2,942	10,083	8,733
Gross profit	2,267	2,036	8,199	10,459
Operating expenses:				
Research and development	2,002	1,289	9,943	3,702
Selling, general and administrative	2,429	2,100	7,378	6,599
Other restructuring costs	—	(903)	—	(903)
Total operating expenses	4,431	2,486	17,321	9,398
(Loss) income from operations	(2,164)	(450)	(9,122)	1,061
Interest and other income	550	681	1,710	1,877
(Loss) income before benefit (provision) for income taxes	(1,614)	231	(7,412)	2,938
Benefit (provision) for income taxes	492	(23)	492	(294)
Net (loss) income	$ (1,122)	$ 208	$ (6,920)	$ 2,644
Net (loss) income per share:				
Basic	$ (0.03)	$ 0.01	$ (0.21)	$ 0.08
Diluted	$ (0.03)	$ 0.01	$ (0.21)	$ 0.08
Shares used in per share computation:				
Basic	32,609	32,371	32,538	32,290
Diluted	32,609	33,530	32,538	33,621

VIVUS, INC.

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

	THREE MONTHS ENDED		NINE MONTHS ENDED	
	SEPTEMBER 30, 2001	SEPTEMBER 30, 2000	SEPTEMBER 30, 2001	SEPTEMBER 30, 2000
	(UNAUDITED)	(UNAUDITED)	(UNAUDITED)	(UNAUDITED)
Net (loss) income	$(1,122)	$ 208	$(6,920)	$2,644
Other comprehensive (loss) income:				
Unrealized gain on securities	258	118	253	192
Income tax provision	—	(12)	—	(19)
	258	106	253	173
Comprehensive (loss) income	$ (864)	$ 314	$(6,667)	$2,817

VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	NINE MONTHS ENDED SEPTEMBER 30,	
	2001	2000
	(UNAUDITED)	(UNAUDITED)
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net (loss) income	$ (6,920)	$ 2,644
Adjustments to reconcile net (loss) income to net cash (used for) provided by operating activities:		
Depreciation and amortization	1,684	1,816
Changes in assets and liabilities:		
Accounts receivable	851	2,071
Inventories	1,591	207
Prepaid expenses and other assets	(208)	3,237
Accounts payable	(339)	(1,094)
Accrued and other liabilities	(2,196)	(5,281)
Net cash (used for) provided by operating activities	(5,537)	3,600
CASH FLOWS FROM INVESTING ACTIVITIES:		
Property and equipment purchases	(305)	(455)
Security purchases	(28,019)	(117,965)
Proceeds from sale/maturity of securities	18,060	132,624
Net cash (used for) provided by investing activities	(10,264)	14,204
CASH FLOWS FROM FINANCING ACTIVITIES:		
Exercise of common stock options	315	293
Sale of common stock through employee stock purchase plan	160	131
Net cash provided by financing activities	475	424
NET (DECREASE) INCREASE IN CASH	(15,326)	18,228
CASH:		
Beginning of period	29,236	8,785
End of period	$ 13,910	$ 27,013
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Unrealized gain on securities	$ 253	$ 192
SUPPLEMENTAL CASH FLOW DISCLOSURE:		
Income taxes paid	$ 151	$ 535

VIVUS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2001

1. BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulations S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the nine-month period ended September 30, 2001 are not necessarily indicative of the results that may be expected for the year ending December 31, 2001. 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, 2000.

2. INVENTORIES

Inventories are recorded net of reserves of $7.5 million and $7.7 million as of September 30, 2001 and December 31, 2000, respectively, and consist of:

	SEPTEMBER 30, 2001	DECEMBER 31, 2000
	(000's)	
Raw materials	$2,259	$3,497
Work in process	113	61
Finished goods	1,082	1,487
Inventory, net	$3,454	$5,045

3. ACCRUED AND OTHER LIABILITIES

Accrued and other liabilities as of September 30, 2001 and December 31, 2000 consist of:

	SEPTEMBER 30, 2001	DECEMBER 31, 2000
	(000's)	
Restructuring	$ 3,923	$ 4,266
Product returns	1,499	2,008
Income taxes	3,185	3,332
Research and clinical expenses	1,249	2,076
Royalties	487	541
Unearned revenue	2,060	1,917
Employee compensation and benefits	1,892	1,670
Other	721	1,402
	15,016	17,212
Amount classified as short-term	(11,093)	(13,289)
Amount classified as long-term	$ 3,923	$ 3,923

4. RESTRUCTURING RESERVE

During 1998, VIVUS, Inc. experienced a significant decline in market demand for MUSE® due to the market launch of sildenafil, the first oral treatment for erectile dysfunction. During the second and third quarters of 1998, the Company took significant steps to restructure its operations in an attempt to bring the cost structure in line with current and projected revenues. (See Notes 1 and 6 to the Consolidated Financial Statements for the year ended December 31, 2000 included in the Company's Annual Report on Form 10-K.) The restructuring reserve balance at September 30, 2001 was $3.9 million, down from $4.3 million at December 31, 2000.

	INVENTORY AND RELATED COMMITMENTS	PROPERTY AND RELATED COMMITMENTS	TOTAL
		(000's)	
Balance at December 31, 2000	$942	$3,324	$4,266
Activity in first quarter 2001	0	(123)	(123)
Activity in second quarter 2001	0	(124)	(124)
Activity in third quarter 2001	(40)	(56)	(96)
Balance at September 30, 2001	$902	$3,021	$3,923

The Company expects that the remaining $3.9 million in cash payments will not occur until periods beyond 2002.

5. CONCENTRATION OF CUSTOMERS AND SUPPLIERS

During the first nine months of 2001 and 2000, sales to significant customers as a percentage of total revenues were as follows:

	2001	2000
Customer A	22%	21%
Customer B	19%	2%
Customer C	16%	20%
Customer D	16%	19%
Customer E	11%	12%

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

This Quarterly Report on Form 10-Q contains forward-looking statements about the potential development and commercialization of pharmaceutical products and reflects management's current beliefs. However, as with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. 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 pharmaceutical company developing innovative products to improve quality of life in men and women. The Company developed and markets in the U.S. MUSE® (alprostadil) and ACTIS®, two innovations in the treatment of erectile dysfunction ("ED"). The Company has entered into a license and supply agreement with Abbott Laboratories ("Abbott") (NYSE:ABT) for the international marketing and distribution of its male transurethral ED products. In Canada, VIVUS has entered into a license and supply agreement with Paladin Labs, Inc. ("Paladin") (TSE:PLB) for the marketing and distribution of MUSE. We have ongoing research and development ("R&D") programs, including projects in ED, female sexual dysfunction ("FSD"), and premature ejaculation ("PE").

Following our restructuring in 1998, substantial efforts were devoted to bring expenses in line with revenues. These efforts resulted in a significant improvement in our cash resources, which has enabled continued investment in our R&D projects. The current status of certain R&D projects is depicted in the chart below.

Indication	Product Candidate	Progress
Erectile Dysfunction	ALIBRA	Regulatory Review
	TA-1790 (oral)	Phase I
	TA-1790 (transurethral)	Pre-clinical
Female Sexual Dysfunction	ALISTA (topical PGE1)	Phase II
	TA-1790	Pre-clinical
Premature Ejaculation	VI-0134	Phase I

Recent progress and current plans in our R&D projects include:

- **ALISTA -** A proprietary formulation of alprostadil applied locally to the female genitalia to treat FSD.
  - Our first Phase II clinical study, which was an in-clinic, multi-center trial designed to evaluate the safety of and response to ALISTA, was completed. Data from this study will be available in the fourth quarter of 2001.
  - Our expanded Phase II study, which will be a trial designed to evaluate the efficacy and safety of ALISTA when used by women at home with their partner, is expected to begin in the first quarter of 2002.
- **TA-1790 -** A fast-acting, highly selective, potent phosphodiesterase type 5 (PDE5) inhibitor for the oral and local treatments of ED and FSD.
  - Discussions were held with the U.S. Food & Drug Administration ("FDA") regarding our anticipated fourth quarter submission of an Investigational New Drug Application ("IND") for TA-1790 as an oral, on demand product for the treatment of ED.
  - We began pre-clinical development work on the local administration of TA-1790, alone and in combination with alprostadil, for the treatment of ED. Our goal for the local administration of TA-1790 is to provide an effective therapy for patients who do not have success with oral treatments.
- **VI-0134** — An on demand, oral treatment for PE.
  - We intend to initiate a clinical trial with the new oral formulation of VI-0134 during the fourth quarter of 2001.

We continue to place significant emphasis on securing global intellectual property rights and are aggressively pursuing new patents to expand upon our strong foundation for commercializing products in development. Recently, we were awarded two new patents in the U.S. in the area of female sexual dysfunction, which further strengthens our patent position. In the U.S., patents and patent applications licensed to and developed by VIVUS currently include 23 in ED, 16 in FSD and 6 in PE.

FISCAL 2001 HIGHLIGHTS

FIRST QUARTER

The Company reported a net loss of $4.9 million, for a $0.15 net loss per share. These results included up-front, non-refundable milestone payments totaling $5 million to Tanabe for licensing TA-1790.

VIVUS signed a development, license and supply agreement with Tanabe for its proprietary phosphodiesterase type 5 (PDE5) inhibitor TA-1790. Under the terms of this agreement, we acquired worldwide rights, except Japan, China and certain Pacific Rim countries, to develop and commercialize TA-1790 for the oral and local treatments of male and female sexual dysfunction.

We initiated a Phase II multi-center, double-blind, placebo controlled clinical trial for our product ALISTA.

SECOND QUARTER

The Company reported a net loss of $914 thousand, for a $0.03 net loss per share. Increased spending for R&D and lower U.S. product revenue contributed to the loss.

VIVUS was awarded a new patent by the U.S. Patent & Trademark Office. This patent strengthens our proprietary protection in the field of PE, allowing for broad treatment claims for PE by administration of 5-HT4 agonists, alone or in combination with other agents.

We reported results from our Phase I safety study for ALISTA, which showed that a single dose of ALISTA topically applied in healthy volunteers was well tolerated both locally and systemically.

THIRD QUARTER

The Company reported a net loss of $1.1 million, for a $0.03 net loss per share. Contributing to the loss were increased R&D expenses partially offset by an income tax benefit.

We completed patient dosing in a Phase II study of our FSD product, ALISTA. The study was conducted to evaluate the safety and efficacy of topically applied ALISTA in subjects with FSD. We also began the manufacture of clinical supplies and clinical site selection for our next Phase II ALISTA study, a multi-center, double-blind, placebo-controlled evaluation of topical alprostadil administered at home for the treatment of women with FSD.

The Company was awarded a new patent by the U.S. Patent & Trademark Office in the area of female sexual dysfunction.

RESULTS OF OPERATIONS

Three Months Ended September 30, 2001 and 2000

U.S. net product revenue for the quarter ended September 30, 2001 was $4.8 million, compared to $4.7 million for the quarter ended September 30, 2000.

International product revenue was $708 thousand for the third quarter of 2001, an increase of $452 thousand over the same period last year. In the third quarter of 2000, initial shipments of product to Abbott did not begin until September.

Cost of goods sold was $3.3 million for the third quarter of 2001, compared to $2.9 million for the third quarter 2000. Gross margin remained constant for both periods at 41%. Lower international production volume is anticipated; thus, the Company expects that gross margin will decline in the fourth quarter of 2001.

Research and development expenses for the third quarter of 2001 increased $713 thousand to $2.0 million, as compared to the three months ended September 30, 2000. The increase is primarily due to expenses related to development work for TA-1790.

Selling, general and administrative expenses of $2.4 million for the third quarter of 2001 were $329 thousand higher than the same period last year due to increased investment in U.S. sales and marketing efforts.

During the third quarter of 2001, the Company recorded a tax benefit of $492 thousand based on an updated estimate of its net tax liabilities for the year. During fiscal year 2000, VIVUS recorded a ten percent (10%) tax provision, which included the effect of net operating losses (“NOLs”) carried forward from prior periods. The 2000 tax rate would have been substantially higher if the NOLs had not been available to offset current income.

Nine Months Ended September 30, 2001 and 2000

Net product revenues for the nine months ended September 30, 2001 were $14.5 million in the U.S. and $3.8 million internationally, compared to $15.8 million in the U.S. and $3.4 million internationally for the same period last year. Demand for MUSE in the U.S., based on prescription information reported by NDC Health, has stabilized at approximately $5.0 million a quarter for 2001 in comparison to declining prescriptions throughout fiscal year 2000.

For the nine months ended September 30, 2001, cost of goods sold increased $1.4 million to $10.1 million, as compared to the same period last year. The increase during 2001 is primarily due to a one-time reduction in the first quarter 2000 cost of goods sold associated with the termination of the distribution agreement with AstraZeneca. Gross profit margin for the first nine months of 2001 was 45%, compared with 54% in the same period last year. Lower revenue and higher cost of goods in the first nine months of 2001 contributed to the decline in margin.

R&D expenses for the nine months ended September 30, 2001 were $9.9 million, $6.2 million higher than the same period last year. The increase is primarily due to expenses associated with licensing and developing the proprietary compound TA-1790 for the oral and local treatments of male and female sexual dysfunction. Included in these expenses are the up-front non-refundable payments totaling $5.0 million made to Tanabe during the first quarter 2001.

Selling, general and administrative expenses were $7.4 million for the nine months ended September 30, 2001, $779 thousand higher than the same period last year. Increased investment in U.S. sales and marketing efforts and expenses associated with the ALZA arbitration contributed to the increase in 2001.

Operating expenses were lower in the nine months ended 2000, compared to the current nine months ended September 30, 2001 due to the reversal of $903 thousand of the restructuring reserve related primarily to inventory commitments and other manufacturing expenses that was not required.

During the third quarter of 2001, the Company recorded a tax benefit of $492 thousand based on an updated estimate of its net tax liabilities for the year. During fiscal year 2000, VIVUS recorded a ten percent (10%) tax provision, which included the effect of net operating losses (“NOLs”) carried forward from prior periods. The 2000 tax rate would have been substantially higher if the NOLs had not been available to offset current income.

LIQUIDITY AND CAPITAL RESOURCES

Since its inception, the Company has financed operations primarily from the sale of preferred and common stock. Through September 30, 2001, VIVUS raised $154.9 million from financing activities and has an accumulated deficit of $90.2 million at September 30, 2001.

Unrestricted cash, cash equivalents and available-for-sale securities totaled $36.8 million at September 30, 2001, a decrease of $5.1 million from December 31, 2000. This decrease is due primarily to the $5 million in milestone payments made to Tanabe for licensing TA-1790.

Capital resources from operating activities are expected to decline over the next several quarters as the Company continues to invest in its R&D pipeline. We expect that our existing capital resources combined with future cash flows will be sufficient to support operating needs throughout the next twelve to twenty-four months. Financing in future periods will most likely be required to fund further development of our R&D pipeline, as well as to enable us to take any future products to the marketplace. Our future capital requirements will depend upon numerous factors, including: (i) the progress of our R&D projects; (ii) the scope, timing and results of pre-clinical testing and clinical trials; (iii) the results of operations; (iv) the cost, timing and outcome of regulatory reviews; (v) the rate of technological advances; (vi) ongoing determinations of the potential commercial success of our products under development; (vii) the level of resources devoted to sales and marketing capabilities; and (viii) the activities of competitors.

To provide additional capital when needed, we will evaluate alternative financing sources, including, but not limited to, the issuance of additional equity or debt securities, corporate alliances, joint ventures, and licensing agreements. However, there can be no assurance that funding will be available on favorable terms, if at all, when needed.

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.

RISK FACTORS

NEW PRODUCT DEVELOPMENT AND UNCERTAINTY OF PRODUCT APPROVALS

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. Given existing treatments and the number of products introduced in the market each year, the drug development process becomes increasingly difficult, expensive and risky. There is no guarantee that future clinical studies will confirm the safety and efficacy of any product in development or that the Company will receive regulatory approval for such products. Further, even if the Company were to receive regulatory approval for a product, there could be no assurance that such product would prove to be commercially successful or profitable.

In January 2001, VIVUS signed a licensing agreement with Tanabe, a leading Japanese pharmaceutical company, for Tanabe's proprietary phosphodiesterase type 5 (PDE5) inhibitor compound TA-1790 for the oral and local treatment of male and female sexual dysfunction. Tanabe has conducted a Phase I clinical trial and VIVUS intends to initiate additional clinical studies required for regulatory approval of an oral treatment for ED. However, as with any pharmaceutical product under development, there are significant risks in development, regulatory approval and commercialization of new compounds. There are no guarantees that future clinical studies will confirm the preliminary pre-clinical and clinical results or that the compound TA-1790 will receive regulatory approval for any indication. Further, even if the Company were to receive regulatory approval for a product, there could be no assurance that such a product would prove to be commercially successful or profitable.

The Company has completed certain clinical studies and plans to continue the development of its product ALISTA through expanded clinical studies for the treatment of FSD. There are no guarantees that future clinical studies will confirm the preliminary pre-clinical and clinical results or that ALISTA will receive regulatory approval for the treatment of FSD. 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. Even if ALISTA eventually becomes an approved product, there can be no assurances that this treatment for FSD will be successful in the marketplace.

The Company plans to initiate a clinical trial in 2001 with its new oral release formulation of VI-0134 for the treatment of PE. However, there can be no assurance that this trial or future clinical studies will be successful or that a product for the treatment of PE, if approved, will prove to be commercially successful.

The Company filed for marketing authorization for ALIBRA with the European Agency for the Evaluation of Medicinal Products (EMEA) under the Centralized Process in Europe in May 2000. The Company subsequently met with the EMEA and submitted its response to inquiries the EMEA had regarding data presented in the original application. A meeting with the EMEA is scheduled for the fourth quarter of 2001 to discuss this filing. Based on the outcome of this meeting, the EMEA may (1) require the Company to provide more data; (2) require 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 December 1999, the Company submitted an NDA to the FDA to market ALIBRA, which it subsequently withdrew in October 2000. The Company met with the FDA in December 2000 and continues to communicate with the agency to determine what additional data is required to obtain marketing clearance for 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 will be approved or that ALIBRA will be successful in the marketplace.

FUTURE CAPITAL NEEDS AND UNCERTAINTY OF ADDITIONAL FINANCING

Capital resources from operating activities are expected to decline over the next several quarters as the Company continues to invest in its R&D projects. The Company expects that its existing capital resources combined with future cash flows will be sufficient to support operating needs throughout the next twelve to twenty-four months. Financing in future periods will most likely be required

to fund further development of our R&D pipeline, as well as to enable the Company to take any future products to the marketplace. Future capital requirements will depend upon numerous factors, including: (i) the progress of R&D projects; (ii) the scope, timing and results of pre-clinical testing and clinical trials; (iii) the results of operations; (iv) the cost, timing and outcome of regulatory reviews; (v) the rate of technological advances; (vi) ongoing determinations of the potential commercial success of products under development; (vii) the level of resources devoted to sales and marketing capabilities; and (viii) the activities of competitors.

To provide additional capital when needed, the Company will evaluate alternative financing sources, including, but not limited to, the issuance of additional equity or debt securities, corporate alliances, joint ventures, and licensing agreements. However, there can be no assurance that funding will be available on favorable terms, if at all, when needed.

INTENSE COMPETITION

Competition in the pharmaceutical and medical products industries is intense and is characterized by extensive research efforts and rapid technological progress. Other treatments for ED exist including 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 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. For instance, both Lilly ICOS LLC and Bayer AG filed NDAs with the FDA in June and September 2001, respectively, for their oral ED medications. These entities may market commercial products either on their own or through collaborative efforts. 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 could render the Company’s marketed and development 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.

LIMITED SALES AND MARKETING IN THE U.S.

The Company supports MUSE sales in the U.S. through a small field-based sales force that targets major accounts and the top prescribers of MUSE. Additionally, telephone marketers focus on the second tier of urologists who prescribe MUSE. Physician and patient information/help telephone lines are available to answer additional questions that may arise after reading the inserts or after actual use of the product. The sales force actively participates in national urologic and sexual dysfunction forums and conferences, such as the American Urological Association annual and regional meetings and the International Society for Impotence Research. From a market demand basis, prescriptions of MUSE declined during the period from 1998 through December 2000. Prescriptions have remained at a consistent level during 2001. With regard to future demand, though, there can be no assurance that the sales efforts will effectively maintain current sales levels. Along with competition and the changing market environment, there can be no assurance that demand for MUSE sales will continue or that the Company will be able to adequately support sales of MUSE in the U.S. in the future.

DEPENDENCE ON THIRD PARTIES

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

VIVUS entered into an agreement granting Abbott exclusive marketing and distribution rights for MUSE in all countries outside the U.S. and Canada. 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. and Canada. There can be no assurance that such efforts will be successful or that Abbott will continue to support the product.

A distribution agreement exists between VIVUS and CORD Logistics, Inc. (“CORD”), a wholly owned subsidiary of Cardinal Health, Inc. Under this agreement, CORD (i) warehouses the Company’s finished goods for U.S. distribution; (ii) takes customer orders; (iii) picks, packs and ships its product; (iv) invoices customers; and (v) collects related receivables. As a result of this distribution agreement, 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.

Gibraltar Laboratories (“Gibraltar”) performs sterility testing on finished product manufactured by the Company to ensure that it complies with product specifications. Gibraltar also performs microbial testing on water and compressed gases used in the manufacturing process and microbial testing on environmental samples to ensure that the manufacturing environment meets appropriate cleanliness standards. The Company is dependent on Gibraltar to perform testing and issue reports on finished product and the manufacturing environment in a manner that meets regulatory compliance standards. There can be no assurance that such efforts will be successful.

The Company has 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 calls and inquiries. There can be no assurance that such efforts will be successful.

VIVUS 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.

RAW MATERIALS

The Company is required to receive regulatory approval for suppliers. The Company has obtained its current supply of alprostadil from two approved sources. The first is Spolana Chemical Works a.s. in Neratovice, Czech Republic (“Spolana”). The second is CHINOIN Pharmaceutical and Chemical Works Co., Ltd. (“Chinoin”). Chinoin is the Hungarian subsidiary of the French pharmaceutical company Sanofi Synthelabo. At the present time, Spolana is the sole source of supply of alprostadil approved for use in the manufacture of product for distribution in Europe, and the Company has a limited supply. Certain restrictions have been put in place by the European regulatory authorities that would require a variation to be approved before VIVUS can use the Chinoin alprostadil supply for European manufacture, if at all. The Company has transferred marketing licenses in Europe to Abbott and Abbott filed the variation with the European regulatory authorities for the use of Chinoin alprostadil on September 26, 2001. There can be no assurance that this variation will be approved in a timely manner or at all, which could result in a material impact on the Company’s ability to supply MUSE to Abbott for distribution in Europe.

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

SINGLE MANUFACTURING FACILITY

The Company leases 90,000 square feet of space in Lakewood, New Jersey, in which it constructed manufacturing, warehousing and testing facilities. The FDA and MCA authorized the Company to begin commercial production and shipment of MUSE from this facility in June and March 1998, respectively. MUSE is manufactured in this facility and the Company has no immediate plans to construct another manufacturing site. Since MUSE is produced with custom-made equipment under specific manufacturing conditions, the inability of our manufacturing facility to produce MUSE for whatever reason would have a material adverse effect on the Company’s business, financial condition and results of 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 U.S. 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 transurethrally.

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 transurethrally administering an active agent. Patents have also been granted in several countries outside of the U.S. 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 ED, and specific drug formulations that can be delivered transurethrally for the treatment of ED. 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. Additionally, foreign patents have been granted in numerous countries outside of the U.S.

The Company is the sole assignee of patent applications filed in the name of Dr. Gary W. Neal and AndroSolutions, Inc. (“ASI”) in the U.S. and internationally that are complementary to the Company’s patents and applications directed to the treatment of FSD.

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

In addition to the Voss, Kock, Neal and Place patents and applications identified above, the Company has numerous issued and pending U.S. patents, as well as foreign patents pending and granted. Many 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 and FSD. One of the Company’s issued patents covers the Company’s ACTIS venous flow control device.

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 sufficient commercial protection to the Company. The Company could incur substantial costs in proceedings before the U.S. 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 can be 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., which is exclusively licensed to VIVUS. As a result of the opposition proceeding, the Opposition Division of the EPO held certain pharmaceutical composition claims in the European patent unpatentable. 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.

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 will 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.

DEPENDENCE ON SINGLE SOURCE OF SUPPLY

The Company relies on a single injection molding company, Porex Medical Products, Inc. ("Porex") (formerly The Kipp Group), for its supply of plastic applicator components. In turn, Porex 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 Porex and E-Beam. If interruptions in these supplies or services were to occur for any reason, including a decision by Porex and/or E-Beam to discontinue manufacturing or services, political unrest, labor disputes or a failure of Porex 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.

RISKS RELATING TO INTERNATIONAL OPERATIONS

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 an 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 U.S.

HISTORY OF LOSSES

The Company has generated a cumulative net loss of $90.2 million for the period from its inception through September 30, 2001 and anticipates losses for the next several quarters due to increased investment in its R&D programs and limited revenues. The Company is subject to a number of risks including its ability to develop and successfully commercialize products in its R&D pipeline, its ability to market, distribute and sell its products in the U.S., its reliance on others to market and distribute MUSE internationally, intense competition, and its reliance on a single therapeutic approach to ED. 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.

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 product, the results of which could have a material effect on the business operations and results of the Company since MUSE is the only transurethral product VIVUS currently produces and sells.

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, regulatory affairs, clinical trial management and pre-clinical testing. There can be no assurance that the Company will be able to hire or retain 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.

GOVERNMENT REGULATION

The Company's research, pre-clinical 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 more than 40 countries worldwide.

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.

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 outcomes. 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 compliance with Current Good Manufacturing Practices ("cGMP") 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 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.

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. 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 products in the U.S., the Company's ability to successfully sell its products 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 re-incorporation in the State of Delaware (the "re-incorporation") and adopted a Preferred Shares Rights Plan. The Company's re-incorporation 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 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. On November 20, 2000, the Company filed its response to the counterclaims, denying all liability. The Company believes that Janssen's counterclaims 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. The arbitration hearing in this matter has been re-scheduled to occur in March 2002.

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

EXHIBIT NUMBER	DESCRIPTION
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 VIVUS International Limited and Janssen Pharmaceutica International
10.28(7)	Lease Agreement made as of January 1, 1997 between the Registrant and Airport Associates
10.29(7)	Lease Amendment No. 1 as of February 15, 1997 between Registrant and Airport Associates
10.29A(10)	Lease Amendment No. 2 dated July 24, 1997 by and between the Registrant and Airport Associates
10.29B(10)	Lease Amendment No. 3 dated July 24, 1997 by and between the Registrant and Airport Associates
10.31(9)+	Manufacture and Supply Agreement between Registrant and Spolana Chemical Works, A.S. dated May 30, 1997
10.32A(11)	Agreement between ADP Marshall, Inc. and the Registrant dated December 19, 1997
10.32B(11)	General Conditions of the Contract for Construction
10.32C(11)	Addendum to General Conditions of the Contract for Construction
10.34(12)+	Agreement dated as of June 30, 1998 between Registrant and Alza Corporation
10.35(12)+	Sales Force Transition Agreement dated July 6, 1998 between Registrant and Alza Corporation
10.36(13)	Form of, “Change of Control Agreements,” dated July 8, 1998 by and between the Registrant and certain Executive Officers of the Company.
10.30A(13)	Amendment of lease agreement made as of October 19, 1998 by and between Registrant and 605 East Fairchild Associates, L.P.
10.37(13)	Sublease agreement made as of November 17, 1998 between Caliper Technologies, Inc. and Registrant
10.22B(13)+	Amendment Two, dated as of December 18, 1998 by and between VIVUS, Inc. and CHINOIN Pharmaceutical and Chemical Works Co.
10.31A(13)+	Amendment One, dated as of December 12, 1998 by and between VIVUS, Inc. and Spolana Chemical Works, A.S.
10.38(14)+	License Agreement by and between ASIVI, LLC, AndroSolutions, Inc., and the Registrant dated February 29, 2000
10.38A(14)+	Operating Agreement of ASIVI, LLC, between AndroSolutions, Inc. and the Registrant dated February 29, 2000
10.39(14)	Sublease agreement between KVO Public Relations, Inc. and the Registrant dated December 21, 1999
10.40(15)+	License and Supply Agreement made as of May 23, 2000 between the Registrant and Abbott Laboratories, Inc.
10.41(16)+	License and Supply Agreement made as of November 20, 2000 between the Registrant and Paladin Labs, Inc.
10.42(16)+	Development, License and Supply Agreement made as of January 22, 2001 between the Registrant and TANABE SEIYAKU CO., LTD.

EXHIBIT NUMBER	DESCRIPTION
10.43(17)++	Settlement and Modification Agreement made as of July 12, 2001 between ASIVI, LLC, AndroSolutions, Inc. Gary W. Neal and the Registrant.

+ Confidential treatment granted.
++ Confidential treatment requested.
(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.

(16) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 2000.
(17) Incorporated by reference to the same numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.

(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, 2001

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
None	

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