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 MARCH 31, 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	94-3136179
(STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION)	(I.R.S. EMPLOYER IDENTIFICATION NUMBER)
1172 CASTRO STREET MOUNTAIN VIEW, CA	94040
(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES)	(ZIP CODE)

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

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

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 March 31, 2001, 32,479,846 shares of common stock were outstanding.

Exhibit Index on Page 23

PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

VIVUS, INC.

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

ASSETS

	MARCH 31, 2001	DECEMBER 31, 2000
	(UNAUDITED)	
Current assets:		
Cash and cash equivalents	$ 20,829	$ 29,236
Available-for-sale securities	9,140	9,187
Accounts receivable, net	3,768	3,434
Inventories, net	4,425	5,045
Prepaid expenses and other assets	816	1,143
Total current assets	38,978	48,045
Property and equipment, net	13,892	14,294
Restricted cash	3,324	3,324
Available-for-sale securities, non-current	6,600	3,511
Total assets	$ 62,794	$ 69,174

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable	$ 1,083	$ 1,775
Accrued and other liabilities	12,425	13,289
Total current liabilities	13,508	15,064
Accrued and other long-term liabilities	3,923	3,923
Total liabilities	17,431	18,987
Stockholders' equity:		
Common stock; $.001 par value; shares authorized 200,000; shares outstanding -- March 31, 2001, 32,480; December 31, 2000, 32,461;	32	32
Paid in capital	133,344	133,288
Accumulated other comprehensive income	169	165
Accumulated deficit	(88,182)	(83,298)
Total stockholders' equity	45,363	50,187
Total liabilities and stockholders' equity	$ 62,794	$ 69,174

VIVUS, INC.

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

	THREE MONTHS ENDED	
	MARCH 31, 2001	MARCH 31, 2000
	(UNAUDITED)	(UNAUDITED)
Revenue		
US product	$ 5,237	$ 5,758
International product	1,418	2,038
Returns	(296)	(329)
Total revenue	6,359	7,467
Cost of goods sold	3,633	2,927
Gross profit	2,726	4,540
Operating expenses:		
Research and development	6,004	1,204
Selling, general and administrative	2,237	2,217
Total operating expenses	8,241	3,421
Income (loss) from operations	(5,515)	1,119
Interest and other income	631	599
Income (loss) before provision for income taxes	(4,884)	1,718
Provision for income taxes	--	(172)
Net income (loss)	$ (4,884)	$ 1,546
Net income (loss) per share:		
Basic	$ (0.15)	$ 0.05
Diluted	$ (0.15)	$ 0.05
Shares used in per share computation:		
Basic	32,472	32,223
Diluted	32,472	33,556

VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(In thousands)

	THREE MONTHS ENDED	
	MARCH 31, 2001	MARCH 31, 2000
	(UNAUDITED)	(UNAUDITED)
Net income (loss)	$(4,884)	$ 1,546
Other comprehensive income:		
Unrealized gain (loss) on securities	4	75
Income tax benefit (provision)	--	(7)
	4	68
Comprehensive income (loss)	$(4,880)	$ 1,614

VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	THREE MONTHS ENDED MARCH 31,	
	2001	2000
	(UNAUDITED)	(UNAUDITED)
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$ (4,884)	$ 1,546
Adjustments to reconcile net income (loss) to net cash provided by (used for) operating activities:		
Depreciation and amortization	564	777
Changes in assets and liabilities:		
Accounts receivable	(334)	1,901
Inventories	620	(206)
Prepaid expenses and other assets	327	3,259
Accounts payable	(692)	(1,281)
Accrued and other liabilities	(864)	(3,894)
Net cash provided by (used for) operating activities	(5,263)	2,102
CASH FLOWS FROM INVESTING ACTIVITIES:		
Property and equipment purchases	(162)	(261)
Investment purchases	(12,109)	(57,534)
Proceeds from sale/maturity of securities	9,071	60,011
Net cash provided by (used for) investing activities	(3,200)	2,216
CASH FLOWS FROM FINANCING ACTIVITIES:		
Exercise of common stock options	56	104
Net cash provided by financing activities	56	104
NET INCREASE (DECREASE) IN CASH	(8,407)	4,422
CASH:		
Beginning of period	29,236	8,785
End of period	$ 20,829	$ 13,207
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Unrealized gain (loss) on securities	$ 4	$ 75
SUPPLEMENTAL CASH FLOW DISCLOSURE:		
Income taxes paid	$ 5	$ 440

VIVUS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
MARCH 31, 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 three-month period ended March 31, 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. RESTRUCTURING RESERVE

During 1998, the Company experienced a significant decline in market demand for MUSE(R) 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 March 31, 2001 was $4.1 million, down from $4.3 million at December 31, 2000.

(000's)	INVENTORY AND RELATED COMMITMENTS	PROPERTY AND RELATED COMMITMENTS	TOTAL
Balance at December 31, 2000	942	3,324	4,266
Activity in first quarter 2001	0	(123)	(123)
Balance at March 31, 2001	$ 942	$ 3,201	$ 4,143

The Company expects that during the next twelve months it will make cash payments of approximately $220 thousand related to the restructuring, with the remaining $3.9 million in cash payments to occur in later periods.

3. ACCRUED AND OTHER LIABILITIES

Accrued and other liabilities as of March 31, 2001 and December 31, 2000 consist of (in thousands):

(000's)	MARCH 31, 2001	DECEMBER 31, 2000
Restructuring	$ 4,143	$ 4,266
Product returns	1,616	2,008
Income taxes	3,328	3,332
Research and clinical expenses	1,897	2,076
Royalties	520	541
Unearned revenue	2,120	1,917
Employee compensation and benefits	1,514	1,670
Other	1,210	1,402
	16,348	17,212
Amount classified as short-term	(12,425)	(13,289)
Amount classified as long-term	$ 3,923	$ 3,923

4. CONCENTRATION OF CUSTOMERS AND SUPPLIERS

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

	2001	2000
Customer A	23%	14%
Customer B	23%	*
Customer C	15%	14%
Customer D	14%	15%
Customer E	10%	11%

* Customer's percentage was less than 10%

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 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 10 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 disorders in men and women, with a focus on sexual dysfunction. The Company developed and markets in the U.S. MUSE(R) (alprostadil) and ACTIS(R), two innovations in the treatment of erectile dysfunction ("ED") and 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) by which Paladin will market and distribute MUSE. VIVUS has ongoing research and development ("R&D") programs in male ED, female sexual dysfunction ("FSD"), and male premature ejaculation ("PE"). Adding to the Company's R&D pipeline in the first quarter of 2001, VIVUS licensed from TANABE SEIYAKU CO, LTD. ("TANABE"), a leading Japanese pharmaceutical company, TANABE's proprietary phosphodiesterase type 5 (PDE5) inhibitor compound TA-1790 for both the oral and local treatment of male and female sexual dysfunction. In January 2001, the Company began enrolling patients in a multi-center clinical study for its female sexual dysfunction product, ALISTA(TM), intended to evaluate the sexual response in women with a primary diagnosis of Female Sexual Arousal Disorder ("FSAD").

During 1998, the Company experienced a significant decline (greater than 80%) in market demand for MUSE as a result of the introduction of sildenafil in April 1998. During the second and third quarters of 1998, the Company took significant steps to restructure its operations to bring its 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 approximately $27 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 diluted 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. 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 also filed a New Drug Application ("NDA") for ALIBRA with the Food and Drug Administration ("FDA") that was subsequently withdrawn in October 2000.

During 2000, the Company continued to strengthen its balance sheet, increasing working capital by $6.4 million, to enable investment in its R&D projects and to pursue targeted technology acquisitions to expand its pipeline. The Company filed an Investigational New Drug ("IND") application and began clinical studies for ALISTA, its product for the treatment of FSD. The Company signed an agreement with Abbott for the marketing of MUSE internationally, except Canada, where Paladin is marketing and distributing MUSE. The Company was awarded several new patents for the treatment of ED and solidified its FSD intellectual property through its agreement with AndroSolutions. The Company also received 510(k) clearance from the FDA in December 2000, for over-the-counter (OTC) marketing of ACTIS, its adjustable constriction band used to improve erections in men with ED.

FISCAL 2001

In the first quarter of 2001, the Company reported a net loss of $4.9 million, for $0.15 net loss per share. The Company signed a development, license and supply agreement with TANABE for its proprietary phosphodiesterase type 5 (PDE5) inhibitor compound TA-1790. Under the terms of this agreement, the Company acquired worldwide rights, except Japan, China and certain Pacific Rim countries, to develop and commercialize the compound for oral and local treatments of male and female sexual dysfunction. During the first quarter 2001, the Company made up-front, non-refundable milestone payments totaling $5 million dollars to TANABE per the agreement. The Company expensed these payments, which was the main reason the Company reported a net loss for the quarter.

RESULTS OF OPERATIONS

Three Months Ended March 31, 2001 and 2000

Product revenues for the quarter ended March 31, 2001 were $5.2 million in the United States and $1.4 million internationally, compared to $5.8 million in the United States and $2.0 million internationally for the quarter ended March 31, 2000. U.S. product revenue decreased in the first quarter of 2001, compared to the first quarter of 2000, due to an approximate 10% decline in MUSE prescriptions over the past twelve months, as reported by NDC Health. International product revenue decreased $620 thousand in the first quarter of 2001, compared to the same period last year. Shipments to Abbott and Paladin account for this year's international revenue, while 2000 revenue included $1.7 million for product shipments associated with the termination of the distribution agreement with AstraZeneca.

Cost of goods sold was $3.6 million for the first quarter of 2001, compared to $2.9 million for the first quarter 2000. Lower cost of goods in 2000 was primarily the result of lower costs associated with product manufactured for AstraZeneca in 1999 that was shipped during the first quarter of 2000 in connection with the termination of the distribution agreement between the Company and AstraZeneca.

Research and development expenses for the first quarter of 2001 were $6.0 million, which included the expensing of up-front, non-refundable payments totaling $5 million to TANABE for licensing their proprietary compound TA-1790 for the oral and local treatment of male and female sexual dysfunction. For the three months ended March 31, 2000, R&D expenses were $1.2 million.

Selling, general and administrative expenses of $2.2 million for the first quarter 2001 were comparable to the same quarter last year.

The Company did not record a tax provision for the first quarter of 2001 due to the net loss recorded for the quarter. In the first quarter of 2000, the Company 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 inception, the Company has financed operations primarily from the sale of preferred and common stock. Through March 31, 2001, VIVUS has raised $154.5 million from financing activities and has an accumulated deficit of $88.2 million at March 31, 2001.

Unrestricted cash, cash equivalents and available-for-sale securities totaled $36.6 million at March 31, 2001, compared with $41.9 million at December 31, 2000. This decrease is due primarily to the $5 million in milestone payments for licensing TA-1790 from TANABE.

Accounts receivable at March 31, 2001 were $3.8 million, compared with $3.4 million at December 31, 2000, an increase of $400 thousand due primarily to the timing of international shipments.

Total liabilities were $17.4 million at March 31, 2001, compared with $19.0 million at December 31, 2000, a decrease of $1.6 million. The decrease primarily relates to lower accounts payable and product returns.

The Company anticipates that its existing capital resources combined with anticipated future cash flows will be sufficient to support the Company's operating needs throughout the next twelve months. However, the Company anticipates that it will be required to obtain additional financing to fund the development of its R&D pipeline in future periods in addition to the possible launch of any future products.

The Company expects to evaluate potential financing sources, including, but not limited to, the issuance of additional equity or debt securities, corporate alliances, joint ventures, and licensing agreements to fund the development and possible commercial launch of 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) the progress of the Company's R&D programs; (ii) the timing and results of preclinical testing and clinical trials; (iii) results of operations; (iv) demand for MUSE; (v) technological advances; (vi) the level of resources that the Company devotes to sales and marketing capabilities; and (vii) the activities of competitors.

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. 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 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.

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 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 results from the Phase I clinical trial 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.

In September 2000, the Company submitted an IND to the FDA to begin clinical studies with its FSD product, ALISTA. Clinical studies will be focused on the treatment of FSAD, a subcategory of FSD. In January 2001, the Company began enrollment of patients in a Phase II multi-center study to evaluate the safety and efficacy of ALISTA. 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 will 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. 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.

In a proof of concept study completed during the first half of 2000, the effect of on-demand therapy with several classes of compounds for the treatment of premature ejaculation (PE) was evaluated. This study demonstrated statistically significant effects on ejaculatory latency, and additional formulation work to optimize the drug product for this indication is ongoing. The Company anticipates resuming clinical studies once this formulation work has been completed. There is no guarantee that the Company will be able to optimize this formulation. Further, even if the formulation is optimized, there can be no assurance that future clinical studies will confirm the preliminary results in the proof of concept study or that a product for the treatment of PE will prove to be commercially successful.

In May 2000, 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. The Company met with the EMEA and continues to discuss its pending European application. Based on these discussions, 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 FDA 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 it will be successful in the marketplace.

INTENSE COMPETITION

Competition in the pharmaceutical and medical products industries is intense and is characterized by extensive research efforts and rapid technological progress. Certain treatments for ED exist, such as oral medications, needle injection therapy, vacuum constriction devices and penile implants, and the manufacturers of these products will continue to improve these therapies. The most significant competitive therapy is sildenafil, an oral medication marketed by Pfizer, which received regulatory approvals in the U.S. in March 1998 and in the European Union in September 1998. The commercial launch of sildenafil in the U.S. in April 1998 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 preclinical testing, human clinical trials and other regulatory approval procedures. For instance, Lilly ICOS LLC and Bayer AG both have oral medications in late stage clinical testing for ED; 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. 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.

FUTURE CAPITAL NEEDS AND UNCERTAINTY OF ADDITIONAL FINANCING

The Company anticipates that its existing capital resources combined with anticipated future cash flows will be sufficient to support the Company's operating needs throughout 2001. However, the Company anticipates that it will be required to obtain additional financing to fund the development of its R&D pipeline in future periods in addition to the possible launch of any future products. There can be no assurance that the Company will be able to obtain such financing when required, on acceptable terms or at all.

The Company expects to evaluate potential financing sources, including, but not limited to, the issuance of additional equity or debt securities, corporate alliances, joint ventures, and licensing agreements to fund the development and possible commercial launch of 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) the progress of the Company's R&D programs; (ii) the timing and results of preclinical testing and clinical trials; (iii) results of operations; (iv) demand for MUSE; (v) technological advances; (vi) the level of resources that the Company devotes to sales and marketing capabilities; and (vii) the activities of competitors.

LIMITED SALES AND MARKETING IN THE U.S.

The Company supports MUSE sales in the U.S. through physician and patient information/help lines, a small targeted sales support group 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. There can be no assurance that demand for the Company's product MUSE will continue or that the Company will be able to adequately support sales of MUSE in the U.S.

DEPENDENCE ON THIRD PARTIES

In November 2000, 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.

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. 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.

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 (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 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 Gibraltar Laboratories (Gibraltar). Under this agreement, Gibraltar performs sterility testing on finished product manufactured by the Company to ensure that they comply 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. As a result of this testing agreement, 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 effort 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 calls and inquiries. 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.

RAW MATERIALS

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. The Company is required to receive regulatory approval for suppliers. At the present time, Spolana is the sole source of supply for alprostadil used 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. The Company is in the process of transferring licenses in Europe to Abbott. Abbott intends to file variations with the European regulatory authorities for the use of Chinoin alprostadil. There can be no assurance that such variations will be approved in a timely manner or at all, which could have 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. The New Jersey facility is currently the only place MUSE is manufactured. 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 the New Jersey manufacturing facility to produce MUSE for whatever reason could have a material adverse effect on the Company's business, financial condition and results of operations.

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 U.S.

HISTORY OF LOSSES

The Company has generated a cumulative net loss of $88.2 million for the period from its inception through March 31, 2001. 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, its reliance on Paladin to market and distribute MUSE in Canada, 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 products, the results of which could have a material effect on the business operations and results of the Company.

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 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 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. 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, Mexico, New Zealand, Norway, Portugal, South Africa and South Korea, and foreign applications are pending in Canada 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-two 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 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 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., 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 ED. 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 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, 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 KEY PERSONNEL

The Company's success is highly dependent upon the skills of a limited number of key management personnel. To reach its business objectives, the Company will need to retain and hire qualified personnel in the areas of manufacturing, research and development, clinical trial management and preclinical testing. There can be no assurance that the Company will be able to 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, 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 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 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.

UNCERTAINTY OF PHARMACEUTICAL PRICING AND REIMBURSEMENT

In the U.S. and elsewhere, sales of pharmaceutical products are dependent, in part, on the availability of reimbursement to the consumer from third party payors, such as government and private insurance plans. Third party payors are increasingly challenging the prices charged for medical products and services. With the introduction of sildenafil, third party payors have begun to restrict or eliminate reimbursement for ED 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 parties began an arbitration hearing in December 2000 that was postponed while the parties are attempting to agree on a settlement of the claims. If the parties are not able to reach a settlement, the hearing is expected to be continued in May 2001.

On August 23, 2000, the Company received a notice of Demand for Arbitration from Alza Corporation ("Alza") alleging a breach of a sales force transition agreement dated July 6, 1998. The sales force transition agreement provided for the transition of VIVUS' sales force to Alza, where they would promote both VIVUS' and Alza's products for a period of time. The agreement

further provided

that VIVUS is to indemnify Alza for claims brought by any member of the sales force relating to such person's employment (or termination) by VIVUS, and that Alza is to indemnify VIVUS for claims brought by any member of the sales force relating to such person's employment (or termination) by Alza. Alza alleges that it is entitled to indemnification from the Company for Alza's attorneys' fees and amounts paid to settle claims relating to Alza's failure to hire a former Company employee. Alza seeks approximately $507,500 in damages. The Company filed an answer with the AAA on September 22, 2000, in which it denied all of the material allegations of the Demand for Arbitration. The Company is currently engaged in discovery. A briefing schedule has been set with all arbitration briefs to be submitted no later than May 17, 2001. No date has yet been set for an arbitration hearing. The Company believes it has meritorious defenses and it intends to vigorously defend the matter. Nevertheless, an adverse judgment in this litigation is not expected to have a material impact on the Company's financial position.

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 AAA 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 and anticipate a hearing in October 2001.

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

EXHIBIT NUMBER	DESCRIPTION
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.

- ------------

+ 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.

(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: April 30, 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.