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, 1997

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)

545 MIDDLEFIELD ROAD, SUITE 200, MENLO PARK, CA 94025
(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES) (ZIP CODE)

(415) 325-5511
(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

APPLICABLE ONLY TO CORPORATE ISSUERS:

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

At May 1, 1997, 16,507,906 shares of common stock were outstanding. Exhibit index on page 19.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

VIVUS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS, EXCEPT SHARE DATA)

ASSETS

	MARCH 31, 1997	DECEMBER 31, 1996
	(UNAUDITED)	
Current assets:		
Cash and cash equivalents	$ 6,549	$ 555
Available-for-sale securities	57,278	60,710
Trade and other receivables	12,780	748
Inventories	4,666	4,540
Prepaid expenses and other	605	587
Total current assets	81,878	67,140
Property, net	6,956	6,332
Available-for-sale securities, non-current	23,929	23,060
Total	$ 112,763	$ 96,532
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,150	$ 3,324
Accrued and other liabilities	9,603	3,428
Total current liabilities	11,753	6,752
Stockholders' equity:		
Preferred stock; no par value; shares authorized -- 5,000,000; shares outstanding -- none	--	--
Common stock; $.001 par value; shares authorized -- 30,000,000; shares outstanding -- March 31, 1997, 16,440,719; December 31, 1996, 16,227,170;	16	16
Paid in capital	158,062	156,189
Unrealized gain (loss) on securities	(225)	77
Deferred compensation	(243)	(348)
Accumulated deficit	(56,600)	(66,154)
Total stockholders' equity	101,010	89,780
Total	$ 112,763	$ 96,532

VIVUS, INC.

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

	THREE MONTHS ENDED MARCH 31,	
	1997	1996
	(UNAUDITED)	(UNAUDITED)
Net product sales	$27,791	$ --
Milestone revenue	5,000	--
Net revenues	32,791	--
Cost of goods sold	8,066	--
Gross margin	24,725	--
Operating expenses:		
Research and development	2,027	5,359
Selling, general and administrative	11,809	1,379
Total operating expenses	13,836	6,738
Income (loss) from operations	10,889	(6,738)
Interest income	1,121	503
Income (loss) before taxes	12,010	(6,235)
Income taxes	2,456	--
Net income (loss)	$ 9,554	$(6,235)
Net income (loss) per common and equivalent share	$ 0.54	$ (0.45)
Shares used in the computation of net income (loss) per share	17,827	13,991

VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED, IN THOUSANDS)

	THREE MONTHS ENDED MARCH 31,	
	1996	1997
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$ 9,554	$(6,235)
Adjustments to reconcile net income (loss) to net cash provided (used) for operating activities:		
Depreciation and amortization	403	238
Amortization of deferred compensation	105	110
Changes in assets and liabilities:		
Receivables	(12,032)	(67)
Inventories	(126)	--
Prepaid expenses and other	(18)	(33)
Accounts payable	(1,174)	(5)
Accrued and other liabilities	6,175	636
Net cash provided by (used for) operating activities	2,887	(5,356)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Property purchases	(1,027)	(499)
Securities purchases	(56,418)	(4,978)
Proceeds from sale/maturity of securities	58,679	10,523
Net cash provided by investing activities	1,234	5,046
CASH FLOWS FROM FINANCING ACTIVITIES:		
Exercise of common stock options	1,873	263
Net cash provided by financing activities	1,873	263
Net Increase (Decrease) in Cash and Cash Equivalents	5,994	(47)
CASH AND CASH EQUIVALENTS:		
Beginning of period	555	973
End of period	$ 6,549	$ 926
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Unrealized loss on securities	$ (302)	$ (161)

VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
MARCH 31, 1997

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 Rule 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, 1997 are not necessarily indicative of the results that may be expected for the year ended December 31, 1997. 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, 1996.

2. PROVISION FOR INCOME TAXES

The Company has recorded a provision for income taxes of twenty percent of income before taxes in 1997. This tax rate includes the effect of net operating losses (NOLs) carried forward from prior periods. The tax rate would have been substantially higher if the NOLs were not available to offset current income. The Company expects to fully utilize all NOLs during 1997, and accordingly, the Company's effective tax rate is expected to increase in the future.

3. NET INCOME (LOSS) PER SHARE

For the three months ended March 31, 1997, net income per common and equivalent share is based on the weighted average number of common and equivalent shares outstanding during the period, including outstanding options and warrants. Such options and warrants are excluded from the net loss per common and equivalent shares for the three months ended March 31, 1996 because they are antidilutive.

4. IMPACT OF NEW ACCOUNTING PRONOUNCEMENT

The Company will adopt SFAS No. 128, "Earnings per Share," effective December 15, 1997 for the year ending December 31, 1997. Had the new pronouncement been in effect for the three months ended March 31, 1997, basic earnings per share would be reported as $0.58 and diluted earnings per share would be $0.54.

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

DESCRIPTION OF BUSINESS

VIVUS, Inc. ("VIVUS" or the "Company") is a leading developer of advanced therapeutic systems for the treatment of erectile dysfunction. Erectile dysfunction, commonly referred to as impotence, is the inability to achieve and maintain an erection of sufficient rigidity for sexual intercourse. The Company's transurethral system for erection is a non-invasive, easy to use system that delivers pharmacologic agents topically to the urethral lining. In November 1996, the Company obtained regulatory marketing clearance from the U.S. Food and Drug Administration (the "FDA") to manufacture and market its first product, MUSE(R) (alprostadil). The Company commenced product shipments to wholesalers in December 1996 and commercially introduced MUSE (alprostadil) in the United States through its direct sales force beginning in January 1997. In addition, the Company submitted applications for regulatory approval to market MUSE (alprostadil) in the United Kingdom and Sweden in 1996, Norway in January 1997 and in Australia and New Zealand in April 1997. These applications will be subject to rigorous approval processes, and there can be no assurance such approval will be granted in a timely manner, if at all. Furthermore, the Company received FDA clearance in December 1996 for ACTIS(R), an adjustable elastomeric venous flow control device designed for those patients who suffer from veno-occlusive dysfunction (commonly referred to as venous leak syndrome). ACTIS is currently being studied for adjunctive use with MUSE, however, there can be no assurance that such studies will demonstrate that adjunctive use of ACTIS with MUSE (alprostadil) is an effective treatment for erectile dysfunction.

In May 1996, the Company entered into an international marketing agreement with Astra AB ("Astra"). Astra will purchase the Company's products for resale in Europe, South America, Central America, Australia and New Zealand. As consideration for execution of the international marketing agreement, Astra paid the Company $10 million in June 1996. In September 1996, the Company received a $10 million milestone payment from Astra upon filing an application for marketing authorization for MUSE (alprostadil) in the United Kingdom. The Company will be paid up to an additional $10 million in the event certain other milestones are achieved. However, there can be no assurance that such milestones will be achieved.

In January 1997, the Company entered into an international marketing agreement with Janssen Pharmaceutica International ("Janssen"), a subsidiary of Johnson & Johnson. Janssen will purchase the Company's products for resale in China, multiple Pacific Rim countries (excluding Japan), Canada, Mexico and South Africa. As consideration for execution of the international marketing agreement, Janssen paid the Company $5 million. The Company will receive additional payments in the event certain other milestones are achieved. However, there can be no assurance that such milestones will be achieved.

The Company has sought and will continue to seek pharmacologic agents for the treatment of erectile dysfunction that are suitable for transurethral delivery for which significant safety data already exists. The Company believes that such agents may progress rapidly through clinical development and the regulatory process due to the preexisting safety data. The Company expects to begin a Phase III multi-center trial in 1997 for its second product candidate, a combination of alprostadil and prazosin delivered via the Company's transurethral system for erection. The Company has several other product candidates in preclinical development.

The Company has limited experience in manufacturing and selling MUSE (alprostadil) in commercial quantities. Whether the Company can successfully manage the transition to a large scale commercial enterprise will depend upon successful further development of its manufacturing capability and its distribution network, and attainment of foreign regulatory approvals for MUSE (alprostadil). Failure to make such a transition successfully would have a material adverse effect on the Company's business, financial condition and results of operations.

The Company's New Jersey manufacturing facility at Paco Pharmaceutical Services Inc. was inspected by the FDA for the first time after the preapproval inspection during twelve days in February and March 1997. That inspection resulted in the issuance by the FDA of an extensive Form FDA 483, which detailed specific areas where the FDA inspector observed that the Company's operations were not in full compliance with some

areas of the Good Manufacturing Practices ("cGMPs") regulations. A corrective action plan addressing all identified cGMP deficiencies was initiated immediately, and the Company submitted a written response to the Form FDA 483 and requested a meeting with the FDA District Office officials to discuss the matter. Approximately 30 days after submitting the initial written response, the Company provided the FDA with a written update of the progress made against the corrective action plan. The FDA has provided the Company with written comments on the initial response, which included requests for clarification and additional information. There can be no assurance that the FDA will accept the Company's corrective action plan, supplemental information or the time frame for completing the corrective action plan. If the corrective action plan is accepted it is likely that the FDA would reinspect the facility shortly after completion of the corrective action plan. The scope of any FDA reinspection could be more comprehensive than the initial inspection. Failure to adequately address these cGMP deficiencies within a reasonable time frame would have an adverse effect on the Company's ability to supply its product in the US and internationally, which would have a material adverse effect on the Company's business, financial condition and results of operations. Accordingly, the Company has undertaken a complete review of its cGMP compliance. However, there can be no assurance that the FDA will deem the Company's corrective action or the timing for the corrective action to be adequate or that additional corrective action, in areas not addressed by Form FDA 483, will not be required. Failure to achieve satisfactory cGMP compliance would have a material adverse effect on the Company's ability to continue to market and distribute its products and in the most serious cases, could result in the issuance of a Warning Letter, seizure or recall of products, civil fines or closure of the Company's New Jersey manufacturing facility until cGMP compliance is achieved.

Based on a published study of more than 1,200 men in Massachusetts, the Company estimates that more than 30% of males in the United States between the ages of 40 and 70 suffer from moderate to complete erectile dysfunction. The Company believes that similar rates of erectile dysfunction prevail outside the United States. An estimate from the National Institute of Health ("NIH") Consensus Statement on Impotence (1992) suggests that the number of men in the United States with erectile dysfunction may be 10 to 20 million. The rate of erectile dysfunction increases significantly with age. In addition to the Company's transurethral system for erection, the primary medical therapies currently used to treat erectile dysfunction are needle injection of pharmacologic agents into the penis, vacuum constriction devices, penile implants and oral medications. Despite the detrimental effect erectile dysfunction may have on a couple's quality of life, the Company believes that, due in part to the limitations of other therapies, less than 10% of men suffering from erectile dysfunction received medical treatment prior to the introduction of MUSE (alprostadil). The Company believes that MUSE (alprostadil) could become first line therapy for erectile dysfunction.

RESULTS OF OPERATIONS

Three Months Ended March 31, 1997 and 1996

Product revenues of $27,791,000 were recorded for the three months ended March 31, 1997. This amount includes $2,636,000 for product shipped in December of 1996; these shipments were made to initially stock wholesalers and were allowed one-time extended rights-of-return which expired during the three months ended March 31, 1997. As consideration for execution of the Janssen marketing agreement, Janssen paid the Company $5 million in January 1997. The Company recorded this receipt as milestone revenue in the condensed consolidated statement of operations.

For the three months ended March 31, 1997, research and development expenses were $2,027,000 compared with $5,359,000 for the three months ended March 31, 1996, an decrease of 62%. Research and development expenses were less than the same period in 1996 due principally to higher clinical and regulatory costs in 1996 associated with the preparation and filing of the Company's New Drug Application (NDA) for MUSE (alprostadil) and pre-launch manufacturing expenses.

Selling, general and administrative expenses for the three months ended March 31, 1997 were $11,809,000 compared with $1,379,000 for the three months ended March 31, 1996, an increase of 756%. The

increase primarily resulted from the addition of a fifty person field sales force, higher marketing expenses and the costs associated with adding personnel to support the growth of the Company's operations and the commercial launch of MUSE (alprostadil).

Spending levels will continue to increase during 1997 as the Company further develops its commercial manufacturing, marketing and sales capabilities.

Interest income for the three months ended March 31, 1997 was $1,121,000 compared with $503,000 for the three months ended March 31, 1996, an increase of 123%. The increases were primarily the result of higher average invested cash balances.

Income taxes for the three months ended March 31, 1997 were $2,456,000, approximately 20% of income before taxes, compared with zero for the three months ended March 31, 1996. The increase is due to the increase in taxable income. The 1997 tax rate includes the effect of net operating losses (NOLs) carried forward from prior periods. The tax rate would have been substantially higher if the NOLs were not available to offset current income. The Company expects to fully utilize all NOLs during 1997, and accordingly, the Company's effective tax rate is expected to increase in the future.

LIQUIDITY AND CAPITAL RESOURCES

Since inception, the Company has financed operations primarily from the sale of preferred and common stock. Through March 31, 1997, VIVUS has raised $149,467,000 from financing activities. Cash, cash equivalents and securities available-for-sale totaled $87,756,000 at March 31, 1997 compared with $84,325,000 at December 31, 1996. The Company maintains its current excess cash balances in a variety of interest bearing investment-grade financial investments such as United States treasury, federal agency and state government securities, repurchase agreements, corporate debt and bank certificates of deposit. Principal preservation, liquidity and safety are the primary investment objectives.

Cash flow from operations in the three months ended March 31, 1997 was $2,887,000 compared with cash used of $5,356,000 in the three months ended March 31, 1996. The decreased use of cash was primarily due to net income of $9,554,000.

Trade and other receivables at March 31, 1997 were $12,780,000 compared with $748,000, an increase of $12,032,000. The increase primarily resulted from the increase in trade receivables resulting from the launch of MUSE (alprostadil).

Current liabilities were $11,753,000 at March 31, 1997 compared with $6,752,000 at December 31, 1996, an increase of $5,001,000. The increase was related primarily to an increase in manufacturing expenditures and accrued income taxes in 1997.

Capital expenditures in the three months ended March 31, 1997 were $1,027,000 compared with $499,000 for the same period ended March 31, 1996. Capital expenditures during the period in 1997 and 1996 consisted primarily of manufacturing and quality control equipment. Capital expenditures were higher in 1997 due to the purchase of additional manufacturing equipment for use at the Company's dedicated manufacturing operation within the Paco Pharmaceutical Services, Inc. ("Paco") facility in Lakewood, New Jersey. Capital expenditures over the next two years are likely to increase as they are expected to include manufacturing facilities in the United States and Europe, and a new corporate headquarters and research and development laboratory facility in the United States.

The Company expects to incur substantial additional costs, including expenses related to a second manufacturing facility in the United States and one in Europe, new product preclinical and clinical costs, ongoing research and development activities, and general corporate purposes. The Company anticipates that its existing capital resources will be sufficient to support the Company's operations through the commercial introduction of MUSE (alprostadil) in Europe, but may not be sufficient for the introduction of any additional future products. The Company anticipates that it may be required to issue additional equity or debt securities and may use other financing sources including, but not limited to, corporate alliances and lease financings to

fund the future development and possible commercial launch of its products. The sale of additional equity securities would result in additional dilution to the Company's stockholders. There can be no assurance that such funds will be available on terms satisfactory to the Company, or at all. Failure to obtain adequate funding could cause a delay or cessation of the Company's product development and marketing efforts and would have a material adverse effect upon the Company's business, financial condition and results of operations. The Company's working capital and additional funding requirements will depend upon numerous factors, including: (i) the level of resources that the Company devotes to sales and marketing capabilities; (ii) the level of resources that the Company devotes to expanding manufacturing capacity; (iii) the activities of competitors; (iv) the progress of the Company's research and development programs; (v) the timing and results of preclinical testing and clinical trials; (vi) technological advances; and (vii) continued profitability.

The Results of Operations and Liquidity and Capital Resources sections contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1993, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended. Actual results could differ materially from those projected in the forward-looking statements as a result of the factors set forth in this Liquidity and Capital Resources section, the Risk Factors section, the Results of Operations section and the Description of Business section. The discussion of those factors is incorporated herein by this reference as if said discussion was fully set forth at this point.

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

RISK FACTORS

LIMITED MANUFACTURING EXPERIENCE AND DEPENDENCE ON SOLE CONTRACT MANUFACTURER

The Company has only limited experience in manufacturing MUSE (alprostadil) in commercial quantities. Since the commercial launch of its product in January 1997, the Company has experienced product shortages due to higher than expected demand. If the Company encounters any manufacturing difficulties, including problems involving production yields, quality control and assurance, supplies of components or raw materials or shortages of qualified personnel, it could have a material adverse effect on the Company's business, financial condition and results of operations.

The formulation, filling, packaging and testing of MUSE (alprostadil) is performed by Paco Pharmaceutical Services, Inc. ("Paco"), a wholly owned subsidiary of The West Company, at its facility in Lakewood, New Jersey. In June 1995, the Company completed construction of its approximately 6,000 square feet manufacturing and testing space within Paco's facility. Due to higher than expected demand, the Company has leased two adjacent buildings in New Jersey, totaling 90,000 square feet, that will be built out to support expansion of the Company's manufacturing capabilities. Until the Company develops an in-house manufacturing capability, it will be entirely dependent upon Paco for the manufacture of its products. There can be no assurance that the Company's reliance on Paco for the manufacture of its products will not result in problems with product supply, and there can be no assurance that the Company will be able to establish a second manufacturing facility. Interruptions in the availability of products could delay or prevent the development and commercial marketing of MUSE (alprostadil) and other potential products and would have a material adverse effect on the Company's business, financial condition and results of operations.

The Company and its third party contract manufacturers, including manufacturers of materials and components, are subject to routine periodic inspections by the FDA and certain state and foreign regulatory agencies for compliance with cGMPs and other applicable regulations. The FDA stringently applies regulatory standards for manufacturing. The Company's third party contract manufacturers were inspected for cGMP compliance as part of the approval process. However, upon routine re-inspection of its contract manufacturers, there can be no assurance that the FDA will find the manufacturing process or facilities to be in compliance with cGMPs and other regulations. Failure to achieve satisfactory cGMP compliance as confirmed by routine regulatory inspections would have a significant adverse effect on the Company's ability to continue to manufacture and distribute its products and, in the most serious cases, result in the issuance of a regulatory warning letter or seizure or recall of products, injunction and/or civil fines.

The Company's New Jersey manufacturing facility at Paco Pharmaceutical Services Inc. was inspected by the FDA for the first time after the preapproval inspection during twelve days in February and March 1997. That inspection resulted in the issuance by the FDA of an extensive Form FDA 483, which detailed specific areas where the FDA inspector observed that the Company's operations were not in full compliance with some areas of the cGMP regulations. A corrective action plan addressing all identified cGMP deficiencies was initiated immediately, and the Company submitted a written response to the Form FDA 483 and requested a meeting with the FDA District Office officials to discuss the matter. There can be no assurance that the FDA will accept the Company's corrective action plan or the time frame for completing the corrective action plan. If the corrective action plan is accepted it is likely that the FDA would reinspect the facility shortly after completion of the corrective action plan. The scope of any FDA reinspection could be more comprehensive than the initial inspection. Failure to adequately address these cGMP deficiencies within a reasonable time frame would have an adverse effect on the Company's ability to supply its product, which would have a material adverse effect on the Company's business, financial condition and results of operations. Accordingly, the Company has undertaken a complete review of its cGMP compliance. However, there can be no assurance

that the FDA will deem the Company's corrective action or the timing for the corrective action to be adequate or that additional corrective action, in areas not addressed by Form FDA 483, will not be required. Failure to achieve satisfactory cGMP compliance would have a material adverse effect on the Company's ability to continue to market and distribute its products and in the most serious cases, could result in the issuance of a Warning Letter, seizure or recall of products, civil fines or closure of the Company's New Jersey manufacturing facility until cGMP compliance is achieved.

LIMITED SALES AND MARKETING EXPERIENCE; DEPENDENCE ON THIRD PARTIES

Before commercially launching its first product, MUSE (alprostadil), in January 1997, the Company had no experience in the sale, marketing and distribution of pharmaceutical products. The Company is marketing and selling its products initially through a direct sales force in the United States. There can be no assurance that the Company's domestic sales and marketing efforts will be successful.

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

In May 1996, the Company entered into an international marketing agreement with Astra to purchase the Company's products for resale in Europe, South America, Central America, Australia and New Zealand. As consideration for execution of the international marketing agreement, Astra paid the Company $10 million in June 1996. In September 1996, the Company received a $10 million milestone payment from Astra upon filing an application for marketing authorization for MUSE (alprostadil) in the United Kingdom. The Company will be paid up to an additional $10 million in the event certain other milestones are achieved. However, there can be no assurance that such milestones will be achieved. The marketing agreement does not have minimum purchase commitments, and Astra may take up to twelve months to introduce a product in a given country following regulatory approval in such country. As a result of this marketing agreement with Astra, the Company is dependent on Astra's efforts to market, distribute and sell the Company's products effectively in the above mentioned markets. There can be no assurance that such efforts will be successful.

In July 1996, the Company entered into a distribution agreement with ASD, a subsidiary of Bergen Brunswig Corporation. ASD provides "direct-to-physician" distribution, telemarketing and customer service capabilities in support of the U.S. marketing and sales efforts. Pursuant to the terms of this agreement, ASD developed a customer service organization to respond to all the Company's sales representative and physician inquiries. As a result of this distribution agreement with ASD, the Company is dependent on ASD's efforts to distribute, telemarket, and provide customer service effectively. There can be no assurance that such efforts will be successful.

In January 1997, the Company signed an international marketing agreement with Janssen, a subsidiary of Johnson & Johnson. Janssen will purchase the Company's products for resale in China, multiple Pacific Rim countries (excluding Japan), Canada, Mexico and South Africa. As consideration for execution of the international marketing agreement, Janssen paid the Company $5 million. The Company will receive additional payments in the event certain other milestones are achieved. However, there can be no assurance that such milestones will be achieved. As a result of this distribution agreement with Janssen, the Company is dependent on Janssen's efforts to distribute and sell the Company's products effectively in the above mentioned markets. There can be no assurance that such efforts will be successful.

The Company intends to market and sell its products in other foreign markets through distribution, co-promotion or license agreements with corporate partners. To date, the Company has entered into international marketing agreements with Astra and Janssen. There can be no assurance that the Company will be able to successfully enter into additional agreements with corporate partners upon reasonable terms, if at all. To the extent that the Company enters into distribution, co-promotion or license agreements for the sale of its products, the Company will be dependent upon the efforts of third parties. These third parties may have

other commitments, and there can be no assurance that they will commit the necessary resources to effectively market, distribute and sell the Company's product.

DEPENDENCE ON THE COMPANY'S TRANSURETHRAL SYSTEM FOR ERECTION

The Company currently relies upon a single therapeutic approach to treat erectile dysfunction, its transurethral system for erection. Certain side effects have been found to occur with the use of MUSE (alprostadil). Occasional mild to moderate transient penile/perineal pain was suffered by 21% to 42% of patients, depending on dosage, treated with MUSE (alprostadil) in the Company's Phase II/III Dose Ranging study. Moderate to severe (i.e., syncope) decreases in blood pressure were experienced by 1% to 4% of patients, depending on dosage treated with MUSE (alprostadil) in such study. The existence of side effects or dissatisfaction with product results may impact a patient's decision to use or continue to use, or a physician's decision to recommend, MUSE (alprostadil) as a therapy for the treatment of erectile dysfunction thereby affecting the commercial viability of MUSE (alprostadil). In addition, technological changes or medical advancements could diminish or eliminate the commercial viability of the Company's products. As a result of the Company's single therapeutic approach and its current focus on MUSE (alprostadil), the failure to successfully commercialize such product would have an adverse effect on the Company and could threaten the Company's ability to continue as a viable entity.

GOVERNMENT REGULATION AND UNCERTAINTY OF PRODUCT APPROVALS

The Company's research, preclinical development, clinical trials, manufacturing and marketing of its products are subject to extensive regulation by numerous governmental authorities in the United States and other countries. Clinical trials, manufacturing and marketing of the Company's products will be subject to the rigorous testing and approval processes of the FDA and equivalent foreign regulatory agencies. The process of obtaining FDA and other required regulatory approvals is lengthy and expensive. The Company completed pivotal clinical trials in 1995 and submitted an NDA for its first product, MUSE (alprostadil), to the FDA in March 1996. In November 1996, the Company received final marketing clearance from the FDA for MUSE (alprostadil). In addition, the Company submitted applications for approval of MUSE (alprostadil) in the United Kingdom and Sweden in 1996, in Norway in January 1997 and in Australia and New Zealand in April 1997. These applications will be subject to rigorous approval processes. There can be no assurance that approval in these or other countries will be granted on a timely basis, if at all, or if granted, that such approval will not contain significant limitations in the form of warnings, precautions or contraindications with respect to conditions of use. Any delay in obtaining, or failure to obtain, such approval would adversely affect the Company's ability to generate product revenue.

The Company's clinical trials for future products will seek safety data as well as efficacy data and will require substantial time and significant funding. There is no assurance that clinical trials related to future products will be completed successfully within any specified time period, if at all. Furthermore, the FDA may suspend clinical trials at any time if it is believed that the subjects participating in such trials are being exposed to unacceptable health risks. There can be no assurance that FDA or other regulatory approvals for any products developed by the Company will be granted on a timely basis, if at all, or if granted, that such approval will not contain significant limitations in the form of warnings, precautions or contraindications with respect to conditions of use. Any delay in obtaining, or failure to obtain, such approvals would adversely affect the Company's ability to generate product revenue. Failure to comply with the applicable regulatory requirements can, among other things, result in fines, suspensions of regulatory approvals, product recalls, operating restrictions and criminal prosecution. In addition, the marketing and manufacturing of pharmaceutical products are subject to continuing FDA review, and later discovery of previously unknown problems with a product, manufacturer or facility may result in the FDA requiring further clinical research or restrictions on the product or the manufacturer, including withdrawal of the product from the market. The restriction, suspension or revocation of regulatory approvals or any other failure to comply with regulatory requirements would have a material adverse effect on the Company's business, financial condition and results of operations.

The Company obtains the necessary raw materials and components for the manufacture of MUSE (alprostadil) from third parties. The Company currently contracts with contract manufacturing organizations,

including foreign manufacturers, that are required to comply with strict standards established by the Company. All contract manufacturers are required by the Federal Food, Drug, and Cosmetic Act, as amended, and by FDA regulations to follow cGMP and are subject to routine periodic inspections by the FDA and certain state and foreign regulatory agencies for compliance with cGMPs and other applicable regulations. The FDA stringently applies regulatory standards for manufacturing. The Company's third party contract manufacturers were inspected for cGMP compliance as part of the approval process. However, upon routine re-inspection of the manufacturing facilities, there can be no assurance that the FDA will find the manufacturing process or facilities to be in compliance with cGMPs and other regulations. Failure to achieve satisfactory cGMP compliance as confirmed by routine inspections could have a significant 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.

The Company's New Jersey manufacturing facility at Paco Pharmaceutical Services Inc. was inspected by the FDA for the first time after the preapproval inspection during twelve days in February and March 1997. That inspection resulted in the issuance by the FDA of an extensive Form FDA 483, which detailed specific areas where the FDA inspector observed that the Company's operations were not in full compliance with some areas of the cGMP regulations. A corrective action plan addressing all identified cGMP deficiencies was initiated immediately, and the Company submitted a written response to the Form FDA 483 and requested a meeting with the FDA District Office officials to discuss the matter. Approximately 30 days after submitting the initial written response, the Company provided the FDA with a written update of the progress made against the corrective action plan. The FDA has provided the Company with written comments on the initial response, which included requests for clarification and additional information. There can be no assurance that the FDA will accept the Company's corrective action plan or the time frame for completing the corrective action plan. If the corrective action plan is accepted it is likely that the FDA would reinspect the facility shortly after completion of the corrective action plan. The scope of any FDA reinspection could be more comprehensive than the initial inspection. Failure to adequately address these cGMP deficiencies within a reasonable time frame would have an adverse effect on the Company's ability to supply its product in the US and internationally, which would have a material adverse effect on the Company's business, financial condition and results of operations. Accordingly, the Company has undertaken a complete review of its cGMP compliance. However, there can be no assurance that the FDA will deem the Company's corrective action or the timing for the corrective action to be adequate or that additional corrective action, in areas not addressed by Form FDA 483, will not be required. Failure to achieve satisfactory cGMP compliance would have a material adverse effect on the Company's ability to continue to market and distribute its products and in the most serious cases, could result in the issuance of a Warning Letter, seizure or recall of products, civil fines or closure of the Company's New Jersey manufacturing facility until cGMP compliance is achieved.

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 erectile dysfunction exist, such as needle injection therapy, vacuum constriction devices, penile implants and oral medications, and the manufacturers of these products will continue to improve these therapies. In July 1995, the FDA approved the use of alprostadil in The Upjohn Company's needle injection therapy product for erectile dysfunction. Previously, Upjohn had obtained approval in a number of European countries. Additional competitive therapies under development include an oral medication by Pfizer, Inc., which is currently in Phase III clinical trials. Other large pharmaceutical companies are also actively engaged in the development of therapies for the treatment of erectile dysfunction. These companies have substantially greater research and development capabilities as well as substantially greater marketing, financial and human resources than the Company. In addition, these companies have significantly greater experience than the Company in undertaking preclinical testing, human clinical trials and other regulatory approval procedures. There are also small companies, academic institutions, governmental agencies and other research organizations that are conducting research in the area of erectile dysfunction. For instance, Zonagen, Inc. and Pentech Pharmaceutical, Inc. have oral medications under development. These entities may also 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 being developed by the Company. Such developments would render the Company's products less competitive or even obsolete. The Company is also competing with respect to marketing capabilities and manufacturing efficiency, areas in which it has limited experience.

PROPRIETARY RIGHTS AND RISK OF LITIGATION

The Company's success will depend, in large part, on the strength of its current and future patent position relating to the transurethral delivery of pharmacologic agents for the treatment of erectile dysfunction. The Company's patent position, like that of other pharmaceutical companies, is highly uncertain and involves complex legal and factual questions. Claims made under patent applications may be denied or significantly narrowed and issued patents may not provide significant commercial protection to the Company. The Company could incur substantial costs in proceedings before the United States Patent Office, including interference proceedings. These proceedings could also result in adverse decisions as to the priority of the Company's licensed or assigned inventions. There is no assurance that the Company's patents will not be successfully challenged or designed around by others. The Company is aware of a US patent application involving the transurethral application of prostaglandin E(2). The corresponding application in Europe has been abandoned. Failure of the Company's licensed patents to block issuance of such patent could have a material adverse effect on the Company's business, financial condition and results of operations.

There can be no assurance that the Company's products do not or will not infringe on the patent or proprietary rights of others. A patent opposition to the Company's exclusively licensed European patents has been filed with the European Patent Office. The Company is vigorously defending the patents, however an adverse decision could affect the Company's ability, based on its patent rights, to limit potential competition in Europe. The Company may be required to obtain additional licenses to the patents, patent applications or other proprietary rights of others. There can be no assurance that any such licenses would be made available on terms acceptable to the Company, if at all. If the Company does not obtain such licenses, it could encounter delays in product introductions while it attempts to design around such patents, or the development, manufacture or sale of products requiring such licenses could be precluded. The Company believes there will continue to be significant litigation in the pharmaceutical industry regarding patent and other intellectual property rights.

A former consultant to the Company has claimed that he is the inventor of certain technology disclosed in two of the Company's patents. The former consultant further claims that the Company defrauded him by allegedly failing to inform him that it intended to use and patent this technology and by failing to compensate him for the technology in the manner allegedly promised. On May 28, 1996, the Company filed a complaint for declaratory judgment against the former consultant in the United States District Court for the Northern District of California, which seeks a declaration from the court that the former consultant is not an inventor of any of the technology disclosed in the patent. On July 17, 1996, the former consultant filed a lawsuit that seeks to have two of the Company's patents declared invalid on the grounds that they fail to list him as an inventor. On September 16, 1996, the Court dismissed the consultant's lawsuit, and ordered the consultant to refile his claims or counterclaims to the action initiated by the Company on May 28, 1996. The consultant filed his counterclaim on September 26, 1996. The Company has conducted a review of the circumstances surrounding this matter and believes that the allegations are without merit. Although the Company believes that it should prevail, the uncertainties inherent in litigation prevent the Company from giving any assurances about the outcome of such litigation.

In a separate matter, on April 10, 1996, the licensors in an agreement by which the Company acquired a patent license filed a lawsuit in a Texas State court that alleges that they were defrauded in connection with the renegotiation of a license agreement between the Company and the licensors. On May 8, 1996, the action was removed to the United States District Court for the Western District of Texas. In addition to monetary damages, the licensors seek to return to the terms of an earlier superseded license agreement. In March 1997, the parties to the Texas action reached an agreement to settle the case. Pursuant to the terms of the Agreement, neither the Company nor its officers will pay any damages to plaintiffs, and the license agreement will remain in effect. The parties are currently negotiating the final terms of the agreement, however, there can

be no assurance that such agreement will be finalized. In the event that no final agreement is executed, although the Company believes it should prevail in the matter, the uncertainties inherent in litigation prevent the Company from giving any assurances concerning the outcome of such litigation.

The Company also relies on trade secrets and other unpatented proprietary technology. No assurance can be given that the Company can meaningfully protect its rights in such unpatented proprietary technology or that others will not independently develop substantially equivalent proprietary products and processes or otherwise gain access to the Company's proprietary technology. The Company seeks to protect its trade secrets and proprietary know-how, in part, with confidentiality agreements with employees and consultants. There can be no assurance that these 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 DUAL SOURCE OF SUPPLY

To date, the Company has obtained its supply of alprostadil from two sources. The first is Spolana Chemical Works AS ("Spolana") pursuant to a supply agreement that expires at the end of 1997. A renewal agreement is currently being negotiated. In January 1996, the Company entered into a long-term alprostadil supply agreement with Chinoin. Chinoin is the Hungarian subsidiary of the French pharmaceutical company Sanofi Winthrop. Alprostadil, a generic drug, is extremely difficult to manufacture and is only available to the Company from a limited number of other suppliers, none of which currently produce it in commercial quantities. While the Company is seeking additional sources, there can be no assurance that it will be able to identify and qualify such sources. The Company is required to identify its suppliers to the FDA. The FDA may require additional clinical trials or other studies prior to accepting a new supplier. Unless the Company secures and qualifies additional sources of alprostadil, it will be entirely dependent upon Spolana and Chinoin for the delivery of alprostadil. If interruptions in the supply of alprostadil were to occur for any reason, including a decision by Spolana and/or Chinoin to discontinue manufacturing, political unrest, labor disputes or a failure of Spolana and/or Chinoin to follow regulatory guidelines, the development and commercial marketing of MUSE (alprostadil) and other potential products could be delayed or prevented. An interruption in the Company's supply of alprostadil would have a material adverse effect on the Company's business, financial condition and results of operations.

HISTORY OF LOSSES AND LIMITED OPERATING HISTORY

The Company has generated a cumulative net loss of $56.6 million for the period from its inception through March 31, 1997. To sustain profitability, the Company must successfully manufacture and market MUSE (alprostadil). The Company is subject to a number of risks including its ability to scale-up manufacturing capabilities and secure adequate supplies of raw materials, its ability to successfully market, distribute and sell its product, its reliance on a single therapeutic approach to erectile dysfunction and intense competition. 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.

The Company began generating revenues from product sales in January 1997. The Company has limited experience in manufacturing and selling MUSE (alprostadil) in commercial quantities. Whether the Company can successfully manage the transition to a large scale commercial enterprise will depend upon successful further development of its manufacturing capability and its distribution network and attainment of foreign regulatory approvals for MUSE (alprostadil). Failure to make such a transition successfully would have a material adverse effect on the Company's business, financial condition and results of operations.

FUTURE CAPITAL NEEDS AND UNCERTAINTY OF ADDITIONAL FINANCING

The Company expects to incur substantial additional costs, including expenses related to building its marketing and sales organization, a second manufacturing plant in the United States and one in Europe, new product preclinical and clinical costs, ongoing research and development activities, and general corporate

purposes. The Company anticipates that its existing capital resources will be sufficient to support the Company's operations through commercial introduction of MUSE (alprostadil) in Europe but may not be sufficient for the introduction of any additional future products. Accordingly, the Company anticipates that it may be required to issue additional equity or debt securities and may use other financing sources including, but not limited to, corporate alliances and lease financings to fund the future development and possible commercial launch of its products. The sale of additional equity securities would result in additional dilution to the Company's stockholders. There can be no assurance that additional funds will be available on terms satisfactory to the Company, or at all. Failure to obtain adequate funding could cause a delay or cessation of the Company's product development and marketing efforts and would have a material adverse effect upon the Company's business, financial condition and results of operations. The Company's working capital and additional funding requirements will depend upon numerous factors, including: (i) the level of resources that the Company devotes to sales and marketing capabilities; (ii) the level of resources that the Company devotes to expanding manufacturing capacity; (iii) the activities of competitors; (iv) the progress of the Company's research and development programs; (v) the timing and results of preclinical testing and clinical trials; (vi) technological advances; and (vii) continued profitability.

DEPENDENCE ON KEY PERSONNEL

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

RISKS RELATING TO INTERNATIONAL OPERATIONS

In the event the Company receives necessary foreign regulatory approvals, the Company plans to market its products 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 anticipated international nature of the Company's business is also expected to subject it and its representatives, agents and distributors to laws and regulations of the foreign jurisdictions in which they operate or the Company's products are sold. The regulation of drug therapies in a number of such jurisdictions, particularly in the European Union, continues to develop, and there can be no assurance that new laws or regulations will not have a material adverse effect on the Company's business, financial condition and results of operations. In addition, the laws of certain foreign countries do not protect the Company's intellectual property rights to the same extent as do the laws of the United States.

PRODUCT LIABILITY AND AVAILABILITY OF INSURANCE

The use of the Company's products in clinical trials and commercially may expose the Company to product liability claims and possible adverse publicity. The Company currently maintains product liability insurance coverage. There can be no assurance that the Company's present or future insurance will provide adequate coverage or be available at a reasonable cost or that product liability claims would not adversely affect the business or financial condition of the Company.

UNCERTAINTY OF PHARMACEUTICAL PRICING AND REIMBURSEMENT

In the United States and elsewhere, sales of pharmaceutical products currently 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. There can be no assurance that the Company's products will be considered cost effective and that

reimbursement to the consumer will be available or sufficient to allow the Company to sell its products on a competitive basis.

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

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.

CONTROL BY EXISTING STOCKHOLDERS

As of May 1, 1997, the Company's executive officers and current directors, and certain of their affiliates, beneficially owned approximately 11.3% of the Company's outstanding Common Stock. Also, Ardsley Advisory Partners, Forstmann-Leff Associates and TCW Group owned 28% of the outstanding Common Stock. Such concentration of ownership may have the effect of delaying, defining or preventing a change in control of the Company. Additionally, these stockholders will have significant influence over the election of directors of the Company. This concentration of ownership may allow significant influence and control over Board decisions and corporate actions.

POTENTIAL VOLATILITY OF STOCK PRICE

The stock market has recently 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 variations in the Company's financial results, comments by security analysts, the Company's ability to scale up its manufacturing capability to commercial levels, the Company's ability to successfully sell its product in the United States and internationally, any loss of key management, the results of the Company's clinical trials or those of its competition, adverse regulatory actions or decisions, announcements of technological innovations or new products by the Company or 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 SHAREHOLDER RIGHTS PLAN AND CERTAIN CHARTER AND BYLAW PROVISIONS

In February 1996, the Company's Board of Directors authorized the Company's reincorporation in the State of Delaware (the "Reincorporation") and adopted a Shareholder Rights Plan. The Company's reincorporation into the State of Delaware was approved by its stockholders and effective in May 1996. The Shareholder 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% 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% 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% of more of the Company's Common Stock.

The Shareholder 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 Shareholder 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

A former consultant to the Company has claimed that he is the inventor of certain technology disclosed in two of the Company's patents. The former consultant further claims that the Company defrauded him by allegedly failing to inform him that it intended to use and patent this technology and by failing to compensate him for the technology in the manner allegedly promised. On May 28, 1996, the Company filed a complaint for declaratory judgment against the former consultant in the United States District Court for the Northern District of California, which seeks a declaration from the court that the former consultant is not an inventor of any of the technology disclosed in the patent. On July 17, 1996, the former consultant filed a lawsuit that seeks to have two of the Company's patents declared invalid on the grounds that they fail to list him as an inventor. On September 16, 1996, the Court dismissed the consultant's lawsuit, and ordered the consultant to refile his claims or counterclaims to the action initiated by the Company on May 28, 1996. The consultant filed his counterclaim on September 26, 1996. The Company has conducted a review of the circumstances surrounding this matter and believes that the allegations are without merit. Although the Company believes that it should prevail, the uncertainties inherent in litigation prevent the Company from giving any assurances about the outcome of such litigation.

In a separate matter, on April 10, 1996, the licensors in an agreement by which the Company acquired a patent license filed a lawsuit in a Texas State court that alleges that they were defrauded in connection with the renegotiation of a license agreement between the Company and the licensors. On May 8, 1996, the action was removed to the United States District Court for the Western District of Texas. In addition to monetary damages, the licensors seek to return to the terms of an earlier superseded license agreement. In March 1997, the parties to the Texas action reached an agreement to settle the case. Pursuant to the terms of the Agreement, neither the Company nor its officers will pay any damages to plaintiffs, and the license agreement will remain in effect. The parties are currently negotiating the final terms of the agreement, however, there can be no assurance that such agreement will be finalized. In the event that no final agreement is executed, although the Company believes it should prevail in the matter, the uncertainties inherent in litigation prevent the Company from giving any assurances concerning the outcome of such litigation.

ITEM 2. CHANGES IN SECURITIES.

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)

****3.1	Certificate of Incorporation of the Company, as currently in effect
###3.2	Form of Amended and Restated Certificate of Incorporation of the Company, to be filed immediately following the Company's Annual Meeting of Stockholders if the stockholders approve Proposal 2 in the Company's Proxy
****3.3	Bylaws of the Registrant, as amended
###4.1	Specimen Common Stock Certificate of the Registrant
*4.2	Registration Rights as amended
**4.3	Form of Agreement Not to Sell by and between the Registrant and certain shareholders and option holders
*4.4	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	Second amended and Restated Preferred Shares Rights Agreement, dated as of April 15, 1997 by and between Vivus, Inc. 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	Assignment Agreement by and between Alza Corporation and the Registrant dated December 31, 1993
*+10.2	Memorandum of Understanding by and between Ortho Pharmaceutical Corporation and the Registrant dated February 25, 1992
*10.3	Assignment Agreement by and between Ortho Pharmaceutical Corporation and the Registrant dated June 9, 1992
*+10.4	License Agreement by and between Gene A. Voss, M.D., Allen C. Eichler, M.D., and the Registrant dated December 28, 1992
*+10.5A	License Agreement by and between Ortho Pharmaceutical Corporation and Kjell Holmquist AB dated June 23, 1989
*+10.5B	Amendment by and between Kjell Holmquist AB and the Registrant dated July 3, 1992
*10.5C	Amendment by and between Kjell Holmquist AB and the Registrant dated April 22, 1992
*+10.5D	Stock Purchase Agreement by and between Kjell Holmquist AB and the Registrant dated April 22, 1992
*+10.6A	License Agreement by and between Amsu, Ltd., and Ortho Pharmaceutical Corporation dated June 23, 1989
*+10.6B	Amendment by and between Amsu, Ltd., and the Registrant dated July 3, 1992
*10.6C	Amendment by and between Amsu, Ltd., and the Registrant dated April 22, 1992
*+10.6D	Stock Purchase Agreement by and between Amsu, Ltd., and the Registrant dated July 10, 1992
*10.7	Supply Agreement by and between Paco Pharmaceutical Services, Inc., and the Registrant dated November 10, 1993
*+10.8	Agreement by and among Pharmatech, Inc., Spolana Chemical Works AS, and the Registrant dated June 23, 1993
*10.9	Master Services Agreement by and between the Registrant and Teknekron Pharmaceutical Systems dated August 9, 1993

*10.10	Lease by and between McCandless-Triad and the Registrant dated November 23, 1992, as amended
***10.11	Form of Indemnification Agreements by and among the Registrant and the Directors and Officers of the Registrant
**10.12	1991 Incentive Stock Plan and Form of Agreement, as amended
*10.13	1994 Director Option Plan and Form of Agreement
*10.14	Form of 1994 Employee Stock Purchase Plan and Form of Subscription Agreement
*10.15	Stock Restriction Agreement between the Company and Virgil A. Place, M.D. dated November 7, 1991
*10.16	Stock Purchase Agreement between the Company and Leland F. Wilson dated June 26, 1991, as amended
*10.17	Letter Agreement between the Registrant and Leland F. Wilson dated June 14, 1991 concerning severance pay
*10.18	Letter Agreement between the Registrant and Paul Doherty dated January 26, 1994 concerning severance pay
**10.19	Guaranteed Maximum Price Contract by and between the Registrant and Marshall Contractors, Inc. dated January 27, 1995
**10.20	Sub-lease by and among the Registrant, Argonaut Technologies, Inc., ESCAgenetics Corp. and Tanklage Construction Co. dated March 13, 1995
****+10.21	Distribution Services Agreement between the Registrant and Synergy Logistics, Inc. (a wholly-owned subsidiary of Cardinal Health, Inc.) dated February 9, 1996
****+10.22	Manufacturing Agreement between the Registrant and CHINOIN Pharmaceutical and Chemical Works Co., Ltd. dated December 20, 1995
##+10.23	Distribution and Services Agreement between the Registrant and Alternate Site Distributors, Inc. dated July 17, 1996
*****+10.24	Distribution Agreement made as of May 29, 1996 between the Registrant and Astra AB
##10.25	Menlo McCandless Office Lease made as of August 30, 1996 by and between Registrant and McCandless-Triad
##10.26	Sublease Agreement made as of August 22, 1996 by and between Registrant and Plant Research Technologies
###++10.27	Distribution Agreement made as of January 22, 1997 between the Registrant and Janssen Pharmaceutical International, a division of Cilag AG International
###10.28	Lease Agreement made as of January 1, 1997 between the Registrant and Airport Associates
###10.29	Lease Amendment No. 1 as of February 15, 1997 between Registrant and Airport Associates
###10.30	Lease agreement by and between 605 East Fairchild Associates, L.P. and Registrant dated as of March 5, 1997
27.1	Financial Data Schedule

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* Incorporated by reference to the same-numbered exhibit filed with the Registrant's Registration Statement on Form S-1 No. 33-75698.

** Incorporated by reference to the same-numbered exhibit filed with the Registrant's Registration Statement on Form S-1 No. 33-90390, as amended.

*** Incorporated by reference to the same-numbered exhibit filed with the Registrant's Form 8-B filed with the Commission on June 24, 1996.

**** Incorporated by reference to the same-numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 1996, as amended.

***** 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.

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.

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.

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.

+ Confidential treatment granted.

++ Confidential treatment requested.

(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.

VIVUS, Inc.

Date: May , 1997

/s/ DAVID C. YNTEMA

David C. Yntema
Chief Financial Officer

/s/ LELAND F. WILSON

Leland F. Wilson
President and Chief Executive Officer

VIVUS, INC.

INDEX TO EXHIBITS

EXHIBIT	DESCRIPTION
27.1	Financial Data Schedule

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1,000

3-MOS
DEC-31-1997
JAN-01-1997
MAR-31-1997
6,549
57,278
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