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

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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, 1998

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) |
| 605 EAST FAIRCHILD DRIVE | MOUNTAIN VIEW, CA 94043 |
| (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, 1998, 31,721,292 shares of common stock were outstanding.

Exhibit index on page 25.

PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

VIVUS, INC.

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

| | THREE MONTHS ENDED MARCH 31, | |
|---|---|---|
| | 1998 | 1997 |
| | (UNAUDITED) | (UNAUDITED) |
| Revenue | | |
| US Product | $24,551 | $27,791 |
| International Product | 1,971 | -- |
| Milestone | 1,000 | 5,000 |
| Total revenue | 27,522 | 32,791 |
| Cost of goods sold | 10,482 | 8,066 |
| Gross margin | 17,040 | 24,725 |
| Operating expenses: | | |
| Research and development | 3,880 | 2,027 |
| Selling, general and administrative | 17,058 | 11,809 |
| Total operating expenses | 20,938 | 13,836 |
| Income (loss) from operations | (3,898) | 10,889 |
| Interest and other income | 911 | 1,121 |
| Income (loss) before taxes | (2,987) | 12,010 |
| Income tax (provision) benefit | 597 | (2,456) |
| Net income (loss) | $(2,390) | $ 9,554 |
| Net income (loss) per share: | | |
| Basic | $ (0.07) | $ 0.29 |
| Diluted | $ (0.07) | $ 0.27 |
| Shares used in the computation of net income (loss) per share: | | |
| Basic | 32,125 | 32,700 |
| Diluted | 32,125 | 35,654 |

VIVUS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS)

| | MARCH 31, 1998 | DECEMBER 31, 1997 |
|---|---|---|
| | (UNAUDITED) | |
| Current assets: | | |
| Cash | $ 3,897 | $ 6,161 |
| Available-for-sale securities | 9,038 | 52,955 |
| Accounts receivable | 16,922 | 11,791 |
| Inventories | 11,675 | 9,084 |
| Prepaid expenses and other assets | 1,971 | 1,636 |
| Total current assets | 43,503 | 81,627 |
| Property and equipment | 41,901 | 36,462 |
| Available-for-sale securities, non-current | 31,270 | 32,580 |
| Total | $116,674 | $150,669 |
| Current Liabilities: | | |
| Accounts payable | $ 7,609 | $ 6,574 |
| Accrued and other liabilities | 10,802 | 20,165 |
| Total current liabilities | 18,411 | 26,739 |
| Stockholders' equity: | | |
| Common stock; $.001 par value; shares authorized 200,000; shares outstanding -- March 31, 1998, 31,721; December 31, 1997, 33,168 | 32 | 33 |
| Paid in capital | 130,182 | 153,336 |
| Accumulated other comprehensive income (loss) | (24) | 98 |
| Accumulated deficit | (31,927) | (29,537) |
| Total stockholders' equity | 98,263 | 123,930 |
| Total | $116,674 | $150,669 |

VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(IN THOUSANDS)

| | THREE MONTHS ENDED MARCH 31, | |
|---|---|---|
| | 1998 | 1997 |
| | (UNAUDITED) | (UNAUDITED) |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net income (loss) | $ (2,390) | $ 9,554 |
| Adjustments to reconcile net income (loss) to net cash provided by (used for) operating activities: | | |
| Depreciation and amortization | 678 | 403 |
| Stock compensation costs | 152 | 105 |
| Changes in assets and liabilities: | | |
| Accounts receivable | (5,131) | (11,538) |
| Inventories | (2,591) | (126) |
| Prepaid expenses and other assets | (335) | (512) |
| Accounts payable | 1,035 | (1,174) |
| Accrued and other liabilities | (9,363) | 6,175 |
| Net cash provided by (used for) operating activities | (17,945) | 2,887 |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Property and equipment purchases | (6,116) | (1,027) |
| Investment purchases | (53,461) | (56,418) |
| Proceeds from sale/maturity of securities | 98,565 | 58,679 |
| Net cash provided by investing activities | 38,988 | 1,234 |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Exercise of common stock options | 277 | 1,873 |
| Repurchase of common stock | (23,584) | -- |
| Net cash provided by (used for) financing activities | (23,307) | 1,873 |
| Net increase (decrease) in cash | (2,264) | 5,994 |
| CASH: | | |
| Beginning of period | 6,161 | 555 |
| End of period | $ 3,897 | $ 6,549 |
| NON-CASH INVESTING AND FINANCING ACTIVITIES: | | |
| Unrealized loss on securities | $ (24) | $ (302) |
| SUPPLEMENTAL CASH FLOW DISCLOSURE: | | |
| Income taxes paid | $ 71 | $ -- |

VIVUS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
MARCH 31, 1998

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, 1998 are not necessarily indicative of the results that may be expected for the year ending December 31, 1998. For further information, refer to the financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 1997.

2. COMPREHENSIVE INCOME

The Company has adopted the Statement of Financial Accounting Standards ("SFAS") No. 130, "Reporting Comprehensive Income", which establishes standards for the reporting and display of comprehensive income and its components in general purpose financial statements for the year ended December 31, 1998. The table below sets forth "comprehensive income" as defined by SFAS No. 130 for the three month period ended March 31:

| | 1998 | 1997 |
|---|---|---|
| | (UNAUDITED) | (UNAUDITED) |
| Net income (loss) | $(2,390) | $9,554 |
| Other comprehensive income: | | |
| Unrealized loss on securities | (122) | (302) |
| Income tax benefit | 24 | 60 |
| | (98) | (242) |
| Comprehensive income (loss) | $(2,488) | $9,313 |

3. NET INCOME (LOSS) PER SHARE

The Company has adopted Statement of Financial Accounting Standards No. 128 ("SFAS 128"), "Earnings per Share' which replaced Accounting Principles Board Opinion No. 15 ("APB 15"). SFAS 128 requires a dual presentation of basic and diluted earnings per share. Basic earnings per share is based on the weighted average number of common shares outstanding during the periods. Diluted earnings per share is based on the weighted average number of common and common equivalent shares, which represent shares that may be issued in the future upon the exercise of outstanding stock options and warrants. Such options and warrants are excluded from the net loss per common and equivalent shares for the three months ended March 31, 1998 because they are antidilutive. Diluted earnings per share is computed similarly to earnings per share previously reported pursuant to APB 15 and for the Company, diluted earnings per share amounts are the same as amounts previously reported under APB 15. Share and per share amounts have been calculated based on post-split shares resulting from the two-for-one stock split effective June 23, 1997.

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 leader in the development 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 minimally invasive, easy to use system that delivers pharmacologic agents topically to the urethral lining. In November 1996, the Company obtained marketing clearance by the U.S. Food and Drug Administration (the "FDA") to manufacture and market its first product, MUSE(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. 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). The Company commenced commercial sales of ACTIS in the United States through its direct sales force in July 1997. ACTIS is currently being studied for adjunctive use with MUSE (alprostadil); however, there can be no assurance that such studies will be completed and if completed that such studies will demonstrate that adjunctive use of ACTIS with MUSE (alprostadil) is a safe and effective treatment for erectile dysfunction.

The Company has entered into international marketing agreements with Astra AB ("Astra") and Janssen Pharmaceutica International ("Janssen") under which Astra and Janssen will purchase MUSE (alprostadil) for resale in various international markets. In November 1997, the Company obtained regulatory marketing clearance by the Medicines Control Agency ("MCA") to market MUSE (alprostadil) in the United Kingdom. The Company began selling MUSE (alprostadil) to Astra in the fourth quarter of 1997. Astra began selling MUSE (alprostadil) in the United Kingdom in February 1998. In addition, applications for regulatory approval to market MUSE (alprostadil) have been submitted in several other countries, including China, Australia, Canada and Mexico. 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.

The Company has limited experience in manufacturing and selling MUSE (alprostadil) in commercial quantities. Since the commercial launch of MUSE (alprostadil) in January 1997, the Company has experienced product shortages due to higher than expected demand and difficulties encountered in scaling up production of MUSE (alprostadil). The Company leased 90,000 square feet of space in New Jersey in which it has constructed additional manufacturing and testing facilities. The Company has filed for regulatory authorization of this facility with both the FDA and MCA. In March 1998, the MCA authorized the Company to begin commercial production and shipment of MUSE (alprostadil) from its new facility. In addition, the Company has negotiated a long-term lease for a site in Ireland for construction of a European manufacturing operation. Until the Company receives the required approvals for its new New Jersey facility, domestic and certain international markets will need to be supplied from its current facility at Paco Pharmaceutical Services, Inc. ("Paco"). There can be no assurance that such approvals will be granted in a timely manner, if at all. If international sales increase as anticipated, product available for the domestic market will be reduced and gross margins will be adversely impacted. If the Company encounters further difficulties with its current manufacturing facility or delays in regulatory approvals of its new manufacturing facility, capacity constraints could continue for an extended period of time, which would have a material adverse effect on the Company's business, financial condition and results of operations.

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. VIVUS currently employs approximately 75 sales representatives who call upon urologists and other specialists. Effective February 1998, the Company entered into a Sales Force Services Agreement with Innovex Inc. ("Innovex"). While the Sales Force Services Agreement allows for approximately 200 contract sales representatives, the Company has decided to initially add approximately 150 contract sales representatives, the substantial majority of whom will be calling upon primary care physicians. The Company may decide to increase the contract sales force to

approximately 200 in the future. As a result of this contract, the Company's ability to increase sales will be highly dependent upon the efforts of Innovex. There can be no assurance that Innovex's sales efforts will be successful or that primary care physicians will recommend the use of MUSE (alprostadil).

In the second quarter, the Company anticipates two significant changes in the erectile dysfunction market. First, the launch of sildenafil, a competitive oral product, is expected to dramatically increase the number of men seeking treatment for impotence. Second, indications are that a large number of current and future impotence patients will want to try this new oral therapy. As a result of this and other factors, including higher costs of good sold as the Company ramps up its new manufacturing facility, and higher marketing and sales costs related to the expansion of the Company's sales force, the Company expects an operating loss in the second quarter of 1998.

The Company has sought and will continue to seek pharmacologic agents suitable for transurethral delivery for which significant safety data already exists. The Company believes that such agents may progress more rapidly through clinical development and the regulatory process than agents without preexisting safety data. The Company expects to begin a Phase III multi-center trial in 1998 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.

RESULTS OF OPERATIONS

THREE MONTHS ENDED MARCH 31, 1998 AND 1997

Product revenues for the first quarter ending March 31, 1998 were $24.5 million in the United States and $2.0 million internationally compared to $27.8 million in the Unites States and zero internationally for the same period in 1997. The demand for MUSE (alprostadil) domestically, as measured by retail prescriptions, remained relatively flat from the fourth quarter 1997 to first quarter 1998. Total revenues for the first quarter ended March 31, 1998 also included a $1 million milestone payment from Janssen Pharmaceutica related to regulatory approval of MUSE (alprostadil) in South Korea, compared to the first quarter of 1997 which included a $5 million milestone payment related to signing the initial distribution agreement with Janssen Pharmaceutica.

The gross margin for the first quarter ending March 31, 1998, was 60% of net product revenues, compared with 71% in the quarter ending March 31, 1997. The lower margin in 1998 was primarily the result of the lower per unit price on international shipments due to the revenue sharing arrangements with international partners, as well as higher cost of goods primarily related to start up costs associated with the new manufacturing facility. The gross margins include the effect of reduced cost of sales related to previously expensed materials of $.8 million and $1.1 million in the first quarter of 1998 and 1997, respectively. The Company anticipates that the previously expensed raw materials will be fully utilized late in 1998. The Company also expects international revenues to continue to increase as a proportion of total revenues. These factors will have the effect of reducing the gross margin but may be offset in part by production efficiencies at the new manufacturing facility.

Research and development expenses for the first quarter ended March 31, 1998 were $3.9 million compared to $2.0 million in the first quarter ending March 31, 1997. The increase was mainly due to new product development.

Selling, general and administrative expenses for the quarter ended March 31, 1998 were $17.1 million, $5.2 million higher than the quarter ending March 31, 1997. The increase was almost entirely due to spending on a direct-to-consumer advertising campaign and costs associated with the recent increase in the Company's direct sales force from fifty to approximately seventy-five sales representatives. At this time, the Company does not plan to continue its direct-to-consumer advertising to create patient awareness because the launch of sildenafil, a competitive oral treatment, is expected to dramatically increase the number of men seeking treatment for impotence. For the remainder of 1998, the Company expects to increase spending directed

primarily at reaching and educating physicians through the expanded sales force, including the Innovex contract sales force.

Interest and other income for the three months ended March 31, 1998 were $.9 million compared with $1.1 million for the three months ended March 31, 1997. The decrease was primarily the result of lower average invested cash balances. The Company expects lower interest income for the remainder of 1998 due to lower average invested cash balances.

Because of the first quarter loss in 1998, the Company recorded a tax benefit of $.6 million. The Company's effective tax rate was 20 percent of income before taxes for the three months ended March 31, 1998 and 1997. The effective tax rate for the year ended December 31, 1997 was 8 percent. The effective tax rate computation for 1997 was lower as it included the effect of operating losses carried forward from prior years.

LIQUIDITY AND CAPITAL RESOURCES

Since inception, the Company has financed operations primarily from the sale of preferred and common stock. Through March 31, 1998, VIVUS has raised $152.6 million from financing activities. Cash, cash equivalents and available-for-sale securities totaled $44.2 million at March 31, 1998 compared with $91.7 million at December 31, 1997. The decrease in cash resulted from several factors, including the Company's repurchase of its common stock ($23.6 million), capital spending associated with the new manufacturing facility, payment of the lawsuit settled in the fourth quarter of 1997 and payment of 1997 sales commissions. The stock repurchased during the first quarter completes the repurchase of a total of two million shares authorized by the Board of Directors.

Accounts receivable at March 31, 1998 were $16.9 million compared with $11.8 million at December 31, 1997, an increase of $5.1 million. The increase was primarily due to the Company shipping approximately $16.5 million of its first quarter product revenues in the month of March 1998.

Current liabilities were $18.4 million at March 31, 1998 compared with $26.7 million at December 31, 1997, a reduction of $8.3 million. The reduction primarily relates to the payment of the lawsuit settled in the fourth quarter 1997 and payment of 1997 sales commissions.

Capital expenditures in the three months ended March 31, 1998 were $6.1 million compared with $1.0 million for the same period in 1997, an increase of $5.1 million. This increase primarily resulted from additional costs associated with the Company's new 90,000 square foot production facility in New Jersey and its new corporate headquarters.

The Company expects to incur substantial additional costs, including expenses related to its manufacturing facilities in New Jersey and a new manufacturing facility in Europe, expenses related to marketing and sales of MUSE (alprostadil), including expenses associated with expanding its sales force by approximately 150 sales representatives, new product preclinical and clinical costs, ongoing research and development activities, and general corporate purposes. The Company anticipates that its existing capital resources may not be sufficient to support the Company's operations through the commercial introduction of MUSE (alprostadil) in all international markets or for the introduction of any additional future products. During 1998, the Company anticipates using financing sources, such as receivables financing, lease financing and credit lines, to provide additional capital resources. The Company may also be required to issue additional equity or debt securities and may use other financing sources including, but not limited to corporate alliances and lease financing to fund the future 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 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) results of operations.

The Management's Discussion and Analysis of Financial Condition and Results of Operations section contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities 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; CAPACITY CONSTRAINTS

The Company has limited experience in manufacturing MUSE (alprostadil) in commercial quantities. Since the commercial launch of MUSE (alprostadil) in January 1997, the Company has experienced product shortages due to higher than expected demand and difficulties encountered in scaling up production of MUSE (alprostadil). The Company leased 90,000 square feet of space in New Jersey in which it has constructed additional manufacturing and testing facilities. The Company has filed for regulatory authorization of this facility with both the FDA and MCA. In March 1998, the MCA authorized the Company to begin commercial production and shipment of MUSE (alprostadil) from its new facility. Before the new facility in New Jersey can produce commercial product for the United States and certain other markets, the Company must obtain FDA approval. There is no assurance FDA approval will be completed and obtained in a timely manner, if at all. Until the Company receives the required approval for its new New Jersey facility, domestic and certain international markets will need to be supplied from its current facility at Paco Pharmaceutical Services, Inc. ("Paco"). If international sales increase as anticipated, product available for the domestic market will be reduced and gross margins will be adversely impacted. If the Company encounters further difficulties with its current manufacturing facility or delays in regulatory approval of its new manufacturing facility, capacity constraints could continue for an extended period of time. Such extended capacity constraints could strain relationships with distribution partners due to the need to allocate product between domestic and international markets, and possibly cause patients to seek alternative therapies. Such events could have a material adverse effect on the Company's business, financial condition and results of operations.

The formulation, filling and packaging of MUSE (alprostadil) is performed at 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 of dedicated 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, in which it has constructed additional manufacturing and testing facilities. Until the Company further develops its in-house manufacturing capability, it will be substantially 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 receive FDA approval for or be able to ramp-up its second manufacturing facility in a timely manner, if at all. Interruptions in the availability of products could delay or prevent the further 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 certain of its suppliers and service providers are subject to routine periodic inspections by the FDA and certain state and foreign regulatory agencies for compliance with current Good Manufacturing Practices (cGMP) and other applicable regulations. Certain of the Company's suppliers were inspected for compliance with cGMP requirements as part of the approval process. However, upon routine re-inspection of these facilities, there can be no assurance that the FDA will find the manufacturing process or facilities to be in compliance with cGMP and other regulations. A routine re-inspection of Chinoin, one of the Company's two sources of alprostadil, resulted in the issuance of an FDA Form 483 which set forth areas where Chinoin was not in compliance with cGMP requirements. 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.

In connection with post-approval inspections of the Company's New Jersey manufacturing facility at Paco, the FDA issued the Company FDA Form 483s and a Warning Letter, which detailed specific areas

where the FDA observed that the Company's operations were not in full compliance with some areas of cGMP requirements. On November 19, 1997, after taking corrective action and providing the FDA a written response to the FDA observations, the Company received a letter from the FDA affirming that the Company's facility at Paco is in substantial compliance with cGMP requirements. Failure to maintain satisfactory cGMP compliance could 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 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. VIVUS currently employs approximately 75 sales representatives who call upon urologists and other specialists. Effective February 1998, the Company entered into a Sales Force Services Agreement with Innovex Inc. ("Innovex"). While the Sales Force Services Agreement allows for approximately 200 contract sales representatives, the Company has decided to initially add approximately 150 contract sales representatives, the substantial majority of whom will be calling upon primary care physicians. The Company may decide to increase the contract sales force to approximately 200 in the future. As a result of this contract, the Company's ability to increase sales will be highly dependent upon the efforts of Innovex. There can be no assurance that Innovex's sales efforts will be successful or that primary care physicians will recommend the use of MUSE (alprostadil).

The Company launched its first domestic direct-to-consumer advertising campaign in January 1998 to increase patient awareness of erectile dysfunction and MUSE (alprostadil). This campaign included major television, newspaper and magazine placements. In February 1998, the FDA notified the Company that it objected to, among other things, the prominence and balance of side effect information relative to efficacy information in certain written materials and the Company's television advertisements. The Company is no longer utilizing the prior written materials and has ceased running its television advertisements. In addition, the Company has modified its written materials in response to the FDA's comments and has held discussions with the FDA to reach agreement on these modifications as well as necessary changes to the Company's television advertisements. If the FDA does not believe the modified written materials respond to its concerns then further modifications would be required resulting in additional cost. If the Company and the FDA cannot reach a resolution regarding the necessary changes to the Company's television advertisements, this could result in additional cost and may prevent broadcast advertising on major networks. At this time, the Company does not plan to continue its direct-to-consumer advertising to create patient awareness because the launch of sildenafil, a competitive oral treatment, is expected to dramatically increase the number of men seeking treatment for impotence. Should the Company decide to resume its direct-to-consumer advertising, however, cost and delay associated with the FDA's objections to the Company's direct-to-consumer advertising materials could have a negative effect upon the Company's domestic sales and marketing efforts. There can be no assurance that the Company's domestic sales and marketing efforts will be successful at increasing the demand for MUSE (alprostadil). In addition, there can be no assurance that the Company's capacity constraints will not prevent the Company from supplying any increased demand.

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. The Company also has access to CORD's information systems that support these functions. As a result of this distribution agreement with CORD, the Company is heavily dependent on CORD's efforts to fulfill orders and warehouse its products effectively. 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, and, in December 1997, received a $2 million milestone payment upon receiving approval of this application by the MCA. The Company will be paid up to an additional $8 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. 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. In October 1997, the Company signed an international marketing agreement, amending the earlier agreement with Janssen, that expanded Janssen's territories to include the Middle East, Russia, the Indian sub-continent, and Africa. As consideration for execution of the expanded international territory marketing agreement, Janssen paid the Company $2 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.

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. In June 1997, Schwartz Pharma announced the FDA approval of their needle injection treatment for erectile dysfunction. The most significant competitive therapy is sildenafil, an oral medication by Pfizer Inc., for which it received regulatory approval in the United States in March 1998 and has filed for regulatory approval in Europe. Commercial introduction of Pfizer Inc.'s oral medication could have a material adverse affect on the Company's business, financial condition and results of operations. As a result of the launch of sildenafil in the second quarter, the Company anticipates two significant changes in the erectile dysfunction market. First, the launch of sildenafil is expected to dramatically increase the number of men seeking treatment for impotence. Second, indications are that a large number of current and future impotence patients will want to try this new oral therapy. As a result of this and other factors, including higher costs of good sold as the Company ramps up its new

manufacturing facility, and higher marketing and sales costs related to the expansion of the Company's sales force, the Company expects an operating loss in the second quarter of 1998.

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 in Phase III clinical trials. These entities may market commercial products either on their own or through collaborative efforts. For example, Zonagen, Inc. announced a worldwide marketing agreement with Schering-Plough in November 1997. The Company's competitors may develop technologies and products that are more effective than those currently marketed or being developed by the Company. Such developments would render the Company's products less competitive or possibly obsolete. The Company is also competing with respect to marketing capabilities and manufacturing efficiency, areas in which it has limited experience.

DEPENDENCE ON 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). Mild to moderate transient penile/perineal pain was experienced by 21 percent to 42 percent of patients (depending on dosage) treated with MUSE (alprostadil) in the Company's Phase II/III Dose Ranging study. Moderate to severe decreases in blood pressure were experienced by 1 percent to 4 percent of patients (depending on dosage) treated with MUSE (alprostadil) in such study, and rarely (0.4 percent) patients experienced syncope (fainting). During 1997, the first year of commercial use of MUSE (alprostadil), the incidence of adverse side effects was consistent with that experienced in clinical trials.

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 November 1997, the Company obtained regulatory marketing clearance by the MCA to market MUSE (alprostadil) in the United Kingdom.

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 the Company must also report certain adverse events involving its drugs to the Agency under regulations issued by the FDA. Additionally, previously unidentified adverse events or an increased frequency of adverse events that occur post-approval could result in labeling modifications of approved products, which could adversely effect future marketing of a drug. Finally, approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing. The restriction, suspension or revocation of

regulatory approvals or any other failure to comply with regulatory requirements would have a material adverse effect on the Company's business, financial condition and results of operations.

The Company has submitted applications for approval of MUSE (alprostadil) in several other countries, including China, Australia, Canada and Mexico. 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 condition of use. Any delay in obtaining, or failure to obtain such approval would adversely affect the Company's ability to generate product revenue.

The Company's clinical trials for future products will generate safety data as well as efficacy data and will require substantial time and significant funding. There is no assurance that clinical 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) 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 certain state and foreign regulatory agencies for compliance with cGMP and other applicable regulations. Certain of the Company's suppliers were inspected for cGMP compliance as part of the approval process. However, upon routine re-inspection of these facilities, there can be no assurance that the FDA will find the manufacturing process or facilities to be in compliance with cGMP and other regulations. A routine re-inspection of Chinoin, one of the Company's two sources of alprostadil, resulted in the issuance of an FDA Form 483 which set forth areas where Chinoin was not in compliance with cGMP requirements. 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.

In connection with post-approval inspections of the Company's New Jersey manufacturing facility at Paco, the FDA issued the Company FDA Form 483s and a Warning Letter, which detailed specific areas where the FDA observed that the Company's operations were not in full compliance with some areas of cGMP requirements. On November 19, 1997, after taking corrective action and providing the FDA a written response to the FDA observations, the Company received a letter from the FDA affirming that the Company's facility at Paco is in substantial compliance with cGMP requirements. Failure to maintain satisfactory cGMP compliance could 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 cGMP compliance is achieved.

PROPRIETARY RIGHTS AND RISK OF PATENT 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 and Trademark Office, including interference proceedings. These proceedings could also result in adverse decisions as to the priority of the Company's licensed or assigned inventions. There is no assurance that the Company's patents will not be successfully challenged or designed around by others.

The Company is presently involved in an opposition proceeding that was instigated by the Pharmedic Company against a European patent that is exclusively licensed to VIVUS. As a result of the opposition proceeding, certain claims in the European patent were held to be unpatentable by the Opposition Division of the European Patent Office ("EPO"). These claims all related to pharmaceutical compositions that include prostaglandin E1. The patentability of all other claims in the patent was confirmed (i.e., claims directed to the use of active agents in the treatment of erectile dysfunction by administration via the urethra to the corpora cavernosa, and 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. Despite the withdrawal of the Pharmedic Company from the appeal process, the Company has continued with its own appeal in an attempt to reinstate the composition claims. The EPO Appeals Board must make its own finding whether the claims that were deemed unpatentable by the Opposition Division are indeed patentable before it can reverse the Opposition Division's decision. There can be no assurance that the appeal will be successful or that further challenges to the Company's European patent will not occur should the Company try to enforce the patent in the various European courts.

There can be no assurance that the Company's products do not or will not infringe on the patent or proprietary rights of others. The Company may be required to obtain additional licenses to the patents, patent applications or other proprietary rights of others. There can be no assurance that any such licenses 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 had claimed that he was the inventor of certain technology disclosed in two of the Company's patents. The former consultant further claimed that the Company and certain of its officers and directors 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. In May 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 sought a declaration from the court that the former consultant was not an inventor of any of the technology. In September 1996, the consultant filed his counterclaim. In December 1997, the Company reached a settlement with the former consultant whereby the former consultant dismissed his claims against the Company and the Company's officers and directors involved in the lawsuit. In return, the Company paid the consultant $5.1 million.

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 AND SINGLE SOURCE OF SUPPLY

The Company obtains its supply of alprostadil from two sources. The first is Spolana Chemical Works a.s. in Neratovice, Czech Republic ("Spolana") pursuant to a supply agreement that was executed in May 1997. In January 1996, the Company entered into an alprostadil supply agreement with CHINOIN Pharmaceutical and Chemical Works Co., Ltd. ("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. The Company is seeking additional sources of alprostadil. In addition, 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 alprostadil and plastic components and 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. Unless the Company secures and qualifies additional sources of alprostadil and plastic components and an additional sterilization facility, it will be entirely dependent upon the existing suppliers and E-Beam. If interruptions in these supplies or services were to occur for any reason, including a decision by existing suppliers and/or E-Beam to discontinue manufacturing or services, political unrest, labor disputes or a failure of the existing suppliers and/or E-Beam to follow regulatory guidelines, the development and commercial marketing of MUSE (alprostadil) and other potential products could be delayed or prevented. An interruption in sterilization services or the Company's supply of alprostadil or plastic components 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 $31.9 million for the period from its inception through March 31, 1998. 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. In the second quarter, the Company anticipates two significant changes in the erectile dysfunction market. First, the launch of sildenafil, a competitive oral product, is expected to dramatically increase the number of men seeking treatment for impotence. Second, indications are that a large number of current and future impotence patients will want to try this new oral therapy. As a result of this and other factors, including higher costs of goods sold as the Company ramps up its new manufacturing facility, and higher marketing and sales costs related to the expansion of the Company's sales force, the Company expects an operating loss in the second quarter of 1998.

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. Until the Company receives FDA approval for its new New Jersey manufacturing facility, domestic and certain international markets will need to be supplied from its current facility at Paco. There can be no assurance such approval will be granted in a timely manner, if at all. If international sales increase as anticipated, product available for the domestic market will be reduced and gross margins will be adversely impacted. If the Company encounters further difficulties with its current manufacturing facility or delays in regulatory approval of its new manufacturing facility, capacity constraints could continue for an extended period of time. Such extended capacity constraints could strain relationships with distribution partners due to the need to allocate product between domestic and international markets, and possibly cause patients to seek alternative therapies. Such

events could have a material adverse effect on the Company's business, financial condition and results of operations. 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 its manufacturing facilities in New Jersey and a new manufacturing facility in Europe, expenses related to marketing and sales of MUSE (alprostadil), including expenses associated with expanding its sales force by approximately 150 sales representatives, new product preclinical and clinical costs, ongoing research and development activities, and general corporate purposes. The Company anticipates that its existing capital resources may not be sufficient to support the Company's operations through the commercial introduction of MUSE (alprostadil) in all international markets or for the introduction of any additional future products. During 1998, the Company anticipates using financing sources, such as receivables financing, lease financing and credit lines, to provide additional capital resources. The Company may also be required to issue additional equity or debt securities and may use other financing sources including, but not limited to corporate alliances and lease financing to fund the future 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 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) results of operations.

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 and retain numerous 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 and 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.

RISKS RELATING TO INTERNATIONAL OPERATIONS

As the Company receives necessary foreign regulatory approvals, the Company will 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 commercial launch of MUSE (alprostadil) 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 included with MUSE (alprostadil), 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 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. While more than 70 percent of prescriptions for MUSE (alprostadil) were reimbursed by third party payors in 1997, there can be no assurance that the Company's products will be considered cost effective and that reimbursement to the consumer will continue to be available or sufficient to allow the Company to sell its products on a competitive basis.

In addition, certain health care providers are moving towards a managed care system in which such providers contract to provide comprehensive health care services, including prescription drugs, for a fixed cost per person. The Company hopes to further qualify 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.

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, announcements of technological innovations or new products by the Company or its competition, comments by security analysts, the Company's ability to scale up its manufacturing capability to commercial levels, adverse regulatory actions or decisions, the Company's ability to increase demand for its product in the United States, 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, 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 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 February 18, 1998, a purported shareholder class action entitled Crain et al. v Vivus, Inc. et al., was filed in Superior Court of the State of California for the County of San Mateo. Five identical complaints were subsequently filed in the same court. These complaints were filed on behalf of a purported class of persons who purchased stock between May 15 and December 9, 1997. The complaints allege that the Company and certain current and former officers or directors artificially inflated the Company's stock price by issuing false and misleading statements concerning the Company's prospects and issuing false financial statements. The complaints do not specify the damages resulting from the alleged conduct. On March 16, 1998, a purported shareholder class action entitled Cramblit et al. v. Vivus, Inc. et al. was filed in the United States District Court for the Northern District of California. Two identical complaints were subsequently filed in the same court. The federal complaints were filed on behalf of a purported class of persons who purchased stock between May 2 and December 9, 1997. The federal complaints assert the same factual allegations as the state court complaints, but asserts legal claims under the Federal Securities Laws. The Company believes the complaints lack merit and the Company will vigorously defend itself in the pending actions.

A former consultant to the Company had claimed that he was the inventor of certain technology disclosed in two of the Company's patents. The former consultant further claimed that the Company and certain of its officers and directors 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. In May 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 sought a declaration from the court that the former consultant was not an inventor of any of the technology. In September 1996, the consultant filed his counterclaim. In December 1997, the Company reached a settlement with the former consultant whereby the former consultant dismissed his claims against the Company and the Company's officers and directors involved in the lawsuit. In return, the Company paid the consultant $5.1 million. The Company recorded the settlement on its books in the fourth quarter of 1997 and paid the settlement on January 5, 1998.

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

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)

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| (7)3.2 | Amended and Restated Certificate of Incorporation of the Company |
| (4)3.3 | Bylaws of the Registrant, as amended |
| (8)3.4 | Certificate of Designations of Rights, Preferences and Privileges of Series A Participating Preferred Stock |
| (7)4.1 | Specimen Common Stock Certificate of the Registrant |
| (1)4.2 | Registration Rights, as amended |
| (1)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 |
| (8)4.5 | 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 |
| (1)+10.1 | Assignment Agreement by and between Alza Corporation and the Registrant dated December 31, 1993 |
| (1)+10.2 | Memorandum of Understanding by and between Ortho Pharmaceutical Corporation and the Registrant dated February 25, 1992 |
| (1)10.3 | Assignment Agreement by and between Ortho Pharmaceutical Corporation and the Registrant dated June 9, 1992 |
| (1)+10.4 | License Agreement by and between Gene A. Voss, M.D., Allen C. Eichler, M.D., and the Registrant dated December 28, 1992 |
| (1)+10.5A | License Agreement by and between Ortho Pharmaceutical Corporation and Kjell Holmquist AB dated June 23, 1989 |
| (1)+10.5B | Amendment by and between Kjell Holmquist AB and the Registrant dated July 3, 1992 |
| (1)10.5C | Amendment by and between Kjell Holmquist AB and the Registrant dated April 22, 1992 |
| (1)+10.5D | Stock Purchase Agreement by and between Kjell Holmquist AB and the Registrant dated April 22, 1992 |
| (1)+10.6A | License Agreement by and between Amsu, Ltd., and Ortho Pharmaceutical Corporation dated June 23, 1989 |
| (1)+10.6B | Amendment by and between Amsu, Ltd., and the Registrant dated July 3, 1992 |
| (1)10.6C | Amendment by and between Amsu, Ltd., and the Registrant dated April 22, 1992 |
| (1)+10.6D | Stock Purchase Agreement by and between Amsu, Ltd., and the Registrant dated July 10, 1992 |
| (1)10.7 | Supply Agreement by and between Paco Pharmaceutical Services, Inc., and the Registrant dated November 10, 1993 |
| (1)10.10 | Lease by and between McCandless-Triad and the Registrant dated November 23, 1992, as amended |
| (4)10.11 | Form of Indemnification Agreements by and among the Registrant and the Directors and Officers of the Registrant |
| (2)10.12 | 1991 Incentive Stock Plan and Form of Agreement, as amended |
| (1)10.13 | 1994 Director Option Plan and Form of Agreement |

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| (1)10.14 | Form of 1994 Employee Stock Purchase Plan and Form of Subscription Agreement |
| (1)10.17 | Letter Agreement between the Registrant and Leland F. Wilson dated June 14, 1991 concerning severance pay |
| (3)+10.21 | Distribution Services Agreement between the Registrant and Synergy Logistics, Inc. (a wholly-owned subsidiary of Cardinal Health, Inc.) dated February 9, 1996 |
| (3)+10.22 | Manufacturing Agreement between the Registrant and CHINOIN Pharmaceutical and Chemical Works Co., Ltd. dated December 20, 1995 |
| (11)++10.22A | 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 |
| (6)+10.23 | Distribution and Services Agreement between the Registrant and Alternate Site Distributors, Inc. dated July 17, 1996 |
| (5)+10.24 | Distribution Agreement made as of May 29, 1996 between the Registrant and Astra AB |
| (7)+10.27 | Distribution Agreement made as of January 22, 1997 between the Registrant and Janssen Pharmaceutica International, a division of Cilag AG International |
| (11)++10.27A | Amended and Restated Addendum 1091, dated as of October 29, 1997, between VIVUS International Limited and Janssen Pharmaceutica International |
| (7)10.28 | Lease Agreement made as of January 1, 1997 between the Registrant and Airport Associates |
| (7)10.29 | Lease Amendment No. 1 as of February 15, 1997 between Registrant and Airport Associates |
| (10)10.29A | Lease Amendment No. 2 dated July 24, 1997 by and between the Registrant and Airport Associates |
| (10)10.29B | Lease Amendment No. 3 dated July 24, 1997 by and between the Registrant and Airport Associates |
| (7)10.30 | Lease agreement by and between 605 East Fairchild Associates, L.P. and Registrant dated as of March 5, 1997 |
| (9)++10.31 | Manufacture and Supply Agreement between Registrant and Spolana Chemical Works, A.S. dated May 30, 1997 |
| (11) 10.32A | Agreement between ADP Marshall, Inc. and the Registrant dated December 19, 1997 |
| (11) 10.32B | General Conditions of the Contract for Construction |
| (11) 10.32C | Addendum to General Conditions of the Contract for Construction |
| (11)++10.33 | Sales Force Services Agreement dated as of February 1, 1998 between the Registrant and Innovex, Inc. |
| 27.1 | Financial Data Schedule |

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(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.

+ 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: April 24, 1998

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David C. Yntema
Chief Financial Officer

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Leland F. Wilson
President and Chief
Executive Officer

VIVUS, INC.

INDEX TO EXHIBITS*

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

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

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3-MOS
DEC-31-1998
JAN-01-1998
MAR-31-1998
3,897
9,038
17,091
169
11,675
43,503
47,095
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116,674
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0
32
98,231
116,674
26,522
27,522
10,482
10,482
20,938
0
0
(2,987)
(597)
(2,390)
0
0
0
(2,390)
(0.07)
(0.07)

FOR PURPOSES OF THIS EXHIBIT, PRIMARY MEANS BASIC.