

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 JUNE 30, 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
(STATE OR OTHER JURISDICTION OF
INCORPORATION OR ORGANIZATION)
605 EAST FAIRCHILD DRIVE
(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES)

94-3136179
(I.R.S. EMPLOYER
IDENTIFICATION NUMBER)
MOUNTAIN VIEW, CA 94043
(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. Yes [X] No []

At June 30, 1998, 31,766,979 shares of common stock were outstanding.

Exhibit index on page [20].

PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

VIVUS, INC.

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

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	1998	1997	1998	1997
	(UNAUDITED)	(UNAUDITED)	(UNAUDITED)	(UNAUDITED)
Revenue				
US Product.....	\$ 6,142	\$33,458	\$ 30,693	\$61,249
International Product.....	9,841	--	11,812	--
Milestone.....	--	--	1,000	5,000
Total revenue.....	15,983	33,458	43,505	66,249
Cost of goods sold.....	10,704	9,584	21,186	17,650
Gross margin.....	5,279	23,874	22,319	48,599
Operating expenses:				
Research and development.....	5,359	1,940	9,239	3,967
Selling, general and administrative.....	17,576	11,258	34,634	23,067
Restructuring costs.....	6,522	--	6,522	--
Total operating expenses.....	29,457	13,198	50,395	27,034
Income (loss) from operations.....	(24,178)	10,676	(28,076)	21,565
Interest and other income.....	597	1,264	1,508	2,385
Income (loss) before taxes.....	(23,581)	11,940	(26,568)	23,950
Income tax (provision) benefit.....	(597)	(1,982)	--	(4,438)
Net income (loss).....	\$(24,178)	\$ 9,958	\$(26,568)	\$19,512
Net income (loss) per share:				
Basic.....	\$ (0.76)	\$ 0.30	\$ (0.83)	\$ 0.59
Diluted.....	\$ (0.76)	\$ 0.28	\$ (0.83)	\$ 0.55
Shares used in the computation of net income (loss) per share:				
Basic.....	31,752	32,990	31,938	32,846
Diluted.....	31,752	35,579	31,938	35,626

VIVUS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS)

	JUNE 30, 1998	DECEMBER 31, 1997
	----- (UNAUDITED)	-----
Current assets:		
Cash.....	\$ 1,420	\$ 6,161
Available-for-sale securities.....	8,913	52,955
Accounts receivable.....	8,170	11,791
Inventories.....	16,772	9,084
Prepaid expenses and other assets.....	2,458	1,636
	-----	-----
Total current assets.....	37,733	81,627
Property and equipment.....	46,878	36,462
Available-for-sale securities, non-current.....	15,073	32,580
	-----	-----
Total.....	\$ 99,684	\$150,669
	=====	=====
Current liabilities:		
Accounts payable.....	\$ 7,370	\$ 6,574
Accrued and other liabilities.....	17,681	20,165
	-----	-----
Total current liabilities.....	25,051	26,739
Stockholders' equity:		
Common stock; \$.001 par value; shares authorized 200,000; shares outstanding -- June 30, 1998, 31,767; December 31, 1997, 33,168.....	32	33
Paid in capital.....	130,699	153,336
Accumulated other comprehensive income.....	7	98
Accumulated deficit.....	(56,105)	(29,537)
	-----	-----
Total stockholders' equity.....	74,633	123,930
	-----	-----
Total.....	\$ 99,684	\$150,669
	=====	=====

VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(IN THOUSANDS)

	SIX MONTHS ENDED JUNE 30,	
	1998	1997
	(UNAUDITED)	(UNAUDITED)
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss).....	\$(26,568)	\$ 19,512
Adjustments to reconcile net income (loss) to net cash provided by (used for) operating activities:		
Depreciation and amortization.....	1,656	892
Stock compensation costs.....	256	201
Changes in assets and liabilities:		
Accounts receivable.....	3,621	(13,663)
Inventories.....	(7,688)	(640)
Prepaid expenses and other assets.....	(822)	(170)
Accounts payable.....	796	3,020
Accrued and other liabilities.....	(2,484)	14,003
Net cash provided by (used for) operating activities.....	(31,233)	23,155
CASH FLOWS FROM INVESTING ACTIVITIES:		
Property and equipment purchases.....	(12,072)	(10,839)
Investment purchases.....	(67,743)	(133,303)
Proceeds from sale/maturity of securities.....	129,201	123,707
Net cash provided by (used for) investing activities.....	49,386	(20,435)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Exercise of common stock options.....	277	2,029
Sale of common stock through employee stock purchase plan.....	413	173
Repurchase of common stock.....	(23,584)	(3,401)
Net cash (used for) financing activities.....	(22,894)	(1,199)
Net increase (decrease) in cash.....	(4,741)	1,521
CASH:		
Beginning of period.....	6,161	555
End of period.....	\$ 1,420	\$ 2,076
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Unrealized loss on securities.....	\$ (91)	\$ (92)
SUPPLEMENTAL CASH FLOW DISCLOSURE:		
Income taxes paid.....	\$ 71	\$ --

VIVUS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
JUNE 30, 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 and six month periods ended June 30, 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 and six month periods ended June 30, 1998 and 1997:

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	1998	1997	1998	1997
(IN THOUSANDS)	(UNAUDITED)	(UNAUDITED)	(UNAUDITED)	(UNAUDITED)
Net income (loss).....	\$(24,178)	\$ 9,958	\$(26,568)	\$19,512
Other comprehensive income:				
Unrealized gain (loss) on				
securities.....	31	209	(91)	(92)
Income tax benefit.....	--	(41)	--	18
	31	168	(91)	(74)
Comprehensive income (loss).....	\$(24,147)	\$10,126	\$(26,659)	\$19,438
	=====	=====	=====	=====

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 and six months ended June 30, 1998 because they are anti-dilutive. 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.

4. RESTRUCTURING COSTS

During June of 1998, the company decided to seek a major pharmaceutical partner to market MUSE (alprostadil) in the United States. Expenses of \$6.5 million were incurred, primarily associated with the Company's agreement to facilitate the transition of its direct U.S. sales force to ALZA Corporation, as well as terminating the contract sales force agreement with Innovex, and personnel reductions in administration, research and development, clinical and marketing departments.

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. MUSE (alprostadil) has also been approved in Argentina, Brazil, Canada, Hong Kong, Korea, Mexico, New Zealand, Philippines, Singapore, South Africa, Sweden, Switzerland and Thailand. In addition, applications for regulatory approval to market MUSE (alprostadil) have been submitted in several other countries, including China, Australia and certain Middle Eastern countries. 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 received indications from one of its international marketing partners that regulatory approvals in certain Middle Eastern countries will be granted later than initially anticipated.

On March 27, 1998, the FDA approved Viagra (sildenafil), an oral pill produced by Pfizer Inc. ("Pfizer") for the treatment of male impotence. Pfizer commercially introduced sildenafil in the U.S. in April 1998. The introduction of sildenafil dramatically increased the number of men seeking treatment for impotence and significantly decreased demand for MUSE (alprostadil). Since the launch of sildenafil, MUSE (alprostadil) prescriptions have declined approximately 70%. As a result of this and other factors, including higher costs of goods sold related to the Company's ramp up of its new manufacturing facility, and higher marketing and sales costs primarily related to the sales force expansion via the Innovex contract pharmaceutical sales organization, the Company experienced an operating loss of \$24.2 million, or \$0.76 per share, in the second quarter of 1998. Included in the second quarter 1998 results is a one-time charge of \$6.5 million related to restructuring the Company's operations. The goal of this restructuring announced on July 8, 1998 is to reduce expenses in order to facilitate a return to profitability. However, there can be no assurance that the restructuring will result in a return to profitability. The Company does not believe that it will return to profitability in 1998 due to a number of factors including costs associated with the restructuring, domestic and international competition from Pfizer and manufacturing difficulties. In connection with the restructuring on July 8, 1998, the Company announced its decision to seek a major pharmaceutical partner to market, distribute and sell MUSE (alprostadil) in the U.S. As a first step, the Company agreed to facilitate the transition of its direct sales force to ALZA Corporation. Sales personnel joining ALZA will continue to sell MUSE on a limited basis until December 31, 1998. Accordingly, the Company is highly dependent upon the efforts of ALZA during this period, and there can be no assurance that ALZA's sales efforts will be successful. In addition, VIVUS also terminated its sales force services agreement with Innovex and reduced personnel in administration, research and development, clinical and marketing departments. As a result of the restructuring, the Company expects its quarterly operating expenses to decrease. There can be no assurance that the Company will partner with a major pharmaceutical company to market, distribute and sell MUSE, or that such a partnership would be on reasonable terms. Further, there can be no assurance that such a partner will be able to successfully market,

distribute and sell MUSE. Should the Company establish such a relationship, the Company's U.S. marketing efforts will depend substantially on the partner's efforts. The partner may have other commitments and may not commit the necessary resources to effectively market, distribute and sell the Company's products. If the Company cannot establish such a relationship, it will have to develop an alternative strategy for marketing, distribution and selling its products in the U.S.

The Company has limited experience in manufacturing and selling MUSE (alprostadil) in commercial quantities. Up until the commercial launch of sildenafil, the Company had initially 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 FDA and MCA authorized the Company to begin commercial production and shipment of MUSE (alprostadil) from its new facility in June and March 1998, respectively. With the added capacity, the Company does not anticipate capacity constraints in the foreseeable future. However, if the Company encounters further difficulties with its current manufacturing facility, capacity issues could arise, which would have a material adverse effect on the Company's business, financial condition and results of operations. The Company has recently experienced various manufacturing difficulties that have resulted in production and shipment delays and higher costs. In turn, revenues from the sale of MUSE (alprostadil) will be delayed, which will have a material adverse effect on the Company's business, financial condition and results of operations.

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 pre-clinical development. There can be no assurance at this point that the Company will be able to fully develop and bring these products to the market.

RESULTS OF OPERATIONS

THREE AND SIX MONTHS ENDED JUNE 30, 1998 AND 1997

Product revenues for the quarter ended June 30, 1998 were \$6.1 million in the United States and \$9.8 million internationally compared to \$33.5 million in the United States and zero internationally for the same period in 1997. Product revenues for the six months ended June 30, 1998 were \$30.7 million in the U.S. and \$11.8 million internationally compared to \$61.2 million domestically and zero internationally for the same period in 1997. The decline in domestic revenue is attributable to the U.S. launch of sildenafil, a competitive oral treatment for erectile dysfunction. Underlying demand for MUSE (alprostadil) domestically, as measured by retail prescriptions, has declined approximately 70% since the commercial launch of sildenafil. Internationally, revenues increased from \$2.0 million in the first quarter of 1998 to \$9.8 million in the second quarter of 1998 as the Company's international marketing partners, Janssen and Astra, launched in various countries. Pfizer has commenced selling sildenafil on a limited basis outside the U.S. As sildenafil is offered in other countries, it is likely that a large number of current and future impotence patients will want to try this new oral therapy. The Company anticipates that the launch of sildenafil in other countries may significantly reduce international demand for MUSE (alprostadil). Such a reduction would have a material adverse effect on the Company's business, financial condition and results of operations.

Total revenues for the six months ended June 30, 1998 also included a \$1 million milestone payment from Janssen related to regulatory approval of MUSE (alprostadil) in South Korea, compared to the six months ended June 30, 1997 which included a \$5 million milestone payment related to signing the initial distribution agreement with Janssen.

The gross margin for the quarter and six months ended June 30, 1998 was 33% and 50% of net product revenues, respectively, compared with 71% and 73%, respectively, in the same periods in 1997. The lower margins in 1998 were 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 \$0.8 million and \$1.8 million in the second quarter of

1998 and 1997, respectively, and \$1.6 million and \$2.9 million in the six months ended June 30, 1998 and 1997, respectively. The Company anticipates that the raw materials, which had been previously expensed prior to FDA approval, will be fully utilized in 1999. 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 quarter ended June 30, 1998 were \$5.4 million compared to \$1.9 million in the quarter ended June 30, 1997. For the six months ended June 30, 1998 and 1997, research and development expenses were \$9.2 million and \$4.0 million, respectively. The increase was mainly due to new product development. As a result of the Company's recent restructuring, it expects that research and development expenses will decrease from current levels.

Selling, general and administrative expenses for the quarter ended June 30, 1998 were \$17.6 million, \$6.3 million higher than the quarter ended June 30, 1997. The increase primarily related to higher selling and marketing expenses associated with the Innovex contract sales organization and expanding the Company's direct sales force from 50 to 74 sales representatives. For the six months ended June 30, 1998, selling, general and administrative expenses were \$34.6 million, \$11.5 million higher than the same period in 1997. The increase was almost entirely due to spending on a direct-to-consumer advertising campaign and costs associated with expanding the direct sales force and adding the Innovex contract sales force. The Company also discontinued its direct-to-consumer advertising program designed to create patient awareness. In addition, on July 8, 1998, the Company announced its decision to seek a major pharmaceutical partner to market, distribute and sell MUSE (alprostadil) in the U.S. and its comprehensive effort to reduce expenses. As a first step, the Company agreed to facilitate the transition of its direct sales force to ALZA. Sales personnel joining ALZA will continue to sell MUSE on a limited basis until December 31, 1998. VIVUS also terminated its sales force services agreement with Innovex and reduced personnel in administration, research and development, clinical and marketing departments. As a result of the restructuring, the Company expects its selling, general and administrative expenses to decrease from the current level.

Interest and other income for the three and six months ended June 30, 1998 were \$0.6 million and \$1.5 million, respectively, compared with \$1.3 million and \$2.4 million for the same periods in 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 \$0.6 million. The Company reversed this tax benefit because of continued losses in the second quarter, resulting in no provision for income taxes for the six months ended June 30, 1998. The Company's effective tax rate was 17% and 19% of income before taxes for the three and six months ended June 30, 1997.

LIQUIDITY AND CAPITAL RESOURCES

Since inception, the Company has financed operations primarily from the sale of preferred and common stock. Through June 30, 1998, VIVUS has raised \$153.0 million from financing activities. Cash, cash equivalents and available-for-sale securities totaled \$25.4 million at June 30, 1998 compared with \$44.2 million at March 31, 1998 and \$91.7 million at December 31, 1997. The \$66.3 million decrease in cash resulted from several factors, including the Company's repurchase of its common stock during the first quarter of 1998 (\$23.6 million), net losses for the first six months of 1998, capital spending associated with the new manufacturing facility in New Jersey, payments in the first quarter of 1998 for 1997 sales commissions and a lawsuit settlement payment.

Accounts receivable at June 30, 1998 were \$8.2 million compared with \$11.8 million at December 31, 1997, a decrease of \$3.6 million. The decrease was primarily due to lower sales.

Current liabilities were \$25.1 million at June 30, 1998, compared with \$26.7 million at December 31, 1997, a reduction of \$1.6 million. The reduction primarily relates to a lawsuit settlement payment and payment of 1997 sales commissions, partially offset by accruals associated with the restructuring charges.

Capital expenditures in the six months ended June 30, 1998 were \$12.1 million compared with \$10.8 million for the same period in 1997, an increase of \$1.4 million. This increase primarily resulted from additional costs associated with the Company's new 90,000 square foot production facility in New Jersey.

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, new product pre-clinical and clinical costs, ongoing research and development activities, and general corporate purposes. The Company anticipates that its existing capital resources will 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. The Company is currently seeking other sources of financing to support its operations. In August 1998, the Company received a nonbinding commitment letter for a proposed \$10 million lease under an equipment leasing program. Initially, the Company would receive \$7.5 million of the total lease balance upon execution of mutually agreeable documentation. The remaining \$2.5 million would become available upon the Company successfully meeting certain financial milestones for the third and fourth quarters of 1998. The proposed lease term would be five years, and as collateral, the lender would have a claim on the equipment being financed, and a security interest to certain other assets of the Company that is junior to the security interest of a working capital lender. The Company is currently negotiating the documentation for the proposed \$10 million lease. There can be no assurance that the proposed lease will be completed, if at all. Failure to successfully negotiate the proposed lease will have a material adverse affect on the Company's business, financial condition and results of operations. The Company is also seeking other financing sources, such as receivables financing and credit lines, to provide additional capital resources. There can be no assurance that the Company will be able to secure financing from other sources. Furthermore, 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) results of operations; (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 pre-clinical testing and clinical trials; (vi) technological advances; and (vii) the level of resources that the Company devotes to sales and marketing capabilities.

The Management's Discussion and Analysis of Financial Condition and Results of Operations section contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Actual results could differ materially from those projected in the forward-looking statements as a result of the factors set forth in 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 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. In the United States, the Company initially marketed and sold its products through a direct sales force of approximately 74 sales representatives. Effective February 1998, the Company entered into a sales force services agreement with Innovex Inc. ("Innovex") under which it added approximately 150 contract sales representatives, the substantial majority of whom called upon primary care physicians ("PCPs"). On March 27, 1998, the FDA approved Viagra (sildenafil), an oral pill produced by Pfizer for the treatment of male impotence. Pfizer commercially introduced sildenafil in the U.S. in April 1998. The introduction of sildenafil dramatically increased the number of men seeking treatment for impotence and significantly decreased demand for MUSE (alprostadil). Since the launch of sildenafil, MUSE (alprostadil) prescriptions have declined approximately 70%. The Company believes that the launch of sildenafil has dramatically increased the role of the PCP in the treatment of erectile dysfunction patients. Under the new erectile dysfunction market dynamics, the Company recognized that the infrastructure of a major pharmaceutical company was needed to support a sales force large enough to effectively address the needs of the PCP. Therefore, on July 8, 1998, the Company announced a strategic decision to seek a major pharmaceutical partner to market, distribute and sell MUSE (alprostadil) in the U.S. As the first step in the implementation of the Company's new strategy and to immediately reduce expenses, the Company terminated its agreement with Innovex and agreed to facilitate the transition of its direct sales representatives to ALZA. Sales personnel joining ALZA will continue to sell MUSE (alprostadil) on a limited basis until December 31, 1998. Accordingly, the Company is highly dependent upon the efforts of ALZA during this period, and there can be no assurance that ALZA's sales efforts will be successful. There can be no assurance that the Company will partner with a major pharmaceutical company to market, distribute and sell MUSE, or that such a partnership would be on reasonable terms. Further, there can be no assurance that such a partner will be able to successfully market, distribute and sell MUSE. Should the Company establish such a relationship, the Company's U.S. marketing efforts will depend substantially on the partner's efforts. The partner may have other commitments and may not commit the necessary resources to effectively market, distribute and sell the Company's products. If the Company cannot establish such a relationship, it will have to develop an alternative strategy for marketing, distributing and selling its products in the U.S.

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 has received indications from Janssen that regulatory approvals in certain Middle Eastern countries will be granted later than initially anticipated.

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 oral medications, needle injection therapy, vacuum constriction devices and penile implants, and the manufacturers of these products will continue to improve these therapies. The most significant competitive therapy is Viagra (sildenafil), an oral medication by Pfizer, for which it received regulatory approval in the United States in March 1998 and has filed for regulatory approval in Europe. The commercial launch of sildenafil in the U.S. in April, 1998 dramatically increased the number of men seeking treatment for impotence and significantly decreased demand for MUSE (alprostadil). Since the launch of sildenafil, MUSE (alprostadil) prescriptions have declined approximately 70%. The Company anticipates that the commercial launch of sildenafil in Europe and other international countries may decrease the international demand for MUSE (alprostadil). Such a decrease would have a material adverse effect on the Company's business, financial condition, and results of operations. As a result of this and other factors, including higher costs of goods sold related to the Company's ramp up of its new manufacturing facility, and higher marketing and sales costs primarily related to the sales force expansion via the Innovex contract pharmaceutical sales organization, the Company experienced an operating loss of \$24.2 million, or \$0.76 per share, in the second quarter of 1998. The Company is currently seeking a major pharmaceutical partner to market, distribute and sell MUSE (alprostadil) in the U.S. There can be no assurance that this strategy will be successful in increasing domestic demand for MUSE (alprostadil).

Additional competitive products in the erectile dysfunction market include needle injection therapy products from The Upjohn Company and Schwartz Pharma, which were approved by the FDA in July 1995

and June 1997, respectively. Other large pharmaceutical companies are also actively engaged in the development of therapies for the treatment of 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 pre-clinical testing, human clinical trials and other regulatory approval procedures. There are also small companies, academic institutions, governmental agencies and other research organizations that are conducting research in the area of erectile dysfunction. For instance, Zonagen, Inc. has filed for FDA approval of its oral treatment and has recently received approval in Mexico; Pentech Pharmaceutical, Inc. has an oral medication in Phase III clinical trials; and Senetek has a needle injection therapy product approved recently in Denmark and has filed for approval in other countries. These entities may market commercial products either on their own or through collaborative efforts. For example, 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.

LIMITED MANUFACTURING EXPERIENCE; CAPACITY CONSTRAINTS

The Company has limited experience in manufacturing MUSE (alprostadil) in commercial quantities. Up until the commercial launch of sildenafil, the Company had 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 FDA and MCA authorized the Company to begin commercial production and shipment of MUSE (alprostadil) from its new facility in June 1998 and March 1998, respectively. With the added capacity, the Company does not anticipate capacity constraints in the foreseeable future. However, if the Company encounters further difficulties with either of its current manufacturing facilities, capacity issues could arise. Such 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 Company has recently experienced various manufacturing difficulties that have resulted in production and shipment delays and higher costs. In turn, revenues from the sale of MUSE (alprostadil) will be delayed, which will 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. Chinoin has successfully responded to the FDA report, and is in compliance with cGMP requirements. Failure to achieve satisfactory cGMP compliance as confirmed by routine regulatory 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 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 Forms 483 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.

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 in a few instances (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.

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, new product pre-clinical and clinical costs, ongoing research and development activities, and general corporate purposes. The Company anticipates that its existing capital resources will 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. The Company is currently seeking other sources of financing to support its operations. In August 1998, the Company received a nonbinding commitment letter for a proposed \$10 million lease under an equipment leasing program. Initially, the Company would receive \$7.5 million of the total lease balance upon execution of mutually agreeable documentation. The remaining \$2.5 million would become available upon the Company successfully meeting certain financial milestones for the third and fourth quarters of 1998. The proposed lease term would be five years, and as collateral, the lender would have a claim on the equipment being financed, and a security interest to certain other assets of the Company that is junior to the security interest of a working capital lender. The Company is currently negotiating the documentation for the proposed \$10 million lease. There can be no assurance that the proposed lease will be completed, if at all. Failure to successfully negotiate the proposed lease will have a material adverse affect on the Company's business financial condition and results of operations. The Company is also seeking other financing sources, such as receivables financing and credit lines, to provide additional capital resources. There can be no assurance that the Company will be able to secure financing from other sources. 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) results of operations; (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 pre-clinical testing and clinical trials; (vi) technological advances; and (vii) the level of resources that the Company devotes to sales and marketing capabilities.

HISTORY OF LOSSES AND LIMITED OPERATING HISTORY

The Company has generated a cumulative net loss of \$56.1 million for the period from its inception through June 30, 1998. In order to return to profitability, the Company must successfully manufacture and market MUSE (alprostadil) and adjust its expenditures in conjunction with lower product revenues. The Company is subject to a number of risks including its ability to successfully market, distribute and sell its product, intense competition, its ability to scale-up manufacturing capabilities, its reliance on a single therapeutic approach to erectile dysfunction and its ability to secure

additional operating capital. 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. Since the launch of sildenafil, a competitive oral product, MUSE (alprostadil) prescriptions have declined approximately 70%. As a result of this and other factors, including higher costs of good sold related to the Company's ramp up its new manufacturing facility, and higher marketing and sales costs primarily related to the sales force expansion via the Innovex contract pharmaceutical sales organization, the Company experienced an operating loss of \$24.2 million, or \$0.76 per share, in the second quarter of 1998. Included in the second quarter 1998 results is a one-time charge of \$6.5 million related to the Company restructuring its operations. The goal of this restructuring is to reduce expenses in order to facilitate a return to profitability. The Company does not believe that it will return to profitability in 1998 due to a number of factors, including costs associated with the restructuring, domestic and international competition from Pfizer and manufacturing difficulties.

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. If international sales increase as anticipated, gross margins will be adversely impacted and will only improve if the Company is successful in lowering its cost of goods sold. If the Company encounters further difficulties with its current manufacturing facility, capacity issues could arise. Such 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 its ability to successfully market, distribute and sell its product, further develop its manufacturing capability and attain 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 has recently experienced various manufacturing difficulties that have resulted in production and shipment delays and higher costs. In turn, revenues from the sale of MUSE (alprostadil) will be delayed which will have a material adverse effect on the Company's business, financial condition and 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 research and development, manufacturing, clinical trial management and pre-clinical testing. Due to recent decreases in the Company's stock price and demand for MUSE (alprostadil), 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

The Company's products are currently marketed internationally. Changes in overseas economic and political conditions, currency exchange rates, foreign tax laws or tariffs or other trade regulations could have a material adverse effect on the Company's business, financial condition and results of operations. The current economic instability in Asia has resulted in weaker than expected sales of MUSE (alprostadil) in the Asian markets. The international nature of the Company's business is also expected to subject it and its representatives, agents and distributors to laws and regulations of the foreign jurisdictions in which they operate or 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.

GOVERNMENT REGULATION AND UNCERTAINTY OF PRODUCT APPROVALS

The Company's research, pre-clinical 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. MUSE (alprostadil) has also been approved in Argentina, Brazil, Canada, Hong Kong, Mexico, New Zealand, Philippines, Singapore, South Africa, Sweden, Switzerland and Thailand.

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 and Australia. 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 has received indications from one of its international marketing partners that regulatory approvals in certain Middle Eastern countries will be granted later than initially anticipated.

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. Chinoin has successfully responded to the FDA report, and is 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 Forms 483 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 administration 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. The claims of any 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 and reexamination proceedings. Interference 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 to a pharmaceutical composition claim for prazosin). The Company appealed the EPO's decision with respect to the pharmaceutical composition claims that were held unpatentable and the Pharmedic Company appealed the EPO's decision with respect to the claims that were held patentable, but Pharmedic's appeal 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.

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.

UNCERTAINTY OF PHARMACEUTICAL PRICING AND REIMBURSEMENT

In the United States and elsewhere, sales of pharmaceutical products are dependent, in part, on the availability of reimbursement to the consumer from third party payors, such as government and private insurance plans. Third party payors are increasingly challenging the prices charged for medical products and services. With the introduction of sildenafil, third party payors have begun to restrict or eliminate reimbursement for patients for erectile dysfunction treatments. While more than 70 percent of prescriptions for MUSE (alprostadil) were reimbursed by third party payors during 1997 and the first half of 1998 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.

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.

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 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 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, variations in the Company's financial results and its ability to obtain needed financing, announcements of technological innovations or new products by the Company or its competition, comments by security analysts, adverse regulatory actions or decisions, any loss of key management, the results of the Company's clinical trials or those of its competition, changing governmental regulations, patents or other proprietary rights, product or patent litigation or public concern as to the safety of products developed by the Company, may have a significant effect on the market price of the Company's Common Stock.

ANTI-TAKEOVER EFFECT OF PREFERRED SHARES RIGHTS PLAN AND CERTAIN CHARTER AND BYLAW PROVISIONS

In February 1996, the Company's Board of Directors authorized its reincorporation in the State of Delaware (the "Reincorporation") and adopted a Preferred Shares Rights Plan. The Company's reincorporation into the State of Delaware was approved by its stockholders and 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. The state court cases have been consolidated, and the Company anticipates that the plaintiffs will file a consolidated and amended complaint. 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. Five additional 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 federal court cases have been consolidated and a lead plaintiff has been appointed. The Company anticipates that the plaintiffs will file a consolidated and amended complaint. The Company believes the complaints lack merit and the Company will vigorously defend itself in the pending actions.

In the normal course of business, the Company receives and makes inquiries regarding patent infringement and other legal matters. The Company believes that it has meritorious claims and defenses and intends to pursue any such matters vigorously. The Company is not aware of any asserted or unasserted claims against it where the resolution would have an adverse material impact on the operations or financial position of the Company.

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS.

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

The annual meeting of stockholders was held May 21, 1998. Matters voted on at that meeting were: (i) the election of seven directors and (ii) the confirmation of the appointment of Arthur Andersen LLP as

independent public accountants for the fiscal year ended December 31, 1998.
Tabulation for each proposal and individual director were as follows:

PROPOSAL I. ELECTION OF DIRECTORS

DIRECTOR -----	FOR ---	WITHHELD -----
Virgil A. Place, MD.....	26,099,480	250,391
Leland F. Wilson.....	26,099,480	250,391
Richard L. Casey.....	26,099,480	250,391
Brian H. Dovey.....	26,099,480	250,391
Elizabeth A. Fetter.....	26,098,180	251,691
Linda Jenckes.....	26,099,480	250,391
Joseph E. Smith.....	26,099,480	250,391

PROPOSAL II. CONFIRMATION OF THE APPOINTMENT OF ARTHUR ANDERSEN LLP

FOR ---	AGAINST -----	ABSTAIN -----	NO VOTE -----
26,230,785	69,955	50,131	--

ITEM 5. OTHER INFORMATION

With respect to stockholder proposals not included in the Company's proxy statement for the 1999 Annual Meeting of Stockholders, the persons named in management's proxy for the 1999 Annual Meeting of Stockholders will be entitled to exercise the discretionary voting power conferred by such proxy under the circumstances specified in Rule 14a-4(c) under the Securities Exchange Act of 1934, of the date of mailing of the proxy statement for the 1999 Annual Meeting of Stockholders.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) EXHIBITS (in accordance with Item 601 of Regulation S-K)

EXHIBIT NUMBER -----

- (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

EXHIBIT
NUMBER

- (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, MD, Allen C. Eichler, MD, 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
- (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

EXHIBIT
NUMBER

- (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
- ++10.34 Agreement dated as of June 30, 1998 between Registrant and Alza Corporation
- ++10.35 Sales Force Transition Agreement dated July 6, 1998 between Registrant and Alza Corporation
- 27.1 Financial Data Schedule

- -----

- (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.

Date: August 14, 1998

VIVUS, Inc.

/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
- - - - -	- - - - -

++10.34	Agreement dated as of June 30, 1998 between Registrant and Alza Corporation
++10.35	Sales Force Transition Agreement dated July 6, 1998, between Registrant and Alza Corporation.
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.

++ Confidential treatment requested.

AGREEMENT

This Agreement is made and entered into as of the 30th day of June, 1998, between Vivus, Inc., a Delaware corporation ("Vivus") and ALZA Corporation, a Delaware corporation ("ALZA"). Vivus and ALZA hereby agree as follows:

ALZA is entering into a Sales Force Services Agreement with Innovex Inc. on or about the date of this Agreement (the "Innovex Agreement"). Vivus shall pay ALZA [*] of the amounts payable to Innovex Inc. for (i) the Daily Fees (as defined in the Innovex Agreement) of up to [*] Territory Representatives (as defined in the Innovex Agreement) and up to[*] Field Coordinators (as defined in the Innovex Agreement) and (ii) related expenses for such personnel (excluding initial training costs and travel expenses associated with initial training) under the Innovex Agreement; during the period of July 1, 1998 to September 30, 1998, but in no event shall the Daily Fees for Territory Representatives and Field Coordinators exceed an amount per day of [*], respectively. In addition, in no event shall total amounts paid pursuant to this Agreement exceed [*]. Vivus shall make payments under this Agreement within thirty (30) days of receiving a copy of the invoices delivered to ALZA from Innovex Inc. Vivus shall indemnify and hold harmless ALZA and its affiliates, employees, officers, directors, successors and assignees from and against any and all liabilities that such person may incur, suffer or be required to pay in connection with or arising out of Vivus' execution, performance or obligations under the Sales Force Services Agreement between Vivus and Innovex Inc. dated February 1, 1998. Subject to the reimbursement provisions hereof, ALZA shall indemnify and hold harmless Vivus and its affiliates, employees, officers, directors, successors and assignees from and against any and all liability that such person may incur, suffer or be required to pay in connection with or arising out of ALZA's execution, performance or obligations under the Innovex Agreement.

ALZA shall use reasonable efforts to minimize the amounts payable by Vivus under this Agreement. It is anticipated that at least [*] former District Managers (as defined in the Sales Forces Services Agreement by Vivus and Innovex Inc., dated February 1, 1998) shall become Innovex Personnel (as defined in the Innovex Agreement).

Vivus shall permit Innovex Personnel to continue promotion of the MUSE product for an interim period, not to extend beyond July 9, 1998. The parties shall draft mutually agreeable press releases regarding the subject matter of this Agreement, which releases shall be made at a time to be agreed upon by the parties, not to be later than July 9, 1998. Except for such press releases or to the extent otherwise required by law, neither party shall make any disclosure or public statement concerning this Agreement without the prior written consent of the other.

[*] Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

Except as expressly set forth in the indemnification provisions above, there are no third party beneficiaries to this Agreement. This Agreement may not be amended except by an instrument in writing signed by both parties that specifically refers to this Agreement. This Agreement constitutes the entire agreement between the parties relating to the subject matter hereof and supersedes all previous writings and understandings, whether oral or written, relating to the subject matter of this Agreement.

This Agreement may be executed in several counterparts, each of which shall be deemed an original but all of which shall constitute one and the same instrument. ALZA and Vivus have executed this Agreement, effective as of the date first above written.

ALZA CORPORATION

VIVUS, INC.

By: /s/ Peter D. Staple

By: /s/ David C. Yntema

Name: Peter D. Staple

Title: Senior Vice President

David Yntema

Chief Financial Officer

SALES FORCE TRANSITION AGREEMENT

This Sales Force Transition Agreement (the "Agreement") is made and entered into as of the 6th day of July, 1998, between Vivus, Inc., a Delaware corporation ("Vivus") and ALZA Corporation, a Delaware corporation ("ALZA").

R E C I T A L S

A. Vivus has created a sales force to promote products to urology specialists in the United States.

B. Due to business considerations, Vivus is considering a decrease in the size of its total sales organization.

C. ALZA desires to increase the size of its sales force by adding sales representatives experienced in promoting products to the urology and primary care markets.

D. The parties desire to effect an orderly transition of the Vivus sales force to ALZA in accordance with the terms and conditions of this Agreement.

NOW THEREFORE, in consideration of the following covenants, promises and obligations, Vivus and ALZA agree as follows:

1. Definitions

1.1 "Affiliate" shall mean any corporation, firm, partnership or other entity which, at the time in question, is directly or indirectly owned or controlled by or under common control with, Vivus or ALZA, as the case may be. For the purposes of this definition "control" shall mean the ownership, directly or indirectly, of more than 50% of the voting stock or stockholders' equity of a corporation or, in the case of a non-corporate entity, the right to receive more than 50% of the profits or of the assets upon dissolution.

1.2 "Confidential Information" shall mean (i) in the case of Vivus, employeespecific information (such as performance and compensation information) disclosed by Vivus to ALZA concerning the Vivus Sales Employees and information included in training materials relating to the MUSE product, and (ii) in the case of ALZA information disclosed by ALZA to Vivus concerning ALZA's products and training and promotional materials relating thereto, and ALZA employment and compensation practices. Confidential Information shall not include any information which is (i) now in the public domain or subsequently enters the public domain without fault on the part of the receiving party; (ii) known by the receiving party from its own sources, as evidenced by the receiving party's written records; or (iii) received from any third party not under any obligation to keep such information confidential.

1.3 "Liabilities" shall mean any and all liabilities, claims, demands, losses or judgments of any kind or nature, primary or secondary, including without limitation any liability for

claims of personal injury or death, and all reasonable attorneys' fees incurred in connection with the defense of any such claims.

1.4 "MUSE" shall mean the MUSE(R) (alprostadil) transurethral delivery product for erectile dysfunction in the form being marketed by Vivus in the United States as of the Effective Date of this Agreement.

1.5 "Transition Date" shall mean July 1, 1998.

2. Vivus Sales Personnel

2.1 Reimbursement for Interim Period. During the period from the Transition Date through July 31, 1998, Vivus shall cause each of the Vivus Sales Employees who remain in Vivus' employ during such period to perform sales and promotion services on behalf of ALZA as requested by ALZA and to undergo training as requested by ALZA. Such services shall be performed in accordance with ALZA's training and instructions and in compliance with applicable laws and regulations. ALZA shall reimburse Vivus for Vivus' out-of-pocket costs incurred in paying salaries and other benefits (to the extent specifically quantified in Exhibit C) incurred for services actually performed for ALZA by Vivus Sales Employees from the Transition Date through July 31, 1998. Such reimbursement will be made within 30 days after receipt of Vivus' invoice for such amounts. To be eligible for such reimbursement to Vivus such employees must perform sales and promotion services on behalf of ALZA as requested by ALZA and undergo training as requested by ALZA. During such interim period Vivus shall not increase the salary, bonus, benefits, perquisites or other incentives to the Vivus Sales Employees (other than the adoption of severance arrangements pursuant to layoffs, for which Vivus shall bear the cost without reimbursement by ALZA) without ALZA's prior written consent. At the conclusion of such interim period Vivus shall promptly return to ALZA any and all promotional or training materials, samples and other items provided by ALZA hereunder, other than those that are in the possession of Vivus Sales Employees who become employees of ALZA hereunder.

2.2 Offers of Employment.

(a) Promptly after execution of this Agreement, Vivus will review with ALZA the employment history of each of the employees listed on Exhibits A-1 and A-2 (the "Vivus Sales Employees"), including, without limitation, salary, benefits, bonuses, defined compensation, options, performance reviews and such other information as ALZA may reasonably request. Vivus shall have obtained the written consent of each of such employees to the provision of information to ALZA. Vivus shall also make such persons available to meet with ALZA, if ALZA so requests.

(b) As soon as reasonably possible, but in any event by July 31, 1998, ALZA shall notify each of the Vivus Sales Employees of ALZA's determination of whether or not to offer employment to each such person and shall make an offer of employment to each person for whom a positive determination is made, such employment to be effective August 3, 1998. ALZA's

determination as to individual employees may be made based upon factors to be determined by ALZA which may include, without limitation, the overall fit with ALZA's sales and marketing organization, experience, motivation, geographic location, compensation and performance. Offers of employment made to such persons by ALZA would be in accordance with the terms and conditions described in Exhibit B. Vivus shall not request or encourage any such persons to remain in the employ of Vivus or to accept employment with a company other than ALZA.

2.3 Communications; Notice. Vivus shall provide to the Vivus Sales Employees any notices required by applicable law or regulation in connection with the prospective termination of their employment with Vivus. Vivus shall provide ALZA with drafts of all proposed notices and communications to the Vivus Sales Employees, and provide ALZA a reasonable opportunity to review and comment on such materials, provided that any notice or communication that relates to ALZA or potential employment with ALZA shall be subject to ALZA's prior approval. Vivus and ALZA's human resource personnel shall meet on a weekly basis to communicate the status of employment offers and other personnel matters.

2.4 Other Costs and Expenses. Except for the reimbursement provided for in Section 2.1, with respect to each Vivus Sales Employee, whether or not subsequently employed by ALZA, Vivus shall bear and discharge, and indemnify and hold harmless ALZA and its Affiliates, employees, officers, directors, successors and assignees from and against all obligations and Liabilities (excluding such obligations and Liabilities resulting from the gross negligence or willful misconduct of ALZA), including but not limited to obligations and Liabilities for wages, compensation, vacation pay, benefits, termination or severance pay (including notice of termination or pay in lieu of notice, damages for wrongful dismissal or similar claims), which relate to such person's employment by Vivus (including without limitation the interim period referred to in Section 2.1) or the termination thereof; including any interest, award, judgment or penalty relating thereto and any costs and expenses (including attorneys' fees) incurred by ALZA in such matters.

2.5 Non-solicitation. Neither Vivus nor its Affiliates shall, without ALZA's prior written consent, prior to [*], directly or indirectly solicit for employment or hire any of the Vivus Sales Employees who become employed by ALZA (except for such employees whose employment is terminated by ALZA).

2.6 ALZA Costs. Except for the compensation provided to ALZA in Section 3.2, with respect only to each Vivus Sales Employee who becomes an employee of ALZA under Section 2.2(b), ALZA shall bear and discharge, and indemnify and hold harmless Vivus and its Affiliates, employees, officers, directors, successors and assignees from and against, all obligations and Liabilities (excluding such obligations and Liabilities resulting from the gross negligence or willful misconduct of Vivus), including but not limited to obligations and Liabilities for wages,

[*] Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

compensation, vacation pay, benefits, termination or severance pay (including notice of termination or pay in lieu of notice, damages for wrongful dismissal or similar claims), which relate to such person's employment by ALZA or any termination thereof; including any interest, award, judgment or penalty relating thereto and any costs and expenses (including attorneys' fees) incurred by Vivus in such matters.

3. Promotion of MUSE

3.1 Promotion Activity. With respect to the period from the Transition Date through December 31, 1998 (the "MUSE Promotion Period"), ALZA shall devote at least [*]% of the aggregate sales call time, measured on a calendar quarter basis, of ALZA's urology sales force to promotional presentations of the MUSE(R) product on behalf of Vivus. For such purposes the ALZA urology sales force will include approximately [*] of ALZA's current sales representatives who will be assigned to promotion of urology products and those Vivus Sales Employees listed in Exhibit A-1 who provide services to ALZA in urology on an interim basis under Section 2.1, or who are subsequently employed by ALZA pursuant to Section 2.2. ALZA shall provide a written report to Vivus within 10 days after the end of each calendar month which [*]. [*] Vivus shall provide to ALZA a report by August 10, 1998, providing all such information for calls made by Vivus sales representatives under Section 2.1. ALZA's promotion activity shall be performed in accordance with instruction and training provided by Vivus and in compliance with applicable laws and regulations. ALZA will not be required to present MUSE in "primary position" during sales calls. ALZA's obligations under this Section 3.1 will be subject to (i) prompt provision of materials and training by Vivus in accordance with Section 3.3; and (ii) continued supply, distribution and customer support for MUSE by Vivus in accordance with applicable laws and regulations. In addition, if there is a substantial adverse medical development relating to MUSE which ALZA, in its reasonable judgment, believes would be likely to result in material harm to the reputation of ALZA or its sales force, then ALZA may notify Vivus of such concern and the parties will agree on appropriate steps for an orderly winding down of promotional activities while complying with applicable regulatory requirements.

3.2 Incentives. During the MUSE Promotion Period, ALZA will provide sales incentives for its urology sales force in which [*]% of the total incentive package is based on sales of MUSE. Vivus shall reimburse ALZA for such portion of the sales incentives that are based on sales of MUSE, within 30 days after ALZA's invoice for such amounts.

3.3 Training, Materials. As a condition to ALZA's obligations under Section 3.1, Vivus shall provide to ALZA at Vivus' cost and expense, promptly after the Transition Date but in any event by July 15, 1998, such promotional materials and training relating to MUSE as are necessary and appropriate for ALZA to provide the promotional services contemplated in this

[*] Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

Article 3. Vivus shall ensure that all such training and promotional materials are in compliance with applicable laws and regulations, including those promulgated by the U.S. Food and Drug Administration.

3.4 Indemnity. Vivus shall indemnify and hold harmless ALZA and its Affiliates, employees, officers, directors, successors and assignees from and against any and all Liabilities which such person may incur, suffer or be required to pay arising out of: (i) any claim relating to or arising out of the manufacture, use, promotion or sale of Vivus' products; (ii) Vivus' breach of any of its obligations under this Agreement; (iii) Vivus' or Vivus personnel's negligence or willful misconduct; (iv) any advertising, training or promotional material furnished by or on behalf of Vivus; or (v) Vivus' or Vivus personnel's failure to materially comply with any applicable law, rule, regulation or order of any governmental authority having jurisdiction. Notwithstanding the foregoing, Vivus shall not be required to indemnify ALZA for any losses to the extent they arise from; (i) the failure by ALZA to promote the Products in accordance with approved labeling and the terms of this Agreement, (ii) the gross negligence or willful misconduct of ALZA, or (iii) any breach by ALZA of its material obligations under this Agreement.

4. Representations and Warranties

4.1 The Parties. Each of Vivus and ALZA represents and warrants to the other that (i) it has the authority and right to enter into this Agreement and to perform its obligations hereunder, and (ii) its execution, delivery and performance of this Agreement will not conflict with the terms of any other agreement or obligation to which it is a party or is bound; (iii) neither it, nor any of its employees who will be undertaking activities related to this Agreement, have been debarred or the subject of debarment proceedings by the U.S. Food and Drug Administration.

4.2 Vivus. Vivus represents and warrants to ALZA that, (i) Vivus has provided to ALZA a true and complete copy of the Innovex Agreement, and the Innovex Agreement has been terminated by mutual agreement of Vivus and Innovex; (ii) Vivus has made all payments due as of the Transition Date under the Innovex Agreement and shall make timely payments of any amounts incurred prior to the Transition Date but not yet paid; (iii) each of the Vivus Sales Employees is employed by and in good standing with Vivus, and none of such employees has made any claim or demand against Vivus for any reason; and (v) the Vivus Sales Employees are not entitled to any payments or benefits relating to their employment by Vivus or the termination thereof, except as specified in Schedule 4.2 of this Agreement.

5. Confidentiality

5.1 Confidential Information. Except as specifically authorized by this Agreement, each party shall, for a period of five years from the date of this Agreement, keep confidential, not disclose to others and use only for the purposes provided for or permitted under this Agreement, all of the other party's Confidential Information, except as provided for or permitted by this Agreement. Notwithstanding the foregoing, such information may be (i) disclosed to

governmental agencies and to others where such information may be required to be included in regulatory filings; (ii) provided to third parties under appropriate terms and conditions including confidentiality provisions substantially equivalent to those in this Agreement for consulting or marketing arrangements; (iii) disclosed to the extent required by applicable laws or regulations or as ordered by a court or other regulatory body having competent jurisdiction. In each of the foregoing cases, the recipient will use its reasonable efforts to limit the disclosure and maintain confidentiality to the extent possible.

5.2 Public Disclosure.

(a) The parties shall draft mutually agreeable separate press releases regarding this Agreement. Such press releases shall be made as agreed upon by the parties following execution of this Agreement.

(b) Except for the press releases described in Section 5.2(a), neither party shall, without the prior written consent of the other party, disclose to third parties, nor originate any publicity, news release or public announcement, written or oral, whether to the public, the press, stockholders or otherwise, referring to the existence or terms of this Agreement, including its existence, the subject matter to which it relates, the performance under it or any of its specific terms and conditions, except such announcements or disclosures as, in the opinion of the counsel for the party making such announcement, are required by law, including United States securities laws, and each party may disclose the existence of this Agreement and the material terms and conditions hereof under circumstances that reasonably ensure the confidentiality thereof to any government or regulatory authorities, including without limitation the United States Securities and Exchange Commission to the extent required by applicable law. If a party decides to make an announcement it believes to be required by law with respect to this Agreement, it will give the other party such notice as is reasonably practicable and an opportunity to comment upon the announcement.

6. Term and Termination

6.1 Term. The term of this Agreement shall continue unless or until otherwise earlier terminated pursuant to this Section 6.

6.2 Termination by Either Party. ALZA may terminate its obligations under Sections 3.1 and 3.2, and Vivus may terminate its obligations under Section 3.2, upon written notice to the other party in the event of any of the following:

(a) a breach by the other party of any material provision herein that is continuing 60 days after the nonbreaching party gives the breaching party notice of such breach, specifying in reasonable detail the particulars of the alleged breach, and such breach has not been cured within such 60 day period (or if such breach cannot by its nature be cured within 60 days, if reasonable progress has not been made by the breaching party during such 60 day period toward curing such breach) or

(b) the other party becomes insolvent, or voluntary or involuntary proceedings are instituted by or against the other party, or a receiver or custodian is appointed for such other party's business, or a substantial portion of such other party's business is subject to attachment or similar process, or the other party is unable to satisfy its financial obligations as they become due, enters into any composition or arrangement with its creditors or enters into liquidation.

6.3 Effect. Any termination pursuant to Section 6.2 shall not effect any other provisions than those set forth in Section 6.2, and such other provisions shall remain in effect.

7. Insurance

7.1 Insurance Policies. Each party shall maintain in effect for at least three years from the date of this Agreement a policy of liability insurance, in an amount not less than \$5,000,000, that provides coverage for such party's indemnity obligations hereunder.

8. Miscellaneous

8.1 Force Majeure. If the performance by either party of any obligation under this Agreement is prevented, restricted, interfered with or delayed by reason of any cause beyond the reasonable control of the party liable to perform, unless conclusive evidence to the contrary is provided, the party so affected shall, upon giving written notice to the other party, be excused from such performance to the extent of such prevention, restriction, interference or delay, provided that the affected party shall use its reasonable efforts to avoid or remove such causes of non-performance and shall continue performance with the utmost dispatch whenever such causes are removed. When such circumstances arise, the parties shall discuss what, if any, modification of the terms of this Agreement may be required in order to arrive at an equitable solution.

8.2 Governing Law. This Agreement shall be deemed to have been made in the State of California and its form, execution, validity, construction and effect shall be determined in accordance with the laws of the State of California, without giving effect to the principles of conflicts of law thereof.

8.3 Headings and References. All section headings contained in this Agreement are for convenience of reference only and shall not affect the meaning or interpretation of this Agreement. Unless the context requires otherwise, all references in this Agreement to any article, section, schedule or exhibit shall be deemed and construed as references to an article or section of, or an exhibit to, this Agreement, and any such exhibits are hereby incorporated in this Agreement by such reference.

8.4 Dispute Resolution.

(a) Any dispute, controversy or claim arising out of or relating to this Agreement, or the breach, termination, or invalidity of this Agreement, shall be submitted in the first instance to the Chief Executive Officer of Vivus and the Chief Executive Officer of ALZA.

(b) If the matter or dispute cannot be resolved by the individuals designated in Section 8.4 (a) within 30 days after such submission, either party shall be entitled to submit the dispute to the next step in the dispute resolution process set forth in subsection (c).

(c) If any dispute is not resolved in accordance with subsection (a) and (b), then either party may submit such matter for binding resolution by arbitration conducted in Santa Clara County, California, in accordance with the then existing rules of the American Arbitration Association, and judgment upon the award rendered by the arbitrators may be entered in any court having jurisdiction thereof. The parties hereby agree that service of any notices in the course of such arbitration at their respective addresses as provided for in Section 8.8 of this Agreement shall be valid and sufficient.

(d) In any arbitration pursuant to this Section 8.4, the award shall be rendered by a majority of the members of a board of arbitration consisting of three members who shall be appointed by the parties jointly, or if the parties cannot agree as to three arbitrators within 30 days after the commencement of the arbitration proceeding, then one arbitrator shall be appointed by ALZA and one arbitrator shall be appointed by Vivus within 60 days after the commencement of the arbitration proceeding. The third arbitrator shall be appointed by mutual agreement of such two arbitrators. In the event of failure of the two arbitrators to agree within 75 days after commencement of the arbitration proceeding upon the appointment of the third arbitrator, the third arbitrator shall be appointed by the American Arbitration Association in accordance with its then existing rules. Notwithstanding the foregoing, in the event that any party shall fail to appoint an arbitrator it is required to appoint within the specified time period, such arbitrator and the third arbitrator shall be appointed by the American Arbitration Association in accordance with its then existing rules. For purposes of this Section 8.4, the "commencement of the arbitration proceeding" shall be deemed to be the date upon which a written demand for arbitration is received by the American Arbitration Association from one of the parties.

8.5 Severability. If any provision of this Agreement is held by a court of competent jurisdiction to be invalid or unenforceable, it shall be modified, if possible, to the minimum extent necessary to make it valid and enforceable or, if such modification is not possible, it shall be stricken and the remaining provisions shall remain in full force and effect; provided, however, that if a provision is stricken so as to significantly alter the economic arrangements of this Agreement, the party adversely affected may terminate this Agreement upon 60 days' prior written notice to the other party. If any of the terms or provisions of this Agreement is in conflict with any applicable statute or rule of law in any jurisdiction, then such term or provision shall be deemed

inoperative in such jurisdiction to the extent of such conflict and the parties will renegotiate the affected terms and conditions of this Agreement to resolve any inequities.

8.6 Entire Agreement. This Agreement, including the exhibits hereto, constitutes the entire agreement between the parties relating to the subject matter hereof and supersedes all previous writings and understandings, whether oral or written, relating to the subject matter of this Agreement. In the event of any inconsistency between this Agreement and any exhibit, standard operating procedure or other ancillary agreement or document contemplated by this Agreement, the terms of this Agreement shall govern.

8.7 Amendment. This Agreement may not be amended, supplemented or otherwise modified except by an instrument in writing signed by both parties that specifically refers to this Agreement.

8.8 Notices. Any notice required or permitted under this Agreement shall be sent by certified mail or courier service, charges prepaid, or by facsimile transmission, to the address or facsimile number specified below:

If to Vivus: Vivus, Inc.
605 East Fairchild
Mountain View, CA 94043
Fax Number: (650) 934-5357
Attention: Chief Financial Officer

If to ALZA: ALZA Corporation
950 Page Mill Road
PO Box 10950
Palo Alto, CA 94303-0802
Fax Number: (650) 496-8048
Attention: Senior Vice President and
General Counsel

Notices will be deemed delivered five days after mailing, if sent by certified mail, or upon delivery, if sent by facsimile or courier.

8.9 Assignment and Binding Effect. This Agreement shall be binding upon and inure to the benefit of the successors and assigns of the parties hereto. Neither party may assign any of its rights, or delegate any of its obligations, under this Agreement without the written consent of the other party, except that either party may assign this Agreement to any Affiliate or to any corporation with which it may merge or consolidate, or to which it may transfer all or substantially all of its assets to which this Agreement relates. Such consent will not be unreasonably withheld if the proposed assignee has capabilities at least comparable to those of the assigning party to carry out its obligations hereunder.

8.10 No Agency. It is understood and agreed that each party shall have the status of an independent contractor under this Agreement and that nothing in this Agreement shall be construed as authorization for either party to act as agent for the other. Neither party shall incur any liability for any act or failure to act by employees of the other party.

8.11 No Third Party Beneficiaries. Except as expressly set forth in the indemnification provisions of this Agreement, nothing contained in this Agreement shall be deemed to create any third party beneficiaries or confer any benefit or rights on or to any person not a party to this Agreement, and no person not a party to this Agreement shall be entitled to enforce any provisions hereof or exercise any rights hereunder.

8.12 No Strict Construction. This Agreement has been prepared jointly and shall not be strictly construed against either party.

8.13 Counterparts. This Agreement may be executed in two counterparts, each of which shall be an original as against any party whose signature appears thereon but both of which together shall constitute one and the same instrument. A facsimile transmission of the signed Agreement shall be legal and binding on both parties.

IN WITNESS WHEREOF, the parties, through their authorized officers, have duly executed this as of the date first written above.

VIVUS, INC.

ALZA CORPORATION

By: /s/ David C. Yntema

By: /s/ Peter D. Staple

(signature)

(signature)

Name: David C. Yntema

Name: Peter D. Staple

(print)

(print)

Title:

Title: Senior Vice President

C O N F I D E N T I A L

EXHIBITS AND SCHEDULES

Exhibit A	Vivus Sales Employees
A-1	(Sales Representatives)
A-2	(Other Sales Personnel)
B	Terms of Employment
C	Existing Salaries and Benefits
Schedule 4.2	Exceptions to Representations and Warranties

EXHIBIT A
VIVUS SALES EMPLOYEES
EXHIBIT A-1

[*]

[*] Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

A-1

EXHIBIT A-2

[*]

[*] Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

A-2

EXHIBIT B

Proposal for Vivus Sales Force

ALZA will review all relevant employee information which may include employee files, performance reviews and discussions with management. By July 31, 1998, ALZA will offer regular ALZA employment at will (the same as other regular ALZA employees) to such Vivus employees as ALZA believes would fit with ALZA's sales force in terms of experience, performance, motivation, geographic location and other considerations.

[*]

In very rare cases, it is possible that some employees would need to relocate as a condition of the offer or to accept different positions.

[*]

If ALZA's offer of employment is accepted, the start date will be Monday, August 3, 1998.

ALZA will endeavor to act as quickly as possible, but no later than July 31, 1998 to determine which Vivus employees will be offered ALZA employment.

[*] Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT C

EXISTING SALARIES AND BENEFITS

Attachment C-1 to this Exhibit C contains the salaries of Vivus Sales Employees. In addition to these salaries Vivus compensates the Vivus Sales Employees with the following non-salary benefits:

- [*]

In no event shall the total expense for the above listed non-salary benefits exceed [*]% of the total salaries paid to the Vivus Sales Employees.

Vivus Sales Employees also receive payments for the following sales related expenses:

- [*]

Vivus will provide ALZA with backup documentation of actual costs during July 1998, and (at ALZA's request) of historical costs for comparison and planning purposes.

[*] Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

ATTACHMENT C-1

[*]

[*] Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

C-2

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1,000

3-MOS
DEC-31-1998
APR-01-1998
JUN-30-1998
1,420
8,913
8,221
(51)
16,772
37,733
52,750
(5,872)
99,684
25,051
0
0
32
74,601
99,684
15,983
15,983
10,704
10,704
29,457
0
0
(23,581)
597
(24,178)
0
0
0
(24,178)
(0.76)
(0.76)

FOR PURPOSES OF THIS EXHIBIT, PRIMARY MEANS BASIC.