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

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FORM 10-Q

☒ [X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 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)

94-3136179  
(I.R.S. EMPLOYER  
IDENTIFICATION NUMBER)

605 EAST FAIRCHILD DRIVE  
(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES)

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. ☒ [X] Yes ☐ [ ] No

At September 30, 1998, 31,823,607 shares of common stock were outstanding.

EXHIBIT INDEX ON PAGE 24

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## PART I: FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

## VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS  
(in thousands, except per share amounts)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	1998	1997	1998	1997
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Revenue				
US Product	\$ 3,485	\$ 39,118	\$ 34,178	\$ 100,367
International Product	14,579	--	26,391	--
Milestone	2,000	--	3,000	5,000
	-----	-----	-----	-----
Total revenue	20,064	39,118	63,569	105,367
Operating Expenses				
Cost of goods sold (1)	28,297	11,270	49,483	28,920
Research and development	4,673	3,947	13,912	7,914
Selling, general and administrative	3,882	11,507	38,516	34,574
Write-down of property	32,163	--	32,163	--
Other restructuring costs	5,968	--	12,490	--
	-----	-----	-----	-----
Total operating expenses	74,983	26,724	146,564	71,408
	-----	-----	-----	-----
Income (loss) from operations	(54,919)	12,394	(82,995)	33,959
Interest and other income	194	1,106	1,702	3,491
	-----	-----	-----	-----
Income (loss) before taxes	(54,725)	13,500	(81,293)	37,450
Income tax (provision) benefit	--	(2,241)	--	(6,679)
	-----	-----	-----	-----
Net income (loss)	\$ (54,725)	\$ 11,259	\$ (81,293)	\$ 30,771
	=====	=====	=====	=====
Net income (loss) per share:				
Basic	\$ (1.72)	\$ 0.34	\$ (2.55)	\$ 0.93
Diluted	\$ (1.72)	\$ 0.31	\$ (2.55)	\$ 0.86
Shares used in the computation of net income (loss) per share:				
Basic	31,806	33,107	31,893	33,107
Diluted	31,806	35,772	31,893	35,602

(1) Cost of goods sold for three months and nine months ended September 30, 1998 include a \$16.0 million write-down for excess inventory and future inventory purchase commitments.

## VIVUS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS  
(in thousands)

	SEPTEMBER 30, 1998 ----- (unaudited)	DECEMBER 31, 1997 -----
Current assets:		
Cash	\$ 4,690	\$ 6,161
Available-for-sale securities	13,516	52,955
Accounts receivable	7,960	11,791
Inventories	7,785	9,084
Prepaid expenses and other assets	961	1,636
	-----	-----
Total current assets	34,912	81,627
Property and equipment	20,036	36,462
Available-for-sale securities, non-current	7,301	32,580
	-----	-----
Total	\$ 62,249 =====	\$ 150,669 =====
Current Liabilities:		
Accounts payable	\$ 13,037	\$ 6,574
Accrued and other liabilities	28,899	20,165
	-----	-----
Total current liabilities	41,936	26,739
Stockholders' equity:		
Common stock; \$.001 par value; shares authorized 200,000; shares outstanding - September 30, 1998, 31,824; December 31, 1997, 33,168;	32	33
Paid in capital	131,086	153,336
Accumulated other comprehensive income	25	98
Accumulated deficit	(110,830)	(29,537)
	-----	-----
Total stockholders' equity	20,313	123,930
	-----	-----
Total	\$ 62,249 =====	\$ 150,669 =====

## VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
(in thousands)

	NINE MONTHS ENDED SEPTEMBER 30,	
	1998	1997
	(unaudited)	(unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	\$( 81,293)	\$ 30,771
Adjustments to reconcile net income (loss) to net cash provided by (used for) operating activities:		
Depreciation and amortization	2,865	1,448
Property write-down	32,163	--
Inventory write-down	16,083	--
Stock compensation costs	360	367
Changes in assets and liabilities:		
Accounts receivable	3,831	(17,357)
Inventories	(14,784)	(1,672)
Prepaid expenses and other assets	675	(65)
Accounts payable	6,463	3,022
Accrued and other liabilities	8,734	18,608
Net cash provided by (used for) operating activities	(24,903)	35,122
CASH FLOWS FROM INVESTING ACTIVITIES:		
Property and equipment purchases	(18,602)	(21,463)
Investment purchases	(134,855)	(210,858)
Proceeds from sale/maturity of securities	199,499	201,099
Net cash provided by (used for) investing activities	46,041	(31,222)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Exercise of common stock options	562	2,918
Sale of common stock through employee stock purchase plan	413	173
Repurchase of common stock	(23,584)	(4,184)
Net cash used for financing activities	(22,609)	(1,093)
NET INCREASE (DECREASE) IN CASH	(1,471)	2,807
CASH:		
Beginning of period	6,161	555
End of period	\$ 4,690	\$ 3,362
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Unrealized loss on securities	\$ (73)	\$ (13)
SUPPLEMENTAL CASH FLOW DISCLOSURE:		
Income taxes paid	\$ 71	--

## VIVUS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
SEPTEMBER 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 nine month periods ended September 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 nine month periods ended September 30, 1998 and 1997:

(IN THOUSANDS)	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	1998 ----- (UNAUDITED)	1997 ----- (UNAUDITED)	1998 ----- (UNAUDITED)	1997 ----- (UNAUDITED)
Net income (loss) .....	\$(54,725)	\$ 11,259	\$(81,293)	\$ 30,771
Other comprehensive income:				
Unrealized gain (loss) on securities ...	18	80	(73)	(13)
Income tax benefit (expense) .....	--	(16)	--	3
	----- 18	----- 64	----- (73)	----- (10)
Comprehensive income (loss) .....	\$(54,707) =====	\$ 11,323 =====	\$(81,366) =====	\$ 30,761 =====

## 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 nine months ended September 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.

## 4. WRITE-DOWN OF PROPERTY AND EQUIPMENT

During the quarter ended September 30, 1998, the Company took multiple steps to restructure the operations of the Company to bring the cost structure more in line with current and anticipated future revenues. These steps included the closing of the Company's contract

manufacturing facility within PACO Pharmaceutical Services, Inc., the abandonment of leased warehouse space, and the abandonment of the Company's leased corporate offices. The Company recorded a \$32.2 million write-down of property and equipment. This write-down was calculated in accordance with the provisions of SFAS No. 121 and represents the excess of the carrying values of, property and equipment, primarily the Company's New Jersey manufacturing leaseholds and equipment, over the projected future discounted cash flows for the Company.

#### 5. WRITE-DOWN OF INVENTORY

During the quarter ended September 30, 1998, the Company wrote down its inventory to a level more in line with current and expected future demand for MUSE(R) (alprostadil). The Company had built up its inventory level prior to and after Pfizer's launch of sildenafil and had not anticipated the impact that sildenafil would have on the demand for MUSE (alprostadil) and anticipating sales to ultimately increase as a result of an expanding impotence market. Given the protracted decline in demand for MUSE (alprostadil), the Company recorded a valuation reserve of \$16.0 million, primarily related to excess raw materials and future inventory purchase commitments for raw materials. This write-down is included in "Cost of Sales" for the quarter ended September 30, 1998.

#### 6. OTHER RESTRUCTURING COSTS

In the quarter ended September 30, 1998, the Company recorded other restructuring costs of \$6.0 million related to personnel reductions in administration, research and development, clinical, and manufacturing, and cancellation of lease commitments. These steps were necessary as the Company needed to reduce its infrastructure to support the current business model. For the nine months ended September 30, 1998, other restructuring costs also include \$6.5 million that were recorded in the quarter ended June 30, 1998, 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. This was as a result of the Company decision to seek a major pharmaceutical partner to market MUSE (alprostadil) in the United States.

#### 7. RE-PRICING OF STOCK OPTIONS

Subsequent to the quarter ended September 30, 1998, the Company's Board of Directors authorized the re-pricing of certain stock options for employees and certain consultants to the closing market value as of October 19, 1998. All repriced stock options have a six-month "blackout" period, whereby the repriced stock options cannot be exercised. This action was done due to the significant cut back in personnel, the recent decline in the Company's stock price, and the Company's increasingly dependency on its smaller personnel structure.

## 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). 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 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 16 countries including: Argentina, Brazil, Canada, Hong Kong, Mexico, New Zealand, Philippines, Singapore, South Africa, South Korea, Sweden, Switzerland and Thailand. In addition, applications for regulatory approval to market MUSE (alprostadil) have been submitted in several other countries, including the European Union, 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 pending Middle Eastern countries will be granted later than initially anticipated.

On March 27, 1998, the FDA approved Viagra(R) (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 75% in the U.S. 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 facilitated the transition of its direct sales force to ALZA Corporation. 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 (alprostadil), 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 (alprostadil). 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.

On August 25, 1998, the Company announced that it has retained the investment banking firm, Credit Suisse First Boston Corporation, to assist the Company in evaluating various strategic alternatives including sales and marketing collaborations or partnerships, acquisition of the Company, or other transactions. There can be no assurance that the efforts will result in collaboration or acquisition of the Company. Failure to successfully negotiate a collaboration or acquisition may have a material adverse affect on the Company's business, financial condition and results of operations.

In September 1998, Pfizer received approval in European Union countries for

Viagra (sildenafil). 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 commercial launch of sildenafil in Europe and other international countries will decrease the international demand for MUSE (alprostadil). As a result, the Company's international marketing partners, Janssen and Astra, have significantly reduced orders for MUSE (alprostadil) which will have a material effect on the Company's business, financial conditions and results of operations. Furthermore, there can be no assurances that Janssen and Astra will not further reduce their orders.

During the third quarter of 1998, the Company took significant steps to restructure its operations in an attempt to bring the cost structure of the business in line with current demand for MUSE (alprostadil). These steps included significant reductions in personnel, closing the



contract manufacturing site located in PACO Pharmaceutical Services, Inc., the abandonment of the Company's leased corporate offices, and recorded a significant write-down of property, equipment and inventory. The Company was able to sub-lease back significantly reduced space in the corporate offices. As a result of these and other factors the Company experienced an operating loss of \$54.7 million, or \$1.72 per share, in the third quarter of 1998. The goal of the restructuring was to reduce the Company's infrastructure to one that is more in line with the lower revenue model. The Company anticipates that these steps have brought the cost structure in line with current demand, however, there can be no assurance that demand will not weaken further or that these steps will result in a return to profitability.

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 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. In September 1998, the Company closed its contract manufacturing site within PACO Pharmaceutical Services, Inc. where it had previously manufactured its product and significantly scaled back its manufacturing operations in the new New Jersey facility as a result of lower demand domestically and internationally for MUSE (alprostadil). Production is significantly below capacity for the plant resulting in higher unit costs, and the Company expects that gross margin from the sale of MUSE (alprostadil) will be lower, which will have a material adverse affect on the Company's business, financial condition and results of operations.

The Company in future periods 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 began enrolling patients in a Phase III multi-center trial in September 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 NINE MONTHS ENDED SEPTEMBER 30, 1998 AND 1997

Product revenues for the quarter ended September 30, 1998 were \$3.5 million in the United States and \$14.6 million internationally compared to \$39.1 million in the United States and zero internationally for the same period in 1997. Product revenues for the nine months ended September 30, 1998 were \$34.2 million in the United States and \$26.4 million internationally compared to \$100.4 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 75% since the commercial launch of sildenafil. Internationally, revenues increased from \$9.8 million in the second quarter of 1998 to \$14.6 million in the third 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. As a result, the Company's international marketing partners, Janssen and Astra, have significantly reduced orders for MUSE (alprostadil) which will have a material adverse effect on the Company's business, financial condition and results of operations.

Total revenues for the nine months ended September 30, 1998 also included a \$1 million and \$2 million milestone payment from Janssen related to regulatory approvals of MUSE (alprostadil) in South Korea and Canada respectively, compared to the nine months ended September 30, 1997 which included a \$5 million milestone payment related to signing the initial distribution agreement with Janssen.

Cost of goods sold for the quarter ended September 30, 1998 were 28.3 million compared to 11.3 million for the same period in 1997. For the nine months ended September 30, 1998, cost of goods sold were \$49.5 million compared to \$28.9 million for the same period in 1997. The increase was primarily a result of a one time charge of \$16.0 million related to the write-down of excess inventory

and future inventory purchase commitments (primarily raw materials) in excess of anticipated future demands. The Company expects higher costs per unit in future periods resulting from lower demand and production at significantly reduced levels.

Research and development expenses for the quarter ended September 30, 1998 were \$4.7 million compared to \$3.9 million in the quarter

ended September 30, 1997. For the nine months ended September 30, 1998 and 1997, research and development expenses were \$13.9 million and \$7.9 million, respectively. The increase was mainly due to increased spending on lab subcontractors associated with new product development. As a result of the Company's recent restructuring, it expects that research and development expenses will decrease from third quarter of 1998.

Selling, general and administrative expenses for the quarter ended September 30, 1998 were \$3.9 million compared to \$11.5 million in the quarter ended September 30, 1997. The decrease was primarily as a result of lower marketing and advertising expenses, as well as personnel reductions in administration and marketing. For the nine months ended September 30, 1998, selling, general and administrative expenses were \$38.5 million compared to \$34.6 million for 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 has 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 (alprostadil) 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. In the quarter ended September 30, 1998, the Company took further charges associated with termination of operating lease commitments. As a result, the Company expects its selling, general and administrative expenses to decrease from the current level.

Interest and other income for the three and nine months ended September 30, 1998 were \$0.2 million and \$1.7 million, respectively, compared with \$1.1 million and \$3.5 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 losses for three and nine months ended September 30, 1998, the Company did not record an income tax provision. The Company's effective tax rate was 17 % and 18 % of income before taxes for the three and nine months ended September 30, 1997.

#### LIQUIDITY AND CAPITAL RESOURCES

Since inception, the Company has financed operations primarily from the sale of preferred and common stock. Through September 30, 1998, VIVUS has raised \$153.3 million from financing activities. Cash, cash equivalents and available-for-sale securities totaled \$25.5 million at September 30, 1998 compared with \$25.4 million at June 30, 1998 and \$91.7 million at December 31, 1997. The \$66.2 million decrease in cash from December 31, 1997 resulted from several factors, including the net losses for the first nine months of 1998, the Company's repurchase of its Common Stock during the first quarter of 1998, capital spending associated with the new manufacturing facility in New Jersey, raw material inventory purchases, payments in the first quarter of 1998 for 1997 sales commissions and a lawsuit settlement payment.

Accounts receivable at September 30, 1998 were \$8.0 million compared with \$11.8 million at December 31, 1997, a decrease of \$3.8 million. The decrease was primarily due to lower sales.

Current liabilities were \$41.9 million at September 30, 1998, compared with \$26.7 million at December 31, 1997, an increase of \$15.2 million. The increase primarily relates to accruals associated with the restructuring charges, higher accounts payable related primarily to inventory purchases, partially offset by the lawsuit settlement payment and payment of 1997 sales commissions.

Capital expenditures in the nine months ended September 30, 1998 were \$18.6 million compared with \$21.5 million for the same period in 1997, an decrease of \$2.9 million. The higher capital expenditure in 1997 was primarily due to the initial phase of the construction of the new manufacturing facility, in Lakewood, New Jersey and the purchase of additional manufacturing equipment.

Current liabilities at September 30, 1998 exceed current assets resulting in negative working capital \$7.0 million. The Company anticipates that its existing capital resources combined with anticipated future revenues may not be sufficient to support the Company's operations through the commercial introduction of MUSE (alprostadil) in all international markets or for the introduction of any additional future products. The Company is currently seeking

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. Subsequently, the lender withdrew their letter of commitment. On October 5, 1998, the Company was named in a civil action by the Company's Lessor ("plaintiff") in connection with the Company's leased manufacturing facilities, located in Lakewood, New Jersey. The Company's lease requires that the

Company provide a removal security deposit in the form of cash or certificate of deposit. The Company and the Lessor ("plaintiff") have not been able to agree on the amount of the deposit, and the Lessor filed suit asking for specific performance in the amount of \$3.3 million. Should the Company not be able to reach a settlement with the plaintiff, the Company may be required to post a certificate of deposit of \$3.3 million, which will have a material adverse effect on the Company's business and financial condition. The Company is currently seeking 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 operations and 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) demand for MUSE (alprostadil); (iii) the outcome of pending litigations; (iv) the activities of competitors; (v) the progress of the Company's research and development programs; (vi) the timing and results of pre-clinical testing and clinical trials; (vii) technological advances; and (viii) 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

### FUTURE CAPITAL NEEDS AND UNCERTAINTY OF ADDITIONAL FINANCING

Current liabilities at September 30, 1998 exceed current assets resulting in negative working capital \$7.0 million. The Company anticipates that its existing capital resources combined with anticipated future revenues may not be sufficient to support the Company's operations through the commercial introduction of MUSE (alprostadil) in all international markets or for the introduction of any additional future products. 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. Subsequently, the lender withdrew their letter of commitment. On October 5, 1998, the Company was named in a civil action by the Company's Lessor ("plaintiff") in connection with the Company's leased manufacturing facilities, located in Lakewood, New Jersey. The Company's lease requires that the Company provide a removal security deposit in the form of cash or letter of credit. The Company and the Lessor ("plaintiff") have not been able to agree on the amount of the deposit, and the Lessor filed suit asking for specific performance in the amount of \$3.3 million. Should the Company not be able to reach a settlement with the plaintiff, the Company may be required to post a certificate of deposit of \$3.3 million, which will have a material adverse effect on the Company's business and financial condition. The Company is currently seeking 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 operations and 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) demand for MUSE (alprostadil); (iii) the outcome of litigations; (iv) the activities of competitors; (v) the progress of the Company's research and development programs; (vi) the timing and results of pre-clinical testing and clinical trials; (vii) technological advances; and (viii) 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 \$110.8 million for the period from its inception through September 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 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 75% in the U.S. In September 1998, Pfizer received approval in European Union countries for Viagra (sildenafil). 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 commercial launch of sildenafil in Europe and other international countries will decrease the international demand for MUSE (alprostadil). As a result, the Company's international marketing partners, Janssen and Astra, have significantly reduced orders for MUSE (alprostadil) which will have a material effect on the Company's business, financial conditions and results of operations. Furthermore, there can be no assurances that Janssen and Astra will not further reduce their orders.

The Company took significant steps to restructure its operations in an attempt to bring the cost structure of the business in line with current demand for MUSE (alprostadil). These steps included significant reductions in personnel, closing the contract manufacturing site located in PACO Pharmaceutical Services, Inc., the abandonment of the Company's leased corporate

offices, and recorded significant write-down of property, equipment and inventory. The Company was able to sub-lease back significantly reduced space in the corporate offices. As a result of these and other factors the Company experienced an operating loss of \$81.3 million, or \$2.55 per share, in the nine months ended September 30, 1998. The goal of the restructuring is to reduce the Company's infrastructure to one that is more in line with the lower revenue model. The Company anticipates that these steps have brought the cost structure in line with current demand , however, there can be no assurance that demand will not weaken further or that these steps will result in a return to profitability in the future.

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. 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 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. In September 1998, the Company closed its contract manufacturing site within PACO Pharmaceutical Services, Inc. and significantly scaled back its manufacturing operations in the new New Jersey facility as a result of lower demand domestically and

internationally for MUSE (alprostadil). Production is currently significantly below capacity for the plant resulting in higher unit cost, and the Company expects that gross margin from the sale of MUSE (alprostadil) will be lower in future periods, which will have a material adverse affect on the Company's business, financial condition and results of operations.

#### 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 75%. 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 (alprostadil), 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 (alprostadil). 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 for U.S. distribution, 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 that 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. 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. As a result, Astra, has significantly reduced orders for MUSE (alprostadil). 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, 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. ASD has recently changed its name to ICS (Integrated Commercialization Services.) 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 that amended the earlier agreement with Janssen and 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. In August 1998, the Company received \$2.0 million payment from Janssen related to regulatory approval of MUSE (alprostadil) in Canada. 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. Pfizer has commenced selling sildenafil on a limited basis outside the U.S. and it is likely that a large number of current and future impotence patients will want to try this new oral therapy. As a result, Janssen, has significantly reduced orders for MUSE (alprostadil). The marketing agreement does not have minimum purchase commitments and the Company is dependent on Janssen's efforts to distribute and sell the Company's products effectively in the above mentioned markets. Janssen may take up to twelve months to introduce a product in a given country following regulatory approval in such country. There can be no assurance that such efforts will be successful. Additionally, 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 received approval in European Union countries in September 1998. 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 75% in the U.S. The Company anticipates that the commercial launch of sildenafil in Europe and other international countries will decrease the international demand for MUSE (alprostadil) and will have a material adverse effect on the Company's business, financial condition, and results of operations. As a result of this, U.S. revenues have decreased dramatically, and international revenues are expected to decrease as well. 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; Icos Corporation has an oral medication in phase II 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; and Icos Corporation formed a joint venture with Eli Lilly in October 1998 to jointly develop and market its oral treatment. 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

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 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. In September 1998, the Company closed its contract manufacturing site within PACO Pharmaceutical Services, Inc. and significantly scaled back its manufacturing operations in the New Jersey facility, as a result of lower demand domestically and internationally for MUSE (alprostadil). Production is currently significantly below capacity for the plant resulting in higher per unit cost. As a result, the Company expects that gross margin from the sale of MUSE (alprostadil) will be lower, 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 observations cited in the FDA Form 483. 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, 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.

## 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. Due to the significant cut back in personnel and decreases in the Company's stock price, the Company's Board of directors authorized a re-pricing of certain stock options for employees and certain consultants to the closing market value as of October 19, 1998. All repriced stock options have a six-month "blackout" period, whereby the repriced stock options cannot be exercised. There can be no assurance that this action will help in retaining key employees. 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 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 16 countries Argentina, Brazil, Canada, Hong Kong, Mexico, New Zealand, Philippines, Singapore, South Africa, South Korea, 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 and other regulatory review, and later discovery of previously unknown problems with a product, manufacturer or facility may result in the FDA and other regulatory agencies requiring further clinical research or restrictions on the product or the manufacturer, including withdrawal of the product from the market. The restriction, suspension or revocation of regulatory approvals or any other failure to comply with regulatory requirements would have a material adverse effect on the Company's business, financial condition and results of operations.

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 and other regulatory agencies 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 observations cited on the FDA Form 483. 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 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 been 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 three quarters 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.

#### 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.

#### DEPENDENCE ON SINGLE SOURCE OF SUPPLY

The Company relies on a single injection molding Company, The Kipp Group ("Kipp"), for its supply of plastic applicator components. In turn, Kipp obtains its supply of resin, a key ingredient of the applicator, from a single source, Huntsman Corporation. The Company also relies on a single source, E-Beam Services, Inc. ("E-Beam"), for sterilization of its product. There can be no assurance that the Company will be able to identify and qualify additional sources of plastic components 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 plastic components or an additional sterilization facility, it will be entirely dependent upon the existing supplier 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 plastic components would have a material adverse effect on the Company's business, financial condition and results of operations.

## 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 were consolidated, and a lead plaintiff has been appointed and the plaintiff filed a consolidated and amended complaint in 1998. The Company believes the complaints lack merit and the Company will vigorously defend itself in the pending actions.

On October 5, 1998, the Company was named in a civil action filed in the Superior Court of New Jersey. This complaint seeks specific performance and other relief in connection with the Company's leased manufacturing facilities, located in Lakewood, New Jersey. The Company's lease agreement requires that the Company provide a removal security deposit in the form of cash or a letter of credit. The Company and lessor ("plaintiff") have not been able to agree on the amount of such deposit and the plaintiff filed suit asking for specific performance in the amount of \$3.3 million. The Company believes that the amount sought by the plaintiff is excessive and will attempt to negotiate a settlement for a reduced amount. Should the Company not be able to reach a settlement with the plaintiff the Company may be required to post a certificate of deposit of \$3.3 million which will have a material adverse effect on the company's business and financial condition.

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

On October 14, 1998, the Company and Generation Ventures, LLC ("GV") entered into a Settlement Agreement and General Release pursuant to which GV released all of its outstanding claims against the Company in exchange for the Company's issuance to GV of 20,000 shares of its Common Stock. In issuing the shares to GV, the Company relied on Section 3(a)(10) of the Securities Act of 1933, as amended. As set forth above, the Company exchanged its Common Stock for the release of all of GV's outstanding claims against the Company. Further, the San Mateo County Superior Court in Redwood City, California approved the fairness of the exchange after a duly noticed hearing.

## ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

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

None

## ITEM 5. OTHER INFORMATION

None

## ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

## (a) EXHIBITS (IN ACCORDANCE WITH ITEM 601 OF REGULATION S-K)

- (7)3.2 Amended and Restated Certificate of Incorporation of the Company
- (4)3.3 Bylaws of the Registrant, as amended
- (8)3.4 Certificate of Designations of Rights, Preferences and Privileges of Series A Participating Preferred Stock
- (7)4.1 Specimen Common Stock Certificate of the Registrant
- (1)4.2 Registration Rights, as amended
- (1)4.4 Form of Preferred Stock Purchase Warrant issued by the Registrant to Invemed Associates, Inc., Frazier Investment Securities, L.P., and Cristina H. Kepner
- (8)4.5 Second Amended and Restated Preferred Shares Rights Agreement, dated as of April 15, 1997 by and between the Registrant and Harris Trust Company of California, including the Certificate of Determination, the form of Rights Certificate and the Summary of Rights attached thereto as Exhibits A, B, and C, respectively
- (1)+10.1 Assignment Agreement by and between Alza Corporation and the Registrant dated December 31, 1993
- (1)+10.2 Memorandum of Understanding by and between Ortho Pharmaceutical Corporation and the Registrant dated February 25, 1992
- (1)10.3 Assignment Agreement by and between Ortho Pharmaceutical Corporation and the Registrant dated June 9, 1992
- (1)+10.4 License Agreement by and between Gene A. Voss, 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
- (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
- (12)+10.34 Agreement dated as of June 30, 1998 between Registrant and Alza Corporation
- (12)+10.35 Sales Force Transition Agreement dated July 6, 1998 between Registrant and Alza Corporation
- 27.1 Financial Data Schedule

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- (1) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Registration Statement on Form S-1 No. 33-75698, as amended.
- (2) Incorporated by reference to the same numbered exhibit filed with the Registrant's Registration Statement on Form S-1 No. 33-90390, as amended.
- (3) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1995, as amended.
- (4) Incorporated by reference to the same numbered exhibit filed with the Registrant's Form 8-B filed with the Commission on June 24, 1996.
- (5) Incorporated by reference to the same numbered exhibit filed with the Registrant's Current Report on Form 8-K/A filed with the Commission on June 21, 1996.
- (6) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1996.
- (7) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1996, as amended.
- (8) Incorporated by reference to exhibit 99.1 filed with Registrant's Amendment Number 2 to the Registration Statement of Form 8-A (File No. 0-23490) filed with the Commission on April 23, 1997.
- (9) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1997
- (10) Incorporated by reference to the same numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1997.
- (11) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1997.

(12) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1998.



+ Confidential treatment granted.

(b) Reports on Form 8-K

None.

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: November 16, 1998

VIVUS, Inc.

/s/ Richard Walliser

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Richard Walliser  
Interim Chief Financial Officer

/s/ Leland F. Wilson

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Leland F. Wilson  
President and Chief  
Executive Officer

VIVUS, INC.  
INDEX TO EXHIBITS\*

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

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FOR PURPOSES OF THIS EXHIBIT, PRIMARY MEAN BASIC