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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, 1997

OR

☐ [] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE
SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM
----- TO

COMMISSION FILE NUMBER: 0-23490

VIVUS, INC.
(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

DELAWARE
(STATE OR OTHER JURISDICTION OF
INCORPORATION OR ORGANIZATION)

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

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

(415) 325-5511
(REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE)

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

Indicate by check mark whether the registrant (1) has filed all reports
required to be filed by Section 13 or 15(d) of the Securities Exchange Act of
1934 during the preceding 12 months (or for such shorter period that the
registrant was required to file such reports), and (2) has been subject to such
filing requirements for the past 90 days. Yes ☒ [X] No ☐ []

At July 31, 1997, 33,125,712 shares of common stock were outstanding.

Exhibit index on page 21.

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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)
(UNAUDITED)

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	1997	1996	1997	1996
Net product sales.....	\$33,458	\$ --	\$61,249	\$ --
Milestone revenue.....	--	10,000	5,000	10,000
Net revenues.....	33,458	10,000	66,249	10,000
Cost of goods sold.....	9,584	--	17,650	--
Gross margin.....	23,874	10,000	48,599	10,000
Operating expenses:				
Research and development.....	1,940	12,187	3,967	17,545
Selling, general and administrative.....	11,258	2,004	23,067	3,383
Total operating expenses.....	13,198	14,191	27,034	20,928
Income (loss) from operations.....	10,676	(4,191)	21,565	(10,928)
Interest income.....	1,264	446	2,385	949
Income (loss) before taxes.....	11,940	(3,745)	23,950	(9,979)
Income taxes.....	1,982	--	4,438	--
Net income (loss).....	\$ 9,958	\$(3,745)	\$19,512	\$(9,979)
Net income (loss) per common and equivalent share.....	\$ 0.28	\$ (0.13)(1)	\$ 0.55(1)	\$ (0.35)(1)
Shares used in the computation of net income (loss) per share.....	35,579	28,448(1)	35,626(1)	28,200(1)

(1) Share and per share amounts have been adjusted to reflect the 2 for 1 stock split which occurred in the second quarter of 1997.

VIVUS, INC.

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

ASSETS

	JUNE 30, 1997	DECEMBER 31, 1996
	----- (UNAUDITED)	-----
Current assets:		
Cash.....	\$ 2,076	\$ 555
Available-for-sale securities.....	78,850	60,710
Trade and other receivables.....	14,411	748
Inventories.....	5,180	4,540
Prepaid expenses and other.....	757	587
	-----	-----
Total current assets.....	101,274	67,140
Property & equipment.....	16,279	6,332
Available-for-sale securities, non-current.....	14,423	23,060
	-----	-----
Total.....	\$ 131,976	\$ 96,532
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable.....	\$ 6,344	\$ 3,324
Accrued and other liabilities.....	17,431	3,428
	-----	-----
Total current liabilities.....	23,775	6,752
	-----	-----
Stockholders' equity:		
Common stock; \$.001 par value; shares authorized 200,000,000; shares outstanding -- June 30, 1997, 33,035,116; December 31, 1996, 32,454,340 (1);.....	33	32
Paid in capital.....	158,374	156,173
Less treasury stock, at cost; 151,000 shares at June 30, 1997; none at December 31, 1996.....	(3,401)	--
Unrealized gain (loss) on securities.....	(16)	77
Deferred compensation.....	(147)	(348)
Accumulated deficit.....	(46,642)	(66,154)
	-----	-----
Total stockholders' equity.....	108,201	89,780
	-----	-----
Total.....	\$ 131,976	\$ 96,532
	=====	=====

(1) Prior period shares have been adjusted to reflect the 2 for 1 stock split which occurred in the second quarter of 1977.

VIVUS, INC.

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

	SIX MONTHS ENDED JUNE 30,	
	1997	1996
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss).....	\$ 19,512	\$ (9,980)
Adjustments to reconcile net income (loss) to net cash provided by (used for) operating activities:		
Depreciation and amortization.....	892	477
Amortization of deferred compensation.....	201	221
Issuance of common stock for patent rights.....	--	5,821
Changes in assets and liabilities:		
Receivables.....	(13,663)	(169)
Inventories.....	(640)	--
Prepaid expenses and other.....	(170)	(164)
Accounts payable.....	3,020	363
Accrued and other liabilities.....	14,003	754
Net cash provided by (used for) operating activities....	23,155	(2,677)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Property purchases.....	(10,839)	(1,264)
Securities purchases.....	(133,303)	(69,402)
Proceeds from sale/maturity of securities.....	123,707	22,770
Net cash used by investing activities.....	(20,435)	(47,896)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Exercise of common stock options.....	2,029	494
Purchase of common stock through employee stock purchase plan...	173	104
Repurchase of common stock through buybacks.....	(3,401)	--
Net cash provided by (used for) financing activities....	(1,199)	598
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS.....	1,521	(177)
Cash and Cash Equivalents:		
Beginning of period.....	555	973
End of period.....	\$ 2,076	\$ 796
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Unrealized loss on securities.....	\$ (93)	\$ (217)

VIVUS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
JUNE 30, 1997

1. BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulations S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three month and six month periods ended June 30, 1997 are not necessarily indicative of the results that may be expected for the year ending December 31, 1997. For further information, refer to the financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 1996.

2. PROVISION FOR INCOME TAXES

The Company's effective tax rate was 18.5 percent of income before taxes for the six months ended June 30, 1997. This tax rate includes the effect of net operating losses (NOLs) carried forward from prior periods. The tax rate would have been substantially higher if the NOLs were not available to offset current income. The Company expects to fully utilize all NOLs during 1997, and accordingly, the Company's effective tax rate is expected to increase in the future.

3. NET INCOME (LOSS) PER SHARE

For the three months and six months ended June 30, 1997, net income per common and equivalent share is based on the weighted average number of common and equivalent shares outstanding during the period, including outstanding options and warrants. Such options and warrants are excluded from the net loss per common and equivalent shares for the three and six months ended June 30, 1996 because they are antidilutive. 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. IMPACT OF NEW ACCOUNTING PRONOUNCEMENT

The Company will adopt SFAS No. 128, "Earnings per Share," effective December 15, 1997 for the year ending December 31, 1997. This Statement cannot be applied before December 15, 1997. It requires that all earnings-per-share data for prior periods presented be restated to conform with the new statement. Had the new pronouncement been in effect for the periods presented, earnings-per-share would have been as follows:

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	-----		-----	
	1997	1996	1997	1996
	----	-----	----	-----
Basic Earnings-per-share.....	0.30	(0.14)	0.59	(0.35)
Diluted Earnings-per-share.....	0.28	(0.14)	0.55	(0.35)

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

DESCRIPTION OF BUSINESS

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

The Company has limited experience in manufacturing and selling MUSE (alprostadil) in commercial quantities. Since the commercial launch of MUSE (alprostadil) in January 1997, the Company has experienced product shortages due to higher than expected demand and difficulties encountered in scaling up production of MUSE (alprostadil). The Company has initiated the build out of 90,000 square feet of additional manufacturing space and it is currently seeking a location for construction of a European manufacturing operation. If the Company encounters further difficulties with its current manufacturing facility or delays in completion or regulatory approval of its new manufacturing facility, capacity constraints could continue for an extended period of time, which would have a material adverse effect on the Company's business, financial condition and results of operations.

The Company's New Jersey manufacturing facility at Paco Pharmaceutical Services Inc. was inspected by the FDA for the first time after the preapproval inspection during twelve days in February and March 1997. That inspection resulted in the issuance by the FDA of an extensive FDA Form 483, which detailed specific areas where the FDA inspector observed that the Company's operations were not in full compliance with some areas of the cGMP regulations. A corrective action plan addressing all identified cGMP deficiencies was initiated immediately, and the Company submitted a written response to the FDA Form 483 and requested a meeting with the FDA district office officials to address the matter. Approximately 30 days after submitting the initial written response, the Company provided the FDA with a written update of the progress made against the corrective action plan. The Company provided an additional written response to comments and questions from the FDA in April and May 1997. Following a meeting with FDA officials on May 23, 1997, the FDA issued a Warning Letter to the Company on May 29, 1997 reiterating the deficiencies noted in the earlier FDA Form 483. The Warning Letter acknowledged that the responses submitted by the Company had been evaluated and "appear satisfactory," subject to reinspection. On June 20, 1997, the Company requested that the FDA reinspect its manufacturing facility in New Jersey. To date, the FDA has not scheduled its reinspection.

The scope of any FDA reinspection is likely to be more comprehensive than the initial inspection. Failure to adequately address cGMP deficiencies within a reasonable time frame would have an adverse effect on the Company's ability to supply its product in the US and internationally, which would have a material adverse effect on the Company's business, financial condition and results of operations. Accordingly, the Company has undertaken a complete review of its compliance with cGMP regulations. However, there can be no assurance

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

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

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

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

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

RESULTS OF OPERATIONS

THREE AND SIX MONTHS ENDED JUNE 30, 1997 AND 1996

Product revenues of \$33,458,000 and \$61,249,000 were recorded for the three months and six months ended June 30, 1997 respectively, compared to zero for each of the same periods in 1996. All product revenue was the result of the commercial launch of Muse (alprostadil) in 1997. Product revenue for the six months period includes \$2,636,000 for product shipped in December of 1996; these shipments were made to initially stock wholesalers and were allowed one-time extended rights-of-return which expired during the six months ended June 30, 1997.

As consideration for execution of the Janssen marketing agreement, Janssen paid the Company \$5 million in January 1997. The Company recorded this receipt as milestone revenue in the condensed consolidated statement of operations.

Cost of goods sold were \$9,584,000 and \$17,650,000 in the three and six months ended June 30, 1997. Cost of Goods Sold were zero for the same periods in 1996 as there were no product sales.

The resulting product gross margin for the three and six months ended June 30, 1997 was 71%.

For the three months ended June 30, 1997, research and development expenses were \$1,940,000 compared with \$12,187,000 for the three months ended June 30, 1996, a decrease of 84%. For the six months ended June 30, 1997, research and development expenses were \$3,967,000, compared with \$17,545,000 for the six months ended June 30, 1996, a decrease of 77%. Research and development expenses were less than the same periods in 1996 due primarily to a \$5.9 million charge incurred as the result of issuing 200,000 pre-split shares of Common Stock in May 1996 to ALZA Corporation to maintain exclusive rights to certain patents and patent applications beyond 1998, as well as higher pre-launch manufacturing, and clinical and regulatory costs in 1996 associated with the preparation and filing of the Company's New Drug Application for MUSE (alprostadil).

Selling, general and administrative expenses for the three months ended June 30, 1997 were \$11,258,000 compared with \$2,004,000 for the three months ended June 30, 1996, an increase of 462%. For six months ended June 30, 1997, selling, general and administrative expenses were \$23,067,000 compared with \$3,383,000 for six months ended June 30, 1996, an increase of 582%. The increase compared with the same periods in 1996 resulted primarily from the addition of a fifty person field sales force, higher marketing expenses and the costs associated with adding personnel to support the growth of the Company's operations and the commercial launch of MUSE (alprostadil).

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

Interest income for the three months ended June 30, 1997 was \$1,264,000 compared with \$446,000 for the three months ended June 30, 1996, an increase of 183%. For six months ended June 30, 1997, interest income was \$2,385,000 compared with \$949,000 for six months ended June 30, 1996, an increase of 151%. The increases were primarily the result of higher average invested balances. As a result of the Company's anticipated additional costs, interest income is expected to decrease in the future as cash balances decrease.

Income taxes for the three months ended June 30, 1997 were \$1,982,000, approximately 16.6% of income before taxes, compared with zero for the three months ended June 30, 1996. For six months ended June 30, 1997, income taxes were \$4,438,000, approximately 18.5% of income before taxes, compared with zero for the six months ended June 30, 1996. The increase is due to the increase in taxable income as a result of increased revenue from product sales. The 1997 tax rate includes the effect of net operating losses (NOLs) carried forward from prior periods. The tax rate would have been substantially higher if the NOLs were not available to offset current income. The Company expects to fully utilize all NOLs during 1997, and accordingly, the Company's effective tax rate is expected to increase in the future.

LIQUIDITY AND CAPITAL RESOURCES

Since inception, the Company has financed operations primarily from the sale of preferred and common stock. Through June 30, 1997, VIVUS has raised \$149,796,000 from financing activities. Cash, cash equivalents and securities available-for-sale totaled \$95,349,000 at June 30, 1997 compared with \$84,325,000 at December 31, 1996. The increase in cash, cash equivalents and securities available-for-sale is primarily a result of accounts receivable collections, partially off-set by operating and capital disbursements and stock repurchases. The Company maintains its current excess cash balances in a variety of interest bearing investment-grade financial investments such as United States treasury, federal agency and state government securities, repurchase agreements, corporate debt and bank certificates of deposit. Principal preservation, liquidity and safety are the primary investment objectives.

Cash flow from operations in the six months ended June 30, 1997 was \$23,155,000 compared with cash used of \$2,677,000 in the six months ended June 30, 1996. The increased cash provided by operations was primarily due to net income of \$19,512,000.

Trade and other receivables at June 30, 1997 were \$14,411,000 compared with \$748,000 at December 31, 1996, an increase of \$13,663,000. The increase primarily resulted from the increase in trade receivables resulting from sales of MUSE (alprostadil).

Current liabilities were \$23,775,000 at June 30, 1997 compared with \$6,752,000 at December 31, 1996, an increase of \$17,023,000. The increase was related primarily to an increase in manufacturing and facilities expenditures, as well as accrued income taxes, incentive compensation, and accrued royalties.

Capital expenditures in the six months ended June 30, 1997 were \$10,839,000 compared with \$1,264,000 for the same period ended June 30, 1996. Capital expenditures during the period in 1996 consisted primarily of manufacturing and quality control equipment. Capital expenditures were higher in 1997 due to the purchase of additional manufacturing equipment for use at the Company's dedicated manufacturing operation within the Paco Pharmaceutical Services, Inc. ("Paco") facility in Lakewood, New Jersey, and the construction of the new manufacturing facility, also in Lakewood. Capital expenditures over the next two years are likely to increase as they are expected to include additional improvements in the current manufacturing facilities, completion of the new manufacturing facility in New Jersey, a new manufacturing facility in Europe, and a new corporate headquarters and a research and development laboratory facility in the United States.

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

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

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

RISK FACTORS

LIMITED MANUFACTURING EXPERIENCE; CAPACITY CONSTRAINTS

The Company has only limited experience in manufacturing MUSE (alprostadi) in commercial quantities. Since the commercial launch of MUSE (alprostadi) in January 1997, the Company has experienced product shortages due to higher than expected demand and difficulties encountered in scaling up production of MUSE (alprostadi). The Company has initiated the build out of 90,000 square feet of additional manufacturing space in New Jersey, and it is currently seeking a location for construction of a European manufacturing operation. The Company anticipates it will complete construction of the new facility by the end of 1997. However, construction of a cGMP compliant manufacturing site of this scale is a very complicated task, and the Company may not be able to meet this schedule. In addition, before the new facility can produce commercial product, the Company must validate the plant and obtain FDA approval. There is no assurance validation and FDA approval will be completed and obtained in a timely manner. If the Company encounters further difficulties with its current manufacturing facility or delays in completion or approval of its new manufacturing facility, capacity constraints could continue for an extended period. Such extended capacity constraints could create the need for product allocations between domestic and international markets and further increase the order backlog following the launch of MUSE (alprostadi) outside of the United States, strain relationships with distribution partners, and possibly cause patients to seek alternative therapies. Such events could have a material adverse effect upon the business, financial condition and operating results of the Company.

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

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

The Company's New Jersey manufacturing facility at Paco Pharmaceutical Services Inc. was inspected by the FDA for the first time after the preapproval inspection during twelve days in February and March 1997. That inspection resulted in the issuance by the FDA of an extensive FDA Form 483, which detailed specific

areas where the FDA inspector observed that the Company's operations were not in full compliance with some areas of the cGMP regulations. A corrective action plan addressing all identified cGMP deficiencies was initiated immediately, and the Company submitted a written response to the FDA Form 483 and requested a meeting with the FDA district office officials to address the matter. Approximately 30 days after submitting the initial written response, the Company provided the FDA with a written update of the progress made against the corrective action plan. The Company provided an additional written response to comments and questions from the FDA in April and May, 1997. Following a meeting with FDA officials on May 23, 1997, the FDA issued a Warning Letter to the Company on May 29, 1997 reiterating the deficiencies noted in the earlier FDA Form 483. The Warning Letter acknowledged that the responses submitted by the Company had been evaluated and "appear satisfactory," subject to reinspection. On June 20, 1997, the Company requested that the FDA reinspect its manufacturing facility in New Jersey.

To date, the FDA has not scheduled its reinspection. The scope of any FDA reinspection is likely to be more comprehensive than the initial inspection. Failure to adequately address cGMP deficiencies within a reasonable time frame would have an adverse effect on the Company's ability to supply its product in the US and internationally, which would have a material adverse effect on the Company's business, financial condition and results of operations. Accordingly, the Company has undertaken a complete review of its cGMP compliance. However, there can be no assurance that the FDA will deem the Company's corrective action to be adequate or that additional corrective action, in areas not addressed by the FDA Form 483, will not be required. Failure to achieve satisfactory cGMP compliance upon reinspection would have a material adverse effect on the Company's ability to continue to market and distribute its products and, in the most serious cases, could result in the issuance of additional Warning Letters, seizure or recall of products, civil fines or closure of the Company's New Jersey manufacturing facility until cGMP compliance is achieved.

LIMITED SALES AND MARKETING EXPERIENCE; DEPENDENCE ON THIRD PARTIES

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

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

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

In July 1996, the Company entered into a distribution agreement with ASD, a subsidiary of Bergen Brunswig Corporation. ASD provides "direct-to-physician" distribution, telemarketing and customer service capabilities in support of the U.S. marketing and sales efforts. Pursuant to the terms of this agreement, ASD developed a customer service organization to respond to all the Company's sales representative and physician inquiries. As a result of this distribution agreement with ASD, the Company is dependent on ASD's efforts to

distribute, telemarket, and provide customer service effectively. There can be no assurance that such efforts will be successful.

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

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

DEPENDENCE ON THE COMPANY'S TRANSURETHRAL SYSTEM FOR ERECTION

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

GOVERNMENT REGULATION AND UNCERTAINTY OF PRODUCT APPROVALS

The Company's research, preclinical development, clinical trials, manufacturing and marketing of its products are subject to extensive regulation by numerous governmental authorities in the United States and other countries. Clinical trials, manufacturing and marketing of the Company's products will be subject to the rigorous testing and approval processes of the FDA and equivalent foreign regulatory agencies. The process of obtaining FDA and other required regulatory approvals is lengthy and expensive. The Company completed pivotal clinical trials in 1995 and submitted an NDA for its first product, MUSE (alprostadil), to the FDA in March 1996. In November 1996, the Company received final marketing clearance from the FDA for MUSE (alprostadil). After regulatory approval is obtained, the Company's products are subject to continual review. 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 affect future marketing of a drug. In addition, the Company submitted applications for regulatory approval to market MUSE (alprostadil) in the United Kingdom and Sweden in 1996; Norway in January 1997; China, Australia and New Zealand in April 1997 and Canada and Switzerland in May 1997. These applications will be subject to rigorous approval processes. There can be no assurance that approval in these or other countries will be granted on a timely

basis, if at all, or if granted, that such approval will not contain significant limitations in the form of warnings, precautions or contraindications with respect to conditions of use. Any delay in obtaining, or failure to obtain, such approval would adversely affect the Company's ability to generate product revenue.

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

The Company obtains the necessary raw materials and components for the manufacture of MUSE (alprostadil) from third parties. The Company currently contracts with contract manufacturing organizations, including foreign manufacturers, that are required to comply with strict standards established by the Company. All contract manufacturers are required by the Federal Food, Drug, and Cosmetic Act, as amended, and by FDA regulations to follow cGMP regulations 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. The FDA stringently applies regulatory standards for manufacturing. The Company's third party contract manufacturers were inspected for compliance with cGMP regulations as part of the approval process. However, upon routine re-inspection of the manufacturing facilities, there can be no assurance that the FDA will find the manufacturing process or facilities to be in compliance with cGMP and other regulations. Failure to achieve satisfactory compliance with cGMP regulations as confirmed by routine inspections could have a significant adverse effect on the Company's ability to continue to manufacture and distribute its products and, in the most serious case, result in the issuance of a regulatory warning letter or seizure or recall of products, injunction and/or civil fines.

The Company's New Jersey manufacturing facility at Paco Pharmaceutical Services Inc. was inspected by the FDA for the first time after the preapproval inspection during twelve days in February and March 1997. That inspection resulted in the issuance by the FDA of an extensive FDA Form 483, which detailed specific areas where the FDA inspector observed that the Company's operations were not in full compliance with some areas of the cGMP regulations. A corrective action plan addressing all identified cGMP deficiencies was initiated immediately, and the Company submitted a written response to the FDA Form 483 and requested a meeting with the FDA district office officials to address the matter. Approximately 30 days after submitting the initial written response, the Company provided the FDA with a written update of the progress made against the corrective action plan. The Company provided an additional written response to comments and questions from the FDA in April and May, 1997. Following a meeting with FDA officials on May 23, 1997, the FDA issued a Warning Letter to the Company on May 29, 1997 reiterating the deficiencies noted in the earlier FDA Form 483. The Warning Letter acknowledged that the responses submitted by the Company had been evaluated and "appear satisfactory," subject to reinspection. On June 20, 1997, the Company requested that the FDA reinspect its manufacturing facility in New Jersey. To date, the FDA has not rescheduled its reinspection.

The scope of any FDA reinspection is likely to be more comprehensive than the initial inspection. Failure to adequately address cGMP deficiencies within a reasonable time frame would have an adverse effect on the Company's ability to supply its product in the US and internationally, which would have a material adverse

effect on the Company's business, financial condition and results of operations. Accordingly, the Company has undertaken a complete review of its compliance with cGMP regulations. However, there can be no assurance that the FDA will deem the Company's corrective action to be adequate or that additional corrective action, in areas not addressed by FDA Form 483, will not be required. Failure to achieve satisfactory compliance with cGMP regulations upon reinspection 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 New Jersey manufacturing facility until compliance with cGMP regulations is achieved.

INTENSE COMPETITION

Competition in the pharmaceutical and medical products industries is intense and is characterized by extensive research efforts and rapid technological progress. Certain treatments for erectile dysfunction exist, such as needle injection therapy, vacuum constriction devices, penile implants and oral medications, and the manufacturers of these products will continue to improve these therapies. In July 1995, the FDA approved the use of alprostadil in The Upjohn Company's needle injection therapy product for erectile dysfunction. Previously, Upjohn had obtained approval in a number of European countries. In June 1997, Schwartz Pharma announced the FDA approval of their needle injection treatment for erectile dysfunction. Additional competitive therapies under development include an oral medication by Pfizer, Inc., which is currently in Phase III clinical trials. Other large pharmaceutical companies are also actively engaged in the development of therapies for the treatment of erectile dysfunction. These companies have substantially greater research and development capabilities as well as substantially greater marketing, financial and human resources than the Company. In addition, these companies have significantly greater experience than the Company in undertaking preclinical testing, human clinical trials and other regulatory approval procedures. There are also small companies, academic institutions, governmental agencies and other research organizations that are conducting research in the area of erectile dysfunction. For instance, Zonagen, Inc. and Pentech Pharmaceutical, Inc. have oral medications under development. These entities may also market commercial products either on their own or through collaborative efforts. The Company's competitors may develop technologies and products that are more effective than those being developed by the Company. Such developments would render the Company's products less competitive or even obsolete. The Company is also competing with respect to marketing capabilities and manufacturing efficiencies, areas in which it has limited experience.

PROPRIETARY RIGHTS AND RISK OF LITIGATION

The Company's success will depend, in large part, on the strength of its current and future patent position relating to the transurethral delivery of pharmacologic agents for the treatment of erectile dysfunction. The Company's patent position, like that of other pharmaceutical companies, is highly uncertain and involves complex legal and factual questions. Claims made under patent applications may be denied or significantly narrowed and issued patents may not provide significant commercial protection to the Company. The Company could incur substantial costs in proceedings before the United States Patent Office, including interference proceedings. These proceedings could also result in adverse decisions as to the priority of the Company's licensed or assigned inventions. There is no assurance that the Company's patents will not be successfully challenged or designed around by others.

The Company is 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 proceedings, certain claims in the European patent were held to be unpatentable by the Opposition Division of the European Patent Office (EPO). These claims related to all pharmaceutical compositions that included prostaglandin E(1). The patentability of other claims in the patent was confirmed. These claims included the use of active agents in the treatment of erectile dysfunction by administration via the urethra to the corpora cavernosa, and a pharmaceutical composition claim for prazosin. The Company appealed the EPO's decision with respect to the pharmaceutical composition claims that were held unpatentable. The Pharmedic Company appealed the EPO's decision with respect to the claims that were held patentable, but has since withdrawn. Despite the withdrawal of the Pharmedic Company from the appeals 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 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 or other intellectual property rights.

A former consultant to the Company has claimed that he is the inventor of certain technology disclosed in two of the Company's patents. The former consultant further claims that the Company and certain of its officers and directors defrauded him by allegedly failing to inform him that they intended to use and patent this technology and by failing to compensate him in the manner allegedly promised. On May 28, 1996, the Company filed a complaint for declaratory judgment against the former consultant in the United States District Court for the Northern District of California, which seeks a declaration from the court that the former consultant is not an inventor of any of the technology. On July 17, 1996, the former consultant filed a lawsuit that sought to have two of the Company's patents corrected to name him as an inventor, or in the alternative, declared invalid on the grounds that they fail to list him as an inventor. On September 16, 1996, the Court dismissed the consultant's lawsuit, and ordered him to refile his claims as counterclaims in the action initiated by the Company on May 28, 1996. The consultant filed his counterclaim on September 26, 1996. On July 25, 1997, the Company filed motions for summary judgment, which request that the Court enter judgment against the former consultant on all of his claims. These motions are scheduled to be heard by the Court on September 8, 1997. The Company has conducted a review of the circumstances surrounding this matter and believes that the allegations are without merit. Although the Company believes that it should prevail in the litigation, the uncertainties inherent in litigation prevent the Company from giving any assurances about the outcome of such litigation.

In a separate matter, on April 10, 1996, the licensors in an agreement by which the Company acquired a patent license filed a lawsuit in a Texas state court that alleged that they were defrauded in connection with the negotiation of the license agreement between the Company and the licensors. On May 8, 1996, the action was removed to the United States District Court for the Western District of Texas. In addition to monetary damages, the licensors sought to return to the terms of an earlier superseded license agreement. This action was settled in May 1997. Pursuant to the terms of the settlement agreement, neither the Company nor its officers will pay any damages to plaintiffs, and the license agreement will remain in effect.

DEPENDENCE ON DUAL SOURCE OF SUPPLY

To date, the Company has obtained its supply of alprostadil from two sources. The first is Spolana Chemical Works AS ("Spolana") pursuant to a long-term supply agreement that was executed in May 1997. In January 1996, the Company entered into a long-term alprostadil supply agreement with Chinoin. Chinoin is the Hungarian subsidiary of the French pharmaceutical company Sanofi Winthrop. Alprostadil, a generic drug, is extremely difficult to manufacture and is only available to the Company from a limited number of other suppliers, none of which currently produce it in commercial quantities. While the Company is seeking additional sources, there can be no assurance that it will be able to identify and qualify such sources. The Company is required to identify its suppliers to the FDA. The FDA may require additional clinical trials or other studies prior to accepting a new supplier. Unless the Company secures and qualifies additional sources of alprostadil, it will be entirely dependent upon Spolana and Chinoin for the delivery of alprostadil. If interruptions in the supply of alprostadil were to occur for any reason, including a decision by Spolana and/or Chinoin to discontinue manufacturing, political unrest, labor disputes or a failure of Spolana and/or Chinoin

to follow regulatory guidelines, the development and commercial marketing of MUSE (alprostadil) and other potential products could be delayed or prevented. An interruption in the Company's supply of alprostadil would have a material adverse effect on the Company's business, financial condition and results of operations.

HISTORY OF LOSSES AND LIMITED OPERATING HISTORY

The Company has generated a cumulative net loss of \$46.6 million for the period from its inception through June 30, 1997. To sustain profitability, the Company must successfully manufacture and market MUSE (alprostadil). The Company is subject to a number of risks including its ability to scale-up manufacturing capabilities and secure adequate supplies of raw materials, its ability to successfully market, distribute and sell its product, its reliance on a single therapeutic approach to erectile dysfunction and intense competition. There can be no assurance that the Company will be able to achieve profitability on a sustained basis. Accordingly, there can be no assurance of the Company's future success.

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

FUTURE CAPITAL NEEDS AND UNCERTAINTY OF ADDITIONAL FINANCING

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

DEPENDENCE ON KEY PERSONNEL

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

RISKS RELATING TO INTERNATIONAL OPERATIONS

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

PRODUCT LIABILITY AND AVAILABILITY OF INSURANCE

The commercial launch of MUSE (alprostadil) exposes the Company to a significant risk of product liability claims due to its availability to a large population of patients. In addition, pharmaceutical products are subject to heightened risk for product liability claims due to inherent side effects. The Company details potential side effects in the patient package insert and the physician package insert, both of which are included with MUSE (alprostadil), and the Company maintains product liability insurance coverage. However, the Company's product liability coverage is limited and may not be adequate to cover potential product liability exposure. Product liability insurance is expensive, difficult to maintain and current or increased coverage may not be available on acceptable terms, if at all. Product liability claims brought against the Company in excess of its insurance coverage, if any, could have a material adverse effect upon the Company's business, financial condition and results of operations.

UNCERTAINTY OF PHARMACEUTICAL PRICING AND REIMBURSEMENT

In the United States and elsewhere, sales of pharmaceutical products currently are dependent, in part, on the availability of reimbursement to the consumer from third party payors, such as government and private insurance plans. Third party payors are increasingly challenging the prices charged for medical products and services. There can be no assurance that the Company's products will be considered cost effective and that reimbursement to the consumer will be available or sufficient to allow the Company to sell its products on a competitive basis.

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

UNCERTAINTY AND POSSIBLE NEGATIVE EFFECTS OF HEALTHCARE REFORM

The healthcare industry is undergoing fundamental changes that are the result of political, economic and regulatory influences. The levels of revenue and profitability of pharmaceutical companies may be affected by the continuing efforts of governmental and third party payors to contain or reduce healthcare costs through various means. Reforms that have been and may be considered include mandated basic healthcare benefits, controls on healthcare spending through limitations on the increase in private health insurance premiums and Medicare and Medicaid spending, the creation of large insurance purchasing groups and fundamental changes to the healthcare delivery system. Due to uncertainties regarding the outcome of healthcare reform initiatives and their enactment and implementation, the Company cannot predict which, if any, of the reform proposals will be adopted or the effect such adoption may have on the Company. There can be no assurance that future

healthcare legislation or other changes in the administration or interpretation of government healthcare or third-party reimbursement programs will not have a material adverse effect on the Company. Healthcare reform is also under consideration in some other countries.

CONTROL BY EXISTING STOCKHOLDERS

As of July 31, 1997, the Company's executive officers and current directors, and certain of their affiliates, beneficially owned approximately 12% of the Company's outstanding Common Stock. Such concentration of ownership may have the effect of delaying, defining or preventing a change in control of the Company. Additionally, these stockholders will have significant influence over the election of directors of the Company. This concentration of ownership may allow significant influence and control over Board decisions and corporate actions.

POTENTIAL VOLATILITY OF STOCK PRICE

The stock market has recently experienced significant price and volume fluctuations unrelated to the operating performance of particular companies. In addition, the market price of the Company's Common Stock has been highly volatile and is likely to continue to be so. Factors such as variations in the Company's financial results, comments by security analysts, the Company's ability to scale up its manufacturing capability to commercial levels, the Company's ability to successfully sell its product in the United States and internationally, any loss of key management, the results of the Company's clinical trials or those of its competition, adverse regulatory actions or decisions, announcements of technological innovations or new products by the Company or its competition, changing governmental regulations, patents or other proprietary rights or product or patent litigation, may have a significant effect on the market price of the Company's Common Stock.

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

In February 1996, the Company's Board of Directors authorized the Company's reincorporation in the State of Delaware (the "Reincorporation") and adopted a Shareholder Rights Plan. The Company's reincorporation into the State of Delaware was approved by its stockholders and effective in May 1996. The Shareholder Rights Plan provides for a dividend distribution of one Preferred Shares Purchase Right (a "Right") on each outstanding share of the Company's Common Stock. The Rights will become exercisable following the tenth day after a person or group announces acquisition of 20% or more of the Company's Common Stock, or announces commencement of a tender offer, the consummation of which would result in ownership by the person or group of 20% or more of the Company's Common Stock. The Company will be entitled to redeem the Rights at \$0.01 per Right at any time on or before the tenth day following acquisition by a person or group of 20% or more of the Company's Common Stock.

The Shareholder Rights Plan and certain provisions of the Company's Certificate of Incorporation and Bylaws may have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, control of the Company. The Company's Certificate of Incorporation allows the Company to issue Preferred Stock without any vote or further action by the stockholders, and certain provisions of the Company's Certificate of Incorporation and Bylaws eliminate the right of stockholders to act by written consent without a meeting, specify procedures for director nominations by stockholders and submission of other proposals for consideration at stockholder meetings, and eliminate cumulative voting in the election of directors. Certain provisions of Delaware law could also delay or make more difficult a merger, tender offer or proxy contest involving the Company, including Section 203, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years unless certain conditions are met. The Shareholder Rights Plan, the possible issuance of Preferred Stock, the procedures required for director nominations and stockholder proposals and Delaware law could have the effect of delaying, deferring or preventing a change in control of the Company, including without limitation, discouraging a proxy contest or making more difficult the acquisition of a substantial block of the Company's Common Stock. These provisions could also limit the price that investors might be willing to pay in the future for shares of the Company's Common Stock.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

A former consultant to the Company has claimed that he is the inventor of certain technology disclosed in two of the Company's patents. The former consultant further claims that the Company and certain of its officers and directors defrauded him by allegedly failing to inform him that they intended to use and patent this technology and by failing to compensate him in the manner allegedly promised. On May 28, 1996, the Company filed a complaint for declaratory judgment against the former consultant in the United States District Court for the Northern District of California, which seeks a declaration from the court that the former consultant is not an inventor of any of the technology. On July 17, 1996, the former consultant filed a lawsuit that sought to have two of the Company's patents corrected to name him as an inventor, or in the alternative, declared invalid on the grounds that they fail to list him as an inventor. On September 16, 1996, the Court dismissed the consultant's lawsuit, and ordered him to refile his claims as counterclaims in the action initiated by the Company on May 28, 1996. The consultant filed his counterclaim on September 26, 1996. On July 25, 1997, the Company filed motions for summary judgment, which request that the Court enter judgment against the former consultant on all of his claims. These motions are scheduled to be heard by the Court on September 8, 1997. The Company has conducted a review of the circumstances surrounding this matter and believes that the allegations are without merit. Although the Company believes that it should prevail in the litigation, the uncertainties inherent in litigation prevent the Company from giving any assurances about the outcome of such litigation.

In a separate matter, on April 10, 1996, the licensors in an agreement by which the Company acquired a patent license filed a lawsuit in a Texas state court that alleged that they were defrauded in connection with the negotiation of the license agreement between the Company and the licensors. On May 8, 1996, the action was removed to the United States District Court for the Western District of Texas. In addition to monetary damages, the licensors sought to return to the terms of an earlier superseded license agreement. This action was settled in May 1997. Pursuant to the terms of the settlement agreement, neither the Company nor its officers will pay any damages to plaintiffs, and the license agreement will remain in effect.

ITEM 2. CHANGES IN SECURITIES

On May 22, 1997, following the Annual Stockholders' Meeting, the Company increased its authorized Common Stock from 30 million to 200 million shares. On June 23, 1997, the Company effected a two-for-one stock split of its outstanding Common Stock. The stock split was originally approved by the Company's Board of Directors on February 20, 1997, and the stockholders approved the stock split at the annual meeting of stockholders on May 22, 1997. The stock split was reflected in the NASDAQ National Market on June 24, 1997. Share and per share data for all periods in this report have been adjusted to give effect to the stock split, unless otherwise indicated.

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 22, 1997. Matters voted on at that meeting were: (i) the election of seven directors; (ii) the amendment of the Certificate of Incorporation to increase the number of authorized shares of Common Stock from 30,000,000 to 200,000,000 in order to effect a two-for-one forward split of the Company's Common Stock; (iii) the amendment of the 1991 Incentive Stock Plan to increase the number of shares available for issuance from 3,100,000 to 3,900,000; (iv) the amendment of the 1994 Director Option Plan to increase the number of shares available for issuance from 100,000 to 200,000, to increase the initial option granted to non-employee directors from 12,500 to 16,000 shares and to increase the subsequent annual options granted to non-employee directors from 2,500 to 4,000 shares; and (v) the

confirmation of the appointment of Arthur Andersen LLP as independent public accountants for the fiscal year ending December 31, 1997. Tabulation for each proposal and individual director were as follows:

PROPOSAL I. ELECTION OF DIRECTORS

DIRECTOR -----	FOR -----	WITHHELD -----
Virgil A. Place, M.D.	13,840,209	76,073
Leland F. Wilson	13,840,709	75,573
Richard L. Casey	13,840,609	75,673
Samuel D. Colella	13,840,809	75,473
Brian H. Dovey	13,731,509	184,773
Elizabeth A. Fetter	13,838,408	77,874
Linda Jenckes	13,839,501	77,173

PROPOSAL II. AMENDMENT OF CERTIFICATE OF INCORPORATION

FOR -----	AGAINST -----	ABSTAIN -----	NO VOTE -----
11,869,501	1,956,302	12,082	73,397

PROPOSAL III. AMENDMENT OF THE 1991 INCENTIVE STOCK PLAN

FOR -----	AGAINST -----	ABSTAIN -----	NO VOTE -----
8,023,584	1,662,388	58,993	4,171,317

PROPOSAL IV. AMENDMENT OF THE 1994 DIRECTOR OPTION PLAN

FOR -----	AGAINST -----	ABSTAIN -----	NO VOTE -----
8,954,911	736,739	53,315	4,171,317

PROPOSAL V. CONFIRMATION OF THE APPOINTMENT OF ARTHUR ANDERSEN

FOR -----	AGAINST -----	ABSTAIN -----	NO VOTE -----
13,875,069	33,576	7,637	--

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

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

****3.1 Certificate of Incorporation of the Company, as currently in effect
 ###3.2 Form of Amended and Restated Certificate of Incorporation of the Company
 ****3.3 Bylaws of the Registrant, as amended
 #3.4 Certificate of Designations of Rights, Preferences and Privileges of Series A Participating Preferred Stock
 ###4.1 Specimen Common Stock Certificate of the Registrant
 *4.2 Registration Rights as amended
 **4.3 Form of Agreement Not to Sell by and between the Registrant and certain shareholders and option holders
 *4.4 Form of Preferred Stock Purchase Warrant issued by the Registrant to Invemed Associates, Inc., Frazier Investment Securities, L.P., and Cristina H. Kepner
 #4.5 Second amended and Restated Preferred Shares Rights Agreement, dated as of April 15, 1997 by and between VIVUS, Inc. and Harris Trust Company of California, including the Certificate of Determination, the form of Rights Certificate and the Summary of Rights attached thereto as Exhibits A, B, and C, respectively.
 *+10.1 Assignment Agreement by and between Alza Corporation and the Registrant dated December 31, 1993
 *+10.2 Memorandum of Understanding by and between Ortho Pharmaceutical Corporation and the Registrant dated February 25, 1992
 *10.3 Assignment Agreement by and between Ortho Pharmaceutical Corporation and the Registrant dated June 9, 1992
 *+10.4 License Agreement by and between Gene A. Voss M.D., Allen C. Eichler, M.D., and the Registrant dated December 28, 1992
 *+10.5A License Agreement by and between Ortho Pharmaceutical Corporation and Kjell Holmquist AB dated June 23, 1989
 *+10.5B Amendment by and between Kjell Holmquist AB and the Registrant dated July 3, 1992
 *10.5C Amendment by and between Kjell Holmquist AB and the Registrant dated April 22, 1992
 *+10.5D Stock Purchase Agreement by and between Kjell Holmquist AB and the Registrant dated April 22, 1992
 *+10.6A License Agreement by and between Amsu, Ltd., and Ortho Pharmaceutical Corporation dated June 23, 1989
 *+10.6B Amendment by and between Amsu, Ltd., and the Registrant dated July 3, 1992
 *10.6C Amendment by and between Amsu, Ltd., and the Registrant dated April 22, 1992
 *+10.6D Stock Purchase Agreement by and between Amsu, Ltd., and the Registrant dated July 10, 1992
 *10.7 Supply Agreement by and between Paco Pharmaceutical Services, Inc., and the Registrant dated November 10, 1993
 *+10.8 Agreement by and among Pharmatech, Inc., Spolana Chemical Works AS, and the Registrant dated June 23, 1993
 *10.9 Master Services Agreement by and between the Registrant and Teknekron Pharmaceutical Systems dated August 9, 1993
 *10.10 Lease by and between McCandless-Triad and the Registrant dated November 23, 1992, as amended

***10.11 Form of Indemnification Agreements by and among the Registrant and the Directors and Officers of the Registrant
 **10.12 1991 Incentive Stock Plan and Form of Agreement, as amended
 *10.13 1994 Director Option Plan and Form of Agreement
 *10.14 Form of 1994 Employee Stock Purchase Plan and Form of Subscription Agreement
 *10.15 Stock Restriction Agreement between the Company and Virgil A. Place, M.D. dated November 7, 1991
 *10.16 Stock Purchase Agreement between the Company and Leland F. Wilson dated June 26, 1991, as amended
 *10.17 Letter Agreement between the Registrant and Leland F. Wilson dated June 14, 1991 concerning severance pay
 *10.18 Letter Agreement between the Registrant and Paul Doherty dated January 26, 1994 concerning severance pay
 **10.19 Guaranteed Maximum Price Contract by and between the Registrant and Marshall Contractors, Inc. dated January 27, 1995
 **10.20 Sub-lease by and among the Registrant, Argonaut Technologies, Inc., ESCAgenetics Corp. and Tanklage Construction Co. dated March 13, 1995
 #####10.21 Distribution Services Agreement between the Registrant and Synergy Logistics, Inc. (a wholly-owned subsidiary of Cardinal Health, Inc.) dated February 9, 1996
 #####10.22 Manufacturing Agreement between the Registrant and CHINOIN Pharmaceutical and Chemical Works Co., Ltd. dated December 20, 1995
 ##+10.23 Distribution and Services Agreement between the Registrant and Alternate Site Distributors, Inc. dated July 17, 1996
 *****10.24 Distribution Agreement made as of May 29, 1996 between the Registrant and Astra AB
 ##10.25 Menlo McCandless Office Lease made as of August 30, 1996 by and between Registrant and McCandless-Triad
 ##10.26 Sublease Agreement made as of August 22, 1996 by and between Registrant and Plant Research Technologies
 #####10.27 Distribution Agreement made as of January 22, 1997 between the Registrant and Janssen Pharmaceutical International, a division of Cilag AG International
 ###10.28 Lease Agreement made as of January 1, 1997 between the Registrant and Airport Associates
 ###10.29 Lease Amendment No. 1 as of February 15, 1997 between Registrant and Airport Associates
 ###10.30 Lease Agreement by and between 605 East Fairchild Associates, L.P. and Registrant dated as of March 5, 1997
 ++10.31 Manufacture and supply agreement between Registrant and Spolana Chemical Works, a.s. dated May 30, 1997
 27.1 Financial Data Schedule

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

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

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

**** Incorporated by reference to the same-numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1996, as amended.

***** Incorporated by reference to the same numbered exhibit filed with the Registrant's Current Report on Form 8-K/A filed with the Commission on June 21, 1996.

Incorporated by reference to exhibit 99.1 filed with Registrant's Amendment Number 2 to the Registration Statement on Form 8-A (File No. 0-23490) filed with the Commission on April 23, 1997.

Incorporated by reference to the same-numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1996.

Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1996, as amended.

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.

+ Confidential treatment granted.

++ Confidential treatment requested.

(b) Reports on Form 8-K

None.

SIGNATURES

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

VIVUS, INC.

Date: August 5, 1997

/s/ DAVID C. YNTEMA

David C. Yntema
Chief Financial Officer

/s/ LELAND F. WILSON

Leland F. Wilson
President and Chief
Executive Officer

VIVUS, INC.

INDEX TO EXHIBITS

EXHIBIT	DESCRIPTION
10.31	Manufacture and supply agreement between Registrant and Spolana Chemical Works, a.s. dated May 30, 1997
27.1	Financial Data Schedule

MANUFACTURE AND SUPPLY AGREEMENT

This Manufacturing and Supply Agreement ("Agreement"), is entered into as of May 30, 1997 ("Effective Date") by and between Vivus, Inc., having a principal place of business at 545 Middlefield Road, Suite 200, Menlo Park, CA 94025, United States of America ("Vivus"), and Spolana Chemical Works, A.S., having a place of business at 277 11 Neratovice, Czech Republic ("Spolana").

BACKGROUND

A. Spolana and Pharmatech, Inc., also known as Pharma Tech International, Inc. ("Pharmatech") have entered into a business arrangement pursuant to which Spolana appointed Pharmatech as Spolana's exclusive worldwide distributor of Alprostadil USP (Prostaglandin E(1)) and Pharmatech agreed to purchase certain quantities of Alprostadil USP all as described in more detail in those certain memoranda between Spolana and Pharmatech dated March 2, 1993 filed in the archives of the commercial department of the zavod kvalifikovane chemie [qualified chemistry company] and that certain agreement in the Czech language dated September 23, 1994, as amended (collectively, the "Spolana-Pharmatech Agreements").

B. Vivus, Spolana and Pharmatech entered into that certain agreement effective as of June 23, 1993 (the "Supply Agreement") pursuant to which Spolana agreed to manufacture Prostaglandins E(1) and E(2) and Pharmatech would supply quantities of Prostaglandins E(1) and E(2) so manufactured to Vivus. Therein, Vivus agreed not to purchase Prostaglandins E(1) and E(2) directly from Spolana during the term of the Supply Agreement but only from Pharmatech.

C. Thereafter, Vivus and Pharmatech have entered into a certain letter agreement dated March 17, 1997 pursuant to which Pharmatech agreed to waive or otherwise terminate its rights under the Spolana-Pharmatech Agreements and the Supply Agreement, so that Vivus may purchase Prostaglandins E(1) and E(2) directly from Spolana and Spolana may supply the same directly to Vivus.

D. Vivus desires to secure a supply of certain quantities of Alprostadil manufactured by Spolana; and Spolana desires to supply such Alprostadil directly to Vivus, and not through Pharmatech, all on the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the mutual covenants and premises herein contained, the parties hereto agree as follows:

ARTICLE 1.
DEFINITIONS

1.1. "DMF" shall mean a drug master file, or its equivalent for the Product filed with a regulatory agency by or on behalf of Spolana which is adequate to comply with the applicable requirements and standards of such regulatory agency with respect to the Product.

1.2. "FDA" shall mean the United States Food and Drug Administration.

1.3. "GMP" shall mean good manufacturing practices as defined by the FDA in 21 CFR Part 211.

1.4. "MUSE System" shall mean Vivus' system for delivery of the Product to treat erectile dysfunction, as modified from time to time during the term of this Agreement.

1.5. "Product" shall mean Alprostadil USP (Prostaglandin E(1)).

1.6. "Specifications" shall mean the particulars as to composition, quality and other characteristics for the Product as set forth in Exhibit A hereto, as may be amended from time to time by mutual agreement of the parties.

1.7. "USP" shall mean United States Pharmacopeia.

ARTICLE 2. SUPPLY

2.1. Product Supply. Subject to the terms and conditions of this Agreement, Spolana shall supply to Vivus quantities of the Product ordered by Vivus from time to time during the term of this Agreement. Without limiting the foregoing, Spolana shall at all times maintain facilities to manufacture, [*].

2.2. Forecasts. During the term of this Agreement, [*], Vivus shall provide Spolana with a rolling written forecast of the quantities of Product estimated to be required [*]. Notwithstanding the foregoing, Vivus' initial forecast of the quantities of Product estimated to be required [*] is attached hereto as Exhibit B.

2.3. Orders.

2.3.1. Orders. Together with each forecast provided under Section 2.2 above (the "Current Forecast"), [*]. Spolana shall accept such orders from Vivus, subject to the remaining terms and conditions of this Agreement, provided that Spolana [*]. All orders placed hereunder shall be for full lots of 500 or 600 grams, or as otherwise mutually agreed.

*Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

2.3.2. Form of Orders. Vivus' orders shall be made pursuant to a written purchase order which is in a form mutually acceptable to the parties, and shall provide for shipment in accordance with reasonable delivery schedules as may be agreed upon from time to time by Spolana and Vivus. Spolana shall use all reasonable efforts to notify Vivus [*] of its ability to fill any amounts of such order in excess of the quantities that Spolana is obligated to supply. No terms contained in any purchase order, order acknowledgment or similar standardized form shall be construed to amend or modify the terms of this Agreement and in the event of any conflict, this Agreement shall control unless expressly agreed in writing.

2.3.3. Minimum Orders. Vivus agrees to order at least [*] of Product for delivery during [*]. In addition, Vivus agrees to order [*].

2.4 Maximum Quantities. Notwithstanding anything herein to the contrary, Spolana shall not be obligated to supply to Vivus more than [*], provided that Spolana agrees to use all reasonable efforts to supply any quantities in excess of such amount as Vivus may order in accordance with Section 2.3 above.

2.5 Price. The price to be paid by Vivus per gram of the Product ordered by Vivus shall be [*] by Spolana during a particular calendar year, as follows:

2.5.1. [*];

2.5.2. [*];

2.5.3. [*]; and

2.5.4. [*].

[*].

2.6 Packaging. Products shall be shipped to Vivus in lots aliquoted to 500 or 600 grams each, packaged in containers in accordance with the United States DMF. Each such container shall be individually labeled with a description of its contents, including the manufacturer name, manufacturer lot number, quantity of Product, and date of manufacture. Each such container shall be resealable and protected from light and breakage. In addition, a separate external plastic container shall be placed outside each such container, and shall in turn be sealed within a heavy plastic bag. The shipment shall be insured and carried by a reputable air freight company reasonably acceptable to Vivus. A copy of a certificate of analysis for each such lot shall accompany such lot. A second copy of such certificate of analysis shall be separately provided to Vivus.

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2.7 Shipping Terms; Payment. [*]. The manner of shipment shall be designated by Spolana and the airport or address shall be designated by Vivus. All payments hereunder shall be made in U.S. dollars, by direct bank transfer to an account designated in Spolana's invoice. Payment terms shall be [*].

2.8 Taxes. [*]

ARTICLE 3.
QUALITY

3.1. Quality. All Product supplied by Spolana shall meet (i) the current USP and European Pharmacopoeia requirements for the Product, (ii) the current Specifications, (iii) additional requirements that the parties may agree to from time to time to reflect to the manufacturing requirements of Vivus' MUSE System and (iv) the requirements of any health regulatory agency to which Vivus has submitted, or notifies Spolana it will submit or sponsor the submission of, an application for regulatory approval. In case of any official monograph or regulatory agency requirement conflicts with the current USP and European Pharmacopoeia requirements for the Product and Spolana's manufacturing and control process of Product described in the DMF, parties will consult to seek a mutually acceptable solution. All Product supplied by Spolana shall be manufactured in accordance with current GMP manufacturing and record keeping procedures and ISO 9000 regulatory requirements and record keeping procedures at Spolana's plant located at 27711 Neratovice, Czech Republic (the "Facility").

3.2. Quality Control. Prior to each shipment of Product, Spolana shall perform quality control procedures to verify that the quantity or batch of such Product to be shipped conforms fully with the Specifications. Each shipment of Product shall be accompanied by a Certificate of Analysis describing all current requirements of the Specifications, results of test performed, as well as a Batch Release Sheet certifying that the batch of Product supplied has been manufactured, controlled and released according to the Specifications, current DMFs and all relevant and current GMP requirements at the Facility stipulated under Section 3.1 above.

3.3. Rejection. Vivus shall have [*] following its receipt of a shipment of Product to reject such Product on the grounds that all or part of the shipment fails to conform to the applicable Specifications or otherwise fails to conform to the warranties given by Spolana in Section 5.1, which rejection shall be accomplished by giving written notice to Spolana specifying the manner in which all or part of such shipment fails to meet the foregoing requirements. If rejection is based on grounds of contamination or Product not passing any physical test of Specification, Vivus' rejection notice shall be accompanied by a satisfactory sample returned to Spolana to verify such non-conformity. If Vivus rejects a shipment before the date on which payment therefor is due, it may

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withhold payment for such shipment or the rejected portion thereof. The warranties given by Spolana in Article 5 below shall survive any failure to reject by Vivus under this Section 3.3.

3.4 Returns and Settlement of Claims. Spolana shall be obliged to respond in writing to Vivus accepting or refusing a rejection notice from Vivus [*] from the date of receipt of such rejection notice in accordance with Section 3.3 above. In case of a disagreement between the parties, the claim shall be submitted for tests and decision to an independent testing organization which meets appropriate GMP or consultant of recognized repute within the United States pharmaceutical industry mutually agreed upon by the parties (the "Laboratory"), the appointment of which shall not be unreasonably withheld or delayed by either party. The determination of such entity with respect to all or part of any shipment of Product shall be final and binding upon the parties. The fees and expenses of the Laboratory making such determination shall be paid by the party against which the determination is made (i.e., the party whose argument is rejected by the Laboratory). Products accepted by Spolana as not meeting the applicable requirements and Specifications or so decided by the Laboratory shall be returned by Vivus to Spolana. Spolana shall use its best efforts to replace the quantities of Product returned by Vivus within the shortest possible time, [*] from the return of such quantities. The replacement of returned Product shall have priority over the supply of Product ordered for shipment, [*] or any time after the return of the rejected quantity to Spolana. Without limiting the remedies of Vivus, if Spolana fails to replace returned Product within [*] days from the date Product is returned to Spolana, Vivus shall have the right (i) to cancel such replacement shipment by written notice and (ii) to reclaim immediately (either through refund or setoff, at Vivus' discretion) the amounts paid pursuant to Section 2.7 above for the Product that was returned but not replaced, if such payment for such Product had already been made to Spolana.

3.5. Presence At Facility. Upon reasonable notice given by Vivus to Spolana and at reasonable frequency, Vivus shall have the right to assign a reasonable number of employees or consultants of Vivus to inspect and audit the Facility at which Product is manufactured in order to verify Spolana's compliance with the current GMP and other agreed requirements, provided, however that (a) such employees or consultants shall not unreasonably interfere with other activities being carried out at the Facility, and (b) that such employees or consultants shall observe all rules and regulations applicable to visitors and to individuals employed at the Facility. It is understood that as of the Effective Date Vivus has engaged Forum (Holdings) Limited ("Forum") pursuant to that certain agreement dated September 26, 1996 pursuant to which Forum agreed to assist Vivus in ensuring, by aiding Spolana, that Spolana meets and maintains current GMP and requirements necessary for the sale of Product throughout the world.

ARTICLE 4. REGULATORY MATTERS

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4.1. Regulatory Approvals.

4.1.1. Requirements. Vivus and its marketing partners shall notify Spolana in a timely fashion about their requirements for the submission and maintenance of DMFs related to the manufacture and control of the Product adequate to comply with applicable regulatory agencies' (including without limitation the FDA's) standards with respect to the Product in the United States, Europe and Canada and other countries as is or becomes necessary for Vivus and its marketing partners to import, export and sell the MUSE System worldwide. Spolana will submit a DMF or its equivalent in any other country imposing requirements fully identical that of United States, Canada or the European Union within [*]. In case Vivus or its marketing partner requires the submission of a DMF in a country not covered by the foregoing stipulations, Vivus will assist Spolana, directly or through others, to obtain the full details of requirements of a DMF on the manufacture and control of the Product in the country concerned. Spolana will use its best efforts to fulfill these requirements and to submit such document with content and form required in the country in question and at the time required by Vivus. Spolana shall keep Vivus and its marketing partners, as appropriate, informed about its ability or inability to submit and maintain such documentation as well as the intended or possible times of such submissions.

4.1.2 DMF Submission. Spolana shall submit DMFs in every country in English or a translation in English. An English copy of the open part of each DMF, where such open part exists, shall be provided to Vivus in parallel with the submission thereof to the applicable regulatory agency. Spolana agrees to maintain all information filed with the FDA and other regulatory bodies current and reflective of current manufacturing practices and product specifications and to update this information as required. From time to time during the term of this Agreement, Spolana shall provide letters of authorization, instruments and/or documents, and take such other actions, as Vivus may reasonably request for purposes of obtaining regulatory approvals necessary for Vivus and its marketing partners to import, export and sell Product as incorporated into the MUSE System and/or other products worldwide. Spolana agrees to notify Vivus in a timely fashion of any significant changes, deletions or modifications to any DMF or Product process or specification, and not to implement any such changes that would cause a delay in obtaining regulatory approvals to market products incorporating the Product without prior written agreement with Vivus.

4.2 Inspections. Spolana shall permit the FDA and other regulatory agencies to conduct such inspections of the Facility as the FDA or such other regulatory agencies may request, and shall cooperate with the FDA or such other regulatory agencies with respect to such inspections and any related matters. Spolana shall give Vivus prior written notice of any such inspections, and shall keep Vivus informed about the results and conclusions of each such regulatory inspection, including actions taken by Spolana to remedy conditions cited in such inspections. In addition, Spolana shall allow Vivus or its representative to assist in the preparation for and be present at such inspections.

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Spolana shall provide Vivus with copies of any written inspection reports issued by such agencies and all correspondence between Spolana and the agency involved, including, but not limited to, FDA Form 483 and all correspondence relating thereto. Vivus and its regulatory consultants, agents, marketing partners or other third parties agreed upon in advance by Spolana, under reasonable confidentiality requirements, shall have access, to quality assurance and current GMP audits of DMFs for the purposes of assessment of regulatory compliance, to the buildings, records and areas of the Facility involved in the manufacture, testing, storage and shipment of the Product.

4.3 Vivus Cooperation. Vivus agrees to keep Spolana reasonably informed as to the status of the development and applications for regulatory approvals of the MUSE System incorporating the Product supplied hereunder.

4.4 Maintenance of Approvals. Notwithstanding anything herein to the contrary, Spolana shall not undertake any modifications to Product manufacturing or testing processes, specifications or filings that could impact Vivus product approvals, regulatory product reviews, IND or any other compliance status without prior written agreement of Vivus. Spolana shall obtain and maintain all licenses, permits and registrations necessary to manufacture the Product and supply it hereunder.

ARTICLE 5. PRODUCT WARRANTIES

5.1 Process and Product Warranties. Spolana warrants and represents that:

5.1.1 Specifications. all Product supplied to Vivus hereunder shall comply with the Specifications for the Product, shall conform with the information shown on the Certificate of Analysis and Batch Release Sheet provided for the particular shipment according to Section 3.2 hereof;

5.1.2. GMP. the Facility, and all Product supplied to Vivus hereunder meets (a) all United States regulatory requirements for commercialization of the Product, including without limitation maintenance of a current DMF with the FDA, compliance with GMP, demonstration of commercial production capability, and demonstration of acceptable stability of such Product; (b) all ISO 9000 regulatory requirements applicable to the Product; and (c) all requirements imposed other regulatory agencies with which a DMF has been filed for the Product;

5.1.3 USP. all Product supplied to Vivus hereunder shall meet all USP and European Pharmacopeia and other applicable standards and shall be fit for human use;

5.1.4 Compliance with FFDCa. none of the Product supplied to Vivus hereunder shall be adulterated or misbranded within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C.A. Section 301 et seq., as amended and in effect of the time of shipment (the "Act"), or within the meaning of any state or municipal laws applicable to the Products and containing terms with

substantially similar meanings as the meanings of adulteration or misbranding under the Act; provided, however, that this provision shall not apply to, and Spolana shall have no responsibility for, misbranding caused directly by Vivus as a result of labels or package text specified by Vivus for the Product;

5.1.5 Timing. all Product supplied to Vivus hereunder shall have been manufactured [*];

5.1.6 Notification. Spolana will provide written notice to Vivus of any proposed alterations to the Facility or to any Product manufacturing or testing process; provided, however, that under no circumstances shall any such alteration be made without Vivus' express prior written consent, or before regulatory approval, if required for any such alteration, is received in each country in which Product is then being sold; and

5.1.7 No Encumbrance. title to all Product supplied to Vivus hereunder shall pass to Vivus as provided herein free and clear of any security interest, lien, or other encumbrance.

5.2 Disclaimer. EXCEPT AS EXPRESSLY PROVIDED IN THIS ARTICLE 5, SPOLANA MAKES NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, AS TO THE PRODUCT, AND SPOLANA HEREBY EXPRESSLY DISCLAIMS ANY AND ALL IMPLIED OR STATUTORY WARRANTIES, INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NONINFRINGEMENT.

ARTICLE 6. TERM AND TERMINATION

6.1 Term. The term of this Agreement shall commence on the Effective Date and continue in full force [*], unless terminated earlier in accordance with this Article 6.

6.2 Termination for Convenience. Either party hereto may terminate this Agreement upon [*] prior written notice to the other party hereto; provided, however, such termination shall not become effective [*].

6.3 Termination by Spolana. Spolana shall have the right to terminate this Agreement on [*] prior written notice to Vivus after the beginning of any calendar year during the term of this Agreement but before [*].

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6.4 Breach. This Agreement may be terminated by either party if the other party breaches any material term or condition of this Agreement and fails to remedy the breach within [*] after being given written notice thereof.

6.5 Effect of Termination. In the case of notice of termination by either party under Section 6.3 or 6.4, the parties' obligations, including Spolana's obligation to supply Product ordered by Vivus, and Vivus' obligation to purchase Product included in any binding forecast pursuant to Section 2.3 shall survive. In addition, Vivus may purchase and Spolana agrees to supply quantities of Product for which Vivus has not found alternate suppliers, at Spolana's then current prices of Product.

6.6 Survival. It is understood that termination or expiration of this Agreement shall not relieve a party from any liability which, at the time of such termination or expiration, has already accrued to the other party. The provisions of Sections 3.3, 3.4, 6.5, 6.6 and 10.1, and Articles 1, 5, 7, 9 and 11 shall survive the termination of this Agreement for any reason. All other rights and obligations of the parties shall cease upon termination of this Agreement. Except as otherwise expressly provided in this Article 6, all other rights and obligations of the parties shall terminate.

ARTICLE 7. CONFIDENTIALITY

7.1 Confidential Information. The parties may from time to time disclose to each other Confidential Information. "Confidential Information" shall mean any information disclosed by one party to the other party hereto which if disclosed in tangible form is marked "confidential" or with other similar designation to indicate its confidential or proprietary nature or if disclosed orally is indicated orally to be confidential or proprietary by the party disclosing such information at the time of such disclosure and is confirmed in writing as confidential or proprietary by the disclosing party within [*] after such disclosure. Notwithstanding the foregoing, Confidential Information shall not include any information that, in each case as demonstrated by written documentation: (i) was already known to the receiving party, other than under an obligation of confidentiality, at the time of disclosure; (ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving party; (iii) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving party in breach of this Agreement; (iv) was subsequently lawfully disclosed to the receiving party by a person other than the disclosing party; or (v) was developed by the receiving party without reference to any Confidential Information of the disclosing party.

7.2 Confidentiality. Each party hereby agrees: (i) to hold and maintain in strict confidence all Confidential Information of the other party; and (ii) not to use or disclose any

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Confidential Information of the other party except to those employees and consultants who have a need to know, as otherwise permitted by this Agreement, or as may be necessary to exercise its rights or perform its obligations under this Agreement; provided that each party to whom Confidential Information is disclosed agrees to be bound by the same terms regarding the disclosure and use of Confidential Information as set forth in this Article 7. Nothing contained in this Article 7 shall prevent either party from disclosing any Confidential Information of the other party to (a) regulatory agencies for the purpose of obtaining approval to distribute and market the Product; provided, however, that all reasonable steps are taken to maintain the confidentiality of such Confidential Information to be disclosed; (b) to accountants, lawyers or other professional advisors or in connection with a merger, acquisition or securities offering, subject in each case to the recipient entering into an agreement to protect such Confidential Information from disclosure; or (c) is required by law or regulation to be disclosed; provided, however, that the party subject to such disclosure requirement has provided written notice to the other party promptly upon receiving notice of such requirement in order to enable the other party to seek a protective order or otherwise prevent disclosure of such Confidential Information.

7.3 Return of Confidential Information. Upon termination or expiration of this Agreement, each party shall return all Confidential Information in its possession that was received from the other party.

ARTICLE 8. REPRESENTATIONS AND WARRANTIES

8.1 Spolana. Spolana represents and warrants that: (i) it has full power to enter into this Agreement and to grant and assign to Vivus the rights granted and assigned to Vivus hereunder; (ii) it has obtained all necessary corporate approvals to enter into and execute the Agreement; (iii) it has not entered and will not enter into any agreements with any third party that are inconsistent with this Agreement; (iv) Spolana shall fully comply with the requirements of any and all applicable federal, state, local and foreign laws, regulations, rules and orders of any governmental body having jurisdiction over the activities contemplated by this Agreement; and (v) that the provisions of this Agreement, and the rights and obligations of the parties hereunder, are enforceable under the laws of the Czech Republic.

8.2 Vivus. Vivus represents and warrants that: (i) it has full power to enter into the Agreement; (ii) it has obtained all necessary corporate approvals to enter and execute into this Agreement; (iii) it has not entered and will not enter into any agreements with any third party that are inconsistent with this Agreement; and (iv) Vivus shall fully comply with the requirements of any and all applicable federal, state, local and foreign laws, regulations, rules and orders of any governmental body having jurisdiction over the activities contemplated by this Agreement.

8.3 Disclaimer. EXCEPT AS PROVIDED IN THIS ARTICLE 8 AND ARTICLE 5 ABOVE, NEITHER PARTY MAKES ANY WARRANTIES OR CONDITIONS (EXPRESS,

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IMPLIED, STATUTORY OR OTHERWISE) WITH RESPECT TO THE SUBJECT MATTER
HEREOF.

ARTICLE 9.
INDEMNIFICATION

9.1 Vivus. Vivus shall indemnify, defend and hold harmless Spolana, its directors, officers, employees, agents, successors and assigns from and against any liabilities, expenses or costs (including reasonable attorneys' fees) arising out of any claim, complaint, suit, proceeding or cause of action against any of them by a third party alleging physical injury or death or otherwise resulting from [*], in each case subject to the requirements set forth in Section 9.3 below. Notwithstanding the foregoing, Vivus shall have no obligations under this Article 9 for any liabilities, expenses or costs arising out of or relating to claims covered under Section 9.2 below.

9.2 Spolana. Spolana shall indemnify, defend and hold harmless Vivus, its directors, officers, employees, agents, successors and assigns from and against all liabilities, expenses, and costs (including reasonable attorneys' fees) arising out of any claim, complaint, suit, proceeding or cause of action against any of them by a third party alleging physical injury or death or otherwise resulting from [*], in each case subject to the requirements set forth in Section 9.3 below.

9.3. Indemnification Procedure. Any party seeking indemnification under this Article 9 (the "Indemnatee") shall (i) promptly notify the indemnifying party (the "Indemnitor") of such claim, (ii) provide the Indemnitor sole control over the defense and/or settlement thereof, and (iii) at the Indemnitor's request and expense, provide full information and reasonable assistance to Indemnitor with respect to such claims. Without limiting the foregoing, with respect to claims brought under Section 9.1 or 9.2 above the Indemnatee, at its own expense, shall have the right to participate with counsel of its own choosing in the defense and/or settlement of any such claim.

ARTICLE 10.
INTERNATIONAL ISSUES

10.1. Language. This Agreement is in the English language only, which language shall be controlling in all respects, and all versions hereof in any other language shall not be binding on the parties hereto. All communications and notices to be made or given pursuant to this Agreement shall be in the English language.

10.2. Government Approvals. Spolana shall:

*Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

10.2.1. at its own expense, comply with all applicable laws, and obtain all approvals and make and maintain in force all filings, registrations, reports, licenses, permits and authorizations required by national and local governments within the Czech Republic in order for Spolana to perform its obligations under this Agreement; and

10.2.2. advise Vivus of any legislation, rule, regulation or other law (including but not limited to any customs, tax, trade, intellectual property or tariff law) which is in effect or which may come into effect in the Czech Republic after the Effective Date of this Agreement and which affects the transfer of Products to Vivus under this Agreement, or which has a material effect on any provision of this Agreement.

ARTICLE 11. GENERAL

11.1 Assignment. The parties agree that their rights and obligations under this Agreement may not be assigned or otherwise transferred to a third party without the prior written consent of the other party hereto. Notwithstanding the foregoing, either party may transfer or assign its rights and obligations under this Agreement to a successor to all or substantially all of its business or assets relating to this Agreement whether by sale, merger, operation of law or otherwise; provided that such assignee or transferee has agreed to be bound by the terms and conditions of this Agreement. Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the parties hereto, their successors and assigns.

11.2 Governing Law. This Agreement shall be governed by, and construed and interpreted in accordance with, the laws of the United Kingdom without reference to conflict of laws principles and excluding the 1980 U.N. Convention on Contracts for the International Sale of Goods.

11.3 Arbitration. Any dispute or claim arising out of or in connection with this Agreement or the performance, breach or termination thereof, shall be finally settled by binding arbitration in London, England under the Rules of Arbitration of the International Chamber of Commerce by three (3) arbitrators appointed in accordance with said rules. The decision and/or award rendered by the arbitrators shall be written, final and non-appealable and may be entered in any court of competent jurisdiction. The parties agree that, any provision of applicable law notwithstanding, they will not request, and the arbitrator shall have no authority to award, punitive or exemplary damages against any party. The costs of any arbitration, including administrative fees and fees of the arbitrators, shall be shared equally by the parties, unless otherwise determined by the arbitrators. Each party shall bear the cost of its own attorneys' and expert fees. The arbitral proceedings and all pleadings and written evidence shall be in the English language. Any written evidence originally in a language other than English shall be submitted in English translation accompanied by the original or true copy thereof. Notwithstanding the foregoing, either party may apply to any court of competent jurisdiction for injunctive relief without breach of this arbitration provision.

11.4 Notices. Any notice or report required or permitted to be given or made under this Agreement by either party shall be in writing and delivered to the other party at its address indicated below (or to such other address as a party may specify by notice hereunder by courier or by registered or certified airmail, postage prepaid, or by facsimile; provided, however, that all facsimile notices shall be promptly confirmed, in writing, by registered or certified airmail, postage prepaid. All notices shall be effective as of the date received by the addressee.

If to Vivus: Vivus, Inc.
545 Middlefield Road, Suite 200
Menlo Park, CA 94025
Attn: C.E.O. and C.F.O.

with a copy to: Wilson, Sonsini, Goodrich & Rosati
650 Page Mill Road
Palo Alto, California 94304-1050
Attn: Kenneth A. Clark, Esq.

If to Spolana: Spolana a.s.
277 11 Neratovice
Czech Republic
Attn: Odd. podeje KCH-OU

with a copy to: _____

11.5. Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY OR ANY THIRD PARTY FOR ANY SPECIAL, CONSEQUENTIAL, EXEMPLARY OR INCIDENTAL DAMAGES (INCLUDING LOST OR ANTICIPATED REVENUES OR PROFITS RELATING TO THE SAME), ARISING FROM ANY CLAIM RELATING TO THIS AGREEMENT, WHETHER SUCH CLAIM IS BASED ON CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, EVEN IF AN AUTHORIZED REPRESENTATIVE OF SUCH PARTY IS ADVISED OF THE POSSIBILITY OR LIKELIHOOD OF SAME. THESE LIMITATIONS SHALL APPLY NOTWITHSTANDING THE FAILURE OF THE ESSENTIAL PURPOSE OF ANY LIMITED REMEDY, AND THE PARTIES ACKNOWLEDGE THAT THIS PARAGRAPH REPRESENTS A REASONABLE ALLOCATION OF RISK.

11.6 Force Majeure. Neither party will be liable for its failure to perform any of its obligations hereunder during any period in which such performance is delayed by acts of God, fire, war, embargo, riots, strikes or other similar cause outside the control of such party.

11.7. Confidential Terms. Except as expressly provided herein, each party agrees not to disclose any terms of this Agreement to any third party without the consent of the other party, except as required by securities or other applicable laws, to prospective investors and to such party's accountants, attorneys and other professional advisors.

11.8. Headings. Headings included herein are for convenience only, do not form a part of this Agreement and shall not be used in any way to construe or interpret this Agreement.

11.9 Non-Waiver. Any waiver of the terms and conditions hereof must be explicitly in writing. The waiver by either of the parties of any breach of any provision hereof by the other shall not be construed to be a waiver of any succeeding breach of such provision or a waiver of the provision itself.

11.10 Severability. Should any section, or portion thereof, of this Agreement be held invalid by reason of any law, statute or regulation existing now or in the future in any jurisdiction by any court of competent authority or by a legally enforceable directive of any governmental body, such section or portion thereof shall be validly reformed so as to approximate the intent of the parties as nearly as possible and, if unreformable, shall be deemed divisible and deleted with respect to such jurisdiction, but the Agreement shall not otherwise be affected.

11.11 Independent Contractors. The relationship of Vivus and Spolana established by this Agreement is that of independent contractors. Nothing in this Agreement shall be construed to create any other relationship between Vivus and Spolana. Neither party shall have any right, power or authority to assume, create or incur any expense, liability or obligation, express or implied, on behalf of the other.

11.12 Trademarks. Vivus, in its sole discretion, shall select the trademarks, trade names and trade dresses to be used in connection with the Product and all such trademarks, trade names and trade dresses shall be and become the exclusive property of Vivus. Spolana shall use said trademarks, trade names and trade dresses for the sole purpose of manufacturing the Product for supply to Vivus and at no time shall adopt any trademark, trade name or trade dress that may be confusingly similar therewith. Spolana shall acquire no rights in and to any trademarks, trade names and trade dresses selected by Vivus under this Section 11.12.

11.13 Entire Agreement. The terms and provisions contained in the Agreement, including the Exhibits hereto, constitute the entire agreement between the parties and shall supersede all previous communications, representations, agreements or understandings, either oral or written, between the parties with respect to the subject matter hereof. Notwithstanding the foregoing, neither party waives any rights it may have under the Supply Agreement. No agreement or understanding varying or extending this Agreement shall be binding upon either party hereto, unless set forth in a writing which specifically refers to the Agreement signed by duly authorized officers or

representatives of the respective parties, and the provisions hereof not specifically amended thereby shall remain in full force and effect.

11.14 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Agreement.

VIVUS, INC.

SPOLANA CHEMICAL WORKS, A.S.

By: _____
Name: _____
Title: _____

By: _____
Name: _____
Title: _____

EXHIBIT A

[*]

*Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

EXHIBIT B
INITIAL FORECAST

MANUFACTURE and SUPPLY AGREEMENT

[*]

*Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

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DEC-31-1997
JAN-01-1997
JUN-30-1997
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