

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549  
FORM 10-Q

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

For the quarterly period ended June 30, 1996

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 0-23490

VIVUS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE

94-3136179

(State or other jurisdiction of  
incorporation or organization)

(I.R.S. Employer  
identification Number)

545 MIDDLEFIELD ROAD, SUITE 200

MENLO PARK, CA 94025

(Address of Principal Executive Offices)

(Zip Code)

(415) 325-5511

(Registrant's Telephone Number, Including Area Code)

N/A

(Former name, former address and former fiscal year, if changed since last  
report)

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

APPLICABLE ONLY TO CORPORATE ISSUERS:

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

At August 8, 1996, 16,162,434 shares of common stock were outstanding.

Exhibit index on page 28

VIVUS, INC.  
(A Development Stage Company)

CONSOLIDATED BALANCE SHEETS  
(In thousands, except share data)

ASSETS

|                                            | JUNE 30,<br>1996<br>-----<br>(unaudited) | DECEMBER 31,<br>1995<br>----- |
|--------------------------------------------|------------------------------------------|-------------------------------|
| Current assets:                            |                                          |                               |
| Cash and cash equivalents                  | \$ 796                                   | \$ 973                        |
| Available-for-sale securities              | 53,105                                   | 21,136                        |
| Interest and other receivables             | 618                                      | 449                           |
| Prepaid expenses and other                 | 352                                      | 141                           |
|                                            | -----                                    | -----                         |
| Total current assets                       | 54,871                                   | 22,699                        |
| Property, net                              | 4,675                                    | 3,888                         |
| Available-for-sale securities, non-current | 31,862                                   | 17,415                        |
| Other                                      | --                                       | 47                            |
|                                            | -----                                    | -----                         |
| Total Assets                               | \$ 91,408<br>=====                       | \$ 44,049<br>=====            |

LIABILITIES AND STOCKHOLDERS' EQUITY

|                                                                                                                                                                                               |                    |                    |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|
| Current liabilities:                                                                                                                                                                          |                    |                    |
| Accounts payable                                                                                                                                                                              | \$ 716             | \$ 353             |
| Accrued and other liabilities                                                                                                                                                                 | 3,269              | 2,515              |
|                                                                                                                                                                                               | -----              | -----              |
| Total current liabilities                                                                                                                                                                     | 3,985              | 2,868              |
|                                                                                                                                                                                               | -----              | -----              |
| Stockholders' equity:                                                                                                                                                                         |                    |                    |
| Preferred stock; no par value; shares authorized -<br>5,000,000 at June 30, 1996 and December 31, 1995;<br>shares outstanding - none at June 30, 1996 and<br>December 31, 1995                | --                 | --                 |
| Common stock; \$.001 par value; shares authorized -<br>30,000,000 at June 30, 1996 and December 31, 1995;<br>shares outstanding - June 30, 1996, 15,820,664;<br>December 31, 1995, 13,475,570 | 16                 | 13                 |
| Paid in capital                                                                                                                                                                               | 147,686            | 91,472             |
| Unrealized gain (loss) on securities                                                                                                                                                          | (103)              | 114                |
| Deferred compensation                                                                                                                                                                         | (570)              | (791)              |
| Accumulated deficit                                                                                                                                                                           | (59,606)           | (49,627)           |
|                                                                                                                                                                                               | -----              | -----              |
| Total stockholders' equity                                                                                                                                                                    | 87,423             | 41,181             |
|                                                                                                                                                                                               | -----              | -----              |
| Total Liabilities and Stockholders' Equity                                                                                                                                                    | \$ 91,408<br>===== | \$ 44,049<br>===== |

VIVUS, INC.  
(A Development Stage Company)

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

|                                                         | PERIOD FROM<br>APRIL 16, 1991<br>(INCEPTION)<br>THROUGH<br>JUNE 30,<br>1996<br>----- | THREE MONTHS ENDED<br>JUNE 30,<br>-----<br>1996                    1995<br>----- |            | SIX MONTHS ENDED<br>JUNE 30,<br>-----<br>1996                    1995<br>----- |            |
|---------------------------------------------------------|--------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|------------|--------------------------------------------------------------------------------|------------|
| Revenue                                                 | \$ 10,000                                                                            | \$ 10,000                                                                        | \$ --      | \$ 10,000                                                                      | \$ --      |
| Operating expenses:                                     |                                                                                      |                                                                                  |            |                                                                                |            |
| Research and development                                | 63,030                                                                               | 12,187                                                                           | 6,103      | 17,545                                                                         | 11,216     |
| General and administrative                              | 12,658                                                                               | 2,004                                                                            | 1,029      | 3,383                                                                          | 1,926      |
|                                                         | -----                                                                                | -----                                                                            | -----      | -----                                                                          | -----      |
| Total operating expenses                                | 75,688                                                                               | 14,191                                                                           | 7,132      | 20,928                                                                         | 13,142     |
|                                                         | -----                                                                                | -----                                                                            | -----      | -----                                                                          | -----      |
| Loss from operations                                    | (65,688)                                                                             | (4,191)                                                                          | (7,132)    | (10,928)                                                                       | (13,142)   |
| Interest income                                         | 6,082                                                                                | 446                                                                              | 719        | 949                                                                            | 1,272      |
|                                                         | -----                                                                                | -----                                                                            | -----      | -----                                                                          | -----      |
| Net Loss                                                | \$(59,606)                                                                           | \$ (3,745)                                                                       | \$ (6,413) | \$ (9,979)                                                                     | \$(11,870) |
|                                                         | =====                                                                                | =====                                                                            | =====      | =====                                                                          | =====      |
| Net loss per common and<br>equivalent share             |                                                                                      | \$ (0.26)                                                                        | \$ (0.47)  | \$ (0.71)                                                                      | \$ (0.92)  |
|                                                         |                                                                                      | =====                                                                            | =====      | =====                                                                          | =====      |
| Shares used in the computation of<br>net loss per share |                                                                                      | 14,224                                                                           | 13,529     | 14,100                                                                         | 12,925     |
|                                                         |                                                                                      | =====                                                                            | =====      | =====                                                                          | =====      |

VIVUS, INC.  
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CASH FLOWS  
(unaudited, in thousands)

|                                                                              | PERIOD FROM<br>APRIL 16, 1991<br>(INCEPTION)<br>THROUGH<br>JUNE 30,<br>1996<br>----- | THREE MONTHS ENDED<br>JUNE 30,<br>-----<br>1996      1995<br>----- |            | SIX MONTHS ENDED<br>JUNE 30,<br>-----<br>1996      1995<br>----- |             |
|------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|--------------------------------------------------------------------|------------|------------------------------------------------------------------|-------------|
| CASH FLOWS FROM OPERATING ACTIVITIES:                                        |                                                                                      |                                                                    |            |                                                                  |             |
| Net loss                                                                     | \$ (59,606)                                                                          | \$ (3,745)                                                         | \$ (6,413) | \$ (9,979)                                                       | \$ (11,870) |
| Adjustments to reconcile net loss to net cash used for operating activities: |                                                                                      |                                                                    |            |                                                                  |             |
| Depreciation and amortization                                                | 1,627                                                                                | 239                                                                | 130        | 477                                                              | 249         |
| Amortization of deferred compensation                                        | 1,205                                                                                | 111                                                                | 111        | 221                                                              | 222         |
| Issuance of common stock for patent rights                                   | 6,683                                                                                | 5,821                                                              | --         | 5,821                                                            | --          |
| Issuance of preferred stock for services                                     | 150                                                                                  | --                                                                 | --         | --                                                               | --          |
| Changes in assets and liabilities:                                           |                                                                                      |                                                                    |            |                                                                  |             |
| Interest and other receivables                                               | (618)                                                                                | (102)                                                              | (148)      | (169)                                                            | (226)       |
| Prepaid expenses and other                                                   | (352)                                                                                | (131)                                                              | (50)       | (211)                                                            | (82)        |
| Accounts payable                                                             | 716                                                                                  | 368                                                                | 8          | 363                                                              | (464)       |
| Accrued and other liabilities                                                | 3,269                                                                                | 118                                                                | (952)      | 754                                                              | 659         |
| Net cash used for operating activities                                       | (46,926)                                                                             | 2,679                                                              | (7,314)    | (2,723)                                                          | (11,512)    |
| CASH FLOWS FROM INVESTING ACTIVITIES:                                        |                                                                                      |                                                                    |            |                                                                  |             |
| Property purchases                                                           | (6,299)                                                                              | (765)                                                              | (976)      | (1,264)                                                          | (1,950)     |
| Securities purchases                                                         | (370,539)                                                                            | (64,424)                                                           | (34,885)   | (69,402)                                                         | (70,227)    |
| Proceeds from sale/maturity of securities                                    | 285,469                                                                              | 12,247                                                             | 22,104     | 22,769                                                           | 62,682      |
| Other assets                                                                 | --                                                                                   | --                                                                 | (1)        | 47                                                               | (5)         |
| Net cash used for investing activities                                       | (91,369)                                                                             | (52,942)                                                           | (13,758)   | (47,850)                                                         | (9,500)     |
| CASH FLOWS FROM FINANCING ACTIVITIES:                                        |                                                                                      |                                                                    |            |                                                                  |             |
| Sale of preferred stock                                                      | 34,252                                                                               | --                                                                 | --         | --                                                               | --          |
| Sale of common stock                                                         | 103,862                                                                              | 49,798                                                             | 22,377     | 49,798                                                           | 22,377      |
| Exercise of common stock options                                             | 652                                                                                  | 231                                                                | 3          | 494                                                              | 51          |
| Purchase of common stock through employee stock purchase plan                | 326                                                                                  | 104                                                                | 80         | 104                                                              | 80          |
| Repurchase of common stock                                                   | (1)                                                                                  | --                                                                 | --         | --                                                               | --          |
| Net cash provided by financing activities                                    | 139,091                                                                              | 50,133                                                             | 22,460     | 50,396                                                           | 22,508      |
| NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS                         | 796                                                                                  | (130)                                                              | 1,388      | (177)                                                            | 1,496       |
| CASH AND CASH EQUIVALENTS:                                                   |                                                                                      |                                                                    |            |                                                                  |             |
| Beginning of period                                                          | --                                                                                   | 926                                                                | 2,145      | 973                                                              | 2,037       |
| End of period                                                                | \$ 796                                                                               | \$ 796                                                             | \$ 3,533   | \$ 796                                                           | \$ 3,533    |
| NON-CASH INVESTING AND FINANCING ACTIVITIES:                                 |                                                                                      |                                                                    |            |                                                                  |             |
| Deferred compensation recorded relating to stock option grants               | \$ 1,774                                                                             | \$ --                                                              | \$ --      | \$ --                                                            | \$ --       |
| Unrealized gain (loss) on securities                                         | (103)                                                                                | (56)                                                               | 352        | (217)                                                            | 610         |

VIVUS, INC.  
(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
JUNE 30, 1996

1. BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Rule 10 of Regulations S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and six month periods ended June 30, 1996 are not necessarily indicative of the results that may be expected for the year ended December 31, 1996. 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, 1995.

2. NET LOSS PER SHARE

Net loss per common and equivalent share is based on the weighted average number of common and equivalent shares outstanding during the period. Pursuant to Securities and Exchange Commission Staff Accounting Bulletin No. 83, common equivalent shares include all common shares issued and options and warrants to purchase shares of common stock granted by the Company at a price less than the initial public offering price during the period January 1, 1993 through the initial public offering date (using the treasury stock method for options and warrants and based on the public offering price of \$14.00 per share) as if they were outstanding for all periods presented prior to the initial public offering. Options granted by the Company prior to January 1, 1993 have been excluded in the calculation of common and common equivalent shares outstanding since they would serve to reduce the net loss per share.

3. DELAWARE REINCORPORATION

The Company was incorporated on April 16, 1991 in California and reincorporated in Delaware on May 24, 1996. The classification of the capital accounts reflects the effect of the reincorporation for all periods presented.

MANAGEMENT'S DISCUSSION AND ANALYSIS  
OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

DESCRIPTION OF BUSINESS

Since its inception in April 1991, VIVUS, Inc. (the "Company"), a development stage company, has focused on the design and development of products for the treatment of erectile dysfunction. The Company has devoted substantially all its efforts to research and development conducted on its behalf and through collaboration with clinical institutions. The Company's primary product, MUSE(R) (alprostadil), has moved from preclinical development to regulatory application phase over the last three years. The Company has generated a cumulative net loss of \$59,606,000 for the period from its inception through June 30, 1996. The ability of the Company to successfully develop, obtain regulatory approval for, manufacture, and market MUSE (alprostadil) is dependent on many factors. The Company is subject to a number of risks including the approval of its product, its ability to scale-up its manufacturing capabilities and secure adequate supply of raw materials, its ability to successfully market, distribute and sell its product, and intense competition. Accordingly, there can be no assurance of the Company's future success.

Spending increased from 1993 through the period ended June 30, 1996 largely as a result of expanded operational activities related to the Company's Phase II and III clinical trials, preparing the MUSE (alprostadil) New Drug Application ("NDA") for the FDA and expansion of its manufacturing capabilities. Spending levels will continue to increase during 1996 as the Company further develops its commercial manufacturing, marketing and sales capabilities.

In May 1996, the Company issued 200,000 shares of common stock to Alza in order for the Company to maintain exclusive rights to certain patents and patent applications beyond 1998. In connection with this issuance, the Company recorded a charge of approximately \$5,900,000 to the consolidated statement of operations.

To date, the Company has received no revenue from product sales. In May 1996, the Company completed a marketing agreement with Astra AB ("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 marketing agreement, Astra paid the Company \$10 million in June 1996. The Company will be paid up to an additional \$20 million in the event it achieves certain milestones. The Company does not anticipate significant revenue from operations for at least two years. The Company does not have any experience in manufacturing or selling MUSE (alprostadil) in commercial quantities. Whether the Company can successfully manage the transition to a large scale commercial enterprise will depend upon the successful further development of its manufacturing capability and its distribution network and attainment of domestic and foreign regulatory approvals for MUSE.

(alprostadil) and other potential products. Failure to make such a transition successfully would have a material adverse effect on the Company's business, financial condition and results of operations.

The Company anticipates that it will continue to incur losses over at least the next twelve months as it expands its operations, prepares for the anticipated commercial introduction of MUSE (alprostadil) and expands its research and development activities with regard to other products. To achieve profitability, the Company must obtain the necessary regulatory approvals and successfully manufacture, introduce and market MUSE (alprostadil). The time required to reach profitability is highly uncertain and there can be no assurance that the Company will be able to obtain profitability on a sustained basis, if at all.

The Company currently relies on a single therapeutic approach to treat erectile dysfunction, the transurethral system for erection. The Company recently completed Phase III clinical trials and submitted an NDA to the FDA for its anticipated first product, MUSE (alprostadil). While the Company's NDA was accepted for priority review by the FDA, there can be no assurance that FDA approval will be granted on a timely basis, if at all, or if granted, that such approval will not contain significant limitations in the form of warnings, precautions or contraindications with respect to condition of use. Failure to obtain approval of the Company's NDA for MUSE (alprostadil) on a timely basis, if at all, or if granted, the failure to successfully commercialize MUSE (alprostadil) would have a material adverse effect on the Company.

In April 1994, the Company successfully completed an initial public offering of 2,473,000 shares of common stock, with net proceeds to the Company of \$31,578,000.

The Company completed a secondary public offering of 1,800,000 shares of common stock in April 1995. Of the total number of shares offered, 1,670,000 shares were sold by the Company and 130,000 shares were sold by a current stockholder. Net proceeds to the Company were \$22,483,000.

The Company completed a third public offering of 2,000,000 shares of common stock in June 1996. Net proceeds to the Company were approximately \$49,800,000. In July 1996, the underwriters for this offering exercised their option to purchase an additional 300,000 shares to cover over-allotments. The Company received approximately \$7,500,000 in net proceeds for these shares.

The second, fourth, fifth and sixth, paragraphs of this Description of Business section 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 the above mentioned paragraphs and the

factors set forth in the Risk Factors section of this quarterly report.

## RESULTS OF OPERATIONS

Three months Ended June 30, 1996 and 1995, and Six Months Ended June 30, 1996 and 1995

No revenues from product sales have been recorded from inception to June 30, 1996. As consideration for execution of the Astra marketing agreement, Astra paid the Company \$10 million in June 1996, which the Company recorded as milestone revenue in the consolidated statement of operations.

For the three months ended June 30, 1996, research and development expenses were \$12,187,000 compared with \$6,103,000 for the three months ended June 30, 1995, an increase of 100%. For the six months ended June 30, 1996, research and development expenses were \$17,545,000 compared with \$11,216,000 for the six months ended June 30, 1995, an increase of 56%. The increase in both periods was due primarily to the Company issuing 200,000 shares of common stock to Alza in May 1996 in order for the Company to maintain exclusive rights to certain patents and patent applications beyond 1998. In connection with this issuance, the Company recorded a charge of approximately \$5,900,000 to the consolidated statement of operations. The increases were also a result of higher pre-launch manufacturing and quality assurance expenses. These were partially offset by lower clinical costs resulting from the completion of the Phase II and III clinical trials in 1995.

General and administrative expenses for the three months ended June 30, 1996 were \$2,004,000 compared with \$1,029,000 for the three months ended June 30, 1995, an increase of 95%. General and administrative expenses for the six months ended June 30, 1996 were \$3,383,000 compared with \$1,926,000 for the six months ended June 30, 1995, an increase of 76%. These increases resulted primarily from hiring additional personnel to support the growth of the Company's operations, and higher marketing and legal expenses.

Spending levels will continue to increase during 1996 as the Company further develops its commercial manufacturing, marketing and sales capabilities.

Interest income for the three months ended June 30, 1996 was \$446,000 compared with \$719,000 for the three months ended June 30, 1995. Interest income for the six months ended June 30, 1996 was \$949,000 compared with \$1,272,000 for the six months ended June 30, 1995. The decreases were primarily the result of lower average invested cash balances.



## LIQUIDITY AND CAPITAL RESOURCES

Since inception, the Company has financed operations primarily from the sale of preferred and common stock. Through June 30, 1996, VIVUS has raised \$144,912,000. Cash, cash equivalents and securities available-for-sale totaled \$85,763,000 at June 30, 1996 compared with \$39,524,000 at December 31, 1995. The Company maintains its current excess cash balances in a variety of interest bearing investment-grade financial investments such as U.S. government securities, corporate debt and certificates of deposit. Principal preservation, liquidity and safety are the primary investment objectives.

Cash used in operations in the three months ended June 30, 1996 was \$3,142,000 compared with \$7,314,000 in the three months ended June 30, 1995. The decreased use of cash was primarily due to a net loss of \$3,745,000 in the three months ended June 30, 1996 compared with a net loss of \$6,413,000 for the same period in 1995. Cash used in operations in the six months ended June 30, 1996 was \$8,544,000 compared with \$11,512,000 in the six months ended June 30, 1995. The decreased use of cash was primarily due to a net loss of \$9,979,000 in the six months ended June 30, 1996 compared with a net loss of \$11,870,000 for the same period in 1995. Cash used for operations is expected to increase in 1996 as the Company further develops its commercial manufacturing, marketing and sales capabilities.

Prepaid and other current assets at June 30, 1996 were \$970,000 compared with \$590,000 at December 31, 1995, an increase of \$380,000. This increase resulted primarily from an increase in interest receivables related to the Company's investment portfolio and prepaid insurance.

Current liabilities were \$3,985,000 at June 30, 1996 compared with \$2,868,000 at December 31, 1995. This increase was primarily due to an increase in alprostadil purchases in 1996.

Capital expenditures in the three months ended June 30, 1996 were \$765,000 compared with \$976,000 for the same period ended June 30, 1995. Capital expenditures in the six months ended June 30, 1996 were \$1,264,000 compared with \$1,950,000 for the same period ended June 30, 1995. Capital expenditures during the period in 1996 and 1995 consisted primarily of manufacturing and quality control equipment. Capital expenditures were higher in 1995 due to the construction of the Company's dedicated manufacturing and testing space within the Paco Pharmaceutical Services, Inc. ("Paco") facility in Lakewood, New Jersey. Major capital expenditures over the next two years are likely to increase as they are expected to include a Company-owned manufacturing facility in Europe, expansion of its current facility in the United States and establishing a research and quality control laboratory.

In 1995, the Company implemented an international product distribution strategy for VIVUS products. Implementation included

the transfer of international product marketing rights to VIVUS International Limited in a taxable transaction. The transfer of rights and related allocation of research and development costs resulted in the current utilization of \$29,467,000 of the Company's net operating loss carryforward.

The Company expects to incur substantial additional costs, including expenses related to its marketing and sales organization, a second manufacturing plant and expansion of the Company's existing plant, 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 the United States and Europe, but may not be sufficient for the introduction of any additional future products. While the Company believes its NDA filing was substantially complete, the Company may have to conduct additional studies or clinical trials in order to obtain regulatory approval of MUSE (alprostadil). 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 can be expected to 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 ability to obtain and timing and costs of obtaining regulatory approvals; (ii) the level of resources that the Company devotes to sales and marketing capabilities; (iii) the level of resources that the Company devotes to expanding manufacturing capacity; (iv) the activities of competitors; (v) the progress of the Company's research and development programs; (vi) the timing and results of preclinical testing and clinical trials; and (vii) technological advances.

The second, fifth, and seventh paragraphs of this Liquidity and Capital Resources section 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 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.

## RISK FACTORS

This quarterly report on Form 10-Q contains forward-looking statements which 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.

## 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. No assurance can be given that the Company's therapeutic approach, or its proposed pharmacologic formulations, will be shown to be safe and effective or ultimately be approved by appropriate regulatory agencies. Certain side effects have been found to occur with the use of MUSE (alprostadil). 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 was 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). The Company has never commercially introduced a product and no assurance can be given that any of the transurethral products, if approved, will be successfully introduced. 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 obtain an approval of its NDA for MUSE (alprostadil) on a timely basis, if at all, or 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 time required for FDA approvals is uncertain, and typically takes a

number of years, depending on the type, complexity and novelty of the product. Since the Company's products involve transurethral delivery, a new therapeutic approach, regulatory approvals may be obtained more slowly than for products produced using more conventional delivery systems. The Company completed pivotal clinical trials in 1995 and submitted an NDA for its anticipated first product, MUSE (alprostadir), to the FDA in March 1996. While the Company believes its NDA filing was substantially complete, there can be no assurance that the Company will not be required to conduct additional research or clinical trials. Although the Company's NDA was accepted for priority review by the FDA, there can be no assurance that FDA approval will be granted on a timely basis, if at all, or if granted, that such approval will not contain significant limitations in the form of warnings, precautions or contraindications with respect to condition of use. Any delay in obtaining, or failure to obtain, such approval would adversely affect the Company's ability to generate product revenue.

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

The Company obtains the necessary raw materials and components for the manufacture of MUSE (alprostadir) from third parties. The Company currently contracts with contract manufacturing organizations that are required to comply with strict standards established by the Company. Contract manufacturers are required by the Federal Food, Drug, and Cosmetic Act, as amended, and by FDA regulations to follow Good Manufacturing Practice ("GMP"). The

Company is required to identify its suppliers to the FDA and is dependent upon its contract manufacturers and its suppliers to comply with the Company's specifications and, as required, GMP or similar standards imposed by foreign regulators. There can be no assurance that the FDA, or a state, local or foreign regulator will not take action against a contract manufacturer or supplier found to be violating applicable regulations. Such an action could have a material adverse effect on the Company's business, financial condition and results of operations.

#### LIMITED MANUFACTURING EXPERIENCE AND DEPENDENCE ON SOLE CONTRACT MANUFACTURER

The Company has only limited experience in manufacturing MUSE (alprostadil) and has not yet manufactured it in commercial quantities. As a result, the Company has no experience manufacturing its product in volumes necessary for the Company to achieve significant commercial sales, and there can be no assurance that reliable high volume manufacturing can be achieved at commercially reasonable cost. If the Company encounters any manufacturing difficulties, including problems involving production yields, quality control and assurance, supplies of components or raw materials or shortages of qualified personnel, it could have a material adverse effect on the Company's business, financial condition and results of operations.

The formulation, filling, packaging and testing of MUSE (alprostadil) is performed by Paco Pharmaceutical Services, Inc. ("Paco"), a wholly owned subsidiary of The West Company, at its facility in Lakewood, New Jersey. In June 1995, the Company completed construction of its approximately 6,000 square feet of dedicated manufacturing and testing space within Paco's facility. The Company will be required to expand its manufacturing and testing space at Paco or to find additional facilities, if regulatory approval is obtained and MUSE (alprostadil) is successfully introduced. The Company also intends to establish a Company owned and operated manufacturing facility in Europe. Until the Company develops an in-house manufacturing capability or is able to identify and qualify alternative contract manufacturers, it will be entirely dependent upon Paco for the manufacture of its products. As part of the approval process for the Company's NDA, Paco will be subject to audit by the FDA as part of its GMP inspection. There can be no assurance that the facility will receive the necessary GMP approval. There can be no assurance that the Company's reliance on Paco or others 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 or expand its existing facility at Paco. Interruptions in the availability of products could delay or prevent the development and commercial marketing of MUSE (alprostadil) and other potential products and would have a material adverse effect on the Company's business, financial condition and results of operations.

## LIMITED SALES AND MARKETING EXPERIENCE

The Company has no experience in the sale, marketing and distribution of pharmaceutical products. If required approvals are received, the Company intends to market and sell its products initially through a direct sales force in the United States. In order to market its products directly, the Company must develop a sales force with proper technical expertise. There can be no assurance that the Company will be able to build a sales force or that the Company's domestic sales and marketing efforts will be successful.

In February 1996, the Company entered into a distribution agreement with a wholly owned subsidiary of Cardinal Health, Inc. ("Cardinal"). Under this agreement, Cardinal will warehouse the Company's finished goods, take customer orders, pick, pack and ship its product, invoice customers and collect related receivables. The Company will also have access to Cardinal's information systems that support these functions. As a result of this distribution agreement with Cardinal, the Company is heavily dependent on Cardinal'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 completed a marketing agreement with Astra AB ("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 marketing agreement, Astra paid the Company \$10 million in June 1996. The Company will be paid up to an additional \$20 million in the event it achieves certain milestones. 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 Alternate Site Distributors, Inc. ("ASD"), a subsidiary of Bergen Brunswig Corporation. ASD will provide "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 will develop a customer service organization to respond to all Vivus sales representative and physician inquiries. A central feature of this customer service will be a dedicated Vivus owned 1-800 number with an automated response menu covering various options. 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.

The Company intends to market and sell its products in other foreign markets through distribution, co-promotion or license agreements with corporate partners. To the extent that the Company enters into distribution, co-promotion or license agreements for the sale of its products, the Company will be dependent upon the efforts of third parties. These third parties may have other commitments, and there can be no assurance that they will commit the necessary resources to effectively market, distribute and sell

the Company's product.

#### INTENSE COMPETITION

Competition in the pharmaceutical and medical products industries is intense and is characterized by extensive research efforts and rapid technological progress. Certain treatments for erectile dysfunction exist, such as needle injection therapy, vacuum constriction devices, penile implants and oral medications, and the manufacturers of these products will continue to improve these therapies. In July 1995, the FDA approved the use of alprostadil in The Upjohn Company's needle injection therapy product for erectile dysfunction. Previously, Upjohn had obtained approval in a number of European countries. 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 available for sale prior to the Company's products or that are more effective than those being developed by the Company. Such developments would render the Company's products less competitive or possibly obsolete. If the Company is permitted to commence commercial sales of products, it will also be competing with respect to marketing capabilities and manufacturing efficiency, areas in which it has limited experience.

#### PROPRIETARY RIGHTS AND RISK OF LITIGATION

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

aware of a patent application involving the transurethral application of prostaglandin E2. The corresponding application in Europe has been abandoned. Failure of the Company's licensed patents to block issuance of such patent could have a material adverse effect on the Company's business, financial condition and results of operations.

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

A former consultant to the Company has claimed that he is the inventor of certain technology disclosed in two of the Company's patents. The former consultant further claims that the Company defrauded him by allegedly failing to inform him that it intended to use and patent this technology and by failing to compensate him for the technology in the manner allegedly promised. On May 28, 1996, the Company filed a complaint for declaratory judgment against the former consultant in the United States District Court for the Northern District of California, which seeks a declaration from the court that the former consultant is not an inventor of any of the technology disclosed in the patent. On July 17, 1996, the former consultant filed a lawsuit which seeks to have two of the Company's patents declared invalid on the grounds that they fail to list him as an inventor. In a separate matter, on April 10, 1996, the licensors in an agreement by which the Company acquired a patent license filed a lawsuit in a Texas State court that alleges that they were defrauded in connection with the renegotiation of 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 seek to return to the terms of the original license agreement. The Company has conducted a review of the circumstances surrounding these two matters and believes that the allegations are without merit. Although the Company believes that it should prevail, the uncertainties inherent in litigation prevent the Company from giving any assurances about the outcome of such litigation.

The Company also relies on trade secrets and other unpatented



proprietary technology. No assurance can be given that the Company can meaningfully protect its rights in such unpatented proprietary technology or that others will not independently develop substantially equivalent proprietary products and processes or otherwise gain access to the Company's proprietary technology. The Company seeks to protect its trade secrets and proprietary know-how, in part, with confidentiality agreements with employees and consultants. There can be no assurance that these agreements will not be breached, that the Company will have adequate remedies for any breach or that the Company's trade secrets will not otherwise become known or be independently developed by competitors. In addition, protracted and costly litigation may be necessary to enforce and determine the scope and validity of the Company's proprietary rights.

#### DEPENDENCE ON DUAL SOURCE OF SUPPLY

To date, the Company has obtained its supply of alprostadil from two sources. The first is Spolana Chemical Works AS ("Spolana") pursuant to a supply agreement that expires at the end of 1996. In January 1996, the Company completed a long-term alprostadil supply agreement with CHINOIN Pharmaceutical and Chemical Works Co., Ltd. ("Chinoin"). Chinoin is the Hungarian subsidiary of the French pharmaceutical company Sanofi Winthrop. The Company's sources of supply will be subject to GMP requirements of the FDA. There can be no assurance FDA approval will be received. 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 and 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 is a development stage company with a limited operating history. The Company has not generated any product revenue since its inception in April 1991. As consideration for execution of the Astra marketing agreement, Astra paid the Company \$10 million in June 1996, which the Company recorded as milestone revenue in the consolidated statement of operations. At June 30,

1996, the Company had an accumulated deficit of approximately \$59.6 million. The Company's losses will increase significantly over the next twelve months as it incurs expenses related to its marketing and sales organization, constructing a second manufacturing plant and expanding the Company's existing plant, preclinical and clinical assessment of potential new products and ongoing research and development activities. To achieve profitability, the Company must successfully obtain required regulatory approvals, manufacture, introduce and market MUSE (alprostadil) product. The time required to reach profitability is highly uncertain and there is no assurance that the Company will be able to achieve profitability on a sustained basis, if at all.

#### FUTURE CAPITAL NEEDS AND UNCERTAINTY OF ADDITIONAL FINANCING

The Company expects to incur substantial additional costs, including expenses related to its marketing and sales organization, a second manufacturing plant and expansion of the Company's existing plant, 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 the United States and Europe but may not be sufficient for the introduction of any additional future products. The Company may have to conduct additional studies or clinical trials in order to obtain regulatory approval of MUSE (alprostadil). 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 can be expected to 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 ability to obtain and timing and costs of obtaining regulatory approvals; (ii) the level of resources that the Company devotes to sales and marketing capabilities; (iii) the level of resources that the Company devotes to expanding manufacturing capacity; (iv) the activities of competitors; (v) the progress of the Company's research and development programs; (vi) the timing and results of preclinical testing and clinical trials; and (vii) technological advances.

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

#### PRODUCT LIABILITY AND AVAILABILITY OF INSURANCE

The use of the Company's products in clinical trials may expose the Company to product liability claims and possible adverse publicity. These risks also exist with respect to the Company's products, if any, that receive regulatory approval for commercial sale. The Company currently maintains insurance coverage for the clinical use of its products, but does not have insurance coverage for the commercial sale of its products. There can be no assurance that the Company will be able to obtain product liability insurance. There can be no assurance that the Company's present or future insurance will provide adequate coverage or be available at a reasonable cost or that product liability claims would not adversely affect the business or financial condition of the Company.

## UNCERTAINTY OF PHARMACEUTICAL PRICING AND REIMBURSEMENT

In the United States and elsewhere, sales of pharmaceutical products currently are dependent, in part, on the availability of reimbursement to the consumer from third party payors, such as government and private insurance plans. Third party payors are increasingly challenging the prices charged for medical products and services. If the Company succeeds in bringing one or more products to the market, there can be no assurance that these 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.

## 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 June 25, 1996, the Company's officers, directors and principal stockholders, and certain of their affiliates, beneficially owned 22.5% 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, like the securities of other therapeutic companies without approved products, 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 Europe, 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 and developments with respect to FDA submissions, patents or other proprietary rights, product or patent litigation or public concern as to the safety of products developed by the Company, may have a significant effect on the market price of the Company's Common Stock.

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

In February 1996, the Company's Board of Directors authorized its reincorporation in the State of Delaware (the "Reincorporation") and adopted a Shareholder Rights Plan. 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. Each Right entitles stockholders to buy 1/100th of a share of VIVUS Series A Participating Preferred Stock at an exercise price of \$100.00. 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 Company's reincorporation into the State of Delaware was approved by its stockholders and effective in May 1996.

The Shareholder Rights Plan and certain provisions of the Company's Certificate of Incorporation and Bylaws, as adopted in connection with the reincorporation, 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.

#### SHARES ELIGIBLE FOR FUTURE SALE

Sales of a substantial number of shares of Common Stock in the public market following the third offering could have an adverse effect on the price of the Company's Common Stock. Each of the Company's directors and executive officers has agreed that for a period of 90 days following the date of this offering, such stockholder will not, without the prior written consent of PaineWebber Incorporated, directly or indirectly, offer to sell, sell or otherwise dispose of shares of Common Stock or any securities convertible or exchangeable for shares of Common Stock. Upon the expiration of these lock-up agreements, approximately 2.8 million shares (including shares issuable upon the exercise of outstanding vested options) will become eligible for sale.

#### ABSENCE OF DIVIDENDS

The Company has never paid dividends on its Common Stock and will not pay dividends in the foreseeable future.

## PART II: OTHER INFORMATION

## Item 1. Legal Proceedings

A former consultant to the Company has claimed that he is the inventor of certain technology disclosed in two of the Company's patents. The former consultant further claims that the Company defrauded him by allegedly failing to inform him that it intended to use and patent this technology and by failing to compensate him for the technology in the manner allegedly promised. On May 28, 1996, the Company filed a complaint for declaratory judgment against the former consultant in the United States District Court for the Northern District of California, which seeks a declaration from the court that the former consultant is not an inventor of any of the technology disclosed in the patent. On July 17, 1996, the former consultant filed a lawsuit which seeks to have two of the Company's patents declared invalid on the grounds that they fail to list him as an inventor. In a separate matter, on April 10, 1996, the licensors in an agreement by which the Company acquired a patent license filed a lawsuit in a Texas State court that alleges that they were defrauded in connection with the renegotiation of 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 seek to return to the terms of the original license agreement. The Company has conducted a review of the circumstances surrounding these two matters and believes that the allegations are without merit. Although the Company believes that it should prevail, the uncertainties inherent in litigation prevent the Company from giving any assurances about the outcome of such litigation.

## Item 4. Submission of Matters to a Vote of Security Holders.

The annual meeting of stockholders was held on May 16, 1996. Matters voted on at that meeting were: (i) a proposal to amend the bylaws to provide for a variable number of directors from five (5) to seven (7), with the number initially set at six (6); (ii) the election of the Company's directors; (iii) a proposal to approve the reincorporation of VIVUS, Inc. from California to Delaware, and (iv) a proposal to confirm the appointment of Arthur Andersen LLP as the independent public accountants of the Company for fiscal year 1996. Tabulation for each proposal and individual director were as follows:

Proposal I      To amend the bylaws to provide for a variable number of directors from five (5) to seven (7), with the number to be initially set at six (6).

| FOR        | AGAINST | ABSTAIN | NON-VOTE |
|------------|---------|---------|----------|
| -----      | -----   | -----   | -----    |
| 11,037,691 | 142,959 | 8,448   | 153,163  |

Proposal II To elect six directors to serve until the next Annual Meeting of Stockholders and until their successors are duly elected and qualified

| NOMINEE               | FOR        | WITHHELD |
|-----------------------|------------|----------|
| Richard L. Casey      | 11,296,383 | 45,878   |
| Samuel D. Colella     | 11,296,833 | 45,428   |
| Brian H. Dovey        | 11,296,433 | 45,828   |
| Peter Barton Hutt     | 11,288,383 | 53,878   |
| Virgil A. Place, M.D. | 11,296,333 | 45,928   |
| Leland F. Wilson      | 11,296,433 | 45,828   |

Proposal III To approve the reincorporation of VIVUS, Inc. from California to Delaware.

| FOR       | AGAINST | ABSTAIN | NON-VOTE  |
|-----------|---------|---------|-----------|
| 8,342,424 | 409,544 | 27,843  | 2,562,450 |

Proposal IV To confirm the appointment of Arthur Andersen LLP as the independent public accountants of the Company for fiscal year 1996.

| FOR        | AGAINST | ABSTAIN | NON-VOTE |
|------------|---------|---------|----------|
| 11,323,502 | 11,487  | 7,272   | 0        |

#### Item 6. Exhibits and Reports on Form 8-K

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

- \*+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                                                                             |
| 11.1        | Computation of net loss per share                                                                                                                              |
| 27.1        | Financial Data Schedule                                                                                                                                        |

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- \* Incorporated by reference to the same-numbered exhibit filed with the Registrant's Registration Statement on Form S-1 No. 33-75698.
  - \*\* Incorporated by reference to the same-numbered exhibit filed with the Registrant's Registration Statement on Form S-1 No. 33-90390.
  - \*\*\* 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 10Q for the quarter ended March 31, 1996.
  - \*\*\*\*\* 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.
  - + Confidential treatment granted.
  - ++ Confidential treatment requested.

(b) Reports on Form 8-K

The following reports on Form 8-K have been filed during the quarter for which this report is filed:

(i) On May 31, 1996, the Company filed a Current Report on Form 8-K ("Form 8-K") to report that on May 29, 1996, VIVUS International Limited, a wholly owned subsidiary of the Company, entered into a distribution agreement (the "Distribution Agreement") with Astra AB. Simultaneously with the filing of Form 8-K, the Company requested confidential treatment for the Distribution Agreement.

(ii) On June 21, 1996, the Company filed Amendment No. 1 to Form 8-K/A solely for the purpose of filing a revised version of the Distribution Agreement, which omitted only those portions for which confidential treatment had been granted.

## 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 9, 1996

/s/ DAVID C. YNTEMA

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David C. Yntema  
Chief Financial  
Officer

/s/ LELAND F. WILSON

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Leland F. Wilson  
President and Chief  
Executive Officer

VIVUS, INC.  
INDEX TO EXHIBITS

| Exhibit   | Description                                                                                                          |
|-----------|----------------------------------------------------------------------------------------------------------------------|
| - - - - - | - - - - -                                                                                                            |
| 10.23     | Distribution and Services Agreement between the Registrant and Alternate Site Distributors, Inc. dated July 17, 1996 |
| 11.1      | Computation of net loss per share                                                                                    |
| 27.1      | Financial Data Schedule                                                                                              |

## DISTRIBUTION AND SERVICES AGREEMENT

This Agreement is made July 17, 1996, between VIVUS, Inc., a California corporation ("VIVUS") and Alternate Site Distributors, Inc., a California corporation ("ASD").

## Background Information

A. VIVUS is, among other things, in the business of manufacturing, selling, and distributing pharmaceutical and therapeutic products in the United States.

B. ASD is, among other things, in the business of purchasing pharmaceutical products for resale to alternate care markets, including to physician offices, and in the business of providing telemarketing to physicians and providing customer service to physicians and manufacturer's sales representatives.

C. VIVUS desires to engage ASD (as limited pursuant to the terms of Section 2 below), for various services relating to its Products (as such term is defined in Appendix A attached hereto) including its first advanced pharmacological and therapeutic product and application system for the treatment of erectile dysfunction known as MUSE(R) (aplprostadi) ("MUSE") as (1) its primary agent on a non-exclusive basis for distribution and reporting of all samples (as such term is defined in Appendix A attached hereto) which VIVUS shall provide in its sole discretion for distribution in the United States, (2) its primary agent on a non-exclusive basis for storage, distribution and reporting of all promotional and literature marketing materials developed by VIVUS for the Products which VIVUS shall provide in its sole discretion for distribution in the United States, (3) its primary telemarketing agent on a non-exclusive basis in the United States, and (4) an agent for servicing 1-800 customer service line(s) to be accessed by U.S. physicians and VIVUS's U.S. sales representatives for the Products. VIVUS also desires to identify ASD to it called on physician practices in the United States for Products as a competitively priced, full service physician supplier for VIVUS's trade pharmaceutical products listed in Exhibit A, and such other products that may be added to Exhibit A by VIVUS and ASD from time to time. All services to be performed by ASD are described in this Agreement, and are to be performed upon the terms and conditions set forth in this Agreement.

## Statement of Agreement

VIVUS and ASD (the "Parties") hereby acknowledge the accuracy of the above background information and agree as follows:

1. Definitions. Except as otherwise provided in this Agreement, capitalized terms used herein shall have the respective meanings assigned thereto in Appendix A for all purposes hereof (all definitions shall be equally applicable to both singular and plural forms of the terms defined.)

2. Appointment. (a) Upon the terms and conditions described in this Agreement, VIVUS hereby appoints ASD: (i) as its primary agent on a non-exclusive basis for distribution of Samples to physicians as selected and approved by VIVUS in the United States, (ii) as its primary agent on a non-exclusive basis for storage of Marketing Materials for the Products and distribution, at VIVUS's direction, to physicians in the United States and to VIVUS's U.S. sales representatives, (iii) as its primary telemarketing agent on a non-exclusive basis for outbound telemarketing for the Products at VIVUS's direction to physician practices in the United States, (iv) an agent for servicing a dedicated VIVUS U.S. customer service operation including VIVUS owned 1-800 inbound telephone service line(s) to be accessed by U.S. physicians and VIVUS's U.S. sales representatives. ASD will be a purchaser of Products for resale to physicians in the United States. VIVUS will identify ASD as a competitively priced, physician supply alternative for Products and a full service supply alternative for other physician product and supply needs. This identification of ASD as a supplier will be provided by VIVUS so long as ASD represents a competitive, full service (as described in this Section 2) supply source for the Products. Notwithstanding the foregoing, VIVUS may elect to appoint other specialty distributors as qualified VIVUS customers for the purchase of Products for resale to physician practices.

(b) The Services shall be performed in accordance with the following agreed upon terms and conditions and in accordance with the implementation timing prescribed in this Agreement and as developed by the joint project team formed by the Parties. The services described in clause (i), (ii), (iii), and (iv) of Subparagraph 2(a) above are hereinafter referred to collectively as the "Services". ASD agrees to use its best efforts to provide the Services and undertake its other obligations under this Agreement.

(c) Samples. VIVUS will supply Samples at no charge to ASD as determined by a forecast developed by VIVUS based on a thirty (30) calendar days' forecasted utilization rate. ASD will warehouse and inventory Samples at ASD's current distribution

facility located at 1851 Monetary Lane, Carrollton, TX [\*] (the "ASD Facility"). [\*]. ASD shall visually inspect each shipment of the Samples for external container or package damage or loss in transit (based upon records provided to ASD from VIVUS) and notify VIVUS when damage or loss has occurred promptly following discovery by ASD of such damage or loss. ASD will store all Samples in full compliance with VIVUS's storage and handling specifications, which are attached hereto as Exhibit B to this Agreement. Such requirements may be supplemented or amended from time to time by VIVUS with prior reasonable notice to ASD and ASD's prior approval.

(d) VIVUS shall pay all costs and expenses of delivery for the Samples to the ASD Facility. VIVUS shall retain title to all Sample inventory until the Samples are received by physicians selected to receive such Samples, at which time title shall rest in the party to which the Samples are shipped.

(e) Sample orders will be directed to ASD from VIVUS sales representatives via telephone, fax, or electronic media and from VIVUS-selected physicians contacted by ASD, at the direction of VIVUS, through outbound telemarketing or via mail, e.g. VIVUS developed Business Reply Cards. ASD will ship Samples after receiving any order that complies with the Requirement(s) of Law. Standard Operating Procedures ("SOPs") will be developed by ASD and approved by VIVUS relative to inventory storage and tracking, inventory handling, inventory variances, disposition of rejected or expired Samples, order acceptance, fulfillment, and reporting.

(f) ASD will assemble Sample orders on a daily basis rotating inventory on a First to Expire, First Out ("FEFO") basis. Sample orders will be shipped via next day air in compliance with SOPs and product handling requirements as set forth in the attached Exhibit B, to be received by the recipient within 48 hours of a lawful Sample order being received by ASD that complies with applicable SOPs. ASD will provide proof of delivery or freight claims processing in the event of lost or damaged shipments.

(g) ASD will provide inventory tracking through its information systems and will comply with all lot traceability, FEFO rotation, expired product disposition, and recalls. However, all costs and expenses incurred by ASD involving product recalls and disposition of Products or Samples because of a lapse or pending lapse of its expiration date will be for the exclusive account of VIVUS and billed by ASD as such costs and expenses are incurred. Additional systems reporting in both electronic and

hard-copy format will be developed by the Parties and will include, among other reports, territory activity tracking for both sampling and sales and any reporting necessary, access to ASD's information systems, however, such access shall be pursuant to procedures set forth, from time to time, in writing by ASD, and ASD's internal SOPs for financial and compliance reporting. ASD will provide VIVUS validation prior to commencement of Sample storage and fulfillment. ASD will provide VIVUS, on an ongoing basis, remote access, pursuant to procedures set forth, from time to time, in writing by ASD, into its information systems for review of VIVUS records and activity.

(h) Marketing Materials. VIVUS will ship all Marketing Materials at no charge to ASD for storage at the ASD Facility. VIVUS will provide ASD with sufficient notice of each quantity of Marketing Materials shipped to ASD. Under normal operating conditions, ASD shall visually inspect each external package of the Marketing Materials for external damage or loss in transit and notify VIVUS when damage or loss has occurred promptly following discovery by ASD of such damage or loss. ASD will store Marketing Materials in compliance with VIVUS's storage and handling specifications. Such requirements may be supplemented or amended from time to time by VIVUS with reasonable prior notice to ASD and its prior approval, which approval shall not be unreasonably withheld.

(i) VIVUS shall pay all costs and expenses of delivering the Marketing Materials to the ASD Facility. For those Marketing Materials directed to physicians, VIVUS shall retain title to Marketing Materials inventory until the Marketing Materials are shipped at VIVUS's direction, at which time title shall rest in the party to which the Marketing Materials are shipped.

(j) Marketing Materials orders will be directed to ASD by VIVUS sales representatives or other authorized VIVUS marketing personnel via telephone, fax, or electronic media. The bulk of the Marketing Materials will be distributed to VIVUS sales representatives in individualized monthly shipments. Other Marketing Materials will be shipped to physicians upon request by VIVUS or by the physicians contacted by ASD, at VIVUS's direction, through outbound telemarketing. Periodic special shipments will be made to supply convention requirements or other special marketing needs as specified by VIVUS. SOPs will be developed by ASD and approved by VIVUS relative to storage, fulfillment and reporting of Marketing Materials.

(k) VIVUS will provide ASD order fulfillment timing requirements and all reporting requirements. ASD will ship Marketing Materials utilizing ground transportation, unless otherwise directed by VIVUS. ASD will establish a separate manifest system for shipment of Marketing Materials. ASD will



perform proof of delivery or freight claims processing in the event of lost or damaged shipments of Marketing Materials.

(l) ASD will provide systems reporting including, among others, inventory tracking and territory activity tracking in a form as agreed to between VIVUS and ASD.

(m) Telemarketing. ASD will provide, at VIVUS's direction, outbound telemarketing services for Products: (i) to build pre-launch awareness and facilitate sales representative access to physicians upon Product Launch, (ii) to physician practices not called on by VIVUS's U.S. sales representatives, (a listing of such physicians to be provided in writing by VIVUS to ASD), (iii) to physicians in vacant VIVUS sales territories, (a list of such vacant territories and physicians within such territories to be provided in writing by VIVUS to ASD), (iv) to develop and at least semi-annually refresh physician profiles, and (v) to conduct market research. In the course of telemarketing activities, ASD will accept physician orders for Products provided the physician meets the customer criteria established by ASD.

(n) VIVUS will identify physicians to be telephoned by ASD and the frequency of such telephone calls, and develop the telescrip messages to which ASD will deliver regarding the Products. SOPs will be developed by ASD and approved by VIVUS. ASD will organize the telemarketing staff so that each telemarketing service representative ("TSR") has primary responsibility for specific VIVUS territories and physicians.

(o) ASD will provide a telemarketing software system to manage its telemarketing activities and to be linked with its customer service system. Systems reports will be developed by the Parties and will include, among others, activity reports for each physician and sales territory detailing the telemarketing calls and the resulting activities including Samples, Marketing Materials and Products shipped.

(p) Customer Service. ASD will develop a customer service organization to respond to all VIVUS sales representative and physician inquiries regarding the Products. A central feature of this customer service is a dedicated, VIVUS owned 1-800 number(s) with an automated response menu covering various options for inbound calls from physicians and VIVUS sales representatives. Call options will include, Marketing Materials ordering, Products ordering from ASD, sample inquiries, information requests, and options for other VIVUS services, not provided by ASD. Technical questions will be referred to VIVUS for response. VIVUS will provide ASD, at no cost or expense to ASD, a dedicated Customer Service line, and related telephone service which will be

operated by ASD from 7:00 a.m. to 7:00 p.m., Central Standard Time.

(q) Orders for Products to be shipped by ASD shall be accepted by ASD by phone, mail, or fax. SOPs will be developed by ASD and approved by VIVUS.

(r) Customer Service representatives will have primary responsibility for a geographic set of VIVUS sales territories and the physicians within those geographic territories. A database of VIVUS sales representatives and physicians will be established by ASD including sales representatives and physician profiles, physician mapping to sales territories, and relating all activities, namely Samples, Marketing Materials and Products. This database shall be linked with the telemarketing software. In establishing the physician profiles, ASD will utilize profile data provided by VIVUS as well as access current physician profiles maintained by[\*].

(s) A component of the customer services provided by ASD, in conjunction with [\*], is the development of a[\*] program for VIVUS targeted physician customers, including the development of a[\*]. Any orders of Products received by [\*] will be accepted by [\*] and coordinated for shipment with ASD, conversely, any orders for [\*] products and services received by ASD will be accepted by ASD and coordinated with [\*].

(t) During the first four (4) months immediately following Product Launch, ASD will provide on a weekly basis, and thereafter on a monthly basis, electronic and hard-copy reports to VIVUS related to, among others, customer service activities, physician orders, sales by VIVUS sales territory, nature and frequency of physician inquiries.

(u) Staffing for Services. ASD will recruit and staff the following positions to provide the Services:

(i) VIVUS Project Manager -- ASD will recruit applicants for the ASD Facility for a dedicated VIVUS Project Manager. VIVUS will participate in the interview process and provide input to the ASD selection decision. VIVUS will also provide training relative to Products, Samples, Marketing Materials, and Services to be provided. ASD will have primary responsibility for training. The hiring date will be mutually agreed upon by the parties and is expected to commence employment no later than [\*].

(ii) Customer Service Representatives ("CSRs") -- ASD will recruit[\*] CSRs for the ASD Facility. VIVUS will

participate in the interview process and provide input to the ASD selection decisions. VIVUS will provide training for the CSRs relative to Products, Samples, and Marketing Materials. ASD will have primary responsibility for Customer Service training. The hiring date will be mutually agreed upon by the Parties and is expected to be approximately[\*] prior to Product Launch.

(iii) Telephone Service Representatives ("TSRs") -- ASD will recruit[\*] dedicated TSRs for the ASD Facility for the Products. VIVUS will participate in the interview process and provide input to the ASD selection decisions. VIVUS will provide training of TSRs relative to Products, Samples, Marketing Materials, and telescripts. ASD will have primary responsibility for telemarketing training. The hiring date will be mutually agreed upon by the Parties and is expected to be[\*] prior to Product Launch.

Warehouse Supervisor: -- ASD will recruit and select one warehouse employee who will be knowledgeable about the SOPs relating to the storage and handling of all Products, Samples, and Marketing Materials. The hiring date will be mutually agreed upon by the Parties and is expected to be approximately [\*] prior to Product Launch.

3. Targeted Physician Supplier. (a) ASD will purchase Products from VIVUS for resale to physicians. ASD will develop physician marketing materials relative to its [\*] and its [\*] services provided in conjunction with [\*]. VIVUS will identify ASD on selected physician marketing materials as its targeted physician supplier provided that ASD represents a competitive, full service supply source for the Products. VIVUS will also communicate the [\*], full service capabilities of ASD and [\*] by delivering the[\*] developed by ASD and [\*] to its called on physicians provided that ASD represents a competitive, full service supply source for the Products. ASD shall provide VIVUS notice of ASD price changes on Products and special discount offers on Products at least [\*] prior to the effective date.

(b) ASD will purchase and take title to Products and will maintain an adequate amount of inventory. ASD will establish the criteria for physicians to whom it sells and will offer, based upon credit availability for such physicians, VISA/Master Card as a payment option. Returns will be accepted and processed according to VIVUS's returned goods policy published for specialty distributors and which is attached hereto as Exhibit C.

(c) VIVUS may enter into contracts with certain physician practices that meet volume and other specifications to be defined by VIVUS ("Key Account Contracts"). Should Key Account Contract customers wish to enter into a prime vendor arrangement, VIVUS will first offer ASD the opportunity to act as the Key Account

Contract's prime vendor. ASD will accept such prime vendor status with such Key Account Contract customer provided, VIVUS's Key Account Contract customer meets ASD's requirements to qualify as a new ASD customer. ASD may elect to act as the Key Account Contract prime vendor for Products and invoice such customer at VIVUS's Key Account Contract price. Key Account Contracts utilizing ASD as its prime vendor will be advised by VIVUS to order from ASD in economic shipping quantities (i.e. shelf cartons or case packs). [\*] ASD will submit to VIVUS a monthly or more frequent electronic report of all sales to Key Account Contracts. The report shall include at least the following information as to each sale made to a Key Account Contract:

- (i) Key Account Contract Name and DEA number
- (ii) VIVUS's contract number
- (iii) ASD's invoice number and date
- (iv) Product NDC
- (v) Units shipped or returned
- (vi) ASD's unit cost
- (vii) VIVUS's Key Account Contract price
- (viii) [\*]
- (ix) Extended chargeback amount
- (x) Total chargeback amount

(d) Upon receipt and approval of ASD's reports submitted, VIVUS shall issue a credit memo to ASD in the amount of the difference between [\*]. VIVUS will pay such invoiced amounts within [\*] from the date of invoice.

4. Performance Criteria. (a) The Parties will mutually agree in writing upon performance measurements and reporting criteria for each of the Service categories and for servicing of Products ordered. Subject to the terms of this Agreement, ASD will use its best efforts to meet such applicable performance criteria.

(b) To enhance the value of the Services, the Parties shall cause their respective representatives to meet routinely for performance review and strategic planning purposes.

5. Fees. As compensation for the Services, VIVUS shall pay ASD, when due, without notice, demand, counterclaim, setoff, deduction, diminution or reduction, the fees described below (the "Fees"):

(a) [\*]Fees -- Based on [\*] Product Launch, VIVUS will reimburse ASD for the [\*] costs incurred at the rate of [\*] per [\*]for the VIVUS Project Manager which is expected to be hired up to [\*] Product Launch and a rate of [\*] per [\*] for additional staffing (one warehouse person, [\*] CSRS and [\*] TSRS) expected to be hired [\*] Product Launch. Should the timing of hiring

decisions or the level of staffing requirements change, the [\*] fee will be prorated accordingly; and

(b) Monthly Service Fees -- Monthly service fees accruing as of the date of this Agreement at [\*] rate of [\*]; and additional staffing may be added at the discretion of VIVUS at the fully loaded rates of [\*] for each additional TSR and [\*] for each additional CSR);

(c) Samples -- A monthly fee (as compensation for all services related to Samples) at the rate of [\*] per [\*]. This fee is all inclusive, including outbound shipping materials and freight; and

(d) Marketing Materials -- Reimbursement for actual shipping charges for Marketing Materials shipped [\*]; and

(e) Custom Reporting -- [\*] fee of [\*] for any custom reporting requested by VIVUS to be developed in accordance with SOP's developed by these Parties. In the event of custom reporting, ASD will provide an estimate of projected costs to VIVUS prior to the commencement of any work. Upon approval by VIVUS, work will commence.

6. Fees, expenses and other charges will be billed and paid according to the following schedule:

(a) [\*] Fees incurred up to [\*] will be billed before [\*] and all other [\*] Fees will be billed on Product Launch, all such [\*] Fees will be due and paid by VIVUS within [\*] from date of invoice.

(b) All other Fees will be pre-billed by ASD on the fifteenth (15th) of the month preceding the Services rendered and VIVUS will pay such fees within [\*] from date of invoice.

(c) Samples Fees will be billed by ASD on the fifteenth (15th) calendar day of the month for the Samples orders shipped during the preceding month. VIVUS will pay the Sample Fees within [\*] from date of invoice.

(d) All other fees, expenses, costs and charges payable by VIVUS to ASD not specifically referenced in Section 6 of this Agreement will be due and payable [\*] from the date ASD bills VIVUS.

(e) Any amounts payable by VIVUS pursuant to this Agreement and not paid when due will be assessed interest (to the extent not prohibited by applicable law) at the rate of 18% per annum from the date such amount is due until paid (or at such lesser rate as may be the maximum permitted by applicable law),

in each case computed on the basis of a 360-day year of twelve 30-day months. All Fee amounts will be reviewed by these parties upon the third anniversary of this Agreement for the purposes of adjusting such Fees to reflect increases in costs and expenses incurred or expected to be incurred by ASD.

7. Products Pricing and Terms. In addition to the fees provided in Section 6 above, and in consideration of the full value of the Services provided by ASD, VIVUS will sell Products to ASD at [\*] its list price to Specialty Distributors. Introductory payment terms (defined as payment terms during the first six months of Product sales) will be [\*] from date of VIVUS's invoice. Thereafter, VIVUS may elect to change payment terms to [\*] from date of VIVUS's invoice. All other sales terms and conditions will be governed by the VIVUS's terms and conditions set forth by VIVUS to the specialty distributor class of trade as set forth in the attached Exhibit D.

8. Term and Termination. (a) The initial term of the agreement (the "Initial Term") shall begin on the date of the agreement and continue until the [\*] anniversary of the Product Launch, unless or until terminated sooner pursuant to the other provisions of this Section. After the Initial Term, this Agreement shall renew automatically for successive renewal terms of one year each unless notice of termination is given by any Party at least one hundred and twenty (120) days prior to the end of the term then in effect, in which case this Agreement shall terminate at the end of that term. Any reference in this Agreement to the "term of this Agreement" shall include the initial term and any such renewal terms.

(b) Either Party shall have the right to terminate this Agreement with or without cause upon one hundred and twenty (120) days prior written notice. In the event either party gives written notice of its intent to terminate this Agreement, VIVUS shall pay ASD, all amounts due and payable ASD and accrued up to and including the date selected for termination of this Agreement. Any payments to be made on a monthly basis shall be prorated on the basis of a 30-day month for any fractional portion of a calendar month included in the term of this Agreement at its commencement or termination.

(c) Either party may terminate this Agreement immediately upon written notice in the event of: (i) the commencement of a voluntary case or other proceeding seeking liquidation, reorganization or other relief with respect to either party or its debts under any bankruptcy, insolvency, corporation or other similar law now or hereafter in effect; or (ii) either party's making a general assignment for the benefit of creditors, or either party's becoming insolvent, or either party taking any corporate action to authorize any of the foregoing.

(d) All accrued payment obligations of the parties under this Agreement, Sections 9 through 15, inclusive and Sections 17 through 23, inclusive, of this Agreement shall survive the termination of this Agreement, and, except as provided elsewhere in this Agreement, no termination of this Agreement shall affect any obligations or liabilities arising, or based upon acts or omissions occurring, prior to the date of such termination.

(e) Upon termination of this Agreement, ASD shall return, at VIVUS's sole cost and expense, all Samples, Marketing Materials, VIVUS records (apart from ASD records), and other VIVUS owned materials which ASD has in its possession.

9. Audits. VIVUS shall have the right during normal business hours (i.e. 8:00 a.m. to 5:00 p.m. local time) at no more than once during any calendar quarter, upon reasonable prior notice, to: (a) review and audit ASD's records related to the Services provided, (b) conduct, together with representatives of ASD, an inventory of the Samples and Marketing Materials at the ASD Facility, and (c) conduct, together with representatives of ASD, a facility audit. Should material issues be discovered during such audits which necessitate ongoing corrective action by ASD or ongoing follow-up action by VIVUS (including the initiation of additional audits on a more frequent basis regarding such area(s) of concern) to ensure ASD's compliance with such corrective action, all such reasonable and directly related expenses will be the responsibility of ASD.

10. Compliance With Laws. During the term of this Agreement, each party shall conduct its activities in connection with this Agreement in compliance with all applicable laws. Specifically, ASD shall comply with all applicable Requirements of Law related to the storage, handling and distribution of Samples, and only the cGMP guidelines as set forth in Section 211.142(b), Section 211.150, Section 211.196 and the Section 211.204, except that ASD shall have no obligation to perform tests or conduct investigations, all of which will be the responsibility of VIVUS, of Part 211 (also known as 21 Code of Federal Regulations, Chapter 1, as such Guidelines and Requirements of Law are applicable to ASD's activities, and VIVUS shall comply with all applicable Requirements of Law related to the importation, manufacture, distribution, labeling, storage, sale and handling of the Products and Samples.

(b) VIVUS agrees and does hereby represent and warrant to ASD during the term of this Agreement that (1) all Samples and Products, and each shipment of each, or other delivery now and hereafter made by VIVUS to or on the order of ASD will not be, at the time of shipment or delivery, adulterated, misbranded or otherwise prohibited within the meaning of the Act or within the meaning of any applicable state or municipal law and (2) such

Samples and Product is not, at the time of shipment or delivery to ASD, merchandise which may not be introduced or delivered for introduction into interstate commerce under the provisions of Sections 404 or 405 of the Act, and (3) all such Samples and Products will be the subject of a duly approved NDA and may be legally transported or sold under applicable Requirements of Law and VIVUS guarantees that only those chemicals or sprays, and the amounts of such chemicals or sprays, approved by Governmental Authority, have been used in any of the Samples and Products, and (4) all Samples and Products have been duly approved by all Governmental Authority for commercial sale and shipment within the United States.

11. Corporate Authority. During the term of this Agreement, each party continually represents and warrants to the other that: (a) it has full power and authority to enter into this Agreement and perform and observe all obligations and conditions to be performed or observed by it under this Agreement without any restriction by any other agreement or otherwise, (b) the execution, delivery and performance of this Agreement has been duly authorized by all necessary corporate action of that Party, (c) this Agreement constitutes the legal, valid and binding obligation of that Party, (d) no approvals, consents, orders or authorizations of or designation, registration, declaration or filing with any Governmental Authority (within, as a part of, or constituting the United States of America) is required for the sale and distribution of the Samples or the Products, (e) there is no action, proceeding, or investigation pending or, so far as each party knows, threatened, which questions the validity of this Agreement, the patents and licenses related to and for the Samples or the Products, any actions taken or to be taken pursuant to this Agreement, and (f) the Samples and the Products, or any part thereof, has been materially adversely affected in any way as a result of any legislative or regulatory change, or any revocation of license or right to manufacture, distribute, handle, store, sell or market any of the Samples or the Products. EXCEPT FOR ANY EXPRESSED REPRESENTATIONS, WARRANTIES, OR COVENANTS SET FORTH IN THIS AGREEMENT, VIVUS MAKES NO OTHER WARRANTIES WITH RESPECT TO THE PRODUCTS, EXPRESS, IMPLIED, STATUTORY OR COMMUNICATION WITH VIVUS, AND VIVUS SPECIFICALLY DISCLAIMS ANY IMPLIED WARRANTY OF NONINFRINGEMENT, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

12. Taxes. VIVUS shall pay when due all Taxes, excluding any personal property tax associated with ASD's equipment used in connection with the Services, and other taxes or similar charges now or hereafter imposed upon or as a result of the Samples and/or the Marketing Materials, none of which have been included in the fees payable to ASD under this Agreement. ASD shall maintain its records for use by VIVUS to complete and file returns relating to such Taxes.



13. Trademarks/Data. Neither Party shall have the right to use the name of the other Party or the other Party's trademarks, service marks, logos, other similar marks or data and information in any manner except with the prior written approval of that Party. Data and information which shall be deemed to belong to VIVUS will be the data and information related to the Products, Samples and Marketing Materials. Data and information which shall be deemed to belong to ASD shall be the data and information related to all goods, products and services offered and sold by ASD (and not described in Exhibit A or Section 2 above) and all data and information relating to any of ASD's customers and their respective profiles.

14. Confidentiality. (a) Each Party acknowledges that as a result of this Agreement, that each Party shall learn Confidential Information of the other Party. Neither Party shall disclose any Confidential Information of the other Party to any person or entity, or use, or permit any person or entity to use, any of such confidential information, excepting only: (a) disclosures on a confidential basis to and use by the directors, officers, employees, and agents of that Party, or its affiliates, who have a reasonable need to know such information in connection with that Party's performance of this Agreement, and (b) disclosures which are required by law, or legal process, as reasonably determined by that Party or its legal counsel, or are made on a confidential basis to that Party's attorneys, accountants, and other professional advisors in connection with matters relating to this Agreement. The specific material terms of this Agreement shall be deemed to be Confidential Information of each Party.

(b) The obligation of confidentiality hereunder shall survive the termination of this Agreement for a period of three (3) years.

(c) Upon termination of this Agreement (for any reason) each Party shall promptly: (i) return to the other Party or destroy all documentation and other materials (including copies of original documentation or other materials) containing any Confidential Information of the other Party; or (ii) certify to the other Party, pursuant to a certificate in form and substance reasonably satisfactory to the other Party, as to the destruction of all such documentation and other materials.

15. Indemnification. (a) Each Party shall indemnify and hold harmless the other and their respective Related Parties from and against all claims, liabilities, losses, damages, costs and expenses (including without limitation reasonable attorneys' fees) arising directly or indirectly out of any act or omission of that Party or any failure of that Party to perform and observe fully all obligations and conditions to be performed or observed

by that Party pursuant to this Agreement or any breach of any warranty made by that Party in this Agreement. Further, VIVUS does hereby protect, indemnify and hold harmless ASD and its related parties from and against all claims, liabilities, losses, damages, costs and expenses (including without limitation, attorneys' fees and expenses) imposed upon or incurred by or asserted against ASD and/or its Related Parties related to or arising from (1) any claim of patent or copyright infringement and (2) any loss of or damage to property, accident, injury to or death of a person or persons occurring or arising from the storage, handling, use, non-use, demonstration, consumption, ingestion, digestion, manufacture, production and assembly, of the Samples and the Products and their transportation to ASD, excepting only for claims arising out of the negligence of ASD or its employees. Further, ASD does hereby agree to protect, indemnify and hold harmless VIVUS and its related parties from and against all claims, liabilities, losses, damages, costs and expenses (including without limitation, attorneys' fees and expenses) imposed upon or incurred by or asserted against VIVUS and/or its Related Parties related to or arising from any loss of or damage to property, accident, injury to or death of a person or persons occurring or arising from the negligence of ASD (or its employees) and the failure of ASD to substantially comply with written and mutually approved SOP's and VIVUS directives, excepting here from, any act, negligence or omission of VIVUS or its Related Parties. NOTWITHSTANDING THE FOREGOING OR ANY OTHER PROVISION TO THE CONTRARY CONTAINED IN THIS AGREEMENT, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY LOST PROFITS, CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, OR OTHER SIMILAR DAMAGES ARISING OUT OF OR IN CONNECTION WITH A BREACH OF THIS AGREEMENT OR ANY EXPENSES, CHARGES, COSTS OR LIABILITIES, WHETHER FORESEEN OR UNFORESEEN, ARISING FROM OR RELATED TO THE ACT OF TERMINATING THIS AGREEMENT.

(b) The obligations and liabilities of VIVUS or ASD with respect to ASD Indemnified Claims or VIVUS Indemnified Claims, respectively, (collectively, the "Indemnified Claims"), resulting from the assertion of liability by third parties (each, a "Third Party Claim") shall be subject to the following terms and conditions:

(i) The party claiming indemnification (the "Indemnified Person") shall give prompt written notice to the other party of any Third Party Claim which may give rise to a Third Party Claim against the other party (the "Indemnifying Person"), stating the nature and basis of said Third Party Claim and the amount thereof to the extent known. Each Notice of Claim shall be accompanied by copies of all relevant documentation with respect to such Third Party Claim, including, without limitation, any summons, complaint or other pleading which may have been served or written demand or other document or instrument.

(ii) If the Indemnifying Person shall acknowledge in a writing delivered to the Indemnified Persons that the Indemnifying Person shall be obligated under the terms of its indemnity hereunder in connection with such Third Party Claim, then the Indemnifying Person shall have the right to assume the defense of any Third Party Claim at its own expense and by its own counsel (reasonably satisfactory to the Indemnified Persons); provided, however, that the Indemnifying Person shall not have the right to assume the defense of any Third Party Claim, notwithstanding the giving of such written acknowledgment, if (aa) such Third Party Claim seeks an injunction, restraining order, declaratory relief or other nonmonetary relief and, if decided adversely, such Third Party Claim could have a material adverse effect on the financial condition, properties, assets, liabilities, business, operations or prospects of any of the Indemnified Persons or (bb) the named parties to any such action or proceeding (including any impleaded parties) include both the Indemnified Persons and the Indemnifying Person and the former shall have been advised by counsel that there are one or more legal or equitable defenses available to them which are different from or additional to those available to the Indemnifying Person, and, in the reasonable opinion of the Indemnified Persons, counsel for the Indemnifying Person could not adequately represent the interests of the Indemnified Persons because such interests could be in conflict with those of the Indemnifying Person (any Third Party Claim of the type referred to in (aa) or (bb) being a "Nonassumable Claim").

(iii) If, in accordance with the provisions of the preceding subparagraph (ii), the Indemnifying Person shall assume the defense of a Third Party Claim (other than a Nonassumable Claim), the Indemnifying Person shall not be responsible for any legal or other defense costs subsequently incurred by the Indemnified Persons in connection with the defense thereof. If the Indemnifying Person does not exercise its right to assume the defense of such a Third Party Claim by giving the written acknowledgment referred to in subparagraph (ii) above or may not assume such defense pursuant to such subparagraph (ii) above, then the Indemnified Persons may assume such defense and the costs, expenses and reasonable attorneys' fees incurred shall continue to constitute Losses hereunder.

(iv) Anything contained herein to the contrary notwithstanding, neither the Indemnifying Person nor the Indemnified Persons shall admit any liability with respect to, or settle, compromise or discharge, any Third Party Claim without the written consent of the other, which consent shall not be unreasonably withheld. In addition, each of the Indemnifying Person and the Indemnified Persons shall cooperate and act in a reasonable and good faith manner to minimize Losses relating to any Third Party Claim.

(v) The foregoing indemnities shall not extend to any claims arising out of one or more of: (aa) the incorrectness of any representation or warranty made by Indemnified Person pursuant to this Agreement; (bb) the failure by such Indemnified Person to perform or observe any agreement or covenant made by it in this Agreement; or (cc) the willful misconduct or gross negligence of such Indemnified Person.

16. Insurance. During the term of this Agreement: (a) each party will maintain product liability and commercial general liability insurance having a limit of not less than \$1 million, pursuant to one or more insurance policies with reputable insurance carriers; and (b) VIVUS shall maintain property damage insurance for the Samples and Marketing Materials located at the ASD Facility or in transit to or from the ASD Facility. Each party shall designate the other party as an "additional insured" under all insurance policies referenced in this paragraph. Prior to the Product Launch and the commencement of Services, each party shall deliver to the other certificates evidencing such insurance. Neither party shall cause or permit such insurance to be canceled or modified to materially reduce its scope or limits of coverage during the term of this Agreement. Except for any losses resulting from the negligence or intentional misconduct of ASD (in which case ASD shall be liable for any damage or loss), VIVUS shall bear all risk of loss or damage with respect to Samples or Marketing Materials, whether located at the ASD Facility or otherwise. ASD shall bear all risk of loss or damage with respect to Products purchased by ASD once said Products are in ASD's possession.

17. Notices. Any notice or other communication required or desired to be given to any Party under this Agreement shall be in writing and shall be deemed given when: (a) deposited in the United States mail, first-class postage prepaid, and addressed to that Party at the address for such Party set forth at the end of this Agreement; (b) delivered to an express delivery service for delivery to that Party at that address; or (c) sent by facsimile transmission, with electronic confirmation, to that Party at its facsimile numbers set forth at the end of this Agreement. Any Party may change its address or facsimile number for notices under this Agreement by giving the other Party notice of such change.

18. Arbitration. Subject to Section 19, below, any and all disagreements or controversies arising out of or with respect to this Agreement may, upon mutual agreement, be settled by binding arbitration to be held, and the award made, in a county located in California, pursuant to the then-applicable rules of the American Arbitration Association (to the extent not inconsistent with this Agreement). Each Party shall bear the costs and expenses of preparing and presenting its case at the arbitration.

All other costs and expenses of arbitration shall be borne by the Parties as determined in the Arbitration.

19. Remedies. With respect to the provisions of Section 14 of this Agreement, each Party acknowledges that in the event of any violation by that Party of any of the provisions of Section 14 of this Agreement, the other Party may suffer irreparable harm and its remedies at law may be inadequate. Accordingly, in the event of any violation or attempted violation of any such provisions of Section 14 by either Party, the other Party shall be entitled to petition for a temporary restraining order, temporary and permanent injunctions, specific performance, and other equitable relief. The rights and remedies of each Party under this Agreement shall be cumulative and in addition to any other rights or remedies available to such Party, whether under any other agreement, at law, or in equity.

20. Governing Law. All questions concerning the validity or meaning of this Agreement or relating to the rights and obligations of the Parties with respect to performance under this Agreement shall be construed and resolved under the laws of the State of California excluding the body of law relating to conflicts of laws.

21. Severability. The intention of the Parties is to comply fully with all laws and public policies, and this Agreement shall be construed consistently with all laws and public policies to the extent possible. If and to the extent that any court of competent jurisdiction determines that it is impossible to construe any provision of this Agreement consistently with any law or public policy and consequently holds that provision to be invalid, such holding shall in no way affect the validity of the other provisions of this Agreement, which shall remain in full force and effect.

22. Non-waiver. No failure by either Party to insist upon strict compliance with any term of this Agreement, to exercise any option, to enforce any right, or to seek any remedy upon any default of the other Party shall affect, or constitute a waiver of, the first Party's right to insist upon strict compliance, to exercise that option, to enforce that right, or to seek that remedy with respect to that default or any prior, contemporaneous, or subsequent default. No custom or practice of the Parties at variance with any provision of this Agreement shall affect, or constitute a waiver of, that Party's right to demand strict compliance with all provisions of this Agreement.

23. Force Majeure. If the performance of any part of this Agreement by either Party shall be affected for any length of time by fire or other casualty, government restrictions, war, riots, strikes or labor disputes, lock out, transportation

delays, electronic disruptions, telecommunication failures, and acts of God, or any other causes which are beyond the control of the Parties (financial inability excepted), such Party shall not be responsible for delay or failure of performance of this Agreement for such length of time, provided, however, that the obligation of one Party to pay amounts due to any other Party shall not be subject to the provisions of this Section.

24. Captions. The captions of the various sections of this Agreement are not part of the context of this Agreement, and are only labels to assist in locating those sections, and shall be ignored in construing this Agreement.

25. Genders and Numbers. Where permitted by the context, each pronoun in this Agreement includes the same pronoun in the other genders or numbers and each noun used in this Agreement includes the same noun in other genders.

26. Complete Agreement. This Agreement contains the entire agreement between the Parties and supersedes all prior or contemporaneous discussions, negotiations, representations, warranties, or agreements relating to the subject matter of this Agreement. No changes to this Agreement shall be made or be binding on either Party unless made in writing and signed by both Parties. All schedules, Exhibits, Appendixes referred to in this Agreement are incorporated herein and made a part hereof as fully as if set forth herein.

27. Successors. Except as set forth in this Section, neither Party shall have the right to assign this Agreement or any of such Party's rights or obligations under this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld. After providing written notice to ASD, VIVUS may assign this Agreement to a party that succeeds to all or substantially all of VIVUS's business or assets relating to this Agreement whether by sale, merger, operation of law or otherwise.

28. Approvals. When this Agreement requires the approval of one or both of the parties to this Agreement, each and every such approval sought will not be unreasonably withheld by the party required to provide its approval.

29. Relationship of the Parties. The relationship of the Parties is and shall be that of independent contractors. This Agreement does not establish or create a partnership or joint venture among the Parties.

30. Interpretation. The parties have jointly negotiated this Agreement and, thus, neither this Agreement nor any provision hereof shall be interpreted for or against any party on

the basis the party or the party's attorney drafted the Agreement or the provision at issue.

This Agreement shall be binding upon, inure to the benefit of, and be enforceable by and against the respective successors and assigns of the Parties.

VIVUS, INC.

ALTERNATE SITE DISTRIBUTORS,  
INC.

By: /s/ LELAND F. WILSON  
-----  
Leland F. Wilson  
President and CEO

By: /s/ STEVEN H. COLLIS  
-----  
Steven H. Collis  
VP and General Manager

Address and facsimile number:

Address and facsimile number:

545 Middlefield Road,  
Suite 200  
Menlo Park, CA 94025  
Attn: President  
Facsimile (415) 325-5546

2340 Trinity Mills Road,  
Suite 250  
Carrollton, TX 75006  
Attn: General Manager  
Facsimile (214) 416-4848



"Act" means the Federal Food, Drug and Cosmetic Act, Title 21, United States Code, as amended, and the regulations thereunder.

"Agreement" means this Distribution and Services Agreement dated \_\_\_\_\_, 1996, by and between VIVUS, Inc., a California Corporation, and Alternate Site Distributors, Inc., a California Corporation, as may be amended from time to time pursuant to the terms providing for such amendments.

"cGMP" shall have the meaning of current good manufacturing practices and guidelines as published by the Federal Food & Drug Administration.

"Confidential Information" shall mean information, data considered confidential by the party owning such information, whether visual, oral or in written form, but does not include (1) information which is or becomes public without the fault or participation of the other party to this Agreement or which is responsive to legal process or obligation, (2) any information lawfully in the receiving party's possession prior to the date the receiving party receives the disclosing party's information, or (3) any information which either party receives from a third party who rightfully possesses and discloses such information.

"Drug" shall have the meaning as set forth in Section 321(g)(1) of the Act.

"Governmental Authority" shall mean any nation or government, any state or other political subdivision thereof, or any entity exercising executive, legislative, judicial, regulatory or administrative functions of or pertaining to government.

"Marketing Materials" shall mean brochures, booklets, letters and pamphlets intended to encourage the purchase and/or disbursing of the Products.

"MUSE" shall mean VIVUS's first products and application systems for the treatment of erectile dysfunction.

"NDA" means a New Drug Application as defined in and contemplated by the Act.

"Person" or "Persons" means any corporation, natural person, firm, joint venture, partnership, trust, unincorporated organization, government or any department or agency of any government.

"Pre-Launch" shall mean that period of time between the date of the Agreement and the date of Product Launch.

"Product Launch" shall mean the date selected by VIVUS after VIVUS obtains FDA approval of the Products and upon which ASD is notified by VIVUS that MUSE may be lawfully available for commercial sale and shipment.

"Product" or "Products" means the pharmaceutical and other products that are a part of, or added to from time to time, to Exhibit A attached hereto and which are intended for commercial sale.

"Related Parties" mean the successors, subsidiaries, parent corporations, affiliates, Directors, employees, agents, representatives, related entities and assigns of any Person.

"Requirement(s) of Law" means any law (including, without limitation, consumer law), treaty, rule or regulation or a final and binding determination of an arbitrator or a determination of a court or other Governmental Authority, in each case applicable to or binding upon such Person or any of its property or to which such Person or any of its property is subject.

"Sample" or "Samples" means a product (as opposed to the term "Product(s)") which is not intended to be sold and is labeled as such and is given free of charge to promote sales.

"SEC" means the Securities and Exchange Commission.

"Taxes" shall mean any and all liabilities, losses, expenses, and costs of any kind whatsoever that are, or are in the nature of taxes, fees, or other governmental charges, including interest, penalties, fines and additions to tax imposed by any Federal, state or local government or taxing authority in the United States on or with respect to: (a) the Agreement or any related agreements or any future amendment, supplement, waiver, or consent requested by VIVUS or any required by the Agreement with respect to the execution, delivery or performance of any thereof, or the issuance, acquisition or subsequent transfer thereof, (b) any interest in the Samples or the Marketing Materials, or any part thereof, (c) the return, acquisition, transfer of title, storage, removal, replacement, substitution, purchase, acceptance, possession, rejection, ownership, delivery, non-delivery, use, operation, sale, abandonment, redelivery or other disposition of any interest in the Samples or the Marketing Materials or any part thereof; (d) the receipts or earnings arising from any interest in the Samples or the Marketing Materials or any part thereof; (e) any payment made pursuant to this Agreement or to any of the Samples or the Marketing Materials; or (f) otherwise as a result of or by reason of the

transactions contemplated by this Agreement, excluding, however; taxes imposed upon ASD that are based upon or measured by gross or net income and any franchise Taxes of ASD or any personal property taxes for Products owned by ASD.

EXHIBIT A

List of Products

MUSE alprostadil product line

EXHIBIT B  
VIVUS'S STANDARD OPERATING PROCEDURES  
FOR HANDLING AND SHIPPING  
SAMPLES

Pursuant to Sections 2(c) and 2(f) of the Distribution and Services Agreement, Vivus is currently in the process of developing operating procedures for handling and shipping samples.

EXHIBIT C  
VIVUS RETURNED GOODS POLICY

Pursuant to Section 3(b) of the Distribution and Services Agreement, Vivus is currently in the process of developing returned goods policy.

EXHIBIT D  
VIVUS TERMS AND CONDITIONS  
FOR SPECIALTY DISTRIBUTOR CLASS  
OF TRADE

Pursuant to Section 7 of the Distribution and Services Agreement, Vivus is currently in the process of developing terms and conditions for specialty distributor class of trade.

VIVUS, INC.  
COMPUTATION OF NET LOSS PER SHARE

|                                                                                                                                                                                                                                                       | Three Months Ended June 30, |                | Six Months Ended June 30, |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------|---------------------------|----------------|
|                                                                                                                                                                                                                                                       | 1996                        | 1995           | 1996                      | 1995           |
| Net Loss .....                                                                                                                                                                                                                                        | \$ (3,745,000)              | \$ (6,413,000) | \$ (9,979,000)            | \$(11,870,000) |
| Weighted average common<br>shares outstanding .....                                                                                                                                                                                                   | 13,770,722                  | 12,949,032     | 13,646,615                | 12,345,051     |
| Common shares, options,<br>and warrants granted<br>(using the treasury stock<br>method assuming an initial<br>public offering price of<br>\$14.00) since January 1,<br>1993 included pursuant to<br>Securities and Exchange<br>Commission Rules ..... | 453,083                     | 580,053        | 453,083                   | 580,053        |
| Weighted average common and<br>equivalent shares .....                                                                                                                                                                                                | 14,223,805                  | 13,529,085     | 14,099,698                | 12,925,104     |
| Net loss per common and<br>equivalent share .....                                                                                                                                                                                                     | \$ (.26)                    | \$ (.47)       | \$ (.71)                  | \$ (.92)       |



5  
1000  
U.S. DOLLARS

|        |             |      |  |
|--------|-------------|------|--|
| 6-MOS  |             |      |  |
|        | DEC-31-1996 |      |  |
|        | JAN-01-1996 |      |  |
|        | JUN-30-1996 |      |  |
|        | 1           |      |  |
|        |             | 796  |  |
|        | 53105       |      |  |
|        | 618         |      |  |
|        | 0           |      |  |
|        | 0           |      |  |
|        | 54871       |      |  |
|        |             | 6293 |  |
|        | 1618        |      |  |
|        | 91408       |      |  |
| 3985   |             |      |  |
|        |             | 0    |  |
| 0      |             |      |  |
|        | 0           |      |  |
|        |             | 16   |  |
|        | 87407       |      |  |
| 91408  |             |      |  |
|        |             | 0    |  |
|        | 10000       |      |  |
|        |             | 0    |  |
|        | 0           |      |  |
|        | 20928       |      |  |
|        | 0           |      |  |
|        | 0           |      |  |
|        | (9979)      |      |  |
|        | 0           |      |  |
| (9979) |             |      |  |
|        | 0           |      |  |
|        | 0           |      |  |
|        |             | 0    |  |
|        | (9979)      |      |  |
|        | (0.71)      |      |  |
|        | 0           |      |  |