UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

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FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2001

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<br>(STATE OR OTHER JURISDICTION OF<br>INCORPORATION OR ORGANIZATION) | 94-3136179<br>(I.R.S. EMPLOYER<br>IDENTIFICATION NUMBER) |
| 1172 CASTRO STREET<br>MOUNTAIN VIEW, CA<br>(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES) | 94040<br>(ZIP CODE) |

(650) 934-5200
(REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE)

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

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

At June 30, 2001, 32,602,653 shares of common stock were outstanding.

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PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

VIVUS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except par value)

ASSETS

| | JUNE 30, 2001 | DECEMBER 31, 2000 |
|---|---|---|
| | (UNAUDITED) | |
| Current assets: | | |
| Cash and cash equivalents | $ 20,468 | $ 29,236 |
| Available-for-sale securities | 8,667 | 9,187 |
| Accounts receivable, net | 3,020 | 3,434 |
| Inventories, net | 4,007 | 5,045 |
| Prepaid expenses and other assets | 1,295 | 1,143 |
| Total current assets | 37,457 | 48,045 |
| Property and equipment, net | 13,427 | 14,294 |
| Restricted cash | 3,324 | 3,324 |
| Available-for-sale securities, non-current | 8,076 | 3,511 |
| Total assets | $ 62,284 | $ 69,174 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | $ 1,151 | $ 1,775 |
| Accrued and other liabilities | 12,424 | 13,289 |
| Total current liabilities | 13,575 | 15,064 |
| Accrued and other long-term liabilities | 3,923 | 3,923 |
| Total liabilities | 17,498 | 18,987 |
| Stockholders' equity: | | |
| Common stock; $.001 par value; shares authorized 200,000; shares outstanding — June 30, 2001, 32,603; December 31, 2000, 32,461; | 33 | 32 |
| Paid in capital | 133,689 | 133,288 |
| Accumulated other comprehensive income | 160 | 165 |
| Accumulated deficit | (89,096) | (83,298) |
| Total stockholders' equity | 44,786 | 50,187 |
| Total liabilities and stockholders' equity | $ 62,284 | $ 69,174 |



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CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data)

| | THREE MONTHS ENDED | | SIX MONTHS ENDED | |
|---|---|---|---|---|
| | JUNE 30, 2001 | JUNE 30, 2000 | JUNE 30, 2001 | JUNE 30, 2000 |
| | (UNAUDITED) | (UNAUDITED) | (UNAUDITED) | (UNAUDITED) |
| Revenue | | | | |
| US product | $ 5,032 | $ 5,945 | $ 10,269 | $ 11,703 |
| International product | 1,633 | 1,140 | 3,051 | 3,178 |
| Returns | (295) | (338) | (591) | (667) |
| Total revenue | 6,370 | 6,747 | 12,729 | 14,214 |
| Cost of goods sold | 3,164 | 2,864 | 6,797 | 5,791 |
| Gross profit | 3,206 | 3,883 | 5,932 | 8,423 |
| Operating expenses: | | | | |
| Research and development | 1,937 | 1,209 | 7,941 | 2,413 |
| Selling, general and administrative | 2,712 | 2,282 | 4,949 | 4,499 |
| Total operating expenses | 4,649 | 3,491 | 12,890 | 6,912 |
| Income (loss) from operations | (1,443) | 392 | (6,958) | 1,511 |
| Interest and other income | 529 | 597 | 1,160 | 1,196 |
| Income (loss) before provision for income taxes | (914) | 989 | (5,798) | 2,707 |
| Provision for income taxes | — | (99) | — | (271) |
| Net income (loss) | $ (914) | $ 890 | $ (5,798) | $ 2,436 |
| Net income (loss) per share: | | | | |
| Basic | $ (0.03) | $ 0.03 | $ (0.18) | $ 0.08 |
| Diluted | $ (0.03) | $ 0.03 | $ (0.18) | $ 0.07 |
| Shares used in per share computation: | | | | |
| Basic | 32,530 | 32,304 | 32,501 | 32,249 |
| Diluted | 32,530 | 33,740 | 32,501 | 33,658 |



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VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME
(In thousands)

| | THREE MONTHS ENDED | | SIX MONTHS ENDED | |
|---|---|---|---|---|
| | JUNE 30, 2001 | JUNE 30, 2000 | JUNE 30, 2001 | JUNE 30, 2000 |
| | (UNAUDITED) | (UNAUDITED) | (UNAUDITED) | (UNAUDITED) |
| Net (loss) income | $ (914) | $ 890 | $ (5,798) | $ 2,436 |
| Other comprehensive (loss) income: | | | | |
| Unrealized (loss) gain on securities | (9) | (1) | (5) | 74 |
| Income tax (provision) benefit | — | — | — | (7) |
| | (9) | (1) | (5) | 67 |
| Comprehensive (loss) income | $ (923) | $ 889 | $ (5,803) | $ 2,503 |



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VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

| | SIX MONTHS ENDED JUNE 30, | |
|---|---|---|
| | 2001 | 2000 |
| | (UNAUDITED) | (UNAUDITED) |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net (loss) income | $ (5,798) | $ 2,436 |
| Adjustments to reconcile net (loss) income to net cash (used for) provided by operating activities: | | |
| Depreciation and amortization | 1,126 | 1,219 |
| Changes in assets and liabilities: | | |
| Accounts receivable | 414 | 901 |
| Inventories | 1,038 | 132 |
| Prepaid expenses and other assets | (152) | 3,149 |
| Accounts payable | (624) | (420) |
| Accrued and other liabilities | (865) | (4,468) |
| Net cash (used for) provided by operating activities | (4,861) | 2,949 |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Property and equipment purchases | (259) | (265) |
| Investment purchases | (16,606) | (96,114) |
| Proceeds from sale/maturity of securities | 12,556 | 98,460 |
| Net cash (used for) provided by investing activities | (4,309) | 2,081 |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Exercise of common stock options | 242 | 181 |
| Sale of common stock through employee stock purchase plan | 160 | 131 |
| Net cash provided by financing activities | 402 | 312 |
| NET (DECREASE) INCREASE IN CASH | (8,768) | 5,342 |
| CASH: | | |
| Beginning of period | 29,236 | 8,785 |
| End of period | $ 20,468 | $ 14,127 |
| NON-CASH INVESTING AND FINANCING ACTIVITIES: | | |
| Unrealized (loss) gain on securities | $ (5) | $ 74 |
| SUPPLEMENTAL CASH FLOW DISCLOSURE: | | |
| Income taxes paid | $ 113 | $ 524 |



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VIVUS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
JUNE 30, 2001

1. BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulations S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the six-month period ended June 30, 2001 are not necessarily indicative of the results that may be expected for the year ending December 31, 2001. 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, 2000.

2. INVENTORIES

Inventories are recorded net of reserves of $7.6 million and $7.7 million as of June 30, 2001 and December 31, 2000, respectively, and consist of (in thousands):

| | JUNE 30, 2001 | DECEMBER 31, 2000 |
|---|---|---|
| Raw materials | $ 2,564 | $ 3,497 |
| Work in process | 55 | 61 |
| Finished goods | 1,388 | 1,487 |
| Inventory, net | $ 4,007 | $ 5,045 |

3. ACCRUED AND OTHER LIABILITIES

Accrued and other liabilities as of June 30, 2001 and December 31, 2000 consist of :

| (000's) | JUNE 30, 2001 | DECEMBER 31, 2000 |
|---|---|---|
| Restructuring | $ 4,019 | $ 4,266 |
| Product returns | 1,498 | 2,008 |
| Income taxes | 3,232 | 3,332 |
| Research and clinical expenses | 2,018 | 2,076 |
| Royalties | 518 | 541 |
| Unearned revenue | 2,161 | 1,917 |
| Employee compensation and benefits | 1,350 | 1,670 |
| Other | 1,551 | 1,402 |
| | 16,347 | 17,212 |
| Amount classified as short-term | (12,424) | (13,289) |
| Amount classified as long-term | $ 3,923 | $ 3,923 |

4. RESTRUCTURING RESERVE

During 1998, VIVUS, Inc. experienced a significant decline in market demand for MUSE® due to the market launch of sildenafil, the first oral treatment for erectile dysfunction. During the second and third quarters of 1998, the Company took significant steps to restructure its operations in an attempt to bring the cost structure in line with current and projected revenues. (See Notes 1 and 6 to the Consolidated Financial Statements for the year ended December 31, 2000 included in the Company's Annual Report on Form 10-K.) The restructuring reserve balance at June 30, 2001 was $4.0 million, down from $4.3 million at December 31, 2000.

| (000's) | INVENTORY AND RELATED COMMITMENTS | PROPERTY AND RELATED COMMITMENTS | TOTAL |
|---|---|---|---|
| Balance at December 31, 2000 | 942 | 3,324 | 4,266 |
| Activity in first quarter 2001 | 0 | (123) | (123) |
| Activity in second quarter 2001 | 0 | (124) | (124) |
| Balance at June 30, 2001 | $ 942 | $ 3,077 | $ 4,019 |

The Company expects that during the next twelve months it will make cash payments of approximately $96 thousand related to the restructuring, with the remaining $3.9 million in cash payments to occur in later periods.



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5. CONCENTRATION OF CUSTOMERS AND SUPPLIERS

During the first six months of 2001 and 2000, sales to significant customers as a percentage of total revenues are as follows:

| | 2001 | 2000 |
|---|---|---|
| Customer A | 23% | * |
| Customer B | 21% | 19% |
| Customer C | 15% | 17% |
| Customer D | 14% | 17% |
| Customer E | 10% | 11% |

* Customer's percentage was less than 10%

The Company did not have any suppliers making up more than 10% of operating costs.

6. SUBSEQUENT EVENT

In July 2001, the Company reached an agreement with AndroSolutions, Inc. ("ASI") to settle all claims related to the arbitration demand filed by VIVUS in September 2000. Under the terms of the settlement agreement, the Company acquired ASI's rights and interest in ASIVI, LLC, including all intellectual property initially contributed by ASI and the Company. In addition, the parties agreed to terminate and/or modify the agreements entered into upon establishing ASIVI, LLC, a limited liability company that was jointly owned and operated by the Company and ASI. The Company made a payment of $750 thousand to ASI upon execution of the settlement agreement. The expense of this payment was provided for in prior periods. The Company may also make additional payments to ASI in the future based on the Company's achieving certain development milestones and royalties on net sales of products covered by the intellectual property, which, in the aggregate, are substantially the same as those required under the previous agreements.



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This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. The Company's actual results could differ from those set forth in such forward-looking statements as a result of certain factors, including those set forth in the Risk Factors section starting on page 11 of this document.

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

OVERVIEW

VIVUS, Inc. ("VIVUS" or the "Company") is a pharmaceutical company developing innovative products to improve quality of life disorders in men and women, with a focus on sexual dysfunction. The Company developed and markets in the U.S. MUSE® (alprostadil) and ACTIS®, two innovations in the treatment of erectile dysfunction ("ED"), and has entered into a license and supply agreement with Abbott Laboratories ("Abbott") (NYSE:ABT) for the international marketing and distribution of its male transurethral ED products. In Canada, VIVUS has entered into a license and supply agreement with Paladin Labs, Inc. ("Paladin") (TSE:PLB) by which Paladin will market and distribute MUSE. VIVUS has ongoing research and development ("R&D") programs in male ED, female sexual dysfunction ("FSD"), and male premature ejaculation ("PE").

Following our restructuring in 1998, substantial efforts were devoted to bring expenses in line with revenues. These efforts resulted in a significant improvement in our cash resources, which enabled continued investment in our R&D projects. During fiscal year 2000, we filed an Investigational New Drug ("IND") application and began clinical studies for ALISTA™, our product for the topical treatment of FSD. Several new patents were awarded to us for the treatment of ED and we solidified our FSD intellectual property through an agreement with AndroSolutions. VIVUS also received 510(k) clearance from the FDA for over-the-counter (OTC) marketing of ACTIS, an adjustable constriction band used to improve erections in men with ED.

In 2001, we expanded our R&D pipeline through the acquisition of rights for TA-1790, a phosphodiesterase type 5 (PDE5) inhibitor for both the oral and local treatment of male and female sexual dysfunction, from TANABE SEIYAKU CO., LTD. ("TANABE"). Since the acquisition of these rights, VIVUS has been working diligently with TANABE in the manufacture of and analytical assay development for TA-1790. Our goal is to begin clinical studies initially with an oral version of TA-1790 for the treatment of ED within the next six to twelve months, while at the same time establishing programs to evaluate feasibility for the use of TA-1790 in a transurethral formulation for ED and in the treatment of FSD.

We initiated a Phase II multi-center, double-blind, placebo controlled clinical study for topical ALISTA, which is intended to evaluate safety and potential efficacy in women with a primary diagnosis of Female Sexual Arousal Disorder ("FSAD"). We are on schedule to complete the dosing portion of this study in August 2001 and plan to initiate expanded Phase II studies in the next six to nine months.

The Company also developed a revised formulation of VI-0134, an oral, on-demand product for the treatment of PE, and we plan to initiate clinical testing of this new formulation in humans later this year.

FISCAL 2001 HIGHLIGHTS

FIRST QUARTER

The Company reported a net loss of $4.9 million, for $0.15 net loss per share. These results included up-front, non-refundable milestone payments totaling $5 million for licensing TA-1790.

VIVUS signed a development, license and supply agreement with TANABE for its proprietary phosphodiesterase type 5 (PDE5) inhibitor compound TA-1790. Under the terms of this agreement, we acquired worldwide rights, except Japan, China and certain Pacific Rim countries, to develop and commercialize the compound for oral and local treatments of male and female sexual dysfunction.

We initiated a Phase II multi-center, double-blind, placebo controlled clinical trial for our product ALISTA, a proprietary topical formulation of alprostadil for the treatment of FSAD.



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SECOND QUARTER

The Company reported a net loss of $914 thousand, for $0.03 net loss per share. Increased spending for R&D and lower U.S. product revenue contributed to the loss.

VIVUS was awarded a new patent by the U.S. Patent & Trademark Office. This patent strengthens our proprietary protection in the field of PE, allowing for broad treatment claims for PE by administration of 5-HT4 agonists, alone or in combination with other agents.

We reported results of our Phase I safety study for ALISTA, which show that a single dose of ALISTA topically applied in healthy volunteers was well tolerated both locally and systemically.

RESULTS OF OPERATIONS

Three Months Ended June 30, 2001 and 2000

U.S. net product revenue for the quarter ended June 30, 2001 was $4.7 million compared to $5.6 million for the quarter ended June 30, 2000. U.S. product revenue decreased 16% in the second quarter of 2001 compared to the second quarter of 2000. Based on information reported by NDC Health, prescriptions for MUSE declined throughout fiscal year 2000 and have remained flat for the first six months of this year.

International product revenue was $1.6 million for the second quarter of 2001, an increase of $493 thousand over the same period last year. Shipments to Abbott and Paladin account for this year's international revenue, while last year's shipments were to Janssen-Cilag and AstraZeneca. Approximately 25% of the shipments to Abbott during the second quarter are expected to be used to meet Abbott's projected third quarter sales in Europe. Accordingly, the Company expects lower shipments to Abbott and a significant decline in international product revenue in the last half of 2001.

Cost of goods sold was $3.2 million for the second quarter of 2001, compared to $2.9 million for the second quarter 2000. Additional costs associated with final packaging of product for Abbott and Paladin accounted for the increase.

Research and development expenses for the second quarter of 2001 increased $700 thousand to $1.9 million as compared to the three months ended June 30, 2000. The increase is primarily due to incremental expenses related to the development of TA-1790 for male erectile dysfunction and VI-0134 for premature ejaculation. We expect that R&D expenses will increase further in the last half of 2001.

Selling, general and administrative expenses of $2.7 million for the second quarter of 2001 were $430 thousand higher than the same period last year. The increase is primarily due to an additional $300 thousand in expense recorded in June 2001 for the demand for arbitration filed by ALZA Corporation in August 2000. The Arbitrator's final ruling requires that the Company reimburse ALZA approximately $550 thousand for this matter, of which the Company had previously provided for $250 thousand in fiscal year 2000.

Six Months Ended June 30, 2001 and 2000

Net product revenues for the six months ended June 30, 2001 were $9.7 million in the U.S. and $3.1 million internationally, compared to $11.0 million in the U.S. and $3.2 million internationally for the same period last year. The decline in U.S. product revenue is attributable to lower demand for MUSE based on information from NDC Health as discussed above.

For the six months ended June 30, 2001, cost of goods sold increased $1.0 million to $6.8 million as compared to the same period last year. The increase for the first half of 2001 is primarily due to a one-time reduction in the first quarter 2000 cost of goods sold associated with the termination of the distribution agreement with AstraZeneca. Gross profit margin for the first six months of 2001 was 47%, compared with 59% in the same period last year. Higher revenue and lower cost of goods in the first six months of 2000 both contributed to the decline in margin this year. Since lower international production volume is anticipated, the Company expects that gross margin will decline further in the last half of 2001.



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R&D expenses for the six months ended June 30, 2001 were $7.9 million, $5.5 million higher than the same period last year. The increase is primarily due to the expensing of up-front, non-refundable payments totaling $5.0 million to TANABE for licensing their proprietary compound TA-1790 for the oral and local treatment of male and female sexual dysfunction.

Selling, general and administrative expenses were $4.9 million for the six months ended June 30, 2001, $450 thousand higher than the same period last year. The increase is primarily due to the additional expense recorded in June 2001 for the ALZA arbitration discussed above.

The Company has not recorded a tax benefit through the first six months of 2001 as we expect to record a net loss for fiscal year 2001. During fiscal year 2000, VIVUS recorded a ten percent (10%) tax provision, which included the effect of net operating losses ("NOLs") carried forward from prior periods. The 2000 tax rate would have been substantially higher if the NOLs had not been available to offset current income.

LIQUIDITY AND CAPITAL RESOURCES

Since its inception, the Company has financed operations primarily from the sale of preferred and common stock. Through June 30, 2001, VIVUS has raised $154.8 million from financing activities and has an accumulated deficit of $89.1 million at June 30, 2001.

Unrestricted cash, cash equivalents and available-for-sale securities totaled $37.2 million at June 30, 2001, a decrease of $4.7 million from December 31, 2000. This decrease is due primarily to the $5 million in milestone payments for licensing TA-1790 from TANABE.

Capital resources from operating activities are expected to decline over the next several quarters as a result of increased spending for R&D projects. We expect that our existing capital resources combined with future cash flows will be sufficient to support operating needs throughout the next twelve to twenty-four months. Financing in future periods will most likely be required to fund development of our R&D pipeline in addition to the possible launch of any future

products. Our future capital requirements will depend upon numerous factors, including: (i) the progress of our R&D programs; (ii) the scope, timing and results of pre-clinical testing and clinical trials; (iii) the results of operations; (iv) the cost, timing and outcome of regulatory reviews; (v) the rate of technological advances; (vi) ongoing determinations of the potential commercial success of our products under development; (vii) the level of resources devoted to sales and marketing capabilities; and (viii) the activities of competitors.

To provide additional capital when needed, we will evaluate alternative financing sources, including, but not limited to, the issuance of additional equity or debt securities, corporate alliances, joint ventures, and licensing agreements. However, there can be no assurance that funding will be available on favorable terms, if at all, when needed.



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

## RISK FACTORS

### NEW PRODUCT DEVELOPMENT AND UNCERTAINTY OF PRODUCT APPROVALS

The Company's future operating results may be adversely affected if the Company is unable to continue to develop, manufacture and bring to market new drug products rapidly. The process of developing new drugs and/or therapeutic products is inherently complex and uncertain. The Company must make long-term investments and commit significant resources before knowing whether its development programs will eventually result in products that will receive regulatory approval and achieve market acceptance. After the FDA and international regulatory authorities approve a product, the Company must manufacture sufficient volumes to meet market demand. This is a process that requires accurate forecasting of market demand. Given existing treatments and the number of products introduced in the market each year, the drug development process becomes increasingly difficult, expensive and risky. There is no guarantee that future clinical studies will confirm the safety and efficacy of any product in development or that the Company will receive regulatory approval for such products. Further, even if the Company were to receive regulatory approval for a product, there could be no assurance that such product would prove to be commercially successful or profitable.

In January 2001, VIVUS signed a licensing agreement with TANABE, a leading Japanese pharmaceutical company, for TANABE's proprietary phosphodiesterase type 5 (PDE5) inhibitor compound TA-1790 for the oral and local treatment of male and female sexual dysfunction. TANABE has conducted a Phase I clinical trial and VIVUS intends to initiate additional clinical studies required for regulatory approval of an oral treatment for ED. However, as with any pharmaceutical under development, there are significant risks in development, regulatory approval and commercialization of new compounds. There are no guarantees that future clinical studies will confirm the preliminary pre-clinical and clinical results or that the compound TA-1790 will receive regulatory approval for any indication. Further, even if the Company were to receive regulatory approval for a product, there could be no assurance that such a product would prove to be commercially successful or profitable.

The Company submitted an IND to the FDA in September 2000 to begin clinical studies with its FSD product, ALISTA. Clinical studies will be focused on the treatment of FSAD, a subcategory of FSD. In January 2001, the Company began enrolling patients in a Phase II study to evaluate the safety and efficacy of ALISTA. This is a multi-center, double-blind trial designed to evaluate the safety and potential efficacy of ALISTA in women with FSAD. Completion of the dosing portion of the study is expected in August 2001. Upon completion of this trial, the Company plans to initiate expanded Phase II studies. There can be no assurances that the clinical studies will be successful. Furthermore, the FDA could suspend clinical studies at any time if it is believed that the subjects participating in such studies are being exposed to unacceptable health risks. Even if the trials are successful, and the Company eventually files a New Drug Application ("NDA") for ALISTA with the FDA, there are no assurances that it will be approved. Even if ALISTA eventually becomes an approved product, there can be no assurances that this treatment for FSD will be successful in the marketplace.

VIVUS continues with the development of VI-0134, its oral, on-demand product for the treatment of PE. The Company has developed a revised formulation of VI-0134, designed to improve the absorption of the compound. Plans are to initiate clinical testing of this new formulation in humans by the end of the year. However, there can be no assurance that future clinical studies with the revised formulation will confirm the preliminary results in the proof-of-concept study or that a product for the treatment of PE will prove to be commercially successful.

The Company filed for marketing authorization for ALIBRA with the European Agency for the Evaluation of Medicinal Products (EMEA) under the Centralized Process in Europe in May 2000. The Company subsequently met with the EMEA and submitted its response to inquiries the EMEA had regarding data presented in the original application. Communication from the EMEA is expected in the third quarter of 2001. Based on the Company's latest response, the EMEA may (1) require the Company to provide more data; (2) require the Company to perform additional clinical trials; or (3) not grant approval of the application. Even if ALIBRA is approved, there can be no assurances that this transurethral system to treat ED will be successful in the marketplace.

In December 1999, the Company submitted an NDA to the FDA to market ALIBRA, which it subsequently withdrew in October 2000. The Company met with the FDA in December 2000 and continues to communicate with the FDA to determine what additional data is required to obtain marketing clearance for ALIBRA. There can be no assurance that the Company will re-file an NDA for



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ALIBRA. Even if the Company does re-file an NDA for ALIBRA, there can be no assurance that it will be approved or that ALIBRA will be successful in the marketplace.

### 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 ED exist, such as oral medications, needle injection therapy, vacuum constriction devices and penile implants, and the manufacturers of these products will continue to improve these therapies. The most significant competitive therapy is sildenafil, an oral medication marketed by Pfizer, which received regulatory approvals in the U.S. in March 1998 and in the European Union in September 1998. The commercial launch of sildenafil in the U.S. in April 1998 significantly decreased demand for MUSE.

Additional competitive products in the ED market include needle injection therapy products from Pharmacia Upjohn and Schwartz Pharma, which were approved by the FDA in July 1995 and June 1997, respectively. Other large pharmaceutical companies are also actively engaged in the development of therapies for the treatment of ED. These companies have substantially greater research and development capabilities as well as substantially greater marketing, financial and human resources abilities than VIVUS. In addition, many of these companies have significantly greater experience than the Company in undertaking pre-clinical testing, human clinical trials and other regulatory approval procedures. For instance, Lilly ICOS LLC filed an NDA with the FDA in June 2001 for their oral ED medication. Additionally, Bayer AG is in final clinical trials with their oral product and expects to file an NDA by the end of this year. These entities may market commercial products either on their own or through collaborative efforts. The Company's competitors may develop technologies and products that are more effective than those currently marketed or being developed by the Company. Such developments could render the Company's marketed and development products less competitive or possibly obsolete. The Company is also competing with respect to marketing capabilities and manufacturing efficiency, areas in which it has limited experience.

FUTURE CAPITAL NEEDS AND UNCERTAINTY OF ADDITIONAL FINANCING

Capital resources from operating activities are expected to decline over the next several quarters as the result of increased spending for R&D projects. We expect that our existing capital resources combined with future cash flows will be sufficient to support operating needs throughout the next twelve to twenty-four months. Financing in future periods will most likely be required to fund development of our R&D pipeline in addition to the possible launch of any future products. Our future capital requirements will depend upon numerous factors, including: (i) the progress of our R&D programs; (ii) the scope, timing and results of pre-clinical testing and clinical trials; (iii) the results of operations; (iv) the cost, timing and outcome of regulatory reviews; (v) the rate of technological advances; (vi) ongoing determinations of the potential commercial success of our products under development; (vii) the level of resources devoted to sales and marketing capabilities; and (viii) the activities of competitors.

To provide additional capital when needed, we will evaluate alternative financing sources, including, but not limited to, the issuance of additional equity or debt securities, corporate alliances, joint ventures, and licensing agreements. However, there can be no assurance that funding will be available on favorable terms, if at all, when needed.

LIMITED SALES AND MARKETING IN THE U.S.

The Company supports MUSE sales in the U.S. through a small sales support group targeting major accounts that include the top prescribers of MUSE. Additionally, telephone marketers focus on the second tier of urologists who prescribe MUSE. Physician and patient information/help telephone lines are available to answer additional questions that may arise after reading the inserts or after actual use of the product. The sales force actively participates in national urologic and sexual dysfunction forums and conferences, such as the American Urological Association annual and regional meetings and the International Society for Impotence Research. Despite our sales efforts, prescriptions of MUSE have been declining since 1998. Although prescriptions have remained flat throughout 2001, there can be no assurance that our sales programs will effectively maintain or increase current sales levels. There can be no assurance that demand for the Company's product MUSE will continue or that the Company will be able to adequately support sales of MUSE in the U.S. in the future.

DEPENDENCE ON THIRD PARTIES

The Company entered into an agreement granting Paladin exclusive marketing and distribution rights for MUSE in Canada. This agreement does not have minimum purchase commitments and the Company is entirely dependent on Paladin's efforts to distribute





and sell the Company's product effectively in Canada. There can be no assurance that such efforts will be successful or that Paladin will continue to support the product.

VIVUS entered into an agreement granting Abbott exclusive marketing and distribution rights for MUSE in all countries outside the U.S. and Canada. This agreement does not have minimum purchase commitments and the Company is entirely dependent on Abbott's efforts to distribute and sell the Company's product effectively in all markets except the U.S. and Canada. There can be no assurance that such efforts will be successful or that Abbott will continue to support the product.

A distribution agreement exists between VIVUS and CORD Logistics, Inc. ("CORD"), a wholly owned subsidiary of Cardinal Health, Inc. Under this agreement, CORD (i) warehouses the Company's finished goods for U.S. distribution; (ii) takes customer orders; (iii) picks, packs and ships its product; (iv) invoices customers; and (v) collects related receivables. As a result of this distribution agreement, the Company is heavily dependent on CORD's efforts to fulfill orders and warehouse its products effectively in the U.S. There can be no assurance that such efforts will be successful.

Gibraltar Laboratories ("Gibraltar") performs sterility testing on finished product manufactured by the Company to ensure that it complies with product specifications. Gibraltar also performs microbial testing on water and compressed gases used in the manufacturing process and microbial testing on environmental samples to ensure that the manufacturing environment meets appropriate cleanliness standards. As a result of this testing agreement, the Company is dependent on Gibraltar to perform testing and issue reports on finished product and the manufacturing environment in a manner that meets regulatory compliance standards. There can be no assurance that such efforts will be successful.

The Company has an agreement with WRB Communications ("WRB") to handle patient and healthcare professional hotlines for the Company. WRB maintains a staff of healthcare professionals to handle questions and inquiries about MUSE and ACTIS. These calls may include complaints about the Company's product due to efficacy or quality, as well as the reporting of adverse events. As a result of this agreement, the Company is dependent on WRB to effectively handle these calls and inquiries. There can be no assurance that such efforts will be successful.

VIVUS entered into a distribution agreement with Integrated Commercialization Services ("ICS"), a subsidiary of Bergen Brunswig Corporation. ICS provides "direct-to-physician" distribution capabilities in support of U.S. marketing and sales efforts. As a result of this distribution agreement with ICS, the Company is dependent on ICS's efforts to distribute product samples effectively. There can be no assurance that such efforts will be successful.

RAW MATERIALS

The Company is required to receive regulatory approval for suppliers. The Company has obtained its current supply of alprostadil from two approved sources. The first is Spolana Chemical Works a.s. in Neratovice, Czech Republic ("Spolana"). The second is CHINOIN Pharmaceutical and Chemical Works Co., Ltd. ("Chinoin"). Chinoin is the Hungarian subsidiary of the French pharmaceutical company Sanofi Synthelabo. At the present time, Spolana is the sole source of supply of alprostadil approved for use in the manufacture of product for distribution in Europe, and the Company has a limited supply. Certain restrictions have been put in place by the European regulatory authorities that would require a variation to be approved before VIVUS can use the Chinoin alprostadil supply for European manufacture, if at all. The Company has transferred marketing licenses in Europe to Abbott and expects Abbott to file variations with the European regulatory authorities for the use of Chinoin alprostadil. There can be no assurance that such variations will be approved in a timely manner or at all, which could result in a material impact on the Company's ability to supply MUSE to Abbott for distribution in Europe.

Furthermore, alprostadil is subject to periodic re-testing to ensure it continues to meet specifications. There can be no guarantees the material will pass these testing procedures and continue to be usable material. There is a long lead time for manufacturing alprostadil. A short supply of alprostadil to be used in the manufacture of MUSE would have a material adverse effect on the Company's business, financial condition and results of operations.

SINGLE MANUFACTURING FACILITY

The Company leases 90,000 square feet of space in Lakewood, New Jersey, in which it constructed manufacturing, warehousing and testing facilities. The FDA and MCA authorized the Company to begin commercial production and shipment of MUSE from this facility in June and March 1998, respectively. MUSE is manufactured in this facility and the Company has no immediate plans to construct another manufacturing site. Since MUSE is produced with custom-made equipment under specific manufacturing





conditions, the inability of our manufacturing facility to produce MUSE for whatever reason would have a material adverse effect on the Company's business, financial condition and results of operations.

RISKS RELATING TO INTERNATIONAL OPERATIONS

MUSE is currently marketed internationally. Changes in overseas economic and political conditions, currency exchange rates, foreign tax laws or tariffs or other trade regulations could have an adverse effect on the Company's business, financial condition and results of operations. The international nature of the Company's business is also expected to subject it and its representatives, agents and distributors to laws and regulations of the foreign jurisdictions in which they operate or where the Company's product is 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 U.S.

HISTORY OF LOSSES

The Company has generated a cumulative net loss of $89.1 million for the period from its inception through June 30, 2001 and anticipates losses for the next several quarters due to increased investment in its R&D programs and limited revenues. The Company is subject to a number of risks including its ability to market, distribute and sell its products in the U.S., its reliance on Abbott to market and distribute MUSE internationally, its reliance on Paladin to market and distribute MUSE in Canada, intense competition, and its reliance on a single therapeutic approach to ED. There can be no assurance that the Company will be able to achieve profitability on a sustained basis. Accordingly, there can be no assurance of the Company's future success.

DEPENDENCE ON THE COMPANY'S TRANSURETHRAL SYSTEM FOR ERECTION

MUSE, a drug product developed by the Company to treat ED, relies on a single therapeutic approach, a transurethral system for erection. The existence of side effects or dissatisfaction with this product may impact a patient's decision to use or continue to use or a physician's decision to recommend this therapeutic approach as a therapy for the treatment of ED, thereby affecting the commercial viability of MUSE. In addition, technological changes or medical advancements could diminish or eliminate the commercial viability of the Company's product, the results of which could have a material effect on the business operations and results of the Company since MUSE is the only transurethral product VIVUS currently produces and sells.

PATENTS AND PROPRIETARY RIGHTS

The Company's policy is to aggressively maintain its patent position and to enforce all of its intellectual property rights.

The Company is the exclusive licensee of U.S. and Canadian patents originally filed in the name of Dr. Gene Voss. These patents claim methods of treating ED with a vasodilator-containing ointment that is administered either topically or transurethrally.

The Company is also the exclusive licensee of patents and patent applications filed in the name of Dr. Nils G. Kock, in numerous countries. Four U.S. patents have issued directed to methods and compositions for treating ED by transurethrally administering an active agent. Patents have also been granted in Australia, Austria, Belgium, Canada, Finland, France, Germany, Great Britain, Greece, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Spain, Sweden and South Africa. Patent applications are pending in Denmark and Romania. The foreign patents and applications, like the U.S. patents, are directed to the treatment of ED by transurethral administration of certain active substances including alpha-receptor blockers, vasoactive polypeptides, prostaglandins or nitroglycerin dispersed in a hydrophilic vehicle.

The Company is the sole assignee of five U.S. patents deriving from patent applications originally filed by ALZA, covering inventions Dr. Virgil Place made while he was an employee of ALZA. The patents are directed to dosage forms for administering a therapeutic agent to the urethra, methods for treating ED, and specific drug formulations that can be delivered transurethrally for the treatment of ED. With one exception, the patents derive from patent applications that were filed in the U.S. prior to June 8, 1995, and will therefore have a seventeen-year patent term calculated from the date of patent grant. Foreign patents have been granted in Australia, Canada, Europe (including Austria, Belgium, Denmark, France, Germany, Great Britain, Greece, Italy, Luxembourg, the Netherlands, Spain, Sweden and Switzerland), Finland, Ireland, Mexico, New Zealand, Norway, Portugal, South Africa and South Korea, and foreign applications are pending in Canada and Japan.



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The Company is the sole assignee of patent applications filed in the name of Dr. Gary W. Neal and AndroSolutions, Inc. (“ASI”) in the U.S. and internationally that are complementary to the Company’s patents and applications directed to the treatment of FSD.

The Company’s license and assignment agreements for these patents and patent applications identified above are royalty bearing and do not expire until the licensed and assigned patents expire. These license and assignment agreements generally provide that the Company assume responsibility for the maintenance and prosecution of the patents and patent applications and may bring infringement actions.

In addition to the Voss, Kock, Neal and Place patents and applications identified above, the Company has fourteen issued U.S. patents, seventeen pending U.S. patent applications, four granted foreign patents, and twenty-one pending foreign patent applications. Several of these patents and applications further address the prevention, treatment and diagnosis of ED, while others are directed to prevention and/or treatment of other types of sexual dysfunction, including PE and FSD. One of the Company’s issued patents covers the Company’s ACTIS venous flow control device.

The Company’s success will depend in large part on the strength of its current and future patent position for the treatment of ED, PE and FSD. The Company’s patent position, like that of other pharmaceutical companies, is highly uncertain and involves complex legal and factual questions. The claims of a U.S. or foreign patent application may be denied or significantly narrowed, and patents that ultimately issue may not provide significant commercial protection to the Company. The Company could incur substantial costs in proceedings before the U.S. Patent and Trademark Office, including interference proceedings. These proceedings could also result in adverse decisions as to the priority of the Company’s licensed or assigned inventions. There can be no assurance that the Company’s patents will not be successfully challenged or designed around by others.

The Company is presently involved in an opposition proceeding that was instigated by the Pharmedic Company against a European patent, inventors Nils G. Kock et al., which is exclusively licensed to VIVUS. As a result of the opposition proceeding, the Opposition Division of the EPO held certain pharmaceutical composition claims in the European patent unpatentable. The patentability of all other claims in the patent was confirmed, i.e., those claims directed to the use of active agents in the treatment of ED, and to a pharmaceutical composition claim for prazosin. The Company appealed the EPO’s decision with respect to the pharmaceutical composition claims that were held unpatentable. The Pharmedic Company appealed the EPO’s decision with respect to the claims that were held patentable, but has since withdrawn the appeal. Despite the withdrawal of the Pharmedic Company from the appeal process, the Company has continued with its own appeal in an attempt to reinstate the composition claims. The EPO Appeals Board must make its own finding whether the claims that were deemed unpatentable by the Opposition Division are indeed patentable before it can reverse the Opposition Division’s decision. There can be no assurance that the appeal will be successful or that further challenges to the Company’s European patent will not occur should the Company try to enforce the patent in the various European courts.

There can be no assurance that the Company’s products do not or will not infringe on the patent or proprietary rights of others. The Company may be required to obtain additional licenses to the patents, patent applications or other proprietary rights of others. There can be no assurance that any such licenses will 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.

In addition to its patent portfolio, 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, through confidentiality agreements with employees and consultants. There can be no assurance that the 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 SINGLE SOURCE OF SUPPLY

The Company relies on a single injection molding company, The Kipp Group (“Kipp”), for its supply of plastic applicator components. In turn, Kipp obtains its supply of resin, a key ingredient of the applicator, from a single source, Huntsman Corporation. The Company also relies on a single source, E-Beam Services, Inc. (“E-Beam”), for sterilization of its product. There can be no



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assurance that the Company will be able to identify and qualify additional sources of plastic components or an additional sterilization facility. The Company is required to receive FDA approval for suppliers. The FDA may require additional clinical trials or other studies prior to accepting a new supplier. Until the Company secures and qualifies additional sources of plastic components or an additional sterilization facility, it is entirely dependent upon Kipp and E-Beam. If interruptions in these supplies or services were to occur for any reason, including a decision by Kipp and/or E-Beam to discontinue manufacturing or services, political unrest, labor disputes or a failure of Kipp and/or E-Beam to follow regulatory guidelines, the development and commercial marketing of MUSE and

other potential products could be delayed or prevented. An extended interruption in sterilization services or the Company's supply of plastic components would have a material adverse effect on the Company's business, financial condition and results of operations.

DEPENDENCE ON KEY PERSONNEL

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

GOVERNMENT REGULATION

The Company's research, pre-clinical development, clinical studies, manufacturing and marketing of its products are subject to rigorous testing and extensive regulation processes of the FDA and equivalent foreign regulatory agencies. To date, the Company's product MUSE has received marketing clearance in more than 40 countries worldwide.

After regulatory approval is obtained, the Company's products are subject to continual review. Manufacturing, labeling and promotional activities are continually regulated by the FDA and equivalent foreign regulatory agencies, and the Company must also report certain adverse events involving its drugs to these agencies. Previously unidentified adverse events or an increased frequency of adverse events that occur post-approval could result in labeling modifications of approved products, which could adversely affect future marketing. Finally, approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing. The restriction, suspension or revocation of regulatory approvals or any other failure to comply with regulatory requirements would have a material adverse effect on the Company's business, financial condition and results of operations.

Failure to comply with the applicable regulatory requirements can result in fines, suspensions of regulatory approvals, product recalls, operating restrictions and criminal prosecution, among other outcomes. In addition, the marketing and manufacturing of pharmaceutical products are subject to continuing FDA and other regulatory review, and later discovery of previously unknown problems with a product, manufacturer or facility may result in the FDA and other regulatory agencies requiring further clinical research or restrictions on the product or the manufacturer, including withdrawal of the product from the market. The restriction, suspension or revocation of regulatory approvals or any other failure to comply with regulatory requirements would have a material adverse effect on the Company's business, financial condition and results of operations.

Failure to maintain satisfactory compliance with Current Good Manufacturing Practices ("cGMP") would have a material adverse effect on the Company's ability to continue to market and distribute its products and, in the most serious cases, could result in the issuance of additional warning letters, seizure or recall of products, civil fines or closure of the Company's manufacturing facility until such cGMP compliance is achieved.

The Company obtains the necessary raw materials and components for the manufacture of MUSE as well as certain services, such as testing and sterilization, from third parties. The Company currently contracts with suppliers and service providers, including foreign manufacturers that are required to comply with strict standards established by the Company. Certain suppliers and service providers are required by the Federal Food, Drug, and Cosmetic Act, as amended, and by FDA regulations to follow cGMP requirements and are subject to routine periodic inspections by the FDA and by certain state and foreign regulatory agencies for compliance with cGMP requirements and other applicable regulations. Certain of the Company's suppliers were inspected for cGMP compliance as part of the approval process. However, upon routine re-inspection of these facilities, there can be no assurance that the FDA and other regulatory agencies will find the manufacturing process or facilities to be in compliance with cGMP requirements and other regulations.



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Failure to achieve satisfactory cGMP compliance as confirmed by routine inspections could have a material adverse effect on the Company's ability to continue to manufacture and distribute its products and, in the most serious case, result in the issuance of a regulatory warning letter or seizure or recall of products, injunction and/or civil fines or closure of the Company's manufacturing facility until cGMP compliance is achieved.

UNCERTAINTY OF PHARMACEUTICAL PRICING AND REIMBURSEMENT

In the U.S. and elsewhere, sales of pharmaceutical products are dependent, in part, on the availability of reimbursement to the consumer from third party payors, such as government and private insurance plans. Third party payors are increasingly challenging the prices charged for medical products and services. While a large percentage of prescriptions in the U.S. for MUSE have been reimbursed by third party payors since its commercial launch in January 1997, there can be no assurance that the Company's products will be considered cost effective and that reimbursement to the consumer will continue to be available or sufficient to allow the Company to sell its products on a competitive basis.

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

PRODUCT LIABILITY AND AVAILABILITY OF INSURANCE

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

UNCERTAINTY AND POSSIBLE NEGATIVE EFFECTS OF HEALTHCARE REFORM

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

POTENTIAL VOLATILITY OF STOCK PRICE

The stock market has experienced significant price and volume fluctuations unrelated to the operating performance of particular companies. In addition, the market price of the Company's common stock has been highly volatile and is likely to continue to be so. Factors such as the Company's ability to increase demand for its product in the U.S., the Company's ability to successfully sell its product in the U.S. and internationally, variations in the Company's financial results and its ability to obtain needed financing, announcements of technological innovations or new products by the Company or its competition, comments by security analysts, adverse regulatory actions or decisions, any loss of key management, the results of the Company's clinical trials or those of its competition, changing governmental regulations, patents or other proprietary rights, product or patent litigation or public concern as to the safety of products developed by the Company may have a significant effect on the market price of the Company's common stock.



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

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

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

## PART II: OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On September 11, 2000, the Company filed a notice and demand for arbitration with the American Arbitration Association ("AAA") against AndroSolutions, Inc. ("ASI") in connection with certain contractual provisions governing ASIVI, LLC ("ASIVI"), a jointly formed and owned limited liability company. The Company was seeking an award declaring that it was not liable to ASI for a $625,000 milestone payment that ASI claimed was due under the parties' Memorandum of Understanding dated October 14, 1999 (the "MOU"). The Company also sought an award directing ASI's specific performance of other non-monetary contractual obligations. On October 5, 2000, ASI responded to the arbitration demand, denying all claims and asserting its entitlement to the $625,000 milestone payment. ASI also asserted counterclaims seeking an award directing VIVUS' specific performance of other non-monetary contractual obligations. In July 2001, the Company reached an agreement with ASI in the settlement of all claims. Under the terms of the settlement agreement, the Company acquired ASI's rights and interest in ASIVI including all intellectual property initially contributed by ASI and the Company. In addition, the parties agreed to terminate and/or modify the agreements entered into upon establishing ASIVI. The Company made a payment of $750 thousand to ASI upon execution of the settlement agreement. The Company may also make additional payments to ASI in the future based on the Company's achieving certain development milestones and royalties on net sales of products covered by the intellectual property, which, in the aggregate, are substantially the same as those required under the previous agreements.

On August 23, 2000, the Company received a notice of demand for arbitration from ALZA Corporation ("ALZA") alleging a breach of a sales force transition agreement dated July 6, 1998. The sales force transition agreement provided for the transition of VIVUS' sales force to ALZA, where they would promote both VIVUS' and ALZA's products for a period of time. The agreement further provided that the Company indemnify ALZA for claims brought by any member of the sales force relating to such person's employment (or termination) by VIVUS. ALZA alleged that it was entitled to indemnification from the Company for ALZA's attorneys' fees and amounts paid to settle claims relating to ALZA's failure to hire a former Company employee. In June 2001, the Company received the Arbitrator's ruling, which requires the Company to reimburse ALZA for approximately $550 thousand in fees and expenses for this matter.

On May 19, 2000, the Company was named, along with other defendants, in a civil action filed in the Superior Court of New Jersey. The Complaint in this action alleges that plaintiff was the victim of sexual harassment during the second quarter of 1998, while she was working as a temporary worker for the Company at a facility operated by PACO Pharmaceutical Services, Inc. At the time, the Company was leasing space and workers from PACO to assist it with the manufacture of the Company's product, MUSE. The complaint alleges hostile work environment and quid pro quo sexual harassment, and seeks compensatory and punitive damages. The Company denies liability, and intends to defend the case vigorously. At this early stage in the litigation, it is not possible to predict the outcome of the suit with any degree of certainty. In addition, plaintiff has not yet provided the Company with information concerning the extent of her alleged damages, so it is not possible to estimate the extent of any loss in the event plaintiff prevails against the Company. Nevertheless, an adverse judgment in this litigation is not expected to have a material impact on the Company's financial position.

On November 3, 1999, the Company filed a demand for arbitration against Janssen Pharmaceutica International ("Janssen") with the AAA pursuant to the terms of the Distribution Agreement entered into on January 22, 1997. The Company seeks compensation for inventory manufactured in 1998 in reliance on contractual forecasts and orders submitted by Janssen. The Company also seeks compensation for forecasts and order shortfalls attributed to Janssen in 1998, pursuant to the terms of the Distribution Agreement. The Company amended its arbitration demand in August 2000 to include claims for lost profits due to Janssen's failure to use the requisite diligence and reasonable efforts to gain regulatory approval for and launch MUSE in each country of the Territory. This amendment also includes claims based on Janssen's development of a competing product intended for use in the treatment of male ED, in violation of the Distribution Agreement. The Company's amended demand seeks an award of $7.9 million plus costs and interest. On October 20, 2000, Janssen submitted its response to the Company's amended arbitration demand denying liability on all claims, and asserting counterclaims against the Company for $1.8 million based on the Company's alleged improper calculation of its cost of goods charged to Janssen pursuant to the Distribution Agreement. On November 20, 2000, the Company filed its response to the counterclaims, denying all liability. The Company believes that Janssen's counterclaims are without merit and intends to defend against them vigorously. Administration of the arbitration has been transferred to JAMS and a three-member arbitration panel has been selected. The parties are currently in the process of conducting discovery and anticipate an arbitration hearing in October 2001.

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

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

None

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None

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

The annual meeting of stockholders was held on June 14, 2001. Matters voted on at that meeting were: (i) the election of six directors, and (ii) the confirmation of the appointment of Arthur Andersen LLP as independent public accountants for the fiscal year ended December 31, 2001. Tabulations for each proposal and individual director were as follows:





Proposal I. Election of Directors

| DIRECTOR | FOR | WITHHELD |
|---|---|---|
| Virgil A. Place, MD | 27,917,514 | 1,378,233 |
| Leland F. Wilson | 27,886,608 | 1,409,139 |
| Mark B. Logan | 28,242,851 | 1,052,896 |
| Linda M. Dairiki Shortliffe, MD | 28,183,752 | 1,111,995 |
| Mario M. Rosati | 28,242,897 | 1,052,850 |
| Graham Strachan | 28,243,112 | 1,052,635 |

Proposal II. Confirmation of the Appointment of Arthur Andersen LLP

| FOR | AGAINST | ABSTAIN | NO VOTE |
|---|---|---|---|
| 29,088,020 | 112,688 | 95,039 | — |

ITEM 5. OTHER INFORMATION

None

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

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

| EXHIBIT NUMBER | DESCRIPTION |
|---|---|
| 3.2(7) | Amended and Restated Certificate of Incorporation of the Company |
| 3.3(4) | Bylaws of the Registrant, as amended |
| 3.4(8) | Certificate of Designations of Rights, Preferences and Privileges of Series A Participating Preferred Stock |
| 4.1(7) | Specimen Common Stock Certificate of the Registrant |
| 4.2(7) | Registration Rights, as amended |
| 4.4(1) | Form of Preferred Stock Purchase Warrant issued by the Registrant to Invemed Associates, Inc., Frazier Investment Securities, L.P., and Cristina H. Kepner |
| 4.5(8) | Second Amended and Restated Preferred Shares Rights Agreement, dated as of April 15, 1997 by and between the Registrant and Harris Trust Company of California, including the Certificate of Determination, the form of Rights Certificate and the Summary of Rights attached thereto as Exhibits A, B, and C, respectively |
| 10.1(1)+ | Assignment Agreement by and between Alza Corporation and the Registrant dated December 31, 1993 |
| 10.2(1)+ | Memorandum of Understanding by and between Ortho Pharmaceutical Corporation and the Registrant dated February 25, 1992 |
| 10.3(1)+ | Assignment Agreement by and between Ortho Pharmaceutical Corporation and the Registrant dated June 9, 1992 |
| 10.4(1)+ | License Agreement by and between Gene A. Voss, MD, Allen C. Eichler, MD, and the Registrant dated December 28, 1992 |
| 10.5A(1)+ | License Agreement by and between Ortho Pharmaceutical Corporation and Kjell Holmquist AB dated June 23, 1989 |
| 10.5B(1)+ | Amendment by and between Kjell Holmquist AB and the Registrant dated July 3, 1992 |
| 10.5C(1) | Amendment by and between Kjell Holmquist AB and the Registrant dated April 22, 1992 |
| 10.5D(1)+ | Stock Purchase Agreement by and between Kjell Holmquist AB and the Registrant dated April 22, 1992 |
| 10.6A(1)+ | License Agreement by and between Amsu, Ltd., and Ortho Pharmaceutical Corporation dated June 23, 1989 |
| 10.6B(1)+ | Amendment by and between Amsu, Ltd., and the Registrant dated July 3, 1992 |
| 10.6C(1) | Amendment by and between Amsu, Ltd., and the Registrant dated April 22, 1992 |
| 10.6D(1)+ | Stock Purchase Agreement by and between Amsu, Ltd., and the Registrant dated July 10, 1992 |
| 10.11(4) | Form of Indemnification Agreements by and among the Registrant and the Directors and Officers of the Registrant |



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| EXHIBIT NUMBER | DESCRIPTION |
|---|---|
| 10.12(2) | 1991 Incentive Stock Plan and Form of Agreement, as amended |
| 10.13(1) | 1994 Director Option Plan and Form of Agreement |
| 10.14(1) | Form of 1994 Employee Stock Purchase Plan and Form of Subscription Agreement |
| 10.17(1) | Letter Agreement between the Registrant and Leland F. Wilson dated June 14, 1991 concerning severance pay |
| 10.21(3)+ | Distribution Services Agreement between the Registrant and Synergy Logistics, Inc. (a wholly-owned subsidiary of Cardinal Health, Inc.)+ dated February 9, 1996 |
| 10.22(3)+ | Manufacturing Agreement between the Registrant and CHINOIN Pharmaceutical and Chemical Works Co., Ltd. dated December 20, 1995 |
| 10.22A(11)+ | Amendment One, dated as of December 11, 1997, to the Manufacturing Agreement by and between VIVUS and CHINOIN Pharmaceutical and Chemical Works Co., Ltd. dated December 20, 1995 |
| 10.23(6)+ | Distribution and Services Agreement between the Registrant and Alternate Site Distributors, Inc. dated July 17, 1996 |
| 10.24(5)+ | Distribution Agreement made as of May 29, 1996 between the Registrant and ASTRAZ AB |
| 10.24A(14)+ | Amended Distribution Agreement dated December 22, 1999 between AstraZeneca and the Registrant |
| 10.27(11)+ | Distribution Agreement made as of January 22, 1997 between the Registrant and Janssen Pharmaceutica International, a division of Cilag AG International |
| 10.27A(11)+ | Amended and Restated Addendum 1091, dated as of October 29, 1997, between VIVUS International Limited and Janssen Pharmaceutica International |
| 10.28(7) | Lease Agreement made as of January 1, 1997 between the Registrant and Airport Associates |
| 10.29(7) | Lease Amendment No. 1 as of February 15, 1997 between Registrant and Airport Associates |
| 10.29A(10) | Lease Amendment No. 2 dated July 24, 1997 by and between the Registrant and Airport Associates |
| 10.29B(10) | Lease Amendment No. 3 dated July 24, 1997 by and between the Registrant and Airport Associates |
| 10.31(9)+ | Manufacture and Supply Agreement between Registrant and Spolana Chemical Works, A.S. dated May 30, 1997 |
| 10.32A(11) | Agreement between ADP Marshall, Inc. and the Registrant dated December 19, 1997 |
| 10.32B(11) | General Conditions of the Contract for Construction |
| 10.32C(11) | Addendum to General Conditions of the Contract for Construction |
| 10.34(12)+ | Agreement dated as of June 30, 1998 between Registrant and Alza Corporation |
| 10.35(12)+ | Sales Force Transition Agreement dated July 6, 1998 between Registrant and Alza Corporation |
| 10.36(13) | Form of, “Change of Control Agreements,” dated July 8, 1998 by and between the Registrant and certain Executive Officers of the Company. |
| 10.30A(13) | Amendment of lease agreement made as of October 19, 1998 by and between Registrant and 605 East Fairchild Associates, L.P. |
| 10.37(13) | Sublease agreement made as of November 17, 1998 between Caliper Technologies, Inc. and Registrant |
| 10.22B(13)+ | Amendment Two, dated as of December 18, 1998 by and between VIVUS, Inc. and CHINOIN Pharmaceutical and Chemical Works Co. |
| 10.31A(13)+ | Amendment One, dated as of December 12, 1998 by and between VIVUS, Inc. and Spolana Chemical Works, A.S. |
| 10.38(14)+ | License Agreement by and between ASIVI, LLC, AndroSolutions, Inc., and the Registrant dated February 29, 2000 |
| 10.38A(14)+ | Operating Agreement of ASIVI, LLC, between AndroSolutions, Inc. and the Registrant dated February 29, 2000 |
| 10.39(14) | Sublease agreement between KVO Public Relations, Inc. and the Registrant dated December 21, 1999 |
| 10.40(15)+ | License and Supply Agreement made as of May 23, 2000 between the Registrant and Abbott Laboratories, Inc. |
| 10.41(16)+ | License and Supply Agreement made as of November 20, 2000 between the Registrant and Paladin Labs, Inc. |
| 10.42(16)+ | Development, License and Supply Agreement made as of January 22, 2001 between the Registrant and TANABE SEIYAKU CO., |

LTD.



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| EXHIBIT NUMBER | DESCRIPTION |
|---|---|
| 10.43++ | Settlement and Modification Agreement made as of July 12, 2001 between ASIVI, LLC, AndroSolutions, Inc. Gary W. Neal and the Registrant. |

+ Confidential treatment granted.
++ Confidential treatment requested.
(1) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Registration Statement on Form S-1 No. 33-75698, as amended.
(2) Incorporated by reference to the same numbered exhibit filed with the Registrant's Registration Statement on Form S-1 No. 33-90390, as amended.
(3) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1995, as amended.
(4) Incorporated by reference to the same numbered exhibit filed with the Registrant's Form 8-B filed with the Commission on June 24, 1996.
(5) Incorporated by reference to the same numbered exhibit filed with the Registrant's Current Report on Form 8-K/A filed with the Commission on June 21, 1996.
(6) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1996.
(7) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1996, as amended.
(8) Incorporated by reference to exhibit 99.1 filed with Registrant's Amendment Number 2 to the Registration Statement of Form 8-A (File No. 0-23490) filed with the Commission on April 23, 1997.
(9) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1997.
(10) Incorporated by reference to the same numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1997.
(11) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1997.
(12) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1998.
(13) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1998.
(14) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1999.
(15) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2000.
(16) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 2000.

(b) REPORTS ON FORM 8-K

None



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SIGNATURES

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

Date: August 9, 2001

VIVUS, Inc.

/s/ RICHARD WALLISER

Richard Walliser
Vice President and Chief Financial Officer

/s/ LELAND F. WILSON

Leland F. Wilson
President and Chief Executive Officer



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VIVUS, INC.

INDEX TO EXHIBITS*

| EXHIBIT | DESCRIPTION |
|---|---|
| 10.43 | Settlement and Modification Agreement made as of July 12, 2001 between ASIVI, LLC, AndroSolutions, Inc. Gary W. Neal and the Registrant. |

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

EXHIBIT 10.43

# SETTLEMENT AND MODIFICATION AGREEMENT

THIS SETTLEMENT AND MODIFICATION AGREEMENT (the "Settlement Agreement"), effective as of the date upon which all parties have signed below (the "Effective Date"), is by and between ASIVI, LLC, a Delaware limited liability company, with offices at 1172 Castro Street, Mountain View, California 94040 ("ASIVI"), VIVUS, INC., a Delaware corporation with a principal place of business at 1172 Castro Street, Mountain View, California 94040 ("VI"), ANDROSOLUTIONS, INC., a Tennessee corporation with a principal place of business at Suite 309, 200 Fort Sanders West Blvd., Knoxville, TN 37922 (collectively with its Affiliates, "ASI"), and Gary W. Neal, M.D., a natural person residing at 4701 Guinn Road, Knoxville, TN 37931 ("GWN").

## BACKGROUND

WHEREAS, the parties have commenced arbitration proceedings before the American Arbitration Association captioned VIVUS, Inc. v. AndroSolutions, Inc.;

WHEREAS, the parties, without admitting liability, wish to settle their dispute by terminating and/or modifying the following agreements previously entered into by the parties and by entering into this Settlement Agreement: the Memorandum of Understanding dated October 14, 1999 ("MOU"); the Confidentiality and Non-Disclosure Agreement dated December 16, 1999 (the "Confidentiality Agreement"); the ASIVI, LLC Operating Agreement dated February 29, 2000 ("Operating Agreement"); the License Agreement dated February 29, 2000 ("License Agreement"); and the Manufacture and Supply Agreement dated February 29, 2000 ("Manufacture and Supply Agreement");

WHEREAS, ASI and VI formerly owned certain intellectual property consisting of issued patents and/or pending patent applications relating to, inter alia, the design, development, manufacture and use of products containing a prostaglandin and/or other vasodilator for the treatment of female sexual dysfunction ("FSD") which VI and ASI each assigned to ASIVI;

WHEREAS, VI desires to obtain, and ASIVI desires to assign, the FSD IP (as defined below) to develop and commercialize Products (as defined below) for the treatment of FSD, on the terms and conditions herein;

WHEREAS, VI desires to obtain, and ASI desires to assign, ASI's entire interest in ASIVI;

WHEREAS, VI desires to obtain, and ASI desires to assign, the Supplemental FSD IP (as defined below); and

WHEREAS, VI, in partial consideration for the assignment of the FSD IP, the Supplemental FSD IP, and assignment of ASI's interest in ASIVI, and in order to settle the dispute which is the subject of the arbitration with ASI, is willing to make an upfront payment, certain milestone payments, and royalty payments to ASI, and ASI is willing to accept such payments on the terms and conditions herein.

NOW, THEREFORE, in consideration of the mutual covenants and undertakings set out herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, ASIVI, VI, ASI and GWN agree as follows:

1. DEFINITIONS

1.1. "Affiliate" shall mean any corporation or other entity that controls, is controlled by or is under common control with a party. For purposes of this definition only, "control" shall mean ownership or control, directly or indirectly, of more than fifty percent (50%) of the shares or other rights of the subject entity entitled to vote in the election of directors (or, in the case of an entity that is not a corporation, to the election of the corresponding managing authority).

1.2. "Commercially Reasonable Efforts" shall, with respect to a Product, mean efforts and resources equivalent to those normally employed by entities in the biopharmaceutical marketplace, substantially comparable to VI, to develop, manufacture, market or sell a product of similar market potential at a similar stage in its product life, taking into account for example the establishment of the Product in the marketplace, the competitiveness of alternative products, the proprietary position of the Product, the likelihood of regulatory approval, including consideration of safety and efficacy, for the Product given the regulatory authority and structure involved, the profitability of the Product and VI's available resources. Commercially Reasonable Efforts shall be determined on a market-by-market basis for each Product.

1.3. "Confidential Information" shall mean only such information of another party to this Settlement Agreement that may be reasonably understood from legends or oral designations, the nature of the information itself or the circumstances of such information's disclosure, to be confidential or proprietary to another party or to a third party to which another party owes a duty of non-disclosure.

1.4. "First Commercial Sale" shall mean, with respect to each Product in each country, the first bona fide commercial sale of such Product in such country by or under authority of VI.

1.5. "FDA" shall mean the U.S. Food and Drug Administration, or any successor agency.

1.6. "FSD IP" shall mean the Know How and Patent Rights, in each case that are owned or controlled by ASIVI as of the Effective Date, and all U.S. and foreign patents and patent applications claiming priority to the Patent Rights.

1.6.1. "Patent Rights" shall mean all United States and foreign patents (including all reissues, extensions, substitutions, re-examinations, supplementary protection certificates, and the like, and patents of addition) and pending patent applications (including without limitation all continuations, continuations-in-part and divisionals thereof) relating to, inter alia, the design, development, manufacture, and use of products containing a prostaglandin and/or other vasodilator for the treatment of FSD.

1.6.2. "Know How" shall mean the Confidential Information owned or controlled by ASIVI pursuant to the terms of the MOU and/or the Operating Agreement necessary for the exercise of the Patent Rights, including technical data, protocols and methods.

1.7. "IP Information" shall mean (***) the FSD IP formerly owned by ASI, and assigned to ASIVI pursuant to the Assignment Agreement executed by ASI and included in Exhibit 2 to the Operating Agreement along with the (***). IP Information shall include (***) in the FSD IP. IP Information shall further include (***)of the FSD IP.

1.8. "Licensee" shall mean a third party to whom VI has granted a license or other right under the FSD IP to make, have made, import, have imported, export, have exported, distribute, have distributed, sell, have sold, use, or offer for sale Products.

1.9. "NDA" shall mean a New Drug Application submitted to the FDA.

1.10. "Net Sales."

1.10.1. "Net Sales by Licensees" shall mean the amount invoiced by VI's Licensees (for purposes of this definition, as applicable, the "Selling Party") for the sale of Products to bona fide independent third parties throughout the world, less (i) ordinary and customary trade discounts actually allowed by the Selling Party to the third party purchaser; (ii) credits, rebates and returns allowed and credited to the third party purchaser (including, but not limited to, wholesaler and retailer returns); (iii) freight, handling and duties paid on shipments by the Selling Party to the third party purchaser and separately identified on the invoice; and (iv) sales taxes, excise taxes, consumption taxes, customs duties and other compulsory payments to governmental authorities actually paid with respect to the sale by the Selling Party to the third party purchaser. For the avoidance of doubt, Net Sales by Licensees shall not include sales by a Selling Party to its Affiliates for resale; provided, however, that if the Selling Party sells a Product to an Affiliate for resale, Net Sales by Licensees shall include the amounts invoiced by such Affiliate to third parties on the resale of such Product.

1.10.2. "Net Sales by VI" shall mean the amount invoiced by VI or its Affiliates (for purposes of this definition, as applicable, the "Selling Party") for the sale of Products to bona fide independent third parties throughout the world, less (i) ordinary and customary trade discounts actually allowed by the Selling Party to the third party purchaser; (ii) credits, rebates and returns allowed and credited to the third party purchaser (including, but not limited to, wholesaler and retailer returns); (iii) freight, handling and duties paid on shipments by the Selling Party to the third party purchaser and separately identified on the invoice; and (iv) sales taxes, excise taxes, consumption taxes, customs duties and other compulsory payments to governmental authorities actually paid with respect to the sale by the Selling Party to the third party purchaser. For the avoidance of doubt, Net Sales by VI

shall not include sales by a Selling Party to its Affiliates or Licensees for resale; provided, however, that if the Selling Party sells a Product to an Affiliate or Licensees for resale, Net Sales shall include the amounts invoiced by such Affiliate or Licensees to third parties on the resale of such Product. For avoidance of doubt, Net Sales by VI shall also include Third Party Payments for the purpose of calculating royalties payable under Section 2.3.1.

1.10.3. "Bundles." In the case of discounts on "bundles" of products or services which include Products, Net Sales by Licensees and Net Sales by VI will be calculated by discounting the bona fide list price of such Product by the average percentage discount of all products of VI and/or its Licensees in a particular "bundle," calculated as follows:

Average percentage discount on a particular bundle = (1 - A/B) x 100

where A equals the total discounted price of a particular "bundle" of products, and B equals the sum of the undiscounted bona fide list prices of each unit of every product in such "bundle." VI shall provide ASI documentation, reasonably acceptable to ASI, establishing such average discount with respect to each "bundle." If VI cannot so establish the average discount of a "bundle," Net Sales shall be based on the undiscounted list price of the Products in the "bundle." If a Product in a "bundle" is not sold separately and no bona fide list price exists for such Product, the parties shall negotiate in good faith an imputed list price for such Product, and Net Sales with respect thereto shall be based on such imputed list price.

1.11. "Product" shall mean any product containing a prostaglandin and/or other vasodilator within the Field of Use, the sale of which would infringe upon a Valid Claim.

1.12. "Valid Claim" means (i) a claim of an issued and unexpired patent included within the Patent Rights which has not been held unenforceable or invalid by a court or other governmental agency of competent jurisdiction, and which has not been disclaimed or admitted to be invalid or unenforceable through reissue or otherwise, or (ii) a claim of a pending patent application within the Patent Rights.

1.13. "Field of Use" shall mean the diagnosis, prophylaxis and/or treatment involving female sexual dysfunction ("FSD"), including without limitation enhancing female sexual desire and responsiveness, and preventing, treating and/or managing female sexual arousal disorder, orgasmic disorder, and pain disorder.

1.14. "Third Party Payments" shall mean any and all cash and non-cash consideration received by VI or VI's Affiliates for the grant of a license or other right attributable to the FSD IP related to the manufacturing, marketing, promotion, distribution, or sale of Products or other method, process or procedure covered by the FSD IP, including but not limited to initial lump-sum payments and milestones. All non-cash consideration will be valued at the fair market value thereof established by agreement of the parties or, failing that, by a qualified "Big 5" or

national independent accountant approved by VI and ASI. VI will bear the cost of such accountant. Third Party Payments shall be included within the definition of Net Sales by VI as of the date such Third Party Payments are actually received by VI for purposes of determining the applicable percentage of Third Party Payments to be paid to ASI under Section 2.3.1 of this Settlement Agreement.

1.15. "Novel Chemical Entity" shall mean a new composition of matter having a molecular structure that was not previously found in nature or synthesized, and that is or comes to be conceived of or developed by ASI or GWN during the term of this Settlement Agreement.

1.16. "Supplemental FSD IP" shall mean the patents and/or patent applications identified in Technology Assignment Agreement C, attached hereto as Exhibit 3.

2. PAYMENTS

2.1. Upfront Payment. Within three (3) business days of the Effective Date, VI shall deposit with its counsel, Wilson Sonsini Goodrich & Rosati, a check in the sum of $750,000, payable to ASI, pending confirmation that pursuant to Section 12.1 ASI has furnished its counsel, Rothwell Figg Ernst & Manbeck, with all IP materials described in Section 12.1 and that ASI has directed its counsel to deposit such materials for overnight delivery to VI counsel. Upon receipt of such confirmation, VI shall direct its counsel to likewise deposit the $750,000 payment for overnight delivery to ASI counsel. VI shall ensure that the bank account from which the $750,000 check is drawn is sufficiently funded to allow for the immediate availability of the $750,000 upon ASI's deposit of said check. For the avoidance of doubt, the depositing of the $750,000 payment for overnight delivery to ASI counsel shall be made on the same day as the deposit of IP materials for overnight delivery to VI counsel under Section 12.1 of this Settlement Agreement.

2.1.1. ASI Right to Rescind. In the event that VI fails to deliver payment to ASI under this Section 2.1, ASI shall have the right to rescind this Settlement Agreement in its entirety.

2.2. Milestone Payments. VI agrees to make the following one-time payments to ASI within thirty (30) days after achievement of the specified milestone: (i) (***) upon the first submission, by VI or on VI's behalf, of an NDA for a product covered by the Patent Rights; and (ii) (***) upon the first approval of an NDA for a product covered by the Patent Rights.

2.3. Continuing Payments.

2.3.1. Payment to ASI on Net Sales by VI or its Affiliates. VI shall make payments to ASI at the applicable percentage of annual Net Sales by VI, as defined herein, as follows:

| Annual Net Sales by VI | Payment Rate |
|---|---|
| Up to (***) | (***) |
| (***)up to (***) | (***) |
| (***)up to (***) | (***) |
| Equal to or greater than (***) | (***) |

2.3.2. Payment to ASI on Net Sales for Products Sold by Licensees. VI shall make payments to ASI at the applicable percentage of annual Net Sales by Licensees, as defined herein, as follows:

| Annual Net Sales by Licensees | Payment Rate |
|---|---|
| Up to (***) | (***) |
| (***)up to (***) | (***) |
| (***)up to (***) | (***) |
| (***)up to (***) | (***) |
| Equal to or greater than (***) | (***) |

2.3.3. Third Party Royalties. If VI, or any Affiliate or Licensees of VI, becomes obligated to pay to third parties royalties or other amounts with respect to any Product through litigation or under agreements for patent rights or other technologies which VI or such Affiliate or Licensee determines are desirable to license or acquire with respect to such Product, VI shall be responsible for making such payments. VI shall not deduct such payments from any payments to ASI, and such payments shall not be deducted from gross invoiced amounts for Products in calculating Net Sales.

2.3.4. One Payment. No more than one payment shall be due to ASI with respect to a sale of a particular Product or for a Third Party Payment received by VI.

2.3.5. Payment Term. The payments due under this Section 2.3 shall be payable until the expiration of the last to expire Valid Claim.

3. PAYMENTS; REPORTS; AND RECORDS

3.1. Payments.

3.1.1. Timing of Payments. After the First Commercial Sale of a Product on which royalties are payable hereunder, VI shall make quarterly written reports to ASI within sixty (60) days after the end of each calendar quarter, stating in such report, separately for Net Sales by VI and Net Sales by Licensees, the number, description and aggregate Net Sales, by country, of each Product sold during the calendar quarter upon which a royalty is

payable. Concurrently with the making of such reports, VI shall pay to ASI payments due at the rates specified hereunder. This Section 3.1.1 shall not apply to any payments for Third Party Payments.

3.1.2. Timing of Payments for Third Party Payments. Within thirty (30) days following VI's actual receipt of any Third Party Payment, VI shall pay any amount due ASI for such Third Party Payment, at the applicable percentage set forth in Section 2.3.1, and provide written notice to ASI indicating the amount of Third Party Payment received and the percentage rate applied to such amount.

3.1.3. Payment Method. All payments due under this Settlement Agreement shall be made by bank wire transfer in immediately available funds to a bank account designated by ASI, with the exception of the Upfront Payment set forth in Section 2.1 above. All payments due to ASI hereunder shall be paid in United States dollars.

3.1.4. Currency Conversion. If any currency conversion shall be required in connection with the calculation of amounts payable hereunder, such conversion shall be made using the buying exchange rate for conversion of the foreign currency into U.S. Dollars, quoted for current transactions reported in The Wall Street Journal (U.S., Western Edition) for the last business day of the calendar quarter to which such payment pertains.

3.1.5. Taxes. All payments required to be paid to ASI pursuant to this Settlement Agreement shall be paid with deduction for withholding for or on account of any applicable sales, use, value-added, or other federal, state or local taxes or import duties or tariffs, or similar governmental charges imposed by a jurisdiction other than the United States ("Withholding Taxes"). VI shall provide ASI a certificate evidencing payment of any Withholding Taxes hereunder, and shall provide any further assistance reasonably requested by ASI to enable ASI to obtain the benefit of any deduction.

3.2. Reports; Inspection. VI shall maintain accurate books and records that enable the calculation of royalties payable hereunder to be verified. VI shall retain the books and records for each calendar year period for three (3) years after the submission of the corresponding report under Section 3.1.1 hereof. Upon thirty (30) days prior notice to VI, independent accountants selected by ASI, which shall be from a "Big 5" or national accounting firm and reasonably acceptable to VI, after entering into a confidentiality agreement with VI, may have access to VI's books and records during VI's normal business hours to conduct a review or audit once per calendar year, for the sole purpose of verifying the accuracy of VI's payments and compliance with this Settlement Agreement. Any such inspection or audit shall be at ASI's expense, however, if an inspection reveals underpayment of five percent (5%) or more in any audit period, VI shall pay the costs of the inspection. VI shall promptly pay to ASI any underpayment identified in such an audit.

4. CONFIDENTIALITY

4.1. Termination of Confidentiality Agreement. The Confidentiality and Non-Disclosure Agreement, dated December 16, 1999, by and between ASI, VI and ASIVI, is hereby terminated and any information deemed Confidential Information under that Confidentiality and Non-Disclosure Agreement shall be deemed Confidential Information under this Settlement Agreement.

4.2. Confidentiality Obligations. Except as expressly provided herein, the party in receipt of Confidential Information (the "Receiving Party") shall not disclose to any third party or use for any purpose any Confidential Information furnished to it by the other party (the "Disclosing Party"). Notwithstanding the foregoing, Confidential Information shall not include any information that, in each case as demonstrated by written documentation: (i) was already known to the Receiving Party, other than under an obligation of confidentiality, at the time of disclosure; (ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party; (iii) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the Receiving Party in breach of this Settlement Agreement; (iv) was subsequently lawfully disclosed to the Receiving Party by a third party who did not acquire it directly or indirectly from the Disclosing Party; or (v) was developed by the Receiving Party without use of or reference to any Confidential Information of the Disclosing Party.

4.3. Permitted Use and Disclosures. The Receiving Party may use and disclose the Confidential Information of the Disclosing Party to the extent necessary to exercise its rights or perform its obligations under this Settlement Agreement, in filing or prosecuting applications and patents, prosecuting or defending litigation, complying with applicable governmental regulations or court order or otherwise submitting information to tax or other governmental authorities, conducting trials, or making a permitted sublicense or otherwise exercising rights expressly granted to it pursuant to the terms of this Settlement Agreement, provided that if the Receiving Party is required to make any such disclosures of the Disclosing Party's Confidential Information, other than pursuant to a confidentiality agreement, it shall give reasonable advance notice to the Disclosing Party of such disclosure and, save to the extent inappropriate in the case of patent applications, shall use its reasonable efforts to secure confidential treatment of such Confidential Information in consultation with the Disclosing Party prior to its disclosure (whether through protective orders or otherwise) and disclose only that portion of the Confidential Information necessary to comply with such requirements.

4.4. Confidential Terms. Each party agrees not to disclose any terms of this Settlement Agreement to any third party without the consent of the other party; provided, disclosures may be made as necessary in the exercise of a party's rights under this Settlement Agreement, as required by securities or other applicable laws, or to a party's accountants, attorneys and other professional advisors, or by VI, ASIVI, and ASI to actual or prospective investors or corporate partners.

4.5. Information Furnished Under Settlement Agreement. All information and materials furnished by a party to another party pursuant to or in connection with the terms of this Settlement Agreement shall be treated as Confidential Information, including but not limited to information furnished under Sections 3.1, 12.1, and 15.9.

5. REPRESENTATIONS, WARRANTIES AND COVENANTS

5.1. ASIVI. ASIVI represents and warrants to VI, ASI, and GWN that: (i) it is a limited liability company duly organized, validly existing and in good standing under the laws of the State of Delaware; and (ii) the execution, delivery and performance of this Settlement Agreement have been duly authorized by all necessary company action on the part of ASIVI; (iii) it is the sole, equal, and exclusive owner of all right, title and interest in the FSD IP; (iv) it has the right to grant the rights granted herein, and the FSD IP is free and clear of any lien, encumbrance or security interest; (v) it has not previously granted, and will not grant, any right, license or interest in and to the FSD IP, or any portion thereof, inconsistent with the assignment to VI; and (vi) there are no threatened or pending actions, lawsuits, claims or arbitration proceedings in any way relating to the FSD IP, other than the arbitration proceeding referenced in the Recitals above.

5.2. VI. VI represents, warrants and covenants to ASIVI, ASI, and GWN that: (i) it is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware; (ii) the execution, delivery and performance of this Settlement Agreement have been duly authorized by all necessary corporate action on the part of VI; (iii) it will use Commercially Reasonable Efforts to develop and commercialize Products under the FSD IP; and (iv) it will use good faith efforts to obtain and maintain the Patent Rights.

5.3. ASI, GWN. ASI and GWN represent, warrant and covenant to VI and ASIVI as follows:

5.3.1. ASI is a corporation duly organized, validly existing and in good standing under the laws of the State of Tennessee.

5.3.2. The execution, delivery and performance of this Settlement Agreement have been duly authorized by all necessary corporate action on the part of ASI.

5.3.3. The Supplemental FSD IP includes all patents and pending patent applications, which are owned or controlled as of the Effective Date by ASI or GWN, or their Affiliates or beneficiaries, that that relate to the Field of Use; that, as of the Effective Date, no other such patents or patent applications exist; that, as of the Effective Date, neither ASI nor GWN, nor their Affiliates or beneficiaries, have transferred, assigned or licensed any rights in such patents and patent applications to any third-party; and that there are no threatened or pending actions, lawsuits, claims or arbitration proceedings in any way

relating to such patents and patent applications, other than the arbitration proceeding referenced in the Recitals above;

5.3.4. ASI and GWN have previously transferred to ASIVI all of the patents and pending patent applications owned or controlled as of February 29, 2000 by ASI or GWN, or their Affiliates or beneficiaries, that relate to the design, development, manufacture, or use of products containing a prostaglandin and/or other vasodilator within the Field of Use; and

5.3.5. ASI and GWN have, concurrent with the execution of this Settlement Agreement, assigned to VI all of the patents and pending patent applications owned or controlled as of the Effective Date by ASI or GWN, or their Affiliates or beneficiaries, that relate to the Field of Use.

5.3.6. ASI and GWN have not assigned, licensed, sold or otherwise transferred any patents or patent applications that relate to the Field of Use during the period from February 29, 2000 up to and including the Effective Date of this Settlement Agreement

6. INTELLECTUAL PROPERTY

6.1. Prosecution and Maintenance of Patent Rights. As provided by Technology Assignment Agreement A, Technology Assignment Agreement B, and Technology Assignment Agreement C, attached hereto as Exhibits 1, 2 and 3, respectively, VI shall, at its expense, have the sole right to file, prosecute, maintain and enforce the Patent Rights, including without limitation the patents and patent applications encompassed thereby. VI shall not be entitled to offset any amount expended in connection with such activities against payments, if any, due under Article 2 of this Settlement Agreement. ASI and GWN shall provide any cooperation reasonably requested by VI in connection therewith, including but not limited to the IP Information delivered to VI pursuant to Section 12.1 below.

6.2. No Liens. ASIVI or VI shall not incur, nor suffer to exist, any lien, claim or other encumbrance on any of the FSD IP.

6.3. Enforcement. If either ASIVI, ASI, or GWN become aware that any Patent Rights are being infringed by any third party, such party shall promptly notify VI in writing describing the facts relating thereto in reasonable detail. As provided in Technology Assignment Agreement A, Technology Assignment Agreement B and Technology Assignment Agreement C, attached hereto as Exhibits 1, 2 and 3, respectively, VI shall have the sole right, in its discretion, to institute any action, suit or proceeding, including any declaratory judgment action (each an "Action"), at its expense, using counsel of its choice. ASI shall provide any cooperation reasonably requested by VI in connection with any such Action, at VI's expense. VI shall retain any amount recovered in any such Action, but shall not be entitled to offset any amount expended in connection with any such Action against payments, if any, due under Article 2.

7. DISPUTE RESOLUTION

7.1. Settlement of Disputes. The parties will attempt to settle any dispute, controversy or claim between them arising out of or relating to the validity, construction, enforceability or performance of this Settlement Agreement, including disputes relating to alleged breach or to termination of this Settlement Agreement (each, a "Dispute") through consultation and negotiation in good faith and in the spirit of mutual cooperation.

7.2. Failure to Settle Dispute. If those attempts fail, then the Dispute may be made the subject of a lawsuit. If VI or ASIVI initiates such a suit, it shall be filed and litigated in the state or federal court in or for Knoxville, Tennessee. If ASI or GWN initiates such a suit, it shall be filed and litigated in the state or federal court in or for Santa Clara County, California.

7.3. Specific Performance. The parties hereto acknowledge that recovery of damages will be an inadequate remedy for a breach of the provisions of this Settlement Agreement and agree that, in the event of any such breach or threatened breach, the respective rights and obligations hereunder shall be enforceable by specific performance, injunction, or other equitable relief, but nothing herein contained is intended to, nor shall it, limit or affect any rights at law or by statute or otherwise of any party aggrieved as against another for such breach, it being the intention of the parties by this Section 7.3 to make clear their agreement that their respective rights and obligations in this Settlement Agreement shall be enforceable in equity as well as at law or otherwise.

7.4. Expenses. Should any party breach this Settlement Agreement, in addition to all other remedies available at law or in equity or otherwise, such party shall pay all of any other party's costs and expenses resulting therefrom and/or incurred in enforcing this Settlement Agreement, including legal fees and expenses.

8. INDEMNIFICATION

8.1. Indemnification of ASI, GWN. VI and ASIVI shall indemnify, defend and hold harmless ASI and its directors, officers and employees, and GWN (each an "ASI Indemnitee") from and against any and all liabilities, damages, losses, costs or expenses (including reasonable attorneys' and professional fees and other expenses of litigation and/or arbitration) (a "Liability") resulting from a claim, suit or proceeding (any of the foregoing, a "Claim") brought by a third party against an ASI Indemnitee, arising from or occurring as a result of (i) a material breach by VI or ASIVI of their respective obligations under this Settlement Agreement, (ii) the negligence or willful misconduct of VI or of ASIVI, or (iii) activities performed by ASIVI, VI, its Affiliates, or its Licensees in connection with the development, manufacture or sale of any Product, except to the extent caused by the negligence or willful misconduct of ASI.

8.2. Indemnification of VI and ASIVI. ASI and GWN shall indemnify, defend and hold harmless VI and ASIVI and their respective directors, officers and employees (each a "VI

Indemnitee") from and against any and all liabilities, damages, losses, costs or expenses (including reasonable attorneys' and professional fees and other expenses of litigation and/or arbitration) (a "Liability") resulting from a claim, suit or proceeding (any of the foregoing, a "Claim") brought by a third party against a VI Indemnitee, arising from or occurring as a result of (i) a material breach by ASI or GWN of their respective obligations under this Settlement Agreement, (ii) the negligence or willful misconduct of ASI or of GWN, or (iii) ASI's or GWN's use of the FSD IP, except to the extent caused by the negligence or willful misconduct of VI, its Affiliates, or Licensees, or of ASIVI.

8.3. Indemnification Procedures. In the event that an Indemnitee intends to claim indemnification under this Article 8, it shall promptly notify the other party (the "Indemnitor") in writing of such alleged Liability. The Indemnitor shall have the sole right to control the defense and/or settlement thereof, provided that the indemnified party may participate in any such proceeding with counsel of its choice at its own expense. The indemnity agreement in this Article 8 shall not apply to amounts paid in settlement of any Claim if such settlement is effected without the consent of the Indemnitor, which consent shall not be withheld unreasonably. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any such action, if prejudicial to its ability to defend such action, shall relieve such Indemnitor of any liability to the Indemnitee under this Article 8 but the omission so to deliver written notice to the Indemnitor shall not relieve the Indemnitor of any liability that it may have to any Indemnitee other than under this Article 8. The Indemnitee under this Article 8, its employees and agents, shall cooperate fully with the Indemnitor and its legal representatives and provide full information in the investigation of any Claim covered by this indemnification. Neither party shall be liable for any costs or expenses incurred by the other party without its prior written authorization.

## 9. TERM AND TERMINATION

9.1. Term. The term of this Settlement Agreement shall commence on the Effective Date, and unless earlier terminated as provided in this Article 9, shall continue in full force and effect until the expiration of the last to expire Valid Claim.

9.2. Termination for Cause. VI and ASIVI will have the right to terminate this Settlement Agreement upon sixty (60) days notice of a material breach by ASI or GWN, provided that ASI or GWN may avoid such termination if before the end of such sixty (60) day period ASI or GWN cures such breach or default. ASI and GWN will have the right to terminate this Settlement Agreement upon sixty (60) days notice of a material breach by VI or ASIVI, provided that VI or ASIVI may avoid such termination if before the end of such sixty (60) day period VI or ASIVI cures such breach or default. However, if the party accused of breach disputes an asserted breach in writing within such sixty (60) day period, the non-breaching party shall not have the right to terminate this Settlement Agreement unless and until it has been determined in a legal proceeding conducted pursuant to Section 7.2 that this Settlement

Agreement was materially breached, and the party accused of the breach fails to cure the breach within sixty (60) days after such determination.

9.3. Termination for Dissolution, Transfer of Interest to ASI. In the event that VI is dissolved and permanently ceases its business operations, ASI may terminate this Settlement Agreement and, to the extent permitted by law, shall immediately become a joint owner with VI of all right, title, and interest in and to the FSD IP, including the Patent Rights. VI agrees to cooperate in good faith and to take any reasonable action necessary to effectuate such joint ownership upon such dissolution.

9.4. Accrued Rights and Obligations. Termination of this Settlement Agreement for any reason shall not release any party hereto from any liability which, at the time of such termination, has already accrued to the other party or which is attributable to a period prior to such termination, nor preclude either party from pursuing any rights and remedies it may have hereunder or at law or in equity which accrued or are based upon any event occurring prior to such termination.

9.5. Survival. The following provisions of this Settlement Agreement shall survive termination of this Settlement Agreement for any reason: Articles 1, 4, 6, 7, 9, 10, 11, 12, 13, 15, and 16, and Sections 14.1, 14.2, 14.3, 14.4, 14.5, 14.7, and 14.9. In the event that this Settlement Agreement is terminated under Section 9.2 as a result of a material breach, Sections 14.8.1 and 14.8.2 shall also survive such termination.

## 10. SETTLEMENT

10.1. Settlement of all Claims and Counterclaims. This Settlement Agreement resolves, satisfies, and settles all claims and counterclaims involved in the aforementioned arbitration proceedings.

## 11. LICENSE AGREEMENT

11.1. Termination of License Agreement. The License Agreement entered into by and between VI and ASIVI dated February 29, 2000 is hereby terminated, and the parties thereto are released of all of their rights and obligations thereunder. For the avoidance of doubt, the survival provisions of Section 11.5 of the License Agreement are likewise terminated and do not survive.

11.2. Effect of Termination of License Agreement. Termination of the License Agreement pursuant to this Settlement Agreement will not be deemed (a) to be a Dissolving Event permitting dissolution of ASIVI pursuant to Section 8 of the Operating Agreement, and (b) to permit termination of the Manufacturing and Supply Agreement between VI and ASI dated February 29, 2000.

12. IP ANALYSIS

12.1. Information and Analysis. Within three (3) business days of the Effective Date, ASI shall deposit with its counsel, Rothwell Figg Ernst & Manbeck, all IP Information, (***) of the patents and patent applications that ASI assigned to ASIVI. ASI shall direct its counsel to prepare all such materials for overnight delivery to the offices of VI counsel, Wilson Sonsini Goodrich & Rosati, 650 Page Mill Rd., Palo Alto, California 94304, and upon receipt of confirmation that VI counsel is in custody of the payment for ASI described in Section 2.1 above, to deposit all such IP Information materials for shipment in the manner previously described. VI may use all IP Information and materials furnished by ASI in order to (***) and to exercise its rights under this Settlement Agreement. At VI's reasonable request and direction, ASI agrees to cooperate with VI in (***). For the avoidance of doubt, the depositing of IP materials for overnight delivery shall be made on the same day as the deposit of the $750,000 payment for overnight delivery under Section 2.1 of this Settlement Agreement.

The parties acknowledge that ASI has previously furnished counsel for VI with certain IP Information, and that additional copies of such materials need not be provided in the manner described above. Nonetheless, ASI and GWN agree to that they shall ensure that VI is in receipt of all IP Information, whether previously furnished or not.

13. MEMORANDUM OF UNDERSTANDING

13.1. Termination of Memorandum of Understanding. The MOU entered into by and between VI and ASI dated October 14, 1999 is hereby terminated, and the parties thereto are released of all of their rights and obligations thereunder. For the avoidance of doubt, any survival provisions of the MOU are terminated and do not survive.

14. ASIVI OPERATING AGREEMENT

14.1. Assignment of FSD IP to VI. ASIVI hereby transfers and assigns to VI its entire right, title, and interest in the FSD IP. Assignment of the Patent Rights is provided for in Technology Assignment Agreement A and Technology Assignment Agreement B, attached hereto as Exhibits 1 and 2, respectively. Such assignments to VI shall include all rights to use and practice the FSD IP and to make, use and sell Products.

14.2. Modification to Allow Transfer of Interest. Section 7.1 of the ASIVI Operating Agreement is deleted in its entirety, and in its place inserted the following: "A Member may Transfer all of its Interest to another Member."

14.3. Transfer and Consent to Transfer of Interest of Managing Member. ASI hereby transfers and assigns, and VI hereby consents to the transfer and assignment by ASI, to VI its entire interest in ASIVI.

14.4. Effect of Transfer of Interest. The transfer of ASI's interest in ASIVI to VI:

14.4.1. will relieve ASI of all obligations and liabilities arising under the Operating Agreement.

14.4.2. will not entitle ASI to any redemption of its interest, distribution, or payment in connection with its assignment other than as set forth in this Settlement Agreement.

14.5. Deletion of Sections. Sections 4.6, 5.4, 8.1(e), 8.1(f), 8.2(d)(iii), 11.4, 11.5, 11.6, and 11.7 are hereby deleted from the Operating Agreement in their entirety.

14.6. Initial Publication. The initial publication of a clinical study resulting from Product development shall list GWN as the lead author.

14.7. Retention of Rights; Abandonment of Supplemental FSD IP. To the extent that any portion of the U.S. Provisional Patent Application filed on September 8, 2002 set forth in Technology Assignment Agreement C, attached hereto as Exhibit 3, discloses, claims, and/or relates to subject matter that is outside the field of sexual function in men and women, all rights in and to such subject matter shall be retained by ASI. Except with respect to that subject matter retained by ASI pursuant to this Section 14.7, if any, ASI shall not claim priority to any patent or patent application that is the subject of the Patent Rights or the Supplemental FSD IP.

Following the Execution Date of this Settlement Agreement, VI agrees to (***)

14.8. Covenants Not to Sue.

14.8.1. VI Covenant Not to Sue. VI shall not make, or threaten to make, any claim against ASI or GWN alleging infringement of any Valid Claim based on the conduct by ASI or GWN of (i) basic research and testing within the Field of Use for non-commercial purposes, (ii) direct patient care by GWN, or (iii) activities outside the Field of Use. The covenant set forth in this Section 14.8.1 shall not extend to activities within the Field of Use related to research, testing and development of products for commercial purposes, and shall not be construed as a grant of any rights to ASI or GWN under any Investigational New Drug application of ASIVI or VI, or under any other patent or other intellectual property owned or controlled by VI, including without limitation the patents and patent applications encompassed by the Patent Rights. The performance by ASI or GWN of any activities under the covenant set forth in this Section 14.8.1 shall not result in any liability of ASIVI or VI, and ASI and GWN agree to indemnify ASIVI and VI to the extent of any such liability. The covenant granted herein is independent of the option and conditional license grant set forth in that certain Manufacture and Supply Agreement between VIVUS, Inc. and AndroSolutions, Inc. dated February 29, 2000. Notwithstanding Section 16.3 below, the covenant set forth in this Section 14.8.1 is personal to ASI and GWN and may not be assigned or otherwise transferred.

14.8.2. ASI, GWN Covenant Not to Sue and Statement of Non-Liability. ASI and GWN shall not make, or threaten to make, any claim against VI, its Affiliates or Licensees alleging infringement based upon VI's, its Affiliates' or its Licensees' making, having made, importing, having imported, exporting, having exported, distributing, having distributed, selling, having sold, using, or offering for sale products within the Field of Use. ASI and GWN further agree that VI, its Affiliates or Licensees cannot be held liable for infringement of a right purportedly originating from ASI or GWN relating to the Field of Use. The parties acknowledge and agree that the covenant not to sue and statement of non-liability set forth in this Section 14.8.2 is intended to and shall bind all present and future successors, heirs, assigns, and licensees of GWN or ASI who come to acquire any rights from GWN or ASI relating to products within the Field of Use, and ASI and GWN shall provide any such third parties with notice of the covenant not to sue and the statement of non-liability.

ASI and GWN further covenant that they shall, within ten (10) days of the Effective Date for any existing patents or patent applications, or concurrently with the filing of any patent application after the Effective Date, record with the U.S. Patent and Trademark Office, or other appropriate government entity in the case of international patents, a short form of the covenant contained in this Section 14.8.2, in the form attached hereto as Exhibit 4, in connection with any patent or patent application within the Field of Use.

The covenant set forth in this Section 14.8.2 shall not extend to activities by VI, its

Affiliates, or its Licensees (i) for products not within the Field of Use, or (ii) involving the use of a Novel Chemical Entity in a product. In addition, other than the covenant set forth in this Section 14.8.2, this Section 14.8.2 shall not be construed as a grant of any other rights to VI, its Affiliates, or its Licensees under any intellectual property owned or controlled by ASI or GWN. The performance by VI, its Affiliates, and its Licensees of any activities under the covenant set forth in this Section 14.8.2 shall not result in any liability of ASI or GWN, and VI agrees to indemnify ASI and GWN to the extent of any such liability.

14.9. ASIVI Dissolution. Subsequent dissolution of ASIVI, for whatever reason, shall have no effect on this Settlement Agreement whatsoever.

15. MANUFACTURE AND SUPPLY AGREEMENT

15.1. Modification of Definitions. The following terms in the Manufacture and Supply Agreement shall have the same meaning and definition as set forth in this Settlement Agreement, notwithstanding the definitions provided in the Manufacture and Supply Agreement: "FSD IP," "Product," and Valid Claim."

15.1.1. FSD IP. All references to or use of the term "ASIVI Technology" in the Manufacture and Supply Agreement are deleted, and in their place inserted the term "FSD IP."

15.2. Deletion of Sections. The following Sections are deleted in their entirety from the Manufacture and Supply Agreement: 1.3, 1.7, 1.7.1, 1.7.2, 1.8, 1.10, and 9.

15.3. Independent Accountant. Section 4.1 of the Manufacturing and Supply Agreement is modified by adding the following text at the end of the section: "Any accountant chosen or designated under this Section 4.1 shall be limited to a "Big 5" or national accounting firm."

15.4. Payments Cumulative. Section 4.3 of the Manufacture and Supply Agreement is modified as follows: all text in Section 4.3 after the word "certain" is deleted, and in its place inserted the following: "Settlement Agreement executed in July 2001."

15.5. Termination. Section 8.1 of the Manufacture and Supply Agreement is modified as follows: the reference to "License Agreement" is deleted, and in its place inserted the following: "Settlement Agreement executed in July 2001."

15.6. Assignment. Section 10.5 is deleted in its entirety, and in its place inserted the following: "Neither party may assign this Supply Agreement or any of its rights or obligations hereunder except with the written consent of the other party."

15.7. VI Best Efforts. Section 3.1 of the Manufacturing and Supply Agreement is modified by adding the following text at the end of the section: "To the extent practicable, VI agrees to

use its best efforts to cause each of its Licensees, if any, to: (i) purchase its requirements for Product from VI, or (ii) purchase the Applicable Percentage of such Licensee's requirements of Product directly from ASI.

15.8. Confidentiality. Article 5 of the Manufacture and Supply Agreement is deleted in its entirety, and in its place inserted the following: "The definition of Confidential Information under Section 1.3 of the Settlement Agreement and the parties' rights and obligations in connection therewith under Article 4 of the Settlement Agreement are incorporated by reference herein."

15.9. VI Disclosure of Manufacturing Specifications, Good Faith Cooperation. In order for ASI to evaluate and consider the exercise of its option under Section 2.1 of the Manufacture and Supply Agreement, VI shall provide to ASI written notice of its intention to submit an NDA for a Product within nine (9) months of such submission. Upon such notice from VI, ASI shall, within 30 days, provide VI with written notice that ASI desires to evaluate its manufacturing option, that ASI possesses the financial wherewithal and capacity to exercise such option, and that it possesses a good faith and reasonable expectation that it is able to exercise such option, furnishing VI with contemporaneous evidence reasonably sufficient to support ASI's representations as to financial wherewithal, capacity and expectations. Upon such notice from ASI, VI shall, within twenty (20) days, disclose the following information relating to the Product that VI reasonably believes will be included in such submission: (i) specifications and test methods for the excipients, active ingredient, drug product, and container closure system; (ii) formulation and master batch records; and (iii) manufacturing equipment list and specifications. The parties acknowledge and agree that the aforementioned information may be modified at any time and is subject to FDA approval. VI agrees to notify ASI of any such modifications and shall update or supplement the disclosures required under this Section 15.9 accordingly. VI further agrees to cooperate in good faith and, at ASI's reasonable request, to provide such additional information necessary and proper for ASI to obtain the full benefit of its option under Section 2.1 of the Manufacture and Supply Agreement.

15.10. Notices. Section 10.3 of the Manufacture and Supply Agreement is deleted in its entirely, and in its place inserted the following: "Any notice required or permitted by this Manufacture and Supply Agreement shall be in writing and shall be sent by hand delivery, by prepaid registered or certified mail, return receipt requested, or by facsimile transmission, addressed to the other party at the address shown in Section 16.4 of the Settlement Agreement or at such other address for which such party gives notice hereunder. Such notice shall be deemed to have been given upon delivery, if sent by hand delivery, three (3) days after deposit in the mail, or upon transmission by facsimile."

16. MISCELLANEOUS

16.1. Governing Law. This Settlement Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without reference to its conflicts of laws provisions.

16.2. Independent Contractors. The relationship of the parties hereto is that of independent contractors. The parties hereto are not deemed to be agents, partners or joint ventures of the other for any purpose as a result of this Settlement Agreement or the transactions contemplated thereby. Neither party shall have the power to obligate or bind the other party in any manner whatsoever.

16.3. Assignment. The parties agree that their rights and obligations under this Settlement Agreement shall not be delegated, transferred or assigned to a third party without the prior written consent of the other party hereto; provided that either party may assign all of its rights and obligations under this Settlement Agreement, without the other party's consent (a) to its Affiliates, and (b) to an entity that acquires all or substantially all of the business or assets of the assigning party to which this Settlement Agreement pertains, whether by merger, reorganization, acquisition, sale or otherwise; which Affiliate or acquiring entity (y) agrees in a writing provided to the non-assigning party prior to any assignment, to assume all of the obligations of the assigning party hereunder, and (z) has provided to the non-assigning party evidence reasonably satisfactory to the non-assigning party of its ability to perform all such obligations in a timely manner. This Settlement Agreement shall be binding upon and inure to the benefit of the parties and their successors and permitted assigns.

16.4. Notices. Any notice required or permitted by this Settlement Agreement shall be in writing and shall be sent by hand delivery, by prepaid registered or certified mail, return receipt requested, or by facsimile transmission, addressed to the other party at the address shown below or at such other address for which such party gives notice hereunder. Such notice shall be deemed to have been given upon delivery, if sent by hand delivery, three (3) days after deposit in the mail, or upon transmission by facsimile.

To ASIVI:
ASIVI, LLC
1172 Castro Street
Mountain View, California 94040
Attention: Legal Affairs
Facsimile: (650) 934-5389

With a copy to:
Wilson Sonsini Goodrich & Rosati, PC
650 Page Mill Road
Palo Alto, CA 94304
Attention: Mark Casper, Esq.
Facsimile: (650) 496-4082

To VIVUS:
VIVUS, Inc.
1172 Castro Street
Mountain View, CA 94040
Attention: Legal Affairs
Facsimile: (650) 934-5389

With a copy to:
Wilson Sonsini Goodrich & Rosati, PC
650 Page Mill Road
Palo Alto, CA 94304
Attention: Mark Casper, Esq.
Facsimile: (650) 496-4082

To ASI:
AndroSolutions, Inc.
200 Fort Sanders West Blvd., Suite 309
Knoxville, TN 37922
Attention: Gary W. Neal, M.D., President
Facsimile: (865) 531-6550

With a copy to:
Zoltick Technology Law Group, PLLC
Loudoun Tech Center
21515 Ridgetop Circle, Suite 200
Sterling, VA 20166
Attention: Martin M. Zoltick, Esq.
Facsimile: (571) 434-7264

To GWN: AndroSolutions, Inc.
200 Fort Sanders West Blvd., Suite 309
Knoxville, TN 37922
Attention: Gary W. Neal, M.D., President
Facsimile: (865) 531-6550

With a copy to: Zoltick Technology Law Group, PLLC
Loudoun Tech Center
21515 Ridgetop Circle, Suite 200
Sterling, VA 20166
Attention: Martin M. Zoltick, Esq.
Facsimile: (571) 434-7264

16.5. Force Majeure. Neither party shall lose any rights hereunder or be liable to the other party for damages or losses (except for payment obligations) on account of failure of performance if such failure is occasioned by war, strike, fire, Act of God, earthquake, flood, lockout, embargo, governmental acts or orders or restrictions, failure of suppliers, or any other reason where failure to perform is beyond the reasonable control and not caused by the negligence, intentional conduct or misconduct of the nonperforming party and such party has exerted all reasonable efforts to avoid or remedy such force majeure; provided, however, that in no event shall a party be required to settle any labor dispute or disturbance.

16.6. Advice of Counsel. VI, ASIVI, ASI, and GWN have each consulted counsel of their choice regarding this Settlement Agreement, and each acknowledges and agrees that this Settlement Agreement shall not be deemed to have been drafted by one party or another and will be construed accordingly.

16.7. Compliance with Laws. Each party shall furnish to the other party any information requested or required by that party during the term of this Settlement Agreement or any extensions hereof to enable that party to comply with the requirements of any U.S. or foreign, state and/or government agency.

16.8. Severability; Waiver. If any provision(s) of this Settlement Agreement are determined to be invalid or unenforceable by a court of competent jurisdiction, the remainder of the Settlement Agreement shall remain in full force and effect without said provision. The parties shall in good faith negotiate a substitute clause for any provision declared invalid or unenforceable, which shall most nearly approximate the intent of the parties in entering this Settlement Agreement. The failure of a party to enforce any provision of the Settlement Agreement shall not be construed to be a waiver of the right of such party to thereafter enforce that provision or any other provision or right.

16.9. Entire Agreement; Modification. This Settlement Agreement sets forth the entire agreement and understanding of the parties with respect to the subject matter hereof, and supersedes all prior discussions, agreements and writings in relation thereto, except that the Operating Agreement, and the Manufacture and Supply Agreement, as modified herein, remain in effect. This Settlement Agreement may not be altered, amended or modified in any way except by a writing signed by both parties.

16.10. Counterparts. This Settlement Agreement may be executed in two counterparts, each of which shall be deemed an original and which together shall constitute one instrument.

IN WITNESS WHEREOF, ASIVI, VI, ASI, and GWN have caused this Settlement Agreement to be executed by their respective duly authorized representatives as of the date first written above.

ASIVI, LLC

By: /s/ Gary W. Neal
AndroSolutions, Inc.
Managing Member
Gary W. Neal, M.D., President

Date: July 10, 2001

VIVUS, INC.

By: /s/ Leland Wilson
Leland F. Wilson
President/Chief Executive Officer

Date: July 12, 2001

By: /s/ Leland Wilson
VIVUS, Inc.
Managing Member
Leland F. Wilson
President/Chief Executive Office

Date: July 12, 2001

ANDROSOLUTIONS, INC.

By: /s/ Gary W. Neal
Gary W. Neal, M.D.
President

Date: July 10, 2001

GARY W. NEAL, M.D.

/s/ Gary W. Neal
Gary W. Neal, M.D.
Individually and on behalf of himself

Date: July 10, 2001

EXHIBIT 1

TECHNOLOGY ASSIGNMENT AGREEMENT A

ASSIGNMENT

ASIVI, LLC, a Delaware limited liability company, with offices at 1172 Castro Street, Mountain View, CA 94040 (ASIVI), for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, hereby assigns, sells and transfers to VIVUS, Inc., a Delaware corporation having offices at 1172 Castro Street, Mountain View, CA 94040, and its successors, assigns and legal representatives, all hereinafter referred to as the "Assignee":

1. its entire right, title and interest in and to any and all patents and pending patent applications relating to, inter alia, the design, development, manufacturing, and use of products containing a prostaglandin and/or other vasodilator for the treatment of female sexual dysfunction, as specified on Exhibit A attached hereto (the "FSD IP");

2. the full and complete right to file patent applications in the name of the Assignee, its designee, or its designee's election, on the aforesaid FSD IP, in all countries of the world;

3. the entire right, title and interest in and to any Letters Patent which may issue thereon in the United States or in any country, and any renewals, revivals, reissues, reexaminations and extensions thereof, and any patents of confirmation, registration and importation of the same; and

4. the entire right, title and interest in all Convention and Treaty Rights of all kinds thereon, including without limitation all rights of priority in any country of the world, in and to the above FSD IP.

ASIVI hereby authorizes and requests the competent authorities to grant and to issue any and all such Letters Patent in the United States and throughout the world to Assignee of the entire right, title and interest therein, as fully and entirely as the same would have been held and enjoyed by ASIVI had this assignment, sale and transfer not been made.

ASIVI further agrees at any time to execute and to deliver upon request of Assignee such additional documents, if any, as are necessary or desirable to secure patent protection on said FSD IP, throughout all countries of the world, and otherwise to do the necessary acts to give full effect to and to perfect the rights of Assignee under this Assignment, including the execution, delivery and procurement of any and all further documents evidencing this assignment, transfer and sale as may be necessary or desirable.

ASIVI hereby covenants that no assignment, sale, agreement or encumbrance has been or will be made or entered into which would conflict with this assignment.

ASIVI further covenants that it will, upon request by Assignee, provide Assignee promptly with all pertinent facts and documents relating to said FSD IP and said Letters Patent and legal equivalents as may be known and accessible to ASIVI, and will testify as to the same in any interference, litigation or proceeding related thereto and will promptly execute and deliver to Assignee or its legal representatives any and all papers, instruments or affidavits required to apply for, obtain, maintain, issue and enforce said application, said FSD IP and said Letters Patent and said equivalents thereof which may be necessary or desirable to carry out the purposes thereof.

ASIVI, LLC

Date: July 12, 2001

By: /s/ Leland Wilson

VIVUS, Inc.
Managing Member
Leland F. Wilson
President/Chief Executive Officer

Date: July 10, 2001

By: /s/ Gary W. Neal

AndroSolutions, Inc.
Managing Member
Gary W. Neal, M.D.
President

EXHIBIT A

DESCRIPTION OF PROPERTY CONTRIBUTED TO VIVUS, INC. BY ASIVI, LLC

(***)

EXHIBIT 2

TECHNOLOGY ASSIGNMENT AGREEMENT B

ASSIGNMENT

ASIVI, LLC, a Delaware limited liability company, with offices at 1172 Castro Street, Mountain View, CA 94040 (ASIVI), for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, hereby assigns, sells and transfers to VIVUS, Inc., a Delaware corporation having offices at 1172 Castro Street, Mountain View, CA 94040, and its successors, assigns and legal representatives, all hereinafter referred to as the "Assignee":

1. its entire right, title and interest in and to any and all patents and pending patent applications relating to, inter alia, the design, development, manufacturing, and use of products containing a prostaglandin and/or other vasodilator for the treatment of female sexual dysfunction, as specified on Exhibit A attached hereto (the "FSD IP");

2. the full and complete right to file patent applications in the name of the Assignee, its designee, or its designee's election, on the aforesaid FSD IP, in all countries of the world;

3. the entire right, title and interest in and to any Letters Patent which may issue thereon in the United States or in any country, and any renewals, revivals, reissues, reexaminations and extensions thereof, and any patents of confirmation, registration and importation of the same; and

4. the entire right, title and interest in all Convention and Treaty Rights of all kinds thereon, including without limitation all rights of priority in any country of the world, in and to the above FSD IP.

ASIVI hereby authorizes and requests the competent authorities to grant and to issue any and all such Letters Patent in the United States and throughout the world to Assignee of the entire right, title and interest therein, as fully and entirely as the same would have been held and enjoyed by ASIVI had this assignment, sale and transfer not been made.

ASIVI further agrees at any time to execute and to deliver upon request of Assignee such additional documents, if any, as are necessary or desirable to secure patent protection on said FSD IP, throughout all countries of the world, and otherwise to do the necessary acts to give full effect to and to perfect the rights of Assignee under this Assignment, including the execution, delivery and procurement of any and all further documents evidencing this assignment, transfer and sale as may be necessary or desirable.

ASIVI hereby covenants that no assignment, sale, agreement or encumbrance has been or will be made or entered into which would conflict with this assignment.

ASIVI further covenants that it will, upon request by Assignee, provide Assignee promptly with all pertinent facts and documents relating to said FSD IP and said Letters Patent and legal equivalents as may be known and accessible to ASIVI, and will testify as to the same in any interference, litigation or proceeding related thereto and will promptly execute and deliver to Assignee or its legal representatives any and all papers, instruments or affidavits required to apply for, obtain, maintain, issue and enforce said application, said FSD IP and said Letters Patent and said equivalents thereof which may be necessary or desirable to carry out the purposes thereof.

ASIVI, LLC

Date: July 12, 2001

By: /s/ Leland Wilson

VIVUS, Inc.
Managing Member
Leland F. Wilson
President/Chief Executive Officer

Date: July 10, 2001

By: /s/ Gary W. Neal

AndroSolutions, Inc.
Managing Member
Gary W. Neal, M.D.
President

EXHIBIT A

DESCRIPTION OF PROPERTY CONTRIBUTED TO VIVUS, INC. BY ASIVI, LLC

(***)

EXHIBIT 3

TECHNOLOGY ASSIGNMENT AGREEMENT C

ASSIGNMENT

AndroSolutions, Inc., a Tennessee corporation with a principal place of business at Suite 309, 200 Fort Sanders West Blvd., Knoxville, TN 37922 (collectively with its Affiliates, "ASI"), for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, hereby assigns, sells and transfers to VIVUS, Inc., a Delaware corporation having offices at 1172 Castro Street, Mountain View, CA 94040, and its successors, assigns and legal representatives, all hereinafter referred to as the "Assignee":

1. its entire right, title and interest in and to any and all patents and pending patent applications relating to, inter alia, the treatment of female sexual dysfunction, as specified on Exhibit A --------- attached hereto (the " Supplemental FSD IP");

2. the full and complete right to file patent applications in the name of the Assignee, its designee, or its designee's election, on the aforesaid SUPPLEMENTAL FSD IP, in all countries of the world;

3. the entire right, title and interest in and to any Letters Patent which may issue thereon in the United States or in any country, and any renewals, revivals, reissues, reexaminations and extensions thereof, and any patents of confirmation, registration and importation of the same; and

4. the entire right, title and interest in all Convention and Treaty Rights of all kinds thereon, including without limitation all rights of priority in any country of the world, in and to the above SUPPLEMENTAL FSD IP.

ASI hereby authorizes and requests the competent authorities to grant and to issue any and all such Letters Patent in the United States and throughout the world to Assignee of the entire right, title and interest therein, as fully and entirely as the same would have been held and enjoyed by ASI had this assignment, sale and transfer not been made.

ASI further agrees at any time to execute and to deliver upon request of Assignee such additional documents, if any, as are necessary or desirable to secure patent protection on said SUPPLEMENTAL FSD IP, throughout all countries of the world, and otherwise to do the necessary acts to give full effect to and to perfect the rights of Assignee under this Assignment, including the execution, delivery and procurement of any and all further documents evidencing this assignment, transfer and sale as may be necessary or desirable.

ASI hereby covenants that no assignment, sale, agreement or encumbrance has been or will be made or entered into which would conflict with this assignment.

ASI further covenants that it will, upon request by Assignee, provide Assignee promptly with all pertinent facts and documents relating to said SUPPLEMENTAL FSD IP and said Letters Patent and legal equivalents as may be known and accessible to ASI, and will testify as to the same in any interference, litigation or proceeding related thereto and will promptly execute and deliver to Assignee or its legal representatives any and all papers, instruments or affidavits required to apply for, obtain, maintain, issue and enforce said application, said SUPPLEMENTAL FSD IP and said Letters Patent and said equivalents thereof which may be necessary or desirable to carry out the purposes thereof.

ANDROSOLUTIONS, INC.

Date: July 10, 2001

By: /s/ Gary W. Neal

Gary W. Neal, M.D.
President

EXHIBIT A

DESCRIPTION OF PROPERTY CONTRIBUTED TO VIVUS, INC.

BY ANDROSOLUTIONS, INC.

(***)

EXHIBIT 4

SHORT FORM PROVIDING NOTICE OF COVENANT NOT TO SUE
AND STATEMENT OF NON-LIABILITY

"All subject matter claimed within this patent or patent application is subject to the following covenant not to sue and statement of non-liability:

THE HOLDER OF ANY RIGHTS UNDER THIS PATENT OR PATENT APPLICATION SHALL NOT MAKE, OR THREATEN TO MAKE, ANY CLAIM AGAINST VIVUS, INC. ("VI"), ITS AFFILIATES OR LICENSEES ALLEGING INFRINGEMENT BASED UPON VI'S, ITS AFFILIATES' OR ITS LICENSEES' MAKING, HAVING MADE, IMPORTING, HAVING IMPORTED, EXPORTING, HAVING EXPORTED, DISTRIBUTING, HAVING DISTRIBUTED, SELLING, HAVING SOLD, USING, OR OFFERING FOR SALE PRODUCTS RELATING TO THE DIAGNOSIS, PROPHYLAXIS, AND/OR TREATMENT OF FEMALE SEXUAL DYSFUNCTION, INCLUDING WITHOUT LIMITATION ENHANCING FEMALE SEXUAL DESIRE AND RESPONSIVENESS, AND PREVENTING, TREATING AND/OR MANAGING FEMALE SEXUAL AROUSAL DISORDER, ORGASMIC DISORDER, AND PAIN DISORDER.

FURTHER, VI, ITS AFFILIATES OR LICENSEES CANNOT BE HELD LIABLE FOR INFRINGEMENT OF ANY RIGHTS UNDER THIS PATENT OR PATENT APPLICATION RELATING TO THE DIAGNOSIS, PROPHYLAXIS, AND/OR TREATMENT OF FEMALE SEXUAL DYSFUNCTION, INCLUDING WITHOUT LIMITATION ENHANCING FEMALE SEXUAL DESIRE AND RESPONSIVENESS, AND PREVENTING, TREATING AND/OR MANAGING FEMALE SEXUAL AROUSAL DISORDER, ORGASMIC DISORDER, AND PAIN DISORDER.

THIS COVENANT NOT TO SUE AND STATEMENT OF NON-LIABILITY IS INTENDED TO AND SHALL BIND ALL PRESENT AND FUTURE SUCCESSORS, HEIRS, ASSIGNS, AND LICENSEES OF ANY RIGHTS UNDER THIS PATENT OR PATENT APPLICATION RELATING TO PRODUCTS FOR THE DIAGNOSIS, PROPHYLAXIS, AND/OR TREATMENT OF FEMALE SEXUAL DYSFUNCTION, INCLUDING WITHOUT LIMITATION ENHANCING FEMALE SEXUAL DESIRE AND RESPONSIVENESS, AND PREVENTING, TREATING AND/OR MANAGING FEMALE SEXUAL AROUSAL DISORDER, ORGASMIC DISORDER, AND PAIN DISORDER.

A HOLDER OF ANY RIGHTS UNDER THIS PATENT OR PATENT APPLICATION MUST PROVIDE NOTICE OF THE ABOVE-STATED COVENANTS AND STATEMENT OF NON-LIABILITY TO ANY THIRD PARTY ACQUIRING RIGHTS UNDER THIS PATENT OR PATENT APPLICATION."