

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

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2004

OR

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

FOR THE TRANSITION PERIOD FROM _____ TO _____ .

COMMISSION FILE NUMBER: 0-23490

VIVUS, INC.

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

DELAWARE
(STATE OR OTHER JURISDICTION OF
INCORPORATION OR ORGANIZATION)

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

1172 CASTRO STREET
MOUNTAIN VIEW, CALIFORNIA 94040
(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES AND ZIP CODE)

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

N/A

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

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

Indicate by check mark whether Registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act.) Yes No

At April 30, 2004, 38,644,570 shares of common stock were outstanding.

PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

VIVUS, INC.

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

ASSETS

	MARCH 31 2004	DECEMBER 31 2003
	(UNAUDITED)	
Current assets:		
Cash and cash equivalents	\$ 4,081	\$ 13,097
Available-for-sale securities	34,460	21,488
Accounts receivable, net	680	2,623
Inventories	3,415	3,109
Prepaid expenses and other assets	1,036	1,108
	<hr/>	<hr/>
Total current assets	43,672	41,425
Property and equipment, net	7,756	8,220
Restricted cash	3,324	3,324

Available-for-sale securities, non-current	5,841	13,763
Total assets	\$ 60,593	\$ 66,732
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 4,056	\$ 2,917
Accrued and other liabilities	8,357	8,409
Total current liabilities	12,413	11,326
Notes payable	316	—
Accrued and other long-term liabilities	6,843	4,171
Total liabilities	19,572	15,497
Stockholders' equity:		
Preferred stock; \$1.00 par value; shares authorized 5,000; shares issued and outstanding — 0 at March 31, 2004 and December 31, 2003	—	—
Common stock; \$.001 par value; shares authorized 200,000; shares issued and outstanding — 37,996 at March 31, 2004 and 37,788 at December 31, 2003	38	38
Additional paid-in capital	152,790	152,093
Accumulated other comprehensive income	52	64
Accumulated deficit	(111,859)	(100,960)
Total stockholders' equity	41,021	51,235
Total liabilities and stockholders' equity	\$ 60,593	\$ 66,732

See accompanying notes to condensed consolidated financial statements.

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VIVUS, INC.

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

	THREE MONTHS ENDED	
	MARCH 31 2004	MARCH 31 2003
	(UNAUDITED)	(UNAUDITED)
Revenue		
United States product	\$ 663	\$ 3,808
International product	1,370	878
Returns provision	(91)	(417)
Total revenue	1,942	4,269
Cost of goods sold	2,280	2,784
Gross profit (loss)	(338)	1,485
Operating expenses:		
Research and development	7,721	2,284
Selling, general and administrative	3,008	2,572
Total operating expenses	10,729	4,856
Loss from operations	(11,067)	(3,371)
Interest and other income:		
Interest income	160	187
Gain (loss) on disposal of property and equipment	1	(1)
Foreign exchange gain (loss)	10	(6)
Loss before provision for income taxes	(10,896)	(3,191)
Provision for income taxes	(3)	—
Net loss	\$ (10,899)	\$ (3,191)
Net loss per share:		
Basic	\$ (0.29)	\$ (0.10)
Diluted	\$ (0.29)	\$ (0.10)
Shares used in per share computation:		
Basic	37,881	33,011
Diluted	37,881	33,011

VIVUS, INC.

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

	THREE MONTHS ENDED	
	MARCH 31 2004	MARCH 31 2003
	(UNAUDITED)	(UNAUDITED)
Net loss	\$ (10,899)	\$ (3,191)
Other comprehensive (loss):		
Unrealized (loss) on securities	(12)	(72)
Comprehensive loss	\$ (10,911)	\$ (3,263)

See accompanying notes to condensed consolidated financial statements.

VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	THREE MONTHS ENDED MARCH 31	
	2004	2003
	(UNAUDITED)	(UNAUDITED)
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (10,899)	\$ (3,191)
Adjustments to reconcile net loss to net cash (used for)		
provided by operating activities:		
Provision for doubtful accounts	(89)	(81)
Depreciation and amortization	490	555
Stock compensation costs	10	—
(Gain) loss on disposal of property and equipment	(1)	1
Changes in assets and liabilities:		
Accounts receivable	2,032	2,406
Inventories	(306)	(223)
Prepaid expenses and other assets	72	525
Accounts payable	1,139	404
Accrued and other liabilities	2,620	(379)
Net cash (used for) provided by operating activities	(4,932)	17
CASH FLOWS FROM INVESTING ACTIVITIES:		
Property and equipment purchases	(26)	(34)
Proceeds from sale of property and equipment	1	—
Investment purchases	(14,226)	(5,147)
Proceeds from sale/maturity of securities	9,164	3,016
Net cash used for investing activities	(5,087)	(2,165)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Borrowing under note agreements	316	—
Exercise of common stock options	687	39
Net cash provided by financing activities	1,003	39
NET DECREASE IN CASH	(9,016)	(2,109)
CASH:		
Beginning of period	13,097	12,296
End of period	\$ 4,081	\$ 10,187
NON-CASH INVESTING ACTIVITIES:		
Unrealized (loss) on securities	\$ (12)	\$ (72)
SUPPLEMENTAL CASH FLOW DISCLOSURE:		
Income taxes paid	\$ 13	\$ 2

See accompanying notes to condensed consolidated financial statements.

VIVUS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
MARCH 31, 2004

1. BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulations S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three-month period ended March 31, 2004 are not necessarily indicative of the results that may be expected for the year ending December 31, 2004. 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, 2003.

2. SIGNIFICANT ACCOUNTING POLICIES

Stock Options

The Company applies the intrinsic-value-based method of accounting prescribed by Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations including Financial Accounting Standards Board, or FASB, Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation, an Interpretation of APB Opinion No. 25*, issued in March 2000, to account for its fixed-plan stock options. Under this method, compensation expense is recorded on the date of the grant only if the current market price of the underlying stock exceeds the exercise price. SFAS No. 123, *Accounting for Stock Based Compensation*, establishes accounting and disclosure requirements using a fair-value-based method of accounting for stock-based employee compensation plans. As allowed by SFAS No. 123, the Company has elected to continue to apply the intrinsic-value-based method of accounting described above, and has adopted only the disclosure requirements of SFAS No. 123. The following table illustrates the effect on net income if the fair-value-based method has been applied to all outstanding and unvested awards during the three months ended March 31, 2004 and 2003.

	Three months ended	
	March 31 2004	March 31 2003
Net (loss), as reported	\$ (10,899)	\$ (3,191)
Deduct total stock-based employee compensation expense determined under fair-value-based method for all rewards, net of tax	(401)	(426)
Pro forma net (loss)	\$ (11,300)	\$ (3,617)
Pro forma net (loss) per share:		
Basic	\$ (0.30)	\$ (0.11)
Diluted	\$ (0.30)	\$ (0.11)

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions used for grants in the first quarter of 2004 and 2003: no dividend yield, expected volatility of 71% and 72%, respectively, risk-free interest rates of between 1% to 5% and 1% to 4%, respectively and an expected life of 5 years for both periods.

3. INVENTORIES

Inventories are recorded net of reserves of \$5.3 million and \$5.6 million as of March 31, 2004 and December 31, 2003, respectively, and consist of:

	MARCH 31, 2004		DECEMBER 31, 2003
Raw materials	\$ 2,303	(000's)	\$ 2,370
Work in process	52		81
Finished goods	1,060		658
Inventory, net	\$ 3,415		\$ 3,109

As noted above, the Company has recorded significant reserves against the carrying value of its inventories. The reserves relate primarily to raw materials inventory that the Company previously estimated would not be used. The Company now estimates that at least some portion of the fully reserved inventory will be used in production. The Company used \$256,000 and \$190,000 of its fully reserved raw materials inventory during the first quarter of 2004 and 2003, respectively. The fully reserved used raw materials were charged to cost of goods sold at a zero basis, which had a favorable impact on gross profit.

4. NOTES PAYABLE

In the first quarter of 2004, we signed an agreement for a line of credit with Tanabe Holding America, Inc. or Tanabe, allowing us to borrow up to \$8.5 million to be used for the development of avanafil (TA-1790), our erectile dysfunction compound currently in Phase 2 clinical trials. The secured line of credit may be drawn upon quarterly and each quarterly borrowing will have a 48-month term and will bear interest at the annual rate of two percent. As of March 31, 2004 we had a long-term notes payable balance of \$316,000.

5. ACCRUED AND OTHER LIABILITIES

Accrued and other liabilities as of March 31, 2004 and December 31, 2003 consist of:

Short-term accrued and other liabilities	MARCH 31, 2004	(000'S)	DECEMBER 31, 2003
Product returns	\$ 2,876		\$ 2,932
Income taxes	1,185		1,216
Research and clinical expenses	866		458
Royalties	320		629
Deferred revenue	281		281
Employee compensation and benefits	1,113		1,249
Chargebacks and rebates	835		900
Customer liabilities	550		135
Other	331		609
Total short-term accrued and other liabilities	\$ 8,357		\$ 8,409
Long-term accrued and other liabilities	MARCH 31, 2004	(000'S)	DECEMBER 31, 2003
Restructuring	\$ 3,021		\$ 3,021
Research and clinical expenses	2,710		—
Deferred revenue	1,112		1,150
Total long-term accrued and other liabilities	\$ 6,843		\$ 4,171

6. 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, 2003 included in the Company's Annual Report on Form 10-K.) The restructuring reserve balance at March 31, 2004 was \$3.0 million, remaining the same as at December 31, 2003.

	PROPERTY AND RELATED COMMITMENTS
Balance at December 31, 2003	\$ 3,021
Activity in first quarter 2004	—
Balance at March 31, 2004	\$ 3,021

The remaining balance in the restructuring reserve is related to the restoration liability for our leased manufacturing facilities. This liability will remain in effect through the end of the lease term, including any renewals. The Company has exercised its first option to renew the original lease, thereby extending any cash payments to be made to this liability out to 2007. The second renewal term, if exercised, would then extend the liability out an additional five years, to 2012.

7. NET INCOME PER SHARE

Net income per share is calculated in accordance with Statement of Financial Accounting Standards No. 128, *Earnings per Share*, which requires a dual presentation of basic and diluted earnings per share. Basic income per share is based on the weighted average number of common shares outstanding during the period. Diluted income per share is based on the weighted average number of common and common equivalent shares, which represent shares that may be issued in the future upon the exercise of outstanding stock options. Certain options are excluded from the diluted income per share for the period presented because they are anti-dilutive. Potentially dilutive options outstanding of 1,005,725 and 509,879 at March 31, 2004 and 2003, respectively, are excluded from the computation of diluted EPS for the first quarter of 2004 and 2003 because the effect would have been anti-dilutive.

8. COMMITMENTS

We lease our manufacturing facilities in Lakewood, New Jersey under a non-cancelable operating lease expiring in 2007 and have the option to extend this lease for one additional renewal term of five years. In January 2000, we entered into a seven-year lease for our corporate headquarters in Mountain View, California, which expires in January 2007.

In November 2002, we entered into a manufacturing agreement to purchase raw materials from a supplier beginning in 2003 and ending in 2008. In 2003, we purchased \$2.1 million of product and are committed to purchase a minimum total of \$3.8 million of product from 2004 through 2008.

In January 2004, we entered into a manufacturing agreement to purchase raw materials from an additional supplier beginning in 2004 and ending in 2006. We will be required to purchase a minimum total of \$2.3 million of product from 2004 through 2006.

In January 2004, we entered into exclusive licensing agreements with Acrux Limited, a specialty pharmaceutical company based in Melbourne, Australia, under which we will develop and commercialize an estradiol spray for the alleviation of the symptoms of menopause and a testosterone spray for the treatment of low sexual desire in women. We reported a total \$2.9 million of licensing fees incurred under the terms of the agreements. Portions of these licensing fees will be paid in September 2004 (\$250,000) and June 2005 (\$930,000). We expect to make other substantial payments to Acrux in accordance with our agreements with them. These payments are based on certain development, regulatory and sales milestones. In addition, we are required to make royalty payments on any future product sales.

In addition, during the first quarter of 2004, we initiated a phase 2 clinical trial with avanafil, our oral phosphodiesterase type 5 (PDE5) inhibitor being studied for the treatment of erectile dysfunction. Under the terms of our 2001 development, licensing and supply agreement with Tanabe Seiyaku Co., LTD., or Tanabe, a Japanese pharmaceutical company, we reported a \$1.8 million milestone obligation to Tanabe in the first quarter of 2004. The payment of this milestone will be made in March

2006. We expect to make other substantial payments to Tanabe in accordance with our agreements with them. These payments are based on certain development, regulatory and sales milestones. In addition, we are required to make royalty payments on any future product sales.

9. CONCENTRATION OF CUSTOMERS AND SUPPLIERS

During the first three months of 2004 and 2003, sales to significant customers as a percentage of total revenues were as follows:

	<u>2004</u>	<u>2003</u>
Customer A	49%	18%
Customer B	14%	18%
Customer C	11%	30%
Customer D	11%	6%
Customer E	7%	19%

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

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

This Management's Discussion and Analysis of Financial Conditions and Results of Operations and other parts of this Form 10-Q contain "forward-looking" statements that involve risks and uncertainties. These statements typically may be identified by the use of forward-looking words or phrases such as "believe," "expect," "intend," "anticipate," "should," "planned," "estimated," and "potential," among others. All forward-looking statements included in this document are based on our current expectations, and we assume no obligation to update any such forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for such forward-looking statements. In order to comply with the terms of the safe harbor, we note that a variety of factors could cause actual results and experiences to differ materially from the anticipated results or other expectations expressed in such forward-looking statements. The risks and uncertainties that may affect the operations, performance, development, and results of our business include but are not limited to: (1) our history of losses and variable quarterly results; (2) substantial competition; (3) risks related to the failure to protect our intellectual property and litigation in which we may become involved; (4) our reliance on sole source suppliers; (5) our limited sales and marketing efforts and our reliance on third parties; (6) failure to continue to develop innovative products; (7) risks related to noncompliance with United States Food and Drug Administration regulations; and (8) other factors that are described from time to time in our periodic filings with the Securities and Exchange Commission, including those set forth in this filing as "Risk Factors Affecting Operations and Future Results."

All percentage amounts and ratios were calculated using the underlying data in thousands. Operating results for the three-month period ended March 31, 2004, are not necessarily indicative of the results that may be expected for the full fiscal year or any future period.

BUSINESS OVERVIEW

VIVUS, Inc. is a specialty pharmaceutical company focused on the research, development and commercialization of products to restore sexual function in men and women. In addition to our currently marketed therapies, we have a pipeline that includes both new chemical entities and existing compounds that are being developed to address unmet medical needs. Our business strategy is to apply our scientific and medical expertise to identify, develop and commercialize therapies that restore sexual function. In the United States, we market MUSE® (alprostadil) and ACTIS®, two products for the treatment of erectile dysfunction. We have entered into supply agreements with Meda AB to market and distribute MUSE and ACTIS in all Member States of the European Union, the Baltic States, the Czech Republic, Hungary, Iceland, Norway, Poland, Switzerland and Turkey. In Canada, we have entered into a license and supply agreement with Paladin Labs, Inc. to market and distribute MUSE.

We currently have four significant research and development programs in progress targeting male and female sexual function:

- **ALISTA™** to treat female sexual arousal disorder;
- **Estradiol MDTS®**, a short-term therapy to alleviate symptoms associated with menopause;
- **Testosterone MDTS®** for treating women with low sexual desire; and
- **Avanafil**, formerly known as TA-1790, for the treatment of erectile dysfunction.

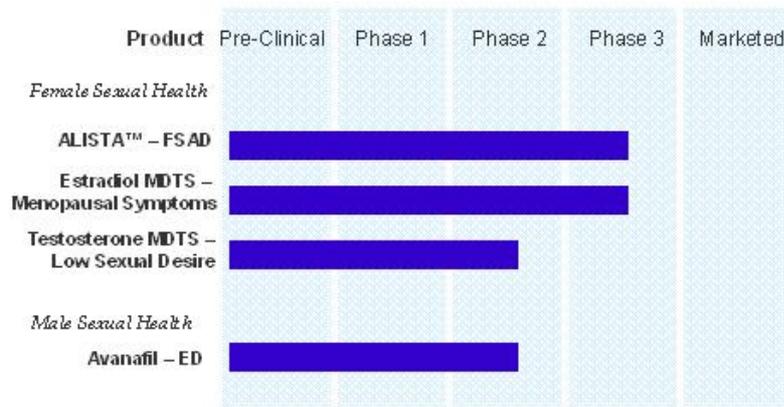
The first two research and development programs are in Phase 3 clinical development and the second two research and development programs are in Phase 2 clinical development. We believe that each of these programs addresses either established markets with sales in excess of \$1.0 billion annually or potential markets with sales that could exceed \$1.0 billion annually.

When we were founded in 1991, our sole purpose was to develop a therapy for men suffering from erectile dysfunction. In 1997, we commercially launched MUSE in the United States. At that time, MUSE revolutionized erectile dysfunction therapy at a time when few effective therapies existed. Developing and bringing MUSE to the market provided us experience in clinical and regulatory matters when no intra-urethral drugs had been approved for this indication. This experience serves us well today in making progress towards developing and commercializing product candidates in our research and development programs.

It is our objective to become a global leader in the development and commercialization of products that help to restore sexual health in men and women. We believe that we have strong intellectual property supporting many opportunities in sexual health. Our future growth will come from further development and approval of our product candidates as well as in-licensing and product line extensions.

The chart below depicts the status of our four significant research and development programs in progress.

Our Research and Development Programs



First Quarter 2004 Update

Female Sexual Health

We believe that the market for the treatment of sexual disorders in women is large and underserved. Today, there are no treatments on the market that have been approved by the United States Food and Drug Administration, or the FDA, for the treatment of sexual disorders in women. A paper by Lauman, et. al., published in the *Journal of the American Medical Association* in 1999, noted 43% of women between the ages of 18 and 65 identified themselves as afflicted with a sexual disorder, with two prevalent conditions being low sexual desire and arousal disorder. We believe these two conditions combined could potentially be a significant market. VIVUS’ research and development programs in female sexual health address both of these conditions.

ALISTA

ALISTA is a topical formulation of alprostadil applied locally to the female genitalia for the treatment of female sexual arousal disorder. It increases blood flow in the genital region, allowing for greater sensitivity and sexual arousal. ALISTA augments natural lubrication and has a fast onset of action with low systemic distribution.

At the end of the first quarter of 2003, we began a second at-home Phase 2 study to assess the efficacy and safety of ALISTA when used by pre-menopausal women with female sexual arousal disorder. The results of this study are expected in the middle of 2004.

We plan to begin Phase 3 clinical development of ALISTA in 2004.

Metered Dose Transdermal Spray, or MDTs

In the first quarter of 2004, we entered into license agreements with Acrux Limited, a specialty pharmaceutical company based in Melbourne, Australia, pursuant to which we have the exclusive rights to market, in the United States, two drugs, estradiol and testosterone, using Acrux’s Metered Dose Transdermal Spray, or MDTs. The MDTs is a small, easy-to-use, handheld spray that delivers estradiol and testosterone topically to the skin. It dries in approximately 30 seconds, and when dry, is invisible. Data generated to date suggests that, once dry, there is little chance for transfer or removal by washing. We believe that MDTs will have high patient acceptability.

The MDTs drug formulations utilize proprietary skin penetration enhancers commonly found in sunscreens. The once-per-day dosing has demonstrated a sustained plasma level of drug over a 24-hour period.

- **Estradiol MDTs** — The estradiol spray is a low-dose estrogen-only treatment addressing the symptoms associated with menopause, primarily hot flashes. This proprietary spray product utilizes the MDTs spray technology, which is patented. This product candidate is simple to use and apply and has the safety of transdermal delivery.

We plan to conduct Phase 3 clinical development of the estradiol spray in 2004.

- **Testosterone MDTS** – This proprietary spray product is designed to treat females with low sexual desire. The clinical name for low sexual desire is hypoactive sexual desire disorder. There are estimated to be over 10 million women in the United States afflicted with low sexual desire and there are no FDA approved therapies for this condition.

The testosterone spray is currently in a Phase 2 clinical trial with 200 patients. Under the terms of our license agreement, Acrux has the responsibility to complete this Phase 2 trial, which is being conducted in Australia under an Investigational New Drug application on file with the FDA. We expect the results of this Phase 2 study to be available in early 2005. All clinical development following this Phase 2 clinical trial will be our responsibility. Assuming that the Phase 2 study is successful, we plan to initiate a Phase 3 clinical trial with Testosterone MDTS by the end of 2005. Our current commercialization plan is to partner with a large pharmaceutical company.

Male Sexual Health

The erectile dysfunction market produces revenues in excess of \$2.0 billion annually. Pfizer reported that it sold approximately \$1.8 billion of Viagra®, a phosphodiesterase type 5 (PDE5) inhibitor, worldwide in 2003. Pfizer received clearance from the FDA to market Viagra in 1998. In late 2003, two additional phosphodiesterase type 5 (PDE5) inhibitors were approved by the FDA: Levitra®, launched by Bayer and GlaxoSmithKlineBeecham, and Cialis®, launched by Lilly ICOS LLC. Following the launch of these new products, the market for PDE5 inhibitors continued to grow. Based on the aging baby boomer population and their desire to maintain a healthy sexual lifestyle, we believe the market for PDE5 inhibitors should continue to grow.

Avanafil

We are developing avanafil, an orally administered PDE5 inhibitor, licensed from Tanabe Seiyaku Co., LTD., or Tanabe, in 2001. Avanafil, formerly known as TA-1790, is currently in Phase 2 clinical development. Pre-clinical and clinical data to date suggests the product candidate is:

- Highly selective to PDE5, which we believe should result in a favorable side effect profile; and
- Fast acting, which should promote spontaneity.

In March 2004, we began enrolling patients in an at-home, double blind, randomized, crossover design phase 2 clinical study to evaluate the safety and efficacy of avanafil. One of the primary goals of this study is to confirm the appropriate dose range in a large group of patients. Enrollment is anticipated to be completed by the end of 2004 and data from this study should be available during the first half of 2005. VIVUS plans to initiate drug interaction studies with avanafil later this year and anticipates completing Phase 2 development in 2005.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our

estimates, including those related to product returns, doubtful accounts, income taxes, restructuring, inventories and contingencies and litigation. (See Critical Accounting Policies and Estimates on page 23 of the Company's Annual Report on Form 10-K for the year ended December 31, 2003.) We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

RESULTS OF OPERATIONS

Three Months Ended March 31, 2004 and 2003

For the three months ended March 31, 2004, we reported a net loss of (\$10.9) million, or (\$0.29) net loss per share as compared to a net loss of (\$3.2) million, or (\$0.10) net loss per share, during the same quarter in 2003. Lower product sales in the United States and \$4.7 million of charges for licensing and milestone payments associated with three of our four late-stage development programs in the pipeline were the primary reasons for the change from the same period last year.

We anticipate continued losses over the next several years. We do not expect year-over-year increases in MUSE sales, and we plan to continue to invest in clinical development of our current research and development product candidates to bring those potential products to market.

Revenue. United States net product revenue for the quarter ended March 31, 2004 was \$572,000 compared to \$3.4 million for the quarter ended March 31, 2003. A decrease in sales in the first quarter of 2004 was anticipated as wholesale customers ordered large quantities of MUSE in the fourth quarter of 2003, in anticipation of a first quarter 2004 price increase.

We expect U.S. quarterly sales levels to increase through the remainder of 2004.

International product revenue was \$1.4 million for the first quarter of 2004, an increase of \$492,000 compared to the same period last year. Based on current forecasts, we anticipate that 2004 international revenue will increase over 2003 levels.

Cost of goods sold and gross margins. Cost of goods sold in the first quarter of 2004 was \$2.3 million, as compared to \$2.8 million for the first quarter of 2003. Cost of goods sold decreased because of lower sales in the first quarter of 2004 versus the same period in 2003. However, we typically expense approximately \$1.3 million of manufacturing overhead costs each quarter as period costs because of excess manufacturing capacity at our New Jersey facility. This accounting treatment is based on the determination made during the 1998 restructuring that the manufacturing capacity of the New Jersey plant far exceeds the level of production required to meet estimated future market demand. Thus, because the revenue dollars in the first quarter of 2004 were not sufficient to cover both the standard cost of product sales and the additional period expenses, negative gross profits resulted. Additionally, we increased production of finished goods in the first quarter of 2004 to replenish our U.S. inventories that were sold during the fourth quarter of 2003. Since manufacturing costs from cost of sales are capitalized as unit costs of inventory on the balance sheet as of March 31, 2004, the increase in production of inventory led to a \$335,000 incremental reduction in cost of goods sold. During the three months ended March 31, 2004 and 2003, we used certain raw material inventory, the cost basis of which had been reduced to zero in prior years. This had a favorable impact on our cost of sales in the first quarter of

2004 and 2003 of \$256,000 and \$190,000, respectively. The lower margins in the first quarter of 2004 were also attributable to increased international sales, which carry lower sales prices and higher material costs than U.S. product.

Research and development expenses. Research and development expenses for the first quarter of 2004 were \$7.7 million, as compared to \$2.3 million for the three months ended March 31, 2003. During the first quarter of 2004, we entered into exclusive licensing agreements with Acrux, under which we will develop and commercialize an estradiol spray for the alleviation of the symptoms of menopause and a testosterone spray for the treatment of low sexual desire in women. We reported a total \$2.9 million licensing fees incurred under the terms of the agreements. Portions of these licensing fees will be paid in September 2004 (\$250,000) and June 2005 (\$930,000). In addition, during the first quarter of 2004, we initiated a phase 2 clinical trial with avanafil, our oral phosphodiesterase type 5 (PDE5) inhibitor being studied for the treatment of erectile dysfunction. Under the terms of our 2001 development, licensing and supply agreement with Tanabe we reported a \$1.8 million milestone obligation to Tanabe in the first quarter of 2004. The payment of this milestone will be made in March 2006. The initiation of the phase 2 clinical trial in March 2004 resulted in an additional \$551,000 increase in expenses over the three months ended March 31, 2003. We do not expect to recognize revenue from sales of any new product candidates being developed through our research and development efforts until 2007 at the earliest.

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Selling, general and administrative expenses. Selling, general and administrative expenses in the first quarter of 2004 of \$3.0 million were \$436,000 higher than the same period last year primarily due to \$156,000 of legal fees related to the Acrux licensing agreements.

Interest income. Interest income for the three months ended March 31, 2004 was \$160,000 as compared to \$187,000 for the three months ended March 31, 2003. Despite an increase in our investments from March 31, 2003 to March 31, 2004, lower interest rates contributed to the reduction in interest income.

Provision for income taxes. During the first quarter of 2004, we recorded a net tax provision of \$3,000 based on minimum state income taxes due. During the first quarter of 2003, there was no such provision.

LIQUIDITY AND CAPITAL RESOURCES

Cash. Unrestricted cash, cash equivalents and available-for-sale securities totaled \$44.4 million at March 31, 2004 as compared to \$48.3 million at December 31, 2003. The decrease is primarily due to low U.S. sales in the first quarter of 2004, normal operating expenses and a \$1.8 million milestone payment to Acrux for our licensing agreement.

Since inception, we have financed operations primarily from the issuance of equity securities. Through March 31, 2004, we raised \$156.7 million from financing activities and had an accumulated deficit of \$111.9 million at March 31, 2004.

Available-for-sale securities. We focus on liquidity and capital preservation in our investments in available-for-sale securities. We restrict our cash investments to:

- Direct obligations of the United States Treasury;
- Federal Agency securities which carry the direct or implied guarantee of the United States government; and
- Corporate securities, including commercial paper, rated A1/P1 or better.

We sequence the maturities of our investments consistent with our cash forecasts. The weighted average maturity of our portfolio is not to exceed 18 months. As investments mature, we re-invest the money by purchasing additional securities. We sell such investment securities based upon our need for cash for the payment of operating expenses. Gains and losses on sales of securities are typically insignificant because we sequence maturities consistent with our cash forecasts.

Accounts Receivable. Accounts receivable (net of allowance for doubtful accounts) at March 31, 2004 was \$680,000 as compared to \$2.6 million at December 31, 2003. The 74.1% decrease in the accounts receivable balance at March 31, 2004 is due to an 91.6% decrease in the number of units sold in March 2004 as compared to December 2003. Currently, we do not have any significant concerns related to accounts receivable or collections.

Liabilities. Total liabilities were \$19.6 million at March 31, 2004, \$4.1 million higher than at December 31, 2003. Accrued research and development expenses increased \$3.0 million due to the future payment of milestones to Acrux and Tanabe and accounts payable increased \$1.1 million primarily due to the timing of payments.

Operating Activities. Our operating activities used \$4.9 million and provided \$17,000 of cash during the three months ended March 31, 2004 and 2003, respectively. During the first quarter of 2004, our net operating loss of \$10.9 million was offset by a \$3.0 million increase in accrued and other liabilities for the future payment of milestones to Acrux and Tanabe and a \$1.1 million increase in accounts payable. During the first quarter of 2003, our net operating loss was offset by a \$2.4 million reduction in our accounts receivable due to the collection of monies owed to us.

Investing Activities. Net cash used for investing activities was \$5.1 million and \$2.2 million during the three months ended March 31, 2004 and 2003, respectively. The fluctuations from period to period are due primarily to the timing of purchases, sales and maturity of investment securities.

Financing Activities. Financing activities provided cash of \$1.0 million and \$39,000 during the three months ended March 31, 2004 and 2003, respectively. These amounts include the proceeds from the exercise of stock options in both the first quarter of 2004 and 2003, and borrowings under note arrangements in the first quarter of 2004.

We anticipate that our existing capital resources combined with anticipated future cash flows will be sufficient to support our operating needs for at least the coming year. However, we anticipate that we will be required to obtain additional financing to fund the development of our research and development pipeline in future periods as well as to support the possible launch of any future products. In particular, we expect to make other substantial payments to Acrux and Tanabe in accordance with our agreements with them in connection with the licensing of certain compounds. These payments are based on certain development, regulatory and sales milestones. In addition, we are required to make royalty payments on any future product sales.

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In the first quarter of 2004, we signed an agreement for a line of credit with Tanabe, allowing us to borrow up to \$8.5 million to be used for the development of avanafil (TA-1790), our erectile dysfunction compound currently in Phase 2 clinical trials. The secured line of credit may be drawn upon quarterly and each quarterly borrowing will have a 48-month term and will bear interest at the annual rate of two percent. As of March 31, 2004 we had a long-term notes payable balance of \$316,000.

We expect to evaluate other potential financing sources, including, but not limited to, the issuance of additional equity or debt securities, corporate alliances, joint ventures, and licensing agreements to fund the development and possible commercial launch of any future products. The sale of additional equity securities would result in additional dilution to our stockholders. Our working capital and additional funding requirements will depend upon numerous factors, including:

- the progress of our research and development programs;
- the timing and results of pre-clinical testing and clinical trials;
- results of operations;
- demand for MUSE;
- technological advances;
- the level of resources that we devote to our sales and marketing capabilities; and
- the activities of competitors.

Overview of Contractual Obligations

Contractual Obligations	Payments Due by Period (in thousands)				
	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Operating Leases (1)	4,074	1,280	2,794	—	—
Purchases (2)	6,120	1,530	3,825	765	—
Notes Payable (3)	316	—	—	316	—
Other Long Term Liabilities (4)	5,981	250	2,710	3,021	—
Total	16,491	3,060	9,329	4,102	—

(1) We lease our manufacturing facilities in Lakewood, New Jersey under a non-cancelable operating lease expiring in 2007 and have the option to extend this lease for one additional renewal term of five years. In January 2000, we entered into a seven-year lease for our corporate headquarters in Mountain View, California, which expires in January 2007.

(2) In November 2002, we entered into a manufacturing agreement to purchase raw materials from a supplier beginning in 2003 and ending in 2008. In 2003, we purchased \$2.1 million of product and are committed to purchase a minimum total of \$3.8 million of product from 2004 through 2008.

In January 2004, we entered into a manufacturing agreement to purchase raw materials from an additional supplier beginning in 2004 and ending in 2006. We will be required to purchase a minimum total of \$2.3 million of product from 2004 through 2006.

(3) In the first quarter of 2004, we signed an agreement for a line of credit with Tanabe, allowing us to borrow up to \$8.5 million to be used for the development of avanafil (TA-1790), our erectile dysfunction compound currently in Phase 2 clinical trials. The secured line of credit may be drawn upon quarterly and each quarterly borrowing will have a 48-month term and will bear interest at the annual rate of two percent.

(4) Other Long Term Liabilities relates to the restoration liability for our leased manufacturing facilities. This liability will remain in effect through the end of the lease term, including any renewals. We exercised our first option to renew the original lease, thereby extending any cash payments to be made relating to this liability out to 2007. The second renewal term, if exercised, would then extend the liability out an additional five years, to 2012.

In January 2004, we entered into exclusive licensing agreements with Acrux under which we will develop and commercialize an estradiol spray for the alleviation of the symptoms of menopause and a testosterone spray for the treatment of low sexual desire in women. We reported a total \$2.9 million of licensing fees incurred under the terms of the agreements. Portions of these licensing fees will be paid in September 2004 (\$250,000) and June 2005 (\$930,000). In addition, during the first quarter of 2004, we initiated a phase 2 clinical trial with avanafil, our oral phosphodiesterase type 5 (PDE5) inhibitor being studied for the treatment of erectile dysfunction. Under the terms of our 2001 development, licensing and supply agreement with Tanabe we reported a \$1.8 million milestone obligation to Tanabe in the first quarter of 2004. The payment of this milestone will be made in March 2006.

RISK FACTORS AFFECTING OPERATIONS AND FUTURE RESULTS

Set forth below and elsewhere in this Form 10-Q and in other documents we file with the Securities and Exchange Commission are risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements contained in this Quarterly Report on Form 10-Q. These are not the only risks and uncertainties facing VIVUS. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

If we were unable to continue to develop, market and obtain regulatory approval for new product candidates, our business would be harmed.

The process of developing new drugs and/or therapeutic products is inherently complex and uncertain. We must make long-term investments and commit significant resources before knowing whether our development programs will eventually result in products that will receive regulatory approval and achieve market acceptance. As with any pharmaceutical product under development, there are significant risks in development, regulatory approval and commercialization of new compounds. During the product development phase, there is no assurance that the United States Food and Drug Administration will approve our clinical trial protocols. There is no guarantee that future clinical studies, if performed, will demonstrate the safety and efficacy of any product in development or that we will receive regulatory approval for such products. Further, the United States Food and Drug Administration can suspend clinical studies at any time if the agency believes that the subjects participating in such studies are being exposed to unacceptable health risks.

We cannot predict with certainty if or when we might submit for regulatory review those product candidates currently under development. Once we submit our potential products for review, we cannot assure you that the United States Food and Drug Administration or other regulatory agencies will grant approvals for any of our proposed products on a timely basis or at all. Further, even if we receive regulatory approval for a product, there can be no assurance that such product will prove to be commercially successful or profitable.

Sales of our products both inside and outside the United States will be subject to regulatory requirements governing marketing approval. These requirements vary widely from country to country and could delay the introduction of our proposed products in those countries. After the United States Food and Drug Administration and international regulatory authorities approve a product, we must manufacture sufficient volumes to meet market demand. This is a process that requires accurate forecasting of market demand. There is no guarantee that there will be market demand for any future products or that we will be able to successfully manufacture or adequately support sales of any future products.

In February 2004, we entered into exclusive license agreements with Acrux for the development and commercialization of topically applied Testosterone MDTs and Estradiol MDTs, in the United States only, for the treatment of low sexual desire and menopausal symptoms in women, respectively. Acrux has conducted clinical trials for both products under Investigational New Drug Applications on file with the United States Food and Drug Administration. Acrux is currently conducting a 200-patient Phase 2 study in Australia for Testosterone MDTs, which is expected to be completed in early 2005. We will conduct all other future development and clinical work for Testosterone MDTs. Assuming favorable results, we anticipate that we will begin Phase 3 clinical development of Testosterone MDTs in 2005. We plan to conduct Phase 3 clinical development for Estradiol MDTs in late 2004 for short-term therapy for women experiencing symptoms associated with menopause. However, there are no guarantees that Testosterone MDTs and/or Estradiol MDTs will prove to be safe and effective or receive regulatory approval for any indication. Further, even if we were to receive regulatory approval for these products, there can be no assurance that such products will prove to be commercially successful or profitable.

We are developing avanafil, formerly known as TA-1790, as potential oral and local treatments for male and female sexual dysfunction, and we are developing ALISTA for the potential treatment of female sexual arousal disorder. We are currently conducting pre-clinical safety studies for avanafil and have completed dosing in two efficacy studies in patients with erectile dysfunction. In March 2004, we began a Phase 2 clinical trial for avanafil, the results of which are expected in the first half of 2005. We also completed two Phase 2 ALISTA clinical trials and a third study began in the first quarter of 2003, the results of which are expected in the middle of 2004. We intend to initiate additional clinical studies that would be required to obtain regulatory approval for avanafil and ALISTA. However, there are no guarantees that avanafil and/or ALISTA will prove to be safe and effective or receive regulatory approval for any indication. Further, even if we were to receive regulatory approval for these products, there can be no assurance that such products will prove to be commercially successful or profitable.

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The markets in which we operate are highly competitive and we may be unable to compete successfully against new entrants or established companies with greater resources.

Competition in the pharmaceutical and medical products industries is intense and is characterized by extensive research efforts and rapid technological progress. The most significant competitive therapy for MUSE is an oral medication marketed by Pfizer under the name Viagra, which received regulatory approvals in the United States in March 1998 and in the European Union in September 1998. The commercial launch of Viagra in the United States in April 1998 significantly decreased demand for MUSE. Another oral medication under the name Uprima was approved and launched in Europe by Abbott Laboratories and Takeda in May 2001. In February 2003, a new oral medication under the name Cialis was launched in Europe by Lilly ICOS LLC and in Australia and New Zealand by Eli Lilly and Company. Cialis was launched in the United States in January 2004. Bayer AG and GlaxoSmithKline plc launched Levitra in the European Union and the United States in March and September 2003, respectively.

Other treatments for erectile dysfunction exist, such as needle injection therapy, vacuum constriction devices and penile implants, and the manufacturers of these products will most likely continue to improve these therapies. Additional competitive products in the erectile dysfunction market include needle injection therapy products from Pfizer (formerly Pharmacia), Schwartz Pharma, Fournier and Senetek.

Several large pharmaceutical companies are also actively engaged in the development of therapies for the treatment of erectile dysfunction and female sexual dysfunction. 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 us in undertaking pre-clinical testing, human clinical trials and other regulatory approval procedures. Our competitors may develop technologies and products that are more effective than those we are currently marketing or developing. Such developments could render our products less competitive or possibly obsolete. We are also competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have limited experience.

If we, or our suppliers, fail to comply with United States Food and Drug Administration and other government regulations, our manufacturing operations could be interrupted, and our product sales and profitability could suffer.

All new drugs, including our products under development, are subject to extensive and rigorous regulation by the United States Food and Drug Administration and comparable foreign authorities. These regulations govern, among other things, the development, pre-clinical and clinical testing, manufacturing, labeling, storage, pre-market approval, advertising, promotion, sale and distribution of our products. To date, MUSE has received marketing approval in more than 40 countries worldwide.

After regulatory approval is obtained, our products are subject to continual regulatory review. Manufacturing, labeling and promotional activities are continually regulated by the United States Food and Drug Administration and equivalent foreign regulatory agencies, and we must also report certain adverse events involving our products 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 could have a material adverse effect on our business, financial condition and results of operations.

Failure to comply with the applicable regulatory requirements can result in, among other things, civil penalties, suspensions of regulatory approvals, product recalls, operating restrictions and criminal prosecution. The marketing and manufacturing of pharmaceutical products are subject to continual United States Food and Drug Administration and other regulatory review, and later discovery of previously unknown problems with a product, manufacturer or facility may result in the United States Food and Drug Administration and/or 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 could have a material adverse effect on our business, financial condition and results of operations.

Failure of our third-party manufacturers to maintain satisfactory compliance with current Good Manufacturing Practices, or cGMPs, could have a material adverse effect on our ability to continue to market and distribute our products and, in the most serious cases, could result in the issuance of warning letters, seizure or recall of products, civil penalties or closure of our manufacturing facility until such cGMP compliance is achieved. We obtain the necessary raw materials and components for the manufacture of MUSE as well as certain services, such as testing and sterilization, from third parties. We currently contract with suppliers and service providers, including foreign manufacturers that are required to comply with strict standards established by us. Certain suppliers and service providers are required to follow cGMP requirements and are subject to routine unannounced periodic inspections by the United States Food and Drug Administration and by certain state and foreign regulatory agencies for compliance with cGMP

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requirements and other applicable regulations. Certain of our 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 United States Food and Drug Administration and other regulatory agencies will find the manufacturing process or facilities to be in compliance with cGMP requirements and other regulations.

Failure to achieve satisfactory cGMP compliance as confirmed by routine unannounced inspections could have a material adverse effect on our ability to continue to manufacture and distribute our 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 penalties or closure of our manufacturing facility until cGMP compliance is achieved.

We have limited sales and marketing capabilities in the United States.

We support MUSE sales in the United States through a small sales support group targeting major accounts that include the top prescribers of MUSE. Telephone marketers also focus on 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. There can be no assurance that our sales programs will effectively maintain or potentially increase current sales levels. There can be no assurance that demand for MUSE will continue or that we will be able to adequately support sales of MUSE in the United States in the future.

We rely on third parties to manufacture sufficient quantities of compounds for use in our pre-clinical and clinical trials and an interruption to this service may harm our business.

We do not have the ability to manufacture the materials we use in our pre-clinical and clinical trials, and we rely on various third parties to perform this function. There can be no assurance that we will be able to identify and qualify additional sources for clinical materials. If interruptions in this supply occur for any reason, including a decision by the third parties to discontinue manufacturing, labor disputes or a failure of the third parties to follow regulations, we may not be able to obtain regulatory approvals for our proposed products and may not be able to successfully commercialize these proposed products.

We rely on third parties to conduct clinical trials for our product candidates in development and those third parties may not perform satisfactorily.

We do not have the ability to independently conduct clinical studies for any of our products currently in development, and we rely on third parties to perform this function. If third parties do not successfully carry out their contractual duties or meet expected timelines, we may not be able to obtain regulatory approvals for our proposed products and may not be able to successfully commercialize these proposed products. If third parties do not perform satisfactorily, we may not be able to locate acceptable replacements or enter into favorable agreements with them, if at all.

If the results of future clinical testing indicate that our proposed products are not safe or effective for human use, our business will suffer.

All of the drug candidates that we are currently developing require extensive pre-clinical and clinical testing before we can submit any application for regulatory approval. Before obtaining regulatory approvals for the commercial sale of any of our proposed drug products, we must demonstrate through pre-clinical testing and clinical trials that our product candidates are safe and effective in humans. Conducting clinical trials is a lengthy, expensive and uncertain process. Completion of clinical trials may take several years or more. Our commencement and rate of completion of clinical trials may be delayed by many factors, including:

- ineffectiveness of the study compound, or perceptions by physicians that the compound is not effective for a particular indication;
- inability to manufacture sufficient quantities of compounds for use in clinical trials;
- failure of the United States Food and Drug Administration to approve our clinical trial protocols;
- slower than expected rate of patient recruitment;
- inability to adequately follow patients after treatment;
- unforeseen safety issues; or
- government or regulatory delays.

The clinical results we have obtained to date do not necessarily predict that the results of further testing, including later stage controlled human clinical testing, will be successful. If our trials are not successful or are perceived as not successful by the United States Food and Drug Administration or physicians, our business, financial condition and results of operations will be materially harmed.

If we require additional capital for our future operating plans, we may not be able to secure the requisite additional funding on acceptable terms, if at all.

Our capital resources from operating activities are expected to continue to decline over the next several quarters as the result of increased spending for research and development projects, including clinical trials. We expect that our existing capital resources combined with future cash flows will be sufficient to support operating needs for at least the coming year. Financing in future periods will most likely be required to fund development of our research and development pipeline and the possible launch of any future products. Our future capital requirements will depend upon numerous factors, including:

- the progress of our research and development programs;
- the scope, timing and results of pre-clinical testing and clinical trials;
- the results of operations;
- the cost, timing and outcome of regulatory reviews;
- the rate of technological advances;
- ongoing determinations of the potential commercial success of our products under development;
- the level of resources devoted to sales and marketing capabilities; and
- the activities of competitors.

To obtain additional capital when needed, we will evaluate alternative financing sources, including, but not limited to, the issuance of 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. If we are unable to obtain additional capital, management may be required to explore alternatives to reduce cash used by operating activities, including the termination of research and development efforts that may appear to be promising to the Company.

We may be sued for infringing on the intellectual property rights of others.

There can be no assurance that our products do not or will not infringe on the patent or proprietary rights of others. Third parties may assert that we are employing our proprietary technology without authorization. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes these patents. We could incur substantial costs and diversion of the time and attention of management and technical personnel in defending ourselves against any such claims. Furthermore, parties making claims against us may be able to obtain injunctive or other equitable relief that could effectively block our ability to further develop, commercialize and sell products, and such claims could result in the award of substantial damages against us. In the event of a successful claim of infringement against us, we may be required to pay damages and obtain one or more licenses from third parties. We may not be able to obtain these licenses at a reasonable cost, if at all. In that event, we could encounter delays in product introductions while we attempt to develop alternative methods or products or be required to cease commercializing affected products and our operating results would be harmed.

Our inability to adequately protect our proprietary technologies could harm our competitive position and have a material adverse effect on our business.

We hold various patents and patent applications in the United States and abroad targeting male and female sexual health. The success of our business depends, in part, on our ability to obtain patents and maintain adequate protection of our intellectual property for our proprietary technology and products in the United States and other countries. The laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting their proprietary rights in these foreign countries. These problems can be caused by, for example, a lack of rules and processes allowing for meaningful defense of intellectual property rights. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode our competitive advantage, and our business and operating results could be harmed.

The patent positions of pharmaceutical companies, including our patent position, are often uncertain and involve complex legal and factual questions. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. We apply for patents covering our technologies and products, as we deem appropriate. However, we may not obtain patents on all inventions for which we seek patents, and any patents we obtain may be challenged and may be narrowed in scope or extinguished as a result of such challenges. We could incur substantial costs in proceedings before the United States Patent and Trademark Office, including interference proceedings. These proceedings could also result in adverse decisions as to the priority of our inventions. There can be no assurance that our patents will not be successfully challenged or designed around by others.

Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Others may independently develop similar or alternative technologies or design around our patented technologies or products. These companies would then be able to develop, manufacture and sell products that compete directly with our products. In that case, our revenues and operating results would decline.

We seek to protect our confidential information by entering into confidentiality agreements with employees, collaborators and consultants. Nevertheless, employees, collaborators or consultants may still disclose or misuse our confidential information, and we may not be able to meaningfully protect our trade secrets. In addition, others may independently develop substantially equivalent information or techniques or otherwise gain access to our trade secrets. Disclosure or misuse of our confidential information would harm our competitive position and could cause our revenues and operating results to decline.

If our raw material suppliers fail to supply us with alprostadil, for which availability is limited, we may experience delays in our product development and commercialization.

We are required to initially receive regulatory approval for suppliers and we obtained our current supply of alprostadil from two approved sources. The first is NeraPharm, formerly Spolana Chemical Works a.s., in Neratovice, Czech Republic. The second is Chinoin Pharmaceutical and Chemical Works Co., Ltd. We have manufacturing agreements with Chinoin and NeraPharm respectively, to produce additional quantities of alprostadil for us. We are currently in the process of assuring the new material meets testing and regulatory specifications. There can be no guarantees the material will pass these requirements and be usable material in our manufacturing process. We are currently in the process of investigating additional sources for our future alprostadil supplies. However, there can be no assurance that we will be able to identify and qualify additional suppliers of alprostadil, in a timely manner, if at all.

Furthermore, alprostadil is subject to periodic re-testing to ensure it continues to meet specifications. There can be no guarantees that our existing inventory of alprostadil will pass these re-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 our business, financial condition and results of operations.

We outsource several key parts of our operations and any interruption in the services provided could harm our business.

We entered into a distribution agreement with Cardinal Health. Under this agreement, Cardinal Health takes the following actions:

- warehouses our finished goods for United States distribution;
- takes customer orders;
- picks, packs and ships our products;
- invoices customers; and
- collects related receivables.

As a result of this distribution agreement, we are heavily dependent on Cardinal Health's efforts to fulfill orders and warehouse our products effectively in the United States. There can be no assurance that such efforts will continue to be successful.

Gibraltar Laboratories performs sterility testing on finished product manufactured by us to ensure that it complies with product specifications. Gibraltar Laboratories 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 cGMP regulations and cleanliness standards. As a result of this testing agreement, we are dependent on Gibraltar Laboratories to perform testing and issue reports on finished product and the manufacturing environment in a manner that meets cGMP regulations. There can be no assurance that such efforts will be successful.

We have an agreement with WRB Communications to handle patient and healthcare professional hotlines for us. WRB Communications maintains a staff of healthcare professionals to answer questions and inquiries about MUSE and ACTIS. These calls may include complaints about our products due to efficacy or quality, as well as the reporting of adverse events. As a result of this agreement, we are dependent on WRB Communications to effectively handle these calls and inquiries. There can be no assurance that such efforts will be successful.

We entered into a distribution agreement with Integrated Commercialization Services, or ICS, a subsidiary of Bergen Brunswig Corporation. ICS provides "direct-to-physician" distribution capabilities in support of United States marketing and sales efforts. As a result of this distribution agreement, we are dependent on ICS's efforts to distribute product samples effectively. There can be no assurance that such efforts will be successful.

We currently depend on a single source for the supply of plastic applicator components, and an interruption to this supply source could harm our business.

We rely on a single injection molding company, Medegen, for our supply of plastic applicator components. In turn, Medegen obtains its supply of resin, a key ingredient of the applicator, from a single source, Huntsman Corporation. There can be no assurance that we will be able to identify and qualify additional sources of plastic components. We are required to initially receive United States Food and Drug Administration approval for suppliers. Until we secure and qualify additional sources of plastic components, we are entirely dependent upon Medegen. If interruptions in this supply occur for any reason, including a decision by Medegen to discontinue manufacturing, labor disputes or a failure of Medegen to follow regulations, the development and commercial marketing of MUSE and other potential products could be delayed or prevented. An extended interruption in the supply of plastic components could have a material adverse effect on our business, financial condition and results of operations.

All of our manufacturing operations are currently conducted at a single location, and a prolonged interruption to our manufacturing operations could harm our business.

We lease 90,000 square feet of space in Lakewood, New Jersey for our manufacturing operation, which includes formulation, filling, packaging, analytical laboratories, storage, distribution and administrative offices. The United States Food and Drug Administration and the Medicines and Healthcare products Regulatory Agency, formerly the Medicines Control Agency, the regulatory authority in the United Kingdom, authorized us to begin commercial production and shipment of MUSE from this facility in June and March 1998, respectively. MUSE is manufactured in this facility and we have 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 could have a material adverse effect on our business, financial condition and results of operations.

We depend exclusively on third-party distributors outside of the United States and we have very limited control over their activities.

We entered into agreements granting Meda AB exclusive marketing and distribution rights for MUSE and ACTIS in all Member States of the European Union, the Baltic States, the Czech Republic, Hungary, Iceland, Norway, Poland, Switzerland and Turkey. These agreements do not have minimum purchase commitments and we are entirely dependent on Meda AB's efforts to distribute and sell our products effectively in all these markets. There can be no assurance that such efforts will be successful or that Meda AB will continue to support the products.

We entered into an agreement granting Paladin Labs exclusive marketing and distribution rights for MUSE in Canada. This agreement does not have minimum purchase commitments and we are entirely dependent on Paladin Labs' efforts to distribute and sell our product effectively in Canada. There can be no assurance that such efforts will be successful or that Paladin Labs will continue to support the product.

We have an accumulated deficit of \$111.9 million at March 31, 2004 and expect to continue to incur substantial operating losses for the foreseeable future.

We have generated a cumulative net loss of \$111.9 million for the period from our inception through March 31, 2004 and we anticipate losses for the next several years due to increased investment in our research and development programs and limited revenues. There can be no assurance that we will be able to achieve profitability on a sustained basis. Accordingly, there can be no assurance of our future success.

We are dependent upon a single approved therapeutic approach to treat erectile dysfunction.

MUSE relies on a single approved therapeutic approach to treat erectile dysfunction, a transurethral system. 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 erectile dysfunction, thereby affecting the commercial viability of MUSE. In addition, technological changes or medical advancements could diminish or eliminate the commercial viability of our product, the results of which could have a material effect on our business operations and results.

If we fail to retain our key personnel and hire, train and retain qualified employees, we may not be able to compete effectively, which could result in reduced revenues.

Our success is highly dependent upon the skills of a limited number of key management personnel. To reach our business objectives, we 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 we will be able to hire or retain such personnel, as we must compete with other companies, academic institutions, government entities and other agencies. The loss of any of our key personnel or the failure to attract or retain necessary new employees could have an adverse effect on our research, product development and business operations.

We are subject to additional risks associated with our international operations.

MUSE and ACTIS are currently marketed internationally. Changes in overseas economic and political conditions, terrorism, currency exchange rates, foreign tax laws or tariffs or other trade regulations could have an adverse effect on our business, financial condition and results of operations. The international nature of our business is also expected to subject us and our representatives, agents and distributors to laws and regulations of the foreign jurisdictions in which we operate or where our products are sold. The regulation of drug therapies in a number of such jurisdictions, particularly in the European Union, continues to develop, and there can be no assurance that new laws or regulations will not have a material adverse effect on our business, financial condition and results of operations. In addition, the laws of certain foreign countries do not protect our intellectual property rights to the same extent, as do the laws of the United States.

Any adverse changes in reimbursement procedures by Medicare and other third-party payors may limit our ability to market and sell our products.

In the United States and elsewhere, sales of pharmaceutical products are dependent, in part, on the availability of reimbursement to the consumer from third-party payors, such as government and private insurance plans. Third party payors are increasingly challenging the prices charged for medical products and services. While a large percentage of prescriptions in the United States for MUSE have been reimbursed by third party payors since our commercial launch in January 1997, there can be no assurance that our products will be considered cost effective and that reimbursement to the consumer will continue to be available or sufficient to allow us to sell our 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. We hope to further qualify MUSE for reimbursement in the managed care environment. However, we are 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.

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, we cannot predict which, if any, of the reform proposals will be adopted or the effect such adoption may have on us. 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 us. Healthcare reform is also under consideration in some other countries.

If we become subject to product liability claims, we may be required to pay damages that exceed our insurance coverage.

The commercial sale of MUSE and our clinical trials exposes us 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. We detail potential side effects in the patient package insert and the physician package insert, both of which are distributed with MUSE. While we believe that we are reasonably insured against these risks, we may not be able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. A product liability claim in excess of, or excluded from, our insurance coverage would have to be paid out of cash reserves and could have a material adverse effect upon our business, financial condition and results of operations. Product liability insurance is expensive, difficult to maintain, and current or increased coverage may not be available on acceptable terms, if at all.

Our stock price has been and may continue to be volatile.

The market price of our common stock has been volatile and is likely to continue to be so. The market price of our common stock may fluctuate due to factors including, but not limited to:

- announcements of technological innovations or new products by us or our competitors;
- our ability to increase demand for our products in the United States;
- our ability to successfully sell our products in the United States and internationally;
- actual or anticipated fluctuations in our financial results;
- our ability to obtain needed financing;
- economic conditions in the United States and abroad;
- comments by or changes in Company assessments or financial estimates by security analysts;
- adverse regulatory actions or decisions;
- any loss of key management;
- the results of our clinical trials or those of our competitors;
- developments or disputes concerning patents or other proprietary rights;
- product or patent litigation; or
- public concern as to the safety of products developed by us.

These factors and fluctuations, as well as political and market conditions, may materially adversely affect the market price of our common stock. Securities class action litigation is often brought against a company following periods of volatility in the market price of its securities. We may be the target of similar litigation. Securities litigation, whether with or without merit, could result in substantial costs and divert management's attention and resources, which could harm our business and financial condition, as well as the market price of our common stock.

Additionally, volatility or a lack of positive performance in our stock price may adversely affect our ability to retain key employees, all of whom have been granted stock options.

Our charter documents and Delaware law could make an acquisition of our company difficult, even if an acquisition may benefit our stockholders.

Our Board of Directors has adopted a Preferred Shares Rights Plan. The Preferred Shares Rights Plan has the effect of causing substantial dilution to a person or group that attempts to acquire us on terms not approved by our Board of Directors. The existence of the Preferred Shares Rights Plan could limit the price that certain investors might be willing to pay in the future for shares of our common stock and could discourage, delay or prevent a merger or acquisition that a stockholder may consider favorable.

Certain provisions of our Amended and Restated Certificate of Incorporation and Bylaws could also delay or prevent a change in control of our company. Some of these provisions:

- authorize the issuance of preferred stock by the Board of Directors without prior stockholder approval, commonly referred to as "blank check" preferred stock, with rights senior to those of common stock;
- prohibit stockholder actions by written consent;
- 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.

In addition, we are governed by the provisions of Section 203 of Delaware General Corporate Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us. These and other provisions in our charter documents could reduce the price that investors might be willing to pay for shares of our common stock in the future and result in the market price being lower than it would be without these provisions.

Changes in accounting standards regarding stock option plans could limit the desirability of granting stock options, which could harm our ability to attract and retain employees, and could also reduce our profitability.

The Financial Accounting Standards Board is considering whether to require all companies to treat the value of stock options granted to employees as an expense. The United States Congress and other governmental and regulatory authorities have also considered requiring companies to expense stock options. If this change were to become mandatory, we and other companies would be required to record a compensation expense equal to the fair market value of each stock option granted. This expense would be spread over the vesting period of the stock option. Currently, we account for stock compensation under Accounting Principles Board, or APB, No. 25, *Accounting for Stock Issued to Employees*, which results in no compensation expenses recorded in connection with stock options granted to our employees. If we were

required to expense stock option grants, it would reduce the attractiveness of granting stock options because of the additional expense associated with these grants, which would reduce our profitability. However, stock options are an important employee recruitment and retention tool, and we may not be able to attract and retain key personnel if we reduce the scope of our employee stock option program. Accordingly, in the event we are required to expense stock option grants, our profitability would be reduced, as would our ability to use stock options as an employee recruitment and retention tool.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Securities and Exchange Commission's rule related to market risk disclosure requires that we describe and quantify our potential losses from market risk sensitive instruments attributable to reasonably possible market changes. Market risk sensitive instruments include all financial or commodity instruments and other financial instruments that are sensitive to future changes in interest rates, currency exchange rates, commodity prices or other market factors. We are not exposed to market risks from changes in foreign currency exchange rates or commodity prices. We do not hold derivative financial instruments nor do we hold securities for trading or speculative purposes. At March 31, 2004, we had drawn \$316,000 of the \$8.5 million line of credit with Tanabe. Each quarterly borrowing will have a 48-month term and will bear interest at the annual rate of two percent. At December 31, 2003 we had no debt outstanding, and therefore no risk exposure associated with increasing interest rates. We, however, are exposed to changes in interest rates on our investments in cash equivalents and available-for-sale securities. A significant portion of all of our investments in cash equivalents and available-for-sale securities are in money market funds that hold short-term investment grade commercial paper, treasury bills or other United States government obligations. Currently, this reduces our exposure to long-term interest rate changes.

ITEM 4. CONTROLS AND PROCEDURES

(a.) Evaluation of disclosure controls and procedures. Our management evaluated, with the participation of our Chief Executive Officer and our Chief Financial Officer, the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

(b.) Changes in internal controls. There was no change in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None

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

None

ITEM 5. OTHER INFORMATION

None

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

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

<u>EXHIBIT NUMBER</u>	<u>DESCRIPTION</u>
3.2(4)	Amended and Restated Certificate of Incorporation of the Company
3.3(3)	Bylaws of the Registrant, as amended
3.4(5)	Certificate of Designations of Rights, Preferences and Privileges of Series A Participating Preferred Stock
4.1(4)	Specimen Common Stock Certificate of the Registrant
4.5(5)	Second Amended and Restated Preferred Shares Rights Agreement, dated as of April 15, 1997 by and between the Registrant and Harris Trust Company of California, including the Certificate of Determination, the form of Rights Certificate and the Summary of Rights attached thereto as Exhibits A, B, and C, respectively
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(3)	Form of Indemnification Agreements by and among the Registrant and the Directors and Officers of the Registrant
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
10.28(4)	Lease Agreement made as of January 1, 1997 between the Registrant and Airport Associates
10.29(4)	Lease Amendment No. 1 as of February 15, 1997 between Registrant and Airport Associates
10.29A(6)	Lease Amendment No. 2 dated July 24, 1997 by and between the Registrant and Airport Associates
10.29B(6)	Lease Amendment No. 3 dated July 24, 1997 by and between the Registrant and Airport Associates
10.36(7)	Form of, "Change of Control Agreements," dated July 8, 1998 by and between the Registrant and certain Executive Officers of the Company.
10.39(8)	Sublease agreement between KVO Public Relations, Inc. and the Registrant dated December 21, 1999
10.41(9)†	License and Supply Agreement made as of November 20, 2000 between the Registrant and Paladin Labs, Inc.
10.42(9)†	Development, License and Supply Agreement made as of January 22, 2001 between the Registrant and TANABE SEIYAKU CO., LTD.
10.42A	Amendment One to Agreement, dated January 9, 2004 between Registrant and TANABE SEIYAKU CO., LTD.
10.43(10)†	Settlement and Modification Agreement made as of July 12, 2001 between ASIVI, LLC, AndroSolutions, Inc. Gary W. Neal and the Registrant.
10.44(11)	2001 Stock Option Plan and Form of Agreement
10.45(12)†	Supply Agreement made as of September 3, 2002 between the Registrant and Meda AB.
10.46(13)†	Amendment Three, dated November 21, 2002 by and between VIVUS, Inc. and CHINOIN Pharmaceutical and Chemical Works, Ltd.

**EXHIBIT
NUMBER**

DESCRIPTION

10.47(13)	Lease Amendment No. 4 and Settlement Agreement dated October 25, 2000 by and between the Registrant and Airport Associates
10.48(13)†	Exclusive Distribution Agreement dated October 1, 2002 between the Registrant and Cord Logistics
10.49(13)†	Distribution and Supply Agreement made as of February 18, 2003 between the Registrant and Meda AB.
10.50††	Testosterone Development and Commercialization Agreement made as of February 7, 2004 between the Registrant, Fempharm Pty Ltd. and Acrux DDS Pty Ltd.

- 10.51†† Estradiol Development and Commercialization Agreement made as of February 12, 2004 between the Registrant, Fempharm Pty Ltd. and Acrux DDS Pty Ltd.
- 10.52†† Note Purchase Agreement, dated January 8, 2004 between Registrant and Tanabe Holding America, Inc.
- 10.53†† Manufacture and Supply Agreement, dated December 22, 2003 between Registrant and NeraPharm spol., s.r.o. and signed by the Company on January 7, 2004.
- 31.1 Certification of Chief Executive Officer, dated May 7, 2004, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended.
- 31.2 Certification of Chief Financial Officer, dated May 7, 2004, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended.
- 32 Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

† 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 Form 8-B filed with the Commission on June 24, 1996.
- (4) 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.
- (5) 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.
- (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, 1997.
- (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, 1998.
- (8) 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.
- (9) 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.
- (10) 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, 2001.
- (11) Incorporated by reference to the same numbered exhibit filed with the Registrant's Registration Statement on Form S-8 filed with the Commission on November 15, 2001.

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- (12) Incorporated by reference to the same numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended November 30, 2002.
 - (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, 2002.
 - (b) Reports on Form 8-K.

On January 30, 2004, we furnished a current report on Form 8-K that disclosed our financial results for the year ended December 31, 2003 and certain other information. The Form 8-K included our audited financial statements for the year ended December 31, 2003.

On February 9, 2004, we filed a current report on Form 8-K that announced that data from our Phase 2 head-to-head at-home study comparing the onset of action between TA-1790, our oral phosphodiesterase type 5 (PDE5) inhibitor for the treatment of erectile dysfunction, and Pfizer's Viagra (sildenafil) showed comparable results.

On February 12, 2004, we filed a current report on Form 8-K that announced the execution of exclusive licensing agreements with Acrux Limited, a pharmaceutical company based in Melbourne, Australia, under which we have the rights and responsibilities to develop and commercialize Testosterone MDTs® and Estradiol MDTs® in the United States for treatment of low sexual desire and menopausal symptoms, respectively.

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: May 7, 2004

VIVUS, Inc.

/s/ LARRY J. STRAUSS

/s/ LELAND F. WILSON

Leland F. Wilson
President and Chief Executive Officer

VIVUS, INC.

INDEX TO EXHIBITS

<u>EXHIBIT</u>	<u>DESCRIPTION</u>
10.42A	Amendment One to Agreement, dated January 9, 2004 between Registrant and TANABE SEIYAKU CO., LTD.
10.50††	Testosterone Development and Commercialization Agreement made as of February 7, 2004 between the Registrant, Fempharm Pty Ltd. and Acrux DDS Pty Ltd.
10.51††	Estradiol Development and Commercialization Agreement made as of February 12, 2004 between the Registrant, Fempharm Pty Ltd. and Acrux DDS Pty Ltd.
10.52††	Note Purchase Agreement, dated January 8, 2004 between Registrant and Tanabe Holding America, Inc.
10.53††	Manufacture and Supply Agreement, dated December 22, 2003 between Registrant and NeraPharm spol., s.r.o. and signed by the Company on January 7, 2004.
31.1	Certification of Chief Executive Officer, dated May 7, 2004, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer, dated May 7, 2004, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended.
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

†† Confidential treatment requested.

AMENDMENT NO. 1 TO AGREEMENT

This Amendment No. 1 to Agreement (this "Amendment"), made as of January 9, 2004, (hereinafter referred to as "EFFECTIVE DATE"), between TANABE SEIYAKU CO., LTD., a Japanese corporation having its principal office at 2-10 Dosho-machi 3-chome, Chuo-ku, Osaka, Japan (hereinafter referred to as "TANABE") and VIVUS, INC., a corporation having its principal office at 1172 Castro Street, Mountain View, CA 94040, USA (hereinafter referred to as "VIVUS"). TANABE and VIVUS are sometimes referred to herein individually as a "Party" or collectively as "Parties."

WITNESSETH:

WHEREAS, the Parties entered into that certain Agreement dated as of December 28, 2000 (the "Agreement") pursuant to which, among other things, TANABE granted to VIVUS certain rights relating to products as further set forth in the Agreement in exchange for the payment by VIVUS to TANABE of certain milestone payments set forth in Section 10 of the Agreement;

WHEREAS, the Parties desire to amend the Agreement to defer the scheduled milestone payment set forth in Section 10(a)(1) of the Agreement;

NOW, THEREFORE, in consideration of the covenants and obligations expressed herein, and intending to be legally bound, the Parties agree as follows:

1. Definitions.

Capitalized terms used but not defined herein shall have the meanings set forth in the Agreement.

2. Amendment and Restatement of Section 10(a)(1).

Section 10(a)(1) of the Agreement, which presently reads as follows:

"two million United States Dollars (U.S. \$2,000,000) upon the enrollment of the first patient in the first PHASE II CLINICAL STUDIES in the TERRITORY."

is amended and restated to read as follows:

"two million United States Dollars (U.S. \$2,000,000) upon the earlier to occur of (A) the second anniversary of the enrollment of the first patient in the first PHASE II CLINICAL STUDIES in the TERRITORY, and (B) the grant by VIVUS of any sublicense to one or more THIRD PARTIES pursuant to Section 2.3 of the Agreement.

3. Governing Law.

This Amendment and any dispute, including without limitation any arbitration, arising from performance or breach hereof shall be governed by and construed and enforced in accordance with the following: (i) if a dispute is filed in court or in arbitration by

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VIVUS, the laws of Japan shall govern such dispute, and (ii) if a dispute is filed in court or in arbitration by TANABE, the laws of the state of California shall govern such dispute, in each case without reference to conflicts of law principles.

4. Authentic Text.

This Amendment is entered into in the English language. In the event of any dispute concerning the construction or meaning of this Amendment, reference shall be made only to this Amendment as written in English and not to any translation into any other language.

IN WITNESS WHEREOF, the Parties have caused this Amendment to be duly executed by their respective officers as of the EFFECTIVE DATE.

TANABE SEIYAKU CO., LTD.

VIVUS, INC.

By: /s/ Natsuki Hayama

By: /s/ Leland Wilson

Title: President & CEO

Title: President & C.E.O.

DATE: FEBRUARY 7, 2004

FEMPHARM PTY LTD

and

VIVUS INC.

and

ACRUX DDS PTY LTD

TESTOSTERONE
DEVELOPMENT AND
COMMERCIALIZATION AGREEMENT

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THIS DEVELOPMENT AND COMMERCIALIZATION AGREEMENT (the "Agreement") is dated and effective as of February 7, 2004 (the "Effective Date").

PARTIES:

FEMPHARM PTY LTD (ABN 35 088 778 018) of 103-113 Stanley Street, West Melbourne, Victoria, Australia ("FemPharm")

and

VIVUS INC. of 1172 Castro Street, Mountain View, California, United States of America ("Vivus")

and

ACRUX DDS PTY LTD

RECITALS

- A. FemPharm, formerly known as Female HRT Pty Ltd., Australian Company Number 088 778 018, is a wholly owned subsidiary of Acrux Limited of 103-113 Stanley Street, West Melbourne, Victoria, Australia ("Acrux Limited"). Acrux DDS Pty Limited ("Acrux DDS Pty Limited"), formerly known as Drug Delivery Solutions Pty Ltd., Australian company number 088 778 009, is also a wholly owned subsidiary of Acrux Limited.
- B. Acrux DDS Pty Limited holds an exclusive global license from Monash University of Wellington Road, Clayton, Victoria, Australia ("Monash") in respect of certain patents and patent applications owned by Monash University covering the metered dose transdermal system described therein.
- C. FemPharm holds an exclusive sublicense from Acrux DDS Pty Limited in respect of the intellectual property described in the license referred to in recital B for the fields of female hormone replacement therapy and human female contraception.

- D. FemPharm and Vivus wish to enter into this agreement pursuant to which FemPharm will exclusively license metered dose transdermal systems to Vivus for the delivery of testosterone to human females on the terms set out in this Agreement.

AGREEMENT

1. DEFINITIONS AND INTERPRETATION

1.1 DEFINITIONS

In this Agreement, the following capitalized terms have the following meanings:

"Acrux DDS License" shall mean the "Licence Agreement" between Female HRT Party Limited (now known as FemPharm) and Drug Delivery Solutions Party Limited (now known as Acrux DDS Pty Limited), dated November 30, 1999, as amended by the Deed of Amendment between Female HRT Party Limited and Drug Delivery Solutions Party Limited dated June 30, 2000, and as such agreement may be subsequently amended by the parties thereto.

"Acrux Penetration Enhancer" shall mean one of the following, whichever is used in the Product being developed or commercialized by or under authority of Vivus under this Agreement, as used in such Product (i) (**), (ii) a different dermal penetration enhancer which is disclosed in the FemPharm Patents, or (iii) the combination of (**) with another dermal penetration enhancer(s) disclosed in the FemPharm Patents.

"Additional Partner" shall mean each third party who is granted by FemPharm or an Acrux Controlled Affiliate, directly or indirectly, a right to market or commercialize a Product in the Field in any part of the world, other than the Territory.

"Affiliate" means, with respect to any Party, any corporation or other legal entity that controls, is controlled by or is in common control with such Party. For purposes of this definition, the term "controls" means (with correlative meanings for the terms "controlled by" and "in common control with"):

- (a) ownership, directly or indirectly, of more than 50% of the voting securities of the applicable party; or

- (b) possession of actual power to direct unilaterally the business and affairs of the applicable party, whether through contract, ownership rights or otherwise.

"Androgen" means (a) any of the naturally occurring androgens, or any derivative thereof, including the substances identified in annexure E, or (b) any SARM. Notwithstanding sub-paragraph (b) of this paragraph above, if Vivus or any Controlled Affiliate of Vivus, or a sublicensee of Vivus that has rights under the Licensed Intellectual Property to market, sell, offer to sell, and import the Products in the Field in the Territory, commences Clinical Trials, or marketing or sales, in the Territory of any product that orally delivers a SARM to treat female sexual dysfunction, then except for SARM's that have been added to the Field, no SARM shall be considered to be an Androgen for purposes of Section 2.5.

"Business Day" means a day upon which banks are open for general banking business in the United States other than a Saturday or Sunday.

"Clinical Trial" shall mean a clinical trial involving the administration of a therapeutic to a human subject after filing an IND, or the equivalent (if necessary) outside the United States, for the purpose of evaluating the safety, efficacy, performance or other characteristic of such therapeutic, including a phase I, phase II and/or phase III trial.

"Committee" means the Development Committee and/or the Steering Committee.

"Confidential Information" of a Party means all information disclosed by such Party to the other pursuant to this Agreement, which may include any of the following to the extent disclosed by such Party:

- (a) Intellectual Property, technical information, specifications, data, software, marketing procedures, pricing information, customer and client records, business and corporate or trade information of a Party relating to or arising out of the Licensed Intellectual Property or its use or application;
- (b) information relating directly or indirectly to the Product including, without limitation, the identity and composition of compounds for producing or manufacturing the Product, formulae for the Product, methods of producing or manufacturing the Product, costs of manufacturing the Product, information relating to the packaging, selling and marketing of the Product including the cost thereof and pricing information; and

- (c) communications between the Parties or information of whatever kind whether recorded or not and, if recorded, in whatever medium, relating to the Licensed Intellectual Property, the Product, this Agreement, or otherwise, whether disclosed prior to or after the Effective Date.

"Commercial Launch Plan" means the plan for launching and initial marketing and promotion of the Product in the Territory as provided in Section 8.3.

"Controlled" means, with respect to any Intellectual Property, that the applicable Party owns or has a license to such Intellectual Property, and has the authority to grant to the other Party access, a license, or a sublicense to such Intellectual Property as provided for in this Agreement without violating an agreement with a non-Affiliate third party in effect at the time such Intellectual Property was first acquired or created by the Party granting or authorizing the license or sublicense herein.

"Controlled Affiliate" means (i) in the case of Vivus; an Affiliate that is controlled by Vivus; and (ii) in the case of FemPharm; Acrux Limited, Acrux DDS Pty Limited or an Affiliate that is controlled by FemPharm, controlled by Acrux DDS Pty Limited, or controlled by Acrux Limited (each of such Affiliates, Acrux DDS Pty Limited and Acrux Limited, an "Acrux Controlled Affiliate"); in each case as "control" is defined in the Affiliate definition in this Section 1.1 above.

"Development Committee" means the committee referred to in Section 5.6.

"Development Plan" means the plan appended to this Agreement as annexure A in accordance with Section 5.7, as such plan may be amended pursuant to Section 5.

"Effective Date" means the date of this Agreement, as set forth on page one.

"Estradiol Agreement" means the agreement titled "Estradiol Development and Commercialization Agreement" entered into by and between the Parties on even date herewith.

"Excluded Applications" shall have the meaning set forth in annexure F.

"FemPharm Patents" means: (a) the Patents set out in annexure B, which shall include all existing Patents licensed under the Monash License or the Acrux DDS License, (b) all continuing patent applications in the Territory based on any Patent in clause (a) above (including any divisionals, continuations, and continuations-in-part); (c) all Patents that issue based on any Patent in clause (a) or (b) above, and including all re-issues, extensions, substitutions, confirmations, re-registrations, re-validations, patents of addition, and supplementary certificates (or equivalents thereof) of any such Patent; and (d) all additional Patents in the Territory that are Controlled by FemPharm, Acrux DDS Pty Limited, an Acrux Controlled Affiliate, or any other Affiliate of FemPharm at any time during the term of this Agreement and that claim or cover an MDTs product, or any portion thereof, or the manufacture or use of an MDTs product or portion thereof, in the Field. For purposes of this definition, Patents that meet, at some time during the term of the Agreement, the requirement of subclause (d) above shall not be excluded from this definition simply because a particular Acrux Controlled Affiliate (that Controlled such Patent) no longer is an Affiliate of Acrux Ltd., and including continuing patent applications in the Territory based on such Patents in clause (d) above (including any divisionals, continuations, and continuations-in-part).

"Field" means delivery of testosterone (and/or any other Androgen that is added to the Field pursuant to Section 2.4 or included pursuant to Section 5.19) to human females using an MDTs, excluding only the Excluded Applications.

"First Commercial Sale" means the first commercial sale or transfer of the Product for use in the Territory (other than for evaluation, research, testing or clinical trial purposes), that occurs after the Product has been approved for marketing in the Territory, by Vivus or Vivus' Affiliate or sublicensee to an independent non-Affiliate third party in exchange for cash or some equivalent to which value can be assigned.

"FDA" means the United States Food & Drug Administration.

"Intellectual Property" means all industrial and intellectual property rights, whether protectable by statute, at common law or in equity, including, without limitation, any rights of copyright, trade secrets, confidential information, know-how, trade mark,

invention, Patent, circuit layout and any rights to registration of such rights, irrespective of whether such rights are created before, on or after the Effective Date.

"Improvement" means an Invention to the extent made by Vivus or its Affiliate in the course of developing or commercializing the Product under this Agreement, which Invention is an improvement of or modification to the Product itself, in the form provided by FemPharm, and is not substantially based upon or derived from other technology or Know-How of Vivus, its Affiliate, or their third party licensor or contractor.

"Improvement Blocking Patent Rights" means any Patent to the extent that it: (i) claims and is specifically directed to an Improvement, (ii) is Controlled by Vivus or its Affiliate at any time during the term of this Agreement, and (iii) is reasonably necessary to make, use, sell, or offer to sell an MDTS product. As used in this paragraph, "reasonably necessary" means there is no commercially reasonable alternative to practicing the subject matter in the applicable claim in such Patent, in order for FemPharm, or its Controlled Affiliate or licensee, to make, use or sell the MDTS products.

"Invention" means any information, idea, invention, know-how, data or results made pursuant to work conducted under this Agreement.

"Joint Patent" means a Patent claiming an Invention invented jointly by the Parties, as provided in Section 11.3.

"Know-How" shall mean all data, inventions (whether or not patentable), discoveries, methods, information (including Confidential Information), reports, analyses, documents, descriptions, procedures, formulae, formulations, expert opinions, knowledge, know-how, experience, marketing, and other information and materials (including physical samples), and the trade secret rights to the foregoing. As used herein, Know-How shall not include Patents.

"Licensed Intellectual Property" means the (i) FemPharm Patents, and (ii) the Licensed Know-How.

"Licensed Know-How" means the Know-How that is Controlled by FemPharm or any Acrux Controlled Affiliate and relates to or is useful for MDTS products in the Field.

"MDTS" means the Acrux metered dose transdermal spray system as described in Annexure C, and including all improvements, derivatives and modifications of such system developed by or under authority of FemPharm or its Affiliate. For clarity, it is understood that "improvements," as used under this paragraph, would include modified or improved versions of the Acrux metered dose transdermal spray system, and novel enhancers, formulations, methods, and mechanical components relating to or useful for the MDTS system, that are not used in the MDTS as of the Effective Date, but that would improve the safety, effectiveness, or other qualities of such a spray system for use in delivery of testosterone, or any other Androgen added to the Field pursuant to Section 2.4 or 5.19.

"Monash License" means the "Technology Agreement" between Monash and Acrux Limited, dated June 7, 1999, and transferred by Acrux Limited to Acrux DDS Pty Limited in the "Deed of Assignment" dated November 22, 1999, as amended by the Deed of Variation between Monash and Acrux Limited dated November 22, 1999 and the Deed of Variation between Monash and Acrux DDS Pty Limited., executed October, 2002.

"Net Sales" means any amounts invoiced by Vivus, or an Affiliate or sublicensee of Vivus, for the sale or other commercial disposition of the Product, less the following amounts to the extent actually accrued, taken or allowed with respect to such sale or disposition:

- (d) trade, cash or quantity discounts or rebates from the invoiced price;
- (e) refunds, credits, charge backs or allowances actually granted upon recalls, rejections, returns, or the like;
- (f) freight charges, insurance and packing charges paid for delivery; and
- (g) amounts actually written off for uncollectable accounts determined in accordance with GAAP, PROVIDED THAT if any such amounts are subsequently

collected, such amounts would be included in Net Sales for the quarter collected;

- (h) taxes (other than income tax, but including value added and sales taxes), duties, or other governmental charges levied on or measured by the disposition or the invoiced amount, whether absorbed by the billing or the billed party.

Notwithstanding the foregoing, if Vivus sells Product for use outside the Field or outside the Territory pursuant to an authorization by FemPharm or an Acrux Controlled Affiliate (such as sales to FemPharm for use in Australia or New Zealand) Net Sales shall not include any amounts invoiced on such sales, whether the sale is to FemPharm, an Acrux Controlled Affiliate, or any other Person (e.g. another licensee of FemPharm).

"Patents" means all rights under all patents (including all re-issues, extensions, substitutions, confirmations, re-registrations, re-validations, patents of addition, supplementary certificates, other governmental grants for the protection of inventions or industrial designs, or equivalents thereof) and under all patent applications (including any divisionals, continuations, continuations-in-part, continued prosecution applications, and divisionals).

"Party" means either of FemPharm or Vivus, and "Parties" means both of them.

"Person" includes a natural person, company, corporation, partnership, trust, estate, joint venture, sole proprietorship, government (including any branch or subdivision thereof), governmental or municipal agency, association, co-operative and any other entity or person whatsoever.

"Phase IIb Study" means the current clinical trial FHRT 11 using a Product conducted in Australia under a US IND application number (**).

"Product" means any MDTs product containing testosterone, or any other Androgen included in the Field pursuant to Section 2.4 or as a result of Section 5.19, and intended for use in the Field.

"Regulatory Materials" means regulatory applications, submissions, notifications, registrations, regulatory approvals and/or other filings made and correspondence to or with the FDA or other regulatory authority that are necessary or reasonably desirable in order to, or in connection with efforts to, develop, manufacture, market, sell or otherwise commercialize a Product in a particular country, territory or possession. Regulatory Materials include INDs, MAAs, and NDAs.

"Restricted Androgen" means any of: (**)

"Royalty Period" means a period of three consecutive months ending on 31 March, 30 June, 30 September or 31 December, provided that the first Royalty Period will be the period from the date of First Commercial Sale until the first to occur of 31 March, 30 June, 30 September or 31 December thereafter.

"SARM" means a generic compound (i.e., the composition of the compound is not covered by a patent in the Territory) that is a selective androgen receptor modulator.

"Steering Committee" means the committee referred to in Section 5.9.

"Territory" means the United States of America, and its territories and protectorates.

"Valid Claim" means: a claim in an issued Patent within the FemPharm Patents, which has not (i) expired or been cancelled, (ii) been declared invalid by an unreversed and unappealable decision of a court or other appropriate body of competent jurisdiction, (iii) been admitted to be invalid or unenforceable through reissue, disclaimer or otherwise, and/or (iv) been abandoned.

1.2 INTERPRETATION

In this Agreement:

- (a) words denoting the singular number include the plural and vice versa;
- (b) words denoting any gender include all genders;

- (c) words importing natural persons include corporations, firms, unincorporated associations, partnerships, trusts and any other entities or groups recognised by law;
- (d) reference to any legislation or to any provision of any legislation includes any amendment, modification, consolidation or re-enactment of, or any legislative provision substituted for, and all legislative and statutory instruments issued under, such legislation or such provision;
- (e) the words "written" and "in writing" include any means of visible reproduction of words in a tangible and permanently visible form;
- (f) reference to Articles, Sections, clauses and schedules and annexures are references to the Articles, Sections, clauses and schedules and annexures of this Agreement, unless expressly stated to the contrary;
- (g) reference to any party to this Agreement or any other agreement or document includes the party's successors and permitted assigns;
- (h) where a word or phrase is defined, other grammatical forms of that word or phrase have corresponding meanings;
- (i) no rule of construction applies to the disadvantage of a party because that party was responsible for the preparation of this Agreement or any part of it;
- (j) the headings to Articles, Sections, annexures or schedules are for ease of reference only and do not form part of this Agreement or affect its interpretation;
- (k) if any day appointed or specified by this Agreement for the payment of any money or the doing of any act falls on a day which is not a Business Day, the day appointed or specified will be the next Business Day;
- (l) a reference to a time or date in connection with the performance of an obligation by a party is a reference to the time and date in San Francisco, California, USA even if the obligation is to be performed elsewhere;

- (m) the terms "including" and "includes" will be interpreted non-restrictively to mean "including without limitation ...".

2. LICENSE RIGHTS

2.1 LICENSE GRANT

- (a) Subject to the terms of this Agreement, FemPharm and Acrux DDS Pty Limited grant to Vivus the sole and exclusive (including with respect to FemPharm, except as otherwise provided in subsection (c) below) license, under the Licensed Intellectual Property, solely to exploit, import, export, make, have made, develop, use, market, offer for sale and sell Products for use in the Field in the Territory.
- (b) Subject to the terms of this Agreement, FemPharm and Acrux DDS Pty Limited grant to Vivus a non-exclusive license under the Intellectual Property that relates to or is useful for a Product, or its manufacture or use, and is Controlled by any of FemPharm, an Acrux Controlled Affiliate, or another Affiliate of FemPharm, to export, make, and have made Products outside the Territory solely for importation, sale, use and other exploitation in the Field in the Territory pursuant to Section 2.1(a). In addition, to the extent permitted by FemPharm on request by Vivus, such permission not to be unreasonably withheld, Vivus may include in the foregoing license the right to conduct specific development activities in particular countries outside the Territory, solely to develop data to be used in the Regulatory Materials in the Territory for the Product in the Field, and marketing of the Product in the Field in the Territory.
- (c) For clarity, FemPharm and Acrux DDS Pty Limited retains the non-exclusive rights under the Licensed Intellectual Property in the Territory, for it and/or the Acrux Controlled Affiliates or any of their respective licensees to export, make, and have made Products in the Territory solely for importation, sale, use and other exploitation in the Field in a country or jurisdiction outside the Territory. In addition, only to the extent permitted by Vivus on request by FemPharm, such permission not to be unreasonably withheld, FemPharm may

conduct specific development activities in the Territory, solely to develop data to be used in the Regulatory Materials outside the Territory for the Product in the Field, and marketing of the Product in the Field outside the Territory.

- (d) For clarity, the license rights granted to Vivus in Section 2.1(a) and (b) do not grant to Vivus the rights under the Licensed Intellectual Property, to export, make, have made, and develop Products for importation, sale, use and other exploitation in the Field in any country or jurisdiction outside the Territory, or for any use outside the Field anywhere in the world.

2.2 RESERVATION OF RIGHTS

Each Party hereby reserves all rights with respect to its Intellectual Property and technology not expressly granted herein. Vivus shall have no right or license under the FemPharm Patents or Licensed Know-How other than the rights expressly set forth in this Agreement. Notwithstanding anything to the contrary, it is acknowledged and agreed that the limitation of FemPharm's rights under the Acrux DDS License, such as the limitation of the field of FemPharm's rights to female hormone replacement therapy or otherwise, shall not limit the rights granted to Vivus under this Agreement.

2.3 VIVUS GRANT-BACK LICENSE AND OPTION TO LICENSE

- (a) Subject to the terms of this Agreement, Vivus grants to FemPharm a non-exclusive, royalty-free, worldwide license (with full rights to grant sublicenses) under any Improvement Blocking Patent Rights solely to develop, exploit, import, make, have made, use, offer for sale and sell MDTs products, excluding only MDTs products intended for use, sale, offer for sale, import, or marketing in the Field in the Territory.
- (b) Vivus grants to FemPharm the option, exercisable in writing by FemPharm at any time after Vivus makes an Improvement, to obtain in accordance with this Section 2.3(b) below a non-exclusive, worldwide license (with such rights to sublicense as are mutually agreed), on commercially reasonable terms, under trade secrets Controlled by Vivus or its Affiliate during the term of this Agreement to the extent embodied in such Improvement and under Patents Controlled by Vivus or its Affiliate during the term of

this Agreement that claim and are specifically directed to such Improvement, (but excluding all Improvement Blocking Patent Rights), solely to develop, exploit, import, make, have made, use, offer for sale and sell MDTs products, excluding only MDTs products intended for use, sale, offer for sale, import, or marketing in the Field in the Territory. If FemPharm exercises such option as to a particular Improvement, then the Parties shall negotiate in good faith in an effort to agree upon the financial and other terms for, and scope of, such a license, within a reasonable time thereafter and will enter into such a license upon reaching agreement, which terms shall be commercially reasonable and shall include the mutually agreed license grant for such Improvement (under the Patents and trade secrets identified above) and other reasonable terms appropriate for such a license grant. Such license shall be royalty free for Products used in the Field in Australia or New Zealand.

2.4 EXPANSION OF FIELD

The Development Committee shall discuss and consider from time to time the possibility of including in the Field one or more additional Androgens, alone or in combination with other active ingredients, and if it determines that such an expansion to the Field is appropriate, it shall make such recommendation to both Parties. If the Parties agree with such recommendation, and solely to the extent such expansion is approved in writing by the Parties, such additional Androgen(s) shall be added to the Field by written amendment of the Agreement on mutually acceptable terms, including financial terms.

2.5 EXCLUSIVITY COVENANTS

- (a) Except as otherwise agreed by the Parties in writing, until (*) years after First Commercial Sale by or under authority of Vivus of a Product for use in the Field and Territory, Vivus and its Controlled Affiliates shall not, directly or indirectly, market, promote, sell, or import any Competitive Products (as defined below) for use in the Territory. As used herein, "Competitive Product" means any product (which is not a Product of Vivus, its Affiliate, or

sublicensee under this Agreement) that is approved for marketing for any human indication and is marketed, promoted, or sold (i) for the transdermal or mucosal delivery of testosterone or any other Restricted Androgen to human females, or (ii) for the transdermal or mucosal delivery of any other Androgen to human females for treatment of female sexual dysfunction; except excluding from the foregoing only products of any of Vivus, its Affiliates, and sublicensees involving application of an Androgen to the genitalia of a human female on an on demand basis as claimed or described in (*). For clarity, no license is granted under this Section 2.5(a) to Vivus by FemPharm or any Acrux Controlled Affiliate under the Licensed Intellectual Property with respect to any Vivus product involving such application of an Androgen to the genitalia of a human female. Vivus and its Controlled Affiliates shall not provide funding prior to such time to third parties for the specific purpose of, or grant a license or other authorization to any third party to, market, sell, promote, or import any Competitive Product for use in the Territory. Vivus shall include, and cause its Controlled Affiliates to include, in any grant or authorization by Vivus or the Controlled Affiliate in accordance with this Agreement of an exclusive sublicense (including with respect to Vivus) to a third party under the Licensed Intellectual Property to market, sell, promote, and import the Products in the Territory, an express covenant by such third party not to market, promote, sell or import, directly or indirectly, any Competitive Product for use in the Territory. If a particular Vivus Controlled Affiliate is no longer controlled by Vivus, then the above shall apply to such entity only if such entity continues to have rights under the Licensed Technology that it could exercise to make, use or sell a Product or a Competitive Product.

- (b) Except as otherwise agreed by the Parties in writing, until (*) after First Commercial Sale by or under authority of Vivus of a Product for use in the Field and Territory, FemPharm and Acrux DDS Pty Limited agree that FemPharm and the Acrux Controlled Affiliates shall not, directly or indirectly, market, promote, sell, or import in the Territory any Competitive Product. For

clarity, FemPharm and the Acrux Controlled Affiliates shall not provide funding prior to such time to third parties for the specific purpose of, or grant a license or other authorization to any third party to, market, sell, promote, or import for use in the Territory any Competitive Product. FemPharm and Acrux DDS Pty Limited shall include, and cause the Acrux Controlled Affiliates to include, in each grant or authorization of any of their Intellectual Property rights to a third party, if the license or authorization could be exercised in a manner that involves the delivery of testosterone (or any other Androgen) to females, an express covenant by such third party not to market, promote, sell or import, directly or indirectly, any Competitive Product for use in the Territory. If a particular Acrux Controlled Affiliate is no longer controlled by Acrux Limited, then the above shall apply to such entity only if such entity continues to have rights under the Licensed Technology that it could exercise to make, use or sell a Competitive Product

- (c) Nothing in this Section 2.5 shall limit the exclusivity of the license rights granted to Vivus in Section 2.1, it being agreed that the exclusivity under Section 2.1 shall not be limited to the periods described in this Section 2.5 above.
- (d) If FemPharm is acquired by, and thus becomes an Affiliate of, a third party other than an Acrux Controlled Affiliate, such third party Affiliate shall be deemed a third party for purposes of the licensing restrictions applied to FemPharm under Section 2.5(b). Similarly, if Vivus is acquired by, and thus becomes an Affiliate of, a third party other than a Vivus Controlled Affiliate, such third party Affiliate shall be deemed a third party for purposes of the licensing restrictions applied to Vivus under Section 2.5(a).

2.6 UNAUTHORIZED SALES

- (a) FemPharm and the Acrux Controlled Affiliates shall not directly or indirectly market, sell, or distribute any MDTs products intended for use in the Field anywhere in the world to a particular third party, including its Affiliates, if FemPharm or an Acrux Controlled Affiliate knows, or has been provided reasonable evidence, that such MDTs products provided directly or indirectly

by FemPharm or an Acrux Controlled Affiliate to such third party are being marketed, distributed or sold in the Territory. If FemPharm or an Acrux Controlled Affiliate grants rights to a third party, directly or indirectly, that could be exercised in a manner that involves the delivery of testosterone (or any other Androgen) to human females, then FemPharm shall make, or cause the Acrux Controlled Affiliate to make, the terms and conditions in this Section 2.6(a) applicable to the third party in the same manner as applicable to FemPharm.

- (b) Vivus and its Controlled Affiliates shall not directly or indirectly market, sell, or distribute any Product in the Territory to a particular third party, including its Affiliates, if Vivus knows, or has been provided reasonable evidence, that such Product provided directly or indirectly by Vivus or its Controlled Affiliates to such third party are being marketed, distributed or sold for use outside the Territory, provided that the sale of such Product in the Territory infringes a Valid Claim in the FemPharm Patents or embodies information that is at the then current time a trade secret of FemPharm, other than as permitted by Section 10.11. If Vivus or its Controlled Affiliate grants a sublicense to a third party under the Licensed Intellectual Property in accordance with this Agreement to market, sell, promote, and import the Products in the Territory, then Vivus shall make, or cause its Controlled Affiliate to make, the terms and conditions in this Section 2.6(b) applicable to the third party in the same manner as applicable to Vivus.

2.7 RIGHT OF NEGOTIATION

If FemPharm or an Acrux Controlled Affiliate desires to enter into a license or other collaboration that involves the research, development, or commercialization in the Territory of a product for delivery of an Androgen, other than testosterone, to females for treatment of female sexual dysfunction, FemPharm shall propose to Vivus the terms and conditions for such a license or collaboration with Vivus prior to entering into the license or collaboration with any third party. If Vivus fails to notify FemPharm in writing, within one hundred twenty (120) days after receiving such proposed terms and conditions from FemPharm, that Vivus desires to negotiate

the terms and conditions for the license or collaboration, or if the Parties do not agree in principle on the terms for such an arrangement notwithstanding good faith, diligent negotiations throughout the remainder of such one hundred twenty (120) day period after Vivus' request, then FemPharm or the Acrux Controlled Affiliate shall have the right to enter into the license or collaboration with a third party. In addition, FemPharm shall notify Vivus in writing upon any of FemPharm or the Acrux Controlled Affiliates commencing, whether directly or indirectly, any clinical development or commercialization of any product involving the transdermal or mucosal deliver to human females of an Androgen or other selective androgen receptor modulator for the treatment of sexual dysfunction in human females, including through licensees and work funded by FemPharm, but subject to any confidentiality obligations that would prevent such disclosure.

3. LICENSE AND MILESTONE PAYMENTS

3.1 LICENSE FEE

Vivus will pay to FemPharm a license fee of:

- (a) US\$ 1,750,000 (One Million Seven Hundred and Fifty Thousand United States Dollars) within five (5) Business Days of the Effective Date;
- (b) US\$ 250,000 (Two Hundred and Fifty Thousand United States Dollars) by September 1, 2004.

3.2 MILESTONE PAYMENTS

Upon achieving the specified milestone, Vivus will pay to FemPharm the following milestone payments (subject to Section 3.3 and 6.2):

- (a) US\$ (*) (*) United States Dollars) within thirty (30) days after the Phase IIb Study is completed, provided that the Phase IIb is completed prior to (*) (where completed means the last patient has completed the "Exit Visit," as defined in the protocol, and at least * (*) eligible patients per study protocol in each treatment group have been enrolled in the study, and provided that FemPharm does not terminate the study early);

- (b) US\$ (*) (**United States Dollars) within thirty (30) days of data analysis of the completed Phase IIb Study which demonstrates a statistically significant improvement over placebo sufficient to meet the primary efficacy endpoint (*) for at least (*) as set out in the current protocol in the Phase IIb Study;
- (c) US\$ (*) (**United States Dollars) within thirty (30) days of Vivus' data analysis of the completed Phase IIb Study showing a skin irritation rate being achieved in each treatment group in the Phase IIb Study at the application site, regardless of severity, of (*)% or less of the total number of patients in the particular treatment group;
- (d) US\$ * (**United States Dollars) within thirty (30) days of a Product Patent (as defined below) issuing in the United States of America, where a "Product Patent" means any Patent that is entitled to the effective filing date of US Patent Application Number (*) and that includes (i) one or more apparatus claims that claim the spray apparatus used in the Product being developed (or sold) by Vivus (or its Affiliate or sublicensee) at the time of issuance, and (ii) one or more composition of matter claims that claim the formulation of the Acrux Penetration Enhancer together with one or more hormones, which include at least the active ingredient in the Product being developed (or sold) by Vivus (or its Affiliate or sublicensee) at the time of issuance. It is understood that no claims of a Patent issued as of the Effective Date satisfy this milestone;
- (e) US\$ (*) (** United States Dollars) within thirty (30) days of Vivus (or its Affiliate or sub-licensee) commencing in the United States the first Phase III study in respect of the Product (such commencement being defined as the date when the first patient has been dosed in accordance with the Phase III protocol); and
- (f) US\$ (*) (** United States Dollars) within thirty (30) days of submission by or under authority of Vivus or its Affiliate or sublicensee in the United States of the first new drug application to the FDA (as new drug application is defined in 21 C.F.R. ss. 314.50 et. Seq, as updated or amended from time to time), or

such other equivalent regulatory application in the United States for approval of marketing of the Product, (the "NDA") in respect of the Product; and

- (g) US\$ (*) (* United States Dollars) within thirty (30) days of the first FDA marketing approval in the United States in respect of the Product (the marketing approval being defined as approval by the FDA of Vivus' or its Affiliate's or sublicensee's NDA for the Product, permitting the Product to be marketed in the United States).

3.3 ONE PAYMENT; LIMITATION

It is understood that once a particular milestone payment under Section 3.2 has been paid (including as a result of the operation of Section 6.2 below), then no payment for such milestone shall be due again with respect to the same Product or any other Product except to the extent otherwise agreed by the Parties in writing in connection with the addition of an Androgen to the Field pursuant to Section 2.4.

4. ROYALTIES

4.1 ROYALTY PAYMENTS

Except as otherwise provided in this Article 4, Vivus will pay to FemPharm royalties as a percentage of Net Sales, where the royalty rate is determined based on the Net Sales during the applicable calendar year in the Territory, according to the following schedule:

- (a) the royalty rate is (*)per cent (%) on the first US\$ (*) (** U.S. Dollars) of Net Sales in the calendar year;
- (b) the royalty rate is (*)per cent (%) of the Net Sales in excess of the first US\$ (*) (** U.S. Dollars) of Net Sales in the calendar year, up to Net Sales in the calendar year of US\$ (*) (** U.S. Dollars);
- (c) the royalty rate is (*) per cent (%) of the Net Sales in excess of US\$ (*) (**U.S. Dollars) in the calendar year.

4.2 ROYALTY REDUCTION

The royalty rate applicable under Section 4.1 to Net Sales from the sale of a Product will be reduced by (*) per cent (* %) upon the expiration, cancellation, invalidation, abandonment, termination, disclaimer, or unenforceability of the last Valid Claim in the FemPharm Patents that would, absent a license, be infringed by the sale or use of such Product in the Territory in the Field. Further, with respect to a particular Product, if there otherwise is no Valid Claim in the FemPharm Patents that would, absent a license, be infringed by the sale or use of such Product in the Territory in the Field, then the royalty rate applicable under Section 4.1 to the Net Sales from the sale of such Product shall be (*) percent (* %) of the royalties set forth in Section 4.1, unless and until such a Valid Claim issues, after which point the rate shall be as set forth in Section 4.1 until the preceding sentence applies.

4.3 THIRD PARTY ROYALTIES

If Vivus or its Affiliate or sublicensee pays royalties to a third party under a patent license that is necessary in order to make, use, import, or sell a Product in the Territory, which royalties are based on net sales of such product, then Vivus shall have the right to credit (*) percent (* %) of such payments against the amounts payable by Vivus under this Section 3 and Section 4, provided that the royalty payable to FemPharm under this Section 4 shall not be so reduced by more than (*) percent (* %). As used in this Section, a license is "necessary" if it is reasonable to obtain the license in light of the risk of infringement. If FemPharm disagrees with Vivus' assertion, under this Section, that a particular license is so necessary, then the Parties will proceed under Section 15.11 to resolve the issue. Notwithstanding the foregoing, if Vivus or its sublicensee adds to the Product a component or feature comprising such technology, and Vivus or its sublicensee must pay royalties for third party patent rights covering such component or feature, such royalties shall not be offset under this Section 4.3 against royalties owed to FemPharm, unless the component or feature is, at the time added, necessary to make the Product approvable or commercially viable. As to any license that Vivus may believe is desirable to enter into with respect to a Product, other than those for which royalties may be offset in accordance with the foregoing, if Vivus so requests the Parties will discuss such license and the possibility of FemPharm sharing some part of the costs of such license.

4.4 ONE ROYALTY; SAMPLES AND DONATIONS

One royalty shall be payable for each Product sold under this Agreement. No royalties shall be due upon the sale or other transfer of Product among Vivus, its Affiliates and sublicensees, but in such cases the royalty shall be due and calculated upon Vivus', its Affiliate's or sublicensee's Net Sales to the first independent third party, or commercial use of such Product by Vivus, the Affiliate, or the sublicensee for profit to treat patients in the ordinary course of its business (in which case "Net Sales" for such use shall be deemed to be the average Net Sales for such Product when sold to third parties in the same royalty period in the Territory). No royalties shall accrue on the disposition of Product by Vivus or its Affiliates or sublicensees in reasonable quantities which are (i) used in clinical trials, (ii) distributed as samples (promotion or otherwise), or (iii) distributed as donations solely for charitable purpose (I.E., without charge).

4.5 ACCRUAL AND PAYMENT OF ROYALTIES; ROYALTY TERM

The royalties owed under this Section 4 accrue on the sale or transfer of the Product, and all royalties that accrue in respect of the Net Sales in a particular Royalty Period:

- (a) if the Territory includes any country outside the United States of America, will be calculated, on a country by country basis, after conversion (based on exchange rate as set forth in Section 4.10 below) into U.S. dollars; and
- (b) will be paid in U.S. dollars no later than the date that the royalty report for that Royalty Period is to be provided pursuant to Section 4.7.

Royalties shall accrue on sales of Products commencing on the date of First Commercial Sale of the first Product hereunder and continuing only until the latest to occur of the following: (i) expiration, cancellation, invalidation, abandonment, termination, disclaimer, or unenforceability of the last Valid Claim in the FemPharm Patents that covers the sale of the Product, or its use, in the Territory; or (ii) twelve (12) years from the date of such First Commercial Sale, or (iii) on a Product by

Product basis, the date there no longer is any substantial trade secret of FemPharm or its Affiliate embodied in the applicable Product which is a trade secret of FemPharm or its Affiliate at the time of the sale.

4.6 LATE PAYMENT OF ROYALTIES

If Vivus fails to pay royalties within the time specified in Section 4.5, Vivus will pay to FemPharm interest on the amount of royalties which were not timely paid from the date upon which they became owing until the date of payment at (*)percent (* %) above the Prime Rate as quoted in the Wall Street Journal, calculated on a daily basis and payable on demand.

4.7 ROYALTY REPORT

Vivus will submit to FemPharm no later than forty five (45) days after the end of each Royalty Period during the term of this Agreement a report stating:

- (a) the total amount of invoiced sales of the Product, (on a country by country basis if the Territory includes any country outside the United States of America);
- (b) the calculation of Net Sales (in each country if the Territory includes any country outside the United States of America), based on such sales, including a description of the deductions used to calculate such Net Sales; and
- (c) if the Territory includes any country outside the United States of America, the calculation of royalties owed based on such Net Sales, on a country by country basis during that Royalty Period, after conversion of such Net Sales into U.S. Dollars as per Section 4.11.

4.8 VERIFICATION OF ROYALTY STATEMENT

FemPharm may at its cost have any report referred to in Section 4.7 verified as set forth below by a reputable firm of chartered accountants or certified public accountants nominated by FemPharm, and reasonably acceptable to Vivus, provided FemPharm completes such verification within thirty-six (36) months of the end of the Royalty Period to which the verification is to relate. Upon not less than ten (10)

Business Days' prior written notice given by FemPharm to Vivus, Vivus will provide the accountants with access during Vivus' (or its Affiliates' or, to the extent Vivus has the right to do so, sublicensee's, as applicable) normal business hours to the revenue and sales records of Vivus, its Affiliates and (to the extent Vivus has the right to do so) sublicensees sufficient for the purposes of verifying the reports referred to in Section 4.7 and for the purpose of verifying the amount of royalties paid to FemPharm. To the extent that Vivus does not have the right to grant to FemPharm the right to audit the books and records of its sublicensees, Vivus will use reasonable, diligent efforts to obtain for itself such rights and, at the request of FemPharm, agree to exercise its audit rights with respect to such sublicensees and provide the results of such audit to FemPharm pursuant to this Section 4.8. Vivus, the Affiliate or sublicensee, as the case may be, may request that, at its expense, a representative or agent familiar with its record keeping systems be present at the audit to assist in the audit. Such audits will be at the expense of FemPharm, except that if such audit establishes that the amount owed by Vivus for the audited period exceeds the amount actually paid by more than (*) percent (* %), then Vivus will pay FemPharm's actual out of pocket costs of such audit.

4.9 NON-DISCLOSURE BY ACCOUNTANT

The accountants appointed under Section 4.8 are not authorized to, and will not, disclose to FemPharm any information other than the accuracy or inaccuracy of the amounts to be verified and will be required to execute a reasonable confidentiality agreement with Vivus and/or the sublicensee or Affiliate, as applicable.

4.10 STATEMENT ERRORS

Should it be established from any report and verification referred to in Sections 4.7 and 4.8 that the royalties which should have been paid in respect of any Royalty Period to which the report and verification relates are more or less than the royalties actually paid then the difference will be remitted within ten (10) Business Days:

- (a) to FemPharm (in the case of the royalty paid being less than that which should have been paid);

- (b) to Vivus (in the case of the royalty paid being more than that which should have been paid).

4.11 CURRENCY CONVERSION

If the Territory includes any country outside the United States of America, all Net Sales resulting from sales of the Product in countries other than the United States of America will be converted into United States dollars for purposes of calculating royalties owed under this Article 4, by using the arithmetic average of the currency exchange rates quoted on each of the last ten (10) Business Days during the applicable Royalty Period in the Wall Street Journal (East Coast Edition). All payments by Vivus hereunder shall be made in US dollars.

4.12 WITHHOLDING TAXES

If any taxes, withholding or otherwise, are levied by any taxing authority in connection with the accrual or payment of royalties or other amounts payable under this Agreement and are obliged to be paid or deducted by Vivus then:

- (a) Vivus will pay such taxes to such taxing authority on behalf of FemPharm; and
- (b) Vivus will remit to FemPharm in full satisfaction of its royalty obligations under this Agreement the net amount after reduction by the amount of such taxes; and
- (c) Vivus will deliver to FemPharm promptly following payment written evidence of such payment and such other related documentation that FemPharm may reasonably require.

5. CLINICAL DEVELOPMENT

5.1 OVERVIEW OF DEVELOPMENT

The Parties intend to work cooperatively to pursue development of the Product in order to obtain regulatory approval for the use of the Product in the Field in the

Territory, using commercially reasonable, diligent efforts in accordance with and subject to the terms of this Agreement.

5.2 TRANSFER OF TECHNICAL INFORMATION

Within sixty (60) days after the Effective Date, FemPharm shall transfer to Vivus without charge copies of all existing Licensed Know-How, including (to the extent existing) (i) copies of all Regulatory Materials and other Know-How developed or acquired in connection with the Phase IIB Study, any preceding phase I or II study on the Product, or any other clinical or pre-clinical development in connection with, or directly applicable to, a Product in the Field, whether developed or acquired by FemPharm, any Acrux Controlled Affiliate, or others working under authority of such entities; and (ii) copies of all material Know-How relating to or used in connection with, or relevant to, the manufacturing of Products by FemPharm, any Acrux Controlled Affiliate, or others, including, such Know-How as generated or used during process development, stability studies, formulation development, scale up of manufacturing, production of preclinical and clinical product batches, validation studies, development of quality assurance/quality control testing, process controls for Products in the Field, and related regulatory affairs (all to the extent relating to Products in the Field); and all Know-How contained in the DMF or in the CMC section of any IND or NDA (or their counterparts in other countries) with respect to Products in the Field. Thereafter during the term of this Agreement, upon request of Vivus, FemPharm shall transfer to Vivus without charge copies of all such previously undisclosed Licensed Know-How, if any, including that developed or acquired after the Effective Date, and shall use all reasonable efforts to enable and assist Vivus in understanding and implementing the Licensed Know-How. FemPharm and the Acrux Controlled Affiliates shall use good faith, diligent efforts to obtain from each of their other licensees the right to disclose to Vivus, its Affiliates and their sublicensees, Know-How and Regulatory Materials that are relevant to, or useful for, Products. In addition, if requested by Vivus and at Vivus' expense for actual reasonable internal time of FemPharm or its Affiliate's time (billed at (*)% the applicable employee's salary and benefits), FemPharm shall generate and provide to Vivus reasonably promptly a report describing in reasonable detail (according to an agreed format) all research and development conducted or completed by or under authority of any of FemPharm and the Acrux Controlled Affiliates, and the results thereof, with respect to MDTs products involving the delivery of testosterone.

5.3 CONDUCT OF PHASE IIB STUDY

As from the Effective Date until the time of transfer of the Phase IIB Study to Vivus pursuant to Section 5.4, FemPharm will, at its expense (except as otherwise provided below), conduct the development of the Product in such trial, in cooperation with and as reasonably directed by Vivus. FemPharm shall consult with Vivus and keep Vivus fully apprised of the status of, and plans and schedule for, all activities related to the Phase IIB Study, including providing reasonable advance notice, before proceeding with any filings, meetings, or telephone or other discussions with the FDA or similar regulatory authority, scheduled or unscheduled, that pertain to the Phase IIB Study, and shall give Vivus control of such matters. Vivus will provide FemPharm reasonable assistance and cooperation in conducting such trial, through the time of transfer to Vivus, and such development work will be managed and supervised by the Development Committee. If Vivus decides to modify the Phase IIB Study, then Vivus will be responsible to pay FemPharm, quarterly in advance, any extra costs that Vivus requires FemPharm incur as a result of such modifications, including fully burdened full time equivalent (FTE) labour costs of scientific, clinical and management personnel at FemPharm and the Acrux Controlled Affiliates that Vivus requires be added due to such modification, but only for that portion of the FTE that is additional and required by Vivus to be dedicated to performance of the Phase IIB Study. For purposes of this Agreement, FemPharm's fully burdened FTE rates shall be (*)% of the employee's salary and benefits (or in the case of a contractor, (*)% of the cash compensation paid to the contractor), calculated in accordance with reasonable accounting principles, consistently applied and in accordance with a budget approved by the Development Committee. Except to the extent otherwise expressly set forth in this Agreement, however, FemPharm shall be solely responsible for, and Vivus shall have no obligation to reimburse, the costs and expenses (i) associated with completing the Phase IIB Study (as currently planned), including for preparation of the final report and analysis, and the report to be delivered to Vivus under Section 5.2, (ii) for any adverse event reporting that FemPharm or an Acrux Controlled Affiliate is required to perform, or (iii) associated

with FemPharm otherwise fulfilling its obligations under this Agreement, or conducting or completing any other research, development, or other work by or on behalf of any of FemPharm and the Acrux Controlled Affiliates.

5.4 TRANSFER OF DEVELOPMENT RESPONSIBILITY

FemPharm will transfer and assign full regulatory and clinical responsibility for the Product in the Field in the Territory, including the IND, to Vivus, provided that the transition of the Phase IIB Study shall be made promptly upon request by Vivus, according to a schedule reasonably specified by Vivus. After full transfer of responsibility to Vivus, FemPharm's involvement will be as set forth below.

5.5 DEVELOPMENT RESPONSIBILITIES

Other than FemPharm's conduct of the ongoing Phase IIB Study in accordance with Section 5.3 and except as otherwise determined by the Parties, Vivus will be solely responsible for conducting, at its own expense, all activities relating to the clinical development, regulatory approval and commercialization of the Product in the Territory, using diligent, commercially reasonable efforts, provided that both Parties will use such efforts to perform their responsibilities to achieve the targets set forth in the Development Plan. Vivus will pay to FemPharm, prior to the beginning of a calendar quarter, an amount equal to the FemPharm expenses in the approved budget in the Development Plan for such quarter, including payments to third parties and fully burdened FTE costs of labour associated with work at FemPharm and its Affiliates pursuant to this Agreement ((*)% of salary and benefits, plus any out of pocket expenses provided for in the Development Plan). FemPharm will maintain reasonably detailed records of the time expended and work performed in the development and will provide copies and a summary of such records, and a reconciliation of expenditures, for each such quarter to Vivus within fifteen (15) Business Days of the end of the quarter. The actual expenditure versus budget for the previous quarter will be reconciled in the payment from Vivus to Acrux for the following quarter or refunded to Vivus, as Vivus requests. Vivus shall not be required to reimburse any cost or expenses, other than those set forth in the Development Plan, except to the extent approved by Vivus in advance in writing. Vivus shall not be required to develop more than one Product at a time, and shall have no obligation to develop another Product in the Territory after a marketing approval of a Product in the Field has been obtained in the Territory.

5.6 DEVELOPMENT COMMITTEE

Within thirty (30) days of the Effective Date, the Parties will establish a committee to review and discuss the development of the Product (the "Development Committee"), comprising two (2) members of FemPharm's (or the Acrux Controlled Affiliate's) staff nominated by FemPharm and two (2) members of Vivus' staff nominated by Vivus. At least one member appointed by each Party shall have appropriate technical credentials, experience and knowledge and ongoing familiarity with, in the case of Vivus, the development under this Agreement and, in the case of FemPharm, any pre-clinical and clinical development of Product by FemPharm or the Acrux Controlled Affiliate, as well as the Licensed Intellectual Property and the development and use thereof. If relevant Product development is being performed by an Acrux Controlled Affiliate, then Vivus shall have the right to require that at least one of FemPharm's members be an employee of the Acrux Controlled Affiliate who is involved in such development or, in the alternative, to require that such an employee otherwise attend the Development Committee meetings. Each Party will give the other written notification concerning its staff members who are nominated to serve on the Development Committee. Subject to the foregoing, either Party may replace any of its members on the Development Committee by written notice. Additionally, Vivus shall be entitled to have representatives of its sublicensees attend the meetings as it considers appropriate. The Development Committee is responsible for review and approval of the Development Plan and is additionally intended to provide a forum to:

- (a) Enable Vivus to obtain scientific, clinical and regulatory input and data from FemPharm relating to development of the Product in the Territory, including with respect to work that each Party has performed in accordance with the Development Plan, and to keep Vivus informed regarding the work of FemPharm and the Acrux Controlled Affiliates related to Product;
- (b) keep FemPharm reasonably apprised of the progress and results of, and planned activities related to, development of Products in the Field in the Territory under the Development Plan, sufficient for FemPharm to understand

the general status of the development under the Development Plan and nature of any significant issues that Vivus has encountered that have caused Vivus to fail to meet the schedule targeted in the Development Plan, and to review and approve, as appropriate, the Development Plans proposed by Vivus;

- (c) evaluate the markets of the Product for use in the Field in relation to the development strategy for the Product, and adjust the Development Plan appropriately based thereon; and
- (d) foster a cooperative relationship between the Parties regarding activities under this Agreement and the other activities of FemPharm and the Acrux Controlled Affiliates with respect to Product.

To the extent requested by the Steering Committee, the Development Committee will keep the Steering Committee informed about the status of the activities conducted by the Development Committee pursuant to this Agreement. The Development Committee will refer all matters that are to be decided by the Development Committee, but for which agreement cannot be reached by the Development Committee, to the Steering Committee for the Steering Committee's review and final decision on such matters. The Development Committee will establish rules for its operation. After marketing approval of a Product is obtained, the Development Committee shall not be required to meet if there is no significant Product development by Vivus to discuss at the applicable time.

5.7 DEVELOPMENT PLANS

The development of the Product will be conducted by the Parties, each using diligent, commercially reasonable efforts to perform its responsibilities set forth in the Development Plan. The Parties expect that an initial Development Plan will be appended to the Agreement as annexure A within one hundred eighty (180) days after the Effective Date, reflecting the Parties' understanding and intent at such time of the planned Product development activities in the Territory for the remainder of then current calendar year (and if mutually desired at the time, the following calendar year). The Development Plans proposed by Vivus will be reviewed and approved by the Development Committee from time to time as appropriate. On an annual basis

commencing in the final calendar year covered by the initial Development Plan (no later than October 15 of each year), Vivus will prepare and submit to the Development Committee for approval a reasonably detailed Development Plan outlining development responsibilities for the Product for the upcoming calendar year, it being agreed that Vivus may propose updates and revisions to the Development Plan more often as Vivus considers appropriate. After reviewing the proposal and discussing the development efforts to date, the Development Committee will consider changes to and amend the Development Plan to reflect revised regulatory and development activities designed to meet the goal of obtaining regulatory approval for the Product in the Territory in a commercially reasonable time frame based on the use of diligent, commercially reasonable efforts by Vivus to perform the development. Notwithstanding the foregoing, no Development Plan shall be required after marketing approval of a Product is obtained except to the extent required by the Development Committee.

5.8 BUDGETS

The Development Committee will prepare and include in the Development Plans, a budget that sets forth the estimated costs and expenses (including fully-burdened internal labor costs, as described in Section 5.5 above) that are budgeted to be incurred by FemPharm in conducting its responsibilities, if any, for Product development under the Development Plan. Each updated Development Plan will include an updated budget for FemPharm's responsibilities, if any, to be approved by the Development Committee. Vivus shall not be required to reimburse any costs or expenses other than those budgeted, unless agreed in advance in writing. Each Party shall bear its own costs and expenses associated with Committee meetings.

5.9 STEERING COMMITTEE

Within thirty (30) days of the Effective Date, the Parties will establish a steering committee (the "Steering Committee"), comprising of one (1) member selected by FemPharm from its senior executives and one (1) member selected by Vivus from its senior executives; each having responsibility at the respective Party for development of Product. Each Party will give the other written notification concerning its executive nominated to serve on the Steering Committee. Either Party may replace its

member on the Steering Committee with an equivalent senior executive by providing written notice of the change to the other Party. A member of the Steering Committee cannot simultaneously serve as a member of the Development Committee. The Steering Committee will be responsible for resolving issues upon which the Development Committee has been unable to reach agreement and for serving as the initial means for discussing and seeking to resolve any issues or disputes between the Parties arising under this Agreement. Members of the Steering Committee will consult with members of the Development Committee, as they consider necessary, when resolving such issues and disputes and the decision of the Steering Committee binds the Development Committee.

5.10 FINAL DECISION

If the Steering Committee has been unable to reach agreement on any issue or matter after diligent discussions, or if such discussions have not occurred due to unreasonable delay by FemPharm's representative, then the issue will be referred to Vivus to determine the issue, except as otherwise provided below. Vivus must consider the issue, having considered the views put forward by the Development Committee and the Steering Committee. Vivus' decision is final and binding on the Parties and the Committees in respect of each such issue and matter, provided that the foregoing does not permit Vivus to amend the terms of this Agreement, or change the Outside Dates, or otherwise impose an obligation on FemPharm, without FemPharm's written consent.

5.11 PROCEDURES OF COMMITTEES

Each Party will provide the other Party in writing with the name, title, e-mail address, telephone number and facsimile number of its nominees to each Committee. The Development Committee will meet semi-annually during the term of the Development Plan, and more often as mutually agreed. The Steering Committee will meet as needed to resolve disputes and issues, promptly on the good faith request of either Party. All Committee meetings will be at such times agreed to by FemPharm and Vivus and will be in person or by telephone or video conference.

5.12 DECISIONS OF COMMITTEES

A quorum of the Development Committee at a meeting is two (2) representatives of each Party present at such meeting in person or by telephone or videoconference. A quorum of the Steering Committee at a meeting is one (1) representative of each Party present at such meeting in person or by telephone or videoconference. A unanimous vote of the members of the Committee present (in person, by telephone or videoconference) at such meeting is required to take any action on behalf of the Committee. In particular, neither Committee may make a binding decision unless a quorum is present. Each Party shall use best efforts to cause a quorum to be present at each meeting. No decision of a Committee shall be considered binding upon either Party, except to the extent set forth in writing and signed by both Parties. Notwithstanding anything to the contrary, no approval of the Development Committee shall be required for the day to day development activities, which shall be controlled by Vivus or its designee.

5.13 CHAIRPERSONS - DEVELOPMENT COMMITTEE

The chair of the Development Committee will be a Vivus member of the Development Committee. Except to the extent otherwise approved by the Development Committee, the chair will be responsible for preparing the timetable for the meetings, and for preparing the agendas, minutes and resolutions, communications with the Steering Committee and other communications regarding tasks assigned by the Development Committee. All drafts of minutes and resolutions must be approved by the members of the Development Committee at the next meeting. The chair does not have a second or deciding vote.

5.14 CHAIRPERSONS - STEERING COMMITTEE

The chair of the Steering Committee will be Vivus' member of the Steering Committee. Except to the extent otherwise approved by the Steering Committee, the chair will be responsible for preparing the timetable for the meetings, and for preparing the agendas, minutes and resolutions, communications with the Development Committee and other communications regarding tasks assigned by the Steering Committee. All drafts of minutes and resolutions must be approved by the members of the Steering Committee at the next meeting. The chair does not have a second or deciding vote.

5.15 MINUTES AND REPORTS

Each Committee will be responsible for keeping accurate minutes of its deliberations or discussions that record all proposed decisions and all actions recommended or taken. The chair will provide the Parties with the approved minutes of each meeting promptly after approval and, in the case of the Development Committee, a written accompanying report summarizing, in reasonable detail, the discussions of the Development Committee concerning: the status of the Development Plan, of the work and progress to date, any issues requiring resolution, and any decisions by the Development Committee. All records made by each Committee will be available to both Parties.

5.16 GLOBAL DEVELOPMENT COMMITTEE

At such time as any pre-clinical or clinical development is undertaken by or under authority of FemPharm or any Acrux Controlled Affiliates anywhere in the world (outside of the Territory) for a Product within the Field, the Parties shall establish a joint committee among Vivus, FemPharm (and/or the Acrux Controlled Affiliate, as the case may be) and any Additional Partner(s) to discuss and coordinate such development of such Product (the "Global Development Committee"). To the extent there are no Additional Partners, and meetings of the Development Committee are ongoing at the time, the function of the Global Development Committee set forth in this Section 5.16 shall be handled by the members of the Development Committee. The primary role of such Global Development Committee shall be to provide a forum for communication between Vivus, FemPharm (and/or an Acrux Controlled Affiliate(s), as the case may be) and any Additional Partner(s) with respect to activities related to the ongoing preclinical and clinical development of Products in the Field, other than the work under the Development Plan under this Agreement. FemPharm, the Acrux Controlled Affiliates, Vivus, and each Additional Partner having rights to Product in the Field shall each have at least two (2) representatives on such Global Development Committee. Each member of the Global Development Committee shall keep the other members fully informed in English (subject to Section 5.17) as to the ongoing preclinical and clinical development of, and regulatory activities with respect to, such Products in the Field. It is understood and agreed, however, that formal approval of such Global Development Committee shall not be required for any such activities. The Global Development Committee shall meet no less frequently than twice each calendar year, or as otherwise agreed by the Parties, until the termination or expiration of this Agreement and each of Vivus, FemPharm, Acrux Controlled Affiliates, and any Additional Parties shall give a full report in English (subject to

Section 5.17) at each such meeting of activities relating to the particular Products to which such Party, the Controlled Affiliate, Acrux Controlled Affiliate or Additional Partner has rights and that is undergoing preclinical or clinical development in the Field. Additional Partners will participate in such meeting only with respect to Products for which they have rights in the Field.

5.17 NO OBLIGATION TO TRANSLATE

It is understood and agreed that any documents to be provided by FemPharm, an Acrux Controlled Affiliate, Vivus, or Additional Partner under Section 5.16 may be provided in the language in which such documents exist, and FemPharm, the Acrux Controlled Affiliate, Vivus, and the Additional Partners shall not be obligated to provide translations of such documents (except to the extent such translation has already been prepared).

5.18 INFORMATION AND RESULTS

Except as otherwise agreed by FemPharm in writing, Vivus shall make available and disclose to FemPharm, no less often than once every six (6) months, in the form selected by Vivus and reasonably acceptable to Vivus, and to the extent not previously disclosed, all patient results from Clinical Trials by Vivus or its Affiliate on Products under this Agreement and all Regulatory Materials prepared by Vivus or its Affiliate, including any NDA filed by Vivus or its Affiliate with the FDA for a Product under this Agreement. It is understood that inadvertent failure to disclose any of the foregoing information will not be deemed a breach, provided that Vivus makes the disclosure of such information promptly after becoming aware that such information has not been disclosed. To the extent Vivus has the right to provide such patient results from the Clinical Trials by its sublicensees on Products under this

Agreement, Vivus will also make such results available in the manner described above. Vivus agrees to use good faith, diligent efforts to obtain such rights from its sublicensee. If the NDA is filed by a sublicensee Vivus, Vivus will use good faith, diligent efforts to obtain the right to disclose the NDA to FemPharm. As between Vivus and FemPharm, each Party will own all results and data that it generates, subject to any licenses granted under this Agreement to the other Party. In particular, as between Vivus and FemPharm, Vivus will own all clinical data and results of testing Product generated by Vivus under this Agreement (the "Data"). FemPharm and its Affiliates have the right to use all Data required to be delivered by Vivus solely in developing and seeking regulatory approval of a Product in the Field in Australia and New Zealand, and no Data, Regulatory Materials, or other Know-How provided by Vivus shall be used for any other purpose, such as without limitation for purposes of development or marketing approval for a country other than New Zealand and Australia, except as otherwise agreed by the Parties in a separate writing. Such Know-How will be disclosed to licensees of FemPharm and the Acrux Controlled Affiliates for Australia or New Zealand only to the extent the licensee provides equivalent disclosure to Vivus and Vivus' sublicensees.

5.19 PRODUCT FAILURE

- (a) Technology Failures. In the event the Product experiences significant technical issues that arise out of or relate to the MDTS system, including failure of the MDTS system to deliver testosterone, or another Androgen added to the Field in accordance with this Agreement, in a manner suitable for development or commercialization of a Product in the Field and Territory, inadequate physical or chemical stability of any portion of the MDTS system, issues arising out of any Acrux Penetration Enhancer or any other formulation developed by FemPharm and used in an MDTS system, or other issues that significantly impact the efficacy, toxicity, safety, or ability to obtain approval, then, to the extent that Vivus reasonably concludes that the issue would likely prevent the approval of the Product in the Field and Territory by the FDA or other appropriate regulatory authority or cause the Product to not be commercially viable, Vivus shall have the right, subject to the terms of Section 5.19(b) below, to select for addition to the Field, and development and

commercialization in the Territory under this Agreement as an alternate Product, an alternate Androgen (excluding any Androgen (other than a Restricted Androgen) for which FemPharm or its Affiliate has commenced Clinical Trials, or which FemPharm or its Affiliate has licensed to a non-Affiliate third party in a fully arms length transaction, in conformance with Section 2.5(b)) or alternate configuration of the MDTs technology.

- (b) Upon selection by Vivus of an alternate Product pursuant to Section 5.19(a) above, development and commercialization of the selected Product shall be in accordance with the terms of this Agreement, including the same milestone payments and, if the alternate Product is based upon another Androgen, no greater royalties than those set forth in Article 4, except that (i) Vivus shall not be required to pay under Section 3.2 any milestone payments for achieving a milestone for which a milestone payment previously was made for a Product, and (ii) the Parties shall discuss in good faith and agree on new, appropriate diligence milestones dates in Section 6.2 for such alternate Product. If Vivus does not select such alternate Product within 90 days of Vivus concluding that the issue will prevent the original Product from being approved or commercially viable, then the Agreement shall terminate under Article 14, with the effects of such termination being the same as if terminated by Vivus under Section 14.3(d).

5.20 SUBCONTRACTS

Subject to the provisions of this Agreement, Vivus may subcontract to third parties portions of the Development Plan to be performed by Vivus, provided Vivus agrees to keep the Development Committee reasonably informed of any contract research organizations or other contractors hired by Vivus, and provided further that such subcontractors are subject to confidentiality provisions consistent with the terms of this Agreement, and that Vivus remains responsible for all work performed by such subcontractors.

5.21 CLINICAL PRODUCT SUPPLY

Except as otherwise provided in this Agreement, as between the Parties, Vivus is solely responsible for all manufacturing of its requirements of the Product for use in development throughout the Territory. Vivus will use diligent, reasonable efforts to manufacture, or to have its designee manufacture, sufficient quantities of the Product meeting all applicable specifications and legal requirements in a timely manner for use in conducting the development of the Product in the Territory pursuant to the Development Plan.

6. DILIGENCE OBLIGATIONS

6.1 PRODUCT DEVELOPMENT DILIGENCE OBLIGATIONS

Each Party will use diligent, commercially reasonable efforts to perform all the tasks and responsibilities assigned to it in the Development Plan in accordance with the development schedule set forth in the Development Plan, in an effort to obtain all necessary regulatory approvals in the Territory. If Vivus knows that it will be unable to meet any timeline or milestone date set out in the Development Plan, then it will bring the matter to the attention of FemPharm at the next Development Committee meeting or, if Vivus reasonably concludes that the delay is caused by a significant issue that is likely, unless it can be addressed by additional work, to prevent the Product from being approved by the FDA, as soon as reasonably practicable. The Development Committee will discuss in good faith the causes of any such delays and Vivus' suggested courses of action to complete the subject tasks and determine whether to return the Product development program to the schedule in the Development Plan or to reasonably adjust the schedule. In such process, the Development Committee shall extend reasonably the timeline or milestone dates in the Development Plan unless the delay was a result of a material breach by Vivus of its obligation to use diligent, commercially reasonable efforts in the development of the Product.

6.2 DILIGENCE PAYMENT FOR DEVELOPMENT DELAYS

If Vivus (including its Affiliates and sub-licensees) does not achieve the milestone event listed in Section 3.2(e) by its Outside Date (as defined below), or the milestone event listed in Section 3.2(f) by its Outside Date, then within ten (10) Business Days after the end of each full month of delay after the applicable Outside Date, Vivus will pay to FemPharm (*) percent (* %) of the milestone payment associated with the delayed event, until the corresponding milestone payment is paid in full, either as a result of meeting the milestone or as a result of such diligence payments. As used herein, "Outside Date" means (i) with respect to the Section 3.2(e) milestone (*); and (ii) with respect to the Section 3.2(f) milestone, (*). To the extent any diligence payments are made under this Section 6.2, and the milestone is achieved before the corresponding milestone payment has been paid in full, then upon achieving the milestone Vivus shall pay the amount of the milestone payment, reduced by the amount of payments for that milestone made under this Section 6.2. If the Section 3.2(e) or 3.2(f) milestone payment is paid in full as a result of this Section 6.2, then such payment will be deemed to satisfy the payment obligation under Section 3.2(e) or 3.2(f), as the case may be, and no further payment shall be due or payable as a result of completion of the particular milestone by any Product. However, if Vivus' inability to meet a milestone event by the applicable Outside Date is caused by delays outside of Vivus' reasonable control, that are circumstances described in subsection (a)-(d) below, then the Parties will meet and agree on reasonable adjustment to the applicable Outside Dates to accommodate such delays, provided that Vivus has used diligent, commercially reasonable efforts to meet the milestone events. The fact that payments become due or payable under this Section 6.2 shall not, itself, necessarily mean or suggest that there has been a lack of diligence by Vivus. For purposes of this Section 6.2, delays due to the following matters will be considered outside of Vivus' control:

- (a) a change in the specifications of the Product, or in the planned development of the Product, required by the FDA or other regulatory authority due to the medical, regulatory or scientific attributes of the Product, that necessitates additional development effort beyond that set forth in the Development Plan or contemplated when establishing the schedule in the Development Plan;

- (b) other delays in development caused by the FDA, or other regulatory authority, that were reasonably unanticipated by Vivus; or
- (c) delays caused by FemPharm not conducting its responsibilities as set out in the Development Plan in a timely manner.
- (d) Additional clinical development work required to be conducted due to failure of the studies conducted under the Development Plan to show sufficient levels of efficacy or safety, or the data is otherwise equivocal.

6.3 REVERSION FOR FAILURE OF DILIGENCE.

If at any time prior to achieving regulatory approval of the Product Vivus fails to use, and/or to continue using, diligent, commercially reasonable efforts to develop the Product in the Territory during the term of the Agreement, then FemPharm may give Vivus written notice of such failure of diligence. If Vivus does not commence within ninety (90) days of such notice using diligent, commercially reasonable efforts to develop Product in the Territory, then FemPharm may no later than ninety (90) days after such failure provide the notice of termination of this Agreement, including the license and other rights granted to Vivus, under Section 14.2(a), but only if such failure constitutes a material breach of this Agreement by Vivus, and subject to Section 15.10.

7. REGULATORY MATTERS

7.1 REGULATORY MATERIALS

- (a) Vivus is solely responsible for preparing and filing all Regulatory Materials for the development of the Product in the Territory except as otherwise set forth in this Agreement, including carrying out all registration and approval procedures necessary to comply with all appropriate laws and regulations relating to the manufacture, packaging, import, promotion, advertising and sale of the Product in the Territory. All costs incurred by Vivus with respect to such registrations and approvals will be borne by Vivus. FemPharm has the right to review and comment on all such Regulatory Materials prepared by Vivus, including application for registration and regulatory approval, (to the

extent disclosure of same does not violate confidentiality obligations) and to the extent reasonably practicable Vivus will consider all such comments provided to Vivus in advance of filing. Vivus will use good faith efforts to obtain for FemPharm the right to so comment on Regulatory Materials from Product of Vivus' sublicensees under the Licensed Intellectual Property. Similarly, Vivus has the right to review and comment on all Regulatory Materials for Product developed by or under authority of FemPharm or an Acrux Controlled Affiliate in the Field outside the Territory (to the extent disclosure of same does not violate confidentiality obligations, subject to the following), and FemPharm, the Acrux Controlled Affiliate, or licensee, as the case may be, shall provide Vivus with a reasonable opportunity to provide comments and consider all of Vivus' comments provided to FemPharm in advance of filing to the extent reasonably practicable.

- (b) FemPharm and its Affiliates and licensees (subject to the last sentence of Section 5.18) have a right of reference (at no cost to them) to the NDA and other Regulatory Materials filed by Vivus for the Product in the Field and Territory, which right of reference shall be solely for Australia and New Zealand as part of the development, approval and commercialisation of the Product in the Field for such countries, and such Regulatory Materials shall not be referenced by or under authority of FemPharm or any Acrux Controlled Affiliate for any other country or Product. FemPharm is solely responsible for carrying out all of its registration and approval procedures necessary to comply with all appropriate laws and regulations relating to the manufacture, packaging, import, promotion, advertising and sale of such Product in the Field in Australia and New Zealand. Without limiting the other terms of this Agreement, each Party will provide the other Party (at no cost to such other Party) with reasonable telephone support to respond to such other Party's questions regarding the Regulatory Materials and supporting materials that it is required to disclose under this Agreement.

7.2 RELATIONSHIP WITH REGULATORY AUTHORITIES

Vivus, as the sponsor of the Regulatory Materials for the Product in the Territory, has sole responsibility for interacting with all regulatory authorities in the Territory with respect to the Product in the Field, including meetings with such regulatory authorities, and responding to inquiries of and conducting other communications with such regulatory authorities, with regard to such Regulatory Materials or the Product. Vivus has sole authority and responsibility for all regulatory obligations regarding the Product in the Field in the Territory, including, but not limited to, the regulatory approval applications and registrations and related materials, all promotional materials, Product labeling, responding to medical inquiries, and Product complaints relating to the Territory, except as otherwise provided in this Agreement or the Development Plan, or determined by the Development Committee. Similarly, FemPharm, as the sponsor of its Regulatory Materials for the Product in the Field in Australia and New Zealand, has sole responsibility for interacting with all regulatory authorities in Australia and New Zealand with respect to its development of such Product in the Field for such countries, and for all such other regulatory obligations in its development of the Product in Australia and New Zealand. Each Party will provide the other Party with reasonable advance notice of, and any preparatory material for, any hearing before, or meeting with, any regulatory authority regarding the Product in such Party's territory (I.E., the Territory in the case of Vivus, and Australia and New Zealand in the case of FemPharm), and such other Party has the right to have two (2) of its employees attend such hearings or meetings at its own cost, to the extent the Party responsible for the meeting has the right to include them and is reasonably practicable under the circumstances. All such materials, and information learned in connection with such meeting or hearings, shall be treated as the Confidential Information of the Party disclosing the materials or conducting the meeting.

7.3 ADVERSE EVENTS AND COMPLAINTS REPORTING

The Parties agree that appropriate reporting of adverse events and other safety data relating to the Product is critical. Specific details regarding the management of information of adverse events, medical inquiries and Product complaints related to the

use of the Product in the Territory and outside will be delineated in a separate document, to be agreed to by the Parties within ninety (90) days after the Effective Date. The pharmacovigilance and product labeling representatives of each Party will work in good faith together to develop a document that identifies:

- (a) which safety information will be exchanged;
- (b) when such information will be exchanged;
- (c) how the global safety database will be established;
- (d) which Party will be obligated to obtain follow-up information on incomplete safety reports;
- (e) which Party will review the literature for safety report information;
- (f) which Party will prepare required periodic safety updates; and
- (g) the identification of any other details required to appropriately manage safety information for the Product.

Subject to any specific details of the above document, it is expected that Vivus will be responsible for pharmacovigilance, adverse reaction reporting and related matters for Products inside the Field in the Territory, and that FemPharm shall be responsible for pharmacovigilance, adverse reaction reporting and related matters for Products in the Field in all countries outside of the Territory. The Parties also agree to use good faith, reasonable efforts to reach agreement with any of their respective licensees (or sublicensees, as applicable) of Products in the Field to include such entities in the pharmacovigilance and related safety and adverse event reporting document discussed above.

8. PRODUCT COMMERCIALIZATION

8.1 OVERVIEW

Vivus has the exclusive rights, subject to the terms of this Agreement, to promote, market, distribute and sell Product for use in the Field throughout the Territory, itself and/or through its Affiliates and sub-licensees.

8.2 COMMERCIALIZATION OBLIGATIONS

Vivus hereby covenants and agrees with FemPharm, during the term of this Agreement commencing with regulatory approval of the NDA for the Product by the FDA in the Field and Territory (permitting marketing of the Product in the Territory), to:

- (a) actively and diligently promote the sale of the Product using commercially reasonable efforts in the Territory;
- (b) not, and to require that its Controlled Affiliates and sub-licensees do not, sell the Product licensed hereunder outside the Territory nor sell such Product to any person which it knows, or for which it has been provided reasonable documentation, is selling such Product outside the Territory, each to the extent set forth in Section 2.6; and
- (c) provide for and maintain, or cause to be provided for and maintained, a sales organisation and a marketing program reasonably adequate and competent to promote, stimulate interest in, and sell the Product effectively in the Territory, for a commercially reasonable period of time after commercial launch.

Additionally, each Party hereby covenants and agrees, during the term of this Agreement, to:

- (1) use reasonable efforts to comply with all governmental and municipal laws, regulations and requirements relating to the manufacture, packaging, promotion, advertising, distribution and sale of the Product;
- (2) take out and maintain at its cost during the term of this Agreement and for a reasonable period of time thereafter whilst any liability may occur to such Party as a result of its distribution of the Product, product liability insurance in the name of such Party in respect of the manufacture, distribution, sale, use and consumption of the Product by such Party for an amount consistent with

industry standard practices and will duly and punctually pay all premiums in respect of such insurance and provide evidence of such insurance and payment of premiums to the other Party when so requested; and

- (3) not make any fraudulent misrepresentations in respect of the quality or contents of the Product.

8.3 COMMERCIALIZATION PLANS

No later than twelve (12) months prior to the expected launch of First Commercial Sales of the Product in the Territory, Vivus will provide to FemPharm a commercial launch plan (the "Commercial Launch Plan"), which will set forth in reasonable detail Vivus' actual plan and budget for the launch and initial marketing and promotion of the Product, including the trademarks to be used in such marketing. Such Commercial Launch Plan will include non-binding sales projections for the Product for at least two years from the planned First Commercial Sale. The form of the Commercial Launch Plan and the amount of detail included will be as established by the Steering Committee. For each full calendar after the First Commercial Sale, Vivus agrees to provide FemPharm, no later than February 1 of such calendar year, a report that describes in reasonable detail the marketing activities planned to be conducted by Vivus (or its Affiliate) for the Territory during the calendar year, and that sets forth the actual IMS (or related source) audited marketing data showing the actual marketing and promotional activities that were conducted by Vivus (or its Affiliate or licensee) in the Territory for the Product during the previous calendar year.

8.4 LAUNCH DILIGENCE

Vivus (or its Affiliate or sub-licensee) will use diligent, commercially reasonable efforts to launch the Product for commercial sale in the Field in the Territory within six (6) months of obtaining regulatory approval of the Product in the Territory, and will expend such efforts and resources in launching and initial promotion and marketing of the Product in the Territory as are commercially reasonable.

8.5 MANUFACTURE IN TERRITORY

Vivus is solely responsible for all manufacturing of its requirements of the Product for sale in the Field in the Territory. Vivus will use diligent, commercially reasonable efforts to meet market demand for the Product in the Territory.

8.6 SUPPLY OF PRODUCT TO FEMPHARM

Vivus will agree to supply to FemPharm needed amounts of the Product (in final finished and packaged form, according to the specifications of Vivus in the Territory) for use by FemPharm in developing and commercializing Product in the Field in Australia and New Zealand under a mutually acceptable supply agreement on terms that are customary and reasonable. Such Product supplied by Vivus shall be used solely for FemPharm to develop and sell the Product in the Field in New Zealand and Australia. Vivus shall have no obligation to supply any Product other than that being developed or commercialized by Vivus under this Agreement at the then current time. The transfer price for such Product shall be (i) (*) percent (* %) above Vivus' actual purchase price if such Product is purchased by Vivus from a contract manufacturer; and (ii) (*) percent (* %) above Vivus' fully burdened manufacturing costs, as determined consistent with Vivus' standard practices applied consistently across all its operations, if Vivus manufactures the Product. Notwithstanding the foregoing, Vivus shall have no obligation to negotiate under this Section 8.6 until after (*).

9. SUB-LICENSING AND ASSIGNMENT

9.1 SUB-LICENSE

Vivus has the right to grant and authorize sub-licenses, under the rights granted to it in this Agreement, to Affiliates of Vivus and to other third parties, without consent, BUT PROVIDED THAT prior to granting a sub-license to a third Party Vivus shall have disclosed the identity of the proposed third party to FemPharm and shall discuss and consider in good faith any reasonable concerns FemPharm may have with regard to granting a sublicense to such third party, and shall consider in good faith FemPharm's suggestions to address any of its reasonable concerns. Vivus is responsible for the actions of any such sub-licensee, and if such sub-licensee breaches any Vivus obligation under the Agreement, such breach will be deemed a breach by Vivus.

9.2 VIVUS BOUND

In the case of sub-licensing, Vivus remains bound by this Agreement and responsible for performing, or having its sub-licensee perform, all its obligations hereunder, subject to Section 9.1 above. Subject only to Section 5.20 and 9.1, however, nothing shall prevent Vivus from relying upon the performance and efforts of its sublicensees and contractors for purposes of satisfying its obligations under this Agreement, including under Articles 7 and 8, notwithstanding anything to the contrary, such as language in Sections 5.5, 5.21, 7.1(a), 7.2, and 8.5 that indicates that Vivus shall have sole responsibility.

9.3 ASSIGNMENT

Each Party is entitled to assign and otherwise transfer without consent all its right, title and interest in this Agreement, including its obligations, to any other Person that acquires all or substantially all of such Party's business or assets, whether by asset purchase, merger, acquisition or other similar transaction, PROVIDED THAT such Person agrees in writing to be bound by the terms hereof as the successor in interest or assignee. Any other attempt to transfer or assign shall be void without the prior written consent of the other Party. If a Party is acquired by another corporation or other entity that was not its Affiliate prior to the acquisition, then no Intellectual Property rights of the acquiring entity developed prior to the acquisition, or developed thereafter without using the Licensed Technology, shall be included in the rights licensed to the other Party under this Agreement.

10. CONFIDENTIALITY

10.1 RESTRICTIONS ON USE

Subject to the further provisions of this Article 10, each Party agrees that it will keep all Confidential Information disclosed to it by the other Party secret and confidential, and will not disclose it to any third party, or use it for its own benefit or the benefit of

any third party, except that either Party may use and disclose the other Party's Confidential Information:

- (a) for the purposes of exercising the licenses and other rights granted by this Agreement; or
- (b) as otherwise permitted with the prior written consent of the other Party.

Any disclosure authorized in accordance with the foregoing shall be subject to reasonable confidentiality provisions materially as protective of the Confidential Information as the terms of this Agreement.

10.2 USE OF OWN INFORMATION

Except for Section 10.13, nothing in this Article 10 prevents a Party from disclosing or dealing in its absolute discretion with any of its own Confidential Information, provided that FemPharm will use reasonable efforts to keep its Confidential Information relating to the Product and the Field secret and confidential so as to avoid any adverse affect on the value or protection of the Licensed Intellectual Property to the extent relevant to the Field and the Territory and further provided that such disclosure and dealing by FemPharm shall be subject to the other terms of this Agreement, including Sections 2.1 and 10.13.

10.3 EXCEPTIONS TO CONFIDENTIALITY

The obligations of confidentiality and non-use as provided in Section 10.1 above do not extend to, and notwithstanding Section 1.1 Confidential Information shall not include, any particular information or Know-How received by a Party that it can demonstrate by competent evidence:

- (a) was available to the public or otherwise in the public domain prior to receipt by such Party, or subsequent to such receipt becomes available to the public or part of the public domain, other than as a result of a breach of this Agreement;
- (b) was already known to the recipient Party by lawful means at the time of receipt (including trade secrets and inventions not disclosed in existing patent applications) other than directly or indirectly from the other Party;

- (c) was obtained by the recipient Party from a third party who has a lawful right to disclose it, provided that the information has not been obtained directly or indirectly from the other Party to this Agreement and is not subject to an obligation of confidentiality; or
- (d) was independently developed by the receiving Party without use of the other Party's Confidential Information.

10.4 EXCEPTIONS TO NON-DISCLOSURE

Notwithstanding the restrictions of Section 10.1, a Party may disclose the Confidential Information of the other Party beyond the disclosure authorized in Section 10.1, subject to compliance with the following provisions of this Section 10.4, solely to the extent such disclosure:

- (a) is to its professional advisors, and provided that such disclosure is reasonably necessary or desirable and is subject to reasonable confidentiality protections;
- (b) is required by any court or other judicial or quasi-judicial tribunal or any administrative or government body, or as is required by law, provided that such disclosure is no more than is necessary to avoid the imposition of a penalty for failing or refusing to disclose the Confidential Information, and that the Confidential Information is disclosed in such a way as to limit as far as possible the disclosure of the Confidential Information, and that such disclosing Party first complies with Section 10.5; or
- (c) as reasonably necessary in prosecuting or defending any litigation or enforcing this Agreement, provided that such Party has first notified the other Party giving full details of the circumstances of the required disclosure and of the relevant information to be disclosed and takes reasonable steps to preserve the confidentiality of the information.

10.5 DISCLOSURE BY LAW

Before any disclosure in reliance on Section 10.4(b), the Party subject to the disclosure obligation must, unless it is not practicable to do so:

- (a) immediately notify the other Party giving full details of the circumstances of the required disclosure and of the relevant information to be disclosed;
- (b) to the maximum extent permitted by law give the other Party a reasonable opportunity in a court of law or other appropriate body to:
 - (i) challenge the proposed disclosure;
 - (ii) challenge the obligation of the Party or any other person to make that disclosure; and/or
 - (iii) secure a protective order or other ruling limiting or preventing the disclosure and/or to protect or preserve the confidentiality of the relevant information; and
- (c) take reasonable steps to preserve the confidentiality of the information being disclosed and to comply with any such protective order or ruling.

10.6 SCOPE OF CONFIDENTIALITY

In the case of uncertainty as to the confidentiality of any information a Party must treat the information as Confidential Information until such Party or the other Party confirms that the information is not Confidential Information.

10.7 SECURITY OF INFORMATION

Each Party must use its reasonable endeavours to minimise the risk of disclosure of any Confidential Information of the other Party, by providing reasonable security of its premises, its records and materials.

10.8 PERSONNEL CONFIDENTIALITY

Each Party agrees to procure written and signed confidentiality and non-publication undertakings with respect to the Confidential Information of the other Party, in terms materially as protective of such other Party's Confidential Information as this Article 10, from all employees, agents and contractors of such Party who have or are likely to have access to Confidential Information of the other Party.

10.9 RETURN OF CONFIDENTIAL INFORMATION

Upon termination of this Agreement, each Party may by written notice to the other Party demand the return of all tangible property comprising Confidential Information provided by such Party, but only to the extent set forth in Article 14 and provided that Vivus shall not be required to return any product.

10.10 PUBLICATIONS

Neither Party shall make or authorize any oral public disclosure, or any submission to any outside person for publication of an abstract or manuscript, disclosing the Confidential Information of the other Party, including any scientific data resulting from the other Party's non-clinical development or clinical development under this Agreement, in each case except to the extent approved in writing by such other Party or as otherwise permitted in this Article 10.

10.11 OTHER RIGHTS

Nothing herein contained excludes the right of either Party at common law or in equity to protect its Confidential Information by application to any court for injunction or otherwise. Notwithstanding anything to the contrary in this Article 10, the Parties agree that the use and disclosure of concepts and information retained in the unaided memories of individuals who had access to Know-How from the other Party shall not be considered a breach of the terms of this Agreement. This Section 10.11 shall not be construed to grant any rights under any Patent in such concepts.

10.12 USE OF OTHER PARTY'S NAME

Neither Party shall make any use of the other Party's name unless approved by the other Party in writing, such approval not to be unreasonably withheld, or in the circumstances set forth in Section 10.13.

10.13 PRESS RELEASES AND OTHER DISCLOSURES

The Parties will issue a joint press release, in the form attached as annexure D, promptly after the Effective Date. The Parties agree that no other publication or other public disclosure of the terms of this Agreement will be made by a Party without the

consent of the other Party, (with failure to respond to any request for consent beyond ten (10) days from the request to be deemed consent), such consent not to be unreasonably withheld. Notwithstanding the foregoing, a Party may make disclosures authorized pursuant to Section 10.10 and may disclose the terms of this Agreement:

- (a) to the extent required by law or regulation or court order, or by the rules of any stock exchange on which the stock or shares of the Party or any of its Affiliates are listed or other government body; and
- (b) in confidence to its professional advisors, and its existing or potential investors, acquirors, and merger partners on a need to know basis under conditions which reasonably ensure the confidentiality thereof;
- (c) in confidence, pursuant to non-disclosure and non-use restrictions at least as stringent as included in this Article 10, to other parties that have a need to know such information for a purpose related to this Agreement;
- (d) in connection with the enforcement of this Agreement or rights under this Agreement;
- (e) in confidence as is reasonable in connection with a merger, acquisition of stock or assets, proposed merger or acquisition, or the like;
- (f) as advisable or required in connection with any government or regulatory filings, including filings with the SEC; provided however, prior to any such disclosure the non-disclosing Party shall be allowed to review the proposed disclosure, and the disclosing Party agrees to consider in good faith any proposed revisions thereof provided to the disclosing Party within ten (10) Business Days of the non-disclosing Party's receipt of the proposed disclosure and the Party making such disclosure shall seek confidential treatment for such disclosure as permitted by applicable law in a similar manner to the actions it takes for its other information of like kind.

11. INVENTIONS

11.1 DISCLOSURE OF INVENTIONS

During the term of this Agreement, each Party will promptly disclose to the other Party the Inventions invented jointly by employees of both Parties and for which the disclosing Party desires to seek Patent protection, and Vivus will promptly disclose to FemPharm all Improvements, provided that Vivus shall not be considered in breach of such disclosure obligation as a result of an inadvertent failure to disclose an Invention so long as Vivus promptly discloses the Improvement after discovering the failure to disclose.

11.2 OWNERSHIP OF INVENTIONS AND INTELLECTUAL PROPERTY RIGHTS

As between the Parties, each Party (or its Affiliate) will own the entire right, title and interest in and to all the Inventions made by such Party's (or its Affiliate's) employees or others acting on behalf of such Party or Affiliate and all Intellectual Property rights in and to such Inventions, subject only to the licenses and other rights (if any) to the extent granted to the other Party thereto under this Agreement.

11.3 JOINT INVENTIONS AND JOINT PATENTS

All right, title and interest in all Patents to the extent claiming Inventions invented jointly by the employees of both Parties ("Joint Inventions") will be owned jointly by FemPharm and Vivus (that is, each Party having an equal and undivided interest therein). Patent filings to the extent claiming a Joint Invention will be conducted as set out in Section 12.2. Neither Party may assign its interest in any Joint Patent unless notice of such transfer has been first given to the other Party and the transferee agrees in writing to be bound by the terms of this Agreement with respect to the interest so transferred and as otherwise set forth in Section 9.3. Except as otherwise expressly provided in this Agreement, neither Party shall have any obligation to account to the other for profits, or to obtain any consent of the other Party to license or exploit, Joint Inventions (whether or not patented) or Joint Patent, by reason of joint ownership thereof, and each Party hereby waives any right it may have under the laws of any jurisdiction to require any such consent or accounting.

11.4 COOPERATION OF EMPLOYEES

Each Party represents and agrees that all employees acting on its behalf in performing its obligations under this Agreement will be obligated under a binding written agreement to assign to such Party, or as such Party will direct, all inventions made or conceived by such employee.

12. PATENTS AND INTELLECTUAL PROPERTY

12.1 PATENT RIGHTS

All right, title and interest owned by a Party in Intellectual Property will remain owned and retained exclusively by such Party, subject only to the applicable license and other rights granted to Vivus and FemPharm in this Agreement. FemPharm will have sole responsibility for and control over, at its discretion, the filing, prosecution, maintenance and enforcement of the FemPharm Patents, at FemPharm's expense, except as otherwise provided below. FemPharm shall use diligent commercially reasonable efforts to obtain and maintain at all times broad Patent protection for the Products in the Field and Territory under this Agreement, including by using reasonable efforts to prepare, file, prosecute and maintain Patents as desirable for Products in the Field and Territory and to pursue as appropriate interferences, re-examinations, reissues, oppositions and similar proceedings regarding the FemPharm Patents. During the term of this Agreement and thereafter to the extent Vivus has surviving rights, FemPharm will keep Vivus reasonably informed regarding the status, preparation, filing, prosecution and maintenance of all patent applications and patents included or to be included in the FemPharm Patents licensed to Vivus pursuant to Section 2.1 (including inventions for which Vivus may desire to have a Patent application filed), and without limiting the foregoing will reasonably consider, and give Vivus a reasonable opportunity to provide, comments on such preparation, filing, prosecution, or maintenance efforts that relate to Product, the Field or the Territory. FemPharm may elect to cease preparing, filing, prosecuting or maintaining any particular FemPharm Patent, or to cease diligently pursue any interferences, re-examinations, reissues, oppositions or similar proceeding relating to a particular FemPharm Patent, but only to the extent that FemPharm has provided to Vivus, as far

in advance as practicable, written notice describing its intent and, to the extent desired by Vivus, has reasonably transitioned the preparation, filing, prosecution, and maintenance to Vivus without prejudice to Vivus' rights under this Agreement. If Vivus then undertakes such activities, Vivus shall bear all of its actual out of pocket costs and expenses incurred in such activities, and may credit against amounts subsequently owed to FemPharm under this Agreement any such actual costs and expenses borne, subject to providing FemPharm with receipts and invoices and other documents as is reasonable to properly evidence the costs and expenses and payment thereof. FemPharm shall use reasonable efforts to cooperate and provide such documents and assistance as is reasonably requested, in connection with such activities by or under authority of Vivus.

12.2 JOINT PATENT RIGHTS

As to each Joint Invention, the Parties will discuss and reasonably agree on whether and where to file a Joint Patent claiming the Joint Invention, and on which Party shall assume responsibility for the preparation, filing, prosecution and maintenance of such Joint Patents, in each country in the world for which prosecution of the Joint Patent is desired by a Party. The Parties will share equally in the expenses of such activities related to Joint Patents. Each Party will reimburse the other for its share of such expenses borne by the other Party upon written request, no less frequently than quarterly and shall cooperate and provide such documents and assistance as is reasonably requested in connection with such activities. Each Party will keep the other reasonably informed of, and consult with the other Party with respect to, all significant actions in the course of such Party's prosecution of the Joint Patents. If the Party having responsibility for prosecuting a particular Joint Patent elects not to assume or continue such responsibility, the other Party will have the right, but not the obligation, to do so. If either Party elects not to continue to support prosecution or maintenance of a particular Joint Patent, it may do so on written notice to the other Party, and in such case it will assign its entire interest in such Joint Patent to the other Party if such other Party elects to prosecute and maintain such Joint Patent at its sole expense; subject to any licenses and exclusivity in this Agreement. Upon any such assignment, the Party that elected to discontinue its involvement, and assign its interest, shall not be required to bear any expenses under this Section 12.2.

12.3 FEMPHARM PATENT PROCEEDINGS

Each Party will promptly notify the other of any legal proceedings, including opposition or declaration of invalidity proceedings, initiated or pursued by any third party against any of the FemPharm Patents. FemPharm has the sole right and authority to defend against any such proceedings, including defending against any defenses or counterclaims of invalidity or unenforceability (including such counterclaims as may arise out of an infringement claim under Section 12.4). For clarity, all infringement actions involving a Field Infringement (as defined in Section 12.4) shall be pursued under Section 12.4, and FemPharm shall have the right to control only the defense of the FemPharm Patents in such Field Infringement actions in the event that a defense or counterclaim is asserted against the FemPharm Patents, shall use reasonable efforts, in such defense, not to adversely impact the Field Infringement action by Vivus. FemPharm will keep Vivus reasonably informed of the actions taken to defend the FemPharm Patents and the progress of such actions. In such case, only (*) % of FemPharm's costs and expenses of such involvement shall be reimbursed out of the recovery in the Field Infringement action. Vivus will provide FemPharm with reasonable assistance and cooperation in such actions, at FemPharm's sole expense, in an effort to obtain a successful resolution or termination of such proceedings or counterclaims governed by this Section 12.3. Vivus will have the right to have counsel of its choosing participate in any such defense of the FemPharm patents, at its sole expense, subject to Section 12.4. FemPharm will not settle any claim, suit or action involving FemPharm Patents in any manner that would materially negatively impact upon the FemPharm Patents, the Licensed Intellectual Property, or Vivus' rights or exclusivity thereunder, or that would materially negatively impact upon or limit or restrict the ability of Vivus to sell the Products in the Territory.

12.4 INFRINGEMENT PROCEEDINGS IN THE FIELD

Each Party will promptly notify the other if it becomes aware that any third party is infringing any FemPharm Patent in the Territory. If any third party is infringing, or believed to be infringing any FemPharm Patent in the Territory in connection with the exploitation, making, use, import, offer for sale, or sale of a product in the Field in the Territory (a "Field Infringement"), then the Parties will promptly thereafter meet and discuss in good faith appropriate steps to take to cause such Field Infringement to cease.

- (a) Vivus or its designee has the first right and authority, but not the obligation, to take reasonable steps to cause termination of such Field Infringement, which may include initiating a lawsuit or other appropriate legal action, at its expense, as Vivus or its designee reasonably determines is appropriate; provided that Vivus agrees that it will not initiate a lawsuit asserting infringement of the FemPharm Patents unless it has first discussed the matter with FemPharm. Vivus will keep FemPharm reasonably informed of the actions taken to cause termination of a Field Infringement and the progress of any such actions (including notifying FemPharm promptly if the third party raises any defenses or counterclaims of invalidity or unenforceability of any FemPharm Patents). FemPharm will provide Vivus or the designee with reasonable assistance and cooperation in such actions, at Vivus's or the designee's expense (other than as set forth in Section 12.3), including joining such action as a party plaintiff and taking such other actions as are required by applicable law for Vivus or the designee to pursue such action. FemPharm will have the right to have counsel of its choosing participate in any such action, at its sole expense, provided that Vivus will have the right to control the action. Vivus will not settle any claim, suit or action that it brought under this Section 12.4 involving FemPharm Patents in any manner that would negatively impact upon the FemPharm Patents or the Licensed Intellectual Property without FemPharm's consent, not to be unreasonably withheld or delayed.
- (b) If Vivus and its designees have not, within four (4) months of request by FemPharm, initiated and pursued reasonable efforts to cause such Field Infringement to cease, then each Party (and Vivus' designees) shall thereafter have the right and authority, but not the obligation, to take any such steps or actions at its expense. Whichever of such parties first does so shall thereafter control the action and the other Party will provide the controlling Party (or designee) with reasonable assistance and cooperation in such actions, at

expense of the controlling Party or designee (except as set forth in Section 12.3), including joining such action as a party plaintiff and taking such other actions as required by applicable law to pursue such action.

- (c) The Party bringing the suit, action or legal proceedings will:
 - (i) be reimbursed for its costs and expenses associated with bringing the legal proceedings out of the proceeds of any damages or costs recovered or as otherwise provided by agreement between the Parties; and
 - (ii) indemnify the other Party against any liability awarded against such other Party as a result of the subject matter of such suit brought by the indemnifying Party, unless caused by the acts or omissions of the indemnified Party.
- (d) Any amounts remaining out of damages and costs and other amounts recovered from a third party due to infringement of the FemPharm Patents under a suit, action or legal proceeding brought against a Field Infringement, will be retained by the Party that brought the action as follows:
 - (i) if Vivus or its designee brought the action, then Vivus or the designee, as the case may be, shall retain (*) percent (* %) of the recovery and will pay the remaining (*) percent (* %) to FemPharm; and
 - (ii) if FemPharm brought the action, the recovery shall be (*)% to Vivus and (*) % to FemPharm.

12.5 OTHER INFRINGEMENT PROCEEDINGS

For clarity, FemPharm retains the sole and exclusive right to enforce and defend the FemPharm Patents against all third party infringements worldwide, except as otherwise provided in Section 12.4 with respect solely to Field Infringement.

13. REPRESENTATIONS AND WARRANTIES; DISCLAIMERS

13.1 WARRANTY

Each Party, and each Acrux Controlled Affiliate, represents, warrants and covenants that: (i) it has the legal power and authority to enter into this Agreement and to perform all of its obligations hereunder; (ii) it has and will have the right and authority to grant the rights and licenses granted by it hereunder; (iii) this Agreement is a legal and valid obligation binding upon it and enforceable in accordance with its terms; (iv) it has not previously made, and during the term of this Agreement will not make, any commitment or grant or authorization of rights which are in conflict in any material way with, or that will restrict or impair, the rights, licenses, or exclusivity granted to Vivus herein.

13.2 ADDITIONAL WARRANTIES OF FEMPHARM AND THE ACRUX CONTROLLED AFFILIATES

Each of FemPharm and Acrux DDS Pty Limited represents, warrants, and covenants as follows:

(a) it has not received notice that it has failed to comply with, and it has not failed to comply with, any obligation, law, regulation, or order in a manner that will materially adversely affect the rights granted to Vivus under this Agreement;

(b) Annexure B sets forth a list of all FemPharm Patents (whether issued or pending) owned by, or licensed to, any of FemPharm and the Acrux Controlled Affiliates. Except for the Patents listed in Annexure B, there are no Patents related to or useful for Products in the Field that are owned by, or licensed to, FemPharm or any Acrux Controlled Affiliate. All Patents in Annexure B are owned by FemPharm or an Acrux Controlled Affiliate, except as expressly identified in Annexure B. None of FemPharm and the Acrux Controlled Affiliates shall grant any third party any license or rights under any Patent that is within the FemPharm Patents that derogate from or reduce the license or rights granted to Vivus under this Agreement;

(c) FemPharm has sufficient rights to the FemPharm Patents identified in the annexure B for it to grant to Vivus the exclusive right (with respect to all Persons) under such Intellectual Property, including the right to grant and authorize

sublicenses, to exploit, import, export, make, have made, use, offer for sale and sell Products for use in the Field in the Territory;

(d) as of the Effective Date: (i) the existing FemPharm Patents are in full force and effect and not subject to any pending re-examination, opposition, interference or claim of invalidity proceedings, none of the Licensed Intellectual Property is subject to any litigation or similar proceedings, and neither FemPharm nor any Acrux Controlled Affiliate has knowledge of a third party threat of such a proceeding, or of facts that likely would be the basis for instituting such proceeding; (ii) none of FemPharm and the Acrux Controlled Affiliates has reason to believe that any of the existing FemPharm Patents likely will be invalid, unenforceable, or will fail to issue, or that the claims of any pending FemPharm Patent likely will be materially limited or restricted beyond the presently pending claims;

(e) as of the Effective Date, none of FemPharm and the Acrux Controlled Affiliates is aware of any Person that is infringing a FemPharm Patent in the Territory;

(f) FemPharm and/or one of the Acrux Controlled Affiliates have access and rights to all Regulatory Materials filed by or under authority of any of them with regulatory authorities, and the supporting raw data for such materials, relevant to Product and may be useful to support the development or marketing approval of the Product in the Field in the Territory, and has the right to include the same within the Know-how disclosed to Vivus hereunder;

(g) FemPharm has not knowingly failed to provide to Vivus any documents or information requested by Vivus as part of its due diligence process, and FemPharm and Acrux DDS Party Limited believe that FemPharm has provided to Vivus, prior to the Effective Date, access to sufficient Know-How Controlled by FemPharm or any Acrux Controlled Affiliate for Vivus to conduct a reasonable and fully informed evaluation of the Licensed Technology and the development status and results relating to the current Product in deciding whether or not to enter into this Agreement, including all adverse information and all relevant agreements. None of the materials provided to Vivus by FemPharm or an Acrux Controlled Affiliate prior to the Effective Date contained any untrue statement of material fact, and to FemPharm's

and Acrux Controlled Affiliate's knowledge, none of FemPharm or any Acrux Controlled Affiliate failed to disclose to Vivus, or concealed, any material fact that would, absent such disclosure, make the materials provided to Vivus materially misleading;

(h) as of the Effective Date, to each of FemPharm's and the Acrux Controlled Affiliates' knowledge, none of FemPharm and the Acrux Controlled Affiliates has made an untrue statement of a material fact, or has failed to disclose a material fact, to any regulatory authority with respect to the Product in the Field, or any portion thereof;

(i) Acrux DDS Pty Limited shall use diligent, commercially reasonable efforts to (*). FemPharm and the Acrux Controlled Affiliates shall not terminate, amend or modify the (*). FemPharm shall notify Vivus in writing immediately if any of FemPharm, Acrux Limited or the Acrux Controlled Affiliates receives from the licensor of any Licensed Intellectual Property any notice of breach or termination, or any other indication of a dispute or matter that could lead to breach or termination, of the license agreement, or which could otherwise affect Vivus' rights thereunder;

(j) FemPharm will not deliver to Vivus confidential or proprietary Know-How of any third party unless FemPharm has the right to do so for use and disclosure by Vivus in the manner set forth in this Agreement, unless FemPharm expressly identifies at the time of such disclosure the particular Know-How that FemPharm does not have the right to license to Vivus hereunder;

(k) all employees, consultants, and other contractors of each of FemPharm and the Acrux Controlled Affiliates performing work related to or useful for any Product in the Field, including Monash, Barry Reed, William Charman, Dr. Barrie Finnin, and Dr. Tim Morgan in each case to the extent acting as an employee, consultant, or contractor of FemPharm or an Acrux Controlled Affiliate, have been and shall be subject to a written agreement that vests in FemPharm or an Acrux Controlled Affiliate all right, title, and interest in and to their work product, including all associated Intellectual Property rights;

(l) none of this Agreement, or the exercise by or under authority of Vivus of the license rights granted to Vivus under this Agreement, will violate or otherwise be affected by any of the terms or conditions imposed in connection any government funding or sponsorship obtained by FemPharm or an Acrux Controlled Affiliate;

(m) FemPharm and the Acrux Controlled Affiliates are not aware, as of the Effective Date, (1) of any Patent of any third party, including Affiliates, that will be infringed by the manufacture, use import, or sale of a Product in the Field in the Territory, or (2) that any Licensed Know-How in any of their possession, and related to or useful for Product, was misappropriated from a third party.

(n) none of the terms and conditions of the Monash License, including Sections 6, 7, 8.1, 8.3, 12.2, and 19.1 of the Monash License, or the Acrux DDS License bind Vivus;

(o) the FemPharm Patents are not subject to any lien or encumbrance (as defined in the Monash License) that could materially limit or adversely affect Vivus' rights granted under this Agreement;

(p) Acrux Limited is not controlled by any Person, and FemPharm and Acrux DDS Pty Limited, and Cosmeceutical Solutions Pty Limited are the only Affiliates of Acrux Limited that have any interest in (i) any Licensed Intellectual Property, (ii) any Competitive Product or (iii) any technology, product or Intellectual Property related to or useful for the Product in the Field, the delivery of testosterone or other Androgen's, or the delivery of a selective androgen receptor modulator, to females, or any transdermal or mucosal delivery; and

(q) none of FemPharm and the Acrux Controlled Affiliates are currently researching or developing, or have current plans to commence research or development of, any MDTs product for the treatment of sexual dysfunction in human females, other than the Product.

13.3 ADDITIONAL WARRANTIES OF VIVUS

Vivus represents, warrants, and covenants to FemPharm that:

(a) Vivus has not received notice that it has failed to comply with, and it has not failed to comply with, any obligation, law, regulation, or order in a manner that will materially adversely affect the rights granted to Vivus under this Agreement;

(b) Vivus has not knowingly failed to provide to FemPharm any documents or information requested by FemPharm as part of its due diligence process, or evaluation of whether or not to enter into this Agreement, except as otherwise stated to FemPharm. None of the materials provided to FemPharm by Vivus prior to the Effective Date contain any untrue statement of material fact, and to Vivus' knowledge, Vivus has not failed to disclose to FemPharm, or conceal, any material fact that would, absent such disclosure, make the materials provided to FemPharm materially misleading;

(c) Vivus will not deliver to FemPharm confidential or proprietary Know-How of any third party unless Vivus has the right to do so for use and disclosure by FemPharm in the manner set forth in this Agreement, unless Vivus expressly identifies at the time of such disclosure the particular Know-How that Vivus does not have the right to license to FemPharm hereunder;

13.4 DISCLAIMER OF WARRANTIES

EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, VIVUS AND FEMPHARM MAKE NO REPRESENTATIONS, WARRANTIES OR CONDITIONS OF ANY KIND, EITHER EXPRESS, IMPLIED, STATUTORY, OR OTHERWISE, AND EACH PARTY HEREBY DISCLAIMS ALL OTHER WARRANTIES, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

13.5 DISCLAIMER OF LIABILITY

EXCEPT WITH RESPECT TO A BREACH OF SECTIONS 2.5, 10, OR THE EXCLUSIVITY IN SECTION 2.1(a), IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER BASED UPON THIS AGREEMENT FOR ANY SPECIAL, CONSEQUENTIAL, INDIRECT, OR INCIDENTAL DAMAGES ARISING OUT OF OR RELATED TO THIS AGREEMENT, HOWEVER CAUSED, ON ANY THEORY OF LIABILITY AND WHETHER OR NOT SUCH PARTY HAS BEEN ADVISED OR IS AWARE OF THE POSSIBILITY OF SUCH DAMAGES.

14. TERM AND TERMINATION

14.1 TERM

This Agreement will continue in full force and effect from the Effective Date until expiration, unless earlier terminated pursuant to Sections 5.19(b), 14.2, 14.3 or 14.8 below, on the date that Vivus no longer has, and shall not have in the future, any payment obligations to FemPharm under this Agreement. Upon such expiration, Vivus retains a non-exclusive, fully-paid license in the Territory to continue to make, have made, use, sell and otherwise exploit Products in the Field.

14.2 TERMINATION BY FEMPHARM

FemPharm is entitled by written notice to Vivus to terminate this Agreement upon the happening of any of the following events, provided that FemPharm provides Vivus with written notice of termination within one hundred eighty (180) days after it becomes aware of the occurrence of the applicable event:

- (a) any material breach by Vivus of any of the terms and conditions of this Agreement, where such breach is not fully cured and rectified within ninety (90) days, or with respect to payment obligations, within forty-five (45) days, after the giving of written notice by FemPharm to Vivus specifying such breach and requiring rectification thereof, provided that if such breach (other than a payment breach) is not capable of cure within the initial ninety (90) day period and Vivus is making diligent good faith efforts to cure, then Vivus shall

have an additional ninety (90) days to cure such breach, and subject to Section 15.10, and except as otherwise provided in Section 14.7;

- (b) a petition or other application or resolution being passed against Vivus, or being presented by Vivus, in a bankruptcy proceeding that requires the winding up, liquidation or dissolution of Vivus or notice by Vivus of its intention to propose such a resolution being given;
- (c) the appointment of a receiver, or receiver and manager, for all of Vivus's property in bankruptcy;
- (d) if Vivus (or any of its Affiliates) bring any action, suit, defense or counterclaim seeking to invalidate or have held unenforceable: (i) any claim in any FemPharm Patent in substantially the same form that the claim is issued or pending on July 31, 2003 (an "Existing FP Claim"); or (ii) any claim in a FemPharm Patent filed after July 31, 2003 that is substantially the same as any such Existing FP Claim and that is entitled to an effective filing date (e.g. as defined under 35 USCss.120) that is the filing date of a FemPharm Patent filed prior to July 31, 2003.

14.3 TERMINATION BY VIVUS

Vivus is entitled by written notice to FemPharm to terminate this Agreement upon the happening of any of the following events, provided that Vivus provides FemPharm (except in case of subsection (d)) with written notice of termination within one hundred eighty (180) days after Vivus becomes aware of the occurrence of the applicable event:

- (a) a material breach by FemPharm of any of the terms and conditions under this Agreement or a material breach by an Acrux Controlled Affiliate of its obligations, representations, or warranties in this Agreement, where such breach is not fully cured or rectified within ninety (90) days after the giving of written notice by Vivus to FemPharm specifying such breach or non-observance and requiring rectification thereof, provided that if such breach is not capable of cure within the initial ninety (90) day period and FemPharm

and the Acrux Controlled Affiliates are making diligent good faith efforts to cure, then FemPharm shall have an additional ninety (90) days to cure such breach, and subject to Section 15.10;

- (b) a petition or other application being presented or resolution being passed by or against FemPharm, Acrux DDS Pty Ltd, or Acrux Limited in a bankruptcy proceeding that requires the winding up, liquidation or dissolution of the applicable entity, or notice by such entity of its intention to propose such a resolution being given;
- (c) the appointment of a receiver, or receiver and manager, for all of FemPharm's property in bankruptcy or the rejection of this Agreement by any such receiver or manager;
- (d) Vivus has provided sixty (60) days written notice that Vivus is terminating the Agreement for its convenience; or
- (e) if FemPharm (or any of its Affiliates) bring any action, suit, defense or counterclaim seeking to invalidate or have held unenforceable: (i) any claim in any Patent Controlled by Vivus or its Affiliate in substantially the same form that the claim is issued or pending on July 31, 2003 (an "Existing V Claim"); or (ii) any claim in a Patent Controlled by Vivus or its Affiliate filed after July 31, 2003 that is substantially the same as any such Existing V Claim and that is entitled to an effective filing date (e.g. as defined under 35 USC§.120) that is the filing date of such a Patent filed prior to the July 31, 2003.

Further, in lieu of proceeding under Section 14.3(a), 14.3(b), 14.3(c) or 14.3(e) based upon a particular event, Vivus shall have the right to avail itself of the provisions of Section 14.6 based upon the event, rather than terminating the Agreement in its entirety under Section 14.3(a), 14.3(b), 14.3(c), or 14.3(e), provided that proceeding under Section 14.6 based upon an event shall not prevent Vivus from proceeding under Section 14.3 with respect to any later event covered by Section 14.3.

14.4 NO RELEASE

Termination of this Agreement does not release either Party from any liability that has accrued prior to such termination, or release either Party from any obligation that survives termination of this Agreement.

14.5 CONSEQUENCES OF AGREEMENT TERMINATION

- (a) The terms of this Section 14.5(a) shall apply upon termination pursuant to Section 14.2 or Section 14.3(d), except if Vivus has previously exercised its rights, under Section 14.3(a) or 14.6 to terminate portions of this Agreement pursuant to Section 14.6 due to uncured material breach.
 - (i) Section 2.1 of this Agreement shall automatically terminate, and Section 2.3 shall survive, except rights under Section 2.3(b) shall survive to the extent set forth below.
 - (ii) Upon such termination, Vivus will be deemed automatically to grant to FemPharm a perpetual, irrevocable, royalty-free, fully paid, non-exclusive license (with full rights to sublicense): (A) under the Improvement Blocking Patent Rights to exploit, import, make, have made, use, offer for sale and sell Products in the Field throughout the Territory; and (B) under the Reversion IP to exploit, import, make, have made, use, offer for sale and sell Products in the Field in the Territory. As used herein, "Reversion IP" means all trade secrets in the Improvements to the extent Controlled by Vivus or its Controlled Affiliate during the term and necessary or reasonably useful for the development, manufacture or commercialization of Products in the Field. Additionally, FemPharm shall have the right under Section 2.3(b) to negotiate toward a non-exclusive license under the Reversion IP for countries outside of the Territory, New Zealand, and Australia, provided that such license shall be royalty free if this Agreement has been terminated by FemPharm under Section 14.2(a) for Vivus' material breach.

- (iii) Upon such termination, Vivus will be deemed automatically to grant to FemPharm the non-exclusive right to access, use and cross reference all Regulatory Materials, including all registrations and regulatory approvals, filed by Vivus with, or obtained by Vivus from, the FDA in the development of Products in the Field and Territory; provided that all access, use or cross reference by and under authority of FemPharm shall be solely for the purpose of development and commercialization of Products in the Field in the Territory. Additionally, the Parties agree that FemPharm's right to negotiate under Section 2.3(b) toward a license under the Reversion IP as set forth in Section 14.5(a)(ii) above includes the right to negotiate toward rights to access, use and cross-reference such Regulatory Materials for countries outside the Territory, New Zealand, and Australia. Notwithstanding anything to the contrary, except as expressly set forth in this Section 14.5(a), no right, license, or exclusivity to or under any Intellectual Property is or shall be granted by Vivus or its Affiliates and Vivus and its Affiliates shall maintain all right, title, and interest in and to all Intellectual Property and Know-How. Without limiting the foregoing, no right or license is or shall be granted by Vivus or its Affiliates in or to any trademarks, trade names, logos, or the like.
- (iv) To the extent not previously disclosed by Vivus, Vivus will use reasonable efforts for a period of 90 days after termination of this Agreement to disclose and provide copies to FemPharm of all the Data (as defined in Section 5.18) generated by Vivus during the term of the Agreement that Section 5.18 requires Vivus to disclose and provide copies to FemPharm, and FemPharm (and its Affiliates and licensees) shall have full rights to use such Data for developing and exploiting Product in the Field to the extent that FemPharm is licensed to do so, and is licensed to authorize its Affiliates and sublicensees to do so, as set forth in Sections 14.5(a)(ii) and 14.5(a)(iii) above, and provided that such Data shall remain the Confidential Information of Vivus and its Affiliate and sublicensee, as the case may be.

- (v) To the extent provided for in any supply agreement between Vivus and FemPharm pursuant to Section 8.6 above, Vivus will continue to manufacture (or have manufactured) and supply to FemPharm the Product covered by such agreement for use in the Field and Territory until FemPharm is able to obtain its own supply of its requirements of Products for use in the Field and Territory (provided that such period shall not exceed one (1) year) and will work cooperatively and reasonably with FemPharm to achieve a smooth transition of the manufacture of the Reverted Product to FemPham, and (if applicable) to assist FemPharm in seeking to obtain a manufacturing agreement with Vivus's contract manufacturer of the Reverted Product on commercially reasonable terms, provided that in each case such transition shall not impose an unreasonable burden on Vivus.
- (vi) Vivus shall, within thirty (30) days after termination, return to FemPharm all Confidential Information delivered or provided by FemPharm to Vivus; provided that Vivus shall be entitled to keep a record copy of such Confidential Information and shall not be required to return any product. Article 10 shall survive termination (excluding the obligation to issue a press release under Section 10.13), but only for a period of five (5) years. Notwithstanding termination of Vivus' rights, Vivus and its Affiliates and sublicensees shall have the right to continue to market, sell, offer to sell, and import any Product, in existence at the time of termination, in the Territory for six (6) months after termination PROVIDED THAT the terms of Article 4 will survive and remain in force as to all such sales.
- (vii) In the event an action under Section 12.4 was commenced during the term of the Agreement and is ongoing at the time of termination, Section 12.4 shall continue to apply to the action in accordance with its terms, except that the Party bringing the action for purposes of allocating any recovery under Section 12.4(d) shall be deemed to be the Party controlling the action at the time of termination. If FemPharm assumes control of an action initiated by Vivus, then

Section 12.4(c)(ii) shall apply as if FemPharm is the Party bringing the action and all costs and expenses incurred by Vivus in the action prior to the date of termination shall be reimbursed out of any recovery before allocation under Section 12.4(d).

(viii) Section 14.5(c) shall apply.

- (b) Upon termination of this Agreement pursuant to Section 14.3 (other than 14.3(d)), or upon any termination (but not expiration) of this Agreement after Vivus had previously exercised its rights, under Section 14.3(a) or 14.6, to terminate portions of this Agreement pursuant to Section 14.6 due to uncured material breach, the terms of this Section 14.5(b) shall apply.
- (i) Section 2.1 of this Agreement shall automatically terminate. Notwithstanding termination of Vivus' rights, Vivus and its Affiliates and sublicensees shall have the right to continue to market, sell, offer to sell, and import any Product, in existence at the time of termination, in the Territory for six (6) months after termination PROVIDED THAT the terms of Article 4 will survive and remain in force as to all such sales.
- (ii) Section 2.3(b) shall automatically terminate.
- (iii) Article 10 (excluding the obligation to issue a press release under Section 10.13) shall survive such termination, but only for a period of five (5) years.
- (iv) Each Party shall, within thirty (30) days after termination, return to the other Party all Confidential Information delivered or provided by such other Party, except that it may keep one copy of such information purely for archival purposes and Vivus shall not be required to return Product.
- (v) In the event an action under Section 12.4 was commenced during the term of the Agreement and is ongoing at the time of termination, Section 12.4 shall continue to apply to the action in accordance with its terms, except that Vivus shall be considered the Party bringing the

action for purposes of allocating any recovery under Section 12.4(d). If FemPharm assumes control of an action initiated by Vivus, then Section 12.4(c)(ii) shall apply as if FemPharm is the Party bringing the action and all costs and expenses incurred by Vivus in the action prior to the date of termination shall be reimbursed out of any recovery before allocation under Section 12.4(d). For clarity, Vivus shall have the right to continue to pursue any such action commenced by Vivus to the extent desired.

(vi) Section 14.5(c) shall apply.

- (c) In addition to survival as set forth in Sections 14.5(a) or 14.5(b) above, as applicable, Sections 1.1, 1.2, 4.9, 9.3, 11.1 (excluding Vivus' obligation to disclose Improvements), 11.2, 11.3, 12.2, 13.4, 13.5, 14.1, 14.4, and 14.5 will survive termination of the Agreement for any reason and expiration of this Agreement, except termination under Section 14.8. Article 15 shall survive any such termination and expiration of this Agreement. Except as otherwise expressly set forth in this Section 14.5 above or 14.8, all terms and conditions of this Agreement shall terminate and have no further force or effect upon any termination or expiration of this Agreement, even if termination of the particular Article or Section is not expressly referenced in this Section 14.5 or 14.8. For clarity, the Development Plan shall be deemed terminated and of no further force or effect upon any termination or expiration of this Agreement. Notwithstanding anything to the contrary, no payment shall be due or payable under Section 3 or 6.2 unless the payment became due and payable prior to the date on which the notice of termination was given.

14.6 VIVUS TERMINATION OF SPECIFIC PROVISIONS FOR UNCURED BREACH

If there occurs a material breach by FemPharm of any of the terms and conditions under this Agreement, and such breach is not fully cured or rectified within ninety (90) days after the giving of written notice by Vivus to FemPharm specifying such breach or non-observance and requiring rectification thereof, then, subject to Section 15.10, Vivus may, as described in Section 14.3, (in lieu of proceeding under Section 14.3(a)), cause the following changes to occur under the Agreement:

- (a) The following Sections of the Agreement shall automatically terminate: 2.3(b), 2.6(b), 5.1, 5.3, 5.6, 5.7, 5.8, 5.9, 5.10, 5.11, 5.12, 5.13, 5.14, 5.15, 5.16 (but only to the extent desired by Vivus), 5.18, 5.21, 7.1(b), 7.2 (except the first two sentences), 8.2(b), 8.2(1), 8.2(2), 8.2(3), 8.3, 8.5, 14.2(d), and 14.5(a). For clarity, all obligations of Vivus to pay reimbursement shall terminate immediately. Vivus shall be entitled to withhold consent to development in the Territory under Section 2.1(c) for any reason or no reason..
- (b) Section 8.6 shall terminate, except for the restrictions on Product purchased from Vivus. The obligation to issue a press release under Section 10.13, and the obligation of Vivus to disclose Improvements under Section 11.1, shall terminate except to the extent otherwise reasonably specified by Vivus. Notwithstanding anything to the contrary, each of FemPharm and the Acrux Controlled Affiliates shall, within thirty (30) days of Vivus' request return to Vivus all Confidential Information delivered or provided by Vivus, except that FemPharm may keep one copy of such information purely for archival purposes.
- (c) Notwithstanding this Section 14.6, Articles 3 and 4 shall survive and remain in force. Section 12.4 shall continue to apply in accordance with its terms, except that if FemPharm assumes control of an action initiated by Vivus, then Section 12.4(c)(ii) shall apply as if FemPharm is the Party bringing the action and all costs and expenses incurred by Vivus in the action prior to the date of Vivus relinquishing control shall be reimbursed out of any recovery before allocation under Section 12.4(d). Section 7.1 shall terminate except for the first and last sentences of Section 7.1(a) which shall survive. FemPharm and the Acrux Controlled Affiliates shall cooperate in any reasonable manner requested by Vivus to achieve a smooth transition to Vivus of any and all Development Plan responsibilities of FemPharm.
- (d) If Vivus elects to exercise its rights under this Section 14.6 due to an uncured material breach by FemPharm of its obligations under Section 2.5(b), then Section 2.5(a) shall be deemed to terminate unless Vivus achieves an injunction that enjoins FemPharm from further violations of the terms of Section 2.5(b).

14.7 LIMITATION OF TERMINATION FOR BREACH AFTER COMMERCIAL LAUNCH

Commencing upon the First Commercial Sale of a Product in the Territory, but subject to Section 15.10, FemPharm shall have the right to terminate the Agreement under Section 14.2(a) only for the following uncured material breaches by Vivus:

- (a) Material breach of the obligations in Section 8.2(a) or 8.2(c);
- (b) Breach of the payment obligations under the Agreement, which breach remains uncured one hundred twenty days after notice.

If Vivus materially breaches any other obligation under the Agreement, and such breach would permit termination of the Agreement under Section 14.2(a) but for this Section 14.7, and such breach is not fully cured or rectified within ninety (90) days after the giving of written notice by FemPharm to Vivus specifying such breach or non-observance and requiring rectification thereof, provided that if such breach (other than a payment breach) is not capable of cure within the initial ninety (90) day period and Vivus is making diligent good faith efforts to cure, then Vivus shall have an additional ninety (90) days to cure such breach, then (subject to Section 15.10) FemPharm shall have the right to cause the following changes to the Agreement on written notice to Vivus (but not to terminate the Agreement in its entirety):

- (i) The following Sections of the Agreement shall automatically terminate: 2.4, 2.7, 5.2, 5.18, and 5.19.
- (ii) The penultimate sentence of Section 7.1(a) shall terminate. The obligations of FemPharm in the penultimate sentence of Section 7.2 shall terminate, and only the rights of FemPharm under such sentence shall survive.
- (iii) If FemPharm elects to exercise its rights under this Section 14.7 due to an uncured material breach by Vivus of its obligations under Section 2.5(a), then Section 2.5(b) shall be deemed to terminate unless FemPharm achieves an injunction that enjoins Vivus from further violations of the terms of Section 2.5(a).

14.8 TERMINATION FOR FAILURE TO ACHIEVE (*)

Vivus has the right to terminate this Agreement by providing written notice thereof to FemPharm within thirty (30) days after the occurrence of the following: Acrux DDS Pty Limited. has not (*) within (*) after the Effective Date that (*). If Vivus terminates the Agreement under this Section 14.8, then:

- (a) FemPharm shall (*), and (*) Additionally, FemPharm and Acrux Limited shall promptly (*) of this Section 14.8.
- (b) In the event of termination under this Section 14.8, all terms and conditions of this Agreement shall terminate and have no further force or effect except that this Section 14.8 and Articles and Sections 9.3, 10 (but only for five (5) years after termination and excluding the obligation to issue a press release under Section 10.13), 11.2, 11.3, 12.2, 13.4, 13.5, 14.4, 14.9, and 15 shall survive. For clarity, all of Vivus' payment obligations, including obligations to reimburse FemPharm, shall terminate and have no further force or effect immediately upon Vivus' notice. The Development Plan shall be deemed terminated and of no further force or effect.

14.9 REMEDIES

Termination of this Agreement as provided in Sections 5.19(b), 14.2, 14.3, and 14.8, and termination of certain provisions of this Agreement as provided in Section 14.6 and 14.7, is a cumulative remedy, and each Party will be entitled to seek any other rights or remedies available to it at law or in equity for any breach or non-observance of this Agreement.

15. GENERAL

15.1 NOTICES

Any notice given pursuant to this Agreement must be in writing and may be given by pre-paid express courier addressed to the other Party at the address specified in this Agreement or as subsequently notified in writing, or by hand delivery or facsimile or electronic transmission to the same address and any such notice is deemed to have been received:

- (a) if served by express courier on the date signed for;
- (b) if served by hand delivery, on the date delivered by hand;
- (c) if sent by facsimile transmission, when the transmitting machine produces a written report that the notice has been effectively sent to the other party, if the sender confirms such notice by express courier or hand delivery;
- (d) if sent by electronic transmission, when the transmitting computer produces a written report that the notice has been effectively sent to the other party, if the sender confirms such notice by express courier or hand delivery;

If a notice is deemed under clause (c) or (d) to have been received on a day which is not a Business Day, it is deemed to have been received on the next Business Day.

The address for service of any notice is:

To FemPharm

FemPharm Pty Ltd
103-113 Stanley Street
West Melbourne Victoria 3003
Australia
Facsimile:
Email:

with a copy to:

Mr. P G Willcocks
Lander & Rogers, Lawyers
Level 12, 600 Bourke Street
Melbourne Victoria 3000
Australia
Facsimile:
Email:

To Vivus

with a copy to:

Facsimile:
Email:

15.2 INDEMNIFICATION

- (a) Vivus is responsible for, and will indemnify, hold harmless and defend FemPharm, its Affiliates and their respective officers, directors, employees and agents against any and all claims, damages, losses, costs, expenses (including reasonable attorneys' and professional fees and other expenses of litigation), and liabilities, resulting from any third party claims, actions, suits, or allegations ("Claims") to the extent the Claim results from or arises out of: (a) the negligence, recklessness, or willful misconduct of Vivus, its Controlled Affiliates, or its sub-licensees, or their respective officers, directors, employees, or agents; (b) Vivus's breach of its obligations, representations or warranties under this Agreement; or (c) the development, manufacture, promotion, use or sale of any Product by Vivus, its Affiliate, or its sub-licensee, or by any of their respective customers or end-users.

Notwithstanding the foregoing, Vivus's obligations under this Section 15.2 will not apply to any Claim, to the extent that such Claim arises out of or results from (i) the development, manufacture, use, promotion, and/or sale of any product or technology (including Product) by FemPharm or its Affiliate or licensee (other than Vivus, but including Product sold by Vivus under any supply agreement with FemPharm or any Acrux Controlled Affiliate), or any of their respective customers or end-users; (ii) FemPharm's or an Acrux Controlled Affiliate's breach of its obligations, representations, or warranties under this Agreement; or (iii) the negligence, recklessness, or willful misconduct of FemPharm, its Affiliates, or licensees (other than Vivus) or their respective officers, directors, employees, or agents; or (iv) claims of any participant in the Phase IIb Study or any other Clinical Trials performed by or under authority of FemPharm or an Acrux Controlled Affiliate.

- (b) FemPharm and Acrux Limited shall be responsible for, and will indemnify, hold harmless and defend Vivus, its Affiliates and their respective officers, directors, employees and agents against any and all claims, damages, losses, costs, expenses (including reasonable attorneys' and professional fees and other expenses of litigation), and liabilities, resulting from any third party claims, actions, suits, or allegations ("Claims") resulting from or arising out of: (i) the development, manufacture, use, promotion, and/or sale of any product (including Product) by FemPharm or an Acrux Controlled Affiliate or their licensees (other than Vivus, but including Product sold by Vivus under any supply agreement with FemPharm or any Acrux Controlled Affiliate and including liability to patients in connection with any Clinical Trials by FemPharm), or any of FemPharm's or an Acrux Controlled Affiliate's or FemPharm licensee's respective customers or end-users; (ii) FemPharm's or an Acrux Controlled Affiliate's breach of its obligations, representations, or warranties under this Agreement; or (iii) the negligence, recklessness, or willful misconduct of FemPharm, an Acrux Controlled Affiliate, or licensees (other than Vivus) or their respective officers, directors, employees, or agents. Notwithstanding the foregoing, FemPharm's and Acrux Limited's obligations under this Section 15.2 will not apply to any Claim, to the extent that such Claim is the subject of an indemnification obligation under Section 15.2(a) above.

- (c) A Party that intends to claim indemnification under this Section 15 (the "Indemnitee") shall promptly notify the other Party (the "Indemnitor") in writing of any Claim, in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have sole control of the defense and/or settlement thereof. The indemnity arrangement in this Section 15 shall not apply to amounts paid in settlement of any action with respect to a 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 action with respect to a Claim, if prejudicial to its ability to defend such action, shall relieve such Indemnitor of any liability to the Indemnitee under this Section 15 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 otherwise than under this Section 15. The Indemnitee under this Section 15, shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action with respect to a Claim covered by this indemnification, at the Indemnitor's expense. Notwithstanding the foregoing, the Indemnitor shall not be responsible for any costs or expenses incurred by the Indemnitee or its Affiliate, or the directors, officers, employees, successors or assigns of the Indemnitee or its Affiliate, without the prior written consent of the Indemnitor, not to be unreasonably withheld.

15.3 DAMAGES FOR BREACH OF REPRESENTATIONS AND WARRANTIES

Notwithstanding anything to the contrary, a breach of warranty under this Agreement shall have the same effect as a breach of a covenant, and each Party shall be entitled to recover for a breach of a warranty by the other Party the same contractual damages as if such other Party had breached a covenant, subject to Section 13.5.

15.4 WAIVER

A waiver by any Party of any breach or a failure to enforce or to insist upon the observance of a condition of this Agreement will not be a waiver of any other or of any subsequent breach. No waiver under this Agreement is binding unless in writing and signed by the Party giving the waiver.

15.5 SEVERANCE

If any part of this Agreement is held to be invalid, unenforceable, illegal, void or voidable for any reason, this Agreement will be construed and be binding on the Parties to the maximum extent possible, as if the invalid, unenforceable, illegal, void or voidable part had been deleted from this Agreement or read down to the extent necessary to overcome the difficulty.

15.6 SUCCESSORS AND ASSIGNS

This Agreement is binding on and continues for the benefit of each Party, its successors and permitted assigns.

15.7 CONTINUING OBLIGATIONS

The expiration or termination of this Agreement does not operate to terminate any of the surviving obligations under this Agreement, which will remain in full force and effect and binding on the Party concerned.

15.8 VARIATION

No variation, modification or amendment of this Agreement is binding on the Parties unless in writing and signed by both Parties.

15.9 APPLICABLE LAW

This Agreement, and all disputes under Section 15.10, shall be governed by and construed in accordance with the laws of California, USA, and the Parties submit themselves to the non-exclusive jurisdiction of the courts having San Francisco within their jurisdiction.

15.10 DISPUTE RESOLUTION

If any claim, controversy, difference or dispute between the Parties arises at any time under this Agreement, including as to its existence, validity, interpretation, effect, breach or termination, (a "Dispute"), then either Party may give the other a written notice of Dispute reasonably identifying and providing a description of the Dispute. Notwithstanding the existence of a Dispute, the Parties must continue to perform this Agreement, unless the Agreement is terminated in accordance with its terms. If there is a Dispute, however, regarding whether or not a breach of this Agreement has occurred, then notice of such a Dispute will toll the cure period, and the Agreement will remain in effect until the Dispute is resolved. If such a Dispute is finally resolved in favour of the Party giving notice of breach, then the Agreement will terminate sixty (60) days after the final determination is made unless the other Party cures the breach within such sixty (60) day period. If a Party gives written notice of a Dispute, then senior executive officers from both Parties will meet promptly thereafter and negotiate in good faith to resolve the Dispute as quickly and cost effectively as possible. If the Parties have not resolved the Dispute within sixty (60) days of the date of the written notice of the Dispute, then either Party may, by written notice to the other Party, submit such Dispute to final and binding arbitration under the then current Comprehensive Arbitration Rules and Procedures of the Judicial Arbitration and Mediation Services ("JAMS"), except as such rules may be modified in this agreement ("Rules"). The Parties agree that any such Dispute will be settled by three (3) arbitrators which are appointed within 90 days of service by one Party of a request for arbitration on the other Party. Each Party will select one arbitrator, and the third arbitrator will be appointed by JAMS, as provided in the Rules. The arbitration proceedings will take place, and the arbitrators' award will be rendered, in Honolulu, Hawaii or such other location as may be agreed in writing by the Parties. The decision of the arbitrators will be final and binding on the Parties. The arbitrators will prepare and deliver to the Parties a written, reasoned opinion conferring their decision. Judgment on the award so rendered may be entered in any court having competent jurisdiction thereover. Each Party may, without breach of this Section 15.10 or waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or

property of that Party pending the arbitration award. Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrators' and any administrative fees of arbitration. The Parties further agree that any payments made pursuant to this Agreement pending resolution of the dispute shall be refunded if an arbitrator or court determines that such payments are not due.

15.11 DISPUTE REGARDING LICENSE NECESSITY.

If FemPharm disputes, under Section 4.3, that a particular patent license is "necessary" as defined in that Section, then the Parties shall resolve such dispute by submitting such dispute for resolution to a mutually agreed independent patent attorney with substantial experience regarding the scope, validity and enforceability of patents covering subject matters similar to the third party patent in question (the "Neutral"). If the Parties cannot agree on a Neutral within thirty (30) days of the request of either Party, then the Neutral shall be selected by the Chairman of the Intellectual Property section of the American Bar Association. The Neutral shall not have any current interest in or current or prior involvement with either Party, unless the Parties agree otherwise. Within 10 days following the identification of the Neutral, each Party shall submit to the Neutral in writing its statement of the issue in dispute; and the basis for its position that the patent license that is the subject of the dispute is, or is not, (as applicable) "necessary" as defined in Section 4.3. No ex-parte communication with the Neutral shall be allowed without the consent of the other Party. The Neutral may follow such procedures as he or she desires, provided that the Neutral shall decide the issue in favor of one Party within thirty (30) days of submission of the statements. If the Neutral determines that the subject patent license is "necessary", then Vivus shall be entitled to credit royalties as provided in Section 4.3, and otherwise no credit shall be permitted (except as may otherwise be agreed by the Parties in writing). The Parties shall equally share the costs associated with the Neutral's activities under this Section 15.11. Each Party shall cooperate to allow the Neutral to complete his/her obligations under this Section. If Vivus has in fact taken a license for the Product, the license shall be considered necessary unless otherwise established in such proceeding.

15.12 COUNTERPARTS

This Agreement may be signed in any number of counterparts and all such counterparts taken together are deemed to constitute one and the same document.

15.13 COSTS

Each Party must pay their own legal, accounting and other costs in relation to the negotiation, preparation, execution and implementation of this Agreement.

15.14 PAYMENT

All payments to be made under this Agreement must be paid by electronic transfer to the bank account nominated in writing by the Party to whom the payment is to be made and received into that account in cleared funds on the date the payment is due.

15.15 ENTIRE AGREEMENT

This Agreement, and the Guaranty Agreement, constitutes the entire agreement and basis of the transaction between the Parties in relation to its subject matter and supersedes all other prior and contemporaneous communications, negotiations, arrangements and agreements between FemPharm and Vivus whether oral or in writing, except that confidential information disclosed by a Party pursuant to the non disclosure agreement between FemPharm and Vivus prior to the Effective Date shall be treated as Confidential Information of the disclosing Party to the extent set forth in this Agreement, and the Estradiol Agreement shall remain in full force and effect.

15.16 INJUNCTIVE RELIEF

Each Party acknowledges that monetary damages alone may not be adequate compensation for a breach of this Agreement by the other Party, including breach of Article 10. Each Party is entitled to seek injunctive relief from a court of competent jurisdiction as a remedy for any breach or threatened breach of this Agreement, in addition to any other remedies available at law or in equity under or independently of this Agreement, each to the extent available in accordance with applicable law.

15.17 INDEPENDENT CONTRACTORS

The relationship of the Parties hereto is that of independent contractors. The Parties hereto shall not be deemed to be agents, partners or joint venturers of the others for any purpose as a result of this Agreement or the transactions contemplated thereby, and neither Party shall have the authority to agree to any obligation or commitment for the other.

15.18 FORCE MAJEURE

Neither Party shall lose any rights hereunder, be considered in breach of this Agreement, or be liable to the other Party for damages or losses on account of its failure to perform if the failure is occasioned by war, strike, fire, act of God, earthquake, flood, lockout, embargo, failure of suppliers, power failures, or any other reason where failure to perform is beyond the reasonable control of the non-performing Party (a "Force Majeure"), provided that after the Force Majeure occurs, the non-performing Party uses reasonable efforts to avoid the effects of such Force Majeure, and to perform its obligations, each to the extent reasonably practicable (it being agreed that in no event shall a Party be required to settle any labor dispute or disturbance).

15.19 BANKRUPTCY

All rights and licenses granted under or pursuant to this Agreement by each Party as a licensor are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11, U.S. Code (the "Bankruptcy Code"), licenses of rights to "intellectual property" as defined under section 101(35A) of the Bankruptcy Code. The Parties agree that each licensee of such rights under this Agreement, shall retain and may fully exercise all rights and elections it would have in the case of a licensor bankruptcy under the Bankruptcy Code. Each Party agrees during the term of this Agreement to create or maintain current copies, or if not amenable to copying, detailed descriptions or other appropriate embodiments, of all such intellectual property licensed to the other Party.

15.20 ACRUX DDS AS A PARTY

Acrux DDS Pty Limited agrees to be fully and independently bound by the Sections to which it is expressly a party under this Agreement, and including also the provisions of Article 14 (it being understood that only Vivus or FemPharm may terminate this Agreement in accordance with its terms). Notwithstanding the foregoing, Acrux DDS Pty Limited acknowledges that Vivus shall have no independent obligations to Acrux DDS Pty Limited under this Agreement, and all of Vivus' obligations under this Agreement and this Section 15.20 shall be satisfied upon Vivus' performance or tender of performance to FemPharm. In addition, any notice given to or from FemPharm and FemPharm's consent, approval, agreement, actions or inactions shall be deemed notices to and from, and the consent, approval, or agreement of, or actions or inactions authorized by Acrux DDS Pty Limited. Acrux DDS Pty Limited agrees to be likewise bound by any and all amendments to this Agreement, which amendments shall not require Acrux DDS Pty Limited's approval. It is understood and agreed that Acrux DDS Pty Limited may look only to FemPharm for any share of or benefit from Vivus' performance or undertakings under this Agreement, and Vivus shall have no responsibilities to Acrux DDS Pty Limited in that regard.

15.21 SURVIVAL OF SUBLICENSES

If FemPharm terminates the Agreement, then any existing sublicense agreement with a non-Affiliate granted by Vivus hereunder shall remain in force provided that such sublicensee agrees in writing to be bound by and perform to the same extent as required of Vivus under this Agreement. For clarity, it is understood that the foregoing shall not have the effect of expanding or increasing the rights of the sublicensee beyond the rights granted to it under the sublicense agreement.

EXECUTION

EXECUTED by FEMPHARM PTY
LTD by being signed by:

)
)
)
)
)
)

/s/ Igor Gonda

/s/ Igor Gonda

Signature of director/secretary

Signature of director

Igor Gonda

Name of director/secretary (please print)

Igor Gonda

Name of director (please print)

EXECUTED by VIVUS INC. by being
signed by:

)
)
)
)
)
)

/s/ Leland Wilson

Signature

Leland Wilson, President & CEO

Name and Title

EXECUTED by ACRUX DDS PTY
LTD by being signed by:

)
)
)
)
)
)

/s/ Igor Gonda

Signature of director/secretary

/s/ Igor Gonda

Signature of director

Igor Gonda

Name of director/secretary (please print)

Igor Gonda

Name of director (please print)

ANNEXURE A
DEVELOPMENT PLAN

ANNEXURE B

FEMPHARM PATENTS AND PATENT APPLICATIONS

PATENTS GRANTED	COUNTRY	PATENT NO.	APPLIC. NO.	DATE OF ISSUE	DATE OF FILING	EXPIRATION DATE
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(**)

ANNEXURE C

METERED DOSE TRANSDERMAL SPRAY SYSTEM

(**)

ANNEXURE D
FORM OF PRESS RELEASE

ANNEXURE E

ANDROGENS

(**)

ANNEXURE F
EXCLUDED INDICATIONS
(**)

DATE: FEBRUARY 12, 2004

FEMPHARM PTY LTD

and

VIVUS INC.

and

ACRUX DDS PTY LTD

ESTRADIOL
DEVELOPMENT AND
COMMERCIALIZATION AGREEMENT

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THIS DEVELOPMENT AND COMMERCIALIZATION AGREEMENT (the "Agreement") is dated and effective as of February 12, 2004 (the "Effective Date").

PARTIES:

FEMPHARM PTY LTD (ABN 35 088 778 018) of 103-113 Stanley Street, West Melbourne, Victoria, Australia ("FemPharm")

and

VIVUS INC. of 1172 Castro Street, Mountain View, California, United States of America ("Vivus")

and

ACRUX DDS PTY LTD

RECITALS

- A. FemPharm, formerly known as Female HRT Pty Ltd., Australian Company Number 088 778 018, is a wholly owned subsidiary of Acrux Limited of 103-113 Stanley Street, West Melbourne, Victoria, Australia ("Acrux Limited"). Acrux DDS Pty Limited ("Acrux DDS Pty Limited"), formerly known as Drug Delivery Solutions Pty Ltd., Australian company number 088 778 009, is also a wholly owned subsidiary of Acrux Limited.
- B. Acrux DDS Pty Limited holds an exclusive global license from Monash University of Wellington Road, Clayton, Victoria, Australia ("Monash") in respect of certain patents and patent applications owned by Monash University covering the metered dose transdermal system described therein.
- C. FemPharm holds an exclusive sublicense from Acrux DDS Pty Limited in respect of the intellectual property described in the license referred to in recital B for the fields of female hormone replacement therapy and human female contraception.

- D. FemPharm and Vivus wish to enter into this agreement pursuant to which FemPharm will exclusively license metered dose transdermal systems to Vivus for the delivery of estradiol monotherapy to human females on the terms set out in this Agreement.

AGREEMENT

1. DEFINITIONS AND INTERPRETATION

1.1 DEFINITIONS

In this Agreement, the following capitalized terms have the following meanings:

"Acrux DDS License" shall mean the "Licence Agreement" between Female HRT Party Limited (now known as FemPharm) and Drug Delivery Solutions Party Limited (now known as Acrux DDS Pty Limited), dated November 30, 1999, as amended by the Deed of Amendment between Female HRT Party Limited and Drug Delivery Solutions Party Limited dated June 30, 2000, and as such agreement may be subsequently amended by the parties thereto.

"Acrux Penetration Enhancer" shall mean one of the following, whichever is used in the Product being developed or commercialized by or under authority of Vivus under this Agreement, as used in such Product (i) (**), (ii) a different dermal penetration enhancer which is disclosed in the FemPharm Patents, or (iii) the combination of (**) with another dermal penetration enhancer(s) disclosed in the FemPharm Patents.

"Additional Partner" shall mean each third party who is granted by FemPharm or an Acrux Controlled Affiliate, directly or indirectly, a right to market or commercialize a Product in the Field in any part of the world, other than the Territory.

"Affiliate" means, with respect to any Party, any corporation or other legal entity that controls, is controlled by or is in common control with such Party. For purposes of this definition, the term "controls" means (with correlative meanings for the terms "controlled by" and "in common control with"):

- (a) ownership, directly or indirectly, of more than 50% of the voting securities of the applicable party; or
- (b) possession of actual power to direct unilaterally the business and affairs of the applicable party, whether through contract, ownership rights or otherwise.

"Business Day" means a day upon which banks are open for general banking business in the United States other than a Saturday or Sunday.

"Clinical Trial" shall mean a clinical trial involving the administration of a therapeutic to a human subject after filing an IND, or the equivalent (if necessary) outside the United States, for the purpose of evaluating the safety, efficacy, performance or other characteristic of such therapeutic, including a phase I, phase II and/or phase III trial.

"Committee" means the Development Committee and/or the Steering Committee.

"Confidential Information" of a Party means all information disclosed by such Party to the other pursuant to this Agreement, which may include any of the following to the extent disclosed by such Party:

- (a) Intellectual Property, technical information, specifications, data, software, marketing procedures, pricing information, customer and client records, business and corporate or trade information of a Party relating to or arising out of the Licensed Intellectual Property or its use or application;
- (b) information relating directly or indirectly to the Product including, without limitation, the identity and composition of compounds for producing or manufacturing the Product, formulae for the Product, methods of producing or manufacturing the Product, costs of manufacturing the Product, information relating to the packaging, selling and marketing of the Product including the cost thereof and pricing information; and
- (c) communications between the Parties or information of whatever kind whether recorded or not and, if recorded, in whatever medium, relating to the Licensed Intellectual Property, the Product, this Agreement, or otherwise, whether disclosed prior to or after the Effective Date.

"Commercial Launch Plan" means the plan for launching and initial marketing and promotion of the Product in the Territory as provided in Section 8.3.

"Controlled" means, with respect to any Intellectual Property, that the applicable Party owns or has a license to such Intellectual Property, and has the authority to grant to the other Party access, a license, or a sublicense to such Intellectual Property as provided for in this Agreement without violating an agreement with a non-Affiliate third party in effect at the time such Intellectual Property was first acquired or created by the Party granting or authorizing the license or sublicense herein.

"Controlled Affiliate" means (i) in the case of Vivus; an Affiliate that is controlled by Vivus; and (ii) in the case of FemPharm; Acrux Limited, Acrux DDS Pty Limited or an Affiliate that is controlled by FemPharm, controlled by Acrux DDS Pty Limited, or controlled by Acrux Limited (each of such Affiliates, Acrux DDS Pty Limited and Acrux Limited, an "Acrux Controlled Affiliate"); in each case as "control" is defined in the Affiliate definition in this Section 1.1 above.

"Development Committee" means the committee referred to in Section 5.4.

"Development Plan" means the plan appended to this Agreement as annexure A in accordance with Section 5.5, as such plan may be amended pursuant to Section 5.

"Effective Date" means the date of this Agreement, as set forth on page one.

"Estradiol" means the compound with the chemical structure shown in Annexure E to this Agreement.

"Estrogen" means (a) any of the naturally occurring estrogens, progestins with estrogenic activity that are used for estrogen replacement therapy for the treatment of menopausal symptoms, or any derivative of such estrogens or progestins, including the estrogens that are approved by the FDA in any form (oral, transdermal, or injectable) for hormone

replacement therapy or the treatment of menopausal symptoms in human females, or (b) any SERM. Notwithstanding sub-paragraph (b) of this paragraph, if Vivus or any Controlled Affiliate of Vivus, or a sublicensee of Vivus that has rights under the Licensed Intellectual Property to market, sell, offer to sell, and import the Products in the Field in the Territory, commences Clinical Trials, or marketing or sales, in the Territory of any product that orally delivers a SERM to treat female menopausal symptoms, then except for SERMs that have been added to the Field, no SERM shall be considered to be an Estrogen for purposes of Section 2.5. For clarity, Androgen (as such term is defined in the Testosterone Agreement, but excluding tibolone), is not or shall not be deemed to be an Estrogen for purposes of this Agreement.

"Excluded Applications" shall have the meaning set forth in annexure F.

"FemPharm Patents" means: (a) the Patents set out in annexure B, which shall include all existing Patents licensed under the Monash License or the Acrux DDS License, (b) all continuing patent applications in the Territory based on any Patent in clause (a) above (including any divisionals, continuations, and continuations-in-part); (c) all Patents that issue based on any Patent in clause (a) or (b) above, and including all re-issues, extensions, substitutions, confirmations, re-registrations, re-validations, patents of addition, and supplementary certificates (or equivalents thereof) of any such Patent; and (d) all additional Patents in the Territory that are Controlled by FemPharm, Acrux DDS Pty Limited, an Acrux Controlled Affiliate, or any other Affiliate of FemPharm at any time during the term of this Agreement and that claim or cover an MDTS product, or any portion thereof, or the manufacture or use of an MDTS product or portion thereof, in the Field. For purposes of this definition, Patents that meet, at some time during the term of the Agreement, the requirement of subclause (d) above shall not be excluded from this definition simply because a particular Acrux Controlled Affiliate (that Controlled such Patent) no longer is an Affiliate of Acrux Ltd., and including continuing patent applications in the Territory based on such Patents in clause (d) above (including any divisionals, continuations, and continuations-in-part).

"Field" means delivery of Estradiol (and/or any other Estrogen that is added to the Field pursuant to Section 2.4 or included pursuant to Section 5.17) in Monotherapy to human females using an MDTs, excluding only the Excluded Applications.

"First Commercial Sale" means the first commercial sale or transfer of the Product for use in the Territory (other than for evaluation, research, testing or clinical trial purposes), that occurs after the Product has been approved for marketing in the Territory, by Vivus or Vivus' Affiliate or sublicensee to an independent non-Affiliate third party in exchange for cash or some equivalent to which value can be assigned.

"FDA" means the United States Food & Drug Administration.

"Intellectual Property" means all industrial and intellectual property rights, whether protectable by statute, at common law or in equity, including, without limitation, any rights of copyright, trade secrets, confidential information, know-how, trade mark, invention, Patent, circuit layout and any rights to registration of such rights, irrespective of whether such rights are created before, on or after the Effective Date.

"Improvement" means an Invention to the extent made by Vivus or its Affiliate in the course of developing or commercializing the Product under this Agreement, which Invention is an improvement of or modification to the Product itself, in the form provided by FemPharm, and is not substantially based upon or derived from other technology or Know-How of Vivus, its Affiliate, or their third party licensor or contractor.

"Improvement Blocking Patent Rights" means any Patent to the extent that it: (i) claims and is specifically directed to an Improvement, (ii) is Controlled by Vivus or its Affiliate at any time during the term of this Agreement, and (iii) is reasonably necessary to make, use, sell, or offer to sell an MDTs product. As used in this paragraph, "reasonably necessary" means there is no commercially reasonable alternative to practicing the subject matter in the applicable claim in such Patent, in order for FemPharm, or its Controlled Affiliate or licensee, to make, use or sell the MDTs products.

"Invention" means any information, idea, invention, know-how, data or results made pursuant to work conducted under this Agreement.

"Joint Patent" means a Patent claiming an Invention invented jointly by the Parties, as provided in Section 11.3.

"Know-How" shall mean all data, inventions (whether or not patentable), discoveries, methods, information (including Confidential Information), reports, analyses, documents, descriptions, procedures, formulae, formulations, expert opinions, knowledge, know-how, experience, marketing, and other information and materials (including physical samples), and the trade secret rights to the foregoing. As used herein, Know-How shall not include Patents.

"Licensed Intellectual Property" means the (i) FemPharm Patents, and (ii) the Licensed Know-How.

"Licensed Know-How" means the Know-How that is Controlled by FemPharm or any Acrux Controlled Affiliate and relates to or is useful for MDTS products in the Field.

"MDTS" means the Acrux metered dose transdermal spray system as described in Annexure C, and including all improvements, derivatives and modifications of such system developed by or under authority of FemPharm or its Affiliate. For clarity, it is understood that "improvements," as used under this paragraph, would include modified or improved versions of the Acrux metered dose transdermal spray system, and novel enhancers, formulations, methods, and mechanical components relating to or useful for the MDTS system, that are not used in the MDTS as of the Effective Date, but that would improve the safety, effectiveness, or other qualities of such a spray system for use in delivery of Estradiol, or any other Estrogen added to the Field pursuant to Section 2.4 or 5.17.

"Monash License" means the "Technology Agreement" between Monash and Acrux Limited, dated June 7, 1999, and transferred by Acrux Limited to Acrux DDS Pty Limited in the "Deed of Assignment" dated November 22, 1999, as amended by the Deed of Variation between Monash and Acrux Limited dated November 22, 1999 and the Deed of Variation between Monash and Acrux DDS Pty Limited., executed October, 2002.

"Monotherapy" means the delivery of Estradiol (or any other Estrogen added to the Field) using an MDTs, without delivering any other active ingredient using the MDTs. For clarity, delivery of Estradiol (or any other Estrogen added to the Field) using an MDTs, without delivering any other active ingredient using the MDTs, shall be considered Monotherapy notwithstanding any concurrent use or delivery of another active ingredient by a method other than spray delivery by the MDTs. For example, oral delivery of a progestin concurrently with delivery of Estradiol using the MDTs shall be considered Monotherapy.

"Net Sales" means any amounts invoiced by Vivus, or an Affiliate or sublicensee of Vivus, for the sale or other commercial disposition of the Product, less the following amounts to the extent actually accrued, taken or allowed with respect to such sale or disposition:

- (d) trade, cash or quantity discounts or rebates from the invoiced price;
- (e) refunds, credits, charge backs or allowances actually granted upon recalls, rejections, returns, or the like;
- (f) freight charges, insurance and packing charges paid for delivery; and
- (g) amounts actually written off for uncollectable accounts determined in accordance with GAAP, PROVIDED THAT if any such amounts are subsequently collected, such amounts would be included in Net Sales for the quarter collected;
- (h) taxes (other than income tax, but including value added and sales taxes), duties, or other governmental charges levied on or measured by the disposition or the invoiced amount, whether absorbed by the billing or the billed party.

Notwithstanding the foregoing, if Vivus sells Product for use outside the Field or outside the Territory pursuant to an authorization by FemPharm or an Acrux Controlled Affiliate

(such as sales to FemPharm for use in Australia or New Zealand) Net Sales shall not include any amounts invoiced on such sales, whether the sale is to FemPharm, an Acrux Controlled Affiliate, or any other Person (e.g. another licensee of FemPharm).

"Patents" means all rights under all patents (including all re-issues, extensions, substitutions, confirmations, re-registrations, re-validations, patents of addition, supplementary certificates, other governmental grants for the protection of inventions or industrial designs, or equivalents thereof) and under all patent applications (including any divisionals, continuations, continuations-in-part, continued prosecution applications, and divisionals).

"Party" means either of FemPharm or Vivus, and "Parties" means both of them.

"Person" includes a natural person, company, corporation, partnership, trust, estate, joint venture, sole proprietorship, government (including any branch or subdivision thereof), governmental or municipal agency, association, co-operative and any other entity or person whatsoever.

"Product" means any MDTs product containing Estradiol, or any other Estrogen included in the Field pursuant to Section 2.4 or as a result of Section 5.17, as the sole active ingredient in such product, and intended for use in the Field.

"Regulatory Materials" means regulatory applications, submissions, notifications, registrations, regulatory approvals and/or other filings made and correspondence to or with the FDA or other regulatory authority that are necessary or reasonably desirable in order to, or in connection with efforts to, develop, manufacture, market, sell or otherwise commercialize a Product in a particular country, territory or possession. Regulatory Materials include INDs, MAAs, and NDAs.

"Restricted Estrogens" means any of: (**).

"Royalty Period" means a period of three consecutive months ending on 31 March, 30 June, 30 September or 31 December, provided that the first Royalty Period will be the

period from the date of First Commercial Sale until the first to occur of 31 March, 30 June, 30 September or 31 December thereafter.

"SERM" means a generic compound (i.e., the composition of the compound is not covered by a patent in the Territory) that is a selective estrogen receptor modulator.

"Steering Committee" means the committee referred to in Section 5.7.

"Territory" means the United States of America, and its territories and protectorates.

"Testosterone Agreement" means the agreement titled "Testosterone Development and Commercialization Agreement" entered into by and between the Parties and dated as of February 7, 2004.

"Valid Claim" means: a claim in an issued Patent within the FemPharm Patents, which has not (i) expired or been cancelled, (ii) been declared invalid by an unreversed and unappealable decision of a court or other appropriate body of competent jurisdiction, (iii) been admitted to be invalid or unenforceable through reissue, disclaimer or otherwise, and/or (iv) been abandoned.

1.2 INTERPRETATION

In this Agreement:

- (a) words denoting the singular number include the plural and vice versa;
- (b) words denoting any gender include all genders;
- (c) words importing natural persons include corporations, firms, unincorporated associations, partnerships, trusts and any other entities or groups recognised by law;
- (d) reference to any legislation or to any provision of any legislation includes any amendment, modification, consolidation or re-enactment of, or any legislative

provision substituted for, and all legislative and statutory instruments issued under, such legislation or such provision;

- (e) the words "written" and "in writing" include any means of visible reproduction of words in a tangible and permanently visible form;
- (f) reference to Articles, Sections, clauses and schedules and annexures are references to the Articles, Sections, clauses and schedules and annexures of this Agreement, unless expressly stated to the contrary;
- (g) reference to any party to this Agreement or any other agreement or document includes the party's successors and permitted assigns;
- (h) where a word or phrase is defined, other grammatical forms of that word or phrase have corresponding meanings;
- (i) no rule of construction applies to the disadvantage of a party because that party was responsible for the preparation of this Agreement or any part of it;
- (j) the headings to Articles, Sections, annexures or schedules are for ease of reference only and do not form part of this Agreement or affect its interpretation;
- (k) if any day appointed or specified by this Agreement for the payment of any money or the doing of any act falls on a day which is not a Business Day, the day appointed or specified will be the next Business Day;
- (l) a reference to a time or date in connection with the performance of an obligation by a party is a reference to the time and date in San Francisco, California, USA even if the obligation is to be performed elsewhere;
- (m) the terms "including" and "includes" will be interpreted non-restrictively to mean "including without limitation ...".

2. LICENSE RIGHTS

2.1 LICENSE GRANT

- (a) Subject to the terms of this Agreement, FemPharm and Acrux DDS Pty Limited grant to Vivus the sole and exclusive (including with respect to FemPharm, except as otherwise provided in subsection (c) below) license, under the Licensed Intellectual Property, solely to exploit, import, export, make, have made, develop, use, market, offer for sale and sell Products for use in the Field in the Territory.
- (b) Subject to the terms of this Agreement, FemPharm and Acrux DDS Pty Limited grant to Vivus a non-exclusive license under the Intellectual Property that relates to or is useful for a Product, or its manufacture or use, and is Controlled by any of FemPharm, an Acrux Controlled Affiliate, or another Affiliate of FemPharm, to export, make, and have made Products outside the Territory solely for importation, sale, use and other exploitation in the Field in the Territory pursuant to Section 2.1(a). In addition, to the extent permitted by FemPharm on request by Vivus, such permission not to be unreasonably withheld, Vivus may include in the foregoing license the right to conduct specific development activities in particular countries outside the Territory, solely to develop data to be used in the Regulatory Materials in the Territory for the Product in the Field, and marketing of the Product in the Field in the Territory.
- (c) For clarity, FemPharm and Acrux DDS Pty Limited retains the non-exclusive rights under the Licensed Intellectual Property in the Territory, for it and/or the Acrux Controlled Affiliates or any of their respective licensees to export, make, and have made Products in the Territory solely for importation, sale, use and other exploitation in the Field in a country or jurisdiction outside the Territory. In addition, only to the extent permitted by Vivus on request by FemPharm, such permission not to be unreasonably withheld, FemPharm may conduct specific development activities in the Territory, solely to develop data to be used in the

Regulatory Materials outside the Territory for the Product in the Field, and marketing of the Product in the Field outside the Territory.

- (d) For clarity, the license rights granted to Vivus in Section 2.1(a) and (b) do not grant to Vivus the rights under the Licensed Intellectual Property, to export, make, have made, and develop Products for importation, sale, use and other exploitation in the Field in any country or jurisdiction outside the Territory, or for any use outside the Field anywhere in the world.

2.2 RESERVATION OF RIGHTS

Each Party hereby reserves all rights with respect to its Intellectual Property and technology not expressly granted herein. Vivus shall have no right or license under the FemPharm Patents or Licensed Know-How other than the rights expressly set forth in this Agreement. Notwithstanding anything to the contrary, it is acknowledged and agreed that the limitation of FemPharm's rights under the Acrux DDS License, such as the limitation of the field of FemPharm's rights to female hormone replacement therapy or otherwise, shall not limit the rights granted to Vivus under this Agreement.

2.3 VIVUS GRANT-BACK LICENSE AND OPTION TO LICENSE

- (a) Subject to the terms of this Agreement, Vivus grants to FemPharm a non-exclusive, royalty-free, worldwide license (with full rights to grant sublicenses) under any Improvement Blocking Patent Rights solely to develop, exploit, import, make, have made, use, offer for sale and sell MDTs products, excluding only MDTs products intended for use, sale, offer for sale, import, or marketing in the Field in the Territory.
- (b) Vivus grants to FemPharm the option, exercisable in writing by FemPharm at any time after Vivus makes an Improvement, to obtain in accordance with this Section 2.3(b) below a non-exclusive, worldwide license (with such rights to sublicense as are mutually agreed), on commercially reasonable terms, under trade secrets Controlled by Vivus or its Affiliate during the term of this Agreement to the

extent embodied in such Improvement and under Patents Controlled by Vivus or its Affiliate during the term of this Agreement that claim and are specifically directed to such Improvement, (but excluding all Improvement Blocking Patent Rights), solely to develop, exploit, import, make, have made, use, offer for sale and sell MDTs products, excluding only MDTs products intended for use, sale, offer for sale, import, or marketing in the Field in the Territory. If FemPharm exercises such option as to a particular Improvement, then the Parties shall negotiate in good faith in an effort to agree upon the financial and other terms for, and scope of, such a license, within a reasonable time thereafter and will enter into such a license upon reaching agreement, which terms shall be commercially reasonable and shall include the mutually agreed license grant for such Improvement (under the Patents and trade secrets identified above) and other reasonable terms appropriate for such a license grant. Such license shall be royalty free for Products used in the Field in Australia or New Zealand.

2.4 EXPANSION OF FIELD

The Development Committee shall discuss and consider from time to time the possibility of including in the Field one or more additional Estrogens, alone or in combination with other active ingredients, and if it determines that such an expansion to the Field is appropriate, it shall make such recommendation to both Parties. If the Parties agree with such recommendation, and solely to the extent such expansion is approved in writing by the Parties, such additional Estrogen(s) shall be added to the Field by written amendment of the Agreement on mutually acceptable terms, including financial terms.

2.5 EXCLUSIVITY COVENANTS

- (a) Except as otherwise agreed by the Parties in writing, until (*) after First Commercial Sale by or under authority of Vivus of a Product for use in the Field and Territory, Vivus and its Controlled Affiliates shall not, directly or indirectly, market, promote, sell, or import any Competitive Products (as defined below) for use in the Territory. As used herein, "Competitive Product" means

any product (which is not a Product of Vivus, its Affiliate, or sublicensee under this Agreement) that is approved for marketing for any human indication and is marketed, promoted, or sold (i) for the transdermal or mucosal delivery to human females of Estradiol, or any other Restricted Estrogen, as the sole active ingredient transdermally or mucosally delivered by such product; or (ii) for the transdermal or mucosal delivery of any other Estrogen, as the sole active ingredient transdermally or mucosally delivered by such product, to human females for treatment of menopausal symptoms; except excluding from the foregoing only products of any of Vivus, its Affiliates, and sublicensees involving application of an estrogen, alone or in combination with a vasoactive agent, to the vagina of a human female to ameliorate or treat menopausal vaginal symptoms such as vaginal atrophy or vaginal dryness, provided that such direct vaginal application of an estrogen does not achieve chronic systemic therapeutic Estradiol blood levels that would be effective for treating menopausal vasomotor symptoms). For clarity, marketing, selling or promoting any orally delivered active ingredient is not a Competitive Product. For clarity, no license is granted under this Section 2.5(a) to Vivus by FemPharm or any Acrux Controlled Affiliate under the Licensed Intellectual Property with respect to any Vivus product involving such application of an Estrogen to the vagina of a human female. Vivus and its Controlled Affiliates shall not provide funding prior to such time to third parties for the specific purpose of, or grant a license or other authorization to any third party to, market, sell, promote, or import any Competitive Product for use in the Territory. Vivus shall include, and cause its Controlled Affiliates to include, in any grant or authorization by Vivus or the Controlled Affiliate in accordance with this Agreement of an exclusive sublicense (including with respect to Vivus) to a third party under the Licensed Intellectual Property to market, sell, promote, and import the Products in the Territory, an express covenant by such third party not to market, promote, sell or import, directly or indirectly, any Competitive Product for use in the Territory. If a particular Vivus Controlled Affiliate is no longer controlled by Vivus, then the

above shall apply to such entity only if such entity continues to have rights under the Licensed Technology that it could exercise to make, use or sell a Product or a Competitive Product.

- (b) Except as otherwise agreed by the Parties in writing, until (*) after First Commercial Sale by or under authority of Vivus of a Product for use in the Field and Territory, FemPharm and Acrux DDS Pty Limited agree that FemPharm and the Acrux Controlled Affiliates shall not, directly or indirectly, market, promote, sell, or import in the Territory any Competitive Product. For clarity, FemPharm and the Acrux Controlled Affiliates shall not provide funding prior to such time to third parties for the specific purpose of, or grant a license or other authorization to any third party to, market, sell, promote, or import for use in the Territory any Competitive Product. Furthermore, if FemPharm or Acrux DDS Pty Limited intend to market, sell, promote or import for use in the Territory any combination therapy involving the delivery of both a Restricted Estrogen and progestin using the MDTs system, then FemPharm and Acrux DDS Pty Limited shall first notify Vivus in writing of such intent. If Vivus is interested in such commercialization opportunities for such combination therapy, it shall so inform FemPharm in writing within thirty (30) days of receiving such notice, after which the Parties shall engage in good faith, diligent negotiation to enter into a collaboration agreement for the commercialization of such combination therapy by Vivus. If Vivus does not inform FemPharm of its interest within thirty (30) days or if the Parties, after one hundred twenty (120) days of good faith, diligent negotiation, are unable to enter into such collaboration agreement, then FemPharm and/or Acrux DDS Pty Limited shall be free to enter into an agreement regarding such opportunity with any third party with no further obligation to Vivus. FemPharm and Acrux DDS Pty Limited shall include, and cause the Acrux Controlled Affiliates to include, in each grant or authorization of any of their Intellectual Property rights to a third party, if the license or authorization could be exercised in a manner that involves the delivery of Estradiol (or any Restricted Estrogen or other Estrogen) to females as a

Monotherapy, an express covenant by such third party not to market, promote, sell or import, directly or indirectly, any Competitive Product for use in the Territory. If a particular Acrux Controlled Affiliate is no longer controlled by Acrux Limited, then the above shall apply to such entity only if such entity continues to have rights under the Licensed Technology that it could exercise to make, use or sell a Competitive Product.

- (c) Nothing in this Section 2.5 shall limit the exclusivity of the license rights granted to Vivus in Section 2.1, it being agreed that the exclusivity under Section 2.1 shall not be limited to the periods described in this Section 2.5 above.
- (d) If FemPharm is acquired by, and thus becomes an Affiliate of, a third party other than an Acrux Controlled Affiliate, such third party Affiliate shall be deemed a third party for purposes of the licensing restrictions applied to FemPharm under Section 2.5(b). Similarly, if Vivus is acquired by, and thus becomes an Affiliate of, a third party other than a Vivus Controlled Affiliate, such third party Affiliate shall be deemed a third party for purposes of the licensing restrictions applied to Vivus under Section 2.5(a).

2.6 UNAUTHORIZED SALES

- (a) FemPharm and the Acrux Controlled Affiliates shall not directly or indirectly market, sell, or distribute any MDTs products intended for use in the Field anywhere in the world to a particular third party, including its Affiliates, if FemPharm or an Acrux Controlled Affiliate knows, or has been provided reasonable evidence, that such MDTs products provided directly or indirectly by FemPharm or an Acrux Controlled Affiliate to such third party are being marketed, distributed or sold in the Territory in the Field. If FemPharm or an Acrux Controlled Affiliate grants rights to a third party, directly or indirectly, that could be exercised in a manner that involves the delivery of Estradiol (or any Restricted Estrogen or other Estrogen) to human females in Monotherapy, then FemPharm shall make, or cause the Acrux Controlled Affiliate to make, the terms

and conditions in this Section 2.6(a) applicable to the third party in the same manner as applicable to FemPharm.

- (b) Vivus and its Controlled Affiliates shall not directly or indirectly market, sell, or distribute any Product in the Territory to a particular third party, including its Affiliates, if Vivus knows, or has been provided reasonable evidence, that such Product provided directly or indirectly by Vivus or its Controlled Affiliates to such third party are being marketed, distributed or sold for use outside the Territory, provided that the sale of such Product in the Territory infringes a Valid Claim in the FemPharm Patents or embodies information that is at the then current time a trade secret of FemPharm, other than as permitted by Section 10.11. If Vivus or its Controlled Affiliate grants a sublicense to a third party under the Licensed Intellectual Property in accordance with this Agreement to market, sell, promote, and import the Products in the Territory, then Vivus shall make, or cause its Controlled Affiliate to make, the terms and conditions in this Section 2.6(b) applicable to the third party in the same manner as applicable to Vivus.

2.7 RIGHT OF NEGOTIATION

If FemPharm or an Acrux Controlled Affiliate desires to enter into a license or other collaboration that involves the research, development, or commercialization in the Territory of a product for delivery of an Estrogen, other than Estradiol, to females for the treatment of menopausal symptoms, FemPharm shall propose to Vivus the terms and conditions for such a license or collaboration with Vivus prior to entering into the license or collaboration with any third party. If Vivus fails to notify FemPharm in writing, within one hundred twenty (120) days after receiving such proposed terms and conditions from FemPharm, that Vivus desires to negotiate the terms and conditions for the license or collaboration, or if the Parties do not agree in principle on the terms for such an arrangement notwithstanding good faith, diligent negotiations throughout the remainder of such one hundred twenty (120) day period after Vivus' request, then FemPharm or the Acrux Controlled Affiliate shall have the right to enter into the license or collaboration

with a third party. In addition, FemPharm shall notify Vivus in writing upon any of FemPharm or the Acrux Controlled Affiliates commencing, whether directly or indirectly, any clinical development or commercialization of any product involving the transdermal or mucosal deliver to human females of an Estrogen or other selective estrogen receptor modulator for hormone replacement therapy or the treatment of menopausal symptoms, including through licensees and work funded by FemPharm, but subject to any confidentiality obligations that would prevent such disclosure.

3. LICENSE AND MILESTONE PAYMENTS

3.1 LICENSE FEE

Vivus will pay to FemPharm a license fee of US\$ 1,000,000 (One Million United States Dollars) no later than June 29, 2005.

3.2 MILESTONE PAYMENTS

Upon achieving the specified milestone, Vivus will pay to FemPharm the following milestone payments (subject to Section 3.3 and 6.2):

- (a) US\$ (*) (** United States Dollars) within thirty (30) days of submission by or under authority of Vivus or its Affiliate or sublicensee in the United States of the first new drug application to the FDA (as new drug application is defined in 21 C.F.R. ss. 314.50 et. Seq, as updated or amended from time to time), or such other equivalent regulatory application in the United States for approval of marketing of the Product, (the "NDA") in respect of the Product; and
- (b) US\$ (*) (** United States Dollars) within thirty (30) days of the first FDA marketing approval in the United States in respect of the Product (the marketing approval being defined as approval by the FDA of Vivus' or its Affiliate's or sublicensee's NDA for the Product, permitting the Product to be marketed in the United States).

3.3 ONE PAYMENT; LIMITATION

It is understood that once a particular milestone payment under Section 3.2 has been paid (including as a result of the operation of Section 6.2 below), then no payment for such milestone shall be due again with respect to the same Product or any other Product except to the extent otherwise agreed by the Parties in writing in connection with the addition of an Estrogen to the Field pursuant to Section 2.4.

4. ROYALTIES

4.1 ROYALTY PAYMENTS

Except as otherwise provided in this Article 4, Vivus will pay to FemPharm royalties as a percentage of Net Sales, where the royalty rate is determined based on the total aggregate Net Sales during the applicable calendar year in the Territory, according to the following schedule:

- (a) the royalty rate is (*) per cent (* %) in any calendar year in which the total Net Sales are less than US\$ (*) (** U.S. Dollars);
- (b) the royalty rate is (*) per cent (* %) in any calendar year in which the total Net Sales are equal to or more than US\$ (*) (**U.S. Dollars) but less than US\$(*) (* U.S. Dollars);
- (c) the royalty rate is (*) per cent (* %) in any calendar year in which the total Net Sales are equal to or more than US\$ (*)(* U.S. Dollars) but less than US\$ (*) (*U.S. Dollars);
- (d) the royalty rate is (*) per cent (* %) in any calendar year in which the total Net Sales are equal to or more than US\$(*) (* U.S. Dollars) but less than US\$ (*) (*U.S. Dollars);

- (e) the royalty rate is (*) per cent (*) % in any calendar year in which the total Net Sales are equal to or more than US\$ (*) (* U.S. Dollars) but less than US\$ (*) (*U.S. Dollars);
- (f) the royalty rate is (*) per cent (*) % in any calendar year in which the total Net Sales are equal to or more than US\$ (*) (* U.S. Dollars) but less than US\$ (*) (*U.S. Dollars);
- (g) the royalty rate is (*) per cent (*) % in any calendar year in which the total Net Sales are equal to or more than US\$ (*) (* U.S. Dollars) but less than US\$ (*) (*U.S. Dollars);
- (h) the royalty rate is (*) per cent (*) % in any calendar year in which the total Net Sales are equal to or more than US\$ (*) (* U.S. Dollars) but less than US\$ (*) (*U.S. Dollars);
- (i) the royalty rate is (*) per cent (*) % in any calendar year in which the total Net Sales are equal to or more than US\$ (*) (* U.S. Dollars) but less than US\$ (*) (*U.S. Dollars);
- (j) the royalty rate is (*) per cent (*) % in any calendar year in which the total Net Sales are equal to or more than US\$ (*) (* U.S. Dollars) but less than US\$ (*) (*U.S. Dollars);
- (k) the royalty rate is (*) per cent (*) % in any calendar year in which the total Net Sales are equal to or more than US\$ (*) (* U.S. Dollars) but less than US\$ (*) (*U.S. Dollars);
- (l) the royalty rate is (*) per cent (*) % in any calendar year in which the total Net Sales are equal to or more than US\$ (*) (* U.S. Dollars) but less than US\$ (*) (*U.S. Dollars);

- (m) the royalty rate is (*) per cent (* %) in any calendar year in which the total Net Sales are equal to or more than US\$ (*) (*U.S. Dollars) but less than US\$ (*) (*U.S. Dollars);
- (n) the royalty rate is (*) per cent (* %) in any calendar year in which the total Net Sales are equal to or more than US\$ (*) (*U.S. Dollars) but less than US\$ (*) (*U.S. Dollars);
- (o) the royalty rate is (*) per cent (* %) in any calendar year in which the total Net Sales are equal to or more than US\$ (*) (*U.S. Dollars) but less than US\$ (*) (*U.S. Dollars);
- (p) the royalty rate is (*) per cent (* 5%) in any calendar year in which the total Net Sales are equal to or more than US\$ (*) (*U.S. Dollars) but less than US\$ (*) (*U.S. Dollars);
- (q) the royalty rate is (*)per cent (* %) in any calendar year in which the total Net Sales are equal to or more than US\$ (*) (*U.S. Dollars) but less than US\$ (*) (*U.S. Dollars);
- (r) the royalty rate is (*) per cent (* %) in any calendar year in which the total Net Sales are equal to or more than US\$ (*) (*U.S. Dollars) but less than US\$ (*) (*U.S. Dollars);
- (s) the royalty rate is (*) per cent (* %) in any calendar year in which the total Net Sales are equal to or more than US\$ (*) (*U.S. Dollars) but less than US\$ (*) (*U.S. Dollars);
- (t) the royalty rate is (*) per cent (* %) in any calendar year in which the total Net Sales are equal to or more than US\$ (*) (*U.S. Dollars) but less than US\$ (*) (*U.S. Dollars);
- (u) the royalty rate is (*)per cent (*%) in any calendar year in which the total Net Sales are equal to or more than US\$ (*)(*U.S. Dollars).

The royalty rate applicable to the Net Sales occurring in any one of the first three Royalty Periods of a particular calendar year shall be determined by annualizing the total aggregate Net Sales amount through the end of the applicable Royalty Period, by multiplying such total aggregate Net Sales amount by the applicable Adjustment Factor (as defined below), and then using such annualized amount in the above royalty schedule. The royalty rate for the last Royalty Period in each calendar year shall be determined using the actual total Net Sales for that calendar year. The "Adjustment Factor" for a particular Royalty Period in a calendar year shall be: (*) for the first Royalty Period in a calendar year; (*) for the second Royalty Period in a calendar year; and (*) for the third Royalty Period in a calendar year.

Royalties payable on the Net Sales occurring in a particular Royalty Period in the calendar year shall be calculated by multiplying the applicable royalty rate, determined as above for such Royalty Period, to the total aggregate actual Net Sales that have accrued during the calendar year through the end of the Royalty Period, and (if such Royalty Period is any other than the first Royalty Period in the calendar year) subtracting from such total royalty amount the amount of royalty (if any) actually paid by Vivus for the Net Sales occurring in the earlier Royalty Periods of such calendar year. If any of the foregoing royalty calculations and payments results in a net overpayment of royalties for the calendar year, then FemPharm shall refund the overpayment to Vivus within forty five (45) days after Vivus' request.

An example of the calculation of royalties is provided in Annexure G.

4.2 ROYALTY REDUCTION

The royalty rate applicable under Section 4.1 to Net Sales from the sale of a Product will be reduced by (*) per cent (* %) upon the expiration, cancellation, invalidation, abandonment, termination, disclaimer, or unenforceability of the last Valid Claim in the FemPharm Patents that would, absent a license, be infringed by the sale or use of such Product in the Territory in the Field. Further, with respect to a particular Product, if there otherwise is no Valid Claim in the FemPharm Patents that would, absent a license, be

infringed by the sale or use of such Product in the Territory in the Field, then the royalty rate applicable under Section 4.1 to the Net Sales from the sale of such Product shall be (*) percent (* %) of the royalties set forth in Section 4.1, unless and until such a Valid Claim issues, after which point the rate shall be as set forth in Section 4.1 until the preceding sentence applies.

4.3 THIRD PARTY ROYALTIES

If Vivus or its Affiliate or sublicensee pays royalties to a third party under a patent license that is necessary in order to make, use, import, or sell a Product in the Territory, which royalties are based on net sales of such product, then Vivus shall have the right to credit (*) percent (* %) of such payments against the amounts payable by Vivus under this Section 3 and Section 4, provided that the royalty payable to FemPharm under this Section 4 shall not be so reduced by more than (*) percent (* %). As used in this Section, a license is "necessary" if it is reasonable to obtain the license in light of the risk of infringement. If FemPharm disagrees with Vivus' assertion, under this Section, that a particular license is so necessary, then the Parties will proceed under Section 15.11 to resolve the issue. Notwithstanding the foregoing, if Vivus or its sublicensee adds to the Product a component or feature comprising such technology, and Vivus or its sublicensee must pay royalties for third party patent rights covering such component or feature, such royalties shall not be offset under this Section 4.3 against royalties owed to FemPharm, unless the component or feature is, at the time added, necessary to make the Product approvable or commercially viable. As to any license that Vivus may believe is desirable to enter into with respect to a Product, other than those for which royalties may be offset in accordance with the foregoing, if Vivus so requests the Parties will discuss such license and the possibility of FemPharm sharing some part of the costs of such license.

4.4 ONE ROYALTY; SAMPLES AND DONATIONS

One royalty shall be payable for each Product sold under this Agreement. No royalties shall be due upon the sale or other transfer of Product among Vivus, its

Affiliates and sublicensees, but in such cases the royalty shall be due and calculated upon Vivus', its Affiliate's or sublicensee's Net Sales to the first independent third party, or commercial use of such Product by Vivus, the Affiliate, or the sublicensee for profit to treat patients in the ordinary course of its business (in which case "Net Sales" for such use shall be deemed to be the average Net Sales for such Product when sold to third parties in the same royalty period in the Territory). No royalties shall accrue on the disposition of Product by Vivus or its Affiliates or sublicensees in reasonable quantities which are (i) used in clinical trials, (ii) distributed as samples (promotion or otherwise), or (iii) distributed as donations solely for charitable purpose (I.E., without charge).

4.5 ACCRUAL AND PAYMENT OF ROYALTIES; ROYALTY TERM

The royalties owed under this Section 4 accrue on the sale or transfer of the Product, and all royalties that accrue in respect of the Net Sales in a particular Royalty Period:

- (a) if the Territory includes any country outside the United States of America, will be calculated, on a country by country basis, after conversion (based on exchange rate as set forth in Section 4.10 below) into U.S. dollars; and
- (b) will be paid in U.S. dollars no later than the date that the royalty report for that Royalty Period is to be provided pursuant to Section 4.7.

Royalties shall accrue on sales of Products commencing on the date of First Commercial Sale of the first Product hereunder and continuing only until the latest to occur of the following: (i) expiration, cancellation, invalidation, abandonment, termination, disclaimer, or unenforceability of the last Valid Claim in the FemPharm Patents that covers the sale of the Product, or its use, in the Territory; or (ii) twelve (12) years from the date of such First Commercial Sale, or (iii) on a Product by Product basis, the date there no longer is any substantial trade secret of FemPharm or its Affiliate embodied in the applicable Product which is a trade secret of FemPharm or its Affiliate at the time of the sale.

4.6 LATE PAYMENT OF ROYALTIES

If Vivus fails to pay royalties within the time specified in Section 4.5, Vivus will pay to FemPharm interest on the amount of royalties which were not timely paid from the date upon which they became owing until the date of payment at (*) percent (* %) above the Prime Rate as quoted in the Wall Street Journal, calculated on a daily basis and payable on demand.

4.7 ROYALTY REPORT

Vivus will submit to FemPharm no later than forty five (45) days after the end of each Royalty Period during the term of this Agreement a report stating:

- (a) the total amount of invoiced sales of the Product, (on a country by country basis if the Territory includes any country outside the United States of America);
- (b) the calculation of Net Sales (in each country if the Territory includes any country outside the United States of America), based on such sales, including a description of the deductions used to calculate such Net Sales; and
- (c) if the Territory includes any country outside the United States of America, the calculation of royalties owed based on such Net Sales, on a country by country basis during that Royalty Period, after conversion of such Net Sales into U.S. Dollars as per Section 4.11.

4.8 VERIFICATION OF ROYALTY STATEMENT

FemPharm may at its cost have any report referred to in Section 4.7 verified as set forth below by a reputable firm of chartered accountants or certified public accountants nominated by FemPharm, and reasonably acceptable to Vivus, provided FemPharm completes such verification within thirty-six (36) months of the end of the Royalty Period to which the verification is to relate. Upon not less than ten (10) Business Days' prior written notice given by FemPharm to Vivus, Vivus will provide the accountants with access during Vivus' (or its Affiliates' or, to the extent Vivus has the right to do so,

sublicensee's, as applicable) normal business hours to the revenue and sales records of Vivus, its Affiliates and (to the extent Vivus has the right to do so) sublicensees sufficient for the purposes of verifying the reports referred to in Section 4.7 and for the purpose of verifying the amount of royalties paid to FemPharm. To the extent that Vivus does not have the right to grant to FemPharm the right to audit the books and records of its sublicensees, Vivus will use reasonable, diligent efforts to obtain for itself such rights and, at the request of FemPharm, agree to exercise its audit rights with respect to such sublicensees and provide the results of such audit to FemPharm pursuant to this Section 4.8. Vivus, the Affiliate or sublicensee, as the case may be, may request that, at its expense, a representative or agent familiar with its record keeping systems be present at the audit to assist in the audit. Such audits will be at the expense of FemPharm, except that if such audit establishes that the amount owed by Vivus for the audited period exceeds the amount actually paid by more than (*), then Vivus will pay FemPharm's actual out of pocket costs of such audit.

4.9 NON-DISCLOSURE BY ACCOUNTANT

The accountants appointed under Section 4.8 are not authorized to, and will not, disclose to FemPharm any information other than the accuracy or inaccuracy of the amounts to be verified and will be required to execute a reasonable confidentiality agreement with Vivus and/or the sublicensee or Affiliate, as applicable.

4.10 STATEMENT ERRORS

Should it be established from any report and verification referred to in Sections 4.7 and 4.8 that the royalties which should have been paid in respect of any Royalty Period to which the report and verification relates are more or less than the royalties actually paid then the difference will be remitted within ten (10) Business Days:

- (a) to FemPharm (in the case of the royalty paid being less than that which should have been paid);

- (b) to Vivus (in the case of the royalty paid being more than that which should have been paid).

4.11 CURRENCY CONVERSION

If the Territory includes any country outside the United States of America, all Net Sales resulting from sales of the Product in countries other than the United States of America will be converted into United States dollars for purposes of calculating royalties owed under this Article 4, by using the arithmetic average of the currency exchange rates quoted on each of the last ten (10) Business Days during the applicable Royalty Period in the Wall Street Journal (East Coast Edition). All payments by Vivus hereunder shall be made in US dollars.

4.12 WITHHOLDING TAXES

If any taxes, withholding or otherwise, are levied by any taxing authority in connection with the accrual or payment of royalties or other amounts payable under this Agreement and are obliged to be paid or deducted by Vivus then:

- (a) Vivus will pay such taxes to such taxing authority on behalf of FemPharm; and
- (b) Vivus will remit to FemPharm in full satisfaction of its royalty obligations under this Agreement the net amount after reduction by the amount of such taxes; and
- (c) Vivus will deliver to FemPharm promptly following payment written evidence of such payment and such other related documentation that FemPharm may reasonably require.

5. CLINICAL DEVELOPMENT

5.1 OVERVIEW OF DEVELOPMENT

The Parties intend to work cooperatively to pursue development of the Product in order to obtain regulatory approval for the use of the Product in the Field in the Territory, using commercially reasonable, diligent efforts in accordance with and subject to the terms of this Agreement.

5.2 TRANSFER OF TECHNICAL INFORMATION

Within sixty (60) days after the Effective Date, FemPharm shall transfer to Vivus without charge copies of all existing Licensed Know-How, including (to the extent existing) (i) copies of all Regulatory Materials and other Know-How developed or acquired in connection with any clinical or pre-clinical development in connection with, or directly applicable to, a Product in the Field, whether developed or acquired by FemPharm, any Acrux Controlled Affiliate, or others working under authority of such entities; and (ii) copies of all material Know-How relating to or used in connection with, or relevant to, the manufacturing of Products by FemPharm, any Acrux Controlled Affiliate, or others, including, such Know-How as generated or used during process development, stability studies, formulation development, scale up of manufacturing, production of preclinical and clinical product batches, validation studies, development of quality assurance/quality control testing, process controls for Products in the Field, and related regulatory affairs (all to the extent relating to Products in the Field); and all Know-How contained in the DMF or in the CMC section of any IND or NDA (or their counterparts in other countries) with respect to Products in the Field. Thereafter during the term of this Agreement, upon request of Vivus, FemPharm shall transfer to Vivus without charge copies of all such previously undisclosed Licensed Know-How, if any, including that developed or acquired after the Effective Date, and shall use all reasonable efforts to enable and assist Vivus in understanding and implementing the Licensed Know-How. FemPharm and the Acrux Controlled Affiliates shall use good faith, diligent efforts to obtain from each of their other licensees the right to disclose to Vivus, its Affiliates and their sublicensees, Know-How and Regulatory Materials that are relevant to, or useful for, Products. In addition, if requested by Vivus and at Vivus' expense for actual reasonable internal time of FemPharm or its Affiliate's time (billed at (*)% the applicable employee's salary and benefits), FemPharm shall generate and provide to Vivus reasonably promptly a report describing in reasonable detail (according to an agreed format) all research and development conducted or completed by or under authority of any of FemPharm and the Acrux Controlled Affiliates, and the results thereof, with respect to MDTS products involving the delivery of Estradiol.

5.3 DEVELOPMENT RESPONSIBILITIES

Except as otherwise determined by the Parties, Vivus will be solely responsible for conducting, at its own expense, all activities relating to the clinical development, regulatory approval and commercialization of the Product in the Territory, using diligent, commercially reasonable efforts, provided that both Parties will use such efforts to perform their responsibilities to achieve the targets set forth in the Development Plan. Vivus will pay to Fempharm, prior to the beginning of a calendar quarter, an amount equal to the FemPharm expenses in the approved budget in the Development Plan for such quarter, including payments to third parties and fully burdened FTE costs of labour associated with work at FemPharm and its Affiliates pursuant to this Agreement ((*)% of salary and benefits, plus any out of pocket expenses provided for in the Development Plan). FemPharm will maintain reasonably detailed records of the time expended and work performed in the development and will provide copies and a summary of such records, and a reconciliation of expenditures, for each such quarter to Vivus within fifteen (15) Business Days of the end of the quarter. The actual expenditure versus budget for the previous quarter will be reconciled in the payment from Vivus to Acrux for the following quarter or refunded to Vivus, as Vivus requests. Vivus shall not be required to reimburse any cost or expenses, other than those set forth in the Development Plan, except to the extent approved by Vivus in advance in writing. Vivus shall not be required to develop more than one Product at a time, and shall have no obligation to develop another Product in the Territory after a marketing approval of a Product in the Field has been obtained in the Territory.

5.4 DEVELOPMENT COMMITTEE

Within thirty (30) days of the Effective Date, the Parties will establish a committee to review and discuss the development of the Product (the "Development Committee"),

comprising two (2) members of FemPharm's (or the Acrux Controlled Affiliate's) staff nominated by FemPharm and two (2) members of Vivus' staff nominated by Vivus. At least one member appointed by each Party shall have appropriate technical credentials, experience and knowledge and ongoing familiarity with, in the case of Vivus, the development under this Agreement and, in the case of FemPharm, any pre-clinical and clinical development of Product by FemPharm or the Acrux Controlled Affiliate, as well as the Licensed Intellectual Property and the development and use thereof. If relevant Product development is being performed by an Acrux Controlled Affiliate, then Vivus shall have the right to require that at least one of FemPharm's members be an employee of the Acrux Controlled Affiliate who is involved in such development or, in the alternative, to require that such an employee otherwise attend the Development Committee meetings. Each Party will give the other written notification concerning its staff members who are nominated to serve on the Development Committee. Subject to the foregoing, either Party may replace any of its members on the Development Committee by written notice. Additionally, Vivus shall be entitled to have representatives of its sublicensees attend the meetings as it considers appropriate. The Development Committee is responsible for review and approval of the Development Plan and is additionally intended to provide a forum to:

- (a) Enable Vivus to obtain scientific, clinical and regulatory input and data from FemPharm relating to development of the Product in the Territory, including with respect to work that each Party has performed in accordance with the Development Plan, and to keep Vivus informed regarding the work of FemPharm and the Acrux Controlled Affiliates related to Product;
- (b) keep FemPharm reasonably apprised of the progress and results of, and planned activities related to, development of Products in the Field in the Territory under the Development Plan, sufficient for FemPharm to understand the general status of the development under the Development Plan and nature of any significant issues that Vivus has encountered that have caused Vivus to fail to meet

the schedule targeted in the Development Plan, and to review and approve, as appropriate, the Development Plans proposed by Vivus;

- (c) evaluate the markets of the Product for use in the Field in relation to the development strategy for the Product, and adjust the Development Plan appropriately based thereon; and
- (d) foster a cooperative relationship between the Parties regarding activities under this Agreement and the other activities of FemPharm and the Acrux Controlled Affiliates with respect to Product.

To the extent requested by the Steering Committee, the Development Committee will keep the Steering Committee informed about the status of the activities conducted by the Development Committee pursuant to this Agreement. The Development Committee will refer all matters that are to be decided by the Development Committee, but for which agreement cannot be reached by the Development Committee, to the Steering Committee for the Steering Committee's review and final decision on such matters. The Development Committee will establish rules for its operation. After marketing approval of a Product is obtained, the Development Committee shall not be required to meet if there is no significant Product development by Vivus to discuss at the applicable time.

5.5 DEVELOPMENT PLANS

The development of the Product will be conducted by the Parties, each using diligent, commercially reasonable efforts to perform its responsibilities set forth in the Development Plan. The Parties expect that an initial Development Plan will be appended to the Agreement as annexure A within one hundred eighty (180) days after the Effective Date, reflecting the Parties' understanding and intent at such time of the planned Product development activities in the Territory for the remainder of then current calendar year (and if mutually desired at the time, the following calendar year). The Development Plans proposed by Vivus will be reviewed and approved by the Development Committee from time to time as appropriate. On an annual basis commencing in the final calendar year covered by the initial Development Plan (no later than October 15 of each year),

Vivus will prepare and submit to the Development Committee for approval a reasonably detailed Development Plan outlining development responsibilities for the Product for the upcoming calendar year, it being agreed that Vivus may propose updates and revisions to the Development Plan more often as Vivus considers appropriate. After reviewing the proposal and discussing the development efforts to date, the Development Committee will consider changes to and amend the Development Plan to reflect revised regulatory and development activities designed to meet the goal of obtaining regulatory approval for the Product in the Territory in a commercially reasonable time frame based on the use of diligent, commercially reasonable efforts by Vivus to perform the development. Notwithstanding the foregoing, no Development Plan shall be required after marketing approval of a Product is obtained except to the extent required by the Development Committee.

5.6 BUDGETS

The Development Committee will prepare and include in the Development Plans, a budget that sets forth the estimated costs and expenses (including fully-burdened internal labor costs, as described in Section 5.3 above) that are budgeted to be incurred by FemPharm in conducting its responsibilities, if any, for Product development under the Development Plan. Each updated Development Plan will include an updated budget for FemPharm's responsibilities, if any, to be approved by the Development Committee. Vivus shall not be required to reimburse any costs or expenses other than those budgeted, unless agreed in advance in writing. Each Party shall bear its own costs and expenses associated with Committee meetings.

5.7 STEERING COMMITTEE

Within thirty (30) days of the Effective Date, the Parties will establish a steering committee (the "Steering Committee"), comprising of one (1) member selected by FemPharm from its senior executives and one (1) member selected by Vivus from its senior executives; each having responsibility at the respective Party for development of Product. Each Party will give the other written notification concerning its executive

nominated to serve on the Steering Committee. Either Party may replace its member on the Steering Committee with an equivalent senior executive by providing written notice of the change to the other Party. A member of the Steering Committee cannot simultaneously serve as a member of the Development Committee, provided that membership in the steering committee or development committee under the Testosterone Agreement shall not preclude membership in either the Steering Committee or the Development Committee hereunder (and vice versa). The Steering Committee will be responsible for resolving issues upon which the Development Committee has been unable to reach agreement and for serving as the initial means for discussing and seeking to resolve any issues or disputes between the Parties arising under this Agreement. Members of the Steering Committee will consult with members of the Development Committee, as they consider necessary, when resolving such issues and disputes and the decision of the Steering Committee binds the Development Committee.

5.8 FINAL DECISION

If the Steering Committee has been unable to reach agreement on any issue or matter after diligent discussions, or if such discussions have not occurred due to unreasonable delay by FemPharm's representative, then the issue will be referred to Vivus to determine the issue, except as otherwise provided below. Vivus must consider the issue, having considered the views put forward by the Development Committee and the Steering Committee. Vivus' decision is final and binding on the Parties and the Committees in respect of each such issue and matter, provided that the foregoing does not permit Vivus to amend the terms of this Agreement, or change the Outside Dates, or otherwise impose an obligation on FemPharm, without FemPharm's written consent.

5.9 PROCEDURES OF COMMITTEES

Each Party will provide the other Party in writing with the name, title, e-mail address, telephone number and facsimile number of its nominees to each Committee. The Development Committee will meet semi-annually during the term of the Development Plan, and more often as mutually agreed. The Steering Committee will meet as needed to

resolve disputes and issues, promptly on the good faith request of either Party. All Committee meetings will be at such times agreed to by FemPharm and Vivus and will be in person or by telephone or video conference.

5.10 DECISIONS OF COMMITTEES

A quorum of the Development Committee at a meeting is two (2) representatives of each Party present at such meeting in person or by telephone or videoconference. A quorum of the Steering Committee at a meeting is one (1) representative of each Party present at such meeting in person or by telephone or videoconference. A unanimous vote of the members of the Committee present (in person, by telephone or videoconference) at such meeting is required to take any action on behalf of the Committee. In particular, neither Committee may make a binding decision unless a quorum is present. Each Party shall use best efforts to cause a quorum to be present at each meeting. No decision of a Committee shall be considered binding upon either Party, except to the extent set forth in writing and signed by both Parties. Notwithstanding anything to the contrary, no approval of the Development Committee shall be required for the day to day development activities, which shall be controlled by Vivus or its designee.

5.11 CHAIRPERSONS - DEVELOPMENT COMMITTEE

The chair of the Development Committee will be a Vivus member of the Development Committee. Except to the extent otherwise approved by the Development Committee, the chair will be responsible for preparing the timetable for the meetings, and for preparing the agendas, minutes and resolutions, communications with the Steering Committee and other communications regarding tasks assigned by the Development Committee. All drafts of minutes and resolutions must be approved by the members of the Development Committee at the next meeting. The chair does not have a second or deciding vote.

5.12 CHAIRPERSONS - STEERING COMMITTEE

The chair of the Steering Committee will be Vivus' member of the Steering Committee. Except to the extent otherwise approved by the Steering Committee, the chair will be responsible for preparing the timetable for the meetings, and for preparing the agendas, minutes and resolutions, communications with the Development Committee and other communications regarding tasks assigned by the Steering Committee. All drafts of minutes and resolutions must be approved by the members of the Steering Committee at the next meeting. The chair does not have a second or deciding vote.

5.13 MINUTES AND REPORTS

Each Committee will be responsible for keeping accurate minutes of its deliberations or discussions that record all proposed decisions and all actions recommended or taken. The chair will provide the Parties with the approved minutes of each meeting promptly after approval and, in the case of the Development Committee, a written accompanying report summarizing, in reasonable detail, the discussions of the Development Committee concerning: the status of the Development Plan, of the work and progress to date, any issues requiring resolution, and any decisions by the Development Committee. All records made by each Committee will be available to both Parties.

5.14 GLOBAL DEVELOPMENT COMMITTEE

At such time as any pre-clinical or clinical development is undertaken by or under authority of FemPharm or any Acrux Controlled Affiliates anywhere in the world (outside of the Territory) for a Product within the Field, the Parties shall establish a joint committee among Vivus, FemPharm (and/or the Acrux Controlled Affiliate, as the case may be) and any Additional Partner(s) to discuss and coordinate such development of such Product (the "Global Development Committee"). To the extent there are no Additional Partners, and meetings of the Development Committee are ongoing at the time, the function of the Global Development Committee set forth in this Section 5.14 shall be handled by the members of the Development Committee. The primary role of such Global Development Committee shall be to provide a forum for communication

between Vivus, FemPharm (and/or an Acrux Controlled Affiliate(s), as the case may be) and any Additional Partner(s) with respect to activities related to the ongoing preclinical and clinical development of Products in the Field, other than the work under the Development Plan under this Agreement. FemPharm, the Acrux Controlled Affiliates, Vivus, and each Additional Partner having rights to Product in the Field shall each have at least two (2) representatives on such Global Development Committee. Each member of the Global Development Committee shall keep the other members fully informed in English (subject to Section 5.15) as to the ongoing preclinical and clinical development of, and regulatory activities with respect to, such Products in the Field. It is understood and agreed, however, that formal approval of such Global Development Committee shall not be required for any such activities. The Global Development Committee shall meet no less frequently than twice each calendar year, or as otherwise agreed by the Parties, until the termination or expiration of this Agreement and each of Vivus, FemPharm, Acrux Controlled Affiliates, and any Additional Parties shall give a full report in English (subject to Section 5.15) at each such meeting of activities relating to the particular Products to which such Party, the Controlled Affiliate, Acrux Controlled Affiliate or Additional Partner has rights and that is undergoing preclinical or clinical development in the Field. Additional Partners will participate in such meeting only with respect to Products for which they have rights in the Field.

5.15 NO OBLIGATION TO TRANSLATE

It is understood and agreed that any documents to be provided by FemPharm, an Acrux Controlled Affiliate, Vivus, or Additional Partner under Section 5.14 may be provided in the language in which such documents exist, and FemPharm, the Acrux Controlled Affiliate, Vivus, and the Additional Partners shall not be obligated to provide translations of such documents (except to the extent such translation has already been prepared).

5.16 INFORMATION AND RESULTS

Except as otherwise agreed by FemPharm in writing, Vivus shall make available and disclose to FemPharm, no less often than once every six (6) months, in the form selected

by Vivus and reasonably acceptable to Vivus, and to the extent not previously disclosed, all patient results from Clinical Trials by Vivus or its Affiliate on Products under this Agreement and all Regulatory Materials prepared by Vivus or its Affiliate, including any NDA filed by Vivus or its Affiliate with the FDA for a Product under this Agreement. It is understood that inadvertent failure to disclose any of the foregoing information will not be deemed a breach, provided that Vivus makes the disclosure of such information promptly after becoming aware that such information has not been disclosed. To the extent Vivus has the right to provide such patient results from the Clinical Trials by its sublicensees on Products under this Agreement, Vivus will also make such results available in the manner described above. Vivus agrees to use good faith, diligent efforts to obtain such rights from its sublicensee. If the NDA is filed by a sublicensee Vivus, Vivus will use good faith, diligent efforts to obtain the right to disclose the NDA to FemPharm. As between Vivus and FemPharm, each Party will own all results and data that it generates, subject to any licenses granted under this Agreement to the other Party. In particular, as between Vivus and FemPharm, Vivus will own all clinical data and results of testing Product generated by Vivus under this Agreement (the "Data"). FemPharm and its Affiliates have the right to use all Data required to be delivered by Vivus solely in developing and seeking regulatory approval of a Product in the Field in Australia and New Zealand, and no Data, Regulatory Materials, or other Know-How provided by Vivus shall be used for any other purpose, such as without limitation for purposes of development or marketing approval for a country other than New Zealand and Australia, except as otherwise agreed by the Parties in a separate writing. Such Know-How will be disclosed to licensees of FemPharm and the Acrux Controlled Affiliates for Australia or New Zealand only to the extent the licensee provides equivalent disclosure to Vivus and Vivus' sublicensees.

5.17 PRODUCT FAILURE

- (a) Technology Failures. In the event the Product experiences significant technical issues that arise out of or relate to the MDTs system, including failure of the MDTs system to deliver Estradiol, or another Estrogen added to the Field in

accordance with this Agreement, in a manner suitable for development or commercialization of a Product in the Field and Territory, inadequate physical or chemical stability of any portion of the MDTS system, issues arising out of any Acrux Penetration Enhancer or any other formulation developed by FemPharm and used in an MDTS system, or other issues that significantly impact the efficacy, toxicity, safety, or ability to obtain approval, then, to the extent that Vivus reasonably concludes that the issue would likely prevent the approval of the Product in the Field and Territory by the FDA or other appropriate regulatory authority or cause the Product to not be commercially viable, Vivus shall have the right, subject to the terms of Section 5.17(b) below, to select for addition to the Field, and development and commercialization in the Territory under this Agreement as an alternate Product, an alternate Estrogen (excluding any Estrogen (other than a Restricted Estrogen) for which FemPharm or its Affiliate has commenced Clinical Trials, or which FemPharm or its Affiliate has licensed to a non-Affiliate third party in a fully arms length transaction, in conformance with Section 2.5(b)) or alternate configuration of the MDTS technology.

- (b) Upon selection by Vivus of an alternate Product pursuant to Section 5.17(a) above, development and commercialization of the selected Product shall be in accordance with the terms of this Agreement, including the same milestone payments and, if the alternate Product is based upon another Estrogen, no greater royalties than those set forth in Article 4, except that (i) Vivus shall not be required to pay under Section 3.2 any milestone payments for achieving a milestone for which a milestone payment previously was made for a Product, and (ii) the Parties shall discuss in good faith and agree on new, appropriate diligence milestones dates in Section 6.2 for such alternate Product. If Vivus does not select such alternate Product within 90 days of Vivus concluding that the issue will prevent the original Product from being approved or commercially viable, then the Agreement shall terminate under Article 14, with the effects of such termination being the same as if terminated by Vivus under Section 14.3(d).

5.18 SUBCONTRACTS

Subject to the provisions of this Agreement, Vivus may subcontract to third parties portions of the Development Plan to be performed by Vivus, provided Vivus agrees to keep the Development Committee reasonably informed of any contract research organizations or other contractors hired by Vivus, and provided further that such subcontractors are subject to confidentiality provisions consistent with the terms of this Agreement, and that Vivus remains responsible for all work performed by such subcontractors.

5.19 CLINICAL PRODUCT SUPPLY

Except as otherwise provided in this Agreement, as between the Parties, Vivus is solely responsible for all manufacturing of its requirements of the Product for use in development throughout the Territory. Vivus will use diligent, reasonable efforts to manufacture, or to have its designee manufacture, sufficient quantities of the Product meeting all applicable specifications and legal requirements in a timely manner for use in conducting the development of the Product in the Territory pursuant to the Development Plan.

6. DILIGENCE OBLIGATIONS

6.1 PRODUCT DEVELOPMENT DILIGENCE OBLIGATIONS

Each Party will use diligent, commercially reasonable efforts to perform all the tasks and responsibilities assigned to it in the Development Plan in accordance with the development schedule set forth in the Development Plan, in an effort to obtain all necessary regulatory approvals in the Territory. If Vivus knows that it will be unable to meet any timeline or milestone date set out in the Development Plan, then it will bring the matter to the attention of FemPharm at the next Development Committee meeting or, if Vivus reasonably concludes that the delay is caused by a significant issue that is likely, unless it can be addressed by additional work, to prevent the Product from being approved by the FDA, as soon as reasonably practicable. The Development Committee

will discuss in good faith the causes of any such delays and Vivus' suggested courses of action to complete the subject tasks and determine whether to return the Product development program to the schedule in the Development Plan or to reasonably adjust the schedule. In such process, the Development Committee shall extend reasonably the timeline or milestone dates in the Development Plan unless the delay was a result of a material breach by Vivus of its obligation to use diligent, commercially reasonable efforts in the development of the Product.

6.2 DILIGENCE PAYMENT FOR DEVELOPMENT DELAYS

If Vivus (including its Affiliates and sub-licensees) does not achieve the milestone event listed in Section 3.2(a) by its Outside Date (as defined below), then within ten (10) Business Days after the end of each full month of delay after the applicable Outside Date, Vivus will pay to FemPharm (*) percent (* %) of the milestone payment associated with the delayed event, until the corresponding milestone payment is paid in full, either as a result of meeting the milestone or as a result of such diligence payments. As used herein, "Outside Date" means with respect to the Section 3.2(a) milestone (*). To the extent any diligence payments are made under this Section 6.2, and the milestone is achieved before the corresponding milestone payment has been paid in full, then upon achieving the milestone Vivus shall pay the amount of the milestone payment, reduced by the amount of payments for that milestone made under this Section 6.2. If the Section 3.2(a) milestone payment is paid in full as a result of this Section 6.2, then such payment will be deemed to satisfy the payment obligation under Section 3.2(a), and no further payment shall be due or payable as a result of completion of the particular milestone by any Product. However, if Vivus' inability to meet a milestone event by the applicable Outside Date is caused by delays outside of Vivus' reasonable control, that are circumstances described in subsection (a)-(d) below, then the Parties will meet and agree on reasonable adjustment to the Outside Date to accommodate such delays, provided that Vivus has used diligent, commercially reasonable efforts to meet the milestone events. The fact that payments become due or payable under this Section 6.2 shall not, itself, necessarily mean or suggest that there has been a lack of diligence by Vivus. For purposes of this Section 6.2, delays due to the following matters will be considered outside of Vivus' control:

- (a) a change in the specifications of the Product, or in the planned development of the Product, required by the FDA or other regulatory authority due to the medical, regulatory or scientific attributes of the Product, that necessitates additional development effort beyond that set forth in the Development Plan or contemplated when establishing the schedule in the Development Plan;
- (b) other delays in development caused by the FDA, or other regulatory authority, that were reasonably unanticipated by Vivus; or
- (c) delays caused by FemPharm not conducting its responsibilities as set out in the Development Plan in a timely manner.
- (d) Additional clinical development work required or necessary for approval in USA to be conducted due to new findings from the Women's Health Initiative Study or failure of the studies conducted under the Development Plan to show sufficient levels of efficacy or safety, or the data is otherwise equivocal.

6.3 REVERSION FOR FAILURE OF DILIGENCE.

If at any time prior to achieving regulatory approval of the Product Vivus fails to use, and/or to continue using, diligent, commercially reasonable efforts to develop the Product in the Territory during the term of the Agreement, then FemPharm may give Vivus written notice of such failure of diligence. If Vivus does not commence within ninety (90) days of such notice using diligent, commercially reasonable efforts to develop Product in the Territory, then FemPharm may no later than ninety (90) days after such failure provide the notice of termination of this Agreement, including the license and other rights granted to Vivus, under Section 14.2(a), but only if such failure constitutes a material breach of this Agreement by Vivus, and subject to Section 15.10.

7. REGULATORY MATTERS

7.1 REGULATORY MATERIALS

- (a) Vivus is solely responsible for preparing and filing all Regulatory Materials for the development of the Product in the Territory except as otherwise set forth in this Agreement, including carrying out all registration and approval procedures necessary to comply with all appropriate laws and regulations relating to the manufacture, packaging, import, promotion, advertising and sale of the Product in the Territory. All costs incurred by Vivus with respect to such registrations and approvals will be borne by Vivus. FemPharm has the right to review and comment on all such Regulatory Materials prepared by Vivus, including application for registration and regulatory approval, (to the extent disclosure of same does not violate confidentiality obligations) and to the extent reasonably practicable Vivus will consider all such comments provided to Vivus in advance of filing. Vivus will use good faith efforts to obtain for FemPharm the right to so comment on Regulatory Materials from Product of Vivus' sublicensees under the Licensed Intellectual Property. Similarly, Vivus has the right to review and comment on all Regulatory Materials for Product developed by or under authority of FemPharm or an Acrux Controlled Affiliate in the Field outside the Territory (to the extent disclosure of same does not violate confidentiality obligations, subject to the following), and FemPharm, the Acrux Controlled Affiliate, or licensee, as the case may be, shall provide Vivus with a reasonable opportunity to provide comments and consider all of Vivus' comments provided to FemPharm in advance of filing to the extent reasonably practicable.
- (b) FemPharm and its Affiliates and licensees (subject to the last sentence of Section 5.16) have a right of reference (at no cost to them) to the NDA and other Regulatory Materials filed by Vivus for the Product in the Field and Territory, which right of reference shall be solely for Australia and New Zealand as part of the development, approval and commercialisation of the Product in the Field for such countries, and such Regulatory Materials shall not be referenced by or under

authority of FemPharm or any Acrux Controlled Affiliate for any other country or Product. FemPharm is solely responsible for carrying out all of its registration and approval procedures necessary to comply with all appropriate laws and regulations relating to the manufacture, packaging, import, promotion, advertising and sale of such Product in the Field in Australia and New Zealand. Without limiting the other terms of this Agreement, each Party will provide the other Party (at no cost to such other Party) with reasonable telephone support to respond to such other Party's questions regarding the Regulatory Materials and supporting materials that it is required to disclose under this Agreement.

7.2 RELATIONSHIP WITH REGULATORY AUTHORITIES

Vivus, as the sponsor of the Regulatory Materials for the Product in the Territory, has sole responsibility for interacting with all regulatory authorities in the Territory with respect to the Product in the Field, including meetings with such regulatory authorities, and responding to inquiries of and conducting other communications with such regulatory authorities, with regard to such Regulatory Materials or the Product. Vivus has sole authority and responsibility for all regulatory obligations regarding the Product in the Field in the Territory, including, but not limited to, the regulatory approval applications and registrations and related materials, all promotional materials, Product labeling, responding to medical inquiries, and Product complaints relating to the Territory, except as otherwise provided in this Agreement or the Development Plan, or determined by the Development Committee. Similarly, FemPharm, as the sponsor of its Regulatory Materials for the Product in the Field in Australia and New Zealand, has sole responsibility for interacting with all regulatory authorities in Australia and New Zealand with respect to its development of such Product in the Field for such countries, and for all such other regulatory obligations in its development of the Product in Australia and New Zealand. Each Party will provide the other Party with reasonable advance notice of, and any preparatory material for, any hearing before, or meeting with, any regulatory authority regarding the Product in such Party's territory (I.E., the Territory in the case of Vivus, and Australia and New Zealand in the case of FemPharm), and such other Party

has the right to have two (2) of its employees attend such hearings or meetings at its own cost, to the extent the Party responsible for the meeting has the right to include them and is reasonably practicable under the circumstances. All such materials, and information learned in connection with such meeting or hearings, shall be treated as the Confidential Information of the Party disclosing the materials or conducting the meeting.

7.3 ADVERSE EVENTS AND COMPLAINTS REPORTING

The Parties agree that appropriate reporting of adverse events and other safety data relating to the Product is critical. Specific details regarding the management of information of adverse events, medical inquiries and Product complaints related to the use of the Product in the Territory and outside will be delineated in a separate document, to be agreed to by the Parties within ninety (90) days after the Effective Date. The pharmacovigilance and product labeling representatives of each Party will work in good faith together to develop a document that identifies:

- (a) which safety information will be exchanged;
- (b) when such information will be exchanged;
- (c) how the global safety database will be established;
- (d) which Party will be obligated to obtain follow-up information on incomplete safety reports;
- (e) which Party will review the literature for safety report information;
- (f) which Party will prepare required periodic safety updates; and
- (g) the identification of any other details required to appropriately manage safety information for the Product.

Subject to any specific details of the above document, it is expected that Vivus will be responsible for pharmacovigilance, adverse reaction reporting and related matters for Products inside the Field in the Territory, and that FemPharm shall be responsible for

pharmacovigilance, adverse reaction reporting and related matters for Products in the Field in all countries outside of the Territory. The Parties also agree to use good faith, reasonable efforts to reach agreement with any of their respective licensees (or sublicensees, as applicable) of Products in the Field to include such entities in the pharmacovigilance and related safety and adverse event reporting document discussed above.

8. PRODUCT COMMERCIALIZATION

8.1 OVERVIEW

Vivus has the exclusive rights, subject to the terms of this Agreement, to promote, market, distribute and sell Product for use in the Field throughout the Territory, itself and/or through its Affiliates and sub-licensees.

8.2 COMMERCIALIZATION OBLIGATIONS

Vivus hereby covenants and agrees with FemPharm, during the term of this Agreement commencing with regulatory approval of the NDA for the Product by the FDA in the Field and Territory (permitting marketing of the Product in the Territory), to:

- (a) actively and diligently promote the sale of the Product using commercially reasonable efforts in the Territory;
- (b) not, and to require that its Controlled Affiliates and sub-licensees do not, sell the Product licensed hereunder outside the Territory nor sell such Product to any person which it knows, or for which it has been provided reasonable documentation, is selling such Product outside the Territory, each to the extent set forth in Section 2.6; and
- (c) provide for and maintain, or cause to be provided for and maintained, a sales organisation and a marketing program reasonably adequate and competent to promote, stimulate interest in, and sell the Product effectively in the Territory, for a commercially reasonable period of time after commercial launch.

Additionally, each Party hereby covenants and agrees, during the term of this Agreement, to:

- (1) use reasonable efforts to comply with all governmental and municipal laws, regulations and requirements relating to the manufacture, packaging, promotion, advertising, distribution and sale of the Product;
- (2) take out and maintain at its cost during the term of this Agreement and for a reasonable period of time thereafter whilst any liability may occur to such Party as a result of its distribution of the Product, product liability insurance in the name of such Party in respect of the manufacture, distribution, sale, use and consumption of the Product by such Party for an amount consistent with industry standard practices and will duly and punctually pay all premiums in respect of such insurance and provide evidence of such insurance and payment of premiums to the other Party when so requested; and
- (3) not make any fraudulent misrepresentations in respect of the quality or contents of the Product.

8.3 COMMERCIALIZATION PLANS

No later than twelve (12) months prior to the expected launch of First Commercial Sales of the Product in the Territory, Vivus will provide to FemPharm a commercial launch plan (the "Commercial Launch Plan"), which will set forth in reasonable detail Vivus' actual plan and budget for the launch and initial marketing and promotion of the Product, including the trademarks to be used in such marketing. Such Commercial Launch Plan will include non-binding sales projections for the Product for at least two years from the planned First Commercial Sale. The form of the Commercial Launch Plan and the amount of detail included will be as established by the Steering Committee. For each full calendar after the First Commercial Sale, Vivus agrees to provide FemPharm, no later than February 1 of such calendar year, a report that describes in reasonable detail the marketing activities planned to be conducted by Vivus (or its Affiliate) for the Territory during the calendar year, and that sets forth the actual IMS (or related source) audited marketing data showing the actual marketing and promotional activities that were conducted by Vivus (or its Affiliate or licensee) in the Territory for the Product during the previous calendar year.

8.4 LAUNCH DILIGENCE

Vivus (or its Affiliate or sub-licensee) will use diligent, commercially reasonable efforts to launch the Product for commercial sale in the Field in the Territory within six (6) months of obtaining regulatory approval of the Product in the Territory, and will expend such efforts and resources in launching and initial promotion and marketing of the Product in the Territory as are commercially reasonable.

8.5 MANUFACTURE IN TERRITORY

Vivus is solely responsible for all manufacturing of its requirements of the Product for sale in the Field in the Territory. Vivus will use diligent, commercially reasonable efforts to meet market demand for the Product in the Territory.

8.6 SUPPLY OF PRODUCT TO FEMPHARM

Vivus will agree to supply to FemPharm needed amounts of the Product (in final finished and packaged form, according to the specifications of Vivus in the Territory) for use by FemPharm in developing and commercializing Product in the Field in Australia and New Zealand under a mutually acceptable supply agreement on terms that are customary and reasonable. Such Product supplied by Vivus shall be used solely for FemPharm to develop and sell the Product in the Field in New Zealand and Australia. Vivus shall have no obligation to supply any Product other than that being developed or commercialized by Vivus under this Agreement at the then current time. The transfer price for such Product shall be (i) (*) percent (* %) above Vivus' actual purchase price if such Product is purchased by Vivus from a contract manufacturer; and (ii) (*) percent (*%) above Vivus' fully burdened manufacturing costs, as determined consistent with Vivus' standard practices applied consistently across all its operations, if Vivus manufactures the Product. Notwithstanding the foregoing, Vivus shall have no obligation to negotiate under this Section 8.6 until after (*).

9. SUB-LICENSING AND ASSIGNMENT

9.1 SUB-LICENSE

Vivus has the right to grant and authorize sub-licenses, under the rights granted to it in this Agreement, to Affiliates of Vivus and to other third parties, without consent, BUT PROVIDED THAT prior to granting a sub-license to a third Party Vivus shall have disclosed the identity of the proposed third party to FemPharm and shall discuss and consider in good faith any reasonable concerns FemPharm may have with regard to granting a sublicense to such third party, and shall consider in good faith FemPharm's suggestions to address any of its reasonable concerns. Vivus is responsible for the actions of any such sub-licensee, and if such sub-licensee breaches any Vivus obligation under the Agreement, such breach will be deemed a breach by Vivus.

9.2 VIVUS BOUND

In the case of sub-licensing, Vivus remains bound by this Agreement and responsible for performing, or having its sub-licensee perform, all its obligations hereunder, subject to Section 9.1 above. Subject only to Section 5.18 and 9.1, however, nothing shall prevent Vivus from relying upon the performance and efforts of its sublicensees and contractors for purposes of satisfying its obligations under this Agreement, including under Articles 7 and 8, notwithstanding anything to the contrary, such as language in Sections 5.4, 5.19, 7.1(a), 7.2, and 8.5 that indicates that Vivus shall have sole responsibility.

9.3 ASSIGNMENT

Each Party is entitled to assign and otherwise transfer without consent all its right, title and interest in this Agreement, including its obligations, to any other Person that acquires all or substantially all of such Party's business or assets, whether by asset purchase, merger, acquisition or other similar transaction, PROVIDED THAT such Person agrees in

writing to be bound by the terms hereof as the successor in interest or assignee. Any other attempt to transfer or assign shall be void without the prior written consent of the other Party. If a Party is acquired by another corporation or other entity that was not its Affiliate prior to the acquisition, then no Intellectual Property rights of the acquiring entity developed prior to the acquisition, or developed thereafter without using the Licensed Technology, shall be included in the rights licensed to the other Party under this Agreement.

10. CONFIDENTIALITY

10.1 RESTRICTIONS ON USE

Subject to the further provisions of this Article 10, each Party agrees that it will keep all Confidential Information disclosed to it by the other Party secret and confidential, and will not disclose it to any third party, or use it for its own benefit or the benefit of any third party, except that either Party may use and disclose the other Party's Confidential Information:

- (a) for the purposes of exercising the licenses and other rights granted by this Agreement; or
- (b) as otherwise permitted with the prior written consent of the other Party.

Any disclosure authorized in accordance with the foregoing shall be subject to reasonable confidentiality provisions materially as protective of the Confidential Information as the terms of this Agreement.

10.2 USE OF OWN INFORMATION

Except for Section 10.13, nothing in this Article 10 prevents a Party from disclosing or dealing in its absolute discretion with any of its own Confidential Information, provided that FemPharm will use reasonable efforts to keep its Confidential Information relating to the Product and the Field secret and confidential so as to avoid any adverse affect on the value or protection of the Licensed Intellectual Property to the extent relevant to the Field and the Territory and further provided that such disclosure and dealing by FemPharm shall be subject to the other terms of this Agreement, including Sections 2.1 and 10.13.

10.3 EXCEPTIONS TO CONFIDENTIALITY

The obligations of confidentiality and non-use as provided in Section 10.1 above do not extend to, and notwithstanding Section 1.1 Confidential Information shall not include, any particular information or Know-How received by a Party that it can demonstrate by competent evidence:

- (a) was available to the public or otherwise in the public domain prior to receipt by such Party, or subsequent to such receipt becomes available to the public or part of the public domain, other than as a result of a breach of this Agreement;
- (b) was already known to the recipient Party by lawful means at the time of receipt (including trade secrets and inventions not disclosed in existing patent applications) other than directly or indirectly from the other Party;
- (c) was obtained by the recipient Party from a third party who has a lawful right to disclose it, provided that the information has not been obtained directly or indirectly from the other Party to this Agreement and is not subject to an obligation of confidentiality; or
- (d) was independently developed by the receiving Party without use of the other Party's Confidential Information.

10.4 EXCEPTIONS TO NON-DISCLOSURE

Notwithstanding the restrictions of Section 10.1, a Party may disclose the Confidential Information of the other Party beyond the disclosure authorized in Section 10.1, subject to compliance with the following provisions of this Section 10.4, solely to the extent such disclosure:

- (a) is to its professional advisors, and provided that such disclosure is reasonably necessary or desirable and is subject to reasonable confidentiality protections;
- (b) is required by any court or other judicial or quasi-judicial tribunal or any administrative or government body, or as is required by law, provided that such disclosure is no more than is necessary to avoid the imposition of a penalty for failing or refusing to disclose the Confidential Information, and that the Confidential Information is disclosed in such a way as to limit as far as possible the disclosure of the Confidential Information, and that such disclosing Party first complies with Section 10.5; or
- (c) as reasonably necessary in prosecuting or defending any litigation or enforcing this Agreement, provided that such Party has first notified the other Party giving full details of the circumstances of the required disclosure and of the relevant information to be disclosed and takes reasonable steps to preserve the confidentiality of the information.

10.5 DISCLOSURE BY LAW

Before any disclosure in reliance on Section 10.4(b), the Party subject to the disclosure obligation must, unless it is not practicable to do so:

- (a) immediately notify the other Party giving full details of the circumstances of the required disclosure and of the relevant information to be disclosed;
- (b) to the maximum extent permitted by law give the other Party a reasonable opportunity in a court of law or other appropriate body to:
 - (i) challenge the proposed disclosure;
 - (ii) challenge the obligation of the Party or any other person to make that disclosure; and/or

(iii) secure a protective order or other ruling limiting or preventing the disclosure and/or to protect or preserve the confidentiality of the relevant information; and

(c) take reasonable steps to preserve the confidentiality of the information being disclosed and to comply with any such protective order or ruling.

10.6 SCOPE OF CONFIDENTIALITY

In the case of uncertainty as to the confidentiality of any information a Party must treat the information as Confidential Information until such Party or the other Party confirms that the information is not Confidential Information.

10.7 SECURITY OF INFORMATION

Each Party must use its reasonable endeavours to minimise the risk of disclosure of any Confidential Information of the other Party, by providing reasonable security of its premises, its records and materials.

10.8 PERSONNEL CONFIDENTIALITY

Each Party agrees to procure written and signed confidentiality and non-publication undertakings with respect to the Confidential Information of the other Party, in terms materially as protective of such other Party's Confidential Information as this Article 10, from all employees, agents and contractors of such Party who have or are likely to have access to Confidential Information of the other Party.

10.9 RETURN OF CONFIDENTIAL INFORMATION

Upon termination of this Agreement, each Party may by written notice to the other Party demand the return of all tangible property comprising Confidential Information provided by such Party, but only to the extent set forth in Article 14 and provided that Vivus shall not be required to return any product.

10.10 PUBLICATIONS

Neither Party shall make or authorize any oral public disclosure, or any submission to any outside person for publication of an abstract or manuscript, disclosing the Confidential Information of the other Party, including any scientific data resulting from the other Party's non-clinical development or clinical development under this Agreement, in each case except to the extent approved in writing by such other Party or as otherwise permitted in this Article 10.

10.11 OTHER RIGHTS

Nothing herein contained excludes the right of either Party at common law or in equity to protect its Confidential Information by application to any court for injunction or otherwise. Notwithstanding anything to the contrary in this Article 10, the Parties agree that the use and disclosure of concepts and information retained in the unaided memories of individuals who had access to Know-How from the other Party shall not be considered a breach of the terms of this Agreement. This Section 10.11 shall not be construed to grant any rights under any Patent in such concepts.

10.12 USE OF OTHER PARTY'S NAME

Neither Party shall make any use of the other Party's name unless approved by the other Party in writing, such approval not to be unreasonably withheld, or in the circumstances set forth in Section 10.13.

10.13 PRESS RELEASES AND OTHER DISCLOSURES

The Parties will issue a joint press release, in the form attached as annexure D, promptly after the Effective Date. The Parties agree that no other publication or other public disclosure of the terms of this Agreement will be made by a Party without the consent of the other Party, (with failure to respond to any request for consent beyond ten (10) days from the request to be deemed consent), such consent not to be unreasonably withheld.

Notwithstanding the foregoing, a Party may make disclosures authorized pursuant to Section 10.10 and may disclose the terms of this Agreement:

- (a) to the extent required by law or regulation or court order, or by the rules of any stock exchange on which the stock or shares of the Party or any of its Affiliates are listed or other government body; and
- (b) in confidence to its professional advisors, and its existing or potential investors, acquirors, and merger partners on a need to know basis under conditions which reasonably ensure the confidentiality thereof;
- (c) in confidence, pursuant to non-disclosure and non-use restrictions at least as stringent as included in this Article 10, to other parties that have a need to know such information for a purpose related to this Agreement;
- (d) in connection with the enforcement of this Agreement or rights under this Agreement;
- (e) in confidence as is reasonable in connection with a merger, acquisition of stock or assets, proposed merger or acquisition, or the like;
- (f) as advisable or required in connection with any government or regulatory filings, including filings with the SEC; provided however, prior to any such disclosure the non-disclosing Party shall be allowed to review the proposed disclosure, and the disclosing Party agrees to consider in good faith any proposed revisions thereof provided to the disclosing Party within ten (10) Business Days of the non-disclosing Party's receipt of the proposed disclosure and the Party making such disclosure shall seek confidential treatment for such disclosure as permitted by applicable law in a similar manner to the actions it takes for its other information of like kind.

11. INVENTIONS

11.1 DISCLOSURE OF INVENTIONS

During the term of this Agreement, each Party will promptly disclose to the other Party the Inventions invented jointly by employees of both Parties and for which the disclosing Party desires to seek Patent protection, and Vivus will promptly disclose to FemPharm all Improvements, provided that Vivus shall not be considered in breach of such disclosure obligation as a result of an inadvertent failure to disclose an Invention so long as Vivus promptly discloses the Improvement after discovering the failure to disclose.

11.2 OWNERSHIP OF INVENTIONS AND INTELLECTUAL PROPERTY RIGHTS

As between the Parties, each Party (or its Affiliate) will own the entire right, title and interest in and to all the Inventions made by such Party's (or its Affiliate's) employees or others acting on behalf of such Party or Affiliate and all Intellectual Property rights in and to such Inventions, subject only to the licenses and other rights (if any) to the extent granted to the other Party thereto under this Agreement.

11.3 JOINT INVENTIONS AND JOINT PATENTS

All right, title and interest in all Patents to the extent claiming Inventions invented jointly by the employees of both Parties ("Joint Inventions") will be owned jointly by FemPharm and Vivus (that is, each Party having an equal and undivided interest therein). Patent filings to the extent claiming a Joint Invention will be conducted as set out in Section 12.2. Neither Party may assign its interest in any Joint Patent unless notice of such transfer has been first given to the other Party and the transferee agrees in writing to be bound by the terms of this Agreement with respect to the interest so transferred and as otherwise set forth in Section 9.3. Except as otherwise expressly provided in this Agreement, neither Party shall have any obligation to account to the other for profits, or to obtain any consent of the other Party to license or exploit, Joint Inventions (whether or not patented) or Joint Patent, by reason of joint ownership thereof, and each Party hereby waives any right it may have under the laws of any jurisdiction to require any such consent or accounting.

11.4 COOPERATION OF EMPLOYEES

Each Party represents and agrees that all employees acting on its behalf in performing its obligations under this Agreement will be obligated under a binding written agreement to assign to such Party, or as such Party will direct, all inventions made or conceived by such employee.

12. PATENTS AND INTELLECTUAL PROPERTY

12.1 PATENT RIGHTS

All right, title and interest owned by a Party in Intellectual Property will remain owned and retained exclusively by such Party, subject only to the applicable license and other rights granted to Vivus and FemPharm in this Agreement. FemPharm will have sole responsibility for and control over, at its discretion, the filing, prosecution, maintenance and enforcement of the FemPharm Patents, at FemPharm's expense, except as otherwise provided below. FemPharm shall use diligent commercially reasonable efforts to obtain and maintain at all times broad Patent protection for the Products in the Field and Territory under this Agreement, including by using reasonable efforts to prepare, file, prosecute and maintain Patents as desirable for Products in the Field and Territory and to pursue as appropriate interferences, re-examinations, reissues, oppositions and similar proceedings regarding the FemPharm Patents. During the term of this Agreement and thereafter to the extent Vivus has surviving rights, FemPharm will keep Vivus reasonably informed regarding the status, preparation, filing, prosecution and maintenance of all patent applications and patents included or to be included in the FemPharm Patents licensed to Vivus pursuant to Section 2.1 (including inventions for which Vivus may desire to have a Patent application filed), and without limiting the foregoing will reasonably consider, and give Vivus a reasonable opportunity to provide, comments on such preparation, filing, prosecution, or maintenance efforts that relate to Product, the

Field or the Territory. FemPharm may elect to cease preparing, filing, prosecuting or maintaining any particular FemPharm Patent, or to cease diligently pursue any interferences, re-examinations, reissues, oppositions or similar proceeding relating to a particular FemPharm Patent, but only to the extent that FemPharm has provided to Vivus, as far in advance as practicable, written notice describing its intent and, to the extent desired by Vivus, has reasonably transitioned the preparation, filing, prosecution, and maintenance to Vivus without prejudice to Vivus' rights under this Agreement. If Vivus then undertakes such activities, Vivus shall bear all of its actual out of pocket costs and expenses incurred in such activities, and may credit against amounts subsequently owed to FemPharm under this Agreement any such actual costs and expenses borne, subject to providing FemPharm with receipts and invoices and other documents as is reasonable to properly evidence the costs and expenses and payment thereof. FemPharm shall use reasonable efforts to cooperate and provide such documents and assistance as is reasonably requested, in connection with such activities by or under authority of Vivus.

12.2 JOINT PATENT RIGHTS

As to each Joint Invention, the Parties will discuss and reasonably agree on whether and where to file a Joint Patent claiming the Joint Invention, and on which Party shall assume responsibility for the preparation, filing, prosecution and maintenance of such Joint Patents, in each country in the world for which prosecution of the Joint Patent is desired by a Party. The Parties will share equally in the expenses of such activities related to Joint Patents. Each Party will reimburse the other for its share of such expenses borne by the other Party upon written request, no less frequently than quarterly and shall cooperate and provide such documents and assistance as is reasonably requested in connection with such activities. Each Party will keep the other reasonably informed of, and consult with the other Party with respect to, all significant actions in the course of such Party's prosecution of the Joint Patents. If the Party having responsibility for prosecuting a particular Joint Patent elects not to assume or continue such responsibility, the other Party will have the right, but not the obligation, to do so. If either Party elects not to continue to support prosecution or maintenance of a particular Joint Patent, it may do so on written

notice to the other Party, and in such case it will assign its entire interest in such Joint Patent to the other Party if such other Party elects to prosecute and maintain such Joint Patent at its sole expense; subject to any licenses and exclusivity in this Agreement. Upon any such assignment, the Party that elected to discontinue its involvement, and assign its interest, shall not be required to bear any expenses under this Section 12.2.

12.3 FEMPHARM PATENT PROCEEDINGS

Each Party will promptly notify the other of any legal proceedings, including opposition or declaration of invalidity proceedings, initiated or pursued by any third party against any of the FemPharm Patents. FemPharm has the sole right and authority to defend against any such proceedings, including defending against any defenses or counterclaims of invalidity or unenforceability (including such counterclaims as may arise out of an infringement claim under Section 12.4). For clarity, all infringement actions involving a Field Infringement (as defined in Section 12.4) shall be pursued under Section 12.4, and FemPharm shall have the right to control only the defense of the FemPharm Patents in such Field Infringement actions in the event that a defense or counterclaim is asserted against the FemPharm Patents, shall use reasonable efforts, in such defense, not to adversely impact the Field Infringement action by Vivus. FemPharm will keep Vivus reasonably informed of the actions taken to defend the FemPharm Patents and the progress of such actions. In such case, only (*) % of FemPharm's costs and expenses of such involvement shall be reimbursed out of the recovery in the Field Infringement action. Vivus will provide FemPharm with reasonable assistance and cooperation in such actions, at FemPharm's sole expense, in an effort to obtain a successful resolution or termination of such proceedings or counterclaims governed by this Section 12.3. Vivus will have the right to have counsel of its choosing participate in any such defense of the FemPharm patents, at its sole expense, subject to Section 12.4. FemPharm will not settle any claim, suit or action involving FemPharm Patents in any manner that would materially negatively impact upon the FemPharm Patents, the Licensed Intellectual Property, or Vivus' rights or exclusivity thereunder, or that would materially negatively impact upon or limit or restrict the ability of Vivus to sell the Products in the Territory.

12.4 INFRINGEMENT PROCEEDINGS IN THE FIELD

Each Party will promptly notify the other if it becomes aware that any third party is infringing any FemPharm Patent in the Territory. If any third party is infringing, or believed to be infringing any FemPharm Patent in the Territory in connection with the exploitation, making, use, import, offer for sale, or sale of a product in the Field in the Territory (a "Field Infringement"), then the Parties will promptly thereafter meet and discuss in good faith appropriate steps to take to cause such Field Infringement to cease.

- (a) Vivus or its designee has the first right and authority, but not the obligation, to take reasonable steps to cause termination of such Field Infringement, which may include initiating a lawsuit or other appropriate legal action, at its expense, as Vivus or its designee reasonably determines is appropriate; provided that Vivus agrees that it will not initiate a lawsuit asserting infringement of the FemPharm Patents unless it has first discussed the matter with FemPharm. Vivus will keep FemPharm reasonably informed of the actions taken to cause termination of a Field Infringement and the progress of any such actions (including notifying FemPharm promptly if the third party raises any defenses or counterclaims of invalidity or unenforceability of any FemPharm Patents). FemPharm will provide Vivus or the designee with reasonable assistance and cooperation in such actions, at Vivus's or the designee's expense (other than as set forth in Section 12.3), including joining such action as a party plaintiff and taking such other actions as are required by applicable law for Vivus or the designee to pursue such action. FemPharm will have the right to have counsel of its choosing participate in any such action, at its sole expense, provided that Vivus will have the right to control the action. Vivus will not settle any claim, suit or action that it brought under this Section 12.4 involving FemPharm Patents in any manner that would negatively impact upon the FemPharm Patents or the Licensed Intellectual Property without FemPharm's consent, not to be unreasonably withheld or delayed.
- (b) If Vivus and its designees have not, within four (4) months of request by FemPharm, initiated and pursued reasonable efforts to cause such Field

Infringement to cease, then each Party (and Vivus' designees) shall thereafter have the right and authority, but not the obligation, to take any such steps or actions at its expense. Whichever of such parties first does so shall thereafter control the action and the other Party will provide the controlling Party (or designee) with reasonable assistance and cooperation in such actions, at expense of the controlling Party or designee (except as set forth in Section 12.3), including joining such action as a party plaintiff and taking such other actions as required by applicable law to pursue such action.

- (c) The Party bringing the suit, action or legal proceedings will:
 - (i) be reimbursed for its costs and expenses associated with bringing the legal proceedings out of the proceeds of any damages or costs recovered or as otherwise provided by agreement between the Parties; and
 - (ii) indemnify the other Party against any liability awarded against such other Party as a result of the subject matter of such suit brought by the indemnifying Party, unless caused by the acts or omissions of the indemnified Party.
- (d) Any amounts remaining out of damages and costs and other amounts recovered from a third party due to infringement of the FemPharm Patents under a suit, action or legal proceeding brought against a Field Infringement, will be retained by the Party that brought the action as follows:
 - (i) if Vivus or its designee brought the action, then Vivus or the designee, as the case may be, shall retain (*) percent (* %) of the recovery and will pay the remaining (*) percent (* %) to FemPharm; and
 - (ii) if FemPharm brought the action, the recovery shall be (*)% to Vivus and (*) % to FemPharm.

12.5 OTHER INFRINGEMENT PROCEEDINGS

For clarity, FemPharm retains the sole and exclusive right to enforce and defend the FemPharm Patents against all third party infringements worldwide, except as otherwise provided in Section 12.4 with respect solely to Field Infringement.

13. REPRESENTATIONS AND WARRANTIES; DISCLAIMERS

13.1 WARRANTY

Each Party, and each Acrux Controlled Affiliate, represents, warrants and covenants that: (i) it has the legal power and authority to enter into this Agreement and to perform all of its obligations hereunder; (ii) it has and will have the right and authority to grant the rights and licenses granted by it hereunder; (iii) this Agreement is a legal and valid obligation binding upon it and enforceable in accordance with its terms; (iv) it has not previously made, and during the term of this Agreement will not make, any commitment or grant or authorization of rights which are in conflict in any material way with, or that will restrict or impair, the rights, licenses, or exclusivity granted to Vivus herein.

13.2 ADDITIONAL WARRANTIES OF FEMPHARM AND THE ACRUX CONTROLLED AFFILIATES

Each of FemPharm and Acrux DDS Pty Limited represents, warrants, and covenants as follows:

(a) it has not received notice that it has failed to comply with, and it has not failed to comply with, any obligation, law, regulation, or order in a manner that will materially adversely affect the rights granted to Vivus under this Agreement;

(b) Annexure B sets forth a list of all FemPharm Patents (whether issued or pending) owned by, or licensed to, any of FemPharm and the Acrux Controlled Affiliates. Except for the Patents listed in Annexure B, there are no Patents related to or useful for Products in the Field that are owned by, or licensed to, FemPharm or any Acrux Controlled

Affiliate. All Patents in Annexure B are owned by FemPharm or an Acrux Controlled Affiliate, except as expressly identified in Annexure B. None of FemPharm and the Acrux Controlled Affiliates shall grant any third party any license or rights under any Patent that is within the FemPharm Patents that derogate from or reduce the license or rights granted to Vivus under this Agreement;

(c) FemPharm has sufficient rights to the FemPharm Patents identified in the annexure B for it to grant to Vivus the exclusive right (with respect to all Persons) under such Intellectual Property, including the right to grant and authorize sublicenses, to exploit, import, export, make, have made, use, offer for sale and sell Products for use in the Field in the Territory;

(d) as of the Effective Date: (i) the existing FemPharm Patents are in full force and effect and not subject to any pending re-examination, opposition, interference or claim of invalidity proceedings, none of the Licensed Intellectual Property is subject to any litigation or similar proceedings, and neither FemPharm nor any Acrux Controlled Affiliate has knowledge of a third party threat of such a proceeding, or of facts that likely would be the basis for instituting such proceeding; (ii) none of FemPharm and the Acrux Controlled Affiliates has reason to believe that any of the existing FemPharm Patents likely will be invalid, unenforceable, or will fail to issue, or that the claims of any pending FemPharm Patent likely will be materially limited or restricted beyond the presently pending claims;

(e) as of the Effective Date, none of FemPharm and the Acrux Controlled Affiliates is aware of any Person that is infringing a FemPharm Patent in the Territory;

(f) FemPharm and/or one of the Acrux Controlled Affiliates have access and rights to all Regulatory Materials filed by or under authority of any of them with regulatory authorities, and the supporting raw data for such materials, relevant to Product and may be useful to support the development or marketing approval of the Product in the Field in the Territory, and has the right to include the same within the Know-how disclosed to Vivus hereunder;

(g) FemPharm has not knowingly failed to provide to Vivus any documents or information requested by Vivus as part of its due diligence process, and FemPharm and Acrux DDS Party Limited believe that FemPharm has provided to Vivus, prior to the Effective Date, access to sufficient Know-How Controlled by FemPharm or any Acrux Controlled Affiliate for Vivus to conduct a reasonable and fully informed evaluation of the Licensed Technology and the development status and results relating to the current Product in deciding whether or not to enter into this Agreement, including all adverse information and all relevant agreements. None of the materials provided to Vivus by FemPharm or an Acrux Controlled Affiliate prior to the Effective Date contained any untrue statement of material fact, and to FemPharm's and Acrux Controlled Affiliate's knowledge, none of FemPharm or any Acrux Controlled Affiliate failed to disclose to Vivus, or concealed, any material fact that would, absent such disclosure, make the materials provided to Vivus materially misleading;

(h) as of the Effective Date, to each of FemPharm's and the Acrux Controlled Affiliates' knowledge, none of FemPharm and the Acrux Controlled Affiliates has made an untrue statement of a material fact, or has failed to disclose a material fact, to any regulatory authority with respect to the Product in the Field, or any portion thereof;

(i) Acrux DDS Pty Limited shall use diligent, commercially reasonable efforts to (*). FemPharm and the Acrux Controlled Affiliates shall not terminate, amend or modify (*). FemPharm shall notify Vivus in writing immediately if any of FemPharm, Acrux Limited or the Acrux Controlled Affiliates receives from the licensor of any Licensed Intellectual Property any notice of breach or termination, or any other indication of a dispute or matter that could lead to breach or termination, of the license agreement, or which could otherwise affect Vivus' rights thereunder;

(j) FemPharm will not deliver to Vivus confidential or proprietary Know-How of any third party unless FemPharm has the right to do so for use and disclosure by Vivus in the manner set forth in this Agreement, unless FemPharm expressly identifies at the time of such disclosure the particular Know-How that FemPharm does not have the right to license to Vivus hereunder;

(k) all employees, consultants, and other contractors of each of FemPharm and the Acrux Controlled Affiliates performing work related to or useful for any Product in the Field, including Monash, Barry Reed, William Charman, Dr. Barrie Finnin, and Dr. Tim Morgan in each case to the extent acting as an employee, consultant, or contractor of FemPharm or an Acrux Controlled Affiliate, have been and shall be subject to a written agreement that vests in FemPharm or an Acrux Controlled Affiliate all right, title, and interest in and to their work product, including all associated Intellectual Property rights;

(l) none of this Agreement, or the exercise by or under authority of Vivus of the license rights granted to Vivus under this Agreement, will violate or otherwise be affected by any of the terms or conditions imposed in connection any government funding or sponsorship obtained by FemPharm or an Acrux Controlled Affiliate;

(m) FemPharm and the Acrux Controlled Affiliates are not aware, as of the Effective Date, (1) of any Patent of any third party, including Affiliates, that will be infringed by the manufacture, use import, or sale of a Product in the Field in the Territory, or (2) that any Licensed Know-How in any of their possession, and related to or useful for Product, was misappropriated from a third party.

(n) none of the terms and conditions of the Monash License, including Sections 6, 7, 8.1, 8.3, 12.2, and 19.1 of the Monash License, or the Acrux DDS License bind Vivus;

(o) the FemPharm Patents are not subject to any lien or encumbrance (as defined in the Monash License) that could materially limit or adversely affect Vivus' rights granted under this Agreement;

(p) Acrux Limited is not controlled by any Person, and FemPharm and Acrux DDS Pty Limited, and Cosmeceutical Solutions Pty Limited are the only Affiliates of Acrux Limited that have any interest in (i) any Licensed Intellectual Property, (ii) any Competitive Product or (iii) any technology, product or Intellectual Property related to or useful for the Product in the Field, the delivery of Estradiol or other estrogens, progestins with estrogenic activity, or derivatives of such estrogens or progestins, or the delivery of a selective estrogen receptor modulator, to females, or any transdermal or mucosal delivery; and

(q) none of FemPharm and the Acrux Controlled Affiliates are currently researching or developing, or have current plans to commence research or development of, any MDTs product using Estrogen Monotherapy for the treatment of menopausal symptoms in human females, other than the Product.

13.3 ADDITIONAL WARRANTIES OF VIVUS

Vivus represents, warrants, and covenants to FemPharm that:

(a) Vivus has not received notice that it has failed to comply with, and it has not failed to comply with, any obligation, law, regulation, or order in a manner that will materially adversely affect the rights granted to Vivus under this Agreement;

(b) Vivus has not knowingly failed to provide to FemPharm any documents or information requested by FemPharm as part of its due diligence process, or evaluation of whether or not to enter into this Agreement, except as otherwise stated to FemPharm. None of the materials provided to FemPharm by Vivus prior to the Effective Date contain any untrue statement of material fact, and to Vivus' knowledge, Vivus has not failed to disclose to FemPharm, or conceal, any material fact that would, absent such disclosure, make the materials provided to FemPharm materially misleading;

(c) Vivus will not deliver to FemPharm confidential or proprietary Know-How of any third party unless Vivus has the right to do so for use and disclosure by FemPharm in the manner set forth in this Agreement, unless Vivus expressly identifies at the time of such disclosure the particular Know-How that Vivus does not have the right to license to FemPharm hereunder;

13.4 DISCLAIMER OF WARRANTIES

EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, VIVUS AND FEMPHARM MAKE NO REPRESENTATIONS, WARRANTIES OR CONDITIONS OF ANY KIND, EITHER EXPRESS, IMPLIED, STATUTORY, OR OTHERWISE, AND EACH PARTY HEREBY DISCLAIMS ALL OTHER WARRANTIES, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

13.5 DISCLAIMER OF LIABILITY

EXCEPT WITH RESPECT TO A BREACH OF SECTIONS 2.5, 10, OR THE EXCLUSIVITY IN SECTION 2.1(a), IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER BASED UPON THIS AGREEMENT FOR ANY SPECIAL, CONSEQUENTIAL, INDIRECT, OR INCIDENTAL DAMAGES ARISING OUT OF OR RELATED TO THIS AGREEMENT, HOWEVER CAUSED, ON ANY THEORY OF LIABILITY AND WHETHER OR NOT SUCH PARTY HAS BEEN ADVISED OR IS AWARE OF THE POSSIBILITY OF SUCH DAMAGES.

14. TERM AND TERMINATION

14.1 TERM

This Agreement will continue in full force and effect from the Effective Date until expiration, unless earlier terminated pursuant to Sections 5.17(b), 14.2, 14.3 or 14.8 below, on the date that Vivus no longer has, and shall not have in the future, any payment obligations to FemPharm under this Agreement. Upon such expiration, Vivus retains a non-exclusive, fully-paid license in the Territory to continue to make, have made, use, sell and otherwise exploit Products in the Field.

14.2 TERMINATION BY FEMPHARM

FemPharm is entitled by written notice to Vivus to terminate this Agreement upon the happening of any of the following events, provided that FemPharm provides Vivus with written notice of termination within one hundred eighty (180) days after it becomes aware of the occurrence of the applicable event:

- (a) any material breach by Vivus of any of the terms and conditions of this Agreement, where such breach is not fully cured and rectified within ninety (90) days, or with respect to payment obligations, within forty-five (45) days, after the giving of written notice by FemPharm to Vivus specifying such breach and requiring rectification thereof, provided that if such breach (other than a payment breach) is not capable of cure within the initial ninety (90) day period and Vivus is making diligent good faith efforts to cure, then Vivus shall have an additional ninety (90) days to cure such breach, and subject to Section 15.10, and except as otherwise provided in Section 14.7;
- (b) a petition or other application or resolution being passed against Vivus, or being presented by Vivus, in a bankruptcy proceeding that requires the winding up, liquidation or dissolution of Vivus or notice by Vivus of its intention to propose such a resolution being given;
- (c) the appointment of a receiver, or receiver and manager, for all of Vivus' property in bankruptcy;
- (d) if Vivus (or any of its Affiliates) bring any action, suit, defense or counterclaim seeking to invalidate or have held unenforceable: (i) any claim in any FemPharm Patent in substantially the same form that the claim is issued or pending on July 31, 2003 (an "Existing FP Claim"); or (ii) any claim in a FemPharm Patent filed after July 31, 2003 that is substantially the same as any such Existing FP Claim and that is entitled to an effective filing date (e.g. as defined under 35 USCss.120) that is the filing date of a FemPharm Patent filed prior to July 31, 2003.

14.3 TERMINATION BY VIVUS

Vivus is entitled by written notice to FemPharm to terminate this Agreement upon the happening of any of the following events, provided that Vivus provides FemPharm (except in case of subsection (d)) with written notice of termination within one hundred eighty (180) days after Vivus becomes aware of the occurrence of the applicable event:

- (a) a material breach by FemPharm of any of the terms and conditions under this Agreement or a material breach by an Acrux Controlled Affiliate of its obligations, representations, or warranties in this Agreement, where such breach is not fully cured or rectified within ninety (90) days after the giving of written notice by Vivus to FemPharm specifying such breach or non-observance and requiring rectification thereof, provided that if such breach is not capable of cure within the initial ninety (90) day period and FemPharm and the Acrux Controlled Affiliates are making diligent good faith efforts to cure, then FemPharm shall have an additional ninety (90) days to cure such breach, and subject to Section 15.10;
- (b) a petition or other application being presented or resolution being passed by or against FemPharm, Acrux DDS Pty Ltd, or Acrux Limited in a bankruptcy proceeding that requires the winding up, liquidation or dissolution of the applicable entity, or notice by such entity of its intention to propose such a resolution being given;
- (c) the appointment of a receiver, or receiver and manager, for all of FemPharm's property in bankruptcy or the rejection of this Agreement by any such receiver or manager;
- (d) Vivus has provided sixty (60) days written notice that Vivus is terminating the Agreement for its convenience; or
- (e) if FemPharm (or any of its Affiliates) bring any action, suit, defense or counterclaim seeking to invalidate or have held unenforceable: (i) any claim in

any Patent Controlled by Vivus or its Affiliate in substantially the same form that the claim is issued or pending on July 31, 2003 (an "Existing V Claim"); or (ii) any claim in a Patent Controlled by Vivus or its Affiliate filed after July 31, 2003 that is substantially the same as any such Existing V Claim and that is entitled to an effective filing date (e.g. as defined under 35 USC§.120) that is the filing date of such a Patent filed prior to the July 31, 2003.

Further, in lieu of proceeding under Section 14.3(a), 14.3(b), 14.3(c) or 14.3(e) based upon a particular event, Vivus shall have the right to avail itself of the provisions of Section 14.6 based upon the event, rather than terminating the Agreement in its entirety under Section 14.3(a), 14.3(b), 14.3(c), or 14.3(e), provided that proceeding under Section 14.6 based upon an event shall not prevent Vivus from proceeding under Section 14.3 with respect to any later event covered by Section 14.3.

14.4 NO RELEASE

Termination of this Agreement does not release either Party from any liability that has accrued prior to such termination, or release either Party from any obligation that survives termination of this Agreement.

14.5 CONSEQUENCES OF AGREEMENT TERMINATION

- (a) The terms of this Section 14.5(a) shall apply upon termination pursuant to Section 14.2 or Section 14.3(d), except if Vivus has previously exercised its rights, under Section 14.3(a) or 14.6 to terminate portions of this Agreement pursuant to Section 14.6 due to uncured material breach.
 - (i) Section 2.1 of this Agreement shall automatically terminate, and Section 2.3 shall survive, except rights under Section 2.3(b) shall survive to the extent set forth below.
 - (ii) Upon such termination, Vivus will be deemed automatically to grant to FemPharm a perpetual, irrevocable, royalty-free, fully paid, non-exclusive

license (with full rights to sublicense): (A) under the Improvement Blocking Patent Rights to exploit, import, make, have made, use, offer for sale and sell Products in the Field throughout the Territory; and (B) under the Reversion IP to exploit, import, make, have made, use, offer for sale and sell Products in the Field in the Territory. As used herein, "Reversion IP" means all trade secrets in the Improvements to the extent Controlled by Vivus or its Controlled Affiliate during the term and necessary or reasonably useful for the development, manufacture or commercialization of Products in the Field. Additionally, FemPharm shall have the right under Section 2.3(b) to negotiate toward a non-exclusive license under the Reversion IP for countries outside of the Territory, New Zealand, and Australia, provided that such license shall be royalty free if this Agreement has been terminated by FemPharm under Section 14.2(a) for Vivus' material breach.

- (iii) Upon such termination, Vivus will be deemed automatically to grant to FemPharm the non-exclusive right to access, use and cross reference all Regulatory Materials, including all registrations and regulatory approvals, filed by Vivus with, or obtained by Vivus from, the FDA in the development of Products in the Field and Territory; provided that all access, use or cross reference by and under authority of FemPharm shall be solely for the purpose of development and commercialization of Products in the Field in the Territory. Additionally, the Parties agree that FemPharm's right to negotiate under Section 2.3(b) toward a license under the Reversion IP as set forth in Section 14.5(a)(ii) above includes the right to negotiate toward rights to access, use and cross-reference such Regulatory Materials for countries outside the Territory, New Zealand, and Australia. Notwithstanding anything to the contrary, except as expressly set forth in this Section 14.5(a), no right, license, or exclusivity to or under any Intellectual Property is or shall be granted by Vivus or its Affiliates and Vivus and its Affiliates shall maintain all right, title, and interest in and to all Intellectual Property and

Know-How. Without limiting the foregoing, no right or license is or shall be granted by Vivus or its Affiliates in or to any trademarks, trade names, logos, or the like.

- (iv) To the extent not previously disclosed by Vivus, Vivus will use reasonable efforts for a period of 90 days after termination of this Agreement to disclose and provide copies to FemPharm of all the Data (as defined in Section 5.16) generated by Vivus during the term of the Agreement that Section 5.16 requires Vivus to disclose and provide copies to FemPharm, and FemPharm (and its Affiliates and licensees) shall have full rights to use such Data for developing and exploiting Product in the Field to the extent that FemPharm is licensed to do so, and is licensed to authorize its Affiliates and sublicensees to do so, as set forth in Sections 14.5(a)(ii) and 14.5(a)(iii) above, and provided that such Data shall remain the Confidential Information of Vivus and its Affiliate and sublicensee, as the case may be.
- (v) To the extent provided for in any supply agreement between Vivus and FemPharm pursuant to Section 8.6 above, Vivus will continue to manufacture (or have manufactured) and supply to FemPharm the Product covered by such agreement for use in the Field and Territory until FemPharm is able to obtain its own supply of its requirements of Products for use in the Field and Territory (provided that such period shall not exceed one (1) year) and will work cooperatively and reasonably with FemPharm to achieve a smooth transition of the manufacture of the Reverted Product to FemPharm, and (if applicable) to assist FemPharm in seeking to obtain a manufacturing agreement with Vivus' contract manufacturer of the Reverted Product on commercially reasonable terms, provided that in each case such transition shall not impose an unreasonable burden on Vivus.

- (vi) Vivus shall, within thirty (30) days after termination, return to FemPharm all Confidential Information delivered or provided by FemPharm to Vivus; provided that Vivus shall be entitled to keep a record copy of such Confidential Information and shall not be required to return any product. Article 10 shall survive termination (excluding the obligation to issue a press release under Section 10.13), but only for a period of five (5) years. Notwithstanding termination of Vivus' rights, Vivus and its Affiliates and sublicensees shall have the right to continue to market, sell, offer to sell, and import any Product, in existence at the time of termination, in the Territory for six (6) months after termination PROVIDED THAT the terms of Article 4 will survive and remain in force as to all such sales.
- (vii) In the event an action under Section 12.4 was commenced during the term of the Agreement and is ongoing at the time of termination, Section 12.4 shall continue to apply to the action in accordance with its terms, except that the Party bringing the action for purposes of allocating any recovery under Section 12.4(d) shall be deemed to be the Party controlling the action at the time of termination. If FemPharm assumes control of an action initiated by Vivus, then Section 12.4(c)(ii) shall apply as if FemPharm is the Party bringing the action and all costs and expenses incurred by Vivus in the action prior to the date of termination shall be reimbursed out of any recovery before allocation under Section 12.4(d).
- (viii) Section 14.5(c) shall apply.
- (b) Upon termination of this Agreement pursuant to Section 14.3 (other than 14.3(d)), or upon any termination (but not expiration) of this Agreement after Vivus had previously exercised its rights, under Section 14.3(a) or 14.6, to terminate portions of this Agreement pursuant to Section 14.6 due to uncured material breach, the terms of this Section 14.5(b) shall apply.

- (i) Section 2.1 of this Agreement shall automatically terminate. Notwithstanding termination of Vivus' rights, Vivus and its Affiliates and sublicensees shall have the right to continue to market, sell, offer to sell, and import any Product, in existence at the time of termination, in the Territory for six (6) months after termination PROVIDED THAT the terms of Article 4 will survive and remain in force as to all such sales.
- (ii) Section 2.3(b) shall automatically terminate.
- (iii) Article 10 (excluding the obligation to issue a press release under Section 10.13) shall survive such termination, but only for a period of five (5) years.
- (iv) Each Party shall, within thirty (30) days after termination, return to the other Party all Confidential Information delivered or provided by such other Party, except that it may keep one copy of such information purely for archival purposes and Vivus shall not be required to return Product.
- (v) In the event an action under Section 12.4 was commenced during the term of the Agreement and is ongoing at the time of termination, Section 12.4 shall continue to apply to the action in accordance with its terms, except that Vivus shall be considered the Party bringing the action for purposes of allocating any recovery under Section 12.4(d). If FemPharm assumes control of an action initiated by Vivus, then Section 12.4(c)(ii) shall apply as if FemPharm is the Party bringing the action and all costs and expenses incurred by Vivus in the action prior to the date of termination shall be reimbursed out of any recovery before allocation under Section 12.4(d). For clarity, Vivus shall have the right to continue to pursue any such action commenced by Vivus to the extent desired.
- (vi) Section 14.5(c) shall apply.

- (c) In addition to survival as set forth in Sections 14.5(a) or 14.5(b) above, as applicable, Sections 1.1, 1.2, 4.9, 9.3, 11.1 (excluding Vivus' obligation to disclose Improvements), 11.2, 11.3, 12.2, 13.4, 13.5, 14.1, 14.4, and 14.5 will survive termination of the Agreement for any reason and expiration of this Agreement, except termination under Section 14.8. Article 15 shall survive any such termination and expiration of this Agreement. Except as otherwise expressly set forth in this Section 14.5 above or 14.8, all terms and conditions of this Agreement shall terminate and have no further force or effect upon any termination or expiration of this Agreement, even if termination of the particular Article or Section is not expressly referenced in this Section 14.5 or 14.8. For clarity, the Development Plan shall be deemed terminated and of no further force or effect upon any termination or expiration of this Agreement. Notwithstanding anything to the contrary, no payment shall be due or payable under Section 3 or 6.2 unless the payment became due and payable prior to the date on which the notice of termination was given.

14.6 VIVUS TERMINATION OF SPECIFIC PROVISIONS FOR UNCURED BREACH

If there occurs a material breach by FemPharm of any of the terms and conditions under this Agreement, and such breach is not fully cured or rectified within ninety (90) days after the giving of written notice by Vivus to FemPharm specifying such breach or non-observance and requiring rectification thereof, then, subject to Section 15.10, Vivus may, as described in Section 14.3, (in lieu of proceeding under Section 14.3(a)), cause the following changes to occur under the Agreement:

- (a) The following Sections of the Agreement shall automatically terminate: 2.3(b), 2.6(b), 5.1, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9, 5.10, 5.11, 5.12, 5.13, 5.14 (but only to the extent desired by Vivus), 5.16, 5.19, 7.1(b), 7.2 (except the first two sentences), 8.2(b), 8.2(1), 8.2(2), 8.2(3), 8.3, 8.5, 14.2(d), and 14.5(a). For clarity, all obligations of Vivus to pay reimbursement shall terminate immediately. Vivus shall be entitled to withhold consent to development in the Territory under Section 2.1(c) for any reason or no reason.

- (b) Section 8.6 shall terminate, except for the restrictions on Product purchased from Vivus. The obligation to issue a press release under Section 10.13, and the obligation of Vivus to disclose Improvements under Section 11.1, shall terminate except to the extent otherwise reasonably specified by Vivus. Notwithstanding anything to the contrary, each of FemPharm and the Acrux Controlled Affiliates shall, within thirty (30) days of Vivus' request return to Vivus all Confidential Information delivered or provided by Vivus, except that FemPharm may keep one copy of such information purely for archival purposes.
- (c) Notwithstanding this Section 14.6, Articles 3 and 4 shall survive and remain in force. Section 12.4 shall continue to apply in accordance with its terms, except that if FemPharm assumes control of an action initiated by Vivus, then Section 12.4(c)(ii) shall apply as if FemPharm is the Party bringing the action and all costs and expenses incurred by Vivus in the action prior to the date of Vivus relinquishing control shall be reimbursed out of any recovery before allocation under Section 12.4(d). Section 7.1 shall terminate except for the first and last sentences of Section 7.1(a) which shall survive. FemPharm and the Acrux Controlled Affiliates shall cooperate in any reasonable manner requested by Vivus to achieve a smooth transition to Vivus of any and all Development Plan responsibilities of FemPharm.
- (d) If Vivus elects to exercise its rights under this Section 14.6 due to an uncured material breach by FemPharm of its obligations under Section 2.5(b), then Section 2.5(a) shall be deemed to terminate unless Vivus achieves an injunction that enjoins FemPharm from further violations of the terms of Section 2.5(b).

14.7 LIMITATION OF TERMINATION FOR BREACH AFTER COMMERCIAL LAUNCH

Commencing upon the First Commercial Sale of a Product in the Territory, but subject to Section 15.10, FemPharm shall have the right to terminate the Agreement under Section 14.2(a) only for the following uncured material breaches by Vivus:

- (a) Material breach of the obligations in Section 8.2(a) or 8.2(c);

- (b) Breach of the payment obligations under the Agreement, which breach remains uncured one hundred twenty days after notice.

If Vivus materially breaches any other obligation under the Agreement, and such breach would permit termination of the Agreement under Section 14.2(a) but for this Section 14.7, and such breach is not fully cured or rectified within ninety (90) days after the giving of written notice by FemPharm to Vivus specifying such breach or non-observance and requiring rectification thereof, provided that if such breach (other than a payment breach) is not capable of cure within the initial ninety (90) day period and Vivus is making diligent good faith efforts to cure, then Vivus shall have an additional ninety (90) days to cure such breach, then (subject to Section 15.10) FemPharm shall have the right to cause the following changes to the Agreement on written notice to Vivus (but not to terminate the Agreement in its entirety):

- (i) The following Sections of the Agreement shall automatically terminate: 2.4, 2.7, 5.16, and 5.17.
- (ii) The penultimate sentence of Section 7.1(a) shall terminate. The obligations of FemPharm in the penultimate sentence of Section 7.2 shall terminate, and only the rights of FemPharm under such sentence shall survive.
- (iii) If FemPharm elects to exercise its rights under this Section 14.7 due to an uncured material breach by Vivus of its obligations under Section 2.5(a), then Section 2.5(b) shall be deemed to terminate unless FemPharm achieves an injunction that enjoins Vivus from further violations of the terms of Section 2.5(a).

14.8 TERMINATION FOR FAILURE TO ACHIEVE (*)

Vivus has the right to terminate this Agreement by providing written notice thereof to FemPharm within thirty (30) days after the occurrence of the following: Acrux DDS Pty Limited. has not (*) after the Effective Date that

(*). If Vivus terminates the Agreement under this Section 14.8, then:

- (a) FemPharm shall (*), and (*). Additionally, FemPharm and Acrux Limited shall promptly (*) of this Section 14.8.
- (b) In the event of termination under this Section 14.8, all terms and conditions of this Agreement shall terminate and have no further force or effect except that this Section 14.8 and Articles and Sections 9.3, 10 (but only for five (5) years after termination and excluding the obligation to issue a press release under Section 10.13), 11.2, 11.3, 12.2, 13.4, 13.5, 14.4, 14.9, and 15 shall survive. For clarity, all of Vivus' payment obligations, including obligations to reimburse FemPharm, shall terminate and have no further force or effect immediately upon Vivus' notice. The Development Plan shall be deemed terminated and of no further force or effect.

14.9 REMEDIES

Termination of this Agreement as provided in Sections 5.17(b), 14.2, 14.3, and 14.8, and termination of certain provisions of this Agreement as provided in Section 14.6 and 14.7, is a cumulative remedy, and each Party will be entitled to seek any other rights or remedies available to it at law or in equity for any breach or non-observance of this Agreement.

15. GENERAL

15.1 NOTICES

Any notice given pursuant to this Agreement must be in writing and may be given by pre-paid express courier addressed to the other Party at the address specified in this Agreement or as subsequently notified in writing, or by hand delivery or facsimile or electronic transmission to the same address and any such notice is deemed to have been received:

- (a) if served by express courier on the date signed for;
- (b) if served by hand delivery, on the date delivered by hand;
- (c) if sent by facsimile transmission, when the transmitting machine produces a written report that the notice has been effectively sent to the other party, if the sender confirms such notice by express courier or hand delivery;
- (d) if sent by electronic transmission, when the transmitting computer produces a written report that the notice has been effectively sent to the other party, if the sender confirms such notice by express courier or hand delivery;

If a notice is deemed under clause (c) or (d) to have been received on a day which is not a Business Day, it is deemed to have been received on the next Business Day.

The address for service of any notice is:
To FemPharm

FemPharm Pty Ltd
103-113 Stanley Street
West Melbourne Victoria 3003
Australia
Facsimile:
Email:

with a copy to:

Mr. P G Willcocks
Lander & Rogers, Lawyers
Level 12, 600 Bourke Street
Melbourne Victoria 3000
Australia Facsimile:
Email:

To Vivus

with a copy to:

Facsimile:
Email:

15.2 INDEMNIFICATION

- (a) Vivus is responsible for, and will indemnify, hold harmless and defend FemPharm, its Affiliates and their respective officers, directors, employees and agents against any and all claims, damages, losses, costs, expenses (including reasonable attorneys' and professional fees and other expenses of litigation), and liabilities, resulting from any third party claims, actions, suits, or allegations ("Claims") to the extent the Claim results from or arises out of: (a) the negligence, recklessness, or willful misconduct of Vivus, its Controlled Affiliates, or its sub-licensees, or their respective officers, directors, employees, or agents; (b) Vivus' breach of its obligations, representations or warranties under this Agreement; or (c) the development, manufacture, promotion, use or sale of any Product by Vivus, its Affiliate, or its sub-licensee, or by any of their respective customers or end-users. Notwithstanding the foregoing, Vivus' obligations under this Section 15.2 will not apply to any Claim, to the extent that such Claim arises out of or results from (i) the development, manufacture, use, promotion, and/or sale of any product or technology (including Product) by FemPharm or its Affiliate or licensee (other than Vivus, but including Product sold by Vivus under any supply agreement with FemPharm or any Acrux Controlled Affiliate), or any

of their respective customers or end-users; (ii) FemPharm's or an Acrux Controlled Affiliate's breach of its obligations, representations, or warranties under this Agreement; or (iii) the negligence, recklessness, or willful misconduct of FemPharm, its Affiliates, or licensees (other than Vivus) or their respective officers, directors, employees, or agents; or (iv) claims of any participant in any Clinical Trials performed by or under authority of FemPharm or an Acrux Controlled Affiliate.

- (b) FemPharm and Acrux Limited shall be responsible for, and will indemnify, hold harmless and defend Vivus, its Affiliates and their respective officers, directors, employees and agents against any and all claims, damages, losses, costs, expenses (including reasonable attorneys' and professional fees and other expenses of litigation), and liabilities, resulting from any third party claims, actions, suits, or allegations ("Claims") resulting from or arising out of: (i) the development, manufacture, use, promotion, and/or sale of any product (including Product) by FemPharm or an Acrux Controlled Affiliate or their licensees (other than Vivus, but including Product sold by Vivus under any supply agreement with FemPharm or any Acrux Controlled Affiliate and including liability to patients in connection with any Clinical Trials by FemPharm), or any of FemPharm's or an Acrux Controlled Affiliate's or FemPharm licensee's respective customers or end-users; (ii) FemPharm's or an Acrux Controlled Affiliate's breach of its obligations, representations, or warranties under this Agreement; or (iii) the negligence, recklessness, or willful misconduct of FemPharm, an Acrux Controlled Affiliate, or licensees (other than Vivus) or their respective officers, directors, employees, or agents. Notwithstanding the foregoing, FemPharm's and Acrux Limited's obligations under this Section 15.2 will not apply to any Claim, to the extent that such Claim is the subject of an indemnification obligation under Section 15.2(a) above.
- (c) A Party that intends to claim indemnification under this Section 15 (the "Indemnitee") shall promptly notify the other Party (the "Indemnitor") in writing

of any Claim, in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have sole control of the defense and/or settlement thereof. The indemnity arrangement in this Section 15 shall not apply to amounts paid in settlement of any action with respect to a 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 action with respect to a Claim, if prejudicial to its ability to defend such action, shall relieve such Indemnitor of any liability to the Indemnitee under this Section 15 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 otherwise than under this Section 15. The Indemnitee under this Section 15, shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action with respect to a Claim covered by this indemnification, at the Indemnitor's expense. Notwithstanding the foregoing, the Indemnitor shall not be responsible for any costs or expenses incurred by the Indemnitee or its Affiliate, or the directors, officers, employees, successors or assigns of the Indemnitee or its Affiliate, without the prior written consent of the Indemnitor, not to be unreasonably withheld.

15.3 DAMAGES FOR BREACH OF REPRESENTATIONS AND WARRANTIES

Notwithstanding anything to the contrary, a breach of warranty under this Agreement shall have the same effect as a breach of a covenant, and each Party shall be entitled to recover for a breach of a warranty by the other Party the same contractual damages as if such other Party had breached a covenant, subject to Section 13.5.

15.4 WAIVER

A waiver by any Party of any breach or a failure to enforce or to insist upon the observance of a condition of this Agreement will not be a waiver of any

other or of any subsequent breach. No waiver under this Agreement is binding unless in writing and signed by the Party giving the waiver.

15.5 SEVERANCE

If any part of this Agreement is held to be invalid, unenforceable, illegal, void or voidable for any reason, this Agreement will be construed and be binding on the Parties to the maximum extent possible, as if the invalid, unenforceable, illegal, void or voidable part had been deleted from this Agreement or read down to the extent necessary to overcome the difficulty.

15.6 SUCCESSORS AND ASSIGNS

This Agreement is binding on and continues for the benefit of each Party, its successors and permitted assigns.

15.7 CONTINUING OBLIGATIONS

The expiration or termination of this Agreement does not operate to terminate any of the surviving obligations under this Agreement, which will remain in full force and effect and binding on the Party concerned.

15.8 VARIATION

No variation, modification or amendment of this Agreement is binding on the Parties unless in writing and signed by both Parties.

15.9 APPLICABLE LAW

This Agreement, and all disputes under Section 15.10, shall be governed by and construed in accordance with the laws of California, USA, and the Parties submit themselves to the non-exclusive jurisdiction of the courts having San Francisco within their jurisdiction.

15.10 DISPUTE RESOLUTION

If any claim, controversy, difference or dispute between the Parties arises at any time under this Agreement, including as to its existence, validity, interpretation, effect, breach or termination, (a "Dispute"), then either Party may give the other a written notice of Dispute reasonably identifying and providing a description of the Dispute. Notwithstanding the existence of a Dispute, the Parties must continue to perform this Agreement, unless the Agreement is terminated in accordance with its terms. If there is a Dispute, however, regarding whether or not a breach of this Agreement has occurred, then notice of such a Dispute will toll the cure period, and the Agreement will remain in effect until the Dispute is resolved. If such a Dispute is finally resolved in favour of the Party giving notice of breach, then the Agreement will terminate sixty (60) days after the final determination is made unless the other Party cures the breach within such sixty (60) day period. If a Party gives written notice of a Dispute, then senior executive officers from both Parties will meet promptly thereafter and negotiate in good faith to resolve the Dispute as quickly and cost effectively as possible. If the Parties have not resolved the Dispute within sixty (60) days of the date of the written notice of the Dispute, then either Party may, by written notice to the other Party, submit such Dispute to final and binding arbitration under the then current Comprehensive Arbitration Rules and Procedures of the Judicial Arbitration and Mediation Services ("JAMS"), except as such rules may be modified in this agreement ("Rules"). The Parties agree that any such Dispute will be settled by three (3) arbitrators which are appointed within 90 days of service by one Party of a request for arbitration on the other Party. Each Party will select one arbitrator, and the third arbitrator will be appointed by JAMS, as provided in the Rules. The arbitration proceedings will take place, and the arbitrators' award will be rendered, in Honolulu, Hawaii or such other location as may be agreed in writing by the Parties. The decision of the arbitrators will be final and binding on the Parties. The arbitrators will prepare and deliver to the Parties a written, reasoned opinion conferring their decision. Judgment on the award so rendered may be entered in any court having competent jurisdiction thereover. Each Party may, without breach of this Section 15.10 or waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or

provisional relief necessary to protect the rights or property of that Party pending the arbitration award. Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrators' and any administrative fees of arbitration. The Parties further agree that any payments made pursuant to this Agreement pending resolution of the dispute shall be refunded if an arbitrator or court determines that such payments are not due.

15.11 DISPUTE REGARDING LICENSE NECESSITY.

If FemPharm disputes, under Section 4.3, that a particular patent license is "necessary" as defined in that Section, then the Parties shall resolve such dispute by submitting such dispute for resolution to a mutually agreed independent patent attorney with substantial experience regarding the scope, validity and enforceability of patents covering subject matters similar to the third party patent in question (the "Neutral"). If the Parties cannot agree on a Neutral within thirty (30) days of the request of either Party, then the Neutral shall be selected by the Chairman of the Intellectual Property section of the American Bar Association. The Neutral shall not have any current interest in or current or prior involvement with either Party, unless the Parties agree otherwise. Within 10 days following the identification of the Neutral, each Party shall submit to the Neutral in writing its statement of the issue in dispute; and the basis for its position that the patent license that is the subject of the dispute is, or is not, (as applicable) "necessary" as defined in Section 4.3. No ex-parte communication with the Neutral shall be allowed without the consent of the other Party. The Neutral may follow such procedures as he or she desires, provided that the Neutral shall decide the issue in favor of one Party within thirty (30) days of submission of the statements. If the Neutral determines that the subject patent license is "necessary", then Vivus shall be entitled to credit royalties as provided in Section 4.3, and otherwise no credit shall be permitted (except as may otherwise be agreed by the Parties in writing). The Parties shall equally share the costs associated with the Neutral's activities under this Section 15.11. Each Party shall cooperate to allow the Neutral to complete his/her obligations under this Section. If

Vivus has in fact taken a license for the Product, the license shall be considered necessary unless otherwise established in such proceeding.

15.12 COUNTERPARTS

This Agreement may be signed in any number of counterparts and all such counterparts taken together are deemed to constitute one and the same document.

15.13 COSTS

Each Party must pay their own legal, accounting and other costs in relation to the negotiation, preparation, execution and implementation of this Agreement.

15.14 PAYMENT

All payments to be made under this Agreement must be paid by electronic transfer to the bank account nominated in writing by the Party to whom the payment is to be made and received into that account in cleared funds on the date the payment is due.

15.15 ENTIRE AGREEMENT

This Agreement and the Guaranty Agreement constitute the entire agreement and basis of the transaction between the Parties in relation to its subject matter and supersedes all other prior and contemporaneous communications, negotiations, arrangements and agreements between FemPharm and Vivus whether oral or in writing, except that confidential information disclosed by a Party pursuant to the non disclosure agreement between FemPharm and Vivus prior to the Effective Date shall be treated as Confidential Information of the disclosing Party to the extent set forth in this Agreement, and the Testosterone Agreement shall remain in full force and effect.

15.16 INJUNCTIVE RELIEF

Each Party acknowledges that monetary damages alone may not be adequate compensation for a breach of this Agreement by the other Party, including breach of Article 10. Each Party is entitled to seek injunctive relief from a court of competent

jurisdiction as a remedy for any breach or threatened breach of this Agreement, in addition to any other remedies available at law or in equity under or independently of this Agreement, each to the extent available in accordance with applicable law.

15.17 INDEPENDENT CONTRACTORS

The relationship of the Parties hereto is that of independent contractors. The Parties hereto shall not be deemed to be agents, partners or joint venturers of the others for any purpose as a result of this Agreement or the transactions contemplated thereby, and neither Party shall have the authority to agree to any obligation or commitment for the other.

15.18 FORCE MAJEURE

Neither Party shall lose any rights hereunder, be considered in breach of this Agreement, or be liable to the other Party for damages or losses on account of its failure to perform if the failure is occasioned by war, strike, fire, act of God, earthquake, flood, lockout, embargo, failure of suppliers, power failures, or any other reason where failure to perform is beyond the reasonable control of the non-performing Party (a "Force Majeure"), provided that after the Force Majeure occurs, the non-performing Party uses reasonable efforts to avoid the effects of such Force Majeure, and to perform its obligations, each to the extent reasonably practicable (it being agreed that in no event shall a Party be required to settle any labor dispute or disturbance).

15.19 BANKRUPTCY

All rights and licenses granted under or pursuant to this Agreement by each Party as a licensor are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11, U.S. Code (the "Bankruptcy Code"), licenses of rights to "intellectual property" as defined under section 101(35A) of the Bankruptcy Code. The Parties agree that each licensee of such rights under this Agreement, shall retain and may fully exercise all rights and elections it would have in the case of a licensor bankruptcy under the Bankruptcy Code. Each Party agrees during the term of this Agreement to create or maintain current copies, or if not amenable to copying, detailed descriptions or other appropriate embodiments, of all such intellectual property licensed to the other Party.

15.20 ACRUX DDS AS A PARTY

Acrux DDS Pty Limited agrees to be fully and independently bound by the Sections to which it is expressly a party under this Agreement, and including also the provisions of Article 14 (it being understood that only Vivus or FemPharm may terminate this Agreement in accordance with its terms). Notwithstanding the foregoing, Acrux DDS Pty Limited acknowledges that Vivus shall have no independent obligations to Acrux DDS Pty Limited under this Agreement, and all of Vivus' obligations under this Agreement and this Section 15.20 shall be satisfied upon Vivus' performance or tender of performance to FemPharm. In addition, any notice given to or from FemPharm and FemPharm's consent, approval, agreement, actions or inactions shall be deemed notices to and from, and the consent, approval, or agreement of, or actions or inactions authorized by Acrux DDS Pty Limited. Acrux DDS Pty Limited agrees to be likewise bound by any and all amendments to this Agreement, which amendments shall not require Acrux DDS Pty Limited's approval. It is understood and agreed that Acrux DDS Pty Limited may look only to FemPharm for any share of or benefit from Vivus' performance or undertakings under this Agreement, and Vivus shall have no responsibilities to Acrux DDS Pty Limited in that regard.

15.21 SURVIVAL OF SUBLICENSES

If FemPharm terminates the Agreement, then any existing sublicense agreement with a non-Affiliate granted by Vivus hereunder shall remain in force provided that such sublicensee agrees in writing to be bound by and perform to the same extent as required of Vivus under this Agreement. For clarity, it is understood that the foregoing shall not have the effect of expanding or increasing the rights of the sublicensee beyond the rights granted to it under the sublicense agreement.

EXECUTION

EXECUTED by FEMPHARM PTY LTD by being signed by:

)
)
)
)
)
)

/s/ Igor Gorda

/s/ Igor Gorda

Signature of director/secretary

Signature of director

Igor Gorda

Igor Gorda

Name of director/secretary (please print)

Name of director (please print)

EXECUTED by VIVUS INC. by being signed by:

)
)
)
)
)
)

/s/ Leland Wilson

Signature

Leland Wilson, President & CEO

Name and Title

EXECUTED by ACRUX DDS PTY) LTD by being signed by:)

)
)
)
)
)

/s/ Igor Gorda

/s/ Igor Gorda

Signature of director/secretary

Signature of director

Igor Gorda

Igor Gorda

Name of director/secretary (please print)

Name of director (please print)

ANNEXURE A
DEVELOPMENT PLAN

ANNEXURE B

FEMPHARM PATENTS AND PATENT APPLICATIONS

PATENTS GRANTED	COUNTRY	PATENT NO.	APPLIC. NO.	DATE OF ISSUE	DATE OF FILING	EXPIRATION DATE
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(**)

ANNEXURE C

METERED DOSE TRANSDERMAL SPRAY SYSTEM

(**)

ANNEXURE D
FORM OF PRESS RELEASE

ANNEXURE E
CHEMICAL STRUCTURE OF ESTRADIOL

(**)

ANNEXURE F
EXCLUDED INDICATIONS
(**)

ANNEXURE G
SAMPLE ROYALTY CALCULATION

NOTE PURCHASE AGREEMENT

This NOTE PURCHASE AGREEMENT (as amended, modified or otherwise supplemented from time to time, this "Purchase Agreement"), dated as of January 8, 2004, is entered into by and between Tanabe Holding America, Inc. ("Purchaser") and VIVUS, Inc. ("Company").

NOW THEREFORE, in consideration of the covenants, conditions and agreements set forth herein, the parties agree as follows:

ARTICLE 1

DEFINITIONS

1.1 "Advance" shall have the meaning given in Section 2.1 of the Purchase Agreement.

1.2 "Business Day" shall mean any day on which commercial banks are not authorized or required to close in San Francisco, California.

1.3 "Carcinogenicity Studies" shall mean animal studies designed to evaluate the carcinogenic effects, if any, of long-term exposure to Compound..

1.4 "Closing Prices Per Share" shall mean, with respect to the Common Stock, for any day, (i) the last reported bid price regular way on the Nasdaq National Market or, (ii) if the Common Stock is not quoted on the Nasdaq National Market, the last reported sale price regular way per share or, in case no such reported sale takes place on such day, the average of the reported closing bid and asked prices regular way, in either case, on the principal national securities exchange on which the Common Stock is listed or admitted to trading, or (iii) if the Common Stock is not quoted on the Nasdaq National Market or listed or admitted to trading on any national securities exchange, the average of the closing bid prices in the over-the-counter market as furnished by any New York Stock Exchange member firm selected from time to time by the Company for that purpose.

1.5 "Common Stock" shall mean the common stock, par value \$0.001 per share, of the Company.

1.6 "Compound" shall have the meaning given in the License Agreement.

1.7 "Compound-Related Intellectual Property" shall mean collectively the Bulk Drug Tablets, Bulk Drug Substance, Compound, Development Plan, Development Work, Drug Approval Applications, IND, Information, Product, Trademarks, Vivus Know-How (as such terms are each defined in the License Agreement), and license rights granted to Company pursuant to Section 2.1 of the License Agreement.

1.8 "Default" shall mean any event or circumstance not yet constituting an Event of Default but which, with the giving of any notice or the lapse of any period of time or both, would become an Event of Default.

1.9 "Environmental Action" shall mean any complaint, summons, citation, notice, directive, order, claim, litigation, investigation, judicial or administrative proceeding, judgment, letter or other communication from any governmental agency, department, bureau, office or other authority, or any third party involving violations of Environmental Laws or releases of Hazardous Materials (i) from any assets, properties or businesses of Company or any of its Subsidiary(-ries) or any predecessor in interest, (ii) from properties or businesses adjoining any properties or businesses of Company or any of its Subsidiary(-ries) or any predecessor in interest or (iii) from or onto any facilities which received Hazardous Materials generated by Company or any of its Subsidiary(-ries) or any predecessor in interest.

1.10 "Environmental Law" shall mean any present or future statute, ordinance, rule, regulation, order, judgment, decree, permit, license or other binding determination of any governmental authority imposing liability or establishing standards of conduct for protection of the environment as the same may be amended or supplemented from time to time.

1.11 "Environmental Liabilities" shall mean all liabilities, monetary obligations, remedial actions, losses, damages, punitive damages, consequential damages, treble damages, costs and expenses (including all reasonable fees, disbursements and expenses of counsel, experts and consultants and costs of investigation and feasibility studies), fines, penalties, sanctions and interest incurred as a result of (i) any claim or demand by any governmental authority or any third party which relates to any environmental condition or a release of Hazardous Materials or (ii) any breach by Company or any of its Subsidiary(-ries) of any Environmental Law.

1.12 "ERISA" shall mean the Employee Retirement Income Security Act of 1974, as amended from time to time, and the rules and regulations and published

interpretations thereof.

1.13 "Event of Default" shall have the meaning given to that term in Section 5.1.

1.14 "Facility Amount" shall mean an amount equal to \$8,500,000.

1.15 "GAAP" shall mean generally accepted accounting principles and practices as promulgated by the Financial Accounting Standards Board and as in effect in the United States of America from time to time, consistently applied. Unless otherwise indicated in this Purchase Agreement, all accounting terms used in this Purchase Agreement shall be construed, and all accounting and financial computations hereunder or thereunder shall be computed, in accordance with GAAP.

1.16 "Governmental Authority" shall mean any domestic or foreign national, state or local government, any political subdivision thereof, any department, agency, authority or bureau of any of the foregoing, or any other entity exercising executive, legislative, judicial, regulatory or administrative functions of or pertaining to government.

1.17 "Hazardous Materials" shall mean (a) petroleum and petroleum products, byproducts or breakdown products, radioactive materials, asbestos-containing materials, polychlorinated biphenyls and radon gas and (b) any other chemicals, materials or substances designated, classified or regulated as hazardous or toxic or as a pollutant or contaminant under any Environmental Law.

1.18 "Indebtedness" of any Person shall mean and include the aggregate amount of, without duplication (a) all obligations of such Person for borrowed money, (b) all obligations of such Person evidenced by bonds, debentures, notes or other similar instruments, (c) all obligations of such Person to pay the deferred purchase price of property or services (other than accounts payable incurred in the ordinary course of business determined in accordance with generally accepted accounting principles), (d) all obligations under capital leases of such Person, (e) all obligations or liabilities of others secured by a lien on any asset of such Person, whether or not such obligation or liability is assumed, (f) all guaranties of such Person of the obligations of another Person; (g) all obligations created or arising under any conditional sale or other title retention agreement with respect to property acquired by such Person (even if the rights and remedies of the seller or purchaser under such agreement upon an event of default are limited to repossession or sale of such property), (h) net exposure under any interest rate swap, currency swap, forward, cap, floor or other similar contract that is not entered into in connection with a bona fide hedging operation that provides offsetting benefits to such Person, which agreements shall be marked to market on a current basis, (i) all reimbursement and other payment obligations, contingent or otherwise, in respect of letters of credit.

1.19 "License Agreement" shall mean that certain agreement dated December 28, 2000 between Tanabe Seiyaku Co., Ltd., a Japanese corporation having its principal office at 2-10 Doshomachi 3-chome, Chuo-ku, Osaka, Japan and VIVUS, Inc., a corporation having its principal office at 1172 Castro Street, Mountain View, CA 94040, USA, as the same may be amended from time to time.

1.20 "Lien" shall mean, with respect to any asset, any mortgage, lien, pledge, charge, security interest or encumbrance of any kind in respect of such asset. For the purposes of this Agreement, Company shall be deemed to own subject to a Lien any asset which it has acquired or holds subject to the interest of a vendor or lessor under any conditional sale agreement, capital lease or other title retention agreement relating to such asset.

1.21 "Maturity Date" shall, with respect to a given Note, mean the fourth (4th) anniversary of the date on which the Advance with respect to such Note was made.

1.22 "Nitrate Interaction Studies" shall mean clinical studies designed to evaluate the hemo-dynamic response to nitrates in subjects receiving Compound.

1.23 "Note" shall have the meaning given in Section 2.1.

1.24 "Obligations" means all loans, advances, debts, liabilities and obligations, howsoever arising, owed by Company to Purchaser of every kind and description (whether or not evidenced by any note or instrument and whether or not for the payment of money), now existing or hereafter arising under or

pursuant to the terms of the Notes and the other Transaction Documents, including, all interest, fees, charges, expenses, attorneys' fees and costs and accountants' fees and costs chargeable to and payable by Company hereunder and thereunder, in each case, whether direct or indirect, absolute or contingent, due or to become due, and whether or not arising after the commencement of a proceeding under Title 11 of the United States Code (11 U.S.C. Section 101 et seq.), as amended from time to time (including post-petition interest) and whether or not allowed or allowable as a claim in any such proceeding.

1.25 "PBGC" shall mean the Pension Benefit Guaranty Corporation or any entity succeeding to any or all of its functions under ERISA.

1.26 "Person" shall mean and include an individual, a partnership, a corporation (including a business trust), a joint stock company, a limited liability company, an unincorporated association, a joint venture or other entity or a Governmental Authority.

1.27 "Phase II Clinical Studies" shall have the meaning given in the License Agreement.

1.28 "Plan" shall mean any pension plan that is covered by Title IV of ERISA and in respect of which Company or a Commonly Controlled Entity is an "employer" as defined in Section 3(5) of ERISA.

1.29 "Prohibited Transaction" shall mean any transaction set forth in Section 406 of ERISA or Section 4975 of the Code.

1.30 "Purchase Agreement" shall have the meaning set forth in the opening paragraph of this document.

1.31 "Purchase Date" shall mean a date upon which an Advance is consummated.

1.32 "Reportable Event" shall mean any of the events set forth in Section 4043 of ERISA.

1.33 "Securities Act" shall mean the United States Securities Act of 1933 (or any successor statute), as amended from time to time.

1.34 "Security Agreement" shall have the meaning given in Section 2.8(a).

1.35 "Senior Debt" shall mean the principal of (and premium, if any) and interest (including all interest accruing subsequent to the commencement of any bankruptcy or similar proceeding, whether or not a claim for post-petition interest is allowable as a claim in any such proceeding) on, and all fees and other amounts payable in connection with, the following, whether absolute or contingent, secured or unsecured, due or to become due, outstanding on the date hereof or thereafter created, incurred or assumed: (a) all obligations of the Company for money borrowed from a bank or other institutional lender, (b) obligations incurred in connection with the acquisition of any businesses, properties or assets, (c) obligations of the Company (i) as lessee under leases

required to be capitalized on the balance sheet of the lessee under generally accepted accounting principles and (ii) as lessee under other leases for facilities, capital equipment or related assets, whether or not capitalized, entered into or leased for financing purposes, and (d) renewals, extensions, modifications, replacements, restatements and refundings of, or any indebtedness or obligation issued in exchange for, any such indebtedness or obligation described in clauses (a) through (c) of this paragraph; provided, however, that Senior Debt shall not include any such indebtedness or obligation if the terms of such indebtedness or obligation (or the terms of the instrument under which, or pursuant to which it is issued) expressly provide that such indebtedness or obligation is not superior in right of payment to the Notes

1.36 "Steering Committee" shall have the meaning given in the License Agreement.

1.37 "Study" shall have the meaning given in Section 2.7.

1.38 "Subsidiary(-ries)" shall mean (a) any corporation(s) of which more than 50% of the issued and outstanding equity securities having ordinary voting power to elect a majority of the Board of Directors of such corporation is at the time directly or indirectly owned or controlled by the Company, (b) any partnership(s), joint venture(s), or other association(s) of which more than 50% of the equity interest having the power to vote, direct or control the management of such partnership, joint venture or other association is at the time directly or indirectly owned and controlled by the Company, (c) any other entity(-ties) included in the financial statements of the Company on a consolidated basis.

1.39 "Termination Date" shall mean the fourth anniversary of the date of this Purchase Agreement.

1.40 "Trading Day" shall mean (i) if the Common Stock is quoted on the Nasdaq National Market or any other system of automated dissemination of quotations of securities prices, days on which trades may be effected through such system, (ii) if the Common Stock is listed or admitted for trading on any national or regional securities exchange, days on which such national or regional securities exchange is open for business, or (iii) if the Common Stock is not listed on a national or regional securities exchange or quoted on the Nasdaq National Market or any other system of automated dissemination of quotation of securities prices, days on which the Common Stock is traded regular way in the over-the-counter market and for which a closing bid and a closing asked price for the Common Stock are available.

1.41 "Transaction Documents" shall mean and include this Purchase Agreement, the Security Agreement, the Notes and any other documents, instruments and agreements delivered to Purchaser in connection with this Purchase Agreement.

ARTICLE 2 ADVANCES

2.1 Terms of Advances. Subject to the terms and conditions of this Purchase Agreement, Purchaser agrees to advance to Company from time to time and until the Termination Date, such sums as Company may request (the "Advances")

but which shall not exceed, in the aggregate principal amount at any one time outstanding, the Facility Amount. The obligation of Company to repay the Advances and to pay interest thereon at the rates specified herein shall be evidenced by secured promissory notes in the form attached hereto as Exhibit A (each a "Note" and collectively, the "Notes"). Advances shall be made in lawful currency of the United States of America and shall be made in same day or immediately available funds. Once repaid, Advances may not be reborrowed.

2.2 Mechanics of the Purchase and Sale of Notes. Notes shall be issued by Company and purchased by Purchaser upon request by Company of an Advance pursuant to a notice of borrowing in the form of Schedule I hereto (a "Notice of Borrowing") and satisfaction of the conditions precedent set forth in Article 4. Each Notice of Borrowing together with any documentation required by Section 4.6 shall be delivered not less than ten (10) Business Days prior to the Purchase Date specified in the Notice of Borrowing in the manner specified in Section 7.1. Subject to Article 4, upon receipt of a Notice of Borrowing, Purchaser shall purchase, and Company shall sell, on the specified Purchase Date a Note in a principal amount equal to the Advance. There shall not occur in any one of Company's fiscal quarters more than one Advance. Upon receipt of the purchase price in immediately available funds from Purchaser, Company shall promptly issue a Note in the amount of such purchase price to Purchaser dated the date of receipt of such funds; provided, however, that Purchaser's rights under such Note shall be deemed to exist from the date of receipt of the purchase price by Company in immediately available funds whether or not such Note has physically been issued.

2.3 Payment upon Maturity. If not paid earlier, the outstanding principal balance of each Advance, together with all accrued but unpaid interest thereon, shall be due and payable to the Purchaser on the Maturity Date with respect to such Advance as defined in the applicable Note.

2.4 Interest Payments. Interest on the outstanding principal balance under each Advance shall accrue at a rate per annum equal to two percent (2%) and shall be paid on the fifteenth day of each December of each year while such Advance is outstanding. All computations of such interest shall be based on a year of 365 days and actual days elapsed for each day on which any principal balance is outstanding under the terms of the applicable Note.

2.5 Other Payment Terms.

(a) PAYMENT IN CASH. Company shall make payments in whole or in part due to Purchaser hereunder in lawful money of the United States and in same day or immediately available funds unless Company elects to make payments pursuant to Section 2.5(b).

(b) PAYMENTS IN COMMON STOCK. At Company's option, Company may make payments in whole or in part due to Purchaser hereunder in Common Stock provided the following conditions are met: (i) the fair market value of shares of Common Stock shall be determined by the Company and shall be equal to the average of the Closing Prices Per Share of the Common Stock for the five consecutive Trading Days immediately preceding and including the third Trading Day prior to the date of payment and the fair market value of a share of Common Stock determined in accordance herewith shall not equal less than Five Dollars (\$5); (ii) the shares of Common Stock to be issued and/or delivered to Purchaser as

payment hereunder shall, immediately after delivery to Purchaser, be freely transferable to any third parties by Purchaser without being subject to any transfer restrictions under the Securities Act and any other federal and state securities laws; (iii) such Common Stock is, or shall have been, approved for quotation on the Nasdaq National Market or listed on a national securities exchange, in either case, prior to the date of issuance of Common Stock as payment hereunder; (iv) all shares of Common Stock which may be issued as payment hereunder will be issued out of the Company's authorized but unissued Common Stock and, will upon issue, be duly and validly issued and fully paid and non-assessable and free of any preemptive or similar rights; and (v) the fair market value of one share of stock determined in accordance with clause (i) of this paragraph multiplied by the number of outstanding fully-diluted shares of the Company shall not total less than Thirty Million Dollars (\$30,000,000).

(c) DATE. Whenever any payment due hereunder shall fall due on a day other than a Business Day, such payment shall be made on the next succeeding Business Day, and such extension of time shall be included in the computation of interest or fees, as the case may be.

(d) DEFAULT RATE. From and after the occurrence of an Event of Default and during the continuance thereof, Company shall pay interest on all Obligations not paid when due, from the date due thereof until such amounts are paid in full at a per annum rate equal to the lower of three (3) percentage points in excess of the rate otherwise applicable to Advances or the highest lawful rate of interest under applicable law. All computations of such interest shall be based on a year of 365 days and actual days elapsed.

2.6 Prepayments.

(a) TERMS OF ALL PREPAYMENTS. Upon the prepayment of any Note (whether such prepayment is a mandatory prepayment or an optional prepayment), Company shall pay to Purchaser all accrued interest to the date of such prepayment on the amount prepaid.

(b) MANDATORY PREPAYMENT. Company shall prepay in accordance with Section 2.5 all Obligations within ten (10) Business Days of the receipt by Company of a lump-sum payment in immediately available funds equal to or greater than (**)Dollars (\$**) from any third-party sublicensor in connection with the execution of a third-party sublicense agreement contemplated by Section 2.3 of the License Agreement.

(c) OPTIONAL PREPAYMENTS. At its option, Company may, upon three (3) Business Days' notice to Purchaser, prepay the Advances in whole, or in part in an amount of at least One Hundred Thousand Dollars, \$100,000, or any lesser amount equal to the entire remaining outstanding principal balance.

(d) REGULATORY CHANGE. If, after the date hereof, the introduction and effectiveness of any applicable law, rule or regulation, or any change in any applicable law, rule or regulation, or in the interpretation or administration thereof by any governmental authority charged with the interpretation or administration thereof, shall make it unlawful for Purchaser to maintain the Advance, Purchaser shall forthwith give notice thereof to Company, whereupon Company shall promptly prepay such Advance.

(e) APPLICATION OF PREPAYMENTS. All prepayments hereunder shall be applied first to unpaid fees, costs and expenses then due and payable under this Purchase Agreement or the other Transaction Documents, second to accrued interest then due and payable under the applicable Notes and finally to reduce the outstanding principal amount of the applicable Notes.

2.7 Proceeds of the Advances. Company shall use the proceeds of the Advances solely for the conduct of (i) Phase II Clinical Studies, (ii) Carcinogenicity Studies, (iii) Nitrate Interaction Studies, and (iv) other studies relating to the development of the Compound, (each of (i) through (iv), a "Study"), such Studies to be performed in each case in accordance with the License Agreement.

2.8 Security; Further Assurances; Designation of Tanabe Study.

(a) SECURITY. The Obligations shall be secured by a Security Agreement in the form attached hereto as Exhibit B (the "Security Agreement").

(b) FURTHER ASSURANCES. Company shall deliver to Purchaser the Security Agreement and such other instruments, agreements, certificates, and documents as Purchaser may reasonably request to create, perfect, evidence and maintain (i) a security interest of Purchaser in certain assets of Company as further set forth in the Security Agreement and (ii) the rights of Purchaser under this Purchase Agreement and the other Transaction Documents. Company shall fully cooperate with Purchaser and perform all additional acts reasonably requested by Purchaser to effect the purposes of the foregoing and the rights granted to Purchaser hereunder, including providing Purchaser with updates on Company's sublicensing activities under the License Agreement.

(c) DESIGNATION OF TANABE STUDY. Company shall designate at least one Study to be conducted by an affiliate of Purchaser to be established for such purposes, the nature of such Study to be determined by Company in its sole discretion.

2.9 Term. This Agreement and all of the parties' rights and obligations hereunder shall terminate upon payment in full of all outstanding Obligations.

ARTICLE 3 REPRESENTATIONS AND WARRANTIES OF COMPANY

To induce Purchaser to enter into this Purchase Agreement and to make Advances hereunder, Company represents and warrants to Purchaser as follows:

3.1 Due Incorporation, Qualification, etc. Company is a corporation duly organized, validly existing and in good standing under the laws of its state of incorporation.

3.2 Authority. The execution, delivery and performance by Company of each Transaction Document to be executed by Company and the consummation of the transactions contemplated thereby (i) are within the power of Company and (ii) have been duly authorized by all necessary actions on the part of Company.

3.3 Enforceability. Each Transaction Document executed, or to be executed, by Company has been, or will be, duly executed and delivered by Company and constitutes, or will constitute, a legal, valid and binding obligation of Company, enforceable against Company in accordance with its terms, except as limited by bankruptcy, insolvency or other laws of general application relating to or affecting the enforcement of creditors' rights generally and general principles of equity.

3.4 Financial Statements. The financial statement of the Company dated as of September 30, 2003, a copy of which has been submitted to the Purchaser, fairly represents the financial position of the Company as of said date, and since the date of the most recent public filing of the financial statements of the Company there has been no development or event which has had a material adverse effect on the business, operations, property, condition or prospects of Company.

3.5 No Proceedings. There is no action, suit, proceeding or investigation at law or in equity by or before any court, governmental body or other agency now pending or, to the knowledge of the Company, threatened against or affecting the Company or any property or rights of the Company which would likely result in a material adverse effect on the business, operations, property, condition or prospects of Company. The Company is not in default under or in violation of any applicable writ, order, injunction or decree of any court, governmental department, board, agency or instrumentality which by itself or aggregated with any other such default or violation would result in a material adverse effect on the business, operations, property, condition or prospects of Company.

3.6 Tax Returns. The Company has filed all material tax returns required to be filed by it and has paid all material taxes and other governmental charges due pursuant to such returns or pursuant to any assessment received by the Company except where the Company may be contesting in good faith such taxes or governmental charges. The charges, accruals and reserves on the books of the Company in respect to any taxes or other governmental charges are adequate in the aggregate to provide for the liabilities in respect thereof.

3.7 Compliance with Laws. It has complied in all material respects with all applicable laws, statutes, regulations and orders of, and all applicable restrictions imposed by, all governmental bodies, domestic or foreign, in respect of the conduct of its businesses and the ownership of its properties.

3.8 Environmental Matters. Except to the extent not reasonably expected to result in a Material Adverse Effect or a Default or an Event of Default, (i) none of the operations of the Company or any of its Subsidiary(-ries) violates, in any material respect, any Environmental Law, (ii) no Environmental Action has been asserted against the Company or any of its Subsidiary(-ries) in writing nor does the Company have any knowledge of any threatened or pending Environmental Action against the Company, any of its Subsidiary(-ries) or any predecessor in interest, (iii) neither the Company nor any of its Subsidiary(-ries) has incurred any Environmental Liabilities and (iv) to the Company's knowledge, neither the Company nor any of its Subsidiary(-ries) has any material contingent liability in connection with any release of any Hazardous Material into the environment.

3.9 ERISA. The Company and each of its Subsidiary(-ries) are in compliance in all material respects with all applicable provisions of ERISA. Neither a Reportable Event nor a Prohibited Transaction has occurred and is continuing with respect to any Plan; no notice of intent to terminate a Plan has been filed, nor has any Plan been terminated; no circumstances exist which constitute grounds entitling the PBGC to institute proceedings to terminate, or appoint a trustee to administer, a Plan, nor has the PBGC instituted any such proceedings; neither the Company nor any Commonly Controlled Entity has completely or partially withdrawn from a Multiemployer Plan; the Company and each Commonly Controlled Entity have met their minimum funding requirements under ERISA with respect to all of their Plans, and the present value of all vested benefits, under each Plan does not exceed the fair market value of all Plan assets allocable to such benefits, as determined on the most recent valuation date of the Plan and in accordance with the provisions of ERISA; and neither the Company nor any Commonly Controlled Entity has incurred any liability to the PBGC under ERISA.

ARTICLE 4
CONDITIONS TO MAKING ADVANCES

Purchaser's obligation to make the initial Advance and each subsequent Advance is subject to the prior satisfaction or waiver of all the conditions set forth in this Article 4.

4.1 Principal Transaction Documents. Company shall have duly executed and delivered to Purchaser: (a) the Purchase Agreement, (b) the Security Agreement and (c) such other documents, instruments and agreements as Purchaser may reasonably request.

4.2 Representations and Warranties Correct. The representations and warranties made by Company in Article 3 hereof shall be true and correct as of the date on which each Advance is made and after giving effect to the making of the Advance. The submission by Company to Purchaser of a request for an Advance shall be deemed to be a certification by the Company that as of the date of borrowing, the representations and warranties made by Company in Article 3 hereof are true and correct.

4.3 No Event of Default or Default. No Event of Default or Default has occurred or is continuing.

4.4 Total Outstanding Advances. The total aggregate principal amount of outstanding Advances does not exceed the Facility Amount.

4.5 Pre-Clinical and Clinical Studies. Company shall have commenced at least one Phase II Clinical Study and two Carcinogenicity Studies by March 31, 2004. There shall not have occurred any material delay in the conduct of the Phase II Clinical Studies, the Carcinogenicity Studies and the Nitrate Interaction Studies that is inconsistent with any schedules approved by the Steering Committee pertaining to such studies.

4.6 Use of Proceeds: Evidence of Reimbursement. Purchaser shall have received from Company evidence (including invoices, copies of checks, other appropriate evidence of payments or other documentation) that, with respect to each Advance, the Company is in compliance with Section 2.7 hereof; provided, however, that Purchaser acknowledges and agrees that the sole purpose of this Section 4.6 is to permit Purchaser to ascertain that the Advances are used to reimburse Company for expenditures identified in Section 2.7 and not to limit or restrict reimbursement for any such expenditures identified in Section 2.7.

ARTICLE 5
EVENTS OF DEFAULT

5.1 Events of Default. The occurrence of any of the following shall constitute an "Event of Default" under the Transaction Documents and each Note:

(a) FAILURE TO PAY. Company shall fail to pay to Purchaser within 30 days when due and payable the outstanding principal amount or any accrued but unpaid interest on any Note.

(b) BREACHES OF COVENANTS. Company shall fail to observe or perform any other covenant, obligation, condition or agreement contained in this Purchase Agreement or any other Transaction Document and (i) such failure shall continue for ten (10) Business Days, or (ii) if such failure is not curable within such ten (10) Business Day period, but is reasonably capable of cure within twenty (20) Business Days, either (A) such failure shall continue for twenty (20) Business Days or (B) Company shall not have commenced a cure in a manner reasonably satisfactory to Purchaser within the initial ten (10) Business Day period; or

(c) REPRESENTATIONS AND WARRANTIES. Any representation, warranty, certificate, or other statement (financial or otherwise) made or furnished by or on behalf of Company to Purchaser in writing in connection with any of the Transaction Documents, or as an inducement to Purchaser to enter into this Purchase Agreement, shall be false, incorrect, incomplete or misleading in any material respect when made or furnished; or

(d) VOLUNTARY BANKRUPTCY OR INSOLVENCY PROCEEDINGS. Company shall (i) apply for or consent to the appointment of a receiver, trustee, liquidation or custodian of itself or of all or a substantial part of its property, (ii) be unable, or admit in writing its inability, to pay its debts generally as they mature, (iii) make a general assignment for the benefit of its or any of its creditors, (iv) be dissolved or liquidated in full or in part, (v) become insolvent (as such term is defined in 11 U.S.C. ss.101 (32), as amended from time to time), (vi) commence a voluntary case or other proceeding seeking liquidation, reorganization or other relief with respect to itself or its debts under any bankruptcy, insolvency or other similar law now or hereafter in effect or consent to any such relief or to the appointment of or taking possession of its property by any official in an involuntary case or other proceeding commenced against it, or (vii) take any action for the purpose of effecting any of the foregoing; or

(e) INVOLUNTARY BANKRUPTCY OR INSOLVENCY PROCEEDINGS. Proceedings for the appointment of a receiver, trustee, liquidator or custodian of Company or of all or a substantial part of the property thereof, or an involuntary case

or other proceedings seeking liquidation, reorganization or other relief with respect to Company or the debts thereof under any bankruptcy, insolvency or other similar law now or hereafter in effect shall be commenced and an order for relief entered or such proceeding shall not be dismissed or discharged within sixty (60) calendar days of commencement; or

(f) OTHER DEFAULTS. Company shall fail to make any payment in respect of any Indebtedness in an amount of \$(**) or more when due or within any applicable grace period therefor, or any event or condition shall occur which results in the acceleration of the maturity of any such Indebtedness; or

(g) JUDGMENTS. A final judgment or order for the payment of money in excess of \$(**) shall be rendered against Company and such judgment or order shall continue unsatisfied or unbonded and in effect for a period of thirty (30) days.

5.2 Rights of Purchaser upon Default.

(a) ACCELERATION. Upon the occurrence or existence of any Event of Default described in Sections 5.1(d) and 5.1(e), automatically and without notice or, at the option of Purchaser, upon the occurrence of any other Event of Default, all outstanding Obligations payable by Company hereunder shall become immediately due and payable, without presentment, demand, protest or any other notice of any kind, all of which are hereby expressly waived, anything contained herein or in the other Transaction Documents to the contrary notwithstanding.

(b) CUMULATIVE RIGHTS, ETC. The rights, powers and remedies of Purchaser under this Purchase Agreement shall be in addition to all rights, powers and remedies given to Purchaser by virtue of any applicable law, rule or regulation of any Governmental Authority, any transaction contemplated thereby or any other agreement, all of which rights, powers, and remedies shall be cumulative and may be exercised successively or concurrently without impairing Purchaser's rights hereunder.

ARTICLE 6 SUBORDINATION

6.1 Agreement to Subordinate. Purchaser agrees to enter into any intercreditor or subordination agreements in connection with the issuance by Company of Senior Debt providing (i) that Purchaser's right to receive payment of the Obligations is and shall be subordinated to the prior payment in full of any such Senior Debt, and (ii) any liens granted by Company to Purchaser on assets of Company other than Compound-Related Intellectual Property are and shall be subordinated to any liens granted by Company securing any such Senior Debt (provided that Purchaser's security interest on Compound-Related Intellectual Property shall remain a first priority security interest), in each case on reasonable terms and conditions requested by a provider to Company of such Senior Debt.

ARTICLE 7
MISCELLANEOUS

7.1 Notices. Except as otherwise provided herein, all notices, requests, demands, consents, instructions or other communications to or upon Purchaser or Company under this Purchase Agreement or the other Transaction Documents shall be in writing and faxed, mailed, sent by electronic mail or delivered, and (i) if to Company, at its fax number, electronic mail address or address set forth below, or (ii) if to Purchaser, at its fax number, electronic mail address or address set forth below (or to such other fax number, electronic mail address or address for any party as indicated in any notice given by that party to the other party). All such notices and communications shall be effective (a) when sent by Federal Express or other overnight service of recognized standing, on the Business Day following the deposit with such service; (b) when mailed by registered or certified mail, first class postage prepaid and addressed as aforesaid through the United States Postal Service, upon receipt; (c) when delivered by hand, upon delivery; and (d) when faxed or sent by electronic mail, upon confirmation of receipt; provided, however, that any notice delivered to Purchaser under Article 2 shall not be effective until received by Purchaser.

PURCHASER: TANABE HOLDING AMERICA, INC.
 401 Hackensack Avenue, 10th Floor
 Hackensack, NJ 07601
 Attention:

COMPANY: VIVUS, INC.
 1172 Castro Street
 Mountain View, CA 94040
 Attention:

7.2 Waivers; Amendments. Any term, covenant, agreement or condition of this Purchase Agreement or any other Transaction Document may be amended or waived if such amendment or waiver is in writing and is signed by Company and Purchaser. No failure or delay by Purchaser in exercising any right hereunder shall operate as a waiver thereof or of any other right nor shall any single or partial exercise of any such right preclude any other further exercise thereof or of any other right. A waiver or consent given hereunder shall be effective only if in writing and in the specific instance and for the specific purpose for which given.

7.3 Successors and Assigns. This Purchase Agreement and the other Transaction Documents shall be binding upon and inure to the benefit of Company, Purchaser and their respective successors and permitted assigns, except that each of Company and Purchaser may not assign or transfer (and any such attempted

assignment or transfer shall be void) any of its rights or obligations under any Transaction Document without the prior written consent of the other respective party.

7.4 Set-off. In addition to any rights and remedies of Purchaser provided by law, Purchaser shall have the right, without prior notice to Company, any such notice being expressly waived by Company to the extent permitted by applicable law, upon the occurrence and during the continuance of an Event of Default, to set-off and apply against any Indebtedness, whether matured or unmatured, of Company to Purchaser (including, without limitation, the Obligations), any amount owing from Purchaser to Company. The aforesaid right of set-off may be exercised by Purchaser against Company or against any trustee in bankruptcy, debtor-in-possession, assignee for the benefit of creditors, receiver or execution, judgment or attachment creditor of Company or against anyone else claiming through or against Company or such trustee in bankruptcy, debtor-in-possession, assignee for the benefit of creditors, receiver, or execution, judgment or attachment creditor, notwithstanding the fact that such right of set-off shall not have been exercised by Purchaser prior to the occurrence of an Event of Default. Purchaser agrees promptly to notify Company after any such set-off and application made by Purchaser, provided that the failure to give such notice shall not affect the validity of such set-off and application.

7.5 No Third Party Rights. Except with respect to Article 6 of this Purchase Agreement, nothing expressed in or to be implied from this Agreement or any other Transaction Document is intended to give, or shall be construed to give, any Person, other than the parties hereto and thereto and their permitted successors and assigns, any benefit or legal or equitable right, remedy or claim under or by virtue of this Agreement or any other Transaction Document.

7.6 Partial Invalidity. If at any time any provision of this Purchase Agreement or any of the Transaction Documents is or becomes illegal, invalid or unenforceable in any respect under the law of any jurisdiction, neither the legality, validity or enforceability of the remaining provisions of the Purchase Agreement or such other Transaction Documents, nor the legality, validity or enforceability of such provision under the law of any other jurisdiction, shall in any way be affected or impaired thereby.

7.7 Governing Law. This Purchase Agreement and each of the other Transaction Documents shall be governed by and construed in accordance with the laws of the State of California without reference to conflicts of law rules.

7.8 Construction. Each of this Purchase Agreement and the other Transaction Documents is the result of negotiations among, and has been reviewed by, Company, Purchaser and their respective counsel. Accordingly, this Purchase Agreement and the other Transaction Documents shall be deemed to be the product of all parties hereto, and no ambiguity shall be construed in favor of or against Company or Purchaser.

7.9 Entire Agreement. This Purchase Agreement and the other Transaction Documents, taken together, constitute and contain the entire agreement of Company and Purchaser with respect to the subject matter hereby and supersede

any and all prior agreements, negotiations, correspondence, understandings and communications among the parties, whether written or oral, respecting the subject matter hereof.

[THE REMAINDER OF THIS PAGE IS INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the parties have executed this Purchase Agreement as of the date first set forth above.

COMPANY:

VIVUS, INC.

By: /s/ Leland Wilson

Name: Leland Wilson
Title: President & C.E.O.

PURCHASER:

TANABE HOLDING AMERICA, INC.

By: /s/ Norihito Ujino

Name: Norihito Ujino
Title: President & CEO

SCHEDULE I

NOTICE OF BORROWING

_____, 200_

TANABE HOLDING AMERICA, INC.

Attn: _____

1. Reference is made to that certain Note Purchase Agreement, dated as of December __, 2003 (the "Purchase Agreement"), between VIVUS, INC. ("Company") and TANABE HOLDING AMERICA, INC. ("Purchaser"). Unless otherwise indicated, all terms defined in the Purchase Agreement have the same respective meanings when used herein.

2. Pursuant to Section 2.1 of the Purchase Agreement, Company hereby requests an Advance from Purchaser upon the following terms:

The principal amount of the requested Advance is \$_____;

The Purchase Date of the requested Advance is _____, 200_.

3. Company hereby certifies that, on the date of such Advance and after giving effect to the requested Advance:

The representations and warranties set forth in Article 3 of the Purchase Agreement will be true and correct as if made on such date, except for those representations and warranties which address matters only as of a particular date (which representations and warranties shall remain true and correct as of such date);

No Event of Default or Default has occurred and is continuing; and

The total aggregate principal amount of outstanding Advances does not exceed the Commitment.

4. Please disburse the purchase price of the Note according to the following wire instructions:

Bank:
Address:
ABA No.
Acct. No.
Acct. Name: VIVUS, Inc.
Reference: Tanabe Loan

IN WITNESS WHEREOF, Company has executed this Notice of Borrowing on the date set forth above.

VIVUS, INC.

By: -----
Name: -----
Title: -----

EXHIBIT A

VIVUS, INC.

SECURED PROMISSORY NOTE

[\$_____]

[_____] , 200_

Mountain View, California

FOR VALUE RECEIVED, VIVUS, Inc., a Delaware corporation (the "COMPANY") promises to pay to Tanabe Holding America, Inc. ("PURCHASER"), or its registered assigns, in lawful money of the United States of America the principal sum of [_____] Dollars (\$[_____]), or such lesser amount as shall equal the outstanding principal amount hereof, together with interest from the date of this Note on the unpaid principal balance at a rate equal to 2.00% per annum, computed on the basis of the actual number of days elapsed and a year of 365 days. All unpaid principal, together with any then unpaid and accrued interest and other amounts payable hereunder, shall be due and payable on demand on the earlier of (i) four years from the date of this Note (the "MATURITY DATE"), or (ii) when, upon or after the occurrence of an Event of Default (as defined below), such amounts are declared due and payable by Purchaser or made automatically due and payable in accordance with the terms hereof. This Note is one of the "Notes" issued pursuant to the Note Purchase Agreement (as amended, modified or supplemented, the "PURCHASE AGREEMENT") between Company and Purchaser.

THE OBLIGATIONS DUE UNDER THIS NOTE ARE SECURED BY A SECURITY AGREEMENT DATED AS OF JANUARY 8, 2004 AND EXECUTED BY COMPANY FOR THE BENEFIT OF PURCHASER. ADDITIONAL RIGHTS OF PURCHASER ARE SET FORTH IN THE SECURITY AGREEMENT AND PURCHASE AGREEMENT.

The following is a statement of the rights of Purchaser and the conditions to which this Note is subject, and to which Purchaser, by the acceptance of this Note, agrees:

1. DEFINITIONS. Capitalized terms used but not otherwise defined herein shall have the meanings assigned to such terms in the Purchase Agreement.

2. INTEREST. Accrued interest on this Note shall be payable on an annual basis on the fifteenth day of December of each year while this Note is outstanding.

3. PREPAYMENT. The prepayment of this Note is governed by Section 2.6 of the Purchase Agreement.

4. RIGHTS OF PURCHASER UPON DEFAULT. The rights of the Purchaser upon an Event of Default are as set forth in Section 5.2 of the Purchase Agreement and Section 6 of the Security Agreement.

5. SUCCESSORS AND ASSIGNS. Subject to the restrictions on transfer described in Section 7 below, the rights and obligations of the Company and Purchaser shall be binding upon and benefit the successors, assigns, heirs, administrators and transferees of the parties.

6. WAIVER AND AMENDMENT. Any provision of this Note may be amended, waived or modified upon the written consent of the Company and Purchaser.

7. TRANSFER OF THIS NOTE. Neither this Note nor any of the rights, interests or obligations hereunder may be assigned, by operation of law or otherwise, in whole or in part, by the Company or the Purchaser without the prior written consent of the other respective party.

8. NOTICES. Except as otherwise provided herein, all notices, requests, demands, consents, instructions or other communications required or permitted hereunder shall be in writing and faxed, mailed or delivered to each party at the respective addresses of the parties as set forth and in the manner set forth in the Purchase Agreement.

9. PAYMENT. Payment shall be made in accordance with Section 2 of the Purchase Agreement, including but not limited to Section 2.5 of the Purchase Agreement.

10. WAIVERS. The Company hereby waives notice of default, presentment or demand for payment, protest or notice of nonpayment or dishonor and all other notices or demands relative to this instrument.

11. GOVERNING LAW. This Note and all actions arising out of or in connection with this Note shall be governed by and construed in accordance with the laws of the State of California, without regard to the conflicts of law provisions of the State of California, or of any other state.

[SIGNATURE PAGE FOLLOWS]

The Company has caused this Note to be issued as of the date first written above.

VIVUS, INC.
a Delaware corporation

By: _____

Name: _____

Title: _____

EXHIBIT B

SECURITY AGREEMENT

This Security Agreement (as amended, modified or otherwise supplemented from time to time, this "SECURITY AGREEMENT"), dated as of January 8, 2004, is executed by VIVUS, Inc., a Delaware corporation ("Company"), in favor of Tanabe Holding America, Inc. ("SECURED PARTY").

RECITALS

A. Company and Secured Party have entered into a Note Purchase Agreement, dated as of the date hereof (the "PURCHASE AGREEMENT"), pursuant to which the Company has issued or will issue promissory notes (as amended, modified or otherwise supplemented from time to time, (each a "NOTE" and collectively, the "NOTES").

B. In order to induce Secured Party to extend the credit evidenced by the Notes, Company has agreed to enter into this Security Agreement and to grant to Secured Party, the security interest in the Collateral described below.

AGREEMENT

NOW, THEREFORE, in consideration of the above recitals and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, Company hereby agrees with Secured Party as follows:

1. Definitions and Interpretation. When used in this Security Agreement, the following terms have the following respective meanings:

"COLLATERAL" has the meaning given to that term in Section 2 hereof.

"LIEN" shall mean, with respect to any property, any security interest, mortgage, pledge, lien, claim, charge or other encumbrance in, of, or on such property or the income therefrom, including, without limitation, the interest of a vendor or lessor under a conditional sale agreement, capital lease or other title retention agreement, or any agreement to provide any of the foregoing, and the filing of any financing statement or similar instrument under the UCC or comparable law of any jurisdiction.

"PERMITTED LIENS" means (a) Liens for taxes not yet delinquent or Liens for taxes being contested in good faith and by appropriate proceedings for which adequate reserves have been established; (b) Liens in respect of property or assets imposed by law which were incurred in the ordinary course of business, such as carriers', warehousemen's, materialmen's and mechanics' Liens and other similar Liens arising in the ordinary course of business which are not delinquent or remain payable without penalty or which are being contested in good faith and by appropriate proceedings; (c) Liens incurred or deposits made in the ordinary course of business in connection with workers'

compensation, unemployment insurance and other types of social security, and mechanic's Liens, carrier's Liens and other Liens to secure the performance of tenders, statutory obligations, contract bids, government contracts, letters of credit, performance and return of money bonds and other similar obligations, incurred in the ordinary course of business, whether pursuant to statutory requirements, common law or consensual arrangements; (d) Liens in favor of the Secured Party; (e) Liens upon any equipment acquired or held by Company or any of its Subsidiaries to secure the purchase price of such equipment or indebtedness incurred solely for the purpose of financing the acquisition of such equipment, so long as such Lien extends only to the equipment financed, and any accessions, replacements, substitutions and proceeds (including insurance proceeds) thereof or thereto; (f) Liens in favor of customs and revenue authorities arising as a matter of law to secure payments of customs duties in connection with the importation of goods, (g) Liens which constitute rights of setoff of a customary nature or banker's liens, whether arising by law or by contract; (h) Liens on insurance proceeds in favor of insurance companies granted solely as security for financed premiums; (i) leases or subleases and licenses or sublicenses granted in the ordinary course of Company's business; (j) Liens securing Senior Debt; (k) Liens on properties in respect of judgments or awards not constituting an Event of Default under the Purchase Agreement; (l) Liens incurred in connection with the securing of interest payments on an issuance of debt securities and customary Liens granted in favor of a trustee to secure fees and other amounts owing to such trustee under an indenture or other agreement; and (m) Liens to secure the performance of hedging, swap or similar transactions.

"UCC" means the Uniform Commercial Code as in effect in the State of California from time to time.

All capitalized terms not otherwise defined herein shall have the respective meanings given in the Purchase Agreement. Unless otherwise defined herein, all terms defined in the UCC have the respective meanings given to those terms in the UCC.

2. GRANT OF SECURITY INTEREST. As security for the Obligations, Company hereby pledges to Secured Party and grants to Secured Party a security interest in all right, title and interests of Company in and to the property described in Attachment 1 hereto, whether now existing or hereafter from time to time acquired, including, without limitation, the Compound-Related Intellectual Property (collectively, the "COLLATERAL"). Subject to Permitted Liens, the security interest granted hereunder on the Compound-Related Intellectual Property shall constitute a first priority security interest. Notwithstanding the foregoing, the security interest granted herein shall not extend to and the term "Collateral" shall not include (a) any equipment or other property financed by a third party, provided that such third party's Liens are Liens of the type described in subsection (e) of the definition of Permitted Liens, and (b) account number _____ located at _____ San Francisco, California, USA, and the contents therein relating to the Company's facility under lease in Lakewood, New Jersey.

3. GENERAL REPRESENTATIONS AND WARRANTIES. Company represents and warrants to Secured Party that (a) Company is the owner of the Collateral (or, in the case of after-acquired Collateral, at the time Company acquires rights in the Collateral, will be the owner thereof) and that no other Person has (or, in the case of after-acquired Collateral, at the time Company acquires rights therein,

will have) any right, title, claim or interest (by way of Lien or otherwise) in, against or to the Collateral, other than Permitted Liens; (b) upon the filing of UCC-1 financing statements in the appropriate filing offices, Secured Party has (or in the case of after-acquired Collateral, at the time Company acquires rights therein, will have) a perfected security interest in the Collateral to the extent that a security interest in the Collateral can be perfected by such filing, except for Permitted Liens; (c) all Inventory has been (or, in the case of hereafter produced Inventory, will be) produced in compliance with applicable laws, including the Fair Labor Standards Act; (d) all accounts receivable and payment intangibles are genuine and enforceable against the party obligated to pay the same; (e) the originals of all documents evidencing all accounts receivable and payment intangibles of Company and the only original books of account and records of Company relating thereto are, and will continue to be, kept at address of the Company set forth in Section 7 of this Security Agreement.

4. COVENANTS RELATING TO COLLATERAL. Company hereby agrees (a) to perform all acts that may be necessary to maintain, preserve, protect and perfect the Collateral, the Lien granted to Secured Party therein and the perfection of such Lien, except for Permitted Liens; (b) not to use or permit any Collateral to be used (i) in violation in any material respect of any applicable law, rule or regulation, or (ii) in violation of any policy of insurance covering the Collateral; (c) to pay promptly when due all taxes and other governmental charges, all Liens and all other charges now or hereafter imposed upon or affecting any Collateral; (d) without 30 days' written notice to Secured Party, (i) not to change Company's name or place of business (or, if Company has more than one place of business, its chief executive office), or the office in which Company's records relating to accounts receivable and payment intangibles are kept, and (ii) not to change Company's state of incorporation; (e) to procure, execute and deliver from time to time any endorsements, assignments, financing statements and other writings reasonably deemed necessary or appropriate by Secured Party to perfect, maintain and protect its Lien hereunder and the priority thereof and to deliver promptly upon the request of Secured Party all originals of Collateral consisting of instruments, and (f) the security interest granted hereunder on the Compound-Related Intellectual Property shall constitute a first priority security interest, subject to Permitted Liens.

5. AUTHORIZED ACTION BY SECURED PARTY. Company hereby irrevocably appoints Secured Party as its attorney-in-fact (which appointment is coupled with an interest) and agrees that Secured Party may perform (but Secured Party shall not be obligated to and shall incur no liability to Company or any third party for failure so to do) any act which Company is obligated by this Security Agreement to perform, and to exercise such rights and powers as Company might exercise with respect to the Collateral, including the right to (a) collect by legal proceedings or otherwise and endorse, receive and receipt for all dividends, interest, payments, proceeds and other sums and property now or hereafter payable on or on account of the Collateral; (b) enter into any extension, reorganization, deposit, merger, consolidation or other agreement pertaining to, or deposit, surrender, accept, hold or apply other property in exchange for the Collateral; (c) make any compromise or settlement, and take any action it deems advisable, with respect to the Collateral; (d) insure, process and preserve the Collateral; (e) pay any indebtedness of Company relating to the Collateral; and (f) file UCC financing statements and execute other documents, instruments and agreements required hereunder; provided, however, that Secured Party shall not exercise any such powers granted pursuant to subsections (a) through (e) prior to the occurrence of an Event of Default and shall only exercise such

powers during the continuance of an Event of Default. Company agrees to reimburse Secured Party upon demand for any reasonable costs and expenses, including attorneys' fees, Secured Party may incur while acting as Company's attorney-in-fact hereunder, all of which costs and expenses are included in the Obligations. It is further agreed and understood between the parties hereto that such care as Secured Party gives to the safekeeping of its own property of like kind shall constitute reasonable care of the Collateral when in Secured Party 's possession; provided, however, that Secured Party shall not be required to make any presentment, demand or protest, or give any notice and need not take any action to preserve any rights against any prior party or any other person in connection with the Obligations or with respect to the Collateral.

6. DEFAULT AND REMEDIES.

(a) Default. Company shall be deemed in default under this Security Agreement upon the occurrence and during the continuance of an Event of Default (as defined in the Purchase Agreement).

(b) Remedies. Upon the occurrence and during the continuance of any such Event of Default, Secured Party shall have the rights of a secured creditor under the UCC, all rights granted by this Security Agreement and by law, including the right to: (a) require Company to assemble the Collateral and make it available to Secured Party at a place to be designated by Secured Party; and (b) prior to the disposition of the Collateral, store, process, repair or recondition it or otherwise prepare it for disposition in any manner and to the extent Secured Party deems appropriate. Company hereby agrees that ten (10) days' notice of any intended sale or disposition of any Collateral is reasonable. In furtherance of Secured Party 's rights hereunder, Company hereby grants to Secured Party an irrevocable, non-exclusive license, exercisable without royalty or other payment by Secured Party, and only in connection with the exercise of remedies hereunder, to use, license or sublicense any patent, trademark, trade name, copyright or other intellectual property in which Company now or hereafter has any right, title or interest together with the right of access to all media in which any of the foregoing may be recorded or stored.

(c) Application of Collateral Proceeds. The proceeds and/or avails of the Collateral, or any part thereof, and the proceeds and the avails of any remedy hereunder (as well as any other amounts of any kind held by Secured Party at the time of, or received by Secured Party after, the occurrence of an Event of Default) shall be paid to and applied as follows:

(i) First, to the payment of reasonable costs and expenses, including all amounts expended to preserve the value of the Collateral, of foreclosure or suit, if any, and of such sale and the exercise of any other rights or remedies, and of all proper fees, expenses, liability and advances, including reasonable legal expenses and attorneys' fees, incurred or made hereunder by Secured Party;

(ii) Second, to the payment to Secured Party of the amount then owing or unpaid to Secured Party (to be applied first to accrued interest and second to outstanding principal);

(iii) Third, to the payment of other amounts then payable to Secured Party under any of the Transaction Documents; and

(iv) Fourth, to the payment of the surplus, if any, to Company, its successors and assigns, or to whomsoever may be lawfully entitled to receive the same.

7. MISCELLANEOUS.

(a) Notices. Except as otherwise provided herein, all notices, requests, demands, consents, instructions or other communications to or upon Secured Party or Company under this Security Agreement or the other Transaction Documents shall be in writing and telecopied, mailed, sent by electronic mail or delivered, and (i) if to Company, at its telecopier number, electronic mail address or address set forth below, or (ii) if to Secured Party, at its telecopier number, electronic mail address or address set forth below (or to such other telecopier number, electronic mail address or address for any party as indicated in any notice given by that party to the other party). All such notices and communications shall be effective (a) when sent by Federal Express or other overnight service of recognized standing, on the Business Day following the deposit with such service; (b) when mailed by registered or certified mail, first class postage prepaid and addressed as aforesaid through the United States Postal Service, upon receipt; (c) when delivered by hand, upon delivery; and (d) when telecopied or sent by electronic mail, upon confirmation of receipt.

SECURED PARTY: TANABE HOLDING AMERICA, INC.
401 Hackensack Avenue, 10th Floor
Hackensack, NJ 07601
Attention:

COMPANY: VIVUS, INC.
1172 Castro Street
Mountain View, CA 94040
Attention:

(b) Termination of Security Interest. Upon the payment in full of all Obligations, the security interest granted herein shall terminate and all rights to the Collateral shall revert to Company. Upon such termination Secured Party hereby authorizes Company to file any UCC termination statements necessary to effect such termination and Secured Party will execute and deliver to Company any additional documents or instruments as Company shall reasonably request to evidence such termination. If Secured Party shall have proceeded to enforce any right under this Security Agreement by foreclosure, sale, entry or otherwise, and such proceedings shall have been discontinued or abandoned for any reason or shall have been determined adversely, then and in every such case (unless ordered otherwise by a court of competent jurisdiction), Secured Party shall be

restored to its former position and rights hereunder with respect to the Collateral subject to the security interest created under this Security Agreement.

(c) Nonwaiver. No failure or delay on Secured Party's part in exercising any right hereunder shall operate as a waiver thereof or of any other right nor shall any single or partial exercise of any such right preclude any other further exercise thereof or of any other right.

(d) Amendments and Waivers. This Security Agreement may not be amended or modified, nor may any of its terms be waived, except by written instruments signed by Company and Secured Party. Each waiver or consent under any provision hereof shall be effective only in the specific instances for the purpose for which given.

(e) Assignments. This Security Agreement shall be binding upon and inure to the benefit of Secured Party and Company and their respective successors and assigns; provided, however, that each of Company and Purchaser may not sell, assign or delegate rights and obligations hereunder without the prior written consent of the other respective party.

(f) Cumulative Rights, etc. The rights, powers and remedies of Secured Party under this Security Agreement shall be in addition to all rights, powers and remedies given to Secured Party by virtue of any applicable law, rule or regulation of any governmental authority, any Transaction Document or any other agreement, all of which rights, powers, and remedies shall be cumulative and may be exercised successively or concurrently without impairing Secured Party's rights hereunder. Company waives any right to require Secured Party to proceed against any person or entity or to exhaust any Collateral or to pursue any remedy in Secured Party's power.

(g) Partial Invalidity. If at any time any provision of this Security Agreement is or becomes illegal, invalid or unenforceable in any respect under the law or any jurisdiction, neither the legality, validity or enforceability of the remaining provisions of this Security Agreement nor the legality, validity or enforceability of such provision under the law of any other jurisdiction shall in any way be affected or impaired thereby.

(h) Construction. Each of this Security Agreement and the other Transaction Documents is the result of negotiations among, and has been reviewed by, Company, Secured Party and their respective counsel. Accordingly, this Security Agreement and the other Transaction Documents shall be deemed to be the product of all parties hereto, and no ambiguity shall be construed in favor of or against Company or Secured Party.

(i) Entire Agreement. This Security Agreement taken together with the other Transaction Documents constitute and contain the entire agreement of Company and Secured Party and supersede any and all prior agreements, negotiations, correspondence, understandings and communications among the parties, whether written or oral, respecting the subject matter hereof.

(j) Other Interpretive Provisions. References in this Security Agreement and each of the other Transaction Documents to any document, instrument or agreement (a) includes all exhibits, schedules and other attachments thereto, (b) includes all documents, instruments or agreements

issued or executed in replacement thereof, and (c) means such document, instrument or agreement, or replacement or predecessor thereto, as amended, modified and supplemented from time to time and in effect at any given time. The words "hereof," "herein" and "hereunder" and words of similar import when used in this Security Agreement or any other Transaction Document refer to this Security Agreement or such other Transaction Document, as the case may be, as a whole and not to any particular provision of this Security Agreement or such other Transaction Document, as the case may be. The words "include" and "including" and words of similar import when used in this Security Agreement or any other Transaction Document shall not be construed to be limiting or exclusive.

(k) Governing Law. This Security Agreement shall be governed by and construed in accordance with the laws of the State of California without reference to conflicts of law rules (except to the extent governed by the UCC).

(l) Counterparts. This Security Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall be deemed to constitute one instrument.

[The remainder of this page is intentionally left blank]

IN WITNESS WHEREOF, Company has caused this Security Agreement to be executed as of the day and year first above written.

VIVUS, INC.

By: _____
Name: _____
Title: _____

AGREED:

Tanabe holding america, inc.,
as Secured Party

By: _____
Name:
Title:

ATTACHMENT 1
TO SECURITY AGREEMENT

All right, title, interest, claims and demands of Company in and to the following property:

(i) All goods and equipment now owned or hereafter acquired, including, without limitation, all laboratory equipment, computer equipment, office equipment, machinery, fixtures, vehicles, and any interest in any of the foregoing, and all attachments, accessories, accessions, replacements, substitutions, additions, and improvements to any of the foregoing, wherever located;

(ii) All inventory now owned or hereafter acquired, including, without limitation, all merchandise, raw materials, parts, supplies, packing and shipping materials, work in process and finished products including such inventory as is temporarily out of Company's custody or possession or in transit and including any returns upon any accounts or other proceeds, including insurance proceeds, resulting from the sale or disposition of any of the foregoing and any documents of title representing any of the above, and Company's books relating to any of the foregoing;

(iii) All contract rights, general intangibles, health care insurance receivables, payment intangibles and commercial tort claims, now owned or hereafter acquired, including, without limitation, all patents, patent rights (and applications and registrations therefor), trademarks and service marks (and applications and registrations therefor), inventions, copyrights, mask works (and applications and registrations therefor), trade names, trade styles, software and computer programs, trade secrets, methods, processes, know how, drawings, specifications, descriptions, and all memoranda, notes, and records with respect to any research and development, goodwill, license agreements, franchise agreements, blueprints, drawings, purchase orders, customer lists, route lists, infringements, claims, computer programs, computer disks, computer tapes, literature, reports, catalogs, design rights, income tax refunds, payments of insurance and rights to payment of any kind and whether in tangible or intangible form or contained on magnetic media readable by machine together with all such magnetic media;

(iv) All now existing and hereafter arising accounts, contract rights, royalties, license rights and all other forms of obligations owing to Company arising out of the sale or lease of goods, the licensing of technology or the rendering of services by Company (subject, in each case, to the contractual rights of third parties to require funds received by Company to be expended in a particular manner), whether or not earned by performance, and any and all credit insurance, guaranties, and other security therefor, as well as all merchandise returned to or reclaimed by Company and Company's books relating to any of the foregoing;

(v) All documents, cash, deposit accounts, letters of credit, letter of credit rights, supporting obligations, certificates of deposit, instruments, chattel paper, electronic chattel paper, tangible chattel paper and investment property, including, without limitation, all securities, whether certificated or uncertificated, security entitlements, securities accounts, commodity contracts and commodity accounts, and all financial assets held in any securities account or otherwise, wherever located, now owned or hereafter acquired and Company's books relating to the foregoing; and

(vi) Any and all claims, rights and interests in any of the above and all substitutions for, additions and accessions to and proceeds thereof, including, without limitation, insurance, condemnation, requisition or similar payments and the proceeds thereof.

Notwithstanding the foregoing, the term "Collateral" shall not include (a) any equipment or other property financed by a third party, provided that such third party's liens are upon any equipment acquired or held by Company or any of its subsidiaries to secure the purchase price of such equipment or indebtedness incurred solely for the purpose of financing the acquisition of such equipment, so long as such lien extends only to the equipment financed, and any accessions, replacements, substitutions and proceeds (including insurance proceeds) thereof or thereto, and (b) account number _____ located at San Francisco, California, and the contents therein relating to the Company's facility under lease in Lakewood, New Jersey.

MANUFACTURE AND SUPPLY AGREEMENT

This Manufacturing and Supply Agreement ("Agreement") is entered into as of December 22, 2003 ("Effective Date") by and between VIVUS, Inc., having a principal place of business at 1172 Castro Street, Mountain View, California 94040, United States of America ("VIVUS"), and NeraPharm spol., s.r.o., having a place of business at 277 11 Neratovice, Czech Republic ("NeraPharm").

WHEREAS, NeraPharm is a worldwide licensed manufacturer of prostaglandin;

WHEREAS, VIVUS desires to acquire a certain prostaglandin produced by NeraPharm.

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

ARTICLE 1 - DEFINITIONS

- 1.1 DMF" shall mean a drug master file, or its equivalent for the Product filed with a regulatory agency by or on behalf of NeraPharm which is adequate to comply with the applicable requirements and standards of such regulatory agency with respect to the Product.
- 1.2 "PH Eur" shall mean European Pharmacopoeia.
- 1.3 "FDA" shall mean the United States Food and Drug Administration.
- 1.4 "GMP" shall mean good manufacturing practices as defined by the FDA in 21 CFR Part 211 and European Guidelines.
- 1.5 "MUSE/ ALISTA System" shall mean VIVUS' system for delivery of the Product to treat male and female sexual dysfunction, as modified from time to time during the term of this Agreement.
- 1.6 "Product" shall mean Alprostadil USP (Prostaglandin E1)/Ph Eur (Prostaglandin E1).
- 1.7 "Specifications" shall mean the particulars as to composition, quality and other characteristics for the Product as set forth in Exhibit A hereto, as may be amended from time to time by mutual agreement of the parties.
- 1.8 "USP" shall mean United States Pharmacopoeia.

ARTICLE 2 - SUPPLY

- 2.1 Supply. NeraPharm shall supply to VIVUS quantities of the Product in full manufacturing lots ordered by VIVUS from time to time in accordance with this Agreement. Without limiting the foregoing, NeraPharm shall at all times maintain facilities to manufacture, with three (3) months prior notice, at least (*) (* - *) of Product per quarter. The (*) and (*) quantity is the expected yield of the manufactured lot that NeraPharm will validate for the production of Product to be supplied by NeraPharm to VIVUS under this Agreement. NeraPharm will use only validated lot sizes and processes for production of Product for supply to VIVUS. VIVUS and NeraPharm must mutually agree to any other batch size NeraPharm may wish to validate and use for Product supply under this Agreement.

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- 2.2 Orders. Quantities of the Product will be supplied by NeraPharm pursuant to purchase orders submitted by VIVUS from time to time. NeraPharm agrees to accept VIVUS' purchase orders for the Product, provided that the purchase order is in accordance with the forecast provided and other stipulations of this Agreement and provides for a lead time of not less than six (6) weeks, but not to exceed ten (10) weeks. NeraPharm's obligation to supply within this lead time period shall be limited to those quantities included in the forecast provided by VIVUS at least six (6) months earlier.
- 2.3 Obligation to Supply. Subject to the terms of this Article 2, NeraPharm shall accept and fill all orders placed by VIVUS for the product. Per Section 2.1 of this Agreement, the yield of the manufactured lot size that NeraPharm will validate for Product supply to VIVUS under this Agreement is expected to be (*) to (*). Forecasts provided by VIVUS to NeraPharm for Product supply will be in whole lot quantities with a target yield of (*) per lot. Beginning in 2005, VIVUS will provide to NeraPharm a binding six (6) month forecast and a non-binding twelve

(12) month forecast starting from the end of the binding six (6) month period. The non-binding twelve (12) month forecast will assist NeraPharm in planning and capacity allocation and the binding six (6) month forecast will set forth quantities that VIVUS will be obligated to buy and NeraPharm will be obligated to supply; provided that due to manufacturing batch yield variances, NeraPharm shall supply quantities in amounts that are plus or minus (*) of the VIVUS ordered quantity in (*), and further provided that VIVUS may order an additional (*) per quarter above the binding forecast amount and up to (*) per four (4) quarter period. Such binding and non-binding forecasts shall be updated by VIVUS on February 28, May 30, August 30 and November 30 for eighteen (18) month periods starting from the first day of the first subsequent calendar quarter. The total of the quantities indicated for the first three months of such updated binding forecasts including the firm orders already placed, but not including back orders, if any, shall be not less than (*) per quarter less than the quantities indicated for the same calendar period in the binding forecast issued three (3) months before. VIVUS, from time to time, may need to purchase quantities in excess of (*) per quarter above the binding forecast or more than (*) per four (4) quarter period. In such case, NeraPharm will use its best efforts to supply VIVUS' requirements.

- 2.4 Form of Orders. VIVUS' orders shall be made pursuant to a written purchase order which is in a form mutually acceptable to the parties, and shall provide for shipment in accordance with reasonable delivery schedules as may be agreed upon from time to time by NeraPharm and VIVUS. NeraPharm shall use all reasonable efforts to notify VIVUS within five (5) days from receipt of an order of its ability to fill any amounts of such order in excess of the quantities that NeraPharm is obligated to supply. No terms contained in any purchase order, order acknowledgment or similar standardized form shall be construed to amend or modify the terms of this Agreement and in the event of any conflict, this Agreement shall control unless expressly agreed in writing.
- 2.5 Minimum Quantities. VIVUS agrees to order at least (*) batches (*) of Product for delivery during the calendar years 2004, 2005 and 2006.
- 2.6 Maximum Quantities. Notwithstanding anything herein to the contrary, NeraPharm shall not be obligated to supply to VIVUS more than (*) batches of Product in any calendar year provided that NeraPharm agrees to use all reasonable efforts to supply any quantities in excess of such amounts as VIVUS may order in accordance with Section 2.3 above.

- 2.7 Price. The price to be paid by VIVUS per (*) of the Product ordered by VIVUS shall be based upon the quantities of the Product ordered by VIVUS and delivered by NeraPharm during a particular calendar year, as follows:
- 2.7.1 The price of Product delivered for the first (*) during the calendar years 2004, 2005 and 2006 shall be \$ (**) per (*).
- 2.7.2 The Price of Product delivered in excess of (*) kg shall be mutually agreed by the parties hereto.
- 2.8 Packaging. Product shall be supplied to VIVUS: (a) in airtight and moisture-proof containers which have stability to support storage; (b) in standard quantities of (*), and no less than (*) and no more than (*); (c) in plastic packing material sufficient to prevent breakage of bottles while in transport; and (d) with a packaging label(s) displaying, in addition to the standard requirements, the tare weight, packaging job number, and bottle serial number per packaging job. The tare weight indicated shall contain the weight of the empty bottle, cap and cap insert, but neither of the label weights or that of external protective materials. A copy of a certificate of analysis for each such lot shall accompany such lot. A second copy of such certificate of analysis shall be separately sent to VIVUS.
- 2.9 Shipping Terms; Payment. All prices set forth in Section 2.7 above shall be CIP (Incoterms 2000) to an airport (in the case of shipment by airfreight) or to an address (in the case of shipment by courier service). The manner of shipment shall be designated by NeraPharm and the airport or address shall be designated by VIVUS. All payments hereunder shall be made in U.S. dollars, by direct bank transfer to an account designated in NeraPharm's Invoice. Payment terms shall be forty-five (45) days from the date of Invoice.
- 2.10 Taxes. VIVUS shall be responsible for the payment of any taxes, tariffs or duties in excess of those covered by NeraPharm pursuant to CIP (Incoterms 2000) related to the import of the Product into the country of destination.

ARTICLE 3 - QUALITY

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

- 3.2 NeraPharm will manufacture (*) batches of Product, approximately (*) each, in a campaign starting in 2004. The first batch will be completed no later than March 31, 2004. The second and third batches will follow thereafter and will be completed no later than June 30, 2004. During this campaign, NeraPharm will apply change of manufacturing process validation to assure NeraPharm's current manufacturing process is in full compliance with current U.S. FDA and European regulatory cGMPs and with NeraPharm's U.S. and European DMFs.
- 3.3 NeraPharm agrees to carry out all tests and studies necessary to prove the equivalence of Product manufactured with NeraPharm's current manufacturing process using these three batches, including stability studies, and submit any necessary Specification or DMF changes and all related results as required by the regulatory authorities in a schedule set forth below:
- a. To the U.S. FDA with three (3) month stability results no later than October 15, 2004;
 - b. To the European and other regulatory authorities no later than thirty (30) days after receipt of a written request from VIVUS, such written request to occur no earlier than September 15, 2004, such submission to include the latest stability results available at the time of submission.
- 3.4 NeraPharm agrees to provide VIVUS with a detailed analytical report on its findings on these batches of Product at the time of their qualification and results of its stability studies at the time such results are available.
- 3.5 VIVUS agrees to carry out all tests and studies necessary to acquire the approval of the U.S., EU and other regulatory authorities for its use of Product manufactured with the current process of NeraPharm as active ingredient in its finished product MUSE.
- 3.6 VIVUS agrees that these tests and studies shall include manufacture and stability studies of validation batches of MUSE using each of the first (*) batches of Product from NeraPharm.
- 3.7 VIVUS agrees to inform NeraPharm about its main findings on these validation batches of MUSE as well as to notify NeraPharm in a timely manner regarding regulatory submissions and their outcome.
- 3.8 Quality Control. Prior to each shipment of Product, NeraPharm shall perform quality control procedures to verify that the quantity or batch of such Product to be shipped conforms fully with the Specifications. Each shipment of Product shall be accompanied by a Certificate of Analysis describing all current requirements of the Specifications, results of test performed, as well as Batch Release Sheet certifying that the batch of Product supplied has been manufactured, controlled and released according to the Specifications, current DMFs and all relevant and current GMP requirements at the Facility stipulated under Section 3.1 above.
- 3.9 Rejection. VIVUS shall have sixty (60) days following its receipt of a shipment of Product to reject such Product on the grounds that all or part of the shipment fails to conform to the applicable Specifications or otherwise fails to conform to the warranties given by NeraPharm in Section 5.1, which rejection shall be accomplished by giving written notice to NeraPharm specifying the manner in which all or part of such shipment fails to meet the foregoing requirements. If rejection is based on grounds of contamination or Product not passing any physical test of Specification, VIVUS' rejection notice shall be accompanied by

satisfactory sample returned to NeraPharm to verify such non-conformity. If VIVUS rejects a shipment before the date on which payment therefore is due, it may withhold payment for such shipment or the rejected portion thereof. The warranties given by NeraPharm in Article 5 below shall survive any failure to reject by VIVUS under Section 3.9.

3.10 Returns and Settlement of Claims. NeraPharm shall be obliged to respond in writing to VIVUS accepting or refusing a rejection notice from VIVUS within forty-five (45) days from the date of receipt of such rejection notice in accordance with Section 3.9 above. In case of disagreement between the parties, the claim shall be submitted for tests and decision to an independent testing organization which meets appropriate GMP or consultant of recognized repute within the United States pharmaceutical industry mutually agreed upon by the parties (the "Laboratory"), the appointment of which shall not be unreasonably withheld or delayed by either party. The determination of such entity with respect to all or part of any shipment of Product shall be final and binding upon the parties. The fees and expenses of the Laboratory making such determination shall be paid by the party against which the determination is made (i.e., the party whose argument is rejected by the Laboratory). Products accepted by NeraPharm as not meeting the applicable requirements and Specifications or so decided by the Laboratory shall be returned by VIVUS to NeraPharm. NeraPharm shall use its best efforts to replace the quantities of Product returned by VIVUS within the shortest possible time, but no later than sixty (60) days from the return of such quantities. The replacement of returned Product shall have priority over the supply of Product ordered for shipment, not more than thirty (30) days before or any time after the return of the rejected quantity to NeraPharm. Without limiting the remedies of VIVUS, if NeraPharm fails to replace returned Product within one-hundred and fifty (150) days from the date Product is returned to NeraPharm, VIVUS shall have the right (i) to cancel such replacement shipment by written notice and (ii) to reclaim immediately (either through refund or setoff, at VIVUS' discretion) the amounts paid pursuant to Section 2.7 above for the Product that was returned but not replaced, if such payment for such Product had already been made to NeraPharm.

3.11 Presence At Facility. Upon reasonable notice given by VIVUS to NeraPharm and at reasonable frequency, VIVUS shall have the right to assign a reasonable number of employees or consultants of VIVUS to inspect and audit the Facility at which Product is manufactured in order to verify NeraPharm's compliance with the current GMP and other agreed requirements, provided, however that (a) such employees or consultants shall not unreasonably interfere with order activities being carried out of Facility, and (b) that such employees or consultants shall observe all rules and regulations applicable to visitors and to individuals employed at the Facility.

ARTICLE 4 - REGULATORY MATTERS

4.1 Regulatory Approvals.

4.1.1 Requirements. VIVUS and its marketing partners shall notify NeraPharm in a timely fashion about their requirements for the submission and maintenance of DMFs related to the manufacture and control of the Product adequate to comply with applicable regulatory agencies' (including without limitation the FDA's) standards with respect to the Product in the United States, Europe, Canada, and other countries as is or becomes necessary for VIVUS and its marketing partners to import, export and sell the MUSE/ALISTA System worldwide. NeraPharm will submit, at NeraPharm's expense, a DMF or its equivalent in any other

country imposing requirements fully identical to that of the United States, Canada or the European Union within two (2) months after such requirement received from VIVUS or its marketing partners. In case VIVUS or its marketing partner requires the submission of a DMF in a country not covered by the foregoing stipulations, VIVUS will assist NeraPharm, directly or through others, to obtain the full details of requirements of a DMF on the manufacture and control of the Product in the country concerned. NeraPharm will use its best efforts to fulfill these requirements and to submit such document with content and form required in the country in question and at the time required by VIVUS. NeraPharm shall keep VIVUS and its marketing partners, as appropriate, informed about its ability or inability to submit and maintain such documentation as well as the intended or possible times of such submissions.

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

4.2 Inspections. NeraPharm shall permit regulatory agencies to conduct such inspections of the Facility as the regulatory agencies may request, and shall cooperate with the regulatory agencies with respect to such inspections and any related matters. NeraPharm shall give VIVUS prior written notice of any inspections, and shall keep VIVUS informed about the results and conclusions of each regulatory inspection, including actions taken by NeraPharm to remedy conditions cited in such inspections. In addition, NeraPharm shall allow VIVUS or its representative to assist in the preparation for and be present at such inspections. NeraPharm shall provide VIVUS with copies of any written inspection reports issued by such agencies and all correspondence between NeraPharm and the agency involved, including, but not limited to, FDA Form 483 and all correspondence relating thereto. VIVUS and its regulatory consultants, agents, marketing partners or other third parties agreed upon in advance by NeraPharm, under reasonable confidentiality requirements, shall have access, to quality assurance and current GMP audits of DMFs for the purposes of assessment of regulatory compliance, to the buildings, records and areas of the Facility involved in the manufacture, testing, storage and shipment of the Product.

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

4.4 Maintenance of Approvals. Notwithstanding anything herein to the contrary, NeraPharm shall not undertake any modifications to Product

manufacturing or testing processes, specifications or filing that could impact VIVUS product approvals, regulatory product reviews, IND or any other compliance status without prior written agreement of VIVUS. NeraPharm shall obtain and maintain all licenses, permits and registrations necessary to manufacture the Product and supply it hereunder.

ARTICLE 5 - PRODUCT WARRANTIES

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

- 5.1.1 Specifications. All Product supplied to VIVUS hereunder shall comply with the Specifications for the Product and shall conform with the information shown on the Certificate of Analysis and Batch Release Sheet provided for the particular shipment according to Section 3.2 hereof;
- 5.1.2 GMP. The Facility, and all Product supplied to VIVUS hereunder meets (a) all United States and European regulatory requirements for commercialization of the Product, including without limitation maintenance of a current DMF, compliance with GMP, demonstration of commercial production capability, and demonstration of acceptable stability of such Product; (b) all ISO 9000 regulatory requirements applicable to the Product; and (c) all requirements imposed by other regulatory agencies with which a DMF has been filed for the Product;
- 5.1.3 USP/Ph Eur. All Product supplied to VIVUS hereunder shall meet all USP and European Pharmacopoeia and other applicable standards and shall be fit for human use;
- 5.1.4 Compliance with FFDC. None of the Product supplied to VIVUS hereunder shall be adulterated or misbranded within the meaning of the Federal Food, Drug and Cosmetics Act, 21 U.S.C.A. ss.301 et seq., as amended and in effect of the time of shipment (the "Act"), or within the meaning of any state or municipal laws applicable to the Products and containing terms with substantially similar meanings as the meanings of adulteration or misbranding under the Act; provided, however, that this provision shall not apply to, and NeraPharm shall have no responsibility for, misbranding caused directly by VIVUS as a result of labels or package text specified by VIVUS for the Product;
- 5.1.5 Timing. All Product supplied to VIVUS hereunder shall have been manufactured within twenty-two (22) weeks prior to receipt by VIVUS;
- 5.1.6 Notification. NeraPharm will provide written notice to VIVUS of any proposed alterations to the Facility or to any Product manufacturing or testing process; provided, however, that under no circumstances shall any such alteration be made without VIVUS' express prior written consent, or before regulatory approval, if required for any such alteration, is received in each country in which Product is then being sold; and
- 5.1.7 No Encumbrance. Title to all Product supplied to VIVUS hereunder shall pass to VIVUS as provided herein free and clear of any security interest, lien, or other encumbrance.

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

ARTICLE 6 - TERM AND TERMINATION

- 6.1 Term. The term of this Agreement shall commence on the Effective Date and continue in full force until December 31, 2006, unless terminated earlier in accordance with this Article 6.
- 6.2 Termination for Convenience. Either party hereto may terminate this Agreement upon ninety (90) days prior written notice to the other party hereto; provided, however, such termination shall not become effective prior to December 31, 2004.
- 6.3 Termination by NeraPharm. NeraPharm shall have the right to terminate this Agreement on thirty (30) days prior written notice to VIVUS after the beginning of any calendar year during the term of this Agreement but before February 28, of such year, if VIVUS fails to order for delivery the minimum purchase obligation set forth in Section 2.5 during the previous calendar year; provided that VIVUS does not order sufficient quantities to cure such shortfall within the foregoing thirty (30)-day period.
- 6.4 Breach. This Agreement may be terminated by either party if the other party breaches any material term or condition of this Agreement and fails to remedy the breach within sixty (60) days after being given written notice thereof.
- 6.5 Effect of Termination. In the case of notice termination by either party under Section 6.3 or 6.4., the parties' obligations, including NeraPharm's obligation to supply Product ordered by VIVUS, and VIVUS' obligation to purchase Product included in any binding forecast pursuant to Section 2.3. shall survive. In addition, VIVUS may purchase and NeraPharm agrees to supply quantities of Product for which VIVUS has not found alternate suppliers, at NeraPharm's then current prices of Product.
- 6.6 Survival. It is understood that termination or expiration of this Agreement shall not relieve a party from any liability which, at the time of such termination or expiration, has already accrued to the other party. The provisions of Sections 3.9, 3.10, 6.5, 6.6 and 10.1, and Articles 1, 5, 7, 9, and 11 shall survive the termination of this Agreement for any reason. All other rights and obligations of the parties shall cease upon termination of this Agreement. Except as otherwise expressly provided in this Article 6, all other rights and obligations of the parties shall terminate.

ARTICLE 7 - CONFIDENTIALITY

7.1 Confidential Information. The parties may from time to time disclose to each other Confidential Information. "Confidential Information" shall mean any information disclosed by one party to the other party hereto which if disclosed in tangible form is marked "confidential" or with other similar designation to indicate its confidential or proprietary nature or if disclosed orally is indicated orally to be confidential or proprietary by the party disclosing such information at the time of such disclosure and is confirmed in writing as confidential or proprietary by the disclosing party within forty-five (45) days after

such disclosure. Notwithstanding the foregoing, Confidential Information shall not include any information that, in each case as demonstrated by written documentation: (i) was already known to the receiving party, other than under an obligation of confidentiality, at the time of disclosure, as can be shown by competent proof; (ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving party; (iii) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving party in breach of this Agreement; (iv) was subsequently lawfully disclosed to the receiving party by a person other than the disclosing party, as can be shown by competent proof; (v) was developed by the receiving party without reference to any Confidential Information of the disclosing party.

7.2 Confidentiality. Each party hereby agrees: (i) to hold and maintain in strict confidence all Confidential Information of the other party; and (ii) not to use or disclose any Confidential Information of the other party except to those employees and consultants who have a need to know, as otherwise permitted by this Agreement, or as may be necessary to exercise its rights or perform its obligations under this Agreement; provided that each party to whom Confidential Information is disclosed is bound by the same terms regarding the disclosure and use of Confidential Information as set forth in this Article 7. Nothing contained in this Article 7 shall prevent either party from disclosing any Confidential Information of the other party to (a) regulatory agencies for the purpose of obtaining approval to distribute and market the Product; provided, however, that all reasonable steps are taken to maintain the confidentiality of such Confidential Information to be disclosed; (b) to accountants, lawyers or other professional advisors or in connection with a merger, acquisition or securities offering, subject in each case to the recipient entering into an agreement to protect such Confidential Information from disclosure; or (c) is required by law or regulation to be disclosed; provided, however, that the party subject to such disclosure requirement has provided written notice to the other party promptly upon receiving notice of such requirement in order to enable the other party to seek a protective order or otherwise prevent disclosure of such Confidential Information.

7.3 Return of Confidential Information. Upon termination or expiration of this Agreement, each party shall return all Confidential Information in its possession that was received from the other party; provided, however, that the recipient may retain one copy of such Confidential Information for its legal files solely for the purpose of monitoring compliance with applicable confidentiality obligations pursuant to this Agreement.

ARTICLE 8 - REPRESENTATIONS AND WARRANTIES

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

8.2 VIVUS. VIVUS represents and warrants that: (i) it has full power to enter into the Agreement; (ii) it has obtained all necessary corporate

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

- 8.3 Disclaimer. EXCEPT AS PROVIDED IN THIS ARTICLE 8 AND ARTICLE 5 ABOVE, NEITHER PARTY MAKES ANY WARRANTIES OR CONDITIONS (EXPRESS, IMPLIED, STATUTORY OR OTHERWISE) WITH RESPECT TO THE SUBJECT MATTER HEREOF.

ARTICLE 9 - INDEMNIFICATION

- 9.1 VIVUS. VIVUS shall indemnify, defend and hold harmless NeraPharm, its directors, officers, employees, agents, successors and assigns from and against any liabilities, expenses or costs (including reasonable attorneys' fees) arising out of any claim, complaint, suit, proceeding or cause of action against any of them by a third party alleging physical injury or death or otherwise resulting from (i) the clinical testing of the Product by or on behalf of VIVUS; (ii) the safety of the Product distributed by or on behalf VIVUS; (iii) the promotion, distribution, sale, handling, possession, or use of the Product by or on behalf of VIVUS following its or their acceptance thereof in accordance with Section 3.3 above; (iv) the negligent or intentionally wrongful acts or omissions of VIVUS; and (v) any breach by VIVUS of its representations and warranties under Section 8.2 above, in each case subject to the requirements set forth in Section 9.3 below. Notwithstanding the foregoing, VIVUS shall have no obligations under this Article 9 for any liabilities, expenses or costs arising out of or relating to claims covered under Section 9.2 below.
- 9.2 NeraPharm. NeraPharm shall indemnify, defend and hold harmless VIVUS, its directors, officers, employees, agents, successors and assigns from and against all liabilities, expenses, and costs (including reasonable attorneys' fees) arising out of any claim, complaint, suit, proceeding or cause of action against any of them by a third party alleging physical injury or death or otherwise resulting from (i) the negligent or intentionally wrongful acts or omissions of NeraPharm; (ii) any loss of Product for which NeraPharm bears the risk under Section 2.9; and (iii) any breach by NeraPharm of any of its representations and warranties under Section 5.1 or 8.1, in each case subject to the requirements set forth in Section 9.3 below.
- 9.3 Indemnification Procedure. Any party seeking indemnification under this Article 9 (the "Indemnatee") shall (i) promptly notify the indemnifying party (the "Indemnitor") of such claim, (ii) provide the Indemnitor sole control over the defense and/ or settlement thereof, and (iii) at the Indemnitor's request and expense, provide full information and reasonable assistance to Indemnitor with respect to such claims. Without limiting the foregoing, with respect to claims brought under Section 9.1 or 9.2 above, the Indemnatee, at its own expense, shall have the right to participate with counsel of its own choosing in the defense and/ or settlement of any such claim.

ARTICLE 10 - INTERNATIONAL ISSUES

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

10.2 Government Approvals. NeraPharm shall:

- 10.2.1 at its own expense, comply with all applicable laws, and obtain all approvals and make and maintain in force all filings, registrations, reports, licenses, permits and authorizations required by national and local governments within the Czech Republic in order for NeraPharm to perform its obligations under this Agreement; and
- 10.2.2 advise VIVUS of any legislation, rule, regulation or other law (including but not limited to any customs, tax, trade, intellectual property or tariff law) which is in effect or which may come into effect in the Czech Republic after the Effective Date of this Agreement and which affects the transfer of Product to VIVUS under this Agreement, or which has a material effect on any provision of this Agreement.

ARTICLE 11 - GENERAL

- 11.1 Assignment. The parties agree that their rights and obligations under this Agreement may not be assigned or otherwise transferred to a third party without the prior written consent of the other party hereto. Notwithstanding the foregoing, either party may transfer or assign its rights and obligations under this Agreement to a successor to all or substantially all of its business or assets relating to this Agreement whether by sale, merger, operation of law or otherwise; provided that such assignee or transferee has agreed to be bound by the terms and conditions of this Agreement. Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the parties hereto, their successors and assigns.
- 11.2 Governing Law. This Agreement shall be governed by, and construed and interpreted in accordance with, the laws of the United Kingdom without reference to conflict of laws principles and excluding the 1980 U. N. Convention on Contracts for the International Sale of Goods.
- 11.3 Arbitration. Any dispute or claim arising out of or in connection with this Agreement or the performance, breach or termination thereof, shall be finally settled by binding arbitration in London, England under the Rules of Arbitration of the International Chamber of Commerce by three (3) arbitrators appointed in accordance with said rules. The decision and/ or award rendered by the arbitrators shall be written, final and non-appealable and may be entered in any court of competent jurisdiction. The parties agree that, any provision of applicable law notwithstanding, they will not request, and the arbitrator shall have no authority to award, punitive or exemplary damages against any party. The costs of any arbitration, including administrative fees and fees of the arbitrators, shall be shared equally by the parties, unless otherwise determined by the arbitrators. Each party shall bear the cost of its own attorneys' and expert fees. The arbitral proceedings and all pleadings and written evidence shall be in the English language. Any written evidence originally in a language other than English shall be submitted in English translation accompanied by the original or true copy thereof. Notwithstanding the foregoing, either party may apply to any court of competent jurisdiction for injunctive relief without breach of this arbitration provision.

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

If to VIVUS: VIVUS, Inc.
1172 Castro Street
Mountain View, CA 94040
Attn: C. E. O. and C. F. O.

With a copy to: Wilson, Sonsini, Goodrich & Rosati
650 Page Mill Road
Palo Alto, California 94304-1050
Attn:

If to NeraPharm: NeraPharm, spol. s.r.o.
Ul. Prace 657
277 11 Neratovice
Czech Republic
Attn:

- 11.5 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY OR ANY THIRD PARTY FOR ANY SPECIAL, CONSEQUENTIAL, EXEMPLARY OR INCIDENTAL DAMAGES (INCLUDING LOST OR ANTICIPATED REVENUES OR PROFITS RELATING TO THE SAME), ARISING FROM ANY CLAIM RELATING TO THIS AGREEMENT, WHETHER SUCH CLAIM IS BASED ON CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, EVEN IF AN AUTHORIZED REPRESENTATIVE OF SUCH PARTY IS ADVISED OF THE POSSIBILITY OR LIKELIHOOD OF SAME. THESE LIMITATIONS SHALL APPLY NOTWITHSTANDING THE FAILURE OF THE ESSENTIAL PURPOSE OF ANY LIMITED REMEDY, AND THE PARTIES ACKNOWLEDGE THAT THIS PARAGRAPH REPRESENTS A REASONABLE ALLOCATION OF RISK.
- 11.6 Force Majeure. Neither party will be liable for its failure to perform any of its obligations hereunder during any period in which such performance is delayed by acts of God, fire, war, embargo, riots, strikes or other similar cause outside the control of such party.
- 11.7 Confidential Terms. Except as expressly provided herein, each party agrees not to disclose any terms of this Agreement to any third party without the consent of the other party, except as required by securities or other applicable laws, to prospective investors and to such party's accountants, attorneys and other professional advisors.
- 11.8 Headings. Headings included herein are for convenience only, do not form a part of this Agreement and shall not be used in any way to construe or interpret this Agreement.
- 11.9 Non-Waiver. Any waiver of the terms and conditions hereof must be explicitly in writing. The waiver by either of the parties of any breach of any provision hereof by the other shall not be construed to be a waiver of any succeeding breach of such provision or a waiver of the provision itself.
- 11.10 Severability. Should any section, or portion thereof, of this Agreement be held invalid by reason of any law, statute or regulation existing now or in the future in any jurisdiction by any court of competent authority or by a legally enforceable directive of any governmental body, such section or portion thereof shall be validly reformed so as to approximate the intent of the parties as nearly as possible and, if unreformable, shall be deemed divisible and deleted with respect to such jurisdiction, but the Agreement shall not otherwise be affected.

- 11.11 Independent Contractors. The relationship of VIVUS and NeraPharm established by this Agreement is that of independent contractors. Nothing in this Agreement shall be construed to create any other relationship between VIVUS and NeraPharm. Neither party shall have any right, power or authority to assume, create or incur any expense, liability or obligation, express or implied, on behalf of the other.
- 11.12 Trademarks. VIVUS, in its sole discretion, shall select the trademarks, trade names and trade dresses to be used in connection with the Product and all such trademarks, trade names and trade dresses shall be and become the exclusive property of VIVUS. NeraPharm shall use said trademarks, trade names and trade dresses for the sole purpose of manufacturing the Product for supply to VIVUS and at no time shall adopt any trademark, trade name or trade dress that may be confusingly similar therewith. NeraPharm shall acquire no rights in and to any trademarks, trade names and trade dresses selected by VIVUS under this Section 11.12.
- 11.13 Entire Agreement. The terms and provisions contained in the Agreement, including the Exhibits hereto, constitute the entire agreement between the parties and shall supersede all previous communications, representations, agreements or understandings, either oral or written, between the parties with respect to the subject matter thereof. Notwithstanding the foregoing, neither party waives any rights it may have under the Supply Agreement. No agreement or understanding varying or extending this Agreement shall be binding upon either party hereto, unless set forth in a writing which specifically refers to the Agreement signed by duly authorized officers or representatives of the respective parties, and the provisions hereof not specifically amended thereby shall remain in full force and effect.
- 11.14 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but which together shall constitute one and the same instrument.

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

VIVUS, INC.

NERAPHARM, SPOL. S. R. O.

By: /s/ Terry Nida

 Name: Terry Nida
 Title: Vice President
 Date: 01/07/04

By: /s/ Ing Miroslav Spacek

 Name: Ing Miroslav Spacek
 Title: Managing Director and
 Member of Board of Directors
 Date: 12/22/03

EXHIBIT A
SPECIFICATIONS TABLE
(**)

CERTIFICATION

I, Leland F. Wilson, certify that:

1. I have reviewed this quarterly report on Form 10-Q of VIVUS, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2004

By: /s/ LELAND F. WILSON

Name: Leland F. Wilson
Title: President and Chief Executive Officer

CERTIFICATION

I, Larry J. Strauss, certify that:

1. I have reviewed this quarterly report on Form 10-Q of VIVUS, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2004

By: /s/ LARRY J. STRAUSS

Name: Larry J. Strauss

Title: Vice President, Finance and Chief Executive Officer

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Leland F. Wilson, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of VIVUS, Inc. on Form 10-Q for the period ending March 31, 2004 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of VIVUS, Inc.

Date: May 7, 2004

By: /s/ LELAND F. WILSON

Leland F. Wilson
President and Chief Executive Officer

I, Larry J. Strauss, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of VIVUS, Inc. on Form 10-Q for the period ending March 31, 2004 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of VIVUS, Inc.

Date: May 7, 2004

By: /s/ LARRY J. STRAUSS

Larry J. Strauss
Vice President, Finance and Chief Financial Officer