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

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

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2000

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

FOR THE TRANSITION PERIOD FROM \_\_\_\_\_ TO \_\_\_\_\_ TO \_\_\_\_

COMMISSION FILE NUMBER: 0-23490

 ${\it VIVUS, INC.} \\ {\it (EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)} \\$ 

DELAWARE
(STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION)

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

1172 CASTRO STREET

MOUNTAIN VIEW, CA
(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES)

94040 (ZIP CODE)

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

N/A

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

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

At June 30, 2000, 32,338,821 shares of common stock were outstanding.

Exhibit Index on Page XX

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#### PART I: FINANCIAL INFORMATION

#### ITEM 1. FINANCIAL STATEMENTS

VIVUS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

	THREE MONTHS ENDED			SIX MONTHS ENDED		
	JUNE 30,	JUNE 30, 1999	JUNE 30,	JUNE 30,		
		(unaudited)				
Revenue						
US product International product Milestone	\$ 5,945 1,140 	\$ 5,239 1,572	\$ 11,703 3,178 	\$ 9,778 3,288 4,000		
Returns provision	(338)	(1,293)	(667)	(1,793)		
Total revenue		5,518				
Operating Expenses						
Cost of goods sold Research and development	2,864 1,209	•	2.413	6,675 3,548		
Selling, general and administrative	2,282	1,554	4,499	2,907		
Settlement of shareholder lawsuits	·			ൈ		
Other restructuring costs		(1,293)		(-/:/		
Total operating expenses	6,355		12,703	11,937		
Income (loss) from operations	392	(177)	1,511	3,336		
Interest and other income	597	484	1,196			
Income before taxes	989	307	2,707	4,299		
Income tax provision	(99)	(15)				
Net income	\$ 890 =====	\$ 292 ======	\$ 2,436 ======	\$ 4,084 ======		
Net income per share:	<b>*</b> 0.00	Φ 0.04	Ф 0.00	<b>.</b> 0.40		
Basic	\$ 0.03	\$ 0.01	\$ 0.08	\$ 0.13		
Diluted	\$ 0.03	\$ 0.01	\$ 0.07	\$ 0.13		
Shares used in the computation of net income per share:  Basic	32,304	32,066	32,249	32,000		
Diluted	33,740	32,889	33,658	32,600		

VIVUS, INC.

# CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (IN THOUSANDS)

	THREE MONTHS ENDED		SIX MONT	HS ENDED
	JUNE 30, 2000	JUNE 30, 1999	JUNE 30, 2000	JUNE 30, 1999
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Net Income	\$ 890	\$ 292	\$ 2,436	\$ 4,084
Other comprehensive income: Unrealized gain (loss) on securities	(1)	231	74	166
Income tax benefit (provision)		(12)	(7)	(9)
	(1)	219	67	157 
Comprehensive income	\$ 889 ====	\$ 511 =====	\$ 2,503 =====	\$ 4,241 =====

### VIVUS, INC.

## CONDENSED CONSOLIDATED BALANCE SHEETS (IN THOUSANDS, EXCEPT PER SHARE AMOUNT)

	2000	DECEMBER 31, 1999
	(unaudited)	
Current assets:	\$ 14,127	\$ 8,785
Available-for-sale securities Accounts receivable Inventories	23,790 3,531	27,049 4,432 3,527
Prepaid expenses and other assets		4,338
Total current assets Property and equipment Available-for-sale securities, non-current	46,032 15,119 5,545	48,131 16,071 4,558
Total	\$ 66,696 ======	\$ 68,760
Current Liabilities:		
Accounts payable Accrued and other liabilities	\$ 2,033 15,546	\$ 2,453 19,062
Total Current liabilities Accrued and other long-term liabilities	17,579 4,797	21,515 5,749
Total liabilities		27,264
Stockholders' equity: Common stock; \$.001 par value; shares authorized 200,000; shares outstanding - June 30, 2000		
32,339; December 31, 1999 32,211; Paid in capital Accumulated other comprehensive income Accumulated deficit	32 132,956 (116) (88,552)	(190)
Total stockholders' equity		41,496
Total	\$ 66,696 ======	

#### VIVUS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (IN THOUSANDS)

JUNE 30, 2000 1999 (unaudited) (unaudited) CASH FLOWS FROM OPERATING ACTIVITIES: Net income \$ 2,436 \$ 4,084 Adjustments to reconcile net income to net cash provided by (used for) operating activities: Depreciation and amortization 1,219 1,654 Stock compensation costs 182 Issuance of common stock for lawsuit settlement 600 Changes in assets and liabilities: Accounts receivable 901 2,679 Inventories 132 1,179 Prepaid expenses and other assets 3,149 (621) (420) (1,473)Accounts payable Accrued and other liabilities (4,468)6,193 Net cash provided by operating activities 2,949 14,477 CASH FLOWS FROM INVESTING ACTIVITIES: Property and equipment purchases (265) (75) (96, 114)(52,817)Investment purchases Proceeds from sale/maturity of securities 98,460 40,345 Net cash provided by (used for) investing activities 2,081 (12,547)CASH FLOWS FROM FINANCING ACTIVITIES: Exercise of common stock options 181 133 Sale of common stock through employee stock purchase plan 100 131 ------Net cash provided by financing activities 312 233 NET INCREASE IN CASH 5,342 2,163 CASH: Beginning of period 8,785 2,989 \$ 5,152 End of period \$ 14,127 ======= ======= NON-CASH INVESTING AND FINANCING ACTIVITIES: Unrealized gain on securities 74 166 SUPPLEMENTAL CASH FLOW DISCLOSURE: Income taxes paid \$ 524 36

SIX MONTHS ENDED

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS JUNE 30, 2000

#### BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulations S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three-month and six-month periods ended June 30, 2000 are not necessarily indicative of the results that may be expected for the year ending December 31, 2000. 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, 1999.

#### RESTRUCTURING RESERVE

During 1998, the Company experienced a significant decline in market demand as the result of the introduction of a competitor's product. As a result, the Company took 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, 1999 included in the Company's Annual Report on Form 10-K). The restructuring reserve balance at June 30, 2000 was \$6.1 million, a decrease of \$2.1 million from \$8.2 million at December 31, 1999.

A)	SEVERANCE ND EMPLOYEE COSTS	INVENTORY AND RELATED COMMITMENTS	PROPERTY AND RELATED COMMITMENTS	MARKETING COMMITMENTS	OTHER	TOTAL
(IN THOUSANDS)						
Restructuring Provision	\$ 3,069	\$ 16,083	\$ 34,684	\$ 3,191	\$ 3,708	\$ 60,735
Incurred in 1998	(1,159)	(10,699)	(30,020)	(1,884)	(1,915)	(45,677)
Incurred in 1999	(1,610)	(1,379)	(784)	(1,307)	(1,793)	(6,873)
Balance at December 31, 1999	300	4,005	3,880			8,185
Incurred in first quarter 2000	(229)	(500)	(158)			(887)
Incurred in second quarter 2000	0	(1,015)	(149)			(1,164)
Balance at June 30, 2000	\$ 71	\$ 2,490	\$ 3,573	\$	\$	\$ 6,134
·	======	=======	=======	======	======	=======

The Company expects that over the next twelve months, it will make cash payments of approximately \$1.3 million related to the restructuring, with the remaining \$4.8 million to occur in later years.

#### 3. ACCRUED AND OTHER LIABILITIES

Accrued and other liabilities as of June 30, 2000 and December 31, 1999, in thousands, consist of:

	JUNE 30, 2000	DECEMBER 31, 1999
Restructuring Product returns* Income taxes Research and clinical expenses Royalties Unearned revenue Employee compensation and benefits Other	\$ 6,134 2,432 2,790 2,377 2,397 1,441 1,487 1,285  \$20,343	\$ 8,185 4,300 3,016 2,803 2,312 1,930 1,287 978

<sup>\*</sup> During the first six months of 2000, the Company recorded a provision for returns of \$667 thousand that was more than offset by actual returns of expired product of \$2.5 million.

#### 4. 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 periods. 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 periods presented because they are anti-dilutive.

#### 5. SEGMENT INFORMATION

During 1998, the Company adopted Statement of Financial Accounting Statement SFAS No. 131, "Disclosure About Segments of an Enterprise and Related Information." SFAS 131 requires a new basis of determining reportable business segments, i.e., the management approach. This approach requires business segment information used by management to assess performance and manage company resources for information disclosure. On this basis, the Company primarily sells its product through wholesale channels in the United States. International sales are made only to the Company's international partners. All transactions are denominated in U.S. dollars; therefore, the Company considers the arrangement as operating in a single segment.

During the first six months of 2000 and 1999, five customers accounted for the following percentages of revenue:

	2000	1999
Customer A	19%	10%
Customer B	17%	9%
Customer C	17%	9%
Customer D	13%	47%
Customer E	11%	6%

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

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

#### **OVERVIEW**

VIVUS, Inc. ("VIVUS" or the "Company") is a leader in the development and commercialization of innovative therapies for the treatment of sexual dysfunction and urologic disorders in men and women. The Company developed and manufactures the drug MUSE(R) and the medical device ACTIS(R), two innovations in the treatment of erectile dysfunction ("ED"), also known as impotence. The Company has filed for regulatory approval with the Food & Drug Administration ("FDA") and the European Agency for the Evaluation of Medicinal Products (EMEA) for ALIBRA(R), its second-generation drug for the treatment of ED. The Company anticipates initiating clinical studies with its female sexual dysfunction ("FSD") product, ALISTA(TM), during 2000. The Company also has ongoing research and development ("R&D") programs in ED and premature ejaculation ("PE"), and intends to pursue targeted technology acquisitions to expand its R&D pipeline.

In November 1996, the Company obtained marketing clearance by the FDA to manufacture and market its first product and commercially introduced MUSE in the United States beginning in January 1997. The launch of MUSE went on to become one of the top 25 most successful drug launches in the U.S., and the Company recorded product revenue of \$129.3 million and a net profit of \$36.6 million for the year ended December 31, 1997.

During 1998, the Company experienced a significant decline (more than 80%) in market demand for MUSE as a result of the introduction of a competitor's product in April 1998. 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. As a result, the Company incurred a net loss of \$80 million and had negative operating cash flow of \$26 million for the year ended December 31, 1998. For further information, refer to the financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 1998.

During 1999, the Company continued to align its operations more closely with the Company's current and expected revenues. The Company achieved profitability for all quarters in 1999, earning \$0.58 per share for the year. Cash, cash equivalents and available-for-sale securities at December 31, 1999 increased \$16.5 million from December 31, 1998 to \$40.4 million, while total liabilities decreased \$5.1 million during the same period, resulting in a stronger balance sheet for investing in the future. The Company was awarded five patents in the areas of FSD, ED and PE to further build and strengthen its patent portfolio. The Company submitted a New Drug Application ("NDA") for ALIBRA, its second-generation treatment for ED, to the FDA in December 1999. The Company also established a targeted sales force in the U.S. for MUSE during 1999.

#### FISCAL 2000

#### FIRST QUARTER

The Company reported net income of \$1.5 million, for \$0.05 per diluted share. The Company continued to strengthen its balance sheet, increasing cash by \$2 million to \$42.4 million while reducing total liabilities by \$5.2 million.

The Company further solidified its FSD intellectual property position through an agreement with AndroSolutions, Inc., whereby VIVUS has exclusive global rights to develop and commercialize FSD technologies based on the combined intellectual property pool.

The Company was awarded two new patents by the U.S. Patent & Trademark Office. The first provides the Company with broad patent protection for commercializing locally delivered PDE5 inhibitors, including the combination of other active agents, for the treatment of ED. The second provides VIVUS with broad patent protection for oral, topical, transdermal and transurethral administration of serotonin antagonists, specifically 5-HT3 antagonists, to treat PE in men.

#### SECOND QUARTER

The Company reported net income of \$890 thousand, for \$0.03 per diluted share. Cash and available-for-sale securities increased \$1.1 million to \$43.5 million from March 31, 2000.

The Company filed for marketing authorization for ALIBRA with the EMEA under the Centralized Procedure in Europe, which provides for marketing authorization in all 15 European Union countries at one time.

The Company and Janssen Pharmaceutica International ("Janssen") agreed to terminate the distribution agreement for MUSE entered into in 1997. The Company and Janssen are working together to transition the countries in this territory to Abbott, the Company's new international partner.

The Company signed a distribution and marketing agreement granting Abbott Laboratories ("Abbott") exclusive rights for MUSE and ALIBRA covering all international markets outside the U.S. This agreement also provides Abbott with the option to co-develop and license future VIVUS transurethral products for the treatment of ED in this territory.

The Company was added to the list of companies included in the Russell 2000(R) Small-Cap U.S. Equity Index, which is widely used as a benchmark for both passive and active investment strategies.

#### RESULTS OF OPERATIONS

#### THREE MONTHS ENDED JUNE 30, 2000 AND 1999

Product revenues for the quarter ended June 30, 2000 were \$5.9 million in the United States and \$1.1 million internationally, compared to \$5.2 million in the United States and \$1.6 million internationally for the quarter ended June 30, 1999. U.S. product revenue increased 13% in the second quarter of 2000, compared to the same period last year, and is more reflective of actual demand, as wholesale inventory levels were much higher in 1999. During the twelve months ended June 30, 2000, wholesale inventory levels have been approximately one-half of one month's supply in the U.S. Lower international product revenue in the second quarter 2000 is attributed to the transitioning of marketing and distribution to a new international partner. The Company anticipates that it will begin initial shipments of MUSE to Abbott during the third quarter of 2000 for certain European markets. International product revenue, however, is not expected to change significantly from current levels until 2001.

Total revenues in the second quarter of 2000 were reduced by a returns provision of \$338 thousand for U.S. shipments, compared to \$1.3 million in the second quarter of 1999. Higher returns in 1999 are attributable to excess inventories at wholesalers and retail pharmacies throughout most of 1998 and the first half of 1999, resulting from the sharp decline in demand for MUSE in April 1998. During 2000, the provision for returns is management's estimate, based on historical experience, of returns in the U.S. expected to occur in the future related to shipments during this period.

Cost of goods sold was \$2.9 million for the second quarter of 2000, compared to \$3.1 million for the second quarter 1999. Gross margin for product sales increased by 14%, to 58%, in the second quarter of 2000 compared to the same period last year. This increase in margin is primarily attributable to a lower returns provision and a higher U.S. sales mix.

Research and development expenses for the second quarter of 2000 were \$1.2 million, compared to \$1.8 million in the second quarter of 1999. Lower spending in the second quarter of 2000 is primarily attributed to timing of R&D projects in the development process. The Company anticipates that R&D expenses will increase from the current levels when the Company begins clinical trials for its FSD product, ALISTA, which are expected to start in the fourth quarter of this year.

Selling, general and administrative expenses were \$2.3 million for the second quarter 2000, compared to \$1.6 million in the second quarter of 1999. This increase is mainly attributed to increased investment in U.S. sales and marketing efforts.

The Company recorded a tax provision of ten percent (10%) of income before taxes for the second quarter of 2000, compared with five percent (5%) recorded in the same period of 1999. Both periods include the effect of net operating loss ("NOL") carried forward from prior periods. The tax rate would have been substantially higher if the NOLs had not been available to offset current income.

#### SIX MONTHS ENDED JUNE 30, 2000 AND 1999

Product revenues for the six months ended June 30, 2000 were \$11.7 million in the United States and \$3.2 million internationally, compared to \$9.8 million in the United States and \$3.3 million internationally for the same period last year. The 20% increase in U.S. product revenue is more reflective of actual demand as wholesale inventory levels were much higher in 1999.

Total revenue for the six months ended June 30, 1999 includes \$4.0 million in milestone revenue related to marketing approval of MUSE in Germany and France. The returns provision in the first half of 2000 of \$667 thousand reflects management's estimate of

returns expected to occur in the future related to shipments during this period. In 1999, the returns provision of \$1.8 million was higher mainly due to the excess inventories at wholesalers and retailers discussed above.

Cost of goods sold was \$5.8 million for the six months ended June 30, 2000, compared to \$6.7 million for the same period of 1999. Gross margin for product sales increased by 18%, to 59%, in the first half of 2000 compared to the same period last year. This increase in margin is primarily attributable to a lower returns provision, a higher U.S. sales mix, and production efficiencies.

Research and development expenses for the six months ended June 30, 2000 were \$2.4 million, compared to \$3.5 million in the same period of 1999 when the Company was completing its Phase III clinical studies for ALIBRA.

Selling, general and administrative expense was \$4.5 million for the six months ended June 30, 2000, compared to \$2.9 million in the same period of 1999. This increase is mainly attributed to increased investments in U.S. sales and marketing efforts.

The Company recorded a tax provision of ten percent (10%) of income before taxes for the first six-month period of 2000, compared with five percent (5%) recorded in the same period of 1999. Both periods include the effect of net operating loss ("NOL") carried forward from prior periods. The tax rate would have been substantially higher if the NOLs had not been available to offset current income.

#### LIQUIDITY AND CAPITAL RESOURCES

Since inception, the Company has financed operations primarily from the sale of preferred and common stock. Through June 30, 2000, VIVUS has raised \$154.1 million from financing activities and has an accumulated deficit of \$88.6 million at June 30, 2000.

Cash, cash equivalents and available-for-sale securities totaled \$43.5 million at June 30, 2000, compared with \$40.4 million at December 31, 1999. The \$3.1 million increase is primarily due to net income of \$2.4 million for the six months and payments received from AstraZeneca of \$5.5 million (\$3.3 million other income and \$2 million milestone revenue, and \$200 thousand for trade accounts receivable) recorded as revenue in the fourth quarter of 1999. These increases were partially offset by the \$4.9 million reduction in total liabilities. During the third quarter of 2000, the Company expects to issue an irrevocable standby letter of credit for \$3.3 million in connection with its leased manufacturing facilities. Upon issuance, this amount will become restricted and not available for use in operations. This restriction will remain through the end of the lease term, including any renewals.

Accounts receivables at June 30, 2000 were \$3.5 million, compared with \$4.4 million at December 31, 1999, a decrease of \$901 thousand. This decrease is primarily the result of the receipt of a \$2 million milestone payment from AstraZeneca for approval of MUSE in Italy, partially offset by an increase in trade receivables from product shipments.

Total liabilities were \$22.4 million at June 30, 2000, compared with \$27.3 million at December 31, 1999, a decrease of \$4.9 million. The decrease is primarily due to payments made associated with the restructuring reserve of \$2.1 million and actual returns of expired product of \$2.5 million.

#### RISK FACTORS

#### LIMITED SALES AND MARKETING EXPERIENCE

The Company supports MUSE sales in the U.S. through physician and patient information/help lines, targeted sales support for major accounts, product education newsletters and participation 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. After the launch of Viagra in April 1998, demand for MUSE has declined more than eighty percent in the U.S. There can be no assurance that demand for the Company's product MUSE will not decline further. The Company has filed an NDA with the FDA for its second ED product, ALIBRA. Pending FDA approval, there can be no assurance that the Company will be able to adequately support sales of ALIBRA in the U.S. The Company is currently evaluating alternative strategic options regarding distribution of ALIBRA in the U.S. There can be no assurance that the Company's options are viable, or that the Company will be able to successfully implement those options.

In June 2000, the Company entered into an agreement granting Abbott Laboratories exclusive marketing and distribution rights for MUSE and ALIBRA (pending regulatory approval) in all countries outside the United States. This agreement does not have minimum purchase commitments and the Company is entirely dependent on Abbott's efforts to distribute and sell the Company's products effectively in all markets except the United States. There can be no assurance that such efforts will be successful or that Abbott will continue to support the product.

#### INTENSE COMPETITION

Competition in the pharmaceutical and medical products industries is intense and is characterized by extensive research efforts and rapid technological progress. Certain treatments for ED exist, such as oral medications, needle injection therapy, vacuum constriction devices and penile implants, and the manufacturers of these products will continue to improve these therapies. The most significant competitive therapy is sildenafil, an oral medication marketed by Pfizer, which received regulatory approvals in the U.S. in March 1998 and in the European Union in September 1998. The commercial launch of sildenafil in the U.S. in April 1998 dramatically increased the number of men seeking treatment for impotence and significantly decreased demand for MUSE.

Additional competitive products in the ED market include needle injection therapy products from Pharmacia Upjohn and Schwartz Pharma, which were approved by the FDA in July 1995 and June 1997, respectively. Other large pharmaceutical companies are also actively engaged in the development of therapies for the treatment of ED. These companies have substantially greater research and development capabilities as well as substantially greater marketing, financial and human resources abilities than the Company. In addition, many of these companies have significantly greater experience than the Company in undertaking pre-clinical testing, human clinical trials and other regulatory approval procedures. There are also small companies, academic institutions, governmental agencies and other research organizations that are conducting research in the area of ED. For instance, ICOS Corporation has an oral medication in clinical testing; and Senetek has a needle injection therapy product approved recently in Denmark and has filed for approval in other countries. These entities may market commercial products either on their own or through collaborative efforts. For example, ICOS Corporation formed a joint venture with Eli Lilly in October 1998 to jointly develop and market its oral treatment. The Company's competitors may develop technologies and products that are more effective than those currently marketed or being developed by the Company. Such developments would render the Company's products less competitive or possibly obsolete. The Company is also competing with respect to marketing capabilities and manufacturing efficiency, areas in which it has limited experience.

#### DEPENDENCE ON SINGLE SOURCE OF SUPPLY

The Company relies on a single injection molding company, The Kipp Group, for its supply of plastic applicator components. In turn, Kipp obtains its supply of resin, a key ingredient of the applicator, from a single source, Huntsman Corporation. The Company also relies on a single source, E-Beam Services, Inc., for sterilization of its product. There can be no assurance that the Company will be able to identify and qualify additional sources of plastic components and an additional sterilization facility. The Company is required to receive FDA approval for suppliers. The FDA may require additional clinical trials or other studies prior to accepting a new supplier. Until the Company secures and qualifies additional sources of plastic components or an additional sterilization facility, it is entirely dependent upon the existing supplier and E-Beam. If interruptions in these supplies or services were to occur for any reason, including a decision by existing suppliers and/or E-Beam to discontinue manufacturing or services, political unrest, labor disputes or a failure of the existing suppliers and/or E-Beam to follow regulatory guidelines, the development and commercial marketing of MUSE and other potential products could be delayed or prevented. An interruption in sterilization services or the

Company's supply of plastic components would have a material adverse effect on the Company's business, financial condition and results of operations.

#### NEW PRODUCT DEVELOPMENT

The Company's future operating results may be adversely affected if the Company is unable to continue to develop, manufacture and bring to market new drug products rapidly. The process of developing new drugs and/or therapeutic products is inherently complex and uncertain. The Company must make long-term investments and commit significant resources before knowing whether its development initiative programs will eventually result in products that will receive regulatory approval and achieve market acceptance. After the FDA and international regulatory authorities approve a product, the Company must quickly manufacture sufficient volumes to meet market demand. This is a process that requires accurate forecasting of market demand. Given existing alternative treatments and the number of products introduced in the market each year, the drug development process becomes increasingly difficult and risky.

In December 1999, the Company submitted an NDA to the FDA to market ALIBRA. The FDA may take up to 12 months or longer to review and approve the Company's application, and may (1) ask the Company to provide more data; (2) ask the Company to perform additional clinical trials; or (3) not grant approval of the application. Even if ALIBRA is approved, there can be no assurances that this transurethral system to treat ED will be successful in the marketplace.

In May 2000, the Company filed for marketing authorization for ALIBRA with the European Agency for the Evaluation of Medicinal Products (EMEA) under the Centralized Process in Europe. The Company's application with the EMEA does not guarantee approval, and the EMEA may (1) ask the Company to provide more data; (2) ask the Company to perform additional clinical trials; or (3) not grant approval of the application. Even if ALIBRA is approved, there can be no assurances that this transurethral system to treat ED will be successful in the marketplace.

#### DEPENDENCE ON THIRD PARTIES

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

In 1996, the Company entered into a distribution agreement with Integrated Commercialization Services ("ICS"), a subsidiary of Bergen Brunswig Corporation. ICS provides "direct-to-physician" distribution capabilities in support of U.S. marketing and sales efforts. ICS also stores and ships various promotional materials to sales personnel, including MUSE patient and in-office instructional videos and brochures. As a result of this distribution agreement with ICS, the Company is dependent on ICS's efforts to distribute product samples effectively. There can be no assurance that such efforts will be successful.

In 1996, the Company entered into an agreement with WRB Communications ("WRB") to handle patient and healthcare professional hotlines for the Company. WRB maintains a staff of healthcare professionals to handle questions and inquiries about MUSE and ACTIS. These calls may include complaints about the Company's product due to efficacy or quality, as well as the reporting of adverse events. As a result of this agreement, the Company is dependent on WRB to effectively handle these hotline calls. There can be no assurance that such effort will be successful.

#### DEPENDENCE ON KEY PERSONNEL

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

#### HISTORY OF LOSSES AND LIMITED OPERATING HISTORY

The Company has generated a cumulative net loss of \$88.6 million for the period from its inception through June 30, 2000. In order to sustain profitable operations, the Company must successfully manufacture and market MUSE and keep its expenditures in line with lower product revenues. The Company is subject to a number of risks including its ability to successfully market, distribute and sell its product, intense competition, and its reliance on a single therapeutic approach to erectile dysfunction. There can be no assurance that the Company will be able to continue to achieve profitability on a sustained basis. Accordingly, there can be no assurance of the Company's future success.

During 1998, the Company took significant steps to restructure its operations in an attempt to bring the cost structure of the business in line with current demand for MUSE. These steps included significant reductions in personnel, closing the contract-manufacturing site located in PACO Pharmaceutical Services, Inc., the termination of the lease for the Company's leased corporate offices, and recorded significant write-down of property, equipment and inventory. As a result of these and other factors, the Company experienced an operating loss of \$80.3 million, or \$2.52 per share, in the year ended December 31, 1998.

In September 1998, the Company significantly scaled back its manufacturing operations as a result of lower demand domestically and internationally for MUSE. Current production is significantly below capacity for the plant, resulting in a higher unit cost. The Company expects the gross margin from sales of MUSE to be less predictable in future periods, which may cause greater volatility in the Company's results of operations and financial condition.

Management believes that the restructuring measures taken were adequate in bringing the cost structure in line with current and projected revenues. However, there can be no assurance that product demand will not weaken further or that these measures will result in sustained profitability in future periods.

#### PATENTS AND PROPRIETARY RIGHTS

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

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

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

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

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

In addition to the Voss, Kock and Place patents and applications identified above, the Company has twelve issued United States patents, six pending United States patent applications, three granted foreign patents, and fifteen pending foreign patent applications. Several of these patents and applications further address the prevention, treatment and diagnosis of ED, while others are directed to

prevention and/or treatment of other types of sexual dysfunction, including premature ejaculation in men, and female sexual dysfunction. One of the Company's issued patents covers the Company's ACTIS(R) venous flow control device

The Company entered into an agreement with AndroSolutions, Inc., a privately held biomedical corporation based in Knoxville, Tennessee, that owns patents and applications complementary to the Company's patents and applications directed to the treatment of FSD. Both the Company and AndroSolutions have contributed their FSD patents and applications into a jointly formed limited liability company, ASIVI, LLC, which exclusively licenses to VIVUS worldwide rights to the common patents and applications, and will work to further develop FSD products of interest to the Company.

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

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

The Company was also the first to file a Notice of Opposition to Pfizer's European patent application claiming the use of phosphodiesterase inhibitors to treat erectile dysfunction. Numerous other companies have also opposed the patent, and the Company will support these other entities in their oppositions as necessary.

There can be no assurance that the Company's products do not or will not infringe on the patent or proprietary rights of others. The Company may be required to obtain additional licenses to the patents, patent applications or other proprietary rights of others. There can be no assurance that any such licenses would be made available on terms acceptable to the Company, if at all. If the Company does not obtain such licenses, it could encounter delays in product introductions while it attempts to design around such patents, or the development, manufacture or sale of products requiring such licenses could be precluded. The Company believes there will continue to be significant litigation in the pharmaceutical industry regarding patent and other intellectual property rights.

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

#### DEPENDENCE ON THE COMPANY'S TRANSURETHRAL SYSTEM FOR ERECTION

MUSE and ALIBRA, drug products developed by the Company to treat ED, rely on a single therapeutic approach, a transurethral system for erection. Failure to successfully commercialize these products will have a material adverse effect on the Company's business. The existence of side effects or dissatisfaction with

these products may impact a patient's decision to use or continue to use  $\ensuremath{\mathsf{T}}$ 

or a physician's decision to recommend this therapeutic approach as a therapy for the treatment of ED, thereby affecting the commercial viability of MUSE and

In addition, technological changes or medical advancements could diminish or eliminate the commercial viability of the Company's products.

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

The Company anticipates that its existing capital resources combined with anticipated future revenues may not be sufficient to support the commercial introduction of any new products and as such, it continually evaluates alternative financing opportunities that may include joint ventures, co-development, or licensing agreements to support the development of its R&D pipeline.

The Company expects that it will be required to issue additional equity or debt securities or use other financing sources including, but not limited to, corporate alliances to fund the development and possible commercial launch of its future products. The sale of additional equity securities would result in additional dilution to the Company's stockholders. The Company's working capital and additional funding requirements will depend upon numerous factors, including: (i) results of operations; (ii) demand for MUSE; (iii) the activities of competitors; (iv) the progress of the Company's research and development programs; (v) the timing and results of pre-clinical testing and clinical trials; (vi) technological advances; and (vii) the level of resources that the Company devotes to sales and marketing capabilities.

#### GOVERNMENT REGULATION AND UNCERTAINTY OF PRODUCT APPROVALS

The Company's research, preclinical development, clinical studies, manufacturing and marketing of its products are subject to rigorous testing and extensive regulation processes of the FDA and equivalent foreign regulatory agencies. The Company's product MUSE has received marketing clearance in 49 countries to date.

The Company has submitted a New Drug Application ("NDA") for ALIBRA to the FDA and is applying for marketing authorization in the European countries via the centralized procedure. There is no guarantee, however, that these applications will be approved. Failure to gain regulatory approval for ALIBRA will prevent this product from being commercialized and will have an adverse effect on the Company's business.

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

The Company's clinical studies for future products will require safety and efficacy data that will entail substantial time and significant funding. There is no assurance that clinical studies related to future products would be completed successfully within any specified time period, if at all. Furthermore, the FDA could suspend clinical studies at any time if it is believed that the subjects participating in such studies are being exposed to unacceptable health risks.

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

Failure to maintain satisfactory cGMP compliance would have a material adverse effect on the Company's ability to continue to market and distribute its products and, in the most serious cases, could result in the issuance of additional Warning Letters, seizure or recall of products, civil fines or closure of the Company's manufacturing facility until such cGMP compliance is achieved.

The Company obtains the necessary raw materials and components for the manufacture of MUSE as well as certain services, such as testing and sterilization, from third parties. The Company currently contracts with suppliers and service providers, including foreign manufacturers that are required to comply with strict standards established by the Company. Certain suppliers and service providers are required by the Federal Food, Drug, and Cosmetic Act, as amended, and by FDA regulations to follow cGMP requirements and are subject to routine periodic inspections by the FDA and by certain state and foreign regulatory agencies for compliance with cGMP requirements and other applicable regulations. Certain of the Company's suppliers were inspected for cGMP compliance as part of the approval process. However, upon routine re-inspection of these facilities, there can be no assurance that the FDA and other regulatory agencies will find the manufacturing process or facilities to be in compliance with cGMP requirements and other regulations. Failure to achieve satisfactory cGMP compliance as confirmed by routine inspections could have a material adverse effect on the Company's ability to continue to manufacture and distribute its products and, in the most serious case, result in the issuance of a regulatory Warning Letter or seizure or recall of products, injunction and/or civil fines or closure of the Company's manufacturing facility until cGMP compliance is achieved.

#### RISKS RELATING TO INTERNATIONAL OPERATIONS

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

#### LIMITED MANUFACTURING EXPERIENCE

The Company has limited experience in manufacturing and selling MUSE in commercial quantities. The Company leases 90,000 square feet of space in New Jersey in which it constructed manufacturing and testing facilities. The FDA and European Medicine Controls Agency ("MCA") authorized the Company to begin commercial production and shipment of MUSE from its new facility in June and March 1998, respectively. In September 1998, the Company closed its contract-manufacturing site within PACO Pharmaceutical Services, Inc. and significantly scaled back its manufacturing operations in the New Jersey facility, as a result of lower domestic and international demand for MUSE. Production is currently significantly below capacity for the plant.

#### UNCERTAINTY OF PHARMACEUTICAL PRICING AND REIMBURSEMENT

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

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

#### PRODUCT LIABILITY AND AVAILABILITY OF INSURANCE

The commercial launch of MUSE exposes the Company to a significant risk of product liability claims due to its availability to a large population of patients. In addition, pharmaceutical products are subject to heightened risk for product liability claims due to inherent side effects. The Company details potential side effects in the patient package insert and the physician package insert, both of which are distributed with MUSE, and the Company maintains product liability insurance coverage. However, the Company's product liability coverage is limited and may not be adequate to cover potential product liability exposure. Product liability insurance is

expensive, difficult to maintain, and current or increased coverage may not be available on acceptable terms, if at all. Product liability claims brought against the Company in excess of its insurance coverage, if any, could have a material adverse effect upon the Company's business, financial condition and results of operations.

#### UNCERTAINTY AND POSSIBLE NEGATIVE EFFECTS OF HEALTHCARE REFORM

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

#### POTENTIAL VOLATILITY OF STOCK PRICE

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

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

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

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

#### PART II: OTHER INFORMATION

#### ITEM 1. LEGAL PROCEEDINGS

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

On November 3, 1999, the Company filed a demand for arbitration against Janssen with the American Arbitration Association pursuant to the terms of the Distribution Agreement entered into on January 22, 1997. The Company seeks compensation for inventory manufactured in 1998 in reliance on contractual forecasts and orders submitted by Janssen. The Company also seeks compensation for forecasts and order shortfalls attributed to Janssen in 1998, pursuant to the terms of the Distribution Agreement. On December 3, 1999, Janssen submitted its response to the Company's arbitration demand denying liability. On June 29, 2000, Janssen filed an amended response that included counterclaims against Vivus for \$1.8 million based on the Company's alleged improper calculation of its Cost of Goods charged to Janssen pursuant to the Distribution Agreement. Although the Company has yet to file its response to the counterclaims, Vivus believes they are without merit and intends to defend against them vigorously. The Company intends to amend its arbitration demand to include claims for lost profits due to Janssen's failure to use the requisite diligence and reasonable efforts to gain regulatory approval for and launch MUSE in each country of the Territory. The Company also intends to include claims based on Janssen's development of a competing product intended for use in the treatment of male ED, in violation of the Distribution Agreement. The Company's amended demand will seek an award of \$7.9 million plus costs and interest. Administration of the arbitration has been transferred to JAMS and a three-member arbitration panel has been selected. The parties are currently in the process of conducting discovery and anticipate a hearing in January of 2001.

On October 5, 1998, the Company was named in a civil action filed in the Superior Court of New Jersey by its landlord. This Complaint sought specific performance and other relief in connection with the Company's leased manufacturing facilities located in Lakewood, New Jersey. The Company's lease agreement requires that the Company provide a removal security deposit in the form of cash or a letter of credit. The litigation was dismissed on the Company's motion for summary judgment, and the parties were directed to proceed to arbitration to determine the amount of removal security to be posted. The Company and its landlord have reached a tentative agreement whereby the Company expects to post removal security in the amount of approximately \$3.3 million through an irrevocable standby letter of credit during the third quarter of

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

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

None

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None

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

The annual meeting of stockholders was held on May 31, 2000. Matters voted on at that meeting were: (i) the election of six directors; (ii) amendment to the 1994 Employee Stock Purchase Plan; and (iii) the confirmation of the appointment of Arthur Andersen LLP as independent public accountants for the fiscal year ended December 31, 2000. Tabulations for each proposal and individual director were as follows:

Proposal I. Election of Directors

DIRECTOR	FOR	WITHHELD
Virgil A. Place, MD	28,689,271	545,663
Leland F. Wilson	28,735,684	499,250
Mark B. Logan	28,701,687	533,247
Linda M. Shortliffe, MD	28,699,086	535,848
Mario M. Rosati	28,750,714	484,220
Joseph E. Smith	28,719,621	515,313

Proposal II. Amendment to the 1994 Employee Stock Purchase Plan

FOR	AGAINST	ABSTAIN	NO VOTE
27,830,642	1,214,352	189,940	

Proposal III. Confirmation of the Appointment of Arthur Andersen LLP

FOR	AGAINST	ABSTAIN	NO VOTE
28,750,908	357,923	126,103	

#### ITEM 5. OTHER INFORMATION

None

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

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

EXHIBIT NUMBER	DESCRIPTION
0.0(7)	Amended and Destated Coutificate of Incommention of the
3.2(7)	Amended and Restated Certificate of Incorporation of the Company
3.3(4)	Bylaws of the Registrant, as amended
3.4(8)	Certificate of Designations of Rights, Preferences and Privileges of Series A Participating Preferred Stock
4.1(7)	Specimen Common Stock Certificate of the Registrant
4.2(7)	Registration Rights, as amended
4.4(1)	Form of Preferred Stock Purchase Warrant issued by the
	Registrant to Invemed Associates, Inc., Frazier
	Investment Securities, L.P., and Cristina H. Kepner
4.5(8)	Second Amended and Restated Preferred Shares Rights
	Agreement, dated as of April 15, 1997 by and between the
	Registrant and Harris Trust Company of California,
	including the Certificate of Determination, the form of
	Rights Certificate and the Summary of Rights attached
	thereto as Exhibits A, B, and C, respectively
10.1(1)+	Assignment Agreement by and between Alza Corporation and the Registrant dated December 31, 1993
10.2(1)+	Memorandum of Understanding by and between Ortho
	Pharmaceutical Corporation and the Registrant dated
	February 25, 1992
10.3(1)+	Assignment Agreement by and between Ortho Pharmaceutical
	Corporation and the Registrant dated June 9, 1992
10.4(1)+	License Agreement by and between Gene A. Voss, MD, Allen
	C. Eichler, MD, and the Registrant dated December 28,
	1992
10.5A(1)+	License Agreement by and between Ortho Pharmaceutical
• •	Corporation and Kjell Holmquist AB dated June 23, 1989
	•

EXHIBIT NUMBER	DESCRIPTION
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
10.6A(1)+	AB and the Registrant dated April 22, 1992 License Agreement by and between Amsu, Ltd., and Ortho
10.6B(1)+	Pharmaceutical Corporation dated June 23, 1989 Amendment by and between Amsu, Ltd., and the Registrant dated July 3, 1992
10.6C(1)	Amendment by and between Amsu, Ltd., and the Registrant dated April 22, 1992
10.6D(1)+	Stock Purchase Agreement by and between Amsu, Ltd., and the Registrant dated July 10, 1992
10.11(4)	Form of Indemnification Agreements by and among the Registrant and the Directors and Officers of the
10.12(2)	Registrant 1991 Incentive Stock Plan and Form of Agreement, as amended
10.13(1) 10.14(1)	1994 Director Option Plan and Form of Agreement Form of 1994 Employee Stock Purchase Plan and Form of
10.17(1)	Subscription Agreement Letter Agreement between the Registrant and Leland F.
10.21(3)+	Wilson dated June 14, 1991 concerning severance pay Distribution Services Agreement between the Registrant
10.21(3)	and Synergy Logistics, Inc. (a wholly-owned subsidiary
10.22(3)+	of Cardinal Health, Inc.)+ dated February 9, 1996 Manufacturing Agreement between the Registrant and CHINOIN Pharmaceutical and Chemical Works Co., Ltd.
10.22A(11)+	dated December 20, 1995  Amendment One, dated as of December 11, 1997, to the Manufacturing Agreement by and between VIVUS and CHINOIN Pharmaceutical and Chemical Works Co., Ltd. dated
10.23(6)+	December 20, 1995 Distribution and Services Agreement between the Registrant and Alternate Site Distributors, Inc. dated
10.24(5)+	July 17, 1996 Distribution Agreement made as of May 29, 1996 between
10.24A(14)++	the Registrant and ASTRAZ AB Amended Distribution Agreement dated December 22, 1999
10.27(11)+	between AstraZeneca and the Registrant Distribution Agreement made as of January 22, 1997 between the Registrant and Janssen Pharmaceutica
10.27A(11)+	International, a division of Cilag AG International Amended and Restated Addendum 1091, dated as of October 29, 1997, between the Registrant and Janssen Pharmaceutica International
10.28(7)	Lease Agreement made as of January 1, 1997 between the
10.29(7)	Registrant and Airport Associates Lease Amendment No. 1 as of February 15, 1997 between
10.29A(10)	Registrant and Airport Associates Lease Amendment No. 2 dated July 24, 1997 by and between
10.29B(10)	the Registrant and Airport Associates Lease Amendment No. 3 dated July 24, 1997 by and between
10.31(9)+	the Registrant and Airport Associates Manufacture and Supply Agreement between Registrant and
10.32A(11)	Spolana Chemical Works, A.S. dated May 30, 1997 Agreement between ADP Marshall, Inc. and the Registrant
10.32B(11)	dated December 19, 1997 General Conditions of the Contract for Construction
10.32C(11)	Addendum to General Conditions of the Contract for Construction
10.34(12)+	Agreement dated as of June 30, 1998 between Registrant and Alza Corporation
10.35(12)+	Sales Force Transition Agreement dated July 6, 1998 between Registrant and Alza Corporation
10.36(13)	Form of, "Change of Control Agreements," dated July 8, 1998 by and between the Registrant and certain Executive
10.30A(13)	Officers of the Company.  Amendment of lease agreement made as of October 19, 1998 by and between Registrant and 605 East Fairchild
10.37(13)	Associates, L.P. Sublease agreement made as of November 17, 1998 between Caliper Technologies, Inc. and Registrant
10.22B(13)+	Amendment Two, dated as of December 18, 1998 by and between VIVUS, Inc. and CHINOIN Pharmaceutical and Chemical Works Co.

EXHIBIT NUMBER	DESCRIPTION
10.31A(13)+	Amendment One, dated as of December 12, 1998 by and between VIVUS, Inc. and Spolana Chemical Works, A.S.
10.38(14)++	License Agreement by and between ASIVI, LLC, AndroSolutions, Inc., and the Registrant dated February 29, 2000
10.38A(14)++	Operating Agreement of ASIVI, LLC, between AndroSolutions, Inc. and the Registrant dated February 29, 2000
10.39(14)	Sublease agreement between KVO Public Relations, Inc. and the Registrant dated December 21, 1999
10.40(15)++	License and Supply Agreement made as of May 23, 2000 between the Registrant and Abbott Laboratories, Inc.
27.1	Financial Data Schedule

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

- (14) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1999.
- (15) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30,
  - (b) REPORTS ON FORM 8-K

None

#### SIGNATURES

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

VIVUS, Inc. Date: August 10, 2000

/s/ RICHARD WALLISER

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Richard Walliser Vice President and Chief Financial Officer

/s/ LELAND F. WILSON

Leland F. Wilson President and Chief Executive Officer

VIVUS, INC.

#### INDEX TO EXHIBITS\*

EXHIBIT	DESCRIPTION
10.40	License and Supply Agreement made as of May 23, 2000 between the Registrant and Abbott Laboratories, Inc.
27.1	Financial Data Schedule

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

#### LICENSE AND SUPPLY AGREEMENT

#### MAY 23, 2000

This Agreement is made as of this 23rd day of May, 2000, by and between Abbott International, Ltd., a company organized under the laws of the State of Delaware, USA, with its principal offices at 200 Abbott Park Road, Abbott Park, IL 60064-6194 ("Abbott") and VIVUS International, Ltd., a company organized under the laws of Bermuda, with its principal offices at Clarendon House, Church Street, Hamilton, Bermuda. ("VIVUS").

#### **RECITALS**

WHEREAS, VIVUS has developed and is developing products for the treatment of erectile dysfunction; and

WHEREAS, Abbott is interested in obtaining a license to and/or certain other rights relating to such products; and VIVUS is interested in granting such license and/or rights to Abbott; and

WHEREAS, VIVUS is a wholly-owned subsidiary of VIVUS, Inc., a Delaware corporation, ("VIVUS INC."), with its offices at 1172 Castro Street, Mountain View, CA 94040, which has guaranteed the performance by VIVUS of this Agreement.

NOW, THEREFORE, in consideration of the mutual obligations and promises as set forth herein, the parties do hereby agree as follows:

#### ARTICLE 1 - DEFINITIONS

For purposes of this Agreement, the following terms shall have the following respective meanings:

1.1 Affiliate means any corporation, firm, partnership or other entity, whether de jure or de facto, which directly or indirectly owns, is owned by or is under common ownership with a party to the extent of in excess of fifty percent (50%) of the outstanding securities or assets having the power to vote on or direct the affairs of the entity.

Page 1 of 55

- 1.2 Confidential Information means any information, data or business plans relating to the Products, the Future Products, or otherwise to the subject of this Agreement, which a party discloses to the other party, except any portion thereof which:
- (i) is known to the receiving party at the time of disclosure and documented by written records made prior to the date of this Agreement;
- (ii) is disclosed to the receiving party by a third person who has a right to make such disclosure;
- (iii) becomes patented, published or otherwise part of the public domain through no fault of the receiving party; or (iv) is independently developed by the receiving party as evidenced by its written records.
- 1.3 Effective Date means the date of this Agreement first written above.
- 1.4 First Commercial Sale means the first sale of Product (as defined below) in the Territory by Abbott or any Abbott Affiliate or sublicensee to any unaffiliated third party following Regulatory Approval of the Product, as evidenced by the selling party's invoice to such third party.
- 1.5 Future Product means any transurethral product for the treatment of male erectile dysfunction, which is owned by or licensed (with the right to sub-license) to VIVUS, VIVUS INC. or its or their Affiliates before the tenth anniversary of the Effective Date, which has at least one different active ingredient as compared to either the MUSE Product or the ALIBRA Product, and which is not a Product or an Improvement. For the avoidance of doubt, "Future Products" do not include any product for the treatment of female sexual dysfunction or premature ejaculation, owned by or licensed (with the right to sub-license) by VIVUS, VIVUS INC. or its or their Affiliates.
- 1.6 Improvement means any and all additions, developments, improvements, modifications, enhancements or adaptations, whether or not patented or patentable, that relate to a Product and that are not a Future Product that comes into existence during the term of this Agreement.
- 1.7 Janssen Territory means the countries listed on Exhibit 1.7 attached to this Agreement, as to which VIVUS has granted certain rights to Janssen subject to the terms and conditions of the Distribution Agreement by and between VIVUS and Janssen Pharmaceutica International dated January 22, 1997 granting certain rights to Janssen for the Products ("Janssen Agreement").
- 1.8 Licensed Patents means all patents and patent applications (including without limitation, continuations, continuations-in-part, divisionals, patents of addition, substitutions, extensions,

reissues, reexaminations, renewals, or SPCs), owned by or licensed (with the right to sublicense) to VIVUS or VIVUS INC. or its or their Affiliates during the term of this Agreement, and generically or specifically claiming a Product, an Improvement, a process for manufacturing a Product or Improvement, an intermediate used in such process, or a use of a Product or Improvement. With respect to such patents or applications which VIVUS or VIVUS INC. or its or their Affiliates licenses or acquires or has licensed or acquired from a third party, the same shall be included within "Licensed Patents" hereunder to the extent that VIVUS or VIVUS INC. or its or their Affiliates has the right to license or sublicense the same hereunder. Exhibit 1.8 attached to this Agreement lists all Licensed Patents in existence as of the Effective Date.

- 1.9 Marketing Authorization means all governmental approvals and authorizations necessary for the commercial marketing and sale of the Products in a country in the Territory, excluding any pricing approval and pricing reimbursement.
- 1.10 Net Sales means the gross sales of a Product shipped by Abbott and/or its Affiliates or sub licensee to third parties in the Territory (as defined below) less deductions allowed to the final buyer against invoiced amounts for:
  - (A) trade discounts earned or granted;
  - (B) cash discounts actually allowed;
- (C) transportation charges (including insurance costs), handling charges, sales taxes, excise, turnover, inventory, value added and similar taxes, duties and charges invoiced to customers;
  - (D) retroactive price reductions imposed by government authorities;
  - (F) wholesaler charge backs earned or granted; and
  - (G) rebates and management fees earned by or granted to third parties.
- 1.11 Product means (a) the product for the transurethral delivery of alprostadil and which VIVUS and/or VIVUS INC. sells outside the Territory, as of the Effective Date, under the trademark MUSE(R) ("MUSE Product"), (b) the product for the transurethral delivery of alprostadil and prazosin, and for which VIVUS plans to file a submission for Marketing Authorization in the European Union, and which VIVUS and/or VIVUS, INC. plans, as of the Effective Date, to market outside the Territory under the trademark ALIBRA(R) ("ALIBRA Product"), each with final packaging and labeling suitable for use by the consumer in the Territory, and (c) any Improvement.

- 1.12 Regulatory Approval means all governmental approvals and authorizations necessary for the commercial sale of the Product in a country in the Territory, including but not limited to Marketing Authorization, pricing approval and pricing reimbursement.
- 1.13 Sales Quarter means for the first Sales Quarter, the period commencing on the date of Abbott's First Commercial Sale and ending on the last day of that Abbott fiscal quarter; and for subsequent Sales Quarters, the successive Abbott fiscal quarters thereafter.
- 1.14 Sales Year means for the first Sales Year, the period commencing on the date of Abbott's First Commercial Sale and ending on the last day of that Abbott fiscal year; and for subsequent Sales Years, the successive Abbott fiscal years thereafter.
- 1.15 Specifications means the written manufacturing release specifications and stability specifications for each of the Products, which shall be agreed upon by the parties and which shall be set forth in Exhibit 1.15 attached hereto or as amended pursuant to Article 6.5 below.
- 1.16 SPC means a right based upon a Licensed Patent to exclude others from making, using or selling a Product, such as a Supplementary Protection Certificate.
- 1.17 Supply Price means the price as set forth in Article 4.2 below.
- 1.18 Trademarks means the trademarks MUSE(R), ALIBRA(R), and BONDIL. The MUSE(R) and ALIBRA(R) Trademarks are registered or have pending registration applications throughout the Territory as of the Effective Date.
- 1.19 Territory means all countries and territories of the world except for the United States and the Janssen Territory.
- 1.20 Valid Claim means any claim of an issued and unexpired patent in the Licensed Patents which has not been held unenforceable, unpatentable or invalid by a decision of a court or government agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal or which has not been admitted by the holder of the patent to be invalid or unenforceable through reissue, disclaimer or otherwise.

#### ARTICLE 2 - GRANT OF RIGHTS

- 2.1 Exclusive License to Abbott.
  - (A) VIVUS hereby grants to Abbott an exclusive license (exclusive even as to VIVUS) to use and sell the Product and any Improvements in the Territory, under the Licensed Patents, with right to sublicense, subject only to the rights of Astra AB under the Distribution Agreement between Astra AB and VIVUS dated May 29, 1996 ("Astra

Agreement"), the December 22, 1999 letter agreement from Astra AB to VIVUS regarding the termination of the Astra Agreement, and any other binding agreement or amendment between VIVUS and Astra relating to the Astra Agreement. Abbott may sublicense any one or more of its Affiliates at Abbott's sole discretion, and may sublicense third parties with VIVUS's prior written consent, such consent not to be unreasonably withheld. This exclusive license is granted to Abbott as to all uses, forms, indications, packages and strengths for the Product and any Product Improvements.

(B) In the event that during the term of this Agreement, any country in the Janssen Territory as of the Effective Date ceases to be part of the Janssen Territory, and VIVUS has the right to grant the same license as to such country or countries as VIVUS has granted to Abbott pursuant to Article 2.1(A) above as to the Territory, then such country or countries (up to and including the entirety of the Janssen Territory, as the case may be) shall automatically become part of the Territory under this Agreement; provided that no such country shall become part of the Territory if, at the time such country becomes otherwise available, there are in effect export restrictions, economic sanctions, or other laws or regulations which prohibit United States corporations from selling goods to such country. The parties acknowledge and agree that neither party shall take any action in violation of VIVUS's contractual obligations to Janssen or otherwise in violation of applicable law, with respect to this Article 2.1(B).

### 2.2 Future Product Rights.

(A) Subject to the provisions of this Article 2.2, VIVUS hereby grants to Abbott an exclusive right of first refusal to obtain an exclusive license (exclusive even as to VIVUS) in the Territory to use and sell Future Products, to the extent VIVUS has the right to grant such a license. Abbott shall have a separate and independent right of first refusal as to each Future Product pursuant to this Article 2.2. The parties acknowledge that VIVUS (or VIVUS INC, or its or their Affiliates, as the case may be) may license or acquire rights to a Future Product from a third party, and that VIVUS may not be permitted to license or sublicense such rights to Abbott for the full Territory or for all fields; but the parties agree that VIVUS and VIVUS INC. shall use their best efforts to obtain rights to any such Future Product from such third party on a basis which will permit VIVUS to license or sublicense such rights to Abbott for the full Territory and for all fields. VIVUS shall not discuss, negotiate, entertain, solicit, offer, accept or enter into any agreement granting to a third party the right to use and sell such Future Product in the Territory except as expressly set forth in Article 2.2(B) below.

- (B) During the term of this Agreement, VIVUS shall use diligent efforts to determine whether and when VIVUS wishes to pursue commercialization (directly or via a third party) of each of the Future Products in the Territory. In each case, but in no event earlier than September 15, 2001, after VIVUS has completed its first Phase II study with a Future Product, VIVUS shall provide Abbott with the results of this Phase II study, the Investigational New Drug Application ("IND") (or the equivalent of an IND filed with any regulatory agency in the Territory) under which this Phase II study was conducted and the results of all completed clinical trials under this IND. Within ninety (90) days following receipt of such data, Abbott shall notify VIVUS of its decision whether or not it wishes to accept an exclusive license for such Future Product in the Territory. If Abbott does not wish to accept such license, then VIVUS shall be free to negotiate with third parties concerning the grant of rights to use and sell such Future Product on terms VIVUS deems appropriate, or pursue commercialization of such Future Product itself and shall have no further obligation under this Article 2.2 with respect to such Future Product.
- (C) If Abbott notifies VIVUS that it does wish to accept such license, then such Future Product shall become a Product under this Agreement as of the date of Abbott's notice of acceptance, and shall be subject to the terms and conditions of this Agreement with the exception of Articles 3 (in its entirety), 4.3, 9.2 and Exhibit 4, provided that each Future Product which so becomes a Product under this Agreement shall also be subject to the provisions expressly set forth in Articles 2.2(D) and 8.6 below, which provisions shall govern for each such Future Product in case of any conflict with other provisions of this Agreement. In no event shall the provisions of Articles 2.2(D) and 8.6 below apply to the MUSE Product or the ALIBRA Product or any Improvements thereof.
- (D) In the event that a Future Product becomes a Product under this Agreement pursuant to Article 2.2(B) and (C) above, then the following provisions shall apply:

- (i) The parties shall promptly form a Development Committee and shall work together on the further development of such Future Product, pursuant to Article 8.6 below;
- (ii) Abbott shall pay to VIVUS an amount equal to (\*\*\*) of VIVUS's actual, verified out-of-pocket costs for the Phase II studies relating to such Future Product, such amount being payable within thirty (30) days of the date upon which the first patient is enrolled in the first Phase III study relating to such Future Product:
- (iii) Abbott shall pay to VIVUS an amount equal to (\*\*\*) of VIVUS's actual, verified out-of-pocket costs for the Phase III studies relating to such Future Product, such amount being payable within thirty (30) days after the end of each calendar quarter, as such costs are incurred subject to Article 8.6 below;
- (iv) Abbott shall pay to VIVUS an amount equal to (\*\*\*) of VIVUS's actual, verified out-of-pocket costs for the Phase II and III studies (in the case of Phase III studies, such costs are payable only if incurred subject to Article 8.6 below) relating to such Future Product (bringing the total such amounts paid by Abbott to (\*\*\*) of such costs), payable within thirty (30) days of the date by which such Future Product has obtained Marketing Authorization in the first two of any of the following countries: France, Italy, Germany, Spain, and the United Kingdom;
- (V) VIVUS shall select a trademark in consultation with Abbott, which trademark shall be owned and registered by VIVUS, and which shall be a Trademark under this Agreement, exclusively licensed to Abbott in the Territory for use in connection with such Future Product, and which shall be used where possible by VIVUS and/or its licensees in connection with such Future Product outside the Territory;
- (vi) VIVUS shall sell such Future Product to Abbott pursuant to Article 4, provided that (i) Article 4.3 and Exhibit 4 shall not apply, and (ii) the price of such Future Product shall in no event be less than VIVUS's actual variable cost (includes direct labor and material and all overhead that is directly related to the manufacture of such Future Product and specifically

excludes fixed overhead items such as facilities rent, depreciation, common utilities, taxes and insurance, etc.) of producing such Future Product plus any royalties actually paid by VIVUS to third parties in connection with the sale of such Future Product; and (iii) the price of such Future Product to be used by Abbott in the Territory as samples shall be VIVUS's actual, variable cost (includes direct labor and material and all overhead that is directly related to the manufacture of such samples and specifically excludes fixed overhead items such as facilities rent, depreciation, common utilities, taxes and insurance, etc.) of producing such samples and;

- (vii) Abbott shall be responsible for, and shall bear all costs of, obtaining and maintaining all Regulatory Approvals for such Future Product in the Territory, provided that clinical development costs for such Future Product which are necessary to support the Marketing Authorization for such Future Product in the European Countries shall be shared by the parties as set forth in Article 8.6(F) below.
- (viii) Abbott shall use due diligence to market and sell such Future Product in accordance with Article 9.1 below.
- (E) The only obligations of VIVUS and Abbott under this Article 2.2 are as expressly stated therein, and there are no further implied obligations relating to the matters contemplated therein. Without limiting the foregoing, it is further understood and agreed that the subject Future Product(s) may or may not be discovered or reduced to practice at all, may or may not be developed through the completion of Phase II, and that further modification and/or variations of a Future Product may be developed after the completion of Phase II studies. Accordingly, so long as VIVUS provides Abbott with such data and information as required by Article 2.2(B) above, the requirements of Article 2.2(B) above shall be deemed satisfied with respect to any and all improvements, modifications, variants or derivatives of the product developed or reduced to practice after the completion of Phase II studies; to the extent that any such improvements, modifications, variants or derivatives were included in the definition of such Future Product as offered shall be deemed to be included with such Future Product when it is offered to Abbott pursuant to this Article 2.2.

## ARTICLE 3 - MILESTONES

- 3.1 Abbott shall pay VIVUS the following one-time, non-creditable and non-cumulative milestone fees within thirty (30) days after the event specified:
  - (A) (\*\*\*), upon the ALIBRA Product obtaining Marketing Authorization in the first three (3) of the following countries: Belgium, France, Germany, Italy, Spain, and the United Kingdom;
  - (B) (\*\*\*), upon the first occasion on which Abbott achieves annual Net Sales of the Products of (\*\*\*) in the Territory; and
  - (C) (\*\*\*), upon the first occasion on which Abbott achieves annual Net Sales of the Products of (\*\*\*) in the Territory.

#### ARTICLE 4 - PURCHASE AND SALE

- 4.1 Purchases and Sale of Product. Subject to the terms and conditions of this Agreement, VIVUS shall sell Products exclusively to Abbott in the Territory and Abbott shall purchase its requirements of Products exclusively from VIVUS, at the Supply Price.
- 4.2 Supply Price. The Supply Price for the MUSE Product shall equal (\*\*\*) of Abbott's Net Sales of the MUSE Product in the Territory, calculated as provided in Article 4.2(B) below. The Supply Price for the ALIBRA Product shall equal (\*\*\*) of Abbott's Net Sales of the ALIBRA Product in the Territory, calculated as provided in Article 4.2(B) below. The Supply Price for both Products shall be subject to the provisions of Article 4.3 below.
  - (A) In order to enable the parties to sell and purchase the Products prior to the time in which Abbott's Net Sales for a Sales Quarter are determined, Abbott shall pay for Products ordered, delivered and accepted pursuant to Article 5 below based upon an interim "Transfer Price," which shall be equal to (\*\*\*) of Abbott's estimated weighted average net selling price for an Abbott fiscal year, for the Products in the Territory, respectively for the MUSE Product and for the ALIBRA Product. Abbott shall advise VIVUS no later than forty-five (45) days prior to the start of each of Abbott's fiscal years, during the term of this Agreement, of Abbott's estimated weighted average net selling price for each of the Products in the Territory for the coming Abbott fiscal year, and the Transfer Price for that fiscal year shall be based upon such price, subject to any adjustment required under Article 4.2(B) helow.

- (B) The parties shall conduct a reconciliation no later than forty-five (45) days after the end of each Sales Quarter, in order to determine whether one party owes the other party any amount in connection with the sale and purchase of the MUSE Product and/or the ALIBRA Product in that Sales Quarter, based upon the difference (if any) between the respective Transfer Price and the Supply Price for that Sales Quarter. For the purposes of such reconciliation, Abbott shall provide to VIVUS a statement of Abbott's sales in units, per country in the Territory, and of Abbott's Net Sales, per country in the Territory and in local currency as well as in U.S. dollars, converted pursuant to Article 4.7 below. In the event that one party owes the other party any amount in  $% \left( 1\right) =\left( 1\right) \left( 1\right)$ accordance with this Article 4.2(B), the owing party shall pay such amount within thirty (30) days of the date upon which the parties have agreed in writing upon the reconciliation calculation. In the event that the Supply Price is greater than one hundred ten percent (110%) or less than ninety percent (90%) of the Transfer Price for two (2) consecutive Sales Quarters, the Transfer Price established in Article 4.2(A) above shall be changed for the remainder of that Sales Year to the Supply Price applicable to the most recent Sales Quarter.
- 4.3 Minimum Supply Price. Starting after the first Sales Year, the Supply Price for the Products shall in no event be less than the Minimum Supply Price as set forth in Exhibit 4 attached to this Agreement.
- 4.4 Samples. VIVUS shall sell a quantity of Products to Abbott for use as samples, at "Sample Prices" as set forth in Exhibit 4 attached to this Agreement. Abbott may purchase such samples in quantities not to exceed the following percentages of Abbott's total unit sales of each Product in the Territory: (\*\*\*) in each of the first two (2) Sales Years; (\*\*\*) in each of the third and fourth Sales Years; and (\*\*\*) in each Sales Year thereafter.
- 4.5 Initial Start-Up Costs. Abbott shall pay VIVUS for VIVUS's actual cost paid to third parties for materials (including but not limited to foil and packaging materials) associated with the modification of the packaging of the MUSE Product to incorporate Abbott trade dress and otherwise to meet Abbott's requirements for the sale by Abbott of the MUSE Product in the Territory ("Initial Start-Up Costs"). VIVUS shall reimburse Abbott for the payment of such Initial Start-Up Costs via a credit against Abbott's purchases of the MUSE Product that include such Initial Start-Up clements. Should any of these Initial Start-Up Costs not be reimbursed to

Abbott, then VIVUS will provide to Abbott all documents, including copies of third-party invoices, evidencing such costs.

#### 4.6 Records.

- (A) Abbott and/or its Affiliates shall keep and maintain records of sales made pursuant to the license granted hereunder so that Abbott's Net Sales and the calculation of the Transfer Price and the Supply Price may be verified. Such records shall be open to inspection upon prior written notice at any reasonable time during business hours, not more than once per calendar year, and each inspection shall cover no more than the two (2) calendar years preceding such notice of inspection. The inspection shall be conducted at VIVUS's expense by a nationally recognized independent certified public accountant who is not VIVUS's auditor of record and who is selected by VIVUS and approved by Abbott, which approval shall not be unreasonably withheld. The accountant shall be bound by confidentiality obligations at least as stringent as those provided in Article 19 of this Agreement, and shall then have the right to examine the records kept pursuant to this Agreement and report to VIVUS the findings (but not the underlying data) of the inspection as are necessary to evidence that the records were or were not maintained and used in accordance with this Agreement. A copy of any report provided to VIVUS by the accountant shall be given concurrently to Abbott. If the inspection of records reveals more than five percent (5%) underpayment by Abbott for the purchase of the Products (calculated as a percentage of all such payments made in connection with a Sales Year), then the expenses for the accountant shall be borne by Abbott and Abbott shall promptly repay to VIVUS the amount of such underpayment, plus interest calculated at the prime rate of interest as published in the Wall Street Journal for the date upon which such underpayment was made. For the purposes of this Article 4.6, an "underpayment" shall not include any amount that the parties determine is owed to VIVUS pursuant to the reconciliation procedure set forth in Article 4.2(B) above.
- (B) VIVUS and VIVUS INC. and/or its or their Affiliates shall keep and maintain records of their costs of clinical development, regulatory work and samples relating to any Future Product which becomes a Product under this Agreement pursuant to Article 2.2 above, so that Abbott may verify such costs to the extent that Abbott is obligated under this Agreement to make payments to VIVUS based on such costs. Such records shall

be open to inspection upon prior written notice at any reasonable time during business hours, not more than once per calendar year, and each inspection shall cover no more than the two (2) calendar years preceding such notice of inspection. The inspection shall be conducted at Abbott's expense by a nationally recognized independent certified public accountant who is not Abbott's auditor of record and who is selected by Abbott and approved by VIVUS, which approval shall not be unreasonably withheld. The accountant shall be bound by confidentiality obligations at least as stringent as those provided in Article 19 of this Agreement, and shall then have the right to examine the records kept pursuant to this Agreement and report to Abbott the findings (but not the underlying data) of the inspection as are necessary to evidence that the records were or were not maintained and used in accordance with this Agreement. A copy of any report provided to Abbott by the accountant shall be given concurrently to VIVUS. If the inspection of records reveals more than five percent (5%) overpayment by Abbott for payments made based on such costs (calculated as a percentage of all such payments made), then the expenses for the accountant shall be borne by VIVUS and VIVUS shall promptly repay to Abbott the amount of such overpayment, plus interest calculated at the prime rate of interest as published in the Wall Street Journal for the date upon which such overpayment was made. For the purposes of this Article 4.6, an "overpayment" shall not include any amount that the parties determine is owed to Abbott pursuant to the reconciliation procedure set forth in Article 4.2(B) above.

4.7 Payments. Any payments due VIVUS or Abbott under this Agreement shall be made by remitting to the bank account designated by the party to whom payment is to be made. Any such payments shall be made in U.S. Dollars and, in the case of quarterly payments based upon Abbott Net Sales in currencies other than U.S. Dollars, such quarterly payments shall be the sum of payments due for the three (3) months of the applicable quarter calculated for each such month using the beginning and ending month's published exchange rate, set one business day prior to month end, by Reuters divided by two (if a Reuters exchange rate is not available for certain countries, an exchange rate established by a recognized third party will be used). Any payment which is more than ten (10) days overdue shall bear interest from the original due date at the prime rate of interest as published in the Wall Street Journal for the due date.

4.8 Taxes. Where any sum due to be paid to VIVUS hereunder is subject to any withholding or similar tax, the parties shall use their best efforts to do all such acts and things and to sign all such documents as will enable them to take advantage of any applicable double taxation agreement or treaty. In the event there is no applicable double taxation agreement or treaty, or if an applicable double taxation agreement or treaty reduces but does not eliminate such withholding or similar tax, Abbott shall pay such withholding or similar tax to the appropriate government authority, deduct the amount paid from the amount due VIVUS and secure and send to VIVUS the best available evidence of such payment.

# ARTICLE 5 - FORECASTS, ORDERS, INVOICES AND TITLE

- 5.1 Initial Forecast. Within sixty (60) days of the Effective Date, Abbott shall give VIVUS its then current best forecast of the quantity of Products that Abbott will require from VIVUS prior to and during the first four Sales Quarters. Abbott shall break down the forecast for the period prior to the first Sales Quarter and for the first two Sales Quarters of such forecast by month and by Stock Keeping Unit ("SKU") per Product.
- 5.2 Rolling Forecasts. No later than seventy-five (75) days prior to the first day of each Sales Quarter after the initial Sales Quarter, Abbott shall give VIVUS its then current best forecast of the quantity of Products that Abbott will require from VIVUS during each of the next four (4) Sales Quarters. Abbott shall break down the forecast for the first two such Sales Quarters of the forecast by month and by SKU per Product.
- 5.3 Order and Acceptance. The forecast for the first Sales Quarter in each of Abbott's rolling forecasts made pursuant to Article 5.2 above shall constitute Abbott's firm order for that Sales Quarter, and all firm orders shall specify delivery date(s) no less than ninety (90) days from the date of such firm order. Abbott shall not increase or decrease its forecast (by SKU and in total), for the second Sales Quarter in each of Abbott's rolling forecasts made pursuant to Article 5.2 above, by more than twenty percent (20%). VIVUS shall accept all firm orders from Abbott for quantities of Products up to and including one hundred twenty percent (120%) of the quantity (by SKU and in total) of Products previously forecasted by Abbott for such Sales Quarter, and shall use its best efforts to accept all firm orders from Abbott for quantities of Products in excess of that quantity of Products. Abbott shall not increase or decrease its forecast, for the third Sales Quarter in each of Abbott's rolling forecasts made pursuant to Article 5.2 above, by more than fifty percent (50%). VIVUS shall accept all firm orders from Abbott for quantities of Products

up to and including one hundred fifty percent (150%) of the quantity of Products previously forecasted by Abbott for such Sales Quarter, and shall use its best efforts to accept all firm orders from Abbott for quantities of Products in excess of that quantity of Products. Once an order has been accepted by VIVUS, then VIVUS shall be obligated to sell, and Abbott shall be obligated to purchase, the ordered Products.

- 5.4 Invoices. VIVUS shall invoice Abbott for the Transfer Price in United States dollars for the Products shipped. Abbott shall pay VIVUS such invoiced amount within thirty (30) days from the date of the invoice.
- 5.5 Delivery. VIVUS shall deliver the Products to Abbott, FOB at VIVUS's facilities located in Lakewood, New Jersey, USA. All shipping costs, liability, ownership and logistics of Product beyond the Lakewood facility's loading dock are the responsibility of Abbott.
- 5.6 Conflicting Terms and Conditions. Except as otherwise provided in this Agreement, the terms and conditions of this Agreement shall govern, notwithstanding any additional or inconsistent terms or conditions in Abbott's form of purchase order or similar document or in VIVUS's acknowledgment, invoice, or similar documents.
- 5.7 Post-Expiration Supply. In the event that this Agreement expires pursuant to Article 17.1 below, and Abbott wishes to continue purchasing the Products from VIVUS, the parties shall promptly negotiate in good faith the terms and conditions of a supply agreement for the Products. The Supply Price shall not be applicable to the sale and purchase of the Products under such separate supply agreement.

### ARTICLE 6 - SAMPLING, TESTING AND ANALYSIS

6.1 Certificate of Analysis. VIVUS shall test or cause to be tested each lot of the Products pursuant to the Specifications before delivery to Abbott. Each test shall set forth the items tested, specifications and test results in a certificate of analysis for each lot delivered. VIVUS shall send or cause to be sent such certificates to Abbott along with delivery of the Products. Abbott is entitled to rely on such certificates for all purposes of this Agreement. Abbott will perform any testing upon entry of the Products into the European Union, or elsewhere in the Territory, that is necessary for the sale or distribution of such Product in the territory.

### 6.2 Manufacturing Compliance.

(A) On each certificate of analysis provided to Abbott pursuant to Article 6.1 above, VIVUS shall provide or cause to be provided for each lot of the Products purchased a

- statement which will certify that the lot of Products was manufactured in accordance with the Specifications and applicable current Good Manufacturing Practices ("cGMP") laws and/or regulations.
- (B) Notwithstanding VIVUS's obligation to provide such statement, within ninety (90) days of the Effective Date, VIVUS shall permit Abbott to inspect, or obtain permission for such inspection, during reasonable business hours and upon reasonable prior notice to VIVUS, those areas of the facilities where the Products are manufactured, stored, tested and handled and to manufacturing records of the Products manufactured by VIVUS and/or VIVUS's third-party contract manufacturer(s).
- (C) VIVUS shall advise Abbott promptly if an authorized agent of any governmental body in the Territory inspects any of the facilities concerning the Products. VIVUS shall promptly furnish to Abbott a copy of all material documents and/or written communications relating to such visit and the application of such visit to the Products, if any.
- (D) If any such governmental body inspection and/or document or communication described in Article 6.2(C) above gives rise to any changes in VIVUS's or VIVUS's third-party contract manufacturer(s) facilities or manufacturing processes, technical documentation or record-keeping relating to the Products (or in the facilities, processes or record-keeping of VIVUS's third-party contract manufacturer(s)), VIVUS shall advise Abbott of such changes no later than ninety (90) days prior to the date upon which such changes become effective; provided that, if VIVUS does not itself receive at least ninety (90) days prior notice of any such change, then VIVUS shall notify Abbott of such change promptly after receiving its own notice.
- (E) If VIVUS or VIVUS's third-party contract manufacturer(s) for any reason, other than under Article 6.2(D) above, makes any changes in its or their facilities or manufacturing processes, technical documentation or record-keeping relating to the Products, VIVUS shall advise Abbott of such changes no later than ninety (90) days prior to the date upon which such changes are to become effective. Such changes shall be deemed accepted by Abbott unless Abbott notifies VIVUS to the contrary within such ninety (90) day or other agreed period. If Abbott notifies VIVUS that Abbott does not accept such changes, then the parties shall promptly meet and mutually determine in good faith any modifications to such changes that should be made in

- order to render such changes acceptable to Abbott. The parties acknowledge and agree that in considering or implementing any changes or modifications to changes being considered and/or made under this Article 6.2, the parties shall act in such a manner as to avoid, as far as possible, any delay or interruption in the supply of Products to Abbott and in Abbott's ability to market and sell the Products in the Territory.
- (F) The parties acknowledge that the specific requirements, including time period, of Section 6.2 (D) and Section 6.2(E) above, may be modified in writing by the separate technical agreement referred to in Section 6.6 helow.
- 6.3 Defective Product. Abbott shall notify VIVUS in writing of any claim relating to damaged, defective or nonconforming Products or any shortage in quantity of any shipment of the Products within thirty (30) days of receipt of such Products. If Abbott fails to give such written claim notice to VIVUS within said thirty (30) day period, the Products shipped shall be deemed to be conforming, not damaged nor defective at the time of delivery and shall be deemed to be sufficient in quantity. If Abbott gives such written claim notice to VIVUS within said thirty (30) day period, then Abbott and VIVUS shall, in an appropriate manner to be agreed, jointly inspect the Products to see if claimed nonconformity, damage or defect actually exists in the Products shipped. If existence of claimed nonconformity, damage, defect or shortage is reasonably verified through such inspection, VIVUS shall replace the rejected Products or make up the shortage as soon as practicable but no later than ninety (90) days after such verification, at no extra cost to Abbott, and shall make arrangements with Abbott for the destruction of any rejected Products, at VIVUS's expense.
- 6.4 Discrepant Inspection Results. In the event of a discrepancy between Abbott's and VIVUS's inspection results such that one party's results fall within the Specifications and the other party's results fall outside the Specifications, the parties shall cause an independent tester, mutually acceptable to the parties, to perform comparative tests on samples of the allegedly defective Products. The independent tester's results shall be final and binding and the parties shall share equally in the cost of the independent tester.
- 6.5 Specifications. The Specifications may be modified from time to time by written agreement of the parties without the necessity of amending this Agreement.
- 6.6 Technical Agreement. Within sixty (60) days, the respective manufacturing groups of VIVUS and Abbott shall enter into a separate technical agreement, in a format suitable for

submission to the regulatory authorities in each country in the Territory, recording the Specifications and Manufacturing Standards and measures to ensure compliance with applicable regulations relating to production, storage, transportation and release of the Products. Such Technical Agreement will also further define, as appropriate, the specific requirements and timing for Section 6.2 (D) and Section 6.2 (E), above.

### ARTICLE 7 - PATENTS

7.1 Patent Prosecution and Maintenance. To the extent it has the right to do so, VIVUS shall, at its sole cost and expense, maintain any patent applications and patents listed in Exhibit 1.8 and/or included in Licensed Patents, and shall diligently prosecute any such patent applications and obtain all available patent term extensions; provided that VIVUS may decide, subject to Abbott's prior written consent (which consent shall not be unreasonably withheld or delayed), not to prosecute certain of the Licensed Patents, or to cause or permit certain of the Licensed Patents to lapse or become abandoned in the Territory if, in VIVUS's reasonable commercial judgment, such decision would not adversely affect Abbott's ability to exercise its rights and perform its obligations under this Agreement. To the extent it does not have the right to maintain such patent applications and patents, prosecute such patent applications and obtain patent term extensions, VIVUS shall use its best efforts to ensure that the third party who has the right to take such actions shall do so. VIVUS shall keep Abbott informed on a quarterly basis and also on Abbott's reasonable written request about the status of such patent applications and/or patents, including but not limited to providing Abbott with copies of all material documents relating to the prosecution and/or the maintenance of the Licensed Patents in a timely manner so as to allow Abbott a reasonable opportunity to review and comment on VIVUS's planned patent strategy.

### ARTICLE 8 - DEVELOPMENT AND REGULATORY ISSUES

 $8.1\ VIVUS\ Responsibilities.\ VIVUS\ shall\ be\ responsible\ for,\ and\ shall\ bear\ all\ costs\ of,\ the\ following:$ 

(A) VIVUS shall be responsible for obtaining all Marketing Authorizations for the Products in Abbott's name in those countries in Europe which are listed on Exhibit 8.1 attached to this Agreement, including but not limited to conducting any clinical studies with the Products which may be necessary to obtain Marketing Authorization for the Products, with labeling for the MUSE Product equivalent to the labeling in effect for the MUSE Product as of the Effective Date, and with labeling for the ALIBRA Product which the parties mutually negotiate with the applicable governmental authorities, and for maintaining such Marketing Authorizations until such Marketing Authorizations are transferred to Abbott. Promptly after the Effective Date, VIVUS shall transfer to Abbott all Marketing Authorizations in the Territory for the MUSE Product, and all Marketing Authorization applications in the Territory for the ALIBRA Product, as expeditiously as possible.

- (B) VIVUS shall provide to Abbott, as expeditiously as possible, any and all authorizations, assistance, information and/or materials in VIVUS's possession or control required by Abbott in order to enable Abbott to market and sell the Products in the Territory (including, but not limited to authorizations, assistance, information and/or materials relating to Regulatory Approval of the Products by the United States Food and Drug Administration and by the European Medicines Evaluation Agency, and to the Drug Master Files for the Products). To the extent that any material, information, data or documents required by Abbott are not in VIVUS's possession or control, VIVUS shall use reasonable efforts to obtain such material, information, data or documents for Abbott.
- (C) In fulfilling its obligations under this Agreement, VIVUS shall use its best efforts to ensure that the Products are entitled to and receive the maximum benefit of any regulatory market exclusivity periods or other safeguards or extensions of proprietary status, which are or may be applicable in the Territory.
- (D) VIVUS shall be responsible for filing trademark applications for, and for the maintenance and upkeep of, the Trademarks in the Territory.
- 8.2 Abbott Responsibilities. During the term of this Agreement, Abbott shall be responsible for, and shall bear all cost of, the following:
  - (A) Abbott shall be responsible for (i) maintaining all Marketing Authorizations obtained by VIVUS for the Products in the countries listed on Exhibit 8.1, once such Marketing Authorizations have been transferred to Abbott; (ii) obtaining all pricing and reimbursement approvals in Abbott's name for the Product in the countries listed on Exhibit 8.1; and (iii) obtaining and maintaining all Regulatory Approvals in Abbott's name, including but not limited to conducting any clinical studies with the Products

which may be necessary to obtain Marketing Authorization for the Products, for the countries in the Territory outside of the countries listed on Exhibit 8.1. Should Abbott in connection with the Products conduct clinical studies, the parties endeavor to work by consensus in the development of protocols for such clinical studies.

- (B) Abbott shall own all registrations and Regulatory Approvals for the Products in the Territory.
- (C) In fulfilling its obligations under this Agreement, Abbott shall use its best efforts to ensure that the Products are entitled to and receive the maximum benefit of any regulatory market exclusivity periods or other safeguards or extensions of proprietary status, which are or may be applicable in the Territory.
- 8.3 Pharmacovigilance. Promptly after the Effective Date, the respective pharmacovigilance groups of VIVUS and Abbott shall enter into a separate agreement covering adverse event information exchange relating to the Products. Such agreement will permit the inclusion of the respective pharmacovigilance groups of other third parties to whom VIVUS has granted or will grant (during the term of this Agreement) a license under the VIVUS Technology to make, have made, use and sell the Products in the United States or in the Janssen Territory.
- 8.4 Regulatory Communications. Abbott and VIVUS shall promptly inform each other of any material communications to or from governmental authorities or agencies relating to the Products, including but not limited to providing each other promptly with copies of any material written communications. With the exception of product recalls, which are to be handled pursuant to Article 10 below, or visits by governmental body to any of the facilities where the Products are manufactured, which are to be handled pursuant to Article 6.2 above, and of adverse event reporting, which is to be handled pursuant to Article 8.3 above, the parties shall consult with each other regarding any issues raised in such communications, and shall attempt in good faith to agree upon any action to be taken or response to be made in connection with such communications. If the parties are unable to agree within a reasonable time prior to when the action is to be taken or the response is to be made the party responsible for obtaining Marketing Authorization for the Product in the country in question shall decide what action to take or response to make.
- 8.5 Improvements. In the event that development and/or regulatory work and/or costs are required in order to commercialize an Improvement, the parties shall negotiate in good faith to

determine the development and/or regulatory strategy and work, and how to allocate the costs therefor.

- 8.6 Future Product Development Committee. For each Future Product that becomes a Product pursuant to Article 2.2 above, Abbott and VIVUS shall form a Development Committee which shall be responsible for creating and implementing the clinical development plan for such Future Product from Phase III forward, and for creating and implementing the regulatory strategy for obtaining Marketing Authorization for such Future Product in the European Countries set forth on Exhibit 8.1 attached hereto, including the creation and management of the budget for such clinical development of and regulatory strategy for such Future Product. The Development Committee shall be organized and operated as set forth in this Article 8.6.
  - (A) The Development Committee shall consist of no more than six (6) individuals, an equal number of which shall be representatives, respectively, from Abbott and VIVUS, and shall be chaired alternatively on an annual basis by one (1) of the VIVUS representatives and by one (1) of the Abbott representatives. Each party's representatives on the Development Committee shall be an employee of such party and each shall have one (1) vote on any matter arising for decision by the Development Committee. Each party shall have the right, at any time, to designate by written notice to the other party, a replacement, on a permanent or temporary basis, for any of such party's members on the Development Committee.
  - (B) The Development Committee shall endeavor to work by consensus. In the event of a deadlock in any vote on any issue to be decided by the Development Committee, the parties shall refer the deadlocked issue to VIVUS's Vice President of Research and Development and Abbott's International Division Vice President of Medical Affairs. These individuals shall attempt, promptly and in good faith, to resolve such issue amicably. If such issue remains deadlocked, the parties shall refer such issue to, respectively, the President of VIVUS, and the President of Abbott's International Division. Any issue remaining deadlocked after this last step shall be resolved through an Alternative Dispute Resolution ("ADR") procedure pursuant to Article 20.11 below.

- (C) The Development Committee shall meet as necessary, in person or otherwise, as the parties shall agree, but no less than once per calendar quarter. The chairperson shall be responsible for scheduling and arranging such meetings and ensuring that all of the members or their designated replacements are able to attend. Each party shall bear its own costs, including travel costs, for its representatives on the Development Committee attending any meeting of the Development Committee.
- (D) Within sixty (60) days of a Future Product becoming a Product under this Agreement in accordance with Article 2.2 above, the parties shall reach written agreement, through the Development Committee, on the plan for the clinical development and regulatory work relating to such Future Product for the remainder of that calendar year ("Initial Period") and, separately, for the budget therefor. It is understood and agreed that any clinical development or regulatory work that had already begun by VIVUS at the time a Future Product becomes a Product under this Agreement in accordance with Article 2.2 above, will automatically become a part of the written agreement on the plan for the clinical development and regulatory work related to such Future Product including the budget therefor and will not require the approval of the Development Committee as long as this plan and a reasonable estimate of costs was provided to Abbott during the ninety (90) day evaluation period described in Article 2.2 (B) above. Following the Initial Period, at least ninety (90) days prior to January 1 of each year, the Development Committee will update such plan and budget therefor for the next calendar year. Each such plan and budget must be approved by the Development Committee, and by VIVUS's President and Abbott's International Division Vice President of Medical Affairs, such approval not to be unreasonably withheld, before the Development Committee may implement such plan and budget. Notwithstanding any other provision in this Agreement to the contrary, Abbott shall not be obligated to make any payments with respect to any clinical development work done in connection with any Future Product unless such work, and the budget therefor, was approved in accordance with this Article 8.6(D).
- (E) All applications for Regulatory Approval for such Future Product in the Territory shall

- be made in Abbott's name and all Regulatory Approvals obtained in the Territory for such Future Product shall be owned by Abbott.
- (F) VIVUS shall bear the costs of all clinical development of such Future Product that are necessary to support the Marketing Authorization for such Future Product in the European Countries, except as provided otherwise expressly in Article 2.2(D) above.
- (G) Abbott shall bear the costs of, and make all final decisions with respect to, the regulatory strategy for all aspects of obtaining Regulatory Approval in the Territory.
- (H) At the written request of VIVUS, the Development Committee for a given Future Product shall be expanded to include VIVUS's other licensee(s), if any, for such Future Product outside the Territory that become a licensee after the Effective Date of this Agreement, for the sole purpose of making the clinical development of such Future Product as efficient as possible on a worldwide basis. Abbott and VIVUS intend that the Development Committee's discussions and activities shall comply at all times with applicable laws and regulations, including but not limited to applicable antitrust and/or competition law, and no commercial information shall be shared, or discussion of commercial issues shall be permitted. Each such additional VIVUS licensee shall have an equal number of members on the Development Committee as do VIVUS and Abbott respectively, and VIVUS shall ensure that each such additional VIVUS licensee complies with the Development Committee procedures as set forth in this Article 8.6. Abbott shall not be required, and VIVUS shall not be permitted, to share any clinical or other data generated by Abbott with such additional licensee(s) without Abbott's prior written consent and such consent will not be unreasonably withheld. Abbott shall not be required to pay any portion of the costs of any clinical studies or other clinical development that relate to any country or area outside the Territory, except as provided otherwise expressly in Article 2.2(D) above.

#### ARTICLE 9 - MARKETING AND SALES

9.1 Abbott Diligence. In addition to the items set forth in Article 3.1 above, Abbott shall use its diligent efforts to market and/or sell the Products in the Territory, consistent with the efforts that Abbott expends on pursuing commercialization of Abbott's own products of similar market

potential, including but not limited to products for the treatment of erectile dysfunction, taking into consideration the proprietary or non-proprietary status of the Products and determining, in Abbott's best commercial judgment, whether and how to launch the Products in a given country of the Territory, and what if any promotional tools are reasonably necessary or desirable in marketing and/or selling the Products in the Territory. Abbott shall make any such launches and utilize any such promotional tools at Abbott's own expense.

9.2 Missed Targets. In the event that the fee provided in Article 3.1(B) above does not become payable by the end of the third Sales Year, or that the fee provided in Article 3.1(C) above does not become payable by the end of the sixth Sales Year, then VIVUS may terminate this Agreement upon thirty (30) days written notice; provided that in either event, if Abbott's annual Net Sales are at least (i) sixty percent (60%) of the amount specified in Article 3.1(B) or (C) (as the case may be) in the European Countries listed in Exhibit 8.1 or (ii) seventy-five percent (75%) of the amount specified in Article 3.1(B) or (C) (as the case may be) in the Territory, as of the date of VIVUS's notice of termination, then Abbott may, at its option, avoid termination by paying to VIVUS an amount equal to the fee otherwise applicable under Article 3.1(B) or (C) (as the case may be). If Abbott makes such payment within thirty (30) days of the date of VIVUS's notice of termination, then such notice shall become null and void, and this Agreement shall remain in full force and effect.

#### ARTICLE 10 - PRODUCT RECALL

10.1 Recall in the Territory. In the event that, in the Territory, (i) any government authority issues a request, directive or order that a Product be recalled, or (ii) a court of competent jurisdiction orders such a recall, or (iii) Abbott and VIVUS jointly determine that a Product should be recalled, Abbott shall take all appropriate corrective actions. If such recall results from any cause or event attributable solely to VIVUS's negligence or fault, VIVUS shall be responsible for the direct expenses of the recall. If such recall results from any cause or event attributable solely to Abbott's negligence or fault, Abbott shall be responsible for the direct expenses of the recall. If such recall results from any other cause or event (including attribution to the negligence or fault of both VIVUS and Abbott), the parties shall share equally the direct expenses of the recall. For the purposes of this Agreement, the direct expenses of recall shall include, without limitation, the expenses of notification and return of the recalled Products and

Abbott's costs for the Products, and shall not include the cost of any relaunch by Abbott of the Products in the Territory subsequent to a recall.

10.2 Recall Outside the Territory. In the event that, outside the Territory, (i) any government authority issues a request, directive or order that a Product be recalled, or (ii) a court of competent jurisdiction orders such a recall, or (iii) VIVUS (or its Affiliates or sublicensees, as the case may be) decides that the Products should be recalled, VIVUS shall notify Abbott no later than five (5) business days prior to the effective date of such recall, and shall provide Abbott with all information and assistance as Abbott may reasonably request in order to enable Abbott to determine any appropriate actions relating to the Products in the Territory arising from such recall.

### ARTICLE 11 - REPRESENTATIONS AND WARRANTIES

Each party hereby represents and warrants for itself as follows:

- 11.1 Organized. It is a corporation duly organized, validly existing and is in good standing under the laws of the jurisdiction of its incorporation, is qualified to do business and is in good standing as a foreign corporation in each jurisdiction in which the conduct of its business or the ownership of its properties requires such qualification and failure to have such would prevent it from performing its obligations under this Agreement and has all requisite corporate power and authority to conduct its business as now being conducted, to own, lease and operate its properties and to execute, deliver and perform this Agreement.
- 11.2. Due Execution. The execution, delivery and performance by it of this Agreement have been duly authorized by all necessary corporate action and do not and will not (i) require any consent or approval of its stockholders, (ii) violate any provision of any law, rule, regulation, order, writ, judgement, injunction, decree, determination or award presently in effect having applicability to it or any provision of its charter or by-laws, or (iii) result in a breach of or constitute a default under any material agreement, mortgage, lease, license (including any license from a third party which is necessary for the full performance of this Agreement), permit or other instrument or obligation to which it is a party or by which it or its properties may be bound or affected.
- 11.3 No Third Party Approval. No authorization, consent, approval, license, exemption of, or filing or registration with, any court or governmental authority or regulatory body (other than health regulatory authorities) is required for the due execution, delivery or performance by it of this Agreement, except as provided herein.

11.4 Binding Agreement. This Agreement is a legal, valid and binding obligation of such party, enforceable against it in accordance with its terms and conditions. It is not under any obligation to any person, contractual or otherwise, that is in conflict with the terms of this Agreement. 11.5 Full Disclosure. Each Party has disclosed to the other in good faith all material information relevant to the subject matter of this Agreement and to such party's ability to observe and perform its obligations hereunder. VIVUS further warrants that it has disclosed to Abbott all material information of which it is aware necessary or appropriate to evaluate the Licensed Patents, the safety and efficacy of the Products, and VIVUS manufacturing capacity for the Products. Such disclosure includes information contained in publicly available filings with the Securities & Exchange Commission.

ARTICLE 12 - COVENANTS, REPRESENTATIONS AND WARRANTIES OF VIVUS

VIVUS covenants, represents and warrants to Abbott that:

12.1 Agreements. The only agreements in existence as of the Effective Date under which VIVUS has acquired rights to Licensed Patents are listed in Exhibit 12.1 attached to this Agreement ("Third Party Licenses"). All rights with respect to Licensed Patents referenced in Exhibit 12.1 as patents for which "Place" or "Place, et al" are listed as inventor are either included in the license from Alza or have otherwise been transferred to VIVUS and are owned by VIVUS. The "Voss Patents," (collectively, the Licensed Patents, rights and technology granted to (i) Ortho Pharmaceutical Corporation by Gene A. Voss and Alan C. Eichler dated January 4, 1991, and assigned to VIVUS by Assignment from Ortho Pharmaceutical Corporation dated January 9, 1992, and (ii) VIVUS by Gene A. Voss and Alan C. Eichler dated December 28, 1992) are not necessary to use, manufacture, have manufactured, sell, or have sold Products in the Territory, and Abbott's use, manufacture, have manufactured, use, sale and have sold of Products in the Territory will not infringe the Voss Patents. To the best of the knowledge of VIVUS as of the Effective Date, and other than as set forth above with respect to the Voss Patents, the Licensed Patents and Third Party Licenses are the only patents, know-how and technology necessary to make, have made, use and sell the Products.

- 12.2 VIVUS Obligations. VIVUS covenants, represents and warrants to Abbott with respect to the Third Party Licenses that (i) VIVUS and its Affiliates will fully comply with all of VIVUS's covenants and obligations thereunder, to the extent material to Abbott's rights under this Agreement, (ii) the Third Party Licenses are in full force and effect, not having been amended, other than as set forth in Exhibit 12.1 attached to this Agreement, (iii) VIVUS and its Affiliates have received no oral or written notification of any alleged breach or default by VIVUS and/ or its Affiliates (iv) VIVUS and its Affiliates are not aware of any breach or default thereof by any third party, (v) VIVUS has the full right and authority to sublicense VIVUS and its Affiliates' rights to Abbott, and (vi) VIVUS and its Affiliates will not terminate, or otherwise amend the Third Party Licenses, in any manner which would materially adversely affect Abbott's rights under this Agreement.
- 12.3 Specifications. All quantities of the Products will comply with, and VIVUS shall only release Products for shipment to Abbott which comply with (i) all specifications of the Products (respectively as to the MUSE Product and the ALIBRA Product) in the Marketing Authorization applications approved by the regulatory authorities in the respective countries of the Territory, (ii) all Specifications, and (iii) all applicable legal and regulatory requirements relating to the manufacture of the Products for sale in the Territory, including but not limited to Good Manufacturing Practices.
- 12.4 Quality of Starting Materials and Packing Materials. All starting materials and packaging materials used in the manufacture of each of the Products shall comply with the applicable Specifications and the Manufacturing Standards (as defined below).
- 12.5 Current Good Manufacturing Practices ("cGMP") /Regulatory Requirements. All manufacturing and quality control methods utilized by VIVUS in the manufacture of the Products shall be carried out according to the procedures and requirements set forth in the then-current version of the VIVUS Site Master File for the Medicines Control Agency, or the Site Master File for Janssen International to the extent that any country listed in Exhibit 1.7 becomes a part of the Territory in accordance with Article 2.1(B) above, with respect to each such Product, and (as to each Product) in accordance with all applicable rules governing medicinal products and/or medical devices in the Good Manufacturing Practice for medicinal products

and/or medical devices and regulations issued by the health regulatory authorities in the countries of the Territory for which such Product is to be sold as in effect at the time and the applicable standards in effect at the time (collectively, the "Manufacturing Standards").

- 12.6 Documentation. VIVUS shall keep and maintain, for the approved shelf life of each Product plus two (2) years (i) reference samples and quality control records for each batch of starting materials and packaging material used in the manufacture of the Products, and (ii) manufacturing and quality control records for each batch of the Products. Each shipment of the Products shall be accompanied by the following written documentation: (i) the date of manufacture, (ii) delivered amount of Product units, (iii) a certificate of analysis pursuant to Article 6.
- 12.7 Abbott Right of Inspection. Following Abbott's initial facilities and records inspection as provided in Article 6.2(B) above, VIVUS shall, upon written request of Abbott, permit Abbott's authorized representative to inspect the following: (i) all manufacturing and quality control records for all manufacture of the Products, and (ii) quality control records of all starting materials used in the manufacture of each of the Products.
- 12.8 Compliance with Laws and Regulations. All Product delivered to Abbott pursuant to this Agreement will, to the best of VIVUS's knowledge, at the time of such delivery not be adulterated or misbranded within the meaning of applicable laws and regulations, and will not be an article which may not, under the provisions of such applicable laws and regulations, be introduced in commerce.
- 12.9 Shelf Life. Each lot of the Products delivered pursuant to this Agreement will continue until the applicable expiration date, to conform to the Specifications. At the time of delivery to Abbott, each lot of the Product delivered pursuant to this Agreement shall be no more than four (4) months past its manufacturing date.
- 12.10 Highest Quality. In manufacturing and releasing to Abbott the Products in compliance with the Specifications, the Manufacturing Standards, and otherwise as represented, warranted and covenanted by VIVUS in this Article 12, VIVUS shall provide to Abbott under this Agreement Products which are of the same or better quality as the Products marketed by VIVUS or its licensee(s) outside the Territory, and which meet any other requirements imposed by the relevant government authorities for the marketing and sale of the Product in the Territory.

- 12.11 Patent Validity and Enforceability As of the Effective Date, VIVUS has no knowledge or information that would materially impact the validity and/or enforceability of the Licensed Patents and the Licensed Patents have not been, and will not be, knowingly obtained through any activity, omission or representation that would limit or destroy the validity of the Licensed Patents.
- 12.12 Legal Actions There are no actions pending, or, to the best of VIVUS's knowledge as of the Effective Date, threatened before any court or other tribunal or body relating to the Licensed Patents.
- 12.13 Complete Patents/Ownership Exhibit 1.8 lists all patents issued and patent applications in existence on or before the Effective Date and, except for the patents licensed to VIVUS, VIVUS is named in the patents and patent applications listed in Exhibit 1.8 and all inventors named therein have assigned, or are under obligation to assign, to VIVUS all of their right, title and interest in the inventions claimed. None of the Licensed Patents as of the Effective Date has lapsed by reason of abandonment or nonpayment of annuities.
- 12.14 VIVUS-Astra Agreement. VIVUS represents, warrants and covenants to Abbott that VIVUS and Astra have mutually agreed to terminate the Astra Agreement, independent of any action by Abbott, and that VIVUS shall use its best efforts, in accordance with applicable law and not in violation of any contractual obligations it may have toward Astra AB, to enable Abbott to exercise the exclusive license granted under this Agreement without restrictions relating to any Astra AB rights, as expeditiously as possible.

### ARTICLE 13 - FORCE MAJEURE

Upon occurrence of an event of force majeure, the party affected shall promptly notify the other party in writing, setting forth the details of the occurrence, its expected duration and how that party's performance of its obligations under this Agreement is affected. The affected party shall resume the performance of its obligations as soon as practicable after the force majeure event ceases. If a party's performance of any obligation under this Agreement is significantly hindered or is prevented by an event of force majeure for more than six (6) months, whether or not consecutive, in any twelve (12) month period, then the other party may terminate this Agreement upon thirty (30) days' notice.

ARTICLE 14 - ALLOCATION OF SUPPLY

- 14.1 Allocation of Supply. In the event of VIVUS's inability for any reason to supply the Products ordered by Abbott, VIVUS shall allocate its available supply between Abbott, VIVUS and VIVUS's licensee(s) outside the Territory on a fair and equitable basis based on a pro-rata share of worldwide Product sales for the six (6) months preceding and the forecasted worldwide Product sales for the next six (6) months following such allocation. If VIVUS is unable to supply ninety percent (90%) of the Products (on a Product-by-Product basis) ordered by Abbott and accepted by VIVUS pursuant to Articles 5.3, 5.5 and 5.6 of this Agreement for a total of four (4) Months, whether or not consecutive, in any consecutive twelve (12) Month period, Abbott may at its sole option: (i) forgo the quantities ordered that VIVUS is unable to supply; (ii) take delivery within a reasonable period of time after VIVUS becomes able to supply the quantities ordered; or (iii) make or have a third party make, or permit VIVUS to have a third party (approved by Abbott) make, the Product that VIVUS fails to supply.
- 14.2 Quality Assurance. In the event that an inspection or report by an authorized agent of a governmental agency in the Territory reveals that VIVUS's (or VIVUS's third-party contractor's) facilities and processes for manufacturing the Products do not comply with applicable laws and regulations, including without limitation Good Manufacturing Practices, and such lack of compliance results in VIVUS's inability to fulfill its obligations to Abbott under this Agreement, then Abbott may, at its sole option, make or have a third party make, or permit VIVUS to have a third party (approved by Abbott) make, the Products that VIVUS is not able to supply.
- 14.3 Right to Manufacture Product. In the event Abbott selects option 14.1(iii) and/or option 14.2 above, then Abbott shall have the right to make and/or have a third party make Product and such right shall continue in effect until such time as VIVUS provides Abbott not less than six (6) months notice and demonstrates that it is able to adequately supply Abbott's reasonable requirements of Product in the Territory and VIVUS shall transfer to Abbott or to Abbott's or VIVUS's designated third party manufacturer all information, assistance, materials and authorizations useful and necessary with respect to the manufacture, storage and shipment of the Products, in a timely manner so as to avoid any delay or interruption in supply of the Products to Abbott. VIVUS shall reimburse Abbott for up to (\*\*\*) of Abbott's actual, verified out-of-pocket start-up costs incurred by Abbott to manufacture Product under this Article 14.3. Abbott shall pay to VIVUS a royalty on the Net Sales of such Products that are manufactured under this Article 14.3 equal to the greater of (i) the Supply Price pursuant to Article 4.2 above less

Abbott's actual cost of obtaining such Product from a third party or its variable cost (includes direct labor and material and all overhead that is directly related to the manufacture of such Product and specifically excludes fixed overhead items such as facilities rent, depreciation, common utilities, taxes and insurance, etc.) to manufacture such Product and, (ii) (\*\*\*) of Net Sales of such Product.

#### ARTICLE 15 - TRADEMARKS

- 15.1 Trademark Rights. VIVUS hereby grants to Abbott the exclusive right, exclusive even as to VIVUS, to use the Trademarks in connection with the Products in the Territory during the term of this Agreement. Abbott acknowledges that such Trademarks shall be and are the sole property of VIVUS. In the event that VIVUS decides to divest itself of the Trademarks, VIVUS shall assign such Trademarks in the Territory to Abbott upon Abbott's written request.
- 15.2 Electronic Address. VIVUS hereby grants to Abbott a non-exclusive right to use VIVUS's registered electronic address, www.vivus.com, for the purpose of linking electronic users with Abbott's relevant web pages, web sites or other electronic addresses relating to the Product in the Territory.
- 15.3 Abbott's Own Mark. In the event that Abbott is unable to use the Trademarks in connection with the Products in the Territory, for legal, regulatory or cultural reasons, Abbott may elect to use trademarks of its own choosing in connection with the Products in the Territory, after consultation with VIVUS, instead of the Trademarks. VIVUS acknowledges that such trademarks shall be and are the sole property of Abbott, and that the cost of adoption and registration of such trademarks shall be borne by Abbott.

#### ARTICLE 16 - INFRINGEMENT

16.1 Third Party Infringement. Each party will notify the other party if it becomes aware of the activities of any third party, which are believed to infringe any of the Licensed Patents or the Trademarks. The parties shall consult as to potential strategies against the alleged infringer, including but not limited to litigation strategy.

#### 16.2 Litigation.

(A) If the efforts of the parties are not successful in abating the alleged infringement, then VIVUS shall have the right, but not the obligation, to bring an appropriate suit or action against such infringement, at its own expense. Abbott agrees to cooperate in any such infringement action and agrees to execute all papers and perform such other acts as may be reasonably requested by Abbott, at VIVUS's expense. VIVUS shall consult with Abbott and take into account Abbott's recommendations regarding the conduct of such action, provided that VIVUS shall have full right and authority to determine the strategy and tactics for such action and to settle, consent to judgment, or otherwise resolve any such action or suit. The provisions of the foregoing notwithstanding, no such resolution shall be binding on Abbott without its prior written consent (which consent shall not be unreasonably withheld) unless such resolution does not (i) impose any liability, loss, cost or obligation upon Abbott and (ii) adversely affect Abbott's rights under this Agreement.

- (B) If VIVUS does not elect to bring suit against the alleged infringer, Abbott shall have the right, but not the obligation, to bring an appropriate suit or action against such infringer in the Territory, at Abbott's own expense. VIVUS agrees to cooperate in any such infringement action and agrees to execute all papers and perform such other acts as may be reasonably requested by Abbott (including but not limited to consent to be joined as a nominal party plaintiff in such action), at Abbott's expense. Abbott shall consult with VIVUS and take into account VIVUS's recommendations regarding the conduct of such action, provided that Abbott shall have full right and authority to determine the strategy and tactics for such action and to settle, consent to judgment, or otherwise resolve any such action or suit. The provisions of the foregoing notwithstanding, no such resolution shall be binding on VIVUS without its prior written consent (which consent shall not be unreasonably withheld) unless such resolution does not (i) impose any liability, loss, cost or obligation upon VIVUS and (ii) adversely affect VIVUS's rights under this Agreement.
- (C) If VIVUS or Abbott brings an infringement action pursuant to this Article 16, any amount recovered in any action or suit against a third party infringer shall be allocated as follows: first, to the party bringing such action in order to reimburse such party for the costs and expenses of such action; second, with respect to any remaining amount, sixty percent (60%) of that portion of such amount resulting from infringement within the Territory to Abbott, and the rest of any remaining amount to VIVUS.

- 16.3 Alleged Infringement of Third Party Intellectual Property.
  - (A) VIVUS shall indemnify and hold Abbott harmless against any judgment, damage, loss, cost or other expense (including legal fees) resulting from any claim or suit alleging infringement of any patent or trademark owned by a third party arising from Abbott's or its Affiliates' or sublicensees' use or sale of the Products and/ or any Improvements and/ or use of any of the Trademarks in the Territory. Abbott shall promptly give notice to VIVUS of any such claim or suit, and VIVUS shall have full control over the defense of such claim or suit; provided that Abbott shall have the right to participate, at its own expense, with counsel of its own choosing, in such defense. Abbott shall provide to VIVUS such reasonable assistance at VIVUS's expense as VIVUS may, from time to time, reasonably request. VIVUS, at its option and expense, may dispose of such claim or may conduct the defense of such suit. If Abbott becomes obligated to make any payment, including but not limited to royalties and/ or damages, to any third party for patent, trademark or other intellectual property infringement allegedly attributable to the Products, in order to use and sell the Products in the Territory, such payments shall be creditable against Abbott's purchases of the Products, which would otherwise be payable to VIVUS hereunder. Abbott shall use its best efforts to minimize its third-party payment obligations under this circumstance. VIVUS shall not dispose of any such claim or suit by agreement, in any fashion which causes Abbott to be enjoined or otherwise prohibited from using or selling the Products in any country or countries of the Territory, without Abbott's prior written consent.
  - (B) If Abbott is enjoined or otherwise prohibited from using or selling the Products in a given country in the Territory as a result of alleged patent or trademark infringement, then Abbott may exclude such country from the Territory upon written notice within thirty (30) days of the date of such final, permanent, unappealable or unappealed injunction or other order. If Abbott is enjoined or otherwise prohibited from making, having made, using or selling any of the Products and/or any of the Improvements and/or from using any of the Trademarks in all or a significant portion of the Territory as a result of alleged patent or trademark infringement, then, at Abbott's sole discretion, Abbott may exclude such portion of the Territory from this Agreement, or terminate this Agreement upon

written notice within thirty (30) days of the date of such final, permanent, unappealable or unappealed injunction or other order.

#### ARTICLE 17 - TERM AND TERMINATION

- 17.1 Term. The term of this Agreement shall commence on the Effective Date and shall, unless earlier terminated pursuant to this Article 17 or other express termination provisions in this Agreement, expire on a country-by-country and Product-by-Product basis upon the later to occur of (i) the expiration of the last Valid Claim that would be infringed by the manufacture, sale or use of the Product in such country, and (ii) the tenth (10th) anniversary of the First Commercial Sale of such Product. Upon the expiration of this Agreement and upon Abbott's request the parties shall negotiate transfer of all rights to the Trademarks in the Territory to Abbott.
- 17.2 Breach. Either party may, in addition to any other remedies available to it by law or in equity, terminate this Agreement upon sixty (60) days' written notice in the event that the other party commits a material breaches of this Agreement and fails to cure such breach within sixty (60) days of notice of the breach. The party giving notice of breach may withhold any payments otherwise due and owing to the breaching party, to be used as a setoff against any loss or damage arising from the breach, and said withholding shall not constitute breach of this Agreement. Any amounts so withheld shall be deposited by the withholding party into an interest-bearing escrow account. If the breaching party cures the breach within the sixty (60) day cure period and this Agreement is not terminated, then the withholding party shall promptly pay to the other party the withheld amount, less that portion of such amount which was applied as a setoff. Notwithstanding the foregoing provision, if Abbott gives notice of breach to VIVUS, Abbott may withhold other payments pursuant to this Article 17.2 but shall not be entitled to withhold payment for Product actually ordered by and delivered to Abbott pursuant to Article 5 of this Agreement.
- 17.3 Insolvency or Bankruptcy. Either party may, in addition to any other remedies available to it by law or in equity, terminate this Agreement, upon thirty (30) days' written notice to the other party in the event the other party shall have become insolvent or bankrupt, or shall have made an assignment for the benefit of its creditors, or there shall have been appointed a trustee or receiver of the other party or for all or a substantial part of its property, or any case or proceeding shall have been commenced or other action taken by or against the other party in bankruptcy or

seeking reorganization, liquidation, dissolution, winding-up, arrangement, composition or readjustment of its debts or any relief under any bankruptcy, insolvency, reorganization or other similar act or law of any jurisdiction now or hereinafter in effect.

- 17.4 Serious Events. Should there occur serious and unexpected events which, from a reasonable pharmaceutical company's point of view, would make it impossible or impracticable to pursue the commercialization of the Products, including but not limited to a serious adverse event associated with the Products, either party may, with full consultation with the other party, terminate this Agreement upon thirty (30) days' written notice. Termination by a party in good faith pursuant to this Article 17.4 shall not, in itself, constitute a basis for any claim for compensation or other remedies by the other party.
- 17.5 Lack of Commercial Viability. Abbott may terminate this Agreement, on a country-by-country and Product-by-Product basis, upon one hundred eighty (180) days' notice if, in Abbott's reasonable commercial judgement, the Product(s) are not commercially viable in such country. In the event that Abbott terminates this Agreement for one but not both of the Products in a country of the Territory under this Article 17.5, all rights to use and sell such Product in such country shall revert to VIVUS as of the effective date of such termination, and Abbott shall ensure that all registrations and Regulatory Approvals for such Product in such country shall be promptly assigned to VIVUS. In the event that Abbott terminates this Agreement for both Products in a country of the Territory under this Article 17.5, such country shall cease to be part of the Territory for all purposes of this Agreement, all rights to use and sell Products in such country shall revert to VIVUS as of the effective date of such termination, and Abbott shall ensure that all registrations and Regulatory Approvals for the Products in such country shall be promptly assigned to VIVUS. Termination by Abbott in good faith pursuant to this Article 17.5 shall not, in itself, constitute a basis for any claim for compensation or other remedies by the other
- 17.6 Change of Control or Ownership. Either party may terminate this Agreement upon thirty (30) days' written notice if the ownership or control of at least fifty percent (50%) of the assets or voting securities of the other party are transferred and, in the non-changing party's reasonable judgement, the other party's new owner or controlling entity is a competitor of the non-changing party in the field of erectile dysfunction.
- 17.7 Survival of Liability. Except as expressly provided otherwise in this Agreement, termination, expiration, cancellation or abandonment of this Agreement through any means and

for any reason shall not relieve the parties of any obligation accruing prior thereto and shall be without prejudice to the rights and remedies of either party with respect to any antecedent breach of any provision of this Agreement.

- 17.8 Remaining Inventory. Abbott shall maintain a normal level of inventory of the Products prior to expiration or termination of this Agreement, and shall have a period of six (6) months from the date of termination of this Agreement during which it may sell its remaining inventory of Products, provided it sell such inventory in a manner substantially similar to the manner in which it was selling Products prior to the termination.
- 17.9 Survival. Upon expiration or termination of this Agreement, all rights and obligations of the parties under this Agreement shall terminate except those rights and obligations described in Articles 1, 4.6, 10.1, 12.6, 17, 18, 19 and 20.

#### ARTICLE 18 - INDEMNITY

- 18.1 By VIVUS. In addition to indemnification expressly provided elsewhere in this Agreement, VIVUS shall indemnify, defend and hold Abbott, its directors, employees, agents and representatives (including but not limited to Abbott's Affiliates and sublicensees) harmless from and against all claims, causes of action, settlement costs (including but not limited to reasonable attorney's fees and expenses) losses or liabilities of any kind which:
  - (A) arise from or are attributable to any negligent act or omission or willful misconduct on the part of VIVUS or its Affiliates, or its or their directors, employees, agents or representatives relating to any of VIVUS's obligations under this Agreement, including but not limited to any breach of a representation or warranty;
  - (B) arise from or are attributable to a defect in the MUSE Product or in the manufacture of a Product, or from the failure of a Product to meet the Specifications and the Manufacturing Standards, including any theory of strict liability or any other theory of product liability, and which in either case are not otherwise attributable to any negligent act or omission or willful misconduct on the part of Abbott, its directors, employees, agents or representatives (including, but not limited to, Abbott's Affiliates); or
  - (C) arise from or are attributable to any act or omission of VIVUS or Astra AB or, respectively, its Affiliates, or its or their directors, employees, agents or

representatives relating to the Astra Agreement, or any act or omission of Abbott or its Affiliates, or its or their directors, employees, agents or representatives which allegedly causes harm or damage or loss of rights to Astra AB or its Affiliates, or its or their directors, employees, agents, shareholders or representatives in connection with the Astra Agreement.

18.2 By Abbott. In addition to indemnification expressly provided elsewhere in this Agreement, Abbott shall indemnify, defend and hold VIVUS, its directors, employees, agents and representatives harmless from and against all claims, causes of action, settlement costs (including but not limited to reasonable attorney's fees and expenses) losses or liabilities of any kind which:

- (A) arise from or are attributable to any negligent act or omission or willful misconduct on the part of Abbott, its directors, employees, agents or representatives relating to any of its obligations under this Agreement; or
- (B) arise from or are attributable to the storage, use, sale, marketing and promotion of the Products by Abbott in the Territory and which in either case are not otherwise attributable to a defect in the MUSE Product or in the manufacture of a Product or the failure of a Product to meet the Specifications and Manufacturing Standards as set forth in Article 18.1(B) above, and which in either case are not otherwise attributable to any negligent act or omission or willful misconduct on the part of VIVUS, its directors, employees, agents or representatives

18.3 Condition of Indemnification. If either party expects to seek indemnification under this Article, it shall promptly give notice to the indemnifying party of the basis for such claim of indemnification. If indemnification is sought as a result of any third party claim or suit, such notice to the indemnifying party shall be within fifteen (15) days after receipt by the other party of such claim or suit (if to Abbott, notice to Abbott Laboratories, Risk Management, D-317, 100 Abbott Park Road, Abbott Park, IL 60064-3500, with copy to the Abbott persons identified in Article 20.5 below; if to VIVUS, notice as set forth in Article 20.5 below); provided, however, that the failure to give notice within such time period shall not relieve the indemnifying party of its obligation to indemnify unless it shall be materially prejudiced by the failure. The indemnifying party shall have full control over the defense of such claim or suit; provided that the indemnified party shall have the right to participate, at its own expense, with counsel of its own choosing, in such defense. The indemnified party shall fully cooperate with the

indemnifying party in the defense of all such claims or suits. The indemnifying party shall make no offer of settlement, settlement or compromise without the prior written consent of the indemnified party (which consent shall not be unreasonably withheld) unless such settlement fully releases the indemnified party without any liability, loss, cost or obligation.

18.4 Term of Indemnification. The obligations of the parties set forth in this Article 18 shall apply during the term of this Agreement and for a period of five (5) years after the date of termination in whole or expiration of this Agreement or any extension thereof.

### ARTICLE 19 - CONFIDENTIALITY AND DISCLOSURE

19.1 Confidentiality. Neither party shall use or disclose any Confidential Information received by it pursuant to this Agreement without the prior written consent of the other. This obligation shall continue for a period of seven (7) years after expiration or termination of this Agreement.

19.2 Disclosure. Nothing contained in this Article shall be construed to restrict the parties from disclosing Confidential Information as required: (i) for regulatory, tax, securities or customs reasons, (ii) by court or other government order, (iii) for confidential audit purposes, or, (iv) from using such Confidential Information as is reasonably necessary to perform acts permitted by this Agreement, including the registration, marketing, sale or use of the Product; provided that the disclosing party shall, in the event of disclosure under Articles (i) or (ii) above, provide the other party with not less than five (5) business days notice prior to disclosure (except where the disclosing party itself receives less than five (5) business days prior notice, in which case the disclosing party shall immediately notify the other party), and the disclosing party shall fully cooperate with the other party to the extent permitted by law, so that the other party may make any objections and/or secure any protective provisions it deems reasonably necessary.

### ARTICLE 20 - MISCELLANEOUS

20.1 Assignment. This Agreement may not be assigned or otherwise transferred, nor, except as expressly provided hereunder, may any right or obligation hereunder be assigned or transferred by either party without the prior written consent of the other party; provided, however, that either VIVUS or Abbott may, without such consent, assign this Agreement and its rights and obligations hereunder in connection with the transfer or sale of all or substantially all of its assets, its merger or consolidation or any similar transaction, and that Abbott may, without

such consent, assign this Agreement and its rights and obligations hereunder to one or more of its Affiliates. Any permitted assignee shall assume all obligations of its assignor under this Agreement.

- 20.2 Sublicensees. In the event that Abbott grants sublicenses under Article 2, Abbott shall ensure that such sublicensees shall abide by all the obligations of Abbott contained in this Agreement to the extent that such obligations are relevant to and applicable to such sublicensees.
- 20.3 Damages. Notwithstanding any provision in this Agreement to the contrary, in no event shall a party hereto be liable to the other party for any indirect or consequential damages, including but not limited to loss of profits or business opportunity.
- 20.4 Severability. Each party intends not to violate any public policy, statutory or common law, rule, regulation, treaty or decision of any government agency or executive body thereof of any country or community or association of countries. If any term or provision of this Agreement is held to be invalid, illegal or unenforceable by a court or other governmental authority of competent jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Agreement, which shall remain in full force and effect. The holding of a term or provision to be invalid, illegal or unenforceable in a jurisdiction shall not have any effect on the application of the term or provision in any other jurisdiction.

20.5 Notices. Any consent or notice required or permitted to be given or made under this Agreement by one party to the other shall be in writing, delivered personally or by facsimile (and promptly confirmed by personal delivery, first-class mail or courier), first-class mail or courier, postage prepaid (where applicable), addressed to the other party as shown below or to such other address as the addressee shall have last furnished in writing to the addresser and (except as otherwise provided in this Agreement) shall be effective upon receipt by the addressee.

If to VIVUS: VIVUS International Limited

c/o VIVUS, Inc. 1172 Castro Street Mountain View, CA 94040 Attention: President Fax: (650)934-5356

cc: Wilson, Sonsini, Goodrich & Rosati

Attention: Kenneth A. Clark

Fax: (650)493-6811

If to Abbott: Abbott International, Ltd.

100 Abbott Park Road Abbott Park, IL 60064-3500

Attention: President, Abbott International Division

Fax: (847)935-3260

cc: Vice President, International Legal Operations

Fax: (847)938-1342

20.6 Applicable Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, excluding its conflict of laws provision. Application of the United Nations Convention On Contracts For The International Sale Of Goods is hereby excluded.

20.7 Entire Agreement. This Agreement contains the entire understanding of the parties with respect to the subject matter hereof. All express or implied agreements and understandings, either oral or written, heretofore made are superseded by this Agreement. Except as expressly provided elsewhere in this Agreement, this Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by both parties hereto.

20.8 Headings. The captions to the Articles hereof are not a part of this Agreement, but are merely guides or labels to assist in locating and reading the Articles hereof.

20.9 Independent Contractors. It is expressly understood and agreed that VIVUS and Abbott are independent contractors and that the relationship between the two parties shall not constitute a partnership, joint venture or agency. Neither VIVUS nor Abbott shall have the authority to make any statement, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of the party to do so.

20.10 Waiver. The waiver by either party of any right hereunder or of a failure to perform or breach by the other party shall not be deemed a waiver of any other right hereunder or of any other failure or breach whether of a similar nature or otherwise.

20.11 Alternative Dispute Resolution. The parties agree that any dispute that arises in connection with this Agreement, which cannot be amicably resolved by the parties, shall be

resolved by Alternative Dispute Resolution ("ADR") pursuant to the procedure set forth in Exhibit 20.11 attached hereto.

20.12 Public Announcements. Except as required by law, in which case the provisions of Article 19.2 shall apply, neither party shall make any public announcement, statement, response to questions or other disclosure concerning this Agreement nor the terms nor the subject matter hereof without the prior written consent of the other party.

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

THEREFORE, the parties hereto have executed this Agreement as of the first day above written.

ABBOTT INTERNATIONAL, LTD.	VIVUS INTERNATIONAL, LTD.
Ву:	Ву:
Title:	Title:
Date:	Date:

Page 40 of 55

### GUARANTEE OF PERFORMANCE

In order to induce Abbott to enter into the foregoing Agreement, VIVUS, INC., a corporation organized under the laws of the state of Delaware and having a principal place of business at 1172 Castro Street, Mountain View, CA 94040, and being the sole shareholder of VIVUS, hereby irrevocably and unconditionally guarantees any and all obligations (including, without limitation, any payment obligations) of VIVUS to Abbott, whether or not existing or hereinafter arising pursuant to the foregoing Agreement (including, without limitation, all agreements, grants, Undertakings, grants, licenses and sublicenses now or hereafter entered into pursuant to the Agreement (collectively, the "VIVUS Undertakings") or as such VIVUS Undertakings may be hereinafter amended or modified (with or without notice to or consent of VIVUS INC.).

VIVUS INC. further agrees that that VIVUS Undertakings may be extended, renewed, modified, amended or compromised in any way, with or without notice to or consent of VIVUS INC.

Notice of acceptance of the Guaranty and of the incurring of any obligation or any default of the VIVUS Undertakings, as well as demand and protest with respect to such VIVUS Undertakings and as well as any right to challenge or dispute the validity and enforceability of this Guarantee, are hereby waived by VIVUS INC.

This Guaranty shall be an irrevocable, continuing, absolute and unconditional guaranty of payment and performance by VIVUS pursuant to the VIVUS Undertakings.

VIVUS INC. represents, covenants and warrants to Abbott as follows, upon which Abbott relies in acceptance of this Guaranty: that (i) VIVUS INC. is the sole shareholder of all of issued and outstanding capital stock of VIVUS, (ii) VIVUS INC. will benefit from the Agreement between VIVUS and Abbott, (iii) VIVUS INC. has received good and valuable consideration for its execution, delivery and performance of this Guaranty, and (iv) VIVUS INC. has executed and delivered this Guaranty to Abbott.

Notice to VIVUS INC. shall be given pursuant to the provisions of Article 20.5 of the Agreement.

This Guaranty shall be governed by and construed in accordance with the laws of the State of Delaware and shall take effect as an instrument under seal

In the event of any dispute under this Guaranty, as to construction or performance of this Guaranty or any of its provisions or otherwise, such dispute shall be settled in accordance with Article 20.11 above, which is incorporated herein by reference, substituting "VIVUS INC." for "VIVUS" in such Article for purposes of this Guaranty. If an action to enforce this Guaranty is undertaken, the party prevailing in such enforcement action shall be entitled to recover its reasonable out-of-pocket expenses (including fees of outside counsel) with respect to such action.

 $\,$  VIVUS INC. shall not assign or transfer this Guaranty without the prior written consent of Abbott.

THEREFORE, VIVUS INC. executes this Guaranty under seal as of this 16th day of May 2000.

VIVUS, INC. /s/ Leland F. Wilson By: Leland Wilson

Title: President and Chief Executive Officer Date:\_\_\_\_\_

### JANSSEN TERRITORY

### ADDENDUM 1097 TERRITORY

### ADDENDUM 1097

### DISTRIBUTION AGREEMENT

Afghanistan
Algeria
Angola
Armenia
Azerbaijan
Bahrain
Bangladesh
Belarus
Benin
Bhutan
Bophuthatswan

Bophuthatswana Botswana Burkina Faso Burundi Cameroon

Central African Republic Chad Comoros Congo Cote d'Ivorie Djibouti Egypt Equatorial Guinea

Eritrea
Ethiopia
Gabon
Gambia
Georgia
Ghana
Guinea
Guinea
Bissau
India

Iran Iraq Israel Mongolia Morocco Mozambique Namibia Nepal Nigeria North Korea Oman Pakistan Qatar Russia Rwanda Saudi Arabia

Senegal Seychelles Sierra Leone Somalia Sri Lanka Sudan Swaziland Syria Tajikistan Tanzania Togo Transkei Tunisia Turkmenistan Uganda Ukraine

United Arab Emirates Uzbekistan Yemen Zaire Zambia Zansibar Antigua Aruba Bahamas Barbados Bermuda Brunei Cambodia Canada Cayman Islands

China

Curacao

Dominican Republic

Grenada Haiti Hong Kong Indonesia Jamaica Laos Macau Malaysia Mexico Myanmar Philippines Saint Martin Saint Vincent Santa Lucia Singapore South Africa South Korea Taiwan

Thailand Tortola Trinidad

Turks and Caicos Islands

Vietnam

Exhibit 1.7 (p. 2 of 2)

# ADDENDUM 1097 TERRITORY

ADDENDUM 1097 TERRITORY
Ivory Coast
Jordan
Kazachstan
Kenya
Krygyzstan
Kuwait
Lebanon
Lesotho
Liberia
Libya
Madagascar
Malawi
Mali
Mauritania

Page 44 of 55

# LICENSED PATENTS

(\*\*\*)

- ------

Ref. No. Title/Inventors Status

Serial and Patent Nos.

Page 45 of 55

 $\label{eq:specifications} {\tt MUSE(R)} \ {\tt RELEASE} \ {\tt AND} \ {\tt SHELF-LIFE} \ ({\tt REGULATORY}) \ {\tt SPECIFICATIONS}$ 

(\*\*\*)

Page 46 of 55

**PRICES** 

	VIVUS produces up to (***) of Product*	VIVUS produces (***) up to (***) of Product*	VIVUS produces (***) up to (***) of Product*	(***) up to	VIVUS produces >(***) of Product*
Sample Price per unit of Product	(***)	(***)	(***)	(***)	(***)
Minimum Supply Price per unit of Product **	(***)	(***)	(***)	(***)	(***)

 $<sup>^{\</sup>star}$  Total VIVUS worldwide unit production of finished Product in a calendar year (not only VIVUS finished Product produced for Abbott)

Page 47 of 55

 $<sup>^{\</sup>star\star}$  No Minimum Supply Price applies until after the first anniversary of the First Commercial Sale in the Territory.

# EUROPEAN COUNTRIES

COUNTRY
Austria
Belgium
Denmark
France
Finland
Germany
Greece
Ireland
Italy
Luxembourg
Netherlands
Portugal
Spain
Sweden
United Kingdom

Page 48 of 55

### THIRD PARTY LICENSES AMENDMENTS TO THIRD PARTY LICENSES

- Assignment Agreement between VIVUS, Inc. and ALZA Corporation dated December 31, 1993.
- Assignment between Ortho Pharmaceutical Corporation ("Ortho") and 2. VIVUS, Inc. dated June 9, 1992 (assigning to VIVUS Ortho's rights under three license agreements between Ortho and:
  - AMSU Ltd. dated June 23, 1989;
  - (b)
  - Kjell Holmquist AB dated June 26, 1989; and Gene A. Voss and Allen C. Eichler dated January 4, 1991. (c)
- License Agreement between VIVUS, Inc. and Gene A. Voss and Allen C. Eichler, dated December 28, 1992 (amending and restating VIVUS' rights under the license agreement between Ortho and Voss and Eichler assigned to VIVUS from Ortho);
- Amendment between VIVUS, Inc. and AMSU, Ltd. dated April 22, 1992 (amending the license agreement between Ortho and AMSU assigned to VIVUS from Ortho);
- Amendment between VIVUS, Inc. and AMSU, Ltd. dated July 3, 1992 (amending the license agreement between Ortho and AMSU assigned to VIVUS from Ortho);
- Amendment between VIVUS, Inc. and Kjell Holmquist AB dated April 22, 1992 (amending the license agreement between Ortho and AMSU assigned to VIVUS from Ortho); and
- Amendment between VIVUS, Inc. and Kjell Holmquist AB dated July 3, 1992 (amending the license agreement between Ortho and AMSU assigned to VIVUS from Ortho).

Page 49 of 55

#### Alternative Dispute Resolution

The parties recognize that bona fide disputes as to certain matters may arise from time to time during the term of this Agreement which relate to either party's rights and/or obligations. To have such a dispute resolved by this Alternative Dispute Resolution ("ADR") provision, a party first must send written notice of the dispute to the other party for attempted resolution by good faith negotiations between their respective presidents (or their designees) of the affected subsidiaries, divisions, or business units within twenty-eight (28) days after such notice is received (all references to "days" in this ADR provision are to calendar days).

If the matter has not been resolved within twenty-eight (28) days of the notice of dispute, or if the parties fail to meet within such twenty-eight (28) days, either party may initiate an ADR proceeding as provided herein. The parties shall have the right to be represented by counsel in such a proceeding.

- 1. To begin an ADR proceeding, a party shall provide written notice to the other party of the issues to be resolved by ADR. Within fourteen (14) days after its receipt of such notice, the other party may, by written notice to the party initiating the ADR, add additional issues to be resolved within the same ADR.
- 2. Within twenty-one (21) days following receipt of the original ADR notice, the parties shall select a mutually acceptable neutral to preside in the resolution of any disputes in this ADR proceeding. If the parties are unable to agree on a mutually acceptable neutral within such period, either party may request the President of the CPR Institute for Dispute Resolution ("CPR"), 366 Madison Avenue, 14th Floor, New York, New York 10017, to select a neutral pursuant to the following procedures:
- (a) The CPR shall submit to the parties a list of not less than five (5) candidates within fourteen (14) days after receipt of the request, along with a Curriculum Vitae for each candidate. No candidate shall be an employee, director, or shareholder of either party or any of their subsidiaries or affiliates.

- (b) Such list shall include a statement of disclosure by each candidate of any circumstances likely to affect his or her impartiality.
- (c) Each party shall number the candidates in order of preference (with the number one (1) signifying the greatest preference) and shall deliver the list to the CPR within seven (7) days following receipt of the list of candidates. If a party believes a conflict of interest exists regarding any of the candidates, that party shall provide a written explanation of the conflict to the CPR along with its list showing its order of preference for the candidates. Any party failing to return a list of preferences on time shall be deemed to have no order of preference.
- (d) If the parties collectively have identified fewer than three (3) candidates deemed to have conflicts, the CPR immediately shall designate as the neutral the candidate for whom the parties collectively have indicated the greatest preference. If a tie should result between two candidates, the CPR may designate either candidate. If the parties collectively have identified three (3) or more candidates deemed to have conflicts, the CPR shall review the explanations regarding conflicts and, in its sole discretion, may either (i) immediately designate as the neutral the candidate for whom the parties collectively have indicated the greatest preference, or (ii) issue a new list of not less than five (5) candidates, in which case the procedures set forth in subparagraphs 2(a) 2(d) shall be repeated.
- 3. No earlier than twenty-eight (28) days or later than fifty-six (56) days after selection, the neutral shall hold a hearing to resolve each of the issues identified by the parties. The ADR proceeding shall take place at a location agreed upon by the parties. If the parties cannot agree, the neutral shall designate a location other than the principal place of business of either party or any of their subsidiaries or affiliates.
- 4. At least seven (7) days prior to the hearing, each party shall submit the following to the other party and the neutral:
- (a) a copy of all exhibits on which such party intends to rely in any oral or written presentation to the neutral;
- (b) a list of any witnesses such party intends to call at the hearing, and a short summary of the anticipated testimony of each witness;

- (c) a proposed ruling on each issue to be resolved, together with a request for a specific damage award or other remedy for each issue. The proposed rulings and remedies shall not contain any recitation of the facts or any legal arguments and shall not exceed one (1) page per issue.
- (d) a brief in support of such party's proposed rulings and remedies, provided that the brief shall not exceed twenty (20) pages. This page limitation shall apply regardless of the number of issues raised in the ADR proceeding.

Except as expressly set forth in subparagraphs 4(a) - 4(d), no discovery shall be required or permitted by any means, including depositions, interrogatories, requests for admissions, or production of documents.

- 5. The hearing shall be conducted on two (2) consecutive days and shall be governed by the following rules:
- (a) Each party shall be entitled to five (5) hours of hearing time to present its case. The neutral shall determine whether each party has had the five (5) hours to which it is entitled.
- (b) Each party shall be entitled, but not required, to make an opening statement, to present regular and rebuttal testimony, documents or other evidence, to cross-examine witnesses, and to make a closing argument. Cross-examination of witnesses shall occur immediately after their direct testimony, and cross-examination time shall be charged against the party conducting the cross-examination.
- (c) The party initiating the ADR shall begin the hearing and, if it chooses to make an opening statement, shall address not only issues it raised but also any issues raised by the responding party. The responding party, if it chooses to make an opening statement, also shall address all issues raised in the ADR. Thereafter, the presentation of regular and rebuttal testimony and documents, other evidence, and closing arguments shall proceed in the same sequence.
- (d) Except when testifying, witnesses shall be excluded from the hearing until closing arguments.

- (e) Settlement negotiations, including any statements made therein, shall not be admissible under any circumstances. Affidavits prepared for purposes of the ADR hearing also shall not be admissible. As to all other matters, the neutral shall have sole discretion regarding the admissibility of any evidence.
- 6. Within seven (7) days following completion of the hearing, each party may submit to the other party and the neutral a post-hearing brief in support of its proposed rulings and remedies, provided that such brief shall not contain or discuss any new evidence and shall not exceed ten (10) pages. This page limitation shall apply regardless of the number of issues raised in the ADR proceeding.
- 7. The neutral shall rule on each disputed issue within fourteen (14) days following completion of the hearing. Such ruling shall adopt in its entirety the proposed ruling and remedy of one of the parties on each disputed issue but may adopt one party's proposed rulings and remedies on some issues and the other party's proposed rulings and remedies on other issues. The neutral shall not issue any written opinion or otherwise explain the basis of the ruling.
- 8. The neutral shall be paid a reasonable fee plus expenses. These fees and expenses, along with the reasonable legal fees and expenses of the prevailing party (including all expert witness fees and expenses), the fees and expenses of a court reporter, and any expenses for a hearing room, shall be paid as follows:
- (a) If the neutral rules in favor of one party on all disputed issues in the ADR, the losing party shall pay 100% of such fees and expenses.
- (b) If the neutral rules in favor of one party on some issues and the other party on other issues, the neutral shall issue with the rulings a written determination as to how such fees and expenses shall be allocated between the parties. The neutral shall allocate fees and expenses in a way that bears a reasonable relationship to the outcome of the ADR, with the party prevailing on more issues, or on issues of greater value or gravity, recovering a relatively larger share of its legal fees and expenses.

- 9. The rulings of the neutral and the allocation of fees and expenses shall be binding, non-reviewable, and non-appealable, and may be entered as a final judgment in any court having jurisdiction.
- 10. Except as provided in paragraph 9 or as required by law, the existence of the dispute, any settlement negotiations, the ADR hearing, any submissions (including exhibits, testimony, proposed rulings, and briefs), and the rulings shall be deemed Confidential Information. The neutral shall have the authority to impose sanctions for unauthorized disclosure of Confidential Information.

Page 54 of 55

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             JUN-30-2000
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For Purposes of this Exhibit, Primary Means Basic