
SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

AMENDMENT NO. 2

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FORM 10-K
ANNUAL REPORT
PURSUANT TO SECTION 13 OR 15(D)
OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED DECEMBER 31, 1996

COMMISSION FILE NUMBER 0-23490

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

DELAWARE (STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION) 94-3136179 (I.R.S. EMPLOYER IDENTIFICATION NUMBER)

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

 $(415) \ 325\text{-}5511 \\ (\text{REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE})$

SECURITIES REGISTERED PURSUANT TO 12(B) OF THE ACT: NONE

SECURITIES REGISTERED PURSUANT TO SECTION 12(G) OF THE ACT: COMMON STOCK, \$.001 PAR VALUE

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. []

As of February 28, 1997, the aggregate market value of the voting stock held by non-affiliates of the Registrant was \$632,342,107 (based upon the closing sales price of such stock as reported by The Nasdaq Stock Market on such date). Shares of Common Stock held by each officer, director, and holder of 5% or more of the outstanding Common Stock on that date have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 28, 1997, the number of outstanding shares of the Registrants' Common Stock was 16,426,606.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required by Items 6, 7 and 8 of Form 10-K is incorporated by reference from the Registrant's annual report to security holders furnished pursuant to Rule 14a-3 (the "Annual Report"). Certain information required by Items 10, 11, 12 and 13 of Form 10-K is incorporated by reference from the Registrant's proxy statement for the 1997 Annual Stockholders' Meeting (the "Proxy Statement"), which will be filed with the Securities and Exchange Commission within 120 days after the close of the Registrant's fiscal year ended December 31, 1996.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information required by this item is incorporated by reference from the discussion in the Proxy Statement captioned "Record Date and Share Ownership."

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

This information required by this item is incorporated by reference from the discussion in the Proxy Statement captioned "Certain Transactions and Reports.'

PART TV

ITEM 14. EXHIBITS, FINANCIAL STATEMENTS SCHEDULES AND REPORTS ON FORM 8-K

(a) The following documents are filed as part of this Report:

1. FINANCIAL STATEMENTS

Financial statements have been incorporated by reference to the Registrant's Annual Report.

2. FINANCIAL STATEMENT SCHEDULES

Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the consolidated financial statements or notes thereto incorporated by reference herein.

3. EXHIBITS

NUMBER

- 3.1 Certificate of Incorporation of the Company, as currently in effect
 - Form of Amended and Restated Certificate of Incorporation of the Company, 3.2 to be filed immediately following the Company's Annual Meeting of Stockholders if the stockholders approve Proposal 2 in the Company's Proxy
- 3.3 #
- Bylaws of the Registrant, as amended Specimen Common Stock Certificate of the Registrant 4.1
- Registration Rights, as amended 4.2
- Form of Agreement Not to Sell by and between the Registrant and certain 4.3 shareholders and option holders
- 4.4 Form of Preferred Stock Purchase Warrant issued by the Registrant to Invemed Associates, Inc., Frazier Investment Securities, L.P. and Cristina
- #### 4.5 Amended and Restated Preferred Shares Rights Agreement dated as of June 18, 1996, by and between Vivus, Inc. and First Interstate Bank of California, including the Certificate of Designation, the form of Rights Certificate and the Summary of Rights attached thereto as Exhibits A, B and C, respectively
 - 10.1 Assignment Agreement by and between Alza Corporation and the Registrant dated December 31, 1993
 - Memorandum of Understanding by and between Ortho Pharmaceutical Corporation 10.2 and the Registrant dated February 25, 1992
 - 10.3 Assignment by and between Ortho Pharmaceutical Corporation and the Registrant dated June 9, 1992
 - 10.4 License Agreement by and between Gene A. Voss, M.D., Allen C. Eichler, M.D., and the Registrant dated December 28, 1992
 - License Agreement by and between Ortho Pharmaceutical Corporation and Kjell 10.5 Holmquist AB dated June 23, 1989

NUMBER

*+	10.5B	Amendment by and between Kjell Holmquist AB and the Registrant dated July 3, 1992
*	10.5C	Amendment by and between Kjell Holmquist AB and the Registrant dated April 22, 1992
*+	10.5D	Stock Purchase Agreement by and between Kjell Holmquist AB and the Registrant dated April 22, 1992
*+	10.6A	License Agreement by and between AMSU, Ltd., and Ortho Pharmaceutical Corporation dated June 23, 1989
*+	10.6B	Amendment by and between AMSU, Ltd., and the Registrant dated July 3, 1992
*	10.6C	Amendment by and between AMSU, Ltd., and the Registrant dated April 22, 1992
*+	10.6D	Stock Purchase Agreement by and between AMSU, Ltd., and the Registrant dated July 10, 1992
*	10.7	Supply Agreement by and between Paco Pharmaceutical Services, Inc., and the Registrant dated November 10, 1993
*+	10.8	Agreement by and among Pharmatech, Inc., Spolana Chemical Works AS, and the Registrant dated June 23, 1993
*	10.9	Master Services Agreement by and between the Registrant and Teknekron Pharmaceutical Systems dated August 9, 1993
*	10.10	Lease by and between McCandless-Triad and the Registrant dated November 23, 1992, as amended
***	10.11	Form of Indemnification Agreements by and among the Registrant and the Directors and Officers of the Registrant
**	10.12	1991 Incentive Stock Plan and Form of Agreement, as amended
*	10.13	1994 Director Option Plan and Form of Agreement
*	10.14	Form of 1994 Employee Stock Purchase Plan and Form of Subscription Agreement
*	10.15	Stock Restriction Agreement between the Company and Virgil A. Place, M.D. dated November 7, 1991
*	10.16	Stock Purchase Agreement between the Company and Leland F. Wilson dated June 26, 1991, as amended
*	10.17	Letter Agreement between the Registrant and Leland F. Wilson dated June 14, 1991 concerning severance pay
*	10.18	Letter Agreement between the Registrant and Paul C. Doherty dated January 26, 1994 concerning severance pay
**	10.19	Guaranteed Maximum Price Contract by and between the Registrant and Marshall Contractors, Inc. dated January 27, 1995
**	10.20	Sub-sublease by and among the Registrant, Argonaut Technologies, Inc., ESCAgenetics Corp. and Tanklage Construction Co. dated January 31, 1995
#+	10.21	Distribution Services Agreement between the Registrant and Synergy Logistics, Inc. (a wholly-owned subsidiary of Cardinal Health, Inc.) dated February 9, 1996
#+	10.22	Manufacturing Agreement between the Registrant and CHINOIN Pharmaceutical and Chemical Works Co., Ltd. dated December
###+	10.23	Distribution and Services Agreement between the Registrant and Alternate Site Distributors, Inc. dated July 17, 1996
##+	10.24	Distribution Agreement made as of May 29, 1996 between the Registrant and Astra AB

NUMBER

###	10.25	Menlo McCandless Office Lease made as of August 30, 1996 by and between
###	10.26	Registrant and McCandless - Triad Sublease Agreement made as of August 22, 1996 by and between Registrant and
	10.20	Plant Research Technologies
X+	10.27	Distribution Agreement made as of January 22, 1997 between the Registrant
		and Janssen Pharmaceutica International, a division of Cilag AG
		International
	10.28	Lease Agreement made as of January 1, 1997 between the Registrant and
		Airport Associates
	10.29	Lease Amendment No. 1 as of February 15, 1997 between Registrant and
		Airport Associates
	10.30	Lease Agreement by and between 605 East Fairchild Associates, L.P. and
		Registrant dated as of March 7, 1997
	11.1	Computation of net loss per share
	13.1	Portions of the 1996 Annual Report to Security Holders
**	16.1	Letter regarding change in independent public accountants
	21.1	Intentionally omitted
	21.2	List of Subsidiaries
	23.1	Consent of Independent Public Accountants
	24.1	Power of Attorney (See "Power of Attorney")

27.1

* Incorporated by reference to the same-numbered exhibit filed with the Registrant's Registration Statement on Form S-1 No. 33-75698, filed with the Commission on February 24, 1996, as amended.

Financial Data Schedule

- ** Incorporated by reference to the same-numbered exhibit filed with the Registrant's Registration Statement on Form S-1 No. 33-90390, filed with the Commission on March 16, 1995, as amended.
- *** Incorporated by reference to the same-numbered exhibit filed with the Registrant's Form 8-B filed with the Commission on June 24, 1996.
 - # Incorporated by reference to the same-numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 1996, as amended.
- ## Incorporated by reference to the same numbered exhibit filed with the Registrant's Current Report on Form 8-K filed with the Commission on May 31, 1996, as amended.
- ### Incorporated by reference to the same-numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1996.
- #### Incorporated by reference to exhibit 99.1 filed with the Registrant's Registration Statement on Form 8-A No. 0-23490, filed with the Commission on June 24, 1996.
 - + Confidential treatment granted.
 - ++ Confidential treatment requested.
 - X Supersedes previously filed exhibit.

${\tt SIGNATURES}$

Pursuant to the requirements of Section 13 or 15(d) 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., a Delaware Corporation

By: /s/ DAVID C. YNTEMA

David C. Yntema
Vice President of Finance and Chief
Financial Officer (Principal
Financial
and Accounting Officer)

Date: June 24, 1997

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EXHIBIT 10.27

DISTRIBUTION AGREEMENT

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

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THIS DISTRIBUTION AGREEMENT (hereinafter "Agreement"), made as of the 22nd day of January, 1997 ("Effective Date"), between VIVUS International Limited, a company organized under the laws of Bermuda and having a place of business at Clarendon House, Church Street, Hamilton, Bermuda ("VIVUS"), a wholly-owned subsidiary of VIVUS, Inc., a Delaware corporation ("VIVUS, Inc."), and Janssen Pharmaceutica International, a division of Cilag AG International, and having its registered office at Kollerstrasse 38, CH-6300, Zug., Switzerland ("Janssen").

RECITALS

- A. VIVUS has developed a Product for the transurethral delivery of alprostadil for the treatment of erectile dysfunction (as defined below, the "Product").
- B. Janssen desires to obtain from VIVUS certain distribution rights, [*], for such Product in the Territory (as defined below) and VIVUS is willing to grant to Janssen such rights on the terms and conditions set forth

AGREEMENT

1. DEFINITIONS

- 1.1 "Affiliates" shall mean (i) 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 hereto to the extent of at least fifty percent (50%) of the equity (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) having the power to vote on or direct the affairs of the entity or, irrespective of such equity ownership, having the power to direct or control the management of such entity, and (ii) any person, firm, partnership, corporation or other entity actually controlled by, controlling or under common control with such party.
- 1.2 [*] delivery transurethrally to treat male erectile dysfunction. It is understood that, as used herein, the [*].
- 1.3 [*] It is understood that [*] shall not include standard, commercially available [*].
- 1.4 "First Commercial Sale" shall mean, with respect to each Product in each country, the first bona fide, arm's length sale of such Product in such country by or under authority of Janssen or its Subdistributors.
- 1.5 "Foil Pouch Package Form" shall mean Product in finished dosage form, including its cap, packaged into an individual foil pouch. The pouches with a minimum of information to the extent required to satisfy regulatory requirements throughout the Territory with respect to markings that must appear on the pouch itself, provided that [*]
- *Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

- 1.6 "MAA" shall mean a marketing authorization application filed by or under authority from Janssen with the requisite health regulatory authority of any country of the Territory requesting approval for commercialization of a Product for a particular indication in such country. It is understood that MAA does not include applications for pricing or reimbursement approval.
- 1.7 "MAA Approval" shall mean, with respect to each country of the Territory for a particular Product, approval of the MAA filed in such country by the health regulatory authority in such country that is the counterpart of the U.S. FDA. It is understood that MAA Approval does not include pricing or reimbursement approval. In any event, MAA Approval shall be deemed to have occurred in a country with respect to a Product no later than the date of the First Commercial Sale of such Product in such country by or under authority of Janssen or its Subdistributors.
- 1.8 "Major Country" shall mean The People's Republic of China or Canada.
 - 1.9 "Net Sales" shall mean the [*]

The amounts described in (a) and (b) above shall be deducted only to the extent they are stated separately on the invoice and paid by the buyer, or to the extent reflected on Janssen's books in accordance with GAAP. [*]

- 1.10 "Patents" shall mean all patents and patent applications (including continuations, continuations-in-part, divisions, patents of addition, reissues, renewals, and extensions) which are or become owned by VIVUS or VIVUS Inc., or to which VIVUS or VIVUS Inc. has, now or in the future, the right to grant licenses and distribution rights, which generically or specifically claim Product, a process for manufacturing Product, an intermediate used in such process or a use of Product. With respect to any such patents or applications which VIVUS or VIVUS Inc. acquires or has acquired from a Third Party, the same shall be included within the "Patents" hereunder to the extent that VIVUS or VIVUS Inc. has the right to license the same hereunder.
 - 1.11 [*] meeting the applicable [*].
- 1.12 "Product(s)" shall mean the VIVUS "MUSE" Product for which an NDA has been approved in the U.S. as of the Effective Date for any indications (hereinafter "First Product"), and any other product useful to treat male erectile dysfunction in humans for any indications which is both delivered locally to the penis and contains alprostadil, and that is owned or controlled by VIVUS or VIVUS Inc or their Affiliates controlled by VIVUS or VIVUS, Inc.
- 1.13 "Specifications" shall have the meaning set forth in Section 5.7 below.
- 1.14 "Subdistributor" shall mean any Affiliate or Third Party to whom Janssen has granted the right, directly or indirectly, to distribute Product and such Affiliate or Third Party is responsible for marketing and/or promotion of such Product within its distribution territory, but does not include wholesalers and resellers of Product who do not engage in any marketing or promotion of the Product.

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- 1.15 "Territory" shall mean Canada, Mexico (including those Caribbean Islands listed in Exhibit A hereto) South Africa, The Peoples Republic of China, South Korea, Taiwan, Malaysia, Indonesia, Philippines, Hong Kong (including Macau) and Singapore (including Brunei), Thailand, Vietnam, Myanmar, Cambodia and Laos. The initial Janssen Subdistributors responsible for each country within the Territory are listed in Exhibit A.
- 1.16 "Third Party(ies)" shall mean any party other than Janssen, VIVUS and their Affiliates.
- 1.17 "VIVUS Alternative Trademark" shall mean a Trademark other than the VIVUS Trademark which VIVUS has designated and the parties agree to use with the Product in those countries in the Territory where the VIVUS Trademark is not used.
 - 1.18 "VIVUS Cost of Goods" shall mean [*].
- 1.19 "VIVUS Know-How" shall mean all methods, procedures, data and information in tangible form owned or controlled by VIVUS [*].
- 1.20 "VIVUS Trademark" shall mean the "MUSE" Trademark which VIVUS has used in connection with the Product. The VIVUS Trademark will be used in connection with the Product in the Territory unless the Parties agree otherwise or unless otherwise provided herein. Each Party agrees that it will consider, in good faith, a request by the other Party to use a VIVUS Alternative Trademark.

2. GRANT OF DISTRIBUTION RIGHTS

- 2.1 Appointment. VIVUS hereby grants to Janssen the exclusive (even as to VIVUS) right to package, label, distribute and market Product for sale in and sell Product in the Territory for all indications, with the right to grant subdistribution rights to subdistributors (Affiliates or otherwise) who distribute other Janssen ethical pharmaceutical products, subject to all the other terms and conditions of this Agreement. Janssen may subdistribute Products through other subdistributors with VIVUS' prior written approval. Notwithstanding anything herein to the contrary, Janssen and each subdistributor shall market, promote, sell and otherwise distribute Product in accordance with all applicable laws and regulations. VIVUS reserves all rights not expressly granted herein.
- 2.2 Janssen No Conflict. During the term of this Agreement, Janssen agrees that neither Janssen nor its Affiliates will develop, market or distribute any products in the Territory for the treatment or prevention of erectile dysfunction other than Products; provided that with VIVUS' prior approval, Janssen may develop, market or distribute within the Territory products for the treatment of erectile dysfunction that are complementary with Products and that do not involve the transurethral delivery, local injection, local topical application or other local delivery of a drug substance.
- 2.3 Sales Outside Territory. Subject to applicable laws and regulations, Janssen agrees to take reasonable efforts to prevent Janssen or its subdistributors from, directly or indirectly, offering for sale, selling, or otherwise transferring Product for use outside the Territory. Likewise, subject to

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applicable laws and regulations, VIVUS agrees to take reasonable efforts to prevent VIVUS (except for through Janssen), its Affiliates or Third Parties from, directly or indirectly, offering for sale, selling, or otherwise transferring Product for use within the Territory.

- 2.4 Licenses. Subject to the terms and conditions of this Agreement, VIVUS hereby grants to Janssen an exclusive, royalty-free, license, without the right to grant or authorize sublicenses, under Patents and VIVUS Know-How to package, label, distribute, market and sell Product in the Territory during the term of this Agreement.
- 2.5 VIVUS No Conflict. VIVUS agrees that it will grant no rights in the Territory to Third Parties which would conflict with the rights granted to Janssen herein, except as permitted by Janssen.

DEVELOPMENT AND MARKETING

- 3.1 Joint Board. Promptly after the Effective Date the parties shall establish a Joint Development and Marketing Board ("JDMB") to oversee the regulatory activities relating to the Product in the Territory, review and discuss overall plans for the commercialization and marketing of the Product, coordinate the exchange of information between the parties regarding the marketing and sale of Product in the Territory and to undertake and/or approve such other matters as are provided for the JDMB under this Agreement. The JDMB will consist of up to three (3) representatives from each party. The JDMB shall meet at least quarterly during the first two (2) years after the Effective Date at mutually agreeable locations outside the United States or, if mutually agreeable, by teleconference and thereafter as necessary. Decisions of the JDMB shall be by unanimous approval; provided, however, if the JDMB cannot reach agreement on a matter, either party may refer the dispute to the Chief Executive Officer of VIVUS and the President of Janssen-Ortho, Canada, who shall meet promptly and negotiate in good faith to resolve any such dispute within 30 days of any such referral. If despite such good faith efforts, the parties are unable to resolve such dispute, [*].
- 3.2 Development. The JDMB will discuss the design and implementation of clinical trials for Product in the Territory. For at least the First Product in each country of the Territory and further Products that Janssen intends to distribute hereunder at its discretion Janssen or its Subdistributor shall, at their sole expense, carry out the remaining preclinical and clinical development of the Products for the Territory to achieve MAA Approval and shall keep the JDMB reasonably informed of its activities. [*] Janssen shall not conduct, or authorize, encourage, assist or contract with any Third Party to conduct any clinical testing of a Product without VIVUS' prior approval, not unreasonably withheld, but subject to VIVUS' right under Section 3.1 above to control the design and protocols of any such clinical testing.
- 3.3 Regulatory Approvals/MAAs. For at least the First Product in each country of the Territory and further Products that Janssen intends to distribute hereunder at its discretion, Janssen shall be responsible, at its sole expense, for filing MAAs for each Product in the Territory up to and including MAA Approval and thereafter maintain such MAA Approvals. All such activity shall be done in full consultation with the JDMB. Janssen shall use reasonable efforts to obtain such MAA

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Approvals for the First Product as soon as practicable in each country within the Territory, consistent generally with the efforts it makes for its other important products. In connection with Janssen's filing of MAAs, VIVUS shall provide Janssen with a copy in English or translations already completed by . VIVUS, of all available information and data required to prepare appropriate regulatory submissions affecting approval to market or of product pricing. Without limiting the foregoing, in the event that filing for the necessary MAAs with the appropriate regulatory agency in any country within the Territory requires access to VIVUS' new drug application for the Product filed with the U.S. FDA ("NDA"), VIVUS shall at its option (i) to the extent legally possible in such country, file the MAA on behalf of Janssen, in which case Janssen shall reimburse VIVUS' reasonable out-of-pocket expenses related to such filing, or (ii) provide the NDA to Janssen solely for the purpose of making such MAA filing. VIVUS agrees to reasonably assist Janssen in responding to any questions raised by the regulatory authorities. This support may include, but not be limited to, attending meetings with Janssen and local regulators in North America to address specific aspects of the Product as part of the review process. [*] All MAA filings will be in the name of VIVUS and Janssen except where otherwise required by local law. Janssen shall ensure that of all registration and regulatory approvals are assigned back and sole ownership transferred to VIVUS promptly upon termination of Janssen's distribution rights with respect to the Product in such country to the extent permitted by applicable laws.

3.4 Marketing Plans.

- Janssen shall prepare reasonably detailed General. marketing plans for the Territory, generally including country- by-country plans, such plans to include plans related to the prelaunch, launch, promotion and sale of Product, and which plans shall be shared with the JDMB (the "Marketing Plans"). The Marketing Plans shall be designed to fulfill Janssen's undertakings pursuant to Section 4.1 below. Notwithstanding anything herein to the contrary, subject to Section 3.1 above, the Marketing Plan for Canada except for pricing shall be subject to approval by the JDMB. Subject to the provisions of this Agreement, and subject to compliance with the Marketing Plans, Janssen shall have full control and authority of commercialization of Product in the Territory and implementation of the Marketing Plans, at Janssen's expense. Janssen shall implement the Marketing Plans, and the JDMB will review the progress of Janssen's marketing efforts under the Marketing Plans. Janssen agrees to keep the JDMB informed of the activities of Janssen and its Subdistributors with respect to Products in the Territory. VIVUS agrees to keep the JDMB informed of key marketing strategies or plans that it has developed or experiences that it has gained in marketing the Product outside the Territory to the extent VIVUS has the right to do so.
- 3.4.2 VIVUS Approval. Any claim, message or other material part of promotional materials, Samples, advertising and materials for training sales representatives with respect to Product, relating to uses, properties, efficacy or positioning of Product, which has not previously been approved or used by VIVUS or VIVUS Inc. in its own promotional or training activities, shall be provided by Janssen to VIVUS along with an English translation thereof, as applicable, and subject to review and approval by VIVUS prior to the use by Janssen and its Subdistributors. VIVUS shall use reasonable efforts to complete any such review and respond to Janssen within fourteen (14) days from notification by Janssen to VIVUS of the relevant matter.

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- 3.5 Exchange of Information. Each party shall keep appropriate records relating to the activities contemplated by this Article 3, and shall report to the other party on the status of such activities on a regular basis. The parties shall exchange data and information relating to Product development to the extent reasonably necessary or appropriate, and each party shall have the right to use such information received from the other in connection with exercising its rights and performing its obligations under this Agreement. In fulfilling its obligations to report or exchange information under this Article 3, delivery by a party in writing to a member of the JDMB of the other party will be considered sufficient.
- 3.6 Adverse Experiences. With respect to adverse drug experiences relating to the Product, the parties shall report to the appropriate regulatory authorities in the countries in which the Product is being developed or commercialized, in accordance with the appropriate laws and regulations of the relevant countries and authorities and Janssen shall ensure that its Subdistributors comply with such reporting obligations. Such reporting activities within the Territory shall be coordinated by the JDMB where time and law permit. A party shall simultaneously with reporting any adverse drug experience relating to the Product to the appropriate regulatory authorities of any country or learning that a Third Party has reported an adverse drug experience relating to the Product to an appropriate regulatory authority of any country, report such adverse drug experience to the other party. As soon as is reasonable after the Effective Date, VIVUS will report to Janssen any adverse drug experience relating to the Product of which it is aware that has been reported to the appropriate regulatory authorities of any country.

COMMERCIALIZATION AND PROMOTION

4.1 Janssen Commercialization.

- 4.1.1 Diligence. Janssen shall [*] (a) to launch the First Product in each country in the Territory as soon as possible after obtaining MAA Approval for such Product; and (b) after the First Commercial Sale of a Product in a country, to achieve high volume sales of Product in such country. Without limiting the foregoing, Janssen agrees to spend within the Territory on promotion of the First Product, [*] after the First Commercial Sale of the First Product in the first Major Country.
- 4.1.2 Failure to Sell. If Janssen fails to launch the First Product in any country in the Territory [*] from the date of MAA Approval for such Product in such country, then such country shall cease to be part of the Territory for all purposes of this Agreement, and all rights to package, label, market, sell and distribute Product in such country shall revert to VIVUS. In countries where price approval of the First Product is required, then the requirement for launch [*] after MAA Approval in the case where the failure to launch is due to lack of price approval at a level no greater than the price charged in other countries of the Territory and Janssen is exerting reasonable efforts to obtain such price approval. In addition, if Janssen decides, in its sole discretion, not to launch the First Product or not to continue sales of at least one Product in any particular or all countries on the terms of this Agreement Janssen may [*] cancel the launch or discontinue sales in such country or countries and such country or countries shall cease to be part of the Territory for all purposes of this Agreement, and all rights to package, label, market, sell and distribute Product in such country shall immediately revert to VIVUS. [*]
- 4.1.3 Subsequent Products. With respect to each Product after the First Product (a "Subsequent Product"), Janssen shall, in its sole discretion, within six (6) months of the approval of

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an NDA in the United States or its equivalent in a country of European Union for such Subsequent Product (i) file the appropriate MAAs necessary to market and distribute such Subsequent Product in at least each of the Major Countries and one (1) of Mexico, South Korea or Taiwan and use reasonable efforts to obtain MAA Approvals for such Subsequent Product as soon as practicable in each such country; or (ii) pay to VIVUS all amounts due for such Subsequent Product under the appropriate clause of Section 6.1 that would otherwise be due upon MAA Approval in both of the Major Countries and in Mexico; provided, however, in the event that Janssen elects not to perform either (i) or (ii) above, then such Subsequent Product shall be excluded from the definition of Product for all purposes under this Agreement, including without limitation Sections 2.1 and 2.4 above, and VIVUS (itself or through an Affiliate or Third Party) shall have the right to package, label, distribute, market and sell such Subsequent Product in the Territory.

4.2 Training. VIVUS will provide a one-time training in English for Janssen's English speaking sales and marketing management personnel with respect to the Product at a first location of Janssen's choosing in the far east and a second location of Janssen's choosing in Canada and will provide to Janssen training materials for the Product prepared by VIVUS for use in training VIVUS Inc.'s U.S. sales representatives. Janssen may copy any training materials provided by VIVUS for future training programs conducted by Janssen in connection with the marketing and sales of the Product hereunder. Janssen will at all times ensure that its sales force is fully trained with respect to the Product.

. PRODUCT SUPPLY AND DISTRIBUTION

- 5.1 Product Supply. Subject to the terms and conditions of this Article 5 (including Section 5.10 below) VIVUS shall supply Janssen with Product for the Territory, in Foil Pouch Package Form or such other form as mutually agreed, and Janssen shall exclusively purchase its requirements from VIVUS, during the term of the Agreement, [*]. Janssen shall prepare all such Product in final packaged form including without limitation all product labeling and other package inserts and materials required by the applicable regulatory agencies. [*].
- 5.2 Samples. VIVUS shall supply Janssen with quantities of Product sales samples ("Promotional Samples"), and with quantities of Product reasonably necessary for Janssen to conduct clinical trials ("Clinical Trial Samples") and quality assurance testing to verify that lots of Product supplied by VIVUS meet the applicable Specifications ("QA Samples") (collectively, "Samples"), all in such amounts as are mutually agreed. Such Product shall be supplied in Foil Pouch Package Form or such other form as mutually agreed. Janssen shall prepare all such Product in final packaged form, except QA Samples utilized by Janssen.
- 5.3 [*]. The parties acknowledge and agree that for legal and/or business reasons it may become desirable to conduct certain [*] as set forth in this Section 5.3.
- 5.3.1 Timing. Although the parties may mutually agree to undertake such activities earlier, [*] beginning five (5) years after the First Commercial Sale of a Product [*]. It is understood, however, that [*] with respect to a Product prior to the eighth anniversary of the First Commercial

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Sale of such Product in the Territory, [*] under this Section 5.3 with respect to such Product. To the extent that the [*] does not otherwise undertake or arrange for such additional [*] shall have the right to undertake such additional [*] under the terms of this Section 5.3.

- 5.3.2 [*]. Promptly following mutual agreement [*] in accordance with Section 5.3.1 above, [*] reasonable specifications). In addition, [*]. In connection with the [*] the cost of the travel and lodging [*] cost to purchase the [*]. [*] under this Section 5.3.2, [*].
- 5.3.3 [*]. At such time as the [*], in accordance with this Article 5. As used in this Section 5.3, [*].
- 5.3.4 [*] agrees to use diligent efforts to protect against and prevent the unauthorized use and disclosure of the [*]. Without limiting the foregoing, [*]. Upon the expiration or any termination [*] that such request has been satisfied. In addition, in such event, upon request by [*] for any purpose not expressly authorized under this Section 5.3, without [*] prior written approval.
- 5.3.5 [*] a worldwide, irrevocable, royalty-free, non-exclusive license, with the right to grant and authorize sublicenses, under any and all [*] to make, use, sell, import, export and otherwise distribute products and otherwise exploit such [*], and have the foregoing performed on its behalf by one or more third parties. For purposes of this Section 5.3.5 the term [*] shall promptly notify [*] and, as reasonably requested by [*] with information and documentation necessary for [*].
- 5.3.6 [*]. Upon mutual agreement [*] in accordance with Section 5.3.1 above, [*] in accordance with the terms of this Section 5.3 during the term of this Agreement for so long as [*] will be used solely for this purpose.
- 5.4 Forecasts. During the term of this Agreement, at least [*] prior to the start of [*], Janssen shall provide VIVUS with [*]. Each forecast shall indicate [*]. Each forecast will also [*].

5.5 Orders

- 5.5.1 Orders. Together with each forecast provided under Section 5.4 above (the [*]), Janssen shall place its [*] order with VIVUS for delivery in [*] of that quantity of Product, [*], reflected for [*] in the [*]. For ordering purposes, the forecast for [*]. Also, the forecasts for [*], respectively, as each rolls to [*]. VIVUS shall accept such orders from Janssen, subject to the remaining terms and condition of this Agreement, provided that VIVUS shall not be obligated to accept orders to the extent the quantity ordered exceeds the quantities forecasted for [*], but shall use good faith efforts to fill orders for such excess quantities from available supplies. All orders placed hereunder shall be for [*] or as otherwise mutually agreed.
- 5.5.2 Form of Order. Janssen's orders shall be made pursuant to a written purchase order which is in a form mutually acceptable to the parties, and shall provide for shipment in accordance with reasonable delivery schedules as may be agreed upon from time to time by VIVUS

and Janssen. VIVUS shall use all reasonable efforts to notify Janssen within five (5) days from receipt of an order of its ability to fill any amounts of such order in excess of the quantities that VIVUS is obligated to supply. No terms contained in any purchase order, order acknowledgment or similar standardized form shall be construed to amend or modify the terms of this Agreement and in the event of any conflict, this Agreement shall control unless expressly agreed in writing.

- 5.6 Delivery. Subject to Section 5.10 below, with respect to exact shipping dates, VIVUS shall use its best efforts to ship quantities of Product ordered in accordance with Section 5.5 above on the dates specified in Janssen's purchase orders ("Shipping Date") submitted and accepted in accordance with Section 5.5 above. Product will be delivered F.C.A. (Incoterms 1990) shipping point designated by VIVUS. The shipping packaging shall be in accordance with good commercial practice with respect to protection of the Product during transportation. As of the Shipping Date, [*] Product to be shipped to Janssen hereunder, unless otherwise mutually agreed.
- 5.7 Product Rejection. If the Product, [*] supplied by VIVUS under this Agreement fail to conform at the time of delivery to the applicable specifications, a current copy of which is attached hereto as Exhibit B (as reasonably modified from time to time by VIVUS according to Section 5.11 below, "Specifications") or if as to such Product, [*], VIVUS fails to meet the GMP Standards/Regulatory practices as warranted in Section 12.2.2, Janssen shall promptly notify VIVUS after its discovery of non-conformity and Janssen shall present reasonable evidence to VIVUS of such nonconformity. VIVUS shall replace, at no additional expense to Janssen, such non-conforming Product with new Product which does conform with the Specifications. VIVUS may analyze any unit of Product rejected by Janssen for nonconformity and if it is objectively established that the Product was conforming, then Janssen shall be responsible for payment for any such units of Product. VIVUS shall give Janssen written for payment for any such units of Product. VIVUS shall give Janssen wri instructions as to how Janssen should, at VIVUS' expense, dispose of any non-conforming material, and such instructions shall comply with all appropriate governmental requirements. With respect to any Products, [*] that do not conform to the applicable Specifications, Janssen shall not have the right to return the same if such non-conformity could have been detected upon reasonable inspection when first delivered and Janssen fails to identify and notify VIVUS of the non-conformity within forty-five (45) days after receipt by Janssen of the goods. In such event Janssen shall be responsible to purchase such goods, and the price thereof shall be the same as accidentally destroyed units under Section 6.2.2 below.
- 5.8 Suppliers. Without limiting VIVUS' responsibility under this Agreement, VIVUS shall have the right at any time, to satisfy its supply obligations to Janssen hereunder, either in whole or in part through arrangements with Third Parties engaged to perform services or supply facilities or goods in connection with the manufacture, testing, and/or packaging of Product, [*]. VIVUS shall ensure that all such facilities comply with applicable regulations and will give Janssen written notice sufficiently in advance of any such arrangement to determine whether such arrangement would require changes to an MAA Approval application filed in the Territory. VIVUS shall bear the costs related to changing the MAA Approval application required as a result of any such change in manufacturing arrangements. As a matter of routine supply, VIVUS shall supply Product to Janssen for the Territory from a single manufacturing facility.

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VIVUS Cost of Goods. VIVUS shall keep complete and accurate records of VIVUS Cost of Goods, such records to be in a form required under U.S. Generally Accepted Accounting Principles (GAAP), consistently applied. Janssen shall have the right, to the extent payments were made to VIVUS on the basis of VIVUS Cost of Goods, at Janssen's expense, through a certified public accountant or other representative acceptable to VIVUS, to examine such records during regular business hours during the life of this Agreement and for one (1) year after its termination; provided, however, that such examination shall not take place more often than once a year and shall not cover such records for more than the preceding three (3) years and provided further that such accountant shall report to Janssen only as to the accuracy of the records. such examination reveals that VIVUS has over reported the VIVUS Cost of Goods by more than [*] for the period of the examination then VIVUS shall promptly reimburse Janssen for its out-of-pocket costs related to such examination plus interest at [*] on any amounts over paid to VIVUS hereunder due to such over reporting. In any case if either party discovers a miscalculation of VIVUS Cost of Goods the parties shall correctly calculate such amount and make all necessary and appropriate adjustments to amounts paid and/or payable hereunder.

5.10 Shortage of Supply.

5.10.1 Allocation. In the event that VIVUS is unable to supply both worldwide requirements of Product and quantities ordered by Janssen under Section 5.5 above due to force majeure or otherwise, VIVUS shall allocate the quantities of Product that VIVUS has in inventory, and that VIVUS is able to produce, so that Janssen receives at least its proportional share of available supplies as determined based on reasonable forecasts of Janssen, VIVUS, VIVUS Inc. and VIVUS' other distributors. SUCH ALLOCATION SHALL BE JANSSEN'S SOLE REMEDY FOR VIVUS' FAILURE TO SUPPLY TO JANSSEN QUANTITIES OF PRODUCT VIVUS IS OTHERWISE OBLIGATED TO SUPPLY UNDER THIS ARTICLE 5. During such periods as supply of Product is subject to allocation pursuant to this Section 5.10, VIVUS agrees to use its best efforts to resolve the situation within a reasonable amount of time.

Joint Manufacturing Team. Without limiting the 5.10.2 provisions of Section 5.10.1 above, if at any time VIVUS becomes unable to supply, or becomes aware that it will be unable to supply, quantities of Product ordered by Janssen in accordance with Section 5.5 above VIVUS shall promptly notify Janssen in writing. In such event, at Janssen's request, the parties shall establish a committee (the "Joint Manufacturing Team") consisting of two (2) representatives from each party and the Joint Manufacturing Team shall immediately convene to address such shortage, including locating alternative suppliers and facilities to increase production and identifying other actions necessary to resolve the shortage. VIVUS agrees to disclose to the Joint Manufacturing Team current production capacity for the Product and the total sales orders and forecasts for worldwide requirements for Product for [*] (as defined in Section 5.4 above) for Janssen, VIVUS, VIVUS Inc. and Third Party distributors without disclosing the identity of Third Parties. to Section 6.9.1(b) of that certain Distribution Agreement between VIVUS and Astra AB dated May 29, 1996, VIVUS agrees to implement all measures established by the Joint Manufacturing Team to remedy the shortage; and if the Joint Manufacturing Team is unable to agree upon the appropriate measures, and the Chief Executive Officer of VIVUS and the President of Janssen-Ortho Canada are

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unable to agree on how to resolve the problem after negotiating in good faith, VIVUS agrees to implement any reasonable suggestions made by Janssen's senior executive for resolving the shortage. In any event, both parties agree to respond with the level of speed and diligence commensurate with the severity of the shortage.

5.11 Modification of Specifications. VIVUS may, from time to time, with the approval of Janssen, not unreasonably withheld, reasonably modify the Specifications attached as Exhibit B. Notice of such modifications to the Specifications must be sufficiently in advance to determine whether such modifications would require changes to an MAA application filed in the Territory. Where such modifications requires changes to the MAA application for any Product [*], then VIVUS will be responsible for the costs associated with such modifications.

PAYMENTS

- 6.1 Initial Payments. In consideration of the costs incurred by VIVUS in connection with the research and development of the Product and in exchange for the exclusive rights granted herein, Janssen shall pay VIVUS the following non-refundable fees:
- (a) Five Million Dollars (\$5,000,000) upon the Effective Date;

(b) [*]

- (c) [*]
- (0)
- (d) [*]
- (e) [*]
- (f) For purposes of determining if a Product is a different Product for which payments may be due under this Section 6.1, each Product shall be deemed a different Product if such Product contains an active ingredient different from (i.e., in addition to) that contained in previous Products for which payments for MAA Approval have already been made to VIVUS hereunder. VIVUS is under no obligation to develop or market any follow on products to the First Product.

Notwithstanding clauses (c), (d) and (e) above, in the event that [*] in a country [*] after First Commercial Sale of the First Product in the Territory, [*] for each month beginning on the date [*] such that no payment shall be due upon [*].

6.2 Transfer Price.

6.2.1 Sale Units.

(a) For units of Product supplied by VIVUS under Section 5.1 above, Janssen shall pay to VIVUS a price per unit equal to a percentage of the Net Sales price of such Product with such percentage based on the total Annual Net Sales volume in each region calculated as set forth below (the "Transfer Price"): [*]

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(b) For purposes of calculating the foregoing, [*] equal the following based upon the particular region:

[*]

- (c) Notwithstanding the foregoing:
- (i) Beginning two (2) years after the first Commercial Sale of the first Product in a particular region, [*].
- (ii) [*] 1 the price per unit to be paid to VIVUS for units of Product [*].
- (d) As used herein:
 - (i) [*]
 - (ii) [*]

In any event, notwithstanding the application of the foregoing formula, the VIVUS Percentage [*]

(iii) [*]

- 6.2.2 Samples and Obsolete Inventory. With respect to units of Products supplied by VIVUS to Janssen for use as Samples in accordance with Section 5.2 above, Janssen shall pay to VIVUS for such units an amount equal to [*] except that a reasonable number of Samples supplied to Janssen to be used in clinical trials to obtain MAA approval [*]. For purposes of determining the transfer price to be paid to VIVUS, units of Products [*], and the transfer price to be paid by Janssen to VIVUS for such units shall [*]; provided the total numbers of such units are within normal and customary levels [*].
- 6.2.3 [*] the price paid to VIVUS shall equal VIVUS' cost calculated in accordance with GAAP and in accordance with VIVUS' then prevailing standard procedures for calculating Cost of Goods as reflected in VIVUS' audited financial statements, together with royalties payable to third parties.

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⁽¹⁾ For purposes of example see Exhibit C.

⁽²⁾ For purposes of example see Exhibit D.

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

- 6.3 Discounting. In the event that Janssen or its Subdistributor sells Products to a Third Party who also purchases other products or services from Janssen or its Affiliates, Janssen agrees not to, and to require its Subdistributors not to, discount the purchase price of the Products to a greater degree than Janssen or its Subdistributors, respectively, generally discounts the price of its other products to such customer. For purposes of this provision "discounting" includes establishing the list price at lower than Janssen's normal pricing level. Without limiting the foregoing, Janssen agrees not to, and to require its Subdistributors not to, treat Products in such a manner that would disadvantage the Product in comparison with other products offered for sale by Janssen or its Subdistributors.
- 6.4 Sales Records. Janssen shall keep and require its Subdistributors to keep complete and accurate records of all Net Sales of Product on a country-by-country basis. VIVUS shall have the right, at VIVUS' expense, through a certified public accountant or other representative, to examine such records during regular business hours provided, however, that such examination shall not take place more often than once a year and shall not cover such records for more than the preceding three (3) years. If such examination reveals an underpayment to VIVUS in excess of [*] for any period then Janssen shall promptly reimburse VIVUS for the costs of such examination and pay the underpayment amount plus interest at [*].

6.5 Provisional Payments.

- 6.5.1 Product Units. Payments due to VIVUS under Sections 6.2.1 and 6.2.2 and 6.2.3 shall be provisionally made, on a per unit of Product, [*] basis, as the case may be, within [*] of delivery to Janssen of each unit of Product, [*]. The provisional payment shall be based on [*] estimates by the parties of those variables necessary to calculate a provisional transfer price in accordance with the provisions of the relevant sections. Such estimates will be made in good faith and shall be consistent with internal estimates on which the party relies to plan capacity, gauge performance or plan inventory. [*] prior to the start of any relevant Janssen accounting year, Janssen and VIVUS will make the estimates and supply to each other the following data to establish a provisional transfer price for that entire year.

[*]

where:

[*]

or, the provisional payment will be based on a [*].

- (b) For Product supplied under 6.2.2, the provisional payment will be based on a [*].
 - (c) [*], the provisional payment will be based on a [*].

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For avoidance of doubt, to the extent the transfer price of a unit of Product is to be determined based on the [*] for purposes of calculating the provisional transfer price above.

[*]

6.6 Reconciliation.

- 6.6.1 Product Units. The provisional transfer price under which Product, and other materials supplied under Section 5.3 above, was received will be reconciled to the actual transfer price as the required data is available within sixty (60) days following the end of each Janssen accounting quarter, provided that VIVUS provides Janssen with the actual cost of good sold within thirty (30) days of the end of such quarter. In the event that the provisional payments by Janssen under Section 6.5 above were greater than the amounts actually due under Section 6.2, Janssen shall be entitled to credit such excess against future purchases of Product hereunder.
- 6.6.2 Timing. No reconciliation shall be made under this Section 6.6 with respect to units for which provisional payments were made until the end of the quarter in which such units are sold or in the case of Samples in the quarter they are distributed.
- 6.7 [*] Janssen agrees to pay to VIVUS a running royalty of [*], sold by Janssen or its Subdistributors. Notwithstanding the foregoing, in the event that a non-royalty payment method would, because of changed circumstances, be more advantageous for either party with respect to Product [*], the parties agree to discuss in good faith the implementation such other method; it being understood, however, that neither party would incur any disadvantage as a result of such other method.
- 6.8 Payment. Within [*] after the end of each calendar quarter, Janssen shall provide VIVUS with a true accounting of all payment obligations, if any, owed in accordance with this Article 6, together with a statement setting out all details necessary to calculate the amounts actually due hereunder with respect to Net Sales made in that calendar quarter, including units of Product sold on a country-by-country basis, gross sales of Product in that calendar quarter including units of Product sold on a country-by-country basis, Net Sales in that calendar quarter on a country-by-country basis, all relevant deductions, and all relevant exchange rate conversions. Any payments due shall accompany such statement.
- 6.9 Taxes. The parties hereto acknowledge and understand that as of the Effective Date, no withholding taxes or similar governmental charges are required to be withheld on amounts to be paid to VIVUS hereunder. In the event that after the Effective Date withholding taxes or similar charges are required by law to be withheld on behalf of VIVUS from amounts due to VIVUS hereunder, Janssen shall deduct said taxes or charges from amounts due to VIVUS hereunder and promptly pay the same to the applicable taxing authority; provided, however that to the extent such withholding taxes or other charges become due as a result of Janssen's assignment or other transfer of this Agreement to an Affiliate or otherwise pursuant to Section 13.8 below or other change in the structure of or the way Janssen does business, Janssen shall gross up all amounts due to VIVUS

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hereunder so that the amounts paid to VIVUS are not reduced by said taxes or other charges. Notwithstanding the foregoing, all amounts to be paid to VIVUS pursuant to Section 6.7 shall not be reduced by any withholding taxes or similar governmental charges (not including U.S. or Bermuda income tax on VIVUS' income). In regard to taxes or charges paid on behalf of VIVUS, Janssen shall furnish VIVUS with proper evidence of the taxes paid.

6.10 U.S. Dollars. All sums due under this Agreement shall be payable in U.S. dollars. Monetary conversion from the currency of a foreign country in which Product is sold into United States currency shall be calculated at the actual average of the buying and selling rates of exchange for the quarter in which such sales were made as such rates are reported, as of the last business day of such quarter, by the Wall Street Journal (U.S., Eastern Edition).

CONFIDENTIALITY

- Nondisclosure. "Confidential Information" means any information, data, or know-how which the disclosing party treats confidentially, is in writing and is identified as confidential, or if disclosed orally is indicated to be confidential at the time of disclosure and is confirmed in writing as confidential by the disclosing party within forty-five (45) days after initial disclosure. VIVUS and Janssen shall not (and shall ensure that its Subdistributors do not) use or reveal or disclose to Third Parties any Confidential Information received from the other party without first obtaining the written consent of the disclosing party, except as may be otherwise provided herein, or as may be required for purposes of marketing Product or for securing essential or desirable authorizations, privileges or rights from governmental agencies. This confidentiality obligation shall not apply to such information which (i) is or becomes a matter of public knowledge through no fault of the receiving party or its Affiliates or Subdistributors, or (ii) is already in the possession of the receiving party, or (iii) is disclosed to the receiving party by a Third Party having the legal right to do so, or (iv) is subsequently and independently developed by employees of the receiving party or Affiliates thereof who had no knowledge of the Confidential Information disclosed, or (v) is required by law to be disclosed. The parties shall take reasonable measures to assure that no unauthorized use or disclosure is made by others to whom access to Confidential Information of the other party is granted.
- 7.2 Disclosure to Subdistributors. Janssen may, to the extent necessary, disclose information received from VIVUS to a Subdistributor of Janssen, provided that each such Subdistributor has agreed in writing to maintain the confidentiality of such information and not use such information except as necessary to fulfill the purposes hereunder. Janssen shall be fully responsible for any breach by its Subdistributors of this Article 7. Janssen shall immediately notify VIVUS of any unauthorized use or disclosure of VIVUS' information that it becomes aware of. Without limiting the foregoing, Janssen shall at its expense, upon request of VIVUS take all other steps necessary to cease all unauthorized use or disclosure of VIVUS Confidential Information obtained from Janssen or Subdistributor, or in the event VIVUS takes such steps, Janssen shall reimburse all reasonable costs related thereto.
- 7.3 Terms of Agreement. No public announcement or other public disclosure concerning the existence of or terms of this Agreement shall be made, either directly or indirectly, by any party to

this Agreement, except as may be legally required or as may be required for recording purposes, without first obtaining the written approval of the other party and Agreement upon the nature and text of such announcement or disclosure. The party desiring to make any such public announcement or other disclosure shall provide the other party with a copy of the proposed announcement or disclosure for review and comment in reasonably sufficient time prior to public release. Each party agrees that it shall cooperate fully with the other with respect to all disclosures regarding this Agreement to the Securities Exchange Commission and any other governmental or regulatory agencies, including requests for confidential treatment of proprietary information of either party included in any such disclosure. In addition, each party agrees not to disclose this Agreement or its terms to Third Parties, except to professional advisors and potential financing sources and under conditions that reasonably protect the confidentiality thereof. The parties will mutually agree upon the contents of a press release (and accompanying Q&A) which may be issued upon the Effective Date, and thereafter the parties may publicly disclose information contained in such press release or Q&A without further approvals.

- 7.4 Clinical Data. All clinical and preclinical data disclosed by VIVUS shall be deemed Confidential Information of VIVUS.
- 7.5 Product Data. Janssen shall not submit for written or oral publication any scientific or medical manuscript, abstract or the like which includes data or other information relating to the Product without first obtaining the prior written consent of VIVUS. The contribution of each party shall be noted in all publications or presentations by acknowledgment or coauthorship, whichever is appropriate.

8. PATENT PROSECUTION AND LITIGATION

8.1 Ownership of Inventions. Janssen shall have and retain sole and exclusive title to all inventions, discoveries and know how ("Inventions") which are made during the term of this Agreement by Janssen, its employees, agents, or other Third Parties acting under authority from Janssen working on matters relating to and made using or comprising a Product and Janssen hereby grants to VIVUS a non- exclusive, worldwide license, with the right to sublicense, to such Inventions to make, have made, use and sell products for any indication.

8.2 Maintenance of Patents.

8.2.1 Filings. As between Janssen and VIVUS, VIVUS shall, at its expense, have responsibility for filing, prosecution and maintenance of all Patents in the Territory. Janssen shall have the right to review pending Patent applications and make recommendations to VIVUS concerning them. VIVUS will consider in good faith all reasonable suggestions of Janssen with respect to such pending applications. VIVUS agrees to keep Janssen informed of the course of Patent prosecution or other proceedings with respect to the Patents within the Territory. Janssen shall provide such Patent consultation to VIVUS at no cost to VIVUS. All information disclosed to Janssen under this Section 8.2 shall be deemed Confidential Information of VIVUS. In the event that

VIVUS does not file or discontinues the prosecution or maintenance of any Patents in the Territory, then Janssen may, at its expense, choose to continue the same with the cooperation of VIVUS.

- 8.2.2 Extensions. Janssen shall have the right but not the obligation to seek extensions of the terms of Patents in the Territory. At Janssen's request, VIVUS shall either authorize Janssen to act as VIVUS' agent for the purpose of making any application for any extensions of the term of Patents and provide reasonable assistance therefor to Janssen or shall diligently seek to obtain such extensions, in either event, at Janssen's expense.
- Infringement by Product. In the event of the institution of any suit by a Third Party against Janssen for patent infringement involving the manufacture, use, sale, distribution or marketing of Product anywhere in the Territory during the term of this Agreement, Janssen shall promptly notify VIVUS in writing. Janssen shall have the right but not the obligation to defend such suit against it. Except in the case of a breach under Section 12.5, Janssen will have the right to offset [*] of the out-of-pocket costs of defending such suit against any sums due VIVUS hereunder; provided that VIVUS shall have the right to reasonably approve the plan of defense under which such costs are incurred. VIVUS and Janssen shall assist one another and cooperate in any such litigation at the other's reasonable request without expense to the requesting party, and in any event VIVUS may participate in any such suit with counsel of its choice at its own expense. Without limiting the foregoing, Janssen may offset from amounts due to VIVUS hereunder [*] of amounts finally awarded against and paid by Janssen to a Third Party to the extent the same arise out of the Product's infringement of Third Party patent rights within the Territory during the term of this Agreement.
- 8.4 Third Party Infringement. In the event that VIVUS or Janssen becomes aware of actual or threatened infringement of a Patent anywhere in the Territory by the manufacture or sale or use of a Product for the transurethral delivery of a formulation containing alprostadil to treat or prevent erectile dysfunction in humans (the "Field"), that party shall promptly notify the other party in writing. VIVUS shall have the first right but not the obligation to bring, at its own expense, an infringement action against any Third Party. If VIVUS does not commence a particular infringement suit within the Field within [*] of receipt of a request by Janssen to do so, then Janssen, after notifying VIVUS in writing shall be entitled to bring such infringement action at its own expense and to include VIVUS as a nominal party plaintiff. VIVUS shall keep Janssen reasonably informed of its activities during the [*] period. The party conducting such action shall have full control over its conduct, including settlement thereof subject to Section 8.6 below. In any event, VIVUS and Janssen shall assist one another and cooperate in any such litigation at the other's reasonable request without expense to the requesting party.
- 8.5 Recovery. VIVUS and Janssen shall recover their respective actual out-of-pocket expenses, or equitable proportions thereof, associated with any litigation against infringers undertaken pursuant to Section 8.4 above or settlement thereof from any resulting recovery made by any party. Any excess amount of such a recovery shall be shared between Janssen and VIVUS with Janssen receiving [*] and VIVUS receiving [*] to the extent such recovery relates to sales in the Territory during the term of this Agreement.

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8.6 Status of Activities. The parties shall keep one another informed of the status of their respective activities regarding any litigation or settlement thereof concerning Product within the Territory, provided however that no settlement or consent judgment or other voluntary final disposition of any suit defended or action brought by a party pursuant to this Article 8 may be entered into without the consent of the other party if such settlement would require the other party to be subject to an injunction or to make a monetary payment or would otherwise adversely affect the other party's rights under this Agreement.

TRADEMARKS

- 9.1 Display. All packaging materials, labels and promotional materials for the Product shall display the VIVUS Trademark (or the VIVUS Alternative Trademark at Janssen's discretion) as appropriate. The Janssen trade dress, style of packaging and the like with respect to each Product may be determined by Janssen so as to be consistent with Janssen's standard trade dress and style provided that the packaging and related materials shall display the "VIVUS" tradename in at least ten (10) point logo type.
- 9.2 License. VIVUS hereby grants to Janssen an exclusive, royalty-free license, to use the VIVUS Trademark, or the VIVUS Alternative Trademark in each country of the Territory for the term of this Agreement in connection with the marketing and promotion of Product as contemplated in this Agreement. The ownership and all good will from the use of the VIVUS Trademark and the VIVUS Alternative Trademark shall vest in and inure to the benefit of VIVUS
- 9.3 Registration. VIVUS agrees to file, register and maintain a registration for the VIVUS Trademark in the countries of the Territory listed on Exhibit E, as VIVUS is reasonably able under the circumstances, for the term of this Agreement, at VIVUS' expense, for use with the Product. In the event that the VIVUS Trademark or VIVUS Alternative Trademark is unavailable for use with the Product in one or more countries listed on Exhibit E, VIVUS agrees to choose in consultation with Janssen a VIVUS Alternative Trademark. Where VIVUS agrees to the use of a VIVUS Alternative Trademark in a country, VIVUS agrees to file, register and maintain a registration for the VIVUS Alternative Trademark in such country, for the term of this Agreement, at VIVUS' expense, for use with the Product in such country.
- 9.4 Recordation. In those countries where a trademark license must be recorded, VIVUS will provide and record a separate trademark license for the VIVUS Trademark and/or VIVUS Alternative Trademark. Janssen shall cooperate in the preparation and execution of such documents.
- 9.5 Approval of Promotional Materials/Quality Control. Janssen shall submit representative promotional materials, packaging, [*] using the VIVUS Trademark and/or VIVUS Alternative Trademark to VIVUS for VIVUS' reasonable approval prior to the first use of such items and prior to any subsequent change or addition to such items, provided that if VIVUS has not responded within four (4) weeks after such submissions, VIVUS' approval will be deemed to have been received. For purposes of quality control, Janssen agrees that for the [*] shall meet sufficient

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standards of quality. In the event that, after review, VIVUS determines that [*] to meet acceptable standards of quality within a reasonable time.

- 9.6 Termination of Rights. Janssen's right to use the VIVUS Trademark and the VIVUS Alternative Trademark shall terminate in each country of the Territory in which Janssen's rights to distribute the Product expire or are terminated in accordance with this Agreement. Janssen shall ensure the cancellation of any Trademark licenses recorded or entered into in such countries in favor of or by or under authority of, Janssen or its Subdistributors to the extent legally possible.
- Trademark Indemnity. VIVUS agrees to defend and/or settle any claim brought against Janssen or its Subdistributor by a Third Party arising out of or resulting from Janssen or its Subdistributor use of the VIVUS Trademark or the VIVUS Alternative Trademark or the tradename VIVUS in the Territory in accordance with the terms and conditions of this Agreement during the term of this Agreement. VIVUS shall pay all resulting damages or settlement amounts finally awarded against Janssen or its Subdistributor (including reasonable attorneys' fees and court costs) which are attributable to such claim during the term of this Agreement. Notwithstanding the foregoing, if the VIVUS Trademark or VIVUS Alternative Trademark or the tradename VIVUS becomes, or in VIVUS' reasonable judgment may become, the subject of any claim as a result of Janssen or its Subdistributors use thereof in any country within the Territory, VIVUS may, upon notice to Janssen, request that Janssen and/or its Subdistributor cease using the VIVUS Trademark or VIVUS Alternative Trademark or the tradename VIVUS, as applicable, in such country. Ninety (90) days after such a request by VIVUS, VIVUS' obligation to defend and settle claims under this Section 9.7 will terminate to the extent any claims, damages or expenses arise out of or result from use after such ninety (90)-day period of said VIVUS Trademark or VIVUS Alternative Trademark or the tradename . VIVUS in such country. The termination of VIVUS' obligation to defend and settle claims is contingent upon VIVUS making available to Janssen, where VIVUS is obligated to supply, adequate supplies of alternately labeled Product in a timely manner sufficient to satisfy Janssen's demand therefor after the end of such ninety (90) day period. After VIVUS' request to cease using a trademark, upon Janssen's request, VIVUS agrees to register a new trademark for use in the said country in accordance with Section 9.3 above.
- 9.8 Trademark Enforcement. In the event that either party becomes aware that a Third Party is misappropriating or otherwise misusing the VIVUS Trademark or VIVUS Alternative Trademark, as the case may be, within the Territory such party shall promptly notify the other party. In which case, the parties agree to discuss such misappropriation or misuse and cooperate to develop a reasonable enforcement plan to deal with the same. VIVUS shall bear [*] and Janssen shall bear [*] of the costs and expenses incurred to bring an action to enforce the VIVUS Trademark or VIVUS Alternative Trademark, as appropriate, in accordance with the mutually agreed upon enforcement plan. Likewise, any recovery from such an action shall be shared between the parties, with VIVUS receiving [*] and Janssen receiving [*] to the extent such recovery relates to misappropriation or misuse in the Territory during the term of this Agreement.

10. TERM AND TERMINATION

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- 10.1 Expiration. Unless otherwise terminated, this Agreement shall expire on the date twelve (12) years after the date of First Commercial Sale of a Product in the Territory. This Agreement may be extended for successive two (2) year terms by mutual written consent of VIVUS and Janssen at least six (6) months prior to expiration of the term hereof; provided however that VIVUS nor Janssen shall not be obligated to approve any such extension and shall have no liability whatsoever by reason of any failure to agree on any such extension.
- 10.2 Events of Termination. If any of the following events (an "Event of Termination") occurs, the party not responsible for such event may terminate this agreement by notice to the other party:
- 10.2.1 Payment Obligation. If a party fails to pay any amount properly due under this Agreement within thirty (30) days following receipt of written notice of such default by the other party.
- 10.2.2 Material Non-Performance. If a party defaults in any other material respect in the performance or observance of any other material term, covenant or provision of this Agreement, or if any representation by a party contained in this Agreement proves to have been incorrect in any material respect when made, resulting in material adverse consequences for the other party (any such material default or material incorrect representation a "Material Non-Performance"), and such Material Non-Performance is not cured within sixty (60) days notice from the non-defaulting party.
- 10.2.3 Bankruptcy Proceedings. Because each party acknowledges that the services to be rendered by the other are personal in nature, inasmuch as the respective capabilities of the parties hereto are uniquely valuable and that the determination to enter into this Agreement was based upon the unique ability of the other party to fulfil its respective obligations hereunder, if (i) such party shall make an assignment of substantially all of its assets for the benefit of creditors, file a petition in bankruptcy, petitions or applies to any tribunal for the appointment of a custodian, receiver or any trustee for such party or substantially all of such party's assets, or shall commence any proceeding under any dissolution or liquidation law or statute of any jurisdiction (provided that no entity succeeds to the business of such party following such dissolution or liquidation) whether now or hereafter in effect which is not dismissed within sixty (60) days; or (ii) there shall have been filed any such petition or application against such party, or any such proceeding shall have been commenced against such party, in which an order for relief is entered or which remains undismissed for a period of ninety (90) days or more; or (iii) such party by an act or knowing failure to act shall indicate such party's consent to, approval of or acquiescence in, any such petition, application or proceeding or order for relief or the appointment of a custodian, receiver or any trustee for such party, or any substantial part of any of such party's properties, or shall suffer any such custodianship, receivership or trusteeship to continue undischarged for a period of ninety (90) days or more.
- 10.2.4 Termination by VIVUS. VIVUS may terminate this Agreement on a country-by-country basis on thirty (30) days notice if MAA Approval has not been received in such county within four (4) years from the Effective Date; provided such notice is given prior to obtaining such MAA Approvals. In the event that this Agreement is terminated with respect to any country such

country shall cease to be within the Territory for all purposes of this Agreement and the threshold Net Sales levels [*].

10.2.5 $\,$ Termination by Janssen. Janssen may terminate this Agreement on $[^{\star}]$ notice to VIVUS.

11. RIGHTS AND DUTIES UPON TERMINATION

- $\,$ 11.1 Payment. Upon expiration or termination, of this Agreement, Janssen and VIVUS shall each pay all sums accrued or credits owed hereunder which are then due.
- 11.2 Sale of Remaining Inventory. Upon early termination of this Agreement under Section 10.2 above, Janssen shall notify VIVUS of the amount of Product Janssen and its Subdistributors then have on hand. Janssen, its Affiliates and its Subdistributors shall thereupon be permitted to sell that amount of Product, within the ninety (90) day period following such termination, subject to the reconciliation under Section 6.6 above and shall destroy any remaining inventory. Units that are so destroyed shall be treated as accidentally destroyed units for purposes of Section 6.2.2 above.
- 11.3 Survival. Upon expiration or termination of this Agreement, all rights and obligations of the parties under this Agreement shall terminate except those described in the following:

Article 1, Definitions
Last Sentence of Section 3.3, Regulatory Approvals/MAAS
Section 3.6, Adverse Experiences
Section 5.3.4, [*]
Section 5.3.5, [*]
Section 5.9, VIVUS Cost of Goods
Section 6.4, Sales Records
Section 6.9, Taxes
Article 7, Confidentiality for a period of 10 years
Section 8.1, Ownership of Inventions
Section 8.3, Infringement by Product
Section 8.5, Recovery
Section 9.6, Termination of Rights
Section 9.7, Trademark Indemnity
Article 10, Term and Termination
Article 11, Rights and Duties Upon Termination
Section 12.3, Indemnification by Janssen
Section 12.4, Indemnification by VIVUS

Article 13, General Provisions

It is understood that termination or expiration of this Agreement shall not relieve a party from any liability which, at the time of such termination or

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expiration, has already accrued to the other party or

which is attributable to a period prior to such termination. Except as otherwise expressly provided herein, termination of the Agreement in accordance with the provisions hereof shall not limit remedies which may be otherwise available in law or equity with respect to a breach hereof that occurred prior to such termination.

12. WARRANTIES, REPRESENTATIONS, AND INDEMNIFICATIONS

- 12.1 General Representations. Each party hereby represents and warrants for itself as follows:
- 12.1.1 Duly 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.
- 12.1.2 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.
- $12.2\,$ Representations and Warranties of VIVUS. VIVUS represents and warrants to Janssen that:
- $12.2.1\,$ VIVUS Rights. VIVUS has the right to grant the rights granted in this Agreement and no provision in any third party agreement to which VIVUS is a party will prevent VIVUS from performing its obligations under this Agreement.
- Standards. All manufacturing and quality control operations utilized by VIVUS in the manufacture of Product supplied under Sections 5.1 and 5.2 above shall be carried out according to the procedures and requirements set forth in the then-current version of the VIVUS Plant Master File with respect to such Product, and (as to each Product) in accordance with all applicable U.S. rules governing medical products and or devices in the GMP for medical products and/or 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, provided that the applicable rules and regulations imposed by the various countries of the Territory are no more burdensome than those imposed by the U.S. [*] shall be carried out according to the procedures and requirements set forth in the then-current version of the VIVUS Plant Master File, and regulations issued by the health regulatory authorities in the countries of the Territory in which such [*] material is to be used as in effect at the time, provided that the applicable rules and regulations imposed by the various countries of the Territory are no more burdensome than those imposed by the U.S.

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- 12.3 Indemnification by Janssen. Janssen shall defend, indemnify and hold harmless VIVUS, its officers, directors, shareholders, employees, successors and assigns from any loss, damage, or liability, including reasonable attorney's fees, resulting from any claim, complaint, suit, proceeding or cause of action against any of them alleging physical injury or death or otherwise arising out of the administration, utilization and/or ingestion of Product manufactured, sold or otherwise provided to the injured party by or under authority of Janssen (or its permitted subdistributor or contractor); or otherwise with respect to Product supplied to, or sold or distributed by, Janssen (or its permitted subdistributor or contractor), provided:
- (a) Janssen shall not be obligated under this Section 12.3 if it is shown by evidence acceptable in a court of law having jurisdiction over the subject matter and meeting the appropriate degree of proof for such action, that the injury was the result of (i) the gross negligence or willful misconduct of any employee or agent of VIVUS or (ii) the supply by VIVUS of Product that fails to meet applicable Specifications;
- (b) Janssen shall have no obligation under this Section 12.3 unless VIVUS (i) gives Janssen prompt written notice of any claim or lawsuit or other action for which it seeks to be indemnified under this Agreement, (ii) Janssen is granted full authority and control over the defense, including settlement, against such claim or lawsuit or other action, and (iii) VIVUS cooperates fully with Janssen and its agents in defense of the claims or lawsuit or other action; and
- (c) VIVUS shall have the right to participate in the defense of any such claim, complaint, suit, proceeding or cause of action referred to in this Section 12.3 utilizing attorneys of its choice, at its own expense, provided, however, that Janssen shall have full authority and control to handle any such claim, complaint, suit, proceeding or cause of action, including any settlement or other disposition thereof, to the extent VIVUS seeks indemnification under this Section 12.3.
- 12.4 Indemnification by VIVUS. VIVUS shall defend, indemnify and hold harmless Janssen, its officers, directors, shareholders, employees, successors and assigns from any loss, damage, or liability, including reasonable attorney's fees, resulting from any claim, complaint, suit, proceeding or cause of action by a Third Party against any of them alleging physical injury or death or otherwise arising out of (a) the administration, utilization and/or ingestion of Product, sold or otherwise provided to the injured party by VIVUS (or its permitted subdistributor or contractor other than by or under authority of Janssen or (b) the supply by VIVUS of Product that fails to meet applicable Specifications, provided:
- (a) VIVUS shall not be obligated under this Section 12.4 if it is shown by evidence acceptable in a court of law having jurisdiction over the subject matter and meeting the appropriate degree of proof for such action, that the injury was the result of the gross negligence or willful misconduct of any employee or agent of Janssen;
- (b) VIVUS shall have no obligation under this Section 12.4 unless Janssen (i) gives VIVUS prompt written notice of any claim or lawsuit or other action for which it seeks to be indemnified under this Agreement, (ii) VIVUS is granted full authority and control over the defense,

including settlement, against such claim or lawsuit or other action, and (iii) Janssen cooperates fully with VIVUS and its agents in defense of the claims or lawsuit or other action; and

- (c) Janssen shall have the right to participate in the defense of any such claim, complaint, suit, proceeding or cause of action referred to in this Section 12.4 utilizing attorneys of its choice, at its own expense, provided, however, that VIVUS shall have full authority and control to handle any such claim, complaint, suit, proceeding or cause of action, including any settlement or other disposition thereof, to the extent Janssen seeks indemnification under this Section 12.4.
- 12.5 Patent Warranties. To the best of its knowledge as of the Effective Date, VIVUS represents and warrants that (i) Patents and VIVUS Know-How are owned or controlled by VIVUS or VIVUS Inc., and are not currently being infringed by a Third Party in the Territory, and (ii) that the practice of such rights do not infringe any property right of any Third Party.

13. GENERAL PROVISIONS

- 13.1 Force Majeure. If either party fails to perform any part of this Agreement due to any cause beyond the reasonable control of such party, the party so affected shall, upon giving written notice to the other party, be excused from such performance, provided that such party shall use its reasonable efforts to avoid or remove such causes of non-performance and shall continue performance with the utmost dispatch whenever such causes are removed. When such circumstances arise, the parties shall discuss what, if any, modification of the terms of this Agreement may be required in order to arrive at an equitable solution.
- 13.2 Governing Law and Arbitration. This Agreement shall be governed by the laws of the State of California without reference to conflict of law principles. In the event of any dispute under this Agreement, both parties shall endeavor to settle such dispute amicably between themselves. the event that the parties fail to agree, such dispute shall be settled by arbitration as follows: Either party may by notice in writing to the other require any issue in dispute to be submitted to arbitration in accordance with this Section 13.2. From the date of the notice in writing and until such time as any matter has been finally settled by arbitration hereunder, the running of the time periods in which a party must cure a breach of this agreement shall be suspended as to the subject matter of the dispute. Such notice shall contain a statement of the arbitrable issue forming the basis of the dispute and the position of the moving party as to the proper resolution of that issue. Within thirty (30) days after receipt of such notice, the responding party shall submit to the moving party a statement of its conception of the arbitrable issue in question and of its position as to the proper resolution of that issue. Within thirty (30)-days of the responding party's response, each party shall appoint an independent arbitrator and give the other party written notice thereof. In the event a party shall fail to appoint an arbitrator and provide written notice thereof to the other party within such thirty (30) day period, an arbitrator shall be appointed for such party by the American Arbitration Association, as promptly as practicable after request by the other party. Thereafter, the two (2) appointed arbitrators shall select a third arbitrator within thirty (30) days after receipt of a list of proposed arbitrators having expertise in the pharmaceutical industry proposed by the American Arbitration Association. If the two (2) arbitrators designated by the parties are unable to agreed on the third arbitrator within

thirty (30) days, then either party with notice to the other party, may call for such appointment by the American Arbitration Association of the third arbitrator. Regardless of the manner of his or her selection, the third arbitrator shall be one who is qualified by knowledge and experience in the pharmaceutical field. Each arbitrator shall agree prior to his or her appointment to hear the dispute promptly and render a decision as soon as practicable thereafter. The arbitration shall be conducted in English in Chicago, Illinois, in accordance with the commercial arbitration rules or successor rules then obtaining of the American Arbitration Association to the extent not inconsistent with this Section 13.2. The Agreement of two (2) of the three (3) arbitrators shall be sufficient to render a decision. decision of the panel shall be final and binding upon the parties and enforcement thereof may be obtained in any court of competent jurisdiction. The arbitrators may award costs and expenses, including reasonable attorneys' fees, to the successful party, as the arbitrators deem appropriate. WITH RESPECT TO DISPUTES REGARDING AMOUNTS DUE HEREUNDER THE PARTIES AND ARBITRATORS SHALL USE ALL REASONABLE EFFORTS TO CONCLUDE THE ARBITRATION WITHIN ONE HUNDRED TWENTY (120) DAYS FROM THE INITIAL NOTICE.

- Agreement, VIVUS shall, upon written request of Janssen, permit Janssen's authorized representative to inspect (and if reasonably necessary to copy) the following: (i) all manufacturing and quality control records for all manufacture of the Product supplied by VIVUS hereunder and (ii) quality control records of all starting materials used in the manufacture of a Product supplied by VIVUS hereunder. In addition, during the term of this Agreement, upon the written request of Janssen, VIVUS shall permit Janssen's authorized representative to inspect, at mutually agreeable times and during normal business hours, the facilities where Product is manufactured for delivery to Janssen hereunder for the purpose of verifying compliance with GMP and other applicable regulatory standards. VIVUS shall remedy any deficiencies discovered as a result of such inspections as soon as reasonably possible upon receipt notice of the same from Janssen.
- 13.4 Waiver of Breach. The failure of either party at any time to require performance of any provision hereof shall not affect its rights at a later time to enforce the same. No waiver by either party of any condition or term in any one or more instances shall be construed as a further or continuing waiver of such condition or term or of another condition or term.
- 13.5 Separability. If any portion of this Agreement is held to be illegal, void or ineffective, the remaining portions shall remain in full force and effect and the parties will renegotiate the terms and conditions of this Agreement to resolve any inequities.
- 13.6 Entire Agreement. This Agreement constitutes the entire Agreement between the parties relating to the subject matter hereof and supersedes all previous writings and understandings. No terms or provisions of this Agreement shall be varied or modified by any prior or subsequent statement, conduct or act of either of the parties, except that the parties may amend this Agreement by written instruments specifically referring to and executed in the same manner as this Agreement.

- 13.7 Approvals. Unless expressly required not to be withheld unreasonably, it is understood that when approval of either party is required, such approval may be withheld in such party's sole discretion, without regard to the reason or basis for withholding such consent.
- $13.8\,$ Notices. Any notice required or permitted under this Agreement shall be sent by air mail, postage pre-paid, to the following addresses of the parties:

VIVUS VIVUS International Limited Clarendon House Church Street Hamilton, Bermuda Attention: President

copies to:

Wilson, Sonsini, Goodrich & Rosati 650 Page Mill Road Palo Alto, California 94304 Attention: Kenneth A. Clark Telephone: (415) 493-9300 Telecopy: (415) 493-6811

Any notice required or permitted to be given concerning this Agreement shall be effective upon receipt by the party to whom it is addressed or within seven (7) days of mailing by certified U.S. Mail or by reputable overnight courier service, receipt confirmed, whichever is earlier.

- 13.9 Assignment. Neither this Agreement nor any interest hereunder shall be assignable by either party without the written consent of the other, except that either party may assign this Agreement and its rights and obligations hereunder to an Affiliate or to any corporation with which it may merge or consolidate, or to which it may transfer all or substantially all of its assets to which this Agreement relates, without obtaining the consent of the other party; provided that the entity to whom this Agreement is assigned agrees in writing to be bound by its terms. This Agreement shall be binding upon and inure to the benefit of the permitted successors in interest of the respective parties.
- $13.10\,$ No Partnership or Joint Venture. This Agreement shall not be deemed to establish a joint venture or partnership between Janssen and VIVUS.
- $13.11\,$ Third Party Rights. The obligations of VIVUS and the rights of Janssen under this Agreement shall be subject to and limited by any agreements pursuant to which VIVUS acquired rights to Patents from a Third Party.
- 13.12 Limited Liability. Except in the case of a Third Party claim against a party hereunder, the parties shall not be liable to each other under any contract, negligence, strict liability or other legal

or equitable theory for any incidental or consequential damages for failure to perform under this $\ensuremath{\mathsf{Agreement}}$.

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

JANSSEN PHARMACEUTICA INTERNATIONAL, A DIVISION OF CILAG AG INTERNATIONAL

BY: /s/ HEINZ SCHMID BY: /s/ ERIK ROMBOUT

Heinz Schmid Erik Rombout

TITLE: General Manager TITLE: Operations Director

VIVUS INTERNATIONAL LIMITED

BY: /s/ TERRY NIDA

Terry Nida

TITLE: Vice President

EXHIBIT A

JANSSEN AFFILIATES AND COUNTRIES OF RESPONSIBILITY

Janssen-Ortho Inc. Canada

19 Green Belt Drive

North York, Ontario, Canada M3C IL9

China Xian-Janssen Pharmaceutical Co. Ltd.

5th Floor, Ocean Building No. 44, Liang Jiu Road

Chao Yang Dist.

100016 Beijing, China

Hong Kong

Janssen Pharmaceutical Division c/o Johnson & Johnson (HK) Ltd. 12th Floor, Tower 3 China Hong Kong City China Ferry Terminal

33 Canton Road, Tsim Sha Tsui

Kowloon, Hongkong (Responsible for Macau)

Indonesia Janssen Pharmaceutica Division

c/o P.T. Johnson & Johnson Indonesia Wisma Mampang, 3rd Floor Jl. Mapang Prapatan Raya No. 1 Jakarta Selatan, Indonesia

Korea Janssen Korea Ltd

12th Floor, Sungwon Building 141, Samsung-dong, Kangam-ku

Seoul 135-090, Korea

Malaysia Janssen Pharmaceutica

(A div. of Johnson & Johnson Sdn. Bhd.)

Third Floor, Wisma Digital Jalan Bersatu 13/4 46200 Petaling Jaya

Selangor, Malaysia (responsible for Malaysia, Singapore, Brunei)

Mexico

Janssen Farmaceutica, S.A. de C.V.

Canoa No. 79 Col. Tizapan - San Angel Delegacion Alvara Obregon

01090 Mexico, D.F. Mexico (responsible for: Caribbean Area: Dominican Republic

Bermuda Bahamas Jamaica

Cayman Islands

Trinidad Haiti Barbados Curacao Aruba Grenada Santa Lucia Antigua Tortola Saint Martin

Saint Vincent Turks and Caicos Islands)

Philippines

Janssen Pharmaceutica A Div. of Johnson & Johnson (Phil.), Inc. 7th Floor Centerpoint Condominium Julia Vargas Cor. Garnet St. Ortigas Center, Pasig Metro Manila, Philippines

South Africa

Janssen-Cilag

Janssen House - 2nd Floor c/o Norwich Close and 5th St. Santon 2146, Gauteng

South Africa

Taiwan

Janssen-Cilag Taiwan 8th Floor, 319, Section 2 Tunhwa South Road

Taipei 106 Taiwan R.O.C.

Thailand

Janssen Pharmaceutica Ltd. 1550 Grand Amarin Tower, 11 Fl. New Petchburi Road Makasan, Rachtevee Bangkok 10310 Thailand (responsible for Thailand, Vietnam, Cambodia, Myanmar and Laos)

EXHIBIT B

SPECIFICATIONS

PRODUCT SPECIFICATIONS

The following release specifications are subject to regulatory review and approval in the Territory. They will be modified as required by regulatory authorities, and all Product delivered to Janssen must comply with such modified specifications. Release Specifications

[*]

TEST

Appearance

Identity

Identity

Assay, alprostadil

Uniformity of Dosage Units

Package Integrity

Sterility

Dissolution

Degradation Products

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

EXHIBIT C

EXAMPLE MINIMUM TRANSFER PRICE CALCULATIONS

			NET SELLING PRICE		
	[*]	[*]	[*]	[*]	[*]
	[*]	[*]	[*]	[*]	[*]
	[*]	[*]	[*]	[*]	[*]
	[*]	[*]	[*]	[*]	[*]
VIVUS	[*]	[*]	[*]	[*]	[*]
COST	[*]	[*]	[*]	[*]	[*]
0F	[*]	[*]	[*]	[*]	[*]
GOODS	[*]	[*]	[*]	[*]	[*]
	[*]	[*]	[*]	[*]	[*]
	[*]	[*]	[*]	[*]	[*]
	[*]	[*]	[*]	[*]	[*]
	[*]	[*]	[*]	[*]	[*]
	[*]	[*]	[*]	[*]	[*]

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

EXAMPLE TRANSFER PRICE CALCULATION IN THE CASE WHERE [*] FORMULA IS IN EFFECT

			NET SELLING PRICE		
	[*]	[*]	[*]	[*]	[*]
	[*]	[*]	[*]	[*]	[*]
	[*]	[*]	[*]	[*]	[*]
	[*]	[*]	[*]	[*]	[*]
VIVUS	[*]	[*]	[*]	[*]	[*]
COST	[*]	[*]	[*]	[*]	[*]
OF	[*]	[*]	[*]	[*]	[*]
GOODS	[*]	[*]	[*]	[*]	[*]
	[*]	[*]	[*]	[*]	[*]
	[*]	[*]	[*]	[*]	[*]
	[*]	[*]	[*]	[*]	[*]
	[*]	[*]	[*]	[*]	[*]
	[*]	[*]	[*]	[*]	[*]

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EXHIBIT E

I KADEMAKK COUNTRI	TRADEMARK	COUNTRIES
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Country	Mark 	Status 	Filing No.	Filing Date	Class
Cambodia	MUSE	Mailed			5
Canada	MUSE	Allowed	735,175	08/19/93	
Canada	MUSE	Filed	802,814	01/29/96	
China	MUSE	Pending/IR		11/07/96	
Hong Kong	MUSE	Filed	1466/96	02/03/96	5
Indonesia	MUSE	Filed		02/12/96	5
Korea, South	MUSE	Filed	1996-3661	01/31/96	5(10)
Laos	MUSE	Mailed			5
Malaysia	MUSE	Filed	MA/3176/96	03/28/96	5
Mexico	MUSE	Filed	175835	08/19/93	5
Myanmar	MUSE	Ordered			5
Philippines	MUSE	Filed	107779	04/29/96	5
Singapore	MUSE	Filed	1037/96	01/29/96	5
South Africa	MUSE	Filed	96/00968	01/26/96	5
Taiwan	MUSE	Filed	85006304	02/06/96	5
Thailand	MUSE	Filed	320906	10/30/96	5
Vietnam	MUSE	Pending/IR		11/07/96	5