

**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**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, 2002

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 (NO FEE REQUIRED)**

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

Commission File Number 0-23490

**VIVUS, INC.**

(Exact name of Registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation or organization)

**94-3136179**  
(IRS employer identification number)

**1172 Castro Street**  
Mountain View, California 94040  
(Address of principal executive offices and zip code)

**(650) 934-5200**  
(Registrant's telephone number,  
including area code)

**Securities registered pursuant to Section 12(b) of the Act:**  
None

**Securities registered pursuant to Section 12(g) of the Act:**  
Common Stock, \$.001 Par Value

**Preferred Share Purchase Rights**

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

Indicate by check mark 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.

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

The aggregate market value of the voting and non-voting Common Stock held by non-affiliates of the Registrant on June 28, 2002, the last business day of Registrant's most recently completed second fiscal quarter, was approximately \$214,524,287, which is based upon the closing price of the common stock on the Nasdaq National Market. There were 31,687,487 shares of the Registrant's common stock, par value \$.001, issued and outstanding held by non-affiliates of the Registrant as of June 28, 2002.

**DOCUMENTS INCORPORATED BY REFERENCE**

**Certain sections of the Proxy Statement to be filed in connection with the 2003 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K Report where indicated.**

VIVUS, INC.

FISCAL 2002 FORM 10-K

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

## PART I

**Item 1. Business****Company Overview**

VIVUS, Inc. is a pharmaceutical company developing innovative products to improve quality of life disorders in men and women, with a focus on sexual dysfunction. VIVUS develops and markets MUSE® (alprostadil) and ACTIS®, two innovations in the treatment of erectile dysfunction in the United States. We have entered into a supply agreement with Meda AB (Stockholm:MEDAA.ST) to market and distribute MUSE internationally in all Member States of the European Union, the Baltic States, the Czech Republic, Hungary, Iceland, Norway, Poland, Switzerland and Turkey. In Canada, we have entered into a license and supply agreement with Paladin Labs, Inc. (TSE:PLB) for the marketing and distribution of MUSE. We have ongoing research and development programs, including projects in erectile dysfunction, female sexual dysfunction, and premature ejaculation.

VIVUS was incorporated in California on April 16, 1991 and completed a re-incorporation in the state of Delaware in May 1996. VIVUS' headquarters and mailing address is 1172 Castro Street, Mountain View, California 94040, and the telephone number at that location is (650) 934-5200. VIVUS' website address is [www.vivus.com](http://www.vivus.com) and it makes its periodic and current reports that are filed with the Securities and Exchange Commission available, free of charge, on its website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the Securities and Exchange Commission. Our common stock trades on the Nasdaq National Market under the symbol "VVUS." VIVUS, Inc. is also referred to herein as "VIVUS," "we," "us" and "our."

**Our Strategy**

It is our objective to become a global leader in the development and commercialization of innovative therapies for the treatment of sexual dysfunction and other genitourinary disorders in men and women. We are pursuing this objective through the following strategies:

#### *Targeted Research and Development Efforts*

We will exploit our expertise and patent portfolio by focusing our research and development activities on sexual dysfunction, including erectile dysfunction, female sexual dysfunction and premature ejaculation, and other genitourinary disorders.

#### *Focus on Development*

We will continue to focus our efforts on clinical development of our current research and development pipeline, targeted acquisitions of new technologies, and the development of patentable uses of known pharmacologic agents for which significant safety data already exists.

#### *Maintain Proprietary Technology*

We will continue to develop, maintain and secure intellectual property rights and aggressively pursue new patents to expand upon our strong foundation for commercializing products in development. VIVUS has various issued and pending United States patents, as well as pending and granted foreign patents. Many of these patents and applications further address the prevention, treatment and diagnosis of erectile dysfunction, while others are directed to the prevention and/or treatment of other types of sexual dysfunction, including premature ejaculation and female sexual dysfunction.

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#### *Marketing and Distribution Strategy*

In the United States, VIVUS markets MUSE through our own dedicated sales force. We have entered into a supply agreement with Meda AB to market and distribute MUSE internationally in all Member States of the European Union, the Baltic States, the Czech Republic, Hungary, Iceland, Norway, Poland, Switzerland and Turkey. In Canada, we have entered into a distribution and supply agreement with Paladin Labs to market and distribute MUSE. We will continue to evaluate distribution, marketing, licensing and other opportunities for our products, as well as out-licensing rights related to products in our pipeline to third parties.

### **2002 Highlights**

#### *First Quarter 2002*

We began our expanded Phase II study for our female sexual dysfunction product, ALISTA<sup>TM</sup>, which was a trial designed to evaluate the safety and efficacy of the product when used by women with female sexual arousal disorder at home with their partner.

We reported a net loss of \$1.9 million, for a \$0.06 net loss per share. Spending for research and development and lower international product revenue contributed to the loss.

After successfully filing an Investigational New Drug application with the United States Food and Drug Administration in December 2001, we began clinical studies to evaluate the safety and efficacy of oral TA-1790 for the treatment of erectile dysfunction.

#### *Second Quarter 2002*

We reported a net loss of \$3.3 million, for a \$0.10 net loss per share. Spending for research and development and lower product revenue contributed to the loss.

VIVUS was awarded a new patent by the United States Patent & Trademark Office for the use of phosphodiesterase inhibitors to treat premature ejaculation.

#### *Third Quarter 2002*

We reported a net loss of \$3.7 million, for a \$0.11 net loss per share. Lower product revenue and spending for research and development contributed to the loss.

We signed an international supply agreement granting Meda AB, a Swedish specialty pharmaceutical company, the right to market, sell, and distribute MUSE in all Member States of the European Union, the Baltic States, the Czech Republic, Hungary, Iceland, Norway, Poland, Switzerland and Turkey.

VIVUS was added to the list of companies in the Russell 2000<sup>®</sup> Small-Cap United States Equity Index, which is widely used as a benchmark for both passive and active investment strategies.

The Company and Abbott Laboratories agreed to terminate the license and supply agreement for MUSE entered into in 2000.

#### *Fourth Quarter 2002*

We reported a net loss of \$1.6 million, for a \$0.05 net loss per share. Higher operating costs were partially offset by an income tax benefit.

We initiated a clinical trial to evaluate the safety and efficacy of VI-0162, a proprietary, oral, on-demand treatment for premature ejaculation.

We announced positive results from a clinical study designed to evaluate the safety of and erectile response to oral TA-1790 in men with erectile dysfunction.

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We were awarded a new patent by the United States Patent & Trademark Office covering the use of vasodilators administered locally to treat dyspareunia, a form of female sexual dysfunction.

## Research and Development

In recent years we have invested in a number of research and development projects. The current status of our most advanced research and development projects is depicted in the table below.

Indication	Product Candidate	Progress
Erectile Dysfunction	ALIBRA	Regulatory Review
	TA-1790 (oral)	Phase I Efficacy—Completed
	TA-1790 (transurethral)	Pre-clinical
Female Sexual Dysfunction	ALISTA (topical PGE1)	Phase II—Dosing Completed
	TA-1790	Pre-clinical
Premature Ejaculation	VI-0134	Phase I
	VI-0162	Phase I

Our research and development expenses for the years ended December 31, 2002, 2001 and 2000, in thousands, were \$13,281, \$12,324, and \$4,670, respectively. We anticipate that our research and development expenses will continue to increase as we focus our efforts on clinical development of our current research and development pipeline, targeted acquisitions of new technologies and the development of patentable uses of known pharmacologic agents for which significant safety data already exists.

Recent progress and current plans in our research and development projects include:

- **ALISTA** – A proprietary formulation of alprostadil applied locally to the female genitalia to treat female sexual arousal disorder.
  - Our first Phase II clinical study, which was an in-clinic, single dose, multi-center trial designed to evaluate the safety of and response to ALISTA in subjects with female sexual arousal disorder, was completed in 2001. The study demonstrated a significant increase in ALISTA-treated women versus placebo and baseline in sexual response associated with visual sexual stimulation. ALISTA was associated with a rapid and sustained improvement in sexual response.
  - An expanded Phase II study, designed to evaluate the efficacy and safety of ALISTA when used by women with female sexual arousal disorder at home with their partner, began in the first quarter of 2002. Dosing was completed in February 2003 and data from this study is expected to be available by the end of the first quarter 2003.
- **TA-1790** – A relatively fast-acting, highly selective, potent phosphodiesterase type 5 (PDE5) inhibitor for the oral and local treatments of erectile dysfunction and female sexual dysfunction.
  - We successfully filed an Investigational New Drug application with the United States Food & Drug Administration in December 2001 to initiate a clinical study to evaluate the safety of and erectile response to oral TA-1790 in men with erectile dysfunction. This single-dose trial began in the first quarter of 2002. Subjects with mild-to-moderate erectile dysfunction were treated with placebo, TA-1790, and Viagra® prior to visual sexual stimulation, and their penile rigidity response was measured over a two-hour period. Dosing was completed during the third quarter 2002 and demonstrated that TA-1790 caused a rapid increase in penile rigidity that was statistically significantly greater than placebo. TA-1790 was safe and well tolerated in this trial. Thus, clinical data from this study demonstrated that TA-1790 is capable of restoring penile function in men with erectile dysfunction.
  - At the end of 2001, we began pre-clinical development work on a transurethral formulation of TA-1790, alone and in combination with alprostadil, for the treatment of erectile dysfunction. Our goal for the local administration of TA-1790 is to provide an effective therapy for patients who do not have success with, or cannot use oral treatments.

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- **VI-0162 and VI-0134** – On demand, oral treatments for premature ejaculation.
    - During the fourth quarter of 2002, we initiated a clinical trial to evaluate the safety and efficacy of VI-0162, a proprietary, oral, on-demand treatment for premature ejaculation. This study is an at-home, double blind, placebo controlled crossover design. The trial is expected to be completed during the second quarter of 2003.
    - During the fourth quarter of 2001, we initiated a clinical trial to evaluate the pharmacokinetic (blood levels in relation to time) profile of our new oral formulation of VI-0134. This study was completed during the second quarter of 2002. We are currently evaluating our strategic options for VI-0134 for this indication. Further development of VI-0134 would be dependent on the outcome of the studies involving VI-0162 as discussed above.

We continue to place significant emphasis on securing global intellectual property rights and are aggressively pursuing new patents to expand upon our strong foundation for commercializing products in development. In the United States, patents and patent applications licensed to and developed by VIVUS currently include 23 in erectile dysfunction, 18 in female sexual dysfunction and 8 in premature ejaculation.

## Clinical Studies

Clinical trial activity at VIVUS is currently focused on the development of ALISTA for the treatment of female sexual arousal disorder, the development of TA-1790 for the treatment of male erectile dysfunction, and the evaluation of VI-0162 and VI-0134 for the treatment of premature ejaculation.

Studies completed during 2001 demonstrated the safety, tolerability, and genital response associated with various doses of ALISTA administered in-clinic. In our study in healthy women, ALISTA was well tolerated and had no greater effect on blood pressure than did placebo. A subsequent multi-center trial evaluated the response of a single dose of ALISTA, administered in-clinic in conjunction with visual sexual stimulation in postmenopausal women with female sexual arousal disorder. This study demonstrated that ALISTA was associated with significantly greater increases compared to placebo in genital vasocongestion, physical arousal and overall sexual arousal and satisfaction. Results from these studies provided data that enabled us to design and initiate a larger-scale Phase II study to evaluate the safety and efficacy of ALISTA when administered in the home setting for the treatment of postmenopausal women with female sexual arousal disorder. This multi-center, double blind, placebo-controlled study was initiated in the first quarter of 2002; treatment was completed in February 2003 and data from this study is expected to be available by the end of the first quarter 2003. Additional studies are planned for 2003.

TA-1790 is an oral type-5 phosphodiesterase inhibitor (PDE5) that VIVUS licensed from Tanabe Seiyaku Co., Ltd for the treatment of sexual dysfunction in men and women. During 2002, VIVUS completed a study to evaluate the erectile response to single doses of TA-1790 administered in-clinic. Responses were assessed using a RigiScan® device. In this study, TA-1790 was well tolerated and demonstrated significant increases over placebo in penile rigidity. Importantly, the peak response to each dose of TA-1790 was achieved within 20-40 minutes of dosing. VIVUS also completed a multi-dose safety and pharmacokinetic (blood levels in relation to time) study with several doses of TA-1790, and the analysis of this study is ongoing. During the first half of 2003, VIVUS plans to initiate a home study to evaluate the safety and efficacy of TA-1790. This study will be designed to evaluate both the onset and duration of drug effect, and should provide information to allow optimal patient dosing in larger phase II studies.

VIVUS previously completed a proof of concept trial evaluating on-demand therapy with several classes of compounds for the treatment of premature ejaculation. In 2002, the Company initiated a similar proof of concept study to evaluate the safety and efficacy of VI-0162 for the treatment of premature ejaculation. This study is scheduled to be completed during the first half of 2003.

## **Sales and Marketing**

### *Domestic*

VIVUS supports MUSE sales in the United States with a small sales team comprised of regional sales managers and telesales personnel calling on targeted physicians. We participate in national urologic and sexual dysfunction forums and conferences, such as the American Urologic Association annual meeting and the International Society for Impotence Research. In addition, we support the ongoing research and clinical investigation of MUSE and the publication of data in peer-reviewed journals.

### *International*

VIVUS signed an international supply agreement with Meda AB in September 2002. Under this supply agreement, Meda AB purchases MUSE from us for resale in all Member States of the European Union, the Baltic States, the Czech Republic, Hungary, Iceland, Norway, Poland, Switzerland and Turkey. Initial shipments to Meda AB began in the fourth quarter of 2002.

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In November of 2000, VIVUS granted Paladin Labs the exclusive rights to distribute and market MUSE in Canada.

## **VIVUS' Transurethral System for Erection**

Administration of the transurethral system for erection is an easy and painless procedure. The end of the applicator is less than half the diameter of a man's urine stream and is inserted approximately one inch into the urethra. To use the transurethral system for erection, a patient urinates, shakes the penis to remove excess urine, inserts the transurethral system for erection into the urethra, releases the medication, and then massages the penis between the hands for 10 seconds to distribute the medication. The application process takes less than a minute.

Once administered, the pharmacologic agent dissolves in the small amount of urine that remains in the urethra, is absorbed across the urethral mucosa, and is transferred via local vasculature to the tissues of the erectile bodies. When successful, an erection is produced within 15 minutes of administration and lasts approximately 30 to 60 minutes. Many patients experience transient penile pain and/or local aching after administration and during intercourse, which is caused by the use of the drug alprostadil.

Alprostadil is the first pharmacologic agent used in the transurethral system for erection. Alprostadil is the generic name for the synthetic version of prostaglandin E1, a naturally occurring vasodilator present throughout the body and at high levels in seminal fluid. There are four dosage strengths of alprostadil utilized in MUSE: 125 mcg, 250 mcg, 500 mcg, and 1000 mcg. It is recommended that patients initiating therapy with MUSE be titrated to the lowest effective dose under the supervision of a physician.

ALIBRA is our second transurethral product for the treatment of erectile dysfunction, and it has not yet received regulatory approval in the United States. ALIBRA utilizes a low 125 mcg dose of alprostadil administered in combination with 500 mcg of prazosin hydrochloride. Because alprostadil and prazosin affect vasodilation by different mechanisms, this combination product is designed to provide adequate efficacy and safety with a relatively low dose of alprostadil.

## **Advantages of Transurethral Therapy**

Our transurethral system for erection is designed to overcome the limitations of other available therapies through its unique product attributes that include:

- *Safety.* Our transurethral system for erection is a safe local treatment for patients. Because therapeutic levels of drug are delivered locally to the erectile tissues with minimal systemic drug exposure, the opportunity for systemic drug-drug and drug-disease interactions is minimized. Transurethral therapy, therefore, offers an alternative to oral treatments that are delivered to the erectile tissues via the systemic circulation and may be more susceptible to these

types of interactions.

- *Ease of Administration.* Our transurethral system for erection is easy to use with minimal instruction, unlike needle injection therapy that requires precise injection into the penis.
- *Minimally invasive.* Our transurethral system for erection utilizes urethral delivery, permitting topical application to the urethral lining.
- *Discreet.* Our transurethral system for erection utilizes a small, single-use disposable applicator that can be discreetly applied and is easily integrated into the normal sexual life of the patient. Administration takes less than a minute.
- *Quality of Erection.* Our transurethral system for erection therapy mimics the normal vasoactive process, producing an erection that is more natural than those resulting from needle injection therapy, vacuum constriction devices or penile implants.

## Current Therapies

In addition to MUSE, other medical and mechanical treatments for erectile dysfunction include:

*Oral Medications.* In 1998, Pfizer Inc. received clearance from the United States Food and Drug Administration to market its oral treatment for erectile dysfunction, Viagra®. Commercial introduction of this new competitive product adversely affected VIVUS' business, financial condition and results of operations. Currently, Viagra accounts for over 95% of prescriptions for pharmaceutical products to treat erectile dysfunction. Another oral medication under the name Uprima® was approved and launched in Europe by Abbott Laboratories in May 2001. Most recently, a new oral medication under the name Cialis™ was approved and launched in Europe by Lilly ICOS LLC and in Australia and New Zealand by Eli Lilly and Company in February 2003.

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*Needle Injection Therapy.* This form of treatment involves the needle injection of pharmacologic agents directly into the penis. The only pharmacologic agent that is currently approved for this indication is alprostadil (which is also the active ingredient in MUSE). Alprostadil is also used by many doctors in combination with other vasodilators, most commonly phentolamine and papaverine. Injection therapy requires a prescription from a physician and instruction on self-injection. Side effects may include pain associated with injection, local pain and aching, priapism (persistent prolonged erections), fibrosis (build-up of scar tissue) and bleeding.

*Vacuum Constriction Devices.* This form of treatment involves the use of a mechanical system that creates a vacuum around the penis, causing the erectile bodies to fill with blood. A constriction band is then placed around the base of the penis to impede blood drainage and maintain the erection. Vacuum constriction devices are large, mechanical devices that can be unwieldy and somewhat difficult to use. In addition, the erection may not seem natural since only the part of the penis beyond the constriction band is rigid, and the penis can become cold and discolored due to the constriction of blood flow. Complications encountered by some users of vacuum constriction devices include pain and difficulty ejaculating.

*Penile Implants.* This therapy involves the surgical implantation of a semi-rigid, rigid or inflatable device into the penile structure to mechanically simulate an erection. In addition to the risks associated with surgical procedures, there is a significant rate of complication with implants such as infection and mechanical failure of the device. This may necessitate a second surgical procedure to remove or reposition the device. In addition, due to the scarring associated with the implant procedure, the patient may no longer be a viable candidate for less radical therapies.

## Manufacturing

VIVUS leases 90,000 square feet of space in Lakewood, New Jersey for its manufacturing operation, which includes formulation, filling, packaging, analytical laboratories, storage, distribution and administrative offices. The United States Food and Drug Administration and the Medicines Control Agency, the regulatory authority in the United Kingdom, authorized us to begin commercial production and shipment of MUSE from this facility in June and March 1998, respectively. We have met all market demands for the supply of MUSE utilizing our high quality New Jersey manufacturing facility.

## Government Regulation

The research, pre-clinical development, clinical trials, manufacturing and marketing of our products are subject to extensive regulation by numerous governmental authorities in the United States and other countries. Pre-clinical studies, clinical trials, manufacturing and marketing of our products are and will be subject to the rigorous testing and approval processes of the United States Food and Drug Administration and equivalent foreign regulatory agencies. The process of obtaining United States Food and Drug Administration and other required regulatory approvals is lengthy and expensive. In November 1996, VIVUS received final marketing clearance from the United States Food and Drug Administration for MUSE. In November 1997, we obtained regulatory marketing clearance by the Medicines Control Agency to market MUSE in the United Kingdom. MUSE has also received marketing clearance in more than 40 countries around the globe.

After regulatory approval is obtained, our products are subject to continual review. In December 1999, we submitted a New Drug Application to the United States Food and Drug Administration to market ALIBRA®, our second-generation product for the treatment of erectile dysfunction, which we subsequently withdrew in October 2000. We met with the United States Food and Drug Administration in December 2000 and continue to communicate with the agency to determine what additional data is required to obtain marketing clearance for ALIBRA. There can be no assurance, however, that we will be successful in obtaining approval for ALIBRA in the United States.

## Segments and Geographic Area Information

We primarily sell our products through the wholesale channel in the United States. International sales are made only to our international distributors. We have entered into a supply agreement with Meda AB for the international marketing and distribution of MUSE. In Canada, we have entered into a license and supply agreement with Paladin Labs for the marketing and distribution of MUSE.

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All material long-lived assets are located in the United States.

## Employees

As of February 28, 2003, VIVUS had 119 employees, including 81 of which are located at the manufacturing facility in Lakewood, New Jersey and 38 of which are located at our corporate headquarters in Mountain View, California and other United States and international locations. None of our current employees are represented by a labor union or are the subject of a collective bargaining agreement. We believe that we maintain good relations with our employees.

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## RISK FACTORS AFFECTING OPERATIONS AND FUTURE RESULTS

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

### **If we were unable to continue to develop, market and obtain regulatory approval for our products, our business would be harmed.**

Our future operating results may be adversely affected if we are unable to continue to develop, manufacture and bring to market new drug products in a timely manner. The process of developing new drugs and/or therapeutic products is inherently complex and uncertain. We must make long-term investments and commit significant resources before knowing whether our development programs will eventually result in products that will receive regulatory approval and achieve market acceptance.

As with any pharmaceutical product under development, there are significant risks in development, regulatory approval and commercialization of new compounds. During the product development phase, there is no assurance that the United States Food and Drug Administration will approve our clinical trial protocols. There is no guarantee that future clinical studies, if performed, will demonstrate the safety and efficacy of any product in development or that we will receive regulatory approval for such products. Further, the United States Food and Drug Administration can suspend clinical studies at any time if the agency believes that the subjects participating in such studies are being exposed to unacceptable health risks.

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

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

We are developing TA-1790 as potential oral and local treatments for male and female sexual dysfunction. In January 2001, we licensed TA-1790, a proprietary phosphodiesterase type 5 (PDE5) inhibitor compound, from Tanabe Seiyaku, a Japanese pharmaceutical company. Tanabe Seiyaku completed a Phase I clinical trial evaluating the safety of orally administered TA-1790 for male erectile dysfunction. We are currently conducting additional pre-clinical safety studies and have recently completed an in-clinic efficacy study in patients with erectile dysfunction. Based on the results of these studies, we intend to initiate additional clinical studies that would be required to obtain regulatory approval. However, there are no guarantees that TA-1790 will prove to be safe and effective or receive regulatory approval for any indication. Further, even if we were to receive regulatory approval for a product, there can be no assurance that such a product would prove to be commercially successful or profitable.

We are developing ALISTA for the potential treatment of female sexual arousal disorder. We completed dosing for our first Phase II clinical study for topical ALISTA during the third quarter of 2001. Our current ALISTA clinical trial, which is a multi-center, double blind, at-home efficacy and safety study, began in the first quarter of 2002. There are no guarantees that ALISTA will prove to be safe and effective or that we will receive regulatory approval for the treatment of female sexual arousal disorder or any other indication. Even if ALISTA eventually becomes an approved product, there can be no assurance that this treatment for female sexual arousal disorder will be successful in the marketplace.

We are developing VI-0134 and VI-0162 for the potential treatment of premature ejaculation. We have recently completed a clinical trial to evaluate the pharmacokinetics (blood levels in relation to time) of VI-0134, our re-formulated oral, on-demand treatment for premature ejaculation. We initiated a clinical trial to evaluate the safety and efficacy of VI-0162, a proprietary, oral, on-demand treatment for premature ejaculation. However, there can be no assurance that these studies or future clinical studies, if performed, will be successful or that a product for the treatment of premature ejaculation, if approved, will prove to be commercially successful.

In December 1999, we submitted a New Drug Application, or NDA, to the United States Food and Drug Administration to market ALIBRA®, our second-generation product for the treatment of erectile dysfunction, which we subsequently withdrew in October 2000. We met with the United States Food and Drug Administration in December 2000 and continue to communicate with the agency to determine what additional data is required to obtain marketing clearance for ALIBRA. There can be no assurance that we will re-file an NDA for ALIBRA. Even if we re-file an NDA for ALIBRA, there can be no assurance that it will be approved or that ALIBRA will be successful in the marketplace.

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

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

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

To obtain additional capital when needed, we will evaluate alternative financing sources, including, but not limited to, the issuance of equity or debt securities, corporate alliances, joint ventures, and licensing agreements. However, there can be no assurance that funding will be available on favorable terms, if at all, when needed. If we are unable to obtain additional capital, management may be required to explore alternatives to reduce cash used by operating activities.

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

We support MUSE sales in the United States through a small sales support group targeting major accounts that include the top prescribers of MUSE. Additionally, telephone marketers focus on additional urologists who prescribe MUSE. Physician and patient information/help telephone lines are available to answer additional questions that may arise after reading the inserts or after actual use of the product. The sales force actively participates in national urologic and sexual dysfunction forums and conferences, such as the American Urological Association annual and regional meetings and the International Society for Impotence Research. There can be no assurance that our sales programs will effectively maintain or potentially increase current sales levels. There can be no assurance that demand for MUSE will continue or that we will be able to adequately support sales of MUSE in the United States in the future.

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

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

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

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

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

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



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

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

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

Competition in the pharmaceutical and medical products industries is intense and is characterized by extensive research efforts and rapid technological progress. Certain treatments for erectile dysfunction exist, such as oral medications, needle injection therapy, vacuum constriction devices and penile implants, and the manufacturers of these products will continue to improve these therapies. The most significant competitive therapy is an oral medication marketed by Pfizer under the name Viagra®, which received regulatory approvals in the United States in March 1998 and in the European Union in September 1998. The commercial launch of Viagra in the United States in April 1998 significantly decreased demand for MUSE. Another oral medication under the name Uprima® was approved and launched in Europe by Abbott Laboratories in May 2001. Most recently, a new oral medication under the name Cialis™ was approved and launched in Europe by Lilly ICOS LLC and in Australia and New Zealand by Eli Lilly and Company in February 2003.

Additional competitive products in the erectile dysfunction market include needle injection therapy products from Pharmacia and Schwartz Pharma, which were approved by the United States Food and Drug Administration in July 1995 and June 1997, respectively. Other large pharmaceutical companies are also actively engaged in the development of therapies for the treatment of erectile dysfunction. These companies have substantially greater research and development capabilities as well as substantially greater marketing, financial and human resources abilities than VIVUS. In addition, many of these companies have significantly greater experience than us in undertaking pre-clinical testing, human clinical trials and other regulatory approval procedures. Lilly ICOS LLC and Bayer AG filed New Drug Applications with the United States Food and Drug Administration in June and September 2001, respectively, for their oral erectile dysfunction medications. These companies may market commercial products either on their own or through collaborative efforts, such as Bayer AG, which signed a worldwide co-promotion agreement with GlaxoSmithKline plc for its product. Our competitors may develop

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technologies and products that are more effective than those we are currently marketing or developing. Such developments could render our products less competitive or possibly obsolete. We are also competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have limited experience.

**Our success depends in large part on the strength of our current and future patent positions for the treatment of sexual dysfunction.**

VIVUS holds various patents and patent applications in three major areas of sexual dysfunction: male erectile dysfunction, female sexual dysfunction and premature ejaculation. We are the exclusive licensee of United States and Canadian patents originally filed in the name of Dr. Gene Voss. These patents claim methods of treating erectile dysfunction with a vasodilator-containing ointment that is administered either topically or transurethraly.

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

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

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

We are the sole assignee of patent applications filed in the name of Dr. Gary W. Neal and AndroSolutions, Inc. that are complementary to our patents and applications directed to the treatment of female sexual dysfunction.

In addition to the Voss, Kock, Place and Neal patents and applications identified above, we have numerous issued and pending United States and foreign patents. Many of these patents and applications further address the prevention, treatment and diagnosis of erectile dysfunction, while others are directed to prevention and/or treatment of other types of sexual dysfunction, including premature ejaculation and female sexual dysfunction. One of our issued patents covers VIVUS' venous flow control device, ACTIS.

Our strategy is to expand our existing patent portfolio through internal development of new intellectual property as well as through licensing and acquiring patents and patent applications that would increase our ability to succeed in the fields of erectile dysfunction, female sexual dysfunction and premature ejaculation. Our success will depend in large part on the strength of our current and future patent position for the treatments of these therapeutic indications. Our patent position, like that of other pharmaceutical companies, is highly uncertain and involves complex legal and factual questions. The claims of a United States or foreign patent application may be denied or significantly narrowed, and patents that are ultimately issued may not provide significant commercial protection to us. We could incur substantial costs in proceedings before the United States Patent and Trademark Office, including interference proceedings. These proceedings could also result in adverse decisions as to the priority of our licensed or assigned inventions. There can be no assurance that our patents will not be successfully challenged or designed around by others.

We were involved in an opposition proceeding that was instigated by the Pharmedic Company against a European patent, inventors Nils G. Kock et al., which is exclusively licensed to VIVUS. As a result of the opposition proceeding and a subsequent appeal by VIVUS, the Opposition Division of the European Patent Office has allowed many of the patent's claims with the exception of certain pharmaceutical composition claims. There can be no assurance that further challenges to the European patent will not be made should we try to enforce the patent in a European court.

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

We are required to initially receive regulatory approval for suppliers and we obtained our current supply of alprostadil from two approved sources. The first is Nera Pharm, formerly Spolana Chemical Works a.s. in Neratovice, Czech Republic. The second is Chinoin Pharmaceutical and Chemical Works Co., Ltd. Chinoin Pharmaceutical is the Hungarian subsidiary of the French pharmaceutical company Sanofi Synthelabo. From July 2000 until March 2002, Nera Pharm was the sole source of supply of alprostadil approved for use in the manufacture of product for distribution in Europe, of which we have a limited supply. Certain restrictions were put in place by the European regulatory authorities that required a variation to be approved before VIVUS could use the Chinoin Pharmaceutical alprostadil supply for European manufacture. After transferring marketing licenses in Europe to Abbott Laboratories, our former distribution partner, Abbott Laboratories filed a variation on September 26, 2001. The variation was approved in March 2002 and allows us to use a portion of our Chinoin Pharmaceutical supply of alprostadil for European manufacture. In the second quarter of 2002, we ended our contractual relationship with Nera Pharm, which leaves Chinoin Pharmaceutical as our sole qualified supplier of alprostadil. We are currently in the process of investigating additional sources for our future alprostadil supplies. However, there can be no assurance that we will be able to identify and qualify additional suppliers of alprostadil, in a timely manner, if at all.

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

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

We entered into a distribution agreement with Cardinal Health (formerly CORD Logistics, Inc.). Under this agreement, Cardinal Health

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

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

Gibraltar Laboratories performs sterility testing on finished product manufactured by us to ensure that it complies with product specifications. Gibraltar Laboratories also performs microbial testing on water and compressed gases used in the manufacturing process and microbial testing on environmental samples to ensure that the manufacturing environment meets appropriate current Good Manufacturing Practice, or cGMP, regulations and cleanliness standards. As a result of this testing agreement, we are dependent on Gibraltar Laboratories to perform testing and issue reports on finished product and the manufacturing environment in a manner that meets cGMP regulations. There can be no assurance that such efforts will be successful.

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

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

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

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

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**We currently depend on a single source to sterilize MUSE, and an interruption to this source could harm our business.**

We rely on a single source, E-Beam Services, Inc., for the sterilization of MUSE. There can be no assurance that we will be able to identify and qualify additional sterilization facilities. We are required to receive prior United States Food and Drug Administration approval for any sterilization facility. Until we secure and qualify an additional sterilization facility, we are entirely dependent upon E-Beam Services. If interruptions in these services occur for any reason, including a decision by E-Beam Services to discontinue manufacturing or services, political unrest, labor disputes or a failure of E-Beam Services to follow regulations, the development and commercial marketing of MUSE and other potential products could be delayed or prevented. An extended interruption in sterilization services would have a material adverse effect on our business, financial condition and results of operations.

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

We lease 90,000 square feet of space in Lakewood, New Jersey, in which we constructed manufacturing, warehousing and testing facilities. The United States Food and Drug Administration and the Medicines Control Agency, the regulatory authority in the United Kingdom, authorized us to begin commercial production and shipment of MUSE from this facility in June and March 1998, respectively. MUSE is manufactured in this facility and we have no immediate plans to construct another manufacturing site. Since MUSE is produced with custom-made equipment under specific manufacturing conditions, the inability of our manufacturing facility to produce MUSE for whatever reason could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

Failure of our third-party manufacturers to maintain satisfactory compliance with cGMPs could have a material adverse effect on our ability to continue to market and distribute our products and, in the most serious cases, could result in the issuance of warning letters, seizure or recall of products, civil penalties or closure of our manufacturing facility until such cGMP compliance is achieved.

We obtain the necessary raw materials and components for the manufacture of MUSE as well as certain services, such as testing and sterilization, from third parties. We currently contract with suppliers and service providers, including foreign manufacturers that are required to comply with strict standards established by us. Certain suppliers and service providers are required to follow cGMP requirements and are subject to routine unannounced periodic inspections by the United States Food and Drug Administration and by certain state and foreign regulatory agencies for compliance with cGMP requirements and other applicable regulations. Certain of our suppliers were inspected for cGMP compliance as part of the approval process. However, upon routine re-inspection of these facilities, there can be no assurance that the United States Food and Drug Administration and other regulatory agencies will find the manufacturing process or facilities to be in compliance with cGMP requirements and other regulations.

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

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

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

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

**We have an accumulated deficit of \$100.9 million at December 31, 2002 and expect to continue to incur substantial operating losses for the foreseeable future.**

We have generated a cumulative net loss of \$100.9 million for the period from our inception through December 31, 2002 and we anticipate losses for the next several quarters due to increased investment in our research and development programs and limited revenues. We are subject to a number of risks, including our ability to develop and successfully commercialize products in our research and development pipeline, our ability to market, distribute and sell our products in the United States, our reliance on others to market and distribute MUSE in countries other than the United States, intense competition, and our reliance on a single therapeutic approach to erectile dysfunction. There can be no assurance that we will be able to achieve profitability on a sustained basis. Accordingly, there can be no assurance of our future success.

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

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

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

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

Our commercial success also depends in part on ensuring we neither infringe patents nor proprietary rights of third parties. In the future, others may file patent applications covering technologies that we may wish to utilize with our proprietary technologies, or products that are similar to products developed with the use of our technologies. If these patent applications result in issued patents and we wish to use the claimed technology, we would need to obtain a license from the third party and this would increase our costs of operations and harm our operating results.

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

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

The patent positions of pharmaceutical companies, including our patent positions, are often uncertain and involve complex legal and factual questions. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. We apply for patents covering our technologies and products, as we deem appropriate. However, we may not obtain patents on all inventions for which we seek patents, and any patents we obtain may be challenged and may be narrowed in scope or extinguished as a result of such challenges. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Others may independently develop similar or alternative technologies or design around our patented technologies or products. These companies would then be able to develop, manufacture and sell products, which compete directly with our products. In that case, our revenues and operating results would decline.

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

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

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

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

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

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

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

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

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

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

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

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

The stock market has experienced significant price and volume fluctuations unrelated to the operating performance of particular companies. In addition, the market price of our common stock has been highly volatile and is likely to continue to be so. The market price of our common stock may fluctuate due to factors including, but not limited to:

- announcements of technological innovations or new products by us or our competitors;
- our ability to increase demand for our products in the United States;
- our ability to successfully sell our products in the United States and internationally;
- actual or anticipated fluctuations in our financial results;
- our ability to obtain needed financing;
- economic conditions in the United States and abroad;

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- comments by or changes in Company assessments or financial estimates by security analysts;
  - adverse regulatory actions or decisions;
  - any loss of key management;

- the results of our clinical trials or those of our competitors;
- changing governmental regulations, patents or other proprietary rights;
- developments or disputes concerning patents or other proprietary rights;
- product or patent litigation; or
- public concern as to the safety of products developed by us.

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

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

**Anti-takeover provisions contained in our Charter, Bylaws and Preferred Shares Rights Plan could impair a takeover attempt and could also limit the market price of our stock.**

In February 1996, our Board of Directors adopted a Preferred Shares Rights Plan. The Preferred Shares Rights Plan provides for a dividend distribution of one Preferred Shares Purchase Right, or a Right, on each outstanding share of our common stock. The Rights will become exercisable following the tenth day after a person or group announces acquisition of twenty percent (20%) or more of our common stock, or announces commencement of a tender offer, the consummation of which would result in ownership by the person or group of twenty percent (20%) or more of our common stock. We will be entitled to redeem the Rights at \$0.01 per Right at any time on or before the tenth day following acquisition by a person or group of twenty percent (20%) or more of our common stock.

The Preferred Shares Rights Plan and certain provisions of our Amended and Restated Certificate of Incorporation and Bylaws contain provisions that could delay or prevent a change in control of our company. Some of these provisions:

- authorize the issuance of preferred stock by the Board of Directors without prior stockholder approval, commonly referred to as "blank check" preferred stock, with rights senior to those of common stock;
- prohibit stockholder actions by written consent;
- specify procedures for director nominations by stockholders and submission of other proposals for consideration at stockholder meetings; and
- eliminate cumulative voting in the election of directors.

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

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

The Financial Accounting Standards Board is considering whether to require all companies to treat the value of stock options granted to employees as an expense. The United States Congress and other governmental and regulatory authorities have also considered requiring companies to expense stock options. If this change were to become mandatory, we and other companies would be required to record a compensation expense equal to the value of each stock option granted. This expense would be spread over the vesting period of the stock option. Currently, we are generally not required to record compensation expenses in connection with stock option grants. If we were required to expense stock option grants, it would reduce the attractiveness of granting stock options because of the additional expense associated with these grants, which would reduce our profitability. However, stock options are an important employee recruitment and retention tool, and we may not be able to attract and retain key personnel if we reduce the scope of our employee stock option program. Accordingly, in the event we are required to expense stock option grants, our profitability would be reduced, as would our ability to use stock options as an employee recruitment and retention tool.

**Our investments could lose market value and consequently harm our ability to fund continuing operations.**

The primary objective of our investment activities is to preserve principal while at the same time maximize yields without significantly increasing risk. To achieve this objective, we maintain our portfolio of cash and cash equivalents, short-term and long-term investments in a variety of securities, including government and corporate obligations and money market funds. These securities are generally classified as available for sale and consequently are recorded on the balance sheet at fair value with unrealized gains or losses reported as a separate component of accumulated other comprehensive (loss) income, net of estimated tax. The market values of these investments may fluctuate due to market conditions and other conditions over which we have no control. Fluctuations in the market price and valuations of these securities may require us to record losses due to an impairment in the value of the securities underlying our investment. This could result in future charges on our earnings. All securities are held in United States currency.

Investments in both fixed rate and floating rate interest earning instruments carry varying degrees of interest rate risk. Fixed rate securities may have their fair market value adversely impacted due to a rise in interest rates. In general, securities with longer maturities are subject to greater interest rate risk than those with shorter maturities. While floating rate securities generally are subject to less interest rate risk than fixed rate securities, floating rate securities may produce less income than expected if interest rates decrease. Due in part to these factors, our investment income may fall short of expectations or we may suffer losses in principal if securities are sold that have declined in market value due to changes in interest rates.

**Item 2. Properties**

VIVUS leases 90,000 square feet of space in New Jersey in which it has constructed manufacturing and testing facilities. The United States Food and Drug Administration and the Medicines Control Agency, the regulatory authority in the United Kingdom, authorized us to begin commercial production and shipment of MUSE from this facility in June and March 1998, respectively. We have met all market demands for the supply of MUSE utilizing this manufacturing facility and we currently have the capacity to manufacture additional units of MUSE if required.

In January 2000, VIVUS leased 14,237 square feet of space in Mountain View, California, which serves as the principal site for administration, clinical trial management, regulatory affairs and our research and development activities.

**Item 3. Legal Proceedings**

On November 3, 1999, the Company filed a demand for arbitration against Janssen Pharmaceutica International with the American Arbitration Association pursuant to the terms of the Distribution Agreement entered into on January 22, 1997. The Company sought compensation for inventory manufactured in 1998 in reliance on contractual forecasts and orders submitted by Janssen Pharmaceutica. The Company also sought compensation for forecasts and order shortfalls attributed to Janssen Pharmaceutica in 1998, pursuant to the terms of the Distribution Agreement. The Company amended its arbitration demand in August 2000 to include claims for lost profits due to Janssen Pharmaceutica’s failure to use the requisite diligence and reasonable efforts to gain regulatory approval for and launch MUSE in China. A full hearing on the merits was conducted before a three-member arbitration panel in Chicago on March 18 – 20, 2002. On July 17, 2002, an Interim Award was issued awarding the Company the purchase price of 332,880 units manufactured for Janssen and lost profits on an additional 421,704 forecasted units. The Panel denied any relief on claims related to diligence in China. The dollar value of the claim will be determined by an audit of VIVUS’ cost of goods sold by an independent accountant. Fieldwork for the audit was completed in mid-August 2002 and a final report is expected shortly. In the meantime, a Second Interim Award denied the Company interest on the amounts that will be owed, but awarded it \$231,711 for reimbursement of attorney’s fees and \$91,738 for reimbursement of costs and expenses related to the arbitration.

In the normal course of business, VIVUS receives and makes inquiries regarding patent infringement and other legal matters. We believe that we have meritorious claims and defenses and intend to pursue any such matters vigorously. We are not aware of any asserted or unasserted claims against us where the resolution would have an adverse material impact on our operations or financial position.

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

We did not submit any matters to a vote of security holders during the fourth quarter of the fiscal year ended December 31, 2002.

**PART II**

**Item 5. Market for Registrant’s Common Equity and Related Stockholder Matters**

The Company’s common stock trades publicly on the Nasdaq National Market System under the symbol “VVUS.” The following table sets forth for the periods indicated the quarterly high and low closing sales prices of the Company’s common stock as reported on the Nasdaq National Market.

		THREE MONTHS ENDED			
		MARCH 31	JUNE 30	SEPTEMBER 30	DECEMBER 31
2002					
High	\$	9.83	\$ 8.50	\$ 6.07	\$ 4.45
Low		5.10	5.76	3.40	3.21
2001					
High	\$	5.00	\$ 4.84	\$ 4.20	\$ 5.46
Low		2.75	3.10	2.96	2.89

As of February 28, 2003, there were 33,012,817 shares of outstanding common stock that were held by 4,774 shareholders of record. As of February 28, 2003, there were no outstanding shares of preferred stock. The Company has not paid any dividends since its inception and does not intend to declare or pay any dividends on its common stock in the foreseeable future. Declaration or payment of future dividends, if any, will be at the discretion of the Company’s Board of Directors after taking into account various factors, including the Company’s financial condition, operating results and current and anticipated cash needs.

## Item 6. Selected Financial Data

This section presents selected historical data of the Company. The financial statements, related notes thereto, and the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in the Form 10-K should be read carefully. The selected data is not intended to replace the financial statements.

### Selected Financial Data

(In thousands, except per share and employee data)

#### Selected Annual Financial Data

	YEAR ENDED DECEMBER 31,				
	2002	2001	2000	1999	1998
<i>Income Statement Data:</i>					
Product revenue—United States	\$ 22,982	\$ 20,764	\$ 22,474	\$ 21,168	\$ 39,041
Product revenue—International	1,387	4,041	5,200	19,996	32,658
Milestone revenue	—	—	—	8,000	3,000
Other revenue	—	—	—	3,142	—
Returns provision	(2,020)	(1,204)	(1,181)	(9,118)	—
Total revenue	22,349	23,601	26,493	43,188	74,699
Gross profit	11,142	10,668	18,427	30,819	19,083
Operating expenses:					
Research and development	13,281	12,324	4,670	7,884	16,178
Selling, general and administrative	10,556	9,314	8,655	6,332	40,477
Other restructuring (income) costs	—	—	(903)	(1,193)	44,653
Total operating expenses	23,837	21,638	12,422	13,023	101,308
Income (loss) from operations	(12,695)	(10,970)	6,005	17,796	(82,225)
Interest and other income	1,211	2,171	2,541	1,994	1,972
Income (loss) before taxes	\$ (11,484)	\$ (8,799)	\$ 8,546	\$ 19,790	\$ (80,253)
Net income (loss)	\$ (10,566)	\$ (7,070)	\$ 7,691	\$ 18,801	\$ (80,253)
Net income (loss) per diluted share	\$ (0.32)	\$ (0.22)	\$ 0.23	\$ 0.58	\$ (2.52)
Shares used in per share computation	32,907	32,572	33,428	32,507	31,876
<i>Balance Sheet Data (at year end):</i>					
Working capital	\$ 18,974	\$ 14,898	\$ 32,981	\$ 26,616	\$ 10,324
Total assets	\$ 49,681	\$ 58,574	\$ 69,174	\$ 68,760	\$ 54,108
Accumulated deficit	\$(100,934)	\$(90,368)	\$(83,298)	\$(90,989)	\$(109,790)
Stockholders' equity	\$ 34,385	\$ 43,975	\$ 50,187	\$ 41,496	\$ 21,677
<i>Other Financial Data:</i>					
Common shares outstanding	32,999	32,693	32,461	32,211	31,890
Number of employees	119	127	136	125	101

## Item 7. Management’s Discussion and Analysis of Financial Conditions and Results of Operations

### Forward Looking Statement

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



*All percentage amounts and ratios were calculated using the underlying data in thousands. Operating results for the year ended December 31, 2002, are not necessarily indicative of the results that may be expected for future fiscal years. The following discussion and analysis should be read in conjunction with our historical financial statements and the notes to those financial statements that are included in Item 8. of Part II of this Form 10-K.*

## Overview

VIVUS is a pharmaceutical company developing innovative products to improve quality of life disorders in men and women, with a focus on sexual dysfunction. We developed and market in the United States MUSE® (alprostadil) and ACTIS®, two innovations in the treatment of erectile dysfunction, and have entered into a supply agreement with Meda AB (Stockholm:MEDAa.ST) for the marketing and distribution of MUSE in all Member States of the European Union, the Baltic States, the Czech Republic, Hungary, Iceland, Norway, Poland, Switzerland and Turkey. In Canada, VIVUS has entered into a license and supply agreement with Paladin Labs, Inc. (TSE:PLB) by which Paladin Labs markets and distributes MUSE. We have ongoing research and development programs in male erectile dysfunction, female sexual dysfunction, and premature ejaculation.

During 1998, VIVUS experienced a significant decline (greater than 80%) in market demand for MUSE as a result of the introduction of Viagra® in April 1998. During the second and third quarters of 1998, we took significant steps to restructure our operations to bring our cost structure in line with current and projected revenues. As a result, VIVUS incurred a net loss of \$80 million and had negative operating cash flow of approximately \$27 million for the year ended December 31, 1998.

During 1999, we continued to align our operations more closely with our current and expected revenues. We achieved profitability for all quarters in 1999, earning \$0.58 per diluted share for the year. Cash, cash equivalents and available-for-sale securities at December 31, 1999 increased \$16.5 million from December 31, 1998 to \$40.4 million, while total liabilities decreased \$5.1 million during the same period. VIVUS was awarded five patents in the areas of female sexual dysfunction, erectile dysfunction and premature ejaculation to further build and strengthen our patent portfolio. We established a targeted sales force in the United States to support our product, MUSE, in the marketplace. A New Drug Application was filed for ALIBRA®, our second-generation product for the treatment of erectile dysfunction, with the United States Food and Drug Administration, which was subsequently withdrawn in October 2000.

During 2000, we continued to strengthen our balance sheet, increasing working capital by \$6.4 million, to enable investment in our research and development projects and to pursue targeted technology acquisitions to expand our pipeline. We filed an Investigational New Drug application and began clinical studies for ALISTA™, our product for the treatment of female sexual arousal disorder. VIVUS signed an agreement with Abbott Laboratories for the marketing of MUSE internationally, except Canada, where Paladin Labs is marketing and distributing MUSE. We were awarded several new patents for the treatment of erectile dysfunction and solidified our female sexual dysfunction intellectual property through an agreement with AndroSolutions. VIVUS also received 510(k) clearance from the United States Food and Drug Administration in December 2000, for over-the-counter (OTC) marketing of ACTIS, our adjustable constriction band used to improve erections in men with erectile dysfunction.

Significant progress was made in our development programs in 2001. Our first Phase II clinical study to evaluate the safety of and response to ALISTA was successfully completed and demonstrated a significant increase versus placebo and baseline in sexual response. We filed an Investigational New Drug application to initiate a clinical study to evaluate the safety and erectile response to oral TA-1790 in men with erectile dysfunction. A clinical trial was initiated during the fourth quarter of 2001 to evaluate the pharmacokinetics (blood levels in relation to time) with our new oral formulation of VI-0134. Prescriptions for MUSE in the United States increased by 2% in the last six months of 2001, as compared to the first six months of 2001. We withdrew our European application for ALIBRA.

Our development programs continued to advance in 2002. An expanded Phase II study designed to evaluate the safety and efficacy of ALISTA when used by women with female sexual arousal disorder at home with their partner began in the first quarter of 2002 and dosing was completed in February 2003. We completed a single dose trial to evaluate the safety of and erectile response to oral TA-1790 in men with erectile dysfunction. Clinical data from this study demonstrated that TA-1790 is capable of restoring penile function in men with erectile dysfunction. We also began pre-clinical development work on a transurethral formulation of TA-1790, alone and in combination with alprostadil, for the treatment of erectile dysfunction. During the fourth quarter of 2002, we initiated a clinical trial to evaluate the safety and efficacy of VI-0162, a proprietary, oral, on-demand treatment for premature ejaculation. With all these research programs in progress, VIVUS' cash and cash equivalents decreased by \$6.9 million during 2002. We signed an international supply agreement with Meda AB for the marketing of MUSE internationally. United States MUSE sales units increased 6.7% over 2001 levels.

## Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to product returns, doubtful accounts, income taxes, restructuring, inventories and contingencies and litigation. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements:

- **Revenue Recognition:** We recognize revenue when persuasive evidence of an arrangement exists, delivery has occurred, the sales price is fixed or determinable and collectibility is reasonably assured.
- **Product Returns:** We record reserves for anticipated returns of expired or damaged product in the United States. We follow this method since reasonably dependable estimates of product returns can be made based on historical experience and our monitoring of inventory levels in the wholesale distribution channel. Revisions in returns estimates are charged to income in the period in which the facts that give rise to the revision become known. There is no

right-of-return on product sold internationally subsequent to shipment, thus no returns reserve is needed.

- Allowance for Doubtful Accounts: We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances could be required.
- Income Taxes: We record a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized. For all periods presented, we have recorded a full valuation allowance against our net deferred tax asset. While we have considered future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for the valuation allowance, in the event we were to determine that we would be able to realize our deferred tax assets in the future in excess of our net recorded amount, an adjustment to the deferred tax asset would increase income in the period such determination was made. We have also recorded income taxes payable for estimated current tax liabilities. We monitor these estimated liabilities and adjust them as conditions warrant.
- Restructuring: In 1998, we experienced a significant restructuring and recorded restructuring related reserves for severance and employee costs, inventory obsolescence, raw material purchase commitments, property and related commitments, marketing commitments and other commitments. We monitor the adequacy of these liabilities and have made periodic adjustments as conditions have changed.
- Inventories: We record inventory reserves for estimated obsolescence or unmarketable inventory equal to the difference between the cost of inventory and the estimated market value based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required. During the quarter ended September 30, 1998, the Company established significant reserves against its inventory to align with new estimates of expected future demand for MUSE. The Company had built up its inventory level prior to and after the launch of Viagra and had not anticipated the impact that Viagra would have on the demand for MUSE. As of December 31, 2002, the remaining inventory reserve balance is \$7.2 million. This remaining balance is related to the raw materials inventory that the Company previously estimated would not be used. The Company estimates that at least some portion of the fully reserved inventory will now be used in production. To the extent that this inventory is used in production, it will be charged to cost of goods sold at a zero basis, which will have a favorable impact on gross profit.
- Contingencies and Litigation: We are periodically involved in disputes and litigation related to a variety of matters. When it is probable that we will experience a loss, and that loss is quantifiable, we record appropriate reserves. We are currently involved in a dispute with our former international distributor, for which arbitration occurred in March 2002. The ultimate outcome of this arbitration is not yet known.

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## Results of Operations

### *Years Ended December 31, 2002 and 2001*

United States product revenue for the year ended December 31, 2002 was \$23.0 million, as compared to \$20.8 million for the year ended December 31, 2001. Approximately \$724 thousand of the increase to United States revenue was attributable to a 4% price increase VIVUS implemented at the end of March 2002. The remainder of the increase was due to a 6.7% increase in the number of MUSE units sold in 2002 versus 2001.

International revenue was \$1.4 million for the year ended December 31, 2002, compared to \$4.0 million for the same period in 2001. Lower international product revenue in 2002 was due to a decrease in product demand by our previous international distributor in anticipation of the transition to our new distribution partner, Meda AB. Based on current forecasts from Meda AB, we anticipate that 2003 international product revenue will increase over 2002 levels.

In 2002 and 2001, the charge for actual and anticipated returns of product was \$2.0 million and \$1.2 million, respectively. Product return data through the first quarter of 2002 indicated an increase to the returns reserve was warranted. Approximately \$403 thousand of the returns provision recorded in 2002 reflects the required increase to the product returns liability for sales made from January 2000 through December 2001. The charge for actual and anticipated returns was increased to 7% of United States gross sales as of January 2002.

Cost of goods sold for the year ended December 31, 2002 was \$11.2 million, compared to \$12.9 million for the same period in 2001. The year-to-date 2002 figure includes a reduction in cost of goods sold of \$802 thousand as a result of settlements of previously recognized purchase commitment liabilities for our major raw material, alprostadil. Adjusting for this item, comparative gross margins for the twelve months ended December 31, 2002 versus 2001 were 46.3% and 45.2%, respectively.

Research and development expenses for the year ended December 31, 2002 were \$13.3 million, \$1.0 million higher than the same period in the previous year, which included a \$5.0 million payment to Tanabe Seiyaku for licensing the proprietary compound TA-1790. If not for this \$5.0 million expense in 2001, research and development costs in 2002 would have been \$6.0 million higher than the same period in 2001 due to increased expenditures for clinical development of our current pipeline.

Selling, general and administrative expenses for the year ended December 31, 2002 were \$10.6 million, compared to \$9.3 million in the year ended December 31, 2001. The increase is due to increased investment in United States sales and marketing efforts and legal expenses relating to the Janssen Pharmaceutica arbitration hearing that was held in mid-March 2002 and is discussed on page 21 of this report.

We recorded a tax benefit of \$918 thousand for 2002 based on an updated estimate of our net tax liabilities as well as filing for a refund of previously paid alternative minimum taxes which became available due to a 2002 tax law change. In 2001, we recorded a tax benefit of \$1.7 million based on an updated estimate of net tax liabilities.

### *Years Ended December 31, 2001 and 2000*

United States product revenue for the year ended December 31, 2001 was \$20.8 million, as compared to \$22.5 million for the year ended December 31, 2000. Although total United States revenues declined 8% from year to year due to overall lower demand for MUSE, prescriptions for MUSE in the United States increased by 2% in the last six months of 2001, as compared to the first six months of 2001.

International revenue was \$4.0 million for the year ended December 31, 2001, compared to \$5.2 million for the same period in 2000. Initial shipments of product to Abbott Laboratories to support their launch of MUSE in Europe were made in the fourth quarter of 2000.

In both 2001 and 2000, the charge for actual and anticipated returns of product was \$1.2 million, or approximately five percent of United States gross sales.

Cost of goods sold for the year ended December 31, 2001 was \$12.9 million, compared to \$8.1 million for the same period in 2000. In 2000, we determined that a portion of the inventory purchase commitment reserves recorded in 1998 was not needed. Accordingly, in 2000, we reversed \$3.1 million of reserves with a corresponding reduction in cost of goods sold. Additionally in 2000, we reversed an accrual for royalties of \$2.0 million related to shipments to our previous international distributors due to the termination of those distribution agreements. Adjusting for these two items, our comparative margins for 2001 versus 2000 would have been 45% and 50%, respectively.

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Research and development expenses for the year ended December 31, 2001 were \$12.3 million, compared to \$4.7 million in the year ended December 31, 2000. The \$7.6 million increase in 2001 was primarily due to licensing and development expenses for TA-1790 as an oral treatment for male erectile dysfunction, clinical expenses for ALISTA, our product for the treatment of female sexual arousal disorder, and development and clinical expenses for VI-0134 to treat premature ejaculation.

Selling, general and administrative expenses for the year ended December 31, 2001 were \$9.3 million, compared to \$8.7 million in the year ended December 31, 2000. We expanded our targeted United States marketing efforts during 2001, which contributed to this increase.

Operating expenses for the year ended December 31, 2000 included a reversal of \$903 thousand of restructuring reserve established in 1998 related primarily to inventory commitments and other manufacturing expenses that were not required.

We recorded a tax benefit of \$1.7 million for 2001 based on an updated estimate of our net tax liabilities. VIVUS recorded a tax provision of ten percent of net income before taxes for 2000. The effective tax rate calculation for 2000 includes the effect of net operating losses, or NOLs, carried forward from prior periods. The tax rate would have been substantially higher if the NOLs had not been available to offset current income. All deferred tax assets continue to be fully reserved.

## Liquidity and Capital Resources

Unrestricted cash, cash equivalents and available-for-sale securities totaled \$29.8 million at December 31, 2002, compared with \$36.7 million at December 31, 2001. The decrease during 2002 was primarily due to research and development expenditures for development of our current pipeline.

Since inception, we have financed operations primarily from the sale of preferred and common stock. Through December 31, 2002, VIVUS raised \$156.0 million from financing activities and had an accumulated deficit of \$100.9 million at December 31, 2002.

Total liabilities were \$15.3 million at December 31, 2002, compared with \$14.6 million at December 31, 2001, an increase of \$697 thousand. The increase in total liabilities is related to the timing of our final payment to our previous international distribution partner.

Our operating activities used \$7.6 million and \$5.8 million of cash during the years ended December 31, 2002 and 2001, respectively. In both 2002 and 2001, operating expenses, particularly research and development expenses, were higher than revenues from product sales accounting for the use of cash.

Net cash provided by investing activities was \$7.4 million during the twelve months ended December 31, 2002 and net cash used for investing activities was \$12.5 million for the same period in 2001. The fluctuations from period to period are due primarily to the timing of purchases, sales and maturity of investment securities.

Financing activities provided cash of \$913 thousand and \$640 thousand during the years ended December 31, 2002 and 2001, respectively. These amounts are primarily the proceeds from the exercise of stock options and the sale of stock under our Employee Stock Purchase Plan in both 2002 and 2001.

We anticipate that our existing capital resources combined with anticipated future cash flows will be sufficient to support our operating needs throughout the next fifteen to eighteen months. However, we anticipate that we will be required to obtain additional financing to fund the development of our research and development pipeline in future periods as well as to support the possible launch of any future products. In particular, other substantial payments will be made in accordance with the agreement for licensing TA-1790. These payments are based on certain development, regulatory and sales milestones. In addition, royalty payments would be required on any future product sales.

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

- the progress of our research and development programs;

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- the timing and results of pre-clinical testing and clinical trials;
  - results of operations;

- demand for MUSE;
- technological advances;
- the level of resources that we devote to our sales and marketing capabilities; and
- the activities of competitors.

## Recent Accounting Pronouncements

We adopted Statement of Financial Accounting Standards, or SFAS, No. 143, *Accounting for Asset Retirement Obligations*, and SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* on January 1, 2002. Adoption of these pronouncements did not impact on our net loss.

SFAS No. 148, *Accounting for Stock-Based Compensation – Transition and Disclosure*, which amends SFAS No. 123 to provide alternative methods of transition for a voluntary change to the fair value based method of stock-based employee compensation and revised disclosure requirements, was issued in December 2002. We adopted the revised disclosure requirements in the fourth quarter of 2002. Because we have not elected to expense stock-based compensation at fair value, adoption of this pronouncement did not impact on our net loss.

## Overview of Contractual Obligations

	Contractual Obligations		Payments Due by Period (in thousands)			
	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years	
Operating Leases (1)	5,552	1,292	4,140	120	—	
Purchases (2)	5,783	1,958	2,295	1,530	—	
Other Long Term Liabilities (3)	3,021	—	—	3,021	—	
<b>Total</b>	<b>14,356</b>	<b>3,250</b>	<b>6,435</b>	<b>4,671</b>	<b>—</b>	

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

(2) In November 2002, the Company entered into a manufacturing agreement to purchase raw materials from a supplier beginning in 2003 and ending in 2008. The initial commitment is to purchase approximately \$405 thousand of product in the first quarter of 2003 for testing and regulatory approval. Assuming that the product proves satisfactory, the Company will be required to purchase an additional \$1.6 million of product in 2003 and a minimum total of \$3.8 million of product from 2004 through 2008.

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

## Off Balance Sheet Financing and Related Party Transactions

VIVUS has not entered into any off-balance sheet financing arrangements and has not established any special purpose entities. VIVUS has not guaranteed any debt or commitments of other entities or entered into any options on non-financial assets. The only transaction between VIVUS and a related party during 2002 was Mario M. Rosati, one of our directors, who is also a member of Wilson Sonsini Goodrich & Rosati, Professional Corporation, which has served as our outside corporate counsel since our formation and has received compensation at normal commercial rates for these services.

## Dividend Policy

The Company has not paid any dividends since its inception and does not intend to declare or pay any dividends on its common stock in the foreseeable future. Declaration or payment of future dividends, if any, will be at the discretion of the Company's Board of Directors after taking into account various factors, including the Company's financial condition, operating results and current and anticipated cash needs.

## Item 7a. Quantitative and Qualitative Disclosures about Market Risk

The Securities and Exchange Commission's rule related to market risk disclosure requires that we describe and quantify our potential losses from market risk sensitive instruments attributable to reasonably possible market changes. Market risk sensitive instruments include all financial or commodity instruments and other financial instruments that are sensitive to future changes in interest rates, currency exchange rates, commodity prices or other market factors. VIVUS is not exposed to market risks from changes in foreign currency exchange rates or commodity prices. We do not hold derivative financial instruments nor do we hold securities for trading or speculative purposes. At December 31, 2002 and 2001, we had no debt outstanding, and consequently VIVUS currently has no risk exposure associated with increasing interest rates. VIVUS, however, is exposed to changes in interest rates on our investments in cash equivalents and available-for-sale securities. A significant portion of our investments in cash equivalents and available-for-sale securities are in money market funds that hold short-term investment grade commercial paper, treasury bills or other United States government obligations. Currently, this reduces our exposure to long-term interest rate changes.

**Item 8. Financial Statements and Supplementary Data****VIVUS, INC.****1. Index to Consolidated Financial Statements**

The following financial statements are filed as part of this Report:

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Consolidated Balance Sheets as of December 31, 2002 and 2001	34
Consolidated Statements of Operations and Other Comprehensive (Loss) Income for the years ended December 31, 2002, 2001 and 2000	35
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2002, 2001 and 2000	36
Consolidated Statements of Cash Flows for the years ended December 31, 2002, 2001 and 2000	37
Notes to Consolidated Financial Statements	38
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**Independent Auditors' Report**

The Board of Directors and Stockholders  
VIVUS, Inc.:

We have audited the accompanying consolidated balance sheet of VIVUS Inc. and subsidiaries as of December 31, 2002, and the related consolidated statements of operations and other comprehensive (loss) income, stockholders' equity, and cash flows for the year then ended. In connection with our audit of the consolidated financial statements, we also have audited the financial statement schedule as listed in Item 17(a)2. These consolidated financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and financial statement schedule based on our audit.

We conducted our audit in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of VIVUS Inc. and subsidiaries as of December 31, 2002, and the results of their operations and their cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the related financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

/s/ KPMG LLP

San Jose, California  
January 17, 2003

# REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To the Stockholders and Board of Directors of VIVUS, Inc.:

We have audited the accompanying consolidated balance sheets of VIVUS, Inc. (a Delaware corporation) and subsidiaries as of December 31, 2001 and 2000, and the related consolidated statements of operations and other comprehensive income, changes in stockholders' equity and cash flows for each of the three years in the period ended December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of VIVUS, Inc. and subsidiaries as of December 31, 2001 and 2000, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

Our audits were made for the purpose of forming an opinion on the basic consolidated financial statements taken as a whole. The schedule listed under Schedule II is presented for the purpose of complying with the Securities and Exchange Commission's rules and is not part of the basic consolidated financial statements. This schedule has been subjected to the auditing procedures applied in our audits of the basic consolidated financial statements and, in our opinion, fairly states in all material respects the financial data required to be set forth therein in relation to the basic consolidated financial statements taken as a whole.

/s/ ARTHUR ANDERSEN LLP

San Jose, California  
January 17, 2002

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## VIVUS, INC.

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

#### ASSETS

	DECEMBER 31,	
	2002	2001
Current assets:		
Cash and cash equivalents	\$ 12,296	\$ 11,545
Available-for-sale securities	11,206	7,835
Accounts receivable (net of allowance for doubtful accounts of \$145 and \$232 at December 31, 2002 and 2001, respectively)	3,592	2,314
Inventories, net	1,358	3,100
Prepaid expenses and other assets	1,497	780
Total current assets	29,949	25,574
Property and equipment, net	10,084	12,378
Restricted cash	3,324	3,324
Available-for-sale securities, non-current	6,324	17,298
Total assets	\$ 49,681	\$ 58,574

#### LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable	\$ 1,866	\$ 1,241
Accrued and other liabilities	9,109	9,435
Total current liabilities	10,975	10,676
Accrued and other long-term liabilities	4,321	3,923
Total liabilities	15,296	14,599
Stockholders' equity:		
Common stock; \$.001 par value; shares authorized— 200,000 at December 31, 2002 and 2001; shares issued and outstanding— December 31,		

2002, 32,999 December 31, 2001, 32,693	33	33
Additional paid-in capital	135,005	133,988
Accumulated other comprehensive income	281	322
	<hr/>	<hr/>
Accumulated deficit	(100,934)	(90,368)
Total stockholders' equity	34,385	43,975
	<hr/>	<hr/>
Total liabilities and stockholders' equity	\$ 49,681	\$ 58,574
	<hr/>	<hr/>

See accompanying notes to consolidated financial statements.

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## VIVUS, INC.

### CONSOLIDATED STATEMENTS OF OPERATIONS AND OTHER COMPREHENSIVE (LOSS) INCOME (In thousands, except per share data)

	YEAR ENDED DECEMBER 31,		
	2002	2001	2000
	<hr/>	<hr/>	<hr/>
Revenue			
United States product	\$ 22,982	\$ 20,764	\$ 22,474
International product	1,387	4,041	5,200
Returns provision	(2,020)	(1,204)	(1,181)
	<hr/>	<hr/>	<hr/>
Total revenue	22,349	23,601	26,493
Cost of goods sold	11,207	12,933	8,066
	<hr/>	<hr/>	<hr/>
Gross profit	11,142	10,668	18,427
	<hr/>	<hr/>	<hr/>
Operating expenses:			
Research and development	13,281	12,324	4,670
Selling, general and administrative	10,556	9,314	8,655
Other restructuring costs (income)	--	--	(903)
	<hr/>	<hr/>	<hr/>
Total operating expenses	23,837	21,638	12,422
	<hr/>	<hr/>	<hr/>
(Loss) income from operations	(12,695)	(10,970)	6,005
Interest and other income:			
Interest income	1,312	2,092	2,601
Gain (loss) on disposal of property and equipment	(134)	87	(32)
Foreign exchange gain (loss)	33	(8)	(28)
	<hr/>	<hr/>	<hr/>
(Loss) income before provision for income taxes	(11,484)	(8,799)	8,546
Benefit (provision) for income taxes	918	1,729	(855)
	<hr/>	<hr/>	<hr/>
Net (loss) income	\$ (10,566)	\$ (7,070)	\$ 7,691
	<hr/>	<hr/>	<hr/>
Other comprehensive (loss) income:			
Unrealized gain (loss) on securities, net of taxes	(41)	157	355
Income tax benefit (provision)	--	--	(36)
	<hr/>	<hr/>	<hr/>
Comprehensive (loss) income	\$ (10,607)	\$ (6,913)	\$ 8,010
	<hr/>	<hr/>	<hr/>
Net (loss) income per share:			
Basic	\$ (0.32)	\$ (0.22)	\$ 0.24
Diluted	\$ (0.32)	\$ (0.22)	\$ 0.23
Shares used in per share computation:			
Basic	32,907	32,572	32,328
Diluted	32,907	32,572	33,428

See accompanying notes to consolidated financial statements.

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**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
(In thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total
	Shares	Amount				
Balances, December 31, 1999	32,211	32	132,643	(190)	(90,989)	41,496
Sale of common stock through employee stock purchase plan	117		276			276
Exercise of common stock options for cash	133		369			369
Change in unrealized gain on securities				355		355
Net income					7,691	7,691
Balances, December 31, 2000	32,461	32	133,288	165	(83,298)	50,187
Sale of common stock through employee stock purchase plan	117	1	319			320
Exercise of common stock options for cash	115		320			320
Stock compensation costs			61			61
Change in unrealized gain on securities				157		157
Net loss					(7,070)	(7,070)
Balances, December 31, 2001	32,693	33	133,988	322	(90,368)	43,975
Sale of common stock through employee stock purchase plan	106		289			289
Exercise of common stock options for cash	200		624			624
Stock compensation costs			104			104
Change in unrealized (loss) on securities				(41)		(41)
Net loss					(10,566)	(10,566)
Balances, December 31, 2002	32,999	33	\$135,005	\$ 281	\$(100,934)	\$ 34,385

See accompanying notes to consolidated financial statements.

**VIVUS, INC.**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)

	Year Ended December 31,		
	2002	2001	2000
<b>Cash flows from operating activities:</b>			
Net (loss) income	\$(10,566)	\$ (7,070)	\$ 7,691
Adjustments to reconcile net (loss) income to net cash (used for) provided by operating activities:			
Provision for doubtful accounts	(87)	(72)	157
Depreciation and amortization	2,288	2,252	2,379
Stock compensation costs	104	61	—
(Gain) loss on disposal of property and equipment	134	(87)	32
Changes in assets and liabilities:			
Accounts receivable	(1,191)	1,192	841
Inventories	1,742	1,945	(1,518)
Prepaid expenses and other assets	(717)	363	3,195
Accounts payable	625	(534)	(678)
Accrued and other liabilities	72	(3,854)	(7,599)
Net cash (used for) provided by operating activities	(7,596)	(5,804)	4,500
<b>Cash flows from investing activities:</b>			
Property and equipment purchases	(169)	(336)	(691)
Proceeds from sale of property and equipment	41	87	57
Investment purchases	(10,567)	(34,958)	(120,941)
Proceeds from sale/maturity of securities	18,129	22,680	140,205
Investment in restricted certificate of deposit	—	—	(3,324)
Net cash (used for) provided by investing activities	7,434	(12,527)	15,306



<b>Cash flows from financing activities:</b>			
Sale of common stock through employee stock purchase plan	289	320	276
Exercise of common stock options	624	320	369
	<u>          </u>	<u>          </u>	<u>          </u>
Net cash provided by financing activities	913	640	645
	<u>          </u>	<u>          </u>	<u>          </u>
<b>Net increase (decrease) in cash</b>	751	(17,691)	20,451
<b>Cash:</b>			
Beginning of year	11,545	29,236	8,785
	<u>          </u>	<u>          </u>	<u>          </u>
End of year	\$ 12,296	\$ 11,545	\$ 29,236
	<u>          </u>	<u>          </u>	<u>          </u>
<b>Non-cash investing and financing activities:</b>			
Unrealized gain (loss) on securities	\$ (41)	\$ 157	\$ 355
<b>Supplemental cash flow disclosure:</b>			
Income taxes (received) paid	\$ (6)	\$ (342)	\$ 532

See accompanying notes to consolidated financial statements.

## VIVUS, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### Note 1. Business and Significant Accounting Policies

##### Business

VIVUS, Inc. was incorporated in 1991. The Company's objective is to become a global leader in the development and commercialization of innovative therapies for the treatment of sexual dysfunction and other genitourinary disorders in men and women.

The Company obtained clearance from the United States Food and Drug Administration to manufacture and market MUSE, a transurethral applicator used for treating erectile dysfunction, in the United States in November 1996. The Medicines Control Agency approved MUSE for marketing in the United Kingdom in November 1997. MUSE has been approved in more than 40 countries around the globe.

During 1998, the Company experienced a significant decline in market demand for MUSE as the result of the introduction of Viagra® in April 1998. During the second and third quarters of 1998, the Company took significant steps to restructure its operation in an attempt to bring the cost structure in line with current and projected revenues. At December 31, 2002, the Company's accumulated deficit was approximately \$100.9 million.

The Company primarily sells its products through wholesale channels in the United States. International sales are made only to the Company's international distributors. All transactions are denominated in United States dollars and the Company operates in a single segment reporting to the chief executive officer, based on the criteria of Statement of Financial Accounting Standards, or SFAS, No. 131, *Disclosures about Segments of an Enterprise and Related Information*.

##### Significant Accounting Policies

###### *Principles of Consolidation*

The consolidated financial statements include the accounts of VIVUS, Inc., VIVUS International Limited, a wholly owned subsidiary, and VIVUS Ireland Limited, VIVUS UK Limited and VIVUS BV Limited, wholly owned subsidiaries of VIVUS International Limited. All significant inter-company transactions and balances have been eliminated in consolidation.

###### *Use of Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

###### *Cash and Cash Equivalents*

The Company considers all highly liquid investments purchased with an original maturity of 90 days or less to be cash equivalents.

###### *Available-for-Sale Securities*

Available-for-sale securities represent investments in debt securities that are stated at fair value. The difference between amortized cost (cost adjusted for amortization of premiums and accretion of discounts which are recognized as adjustments to interest income) and fair value, representing unrealized holding gains or losses, are recorded in "Accumulated Other Comprehensive (Loss) Income," a separate component of stockholders' equity until realized. The change in unrealized gains (losses) on investments included in accumulated other comprehensive (loss) income for 2002, 2001 and 2000, in thousands, are \$(41), \$157, and \$355, respectively.

The Company's policy is to record investments in debt securities as available-for-sale because the sale of such securities may be required prior to maturity. Any gains and losses on the sale of debt securities are determined on a specific identification basis and are included in interest and other income in the accompanying consolidated statements of operations. Available-for-sale securities with maturities beyond one year from the balance sheet date are classified as non-current.

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### *Inventories*

Inventories are stated at the lower of cost (first-in, first-out basis) or market and consist of raw materials, work in process and finished goods. Cost includes material and conversion costs.

During the quarter ended September 30, 1998, the Company established significant reserves against its inventory to align with new estimates of expected future demand for MUSE. The Company had built up its inventory level prior to and after the launch of Viagra and had not anticipated the impact that Viagra would have on the demand for MUSE. The Company had anticipated sales to ultimately increase as a result of an expanding market for impotence products. Given the decline in demand for MUSE, in 1998 the Company recorded reserves of \$16.0 million related to excess raw materials and future inventory purchase commitments for raw materials.

As of December 31, 2002, the remaining inventory reserve balance is \$7.2 million. This remaining balance is related to the raw materials inventory that the Company previously estimated would not be used.

The Company estimates that at least some portion of the fully reserved inventory will now be used in production. In 2002, the Company used \$163 thousand of its fully reserved raw materials inventory and expects to continue to use the fully reserved raw materials in future periods. The fully reserved raw materials are charged to cost of goods sold at a zero basis when used, which has a favorable impact on gross profit.

### *Prepaid Expenses and Other Assets*

Prepaid expenses and other assets generally consist of deposits and prepayments for future services. Prepayments are expensed when the services are received.

### *Property and Equipment*

Property and equipment is stated at cost and includes machinery and equipment, computers and software, furniture and fixtures and building improvements. For financial reporting, depreciation and amortization are computed using the straight-line method over estimated useful lives of two to seven years. Leasehold improvements are amortized using the straight-line method over the lesser of the estimated useful lives or remaining lease term. Expenditures for repairs and maintenance, which do not extend the useful life of the property and equipment, are expensed as incurred. Upon retirement, the asset cost and related accumulated depreciation are relieved from the accompanying consolidated financial statements. Gains and losses associated with dispositions or impairment of equipment, vehicles and leasehold improvements are reflected as a component of other income, net in the accompanying consolidated statements of operations.

In accordance with SFAS No. 144, long-lived assets, such as property, plant and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of the asset exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset. Assets to be disposed of would be separately presented in the balance sheet and reported at the lower of the carrying amount or fair value less costs to sell, and are no longer depreciated. The assets and liabilities of a disposed group classified as held for sale would be presented separately in the appropriate asset and liability sections of the balance sheet.

Prior to the adoption of SFAS No. 144, the Company accounted for long-lived assets in accordance with SFAS No. 121, *Accounting for Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of*.

### *Restricted Cash*

The Company issued an irrevocable standby letter of credit for \$3.3 million during the fourth quarter of 2000, in connection with its leased manufacturing facilities. The Company purchased a certificate of deposit as collateral for this letter of credit, which is restricted and not available for use in operations, and is presented accordingly as restricted cash in the non-current asset section of the accompanying consolidated balance sheets. This restriction will remain through the end of the lease term, including any renewals. The Company has exercised its first option to renew the original lease, thereby extending its commitment to 2007. The second renewal term, if exercised, would then extend the lease for an additional five years, to 2012.

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### *Revenue Recognition*

The Company recognizes revenue when persuasive evidence of an arrangement exists, delivery has occurred, the sales price is fixed or determinable and collectibility is reasonably assured. Generally, these criteria are met at the time the product is shipped.

### *United States*

The Company primarily sells its products through the wholesale channel in the United States. Product sales are recorded upon shipment net of reserves for returns and allowances. The reserve for product returns is derived by reviewing the history of product returns. The reserves are reviewed at each reporting period and adjusted to reflect data available at that time. Any changes in the reserve will result in changes in the amount of product sales revenue recognized in the period.

### *International*

The Company invoices its international distributors based on an agreed transfer price per unit, which is subject to revision based on contractual formulas upon quarterly reconciliations. Final pricing for product shipments to international distributors is subject to contractual formulas based on the distributor's net realized price to their customers. At the time of shipment, the Company recognizes revenue at the lowest possible price in accordance with contractual formulas and recognizes additional revenue, if any, upon finalization of pricing with its international distributors. As of December 31, 2002, the Company had recorded deferred revenue of \$1.5 million representing amounts billed and received in excess of revenue recognized. The Company also recorded \$1.5 million of unearned revenue related to the international supply agreement signed with Meda AB in September 2002. This amount is being recognized as income ratably over the term of the supply agreement.

#### Stock Option Plans

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

	2002	2001	2000
Net income, as reported	\$ (10,566)	\$ (7,070)	\$ 7,691
Deduct total stock-based employee compensation expense determined under fair-value-based method for all rewards, net of tax	(1,820)	(916)	(1,182)
Pro forma net (loss) income	\$ (12,386)	\$ (7,986)	\$ 6,509
Pro forma net (loss) income per share:			
Basic	\$ (0.38)	\$ (0.25)	\$ 0.20
Diluted	\$ (0.38)	\$ (0.25)	\$ 0.19

The weighted-average fair value of options granted in 2002, 2001 and 2000 was \$5.64, \$2.10 and \$2.01, respectively.

The fair value of each option grant is estimated on the date of grant using the Black Scholes option-pricing model with the following weighted-average assumptions used for grants in 2002, 2001 and 2000: no dividend yield, expected volatility of 75%, 86% and 55%, respectively, risk-free interest rates of between 2% to 6%, 3% to 5% and 5% to 6%, respectively and an expected life of 5 years for all years.

#### Income Taxes

Income taxes are accounted for under the asset and liability method. The realization of deferred tax assets and liabilities is based on historical tax positions and expectations about future taxable income. Deferred income tax assets and liabilities are computed for differences between the financial statement carrying amount and tax basis of assets and liabilities based on enacted tax laws and rates applicable to the period in which differences are expected to be recovered or settled. Valuation allowances are established, when necessary, to reduce deferred tax assets to amounts that are more likely than not to be realized.

#### License Agreements

The Company has obtained rights to patented technologies under several licensing agreements. Non-refundable licensing payments made on technologies that are yet to be proven are expensed to research and development. Royalties paid associated with existing products are expensed to cost of goods sold when the liability is generated upon sale of product.

#### Net (Loss) Income Per Share

Basic (loss) earnings per share, or EPS, is computed using the weighted average number of common shares outstanding during the periods. Diluted EPS is based on the weighted average number of common and common equivalent shares, which represent shares that may be issued in the future upon the exercise of outstanding stock options under the treasury stock method. The computation of basic and diluted EPS for the years ended December 31, 2002, 2001 and 2000 are as follows:

	2002	2001	2000
	(In thousands, except per share data)		
Net (loss) income	\$(10,566)	\$ (7,070)	\$ 7,691
Net (loss) income per share — basic	\$ (.32)	\$ (.22)	\$ .24
Effect of dilutive securities (stock options)	—	—	(.01)
Net (loss) income per share — diluted	\$ (.32)	\$ (.22)	\$ .23
Shares used in the computation of net income (loss) per share — basic	32,907	32,572	32,328
Effect of dilutive securities (stock options)	—	—	1,100

Options outstanding of 1,153,276 and 589,655 at December 31, 2002 and 2001, respectively, are excluded from the computation of diluted EPS for 2002 and 2001 because the effect would have been antidilutive. Options to purchase 290,041 shares at prices ranging from \$5.81 to \$25.88, which were outstanding at December 31, 2000, are not included in the computation of diluted EPS for 2000 because the exercise price of the options were greater than the average market price of common shares and the effect, therefore, would have been antidilutive.

#### Recent Pronouncements

We adopted SFAS No. 143, *Accounting for Asset Retirement Obligations*, and SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, on January 1, 2002. Adoption of these pronouncements did not impact on our net loss.

SFAS No. 148, *Accounting for Stock-Based Compensation – Transition and Disclosure*, which amends SFAS No. 123 to provide alternative methods of transition for a voluntary change to the fair value based method of stock-based employee compensation and revised disclosure requirements, was issued in December 2002. We adopted the revised disclosure requirements in the fourth quarter of 2002. Because we have not elected to expense stock-based compensation at fair value, adoption of this pronouncement did not impact on our net loss.

#### Note 2. Available-for-Sale Securities

The fair value and the amortized cost of available-for-sale securities at December 31, 2002 and 2001 are presented in the table that follows. Fair values are based on quoted market prices obtained from an independent broker. For each category of investment securities, the table presents gross unrealized holding gains and losses.

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As of December 31, 2002 (in thousands):

	Amortized Cost	Fair Market Value	Unrealized Holding Gains	Unrealized Holding Losses
United States government securities	\$ 11,051	\$ 11,275	\$ 224	\$ —
Corporate debt	6,198	6,255	58	(1)
Total	17,249	17,530	282	(1)
Amount classified as short-term	(11,101)	(11,206)	(106)	(1)
Amount classified as long-term	\$ 6,148	\$ 6,324	\$ 176	\$ (0)

As of December 31, 2001 (in thousands):

	Amortized Cost	Fair Market Value	Unrealized Holding Gains	Unrealized Holding Losses
United States government securities	\$ 12,168	\$ 12,329	\$ 169	\$ (8)
Corporate debt	12,643	12,804	170	(9)
Total	24,811	25,133	339	(17)
Amount classified as short-term	(7,750)	(7,835)	(93)	8
Amount classified as long-term	\$ 17,061	\$ 17,298	\$ 246	\$ (9)

Maturity dates for long-term investments range from March 2004 through January 2005.

#### Note 3. Inventories

Inventories are recorded net of reserves of \$7.2 million and \$7.5 million as of December 31, 2002 and 2001, respectively, and consist of (in thousands):

	2002	2001
Raw materials	\$ 393	\$ 1,845
Work in process	32	44
Finished goods	933	1,211
Inventory, net	\$ 1,358	\$ 3,100

As noted above, the Company has recorded significant reserves against the carrying value of its inventories. The reserves relate primarily to raw materials inventory that the Company previously estimated would not be used. The Company estimates that at least some portion of the fully reserved inventory will now be used in production. In 2002, the Company used \$163 thousand of its fully reserved raw materials inventory and expects to continue to use the fully reserved

raw materials inventory in future periods. Fully reserved raw materials are charged to cost of goods sold at a zero basis when used, which has a favorable impact on gross profit.

#### Note 4. Property and Equipment

Property and equipment as of December 31, 2002 and 2001, respectively, consist of (in thousands):

	<u>2002</u>	<u>2001</u>
Machinery and equipment	\$ 18,144	\$ 19,125
Computers and software	2,414	4,266
Furniture and fixtures	1,249	2,257
Building improvements	11,916	11,855
	<u>33,723</u>	<u>37,503</u>
Accumulated depreciation and amortization	(23,639)	(25,125)
	<u>\$ 10,084</u>	<u>\$ 12,378</u>

For the years ended December 31, 2002, 2001 and 2000, depreciation expense was \$2,288, \$2,252 and \$2,379, respectively.

#### Note 5. Accrued and Other Liabilities

Accrued and other liabilities as of December 31, 2002 and 2001, respectively, consist of (in thousands):

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	<u>2002</u>	<u>2001</u>
Short-term accrued and other liabilities		
Product returns	\$ 2,280	\$ 1,523
Income taxes	1,554	1,952
Research and clinical expenses	1,363	1,118
Royalties	539	473
Deferred revenue	1,644	2,151
Employee compensation and benefits	1,129	1,485
Other	600	733
	<u>\$ 9,109</u>	<u>\$ 9,435</u>

	<u>2002</u>	<u>2001</u>
Long-term accrued and other liabilities		
Restructuring	\$ 3,021	\$ 3,923
Deferred revenue	1,300	--
	<u>\$ 4,321</u>	<u>\$ 3,923</u>

#### Note 6. Restructuring and Related Charges

During the second quarter of 1998, the Company recorded restructuring and related costs of \$6.5 million. The charge included costs of \$3.2 million resulting from the termination of certain marketing and promotional programs, a provision of \$2.3 million for reductions in the Company's workforce that included severance compensation and benefit costs, and \$1.0 million in write-downs of fixed assets.

During the third quarter of 1998, the Company took additional steps to restructure its operations and recorded \$54.2 million of costs and write-downs in accordance with Emerging Issues Task Force, or EITF, 94-3. These charges included a \$16.0 million write-down of inventory, primarily raw materials and commitments to buy raw materials, a \$32.2 million write-down in property, and \$6.0 million of other restructuring costs primarily related to personnel costs and operating lease commitments. The property write-downs were calculated in accordance with the provisions of SFAS No. 121 and represent the excess of the carrying value of property and equipment, primarily the Company's New Jersey manufacturing leaseholds and equipment, over the projected future discounted cash flows for the Company.

In 2000 the Company reversed \$903 thousand of the restructuring reserve related primarily to inventory commitments and other manufacturing expenses that were not required. The remainder of the activity in 2000 related to payments made against the reserve.

All activity in 2001 was related to payments made against the reserve.

In 2002, the Company paid \$100 thousand and reversed \$508 thousand of the restructuring reserve related to inventory purchase commitments that were not required based on the outcome of negotiations with a supplier. The Company also reversed \$294 thousand of the restructuring reserve as a result of settlements of

Restructuring and related charges in fiscal 2002, 2001 and 2000 (in thousands):

	Severance and Employee Costs	Inventory and Related Commitments	Property and Related Commitments	Marketing Commitments	Other	Total
Balance at December 31, 1999	300	4,005	3,880	0	0	8,185
Activity in 2000	(300)	(3,063)	(556)	—	—	(3,919)
Balance at December 31, 2000	0	942	3,324	0	0	4,266
Activity in 2001	—	(40)	(303)	—	—	(343)
Balance at December 31, 2001	0	902	3,021	0	0	3,923
Activity in 2002	—	(902)	—	—	—	(902)
Balance at December 31, 2002	\$ 0	\$ 0	\$ 3,021	\$ 0	\$ 0	\$ 3,021

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

## Note 7. Stockholders' Equity

### Common Stock

The Company is authorized to issue 200 million shares of common stock. As of December 31, 2002 and 2001, there were 32,999,167 and 32,693,205 shares, respectively, issued and outstanding.

### Preferred Stock

The Company is authorized to issue 5,000,000 shares of undesignated preferred stock with a par value of \$1.00 per share. As of December 31, 2002 and 2001, there are no preferred shares issued or outstanding. The Company may issue shares of preferred stock in the future, without stockholder approval, upon such terms as the Company's management and Board of Directors may determine.

## Note 8. Stock Option and Purchase Plans

### Stock Option Plan

Under the 2001 Stock Option Plan, or the 2001 Plan, which was approved by the stockholders at the annual meeting held on June 5, 2002, the Company may grant incentive or non-statutory stock options or stock purchase rights, or SPRs. The maximum aggregate number of shares that may be optioned and sold under the Plan is 1,000,000 shares plus (a) any shares that have been reserved but not issued under the Company's 1991 Incentive Stock Option Plan, or the 1991 Plan; (b) any shares returned to the 1991 Plan as a result of termination of options or repurchase of shares issued under the 1991 Plan; and (c) an annual increase to be added on the first day of the Company's fiscal year beginning 2003, equal to the lesser of (i) 1,000,000 shares, (ii) 2.5% of the outstanding shares on such date, or (iii) a lesser amount determined by the Board. The 2001 Plan allows the Company to grant incentive stock options to employees at not less than 100% of the fair market value of the stock (110% of fair market value for individuals who control more than 10% of the Company stock) at the date of grant, as determined by the Board of Directors. The 2001 Plan allows the Company to grant non-statutory stock options to employees, directors and consultants at a price to be determined by the Board of Directors. The term of the option is determined by the Board of Directors on the date of grant but shall not be longer than ten years. The 2001 Plan allows the Company to grant SPRs to employees and consultants. Sales of stock under SPRs are made pursuant to restricted stock purchase agreements containing provisions established by the Board of Directors. The Company has a right, but not the obligation, to repurchase the shares at the original sale price, which expires at a rate to be determined by the Board of Directors. As of December 31, 2002, no SPRs have been granted under the 2001 Plan.

Under the 2001 Plan, non-employee directors will receive an option to purchase 32,000 shares of common stock when they join the Board of Directors. These options vest 25% after one year and 25% annually thereafter. Each non-employee director shall automatically receive an option to purchase 8,000 shares of the Company's common stock annually upon their reelection and these options are fully exercisable ratably over eight months. Non-employee directors are also eligible to receive additional stock option grants.

2,278,874 shares expired under the 1991 Plan and were transferred to the 2001 Plan upon stockholder approval in June 2002, and 26,884 shares were returned to the 1991 Plan as a result of termination of options and were subsequently transferred to the 2001 Stock Option Plan. In addition, 185,000 shares from the 1994 Director Option Plan were also transferred to the 2001 Plan in June 2002.

Details of option activity under these plans are as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding, December 31, 1999	2,944,276	\$ 3.52

Granted	579,660	4.90
Exercised	(133,166)	2.77
Cancelled	(155,815)	3.19
Outstanding, December 31, 2000	3,234,955	\$ 3.81
Granted	527,961	3.84
Exercised	(115,181)	2.78
Cancelled	(201,836)	7.57
Outstanding, December 31, 2001	3,445,899	\$ 3.63
Granted	503,645	7.59
Exercised	(200,240)	3.12
Cancelled	(77,429)	5.03
Outstanding, December 31, 2002	3,671,875	\$ 4.16

Options Outstanding		Options Exercisable			
Range of Exercise Prices	Number Outstanding at December 31, 2001	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable December 31, 2002	Weighted-Average Exercise Price
\$0.24 — \$2.94	1,405,016	3.9 years	\$2.40	1,387,993	\$2.40
\$3.13 — \$4.50	1,273,855	5.9 years	\$4.11	932,578	\$4.21
\$4.84 — \$8.08	993,004	7.0 years	\$6.74	457,317	\$5.87
\$0.24 — \$8.08	3,671,875	5.4 years	\$4.16	2,777,888	\$3.58

At December 31, 2002, 3,007,928 options remain available for grant.

During 2002, options to purchase 15,000 shares of common stock were granted to research consultants. The fair value of each grant option was estimated on the date of grant using the Black Scholes option-pricing model with the following assumptions: no dividend yield, expected volatility of 86%, risk-free interest rate of 3.84% and an expected life of 10 years.

As permitted under SFAS No. 123, *Accounting for Stock-Based Compensation*, the Company accounts for these plans under APB Opinion No. 25. Except for compensation as discussed above, no compensation cost has been recognized because the exercise price equals the market value of stock on the date of grant. Options under these plans generally vest over four years, and all options expire after ten years.

#### Stock Purchase Plan

Under the 1994 Employee Stock Purchase Plan, or the Stock Purchase Plan, the Company reserved 800,000 shares of common stock for issuance to employees pursuant to the Stock Purchase Plan, under which eligible employees may authorize payroll deductions of up to 10% of their base compensation (as defined) to purchase common stock at a price equal to 85% of the lower of the fair market value as of the beginning or the end of the offering period. As of December 31, 2002, 609,184 shares have been issued to employees and there are 190,816 available for issuance under the Stock Purchase Plan. During 2002, the weighted average fair market value of shares issued under the Stock Purchase Plan was \$2.76 per share.

#### Note 9. License Agreements

In January 2001, the Company entered into a licensing agreement for a proprietary phosphodiesterase type 5 (PDE5) inhibitor for the oral and local treatment of male and female sexual dysfunction. Up-front, non-refundable payments totaling \$5 million were made and expensed to research and development upon execution of this agreement. Other substantial payments are required to be made based on certain development, regulatory and sales milestones. No payments were made in 2002, as the Company did not reach the next development stage based on the agreement. In addition, royalty payments would be required on any future product sales.

The Company has entered into several agreements to license patented technologies that are essential to the development and production of the Company's transurethral products for the treatment of erectile dysfunction. These agreements generally required milestone payments during the development period. In connection with these agreements, the Company is obligated to pay royalties on product sales covered by the license agreements (4% of United States and Canadian product sales and 3% of sales elsewhere in the world). In 2000, 2001 and 2002, the Company recorded royalty expenses, in thousands, of (\$783), \$959, and \$978, respectively, as cost of goods sold based on product sales. The Company reversed \$2.0 million of accrued royalties in 2000 related to shipments to its previous international distributors due to the termination of those distribution agreements.

#### Note 10. Commitments

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

Future minimum lease payments under operating leases are as follows (in thousands):

2003	1,292
2004	1,330
2005	1,379
2006	1,431
2007	120
	\$ 5,552

Rent expense, in thousands, under operating leases totaled \$1,342, \$1,263, and \$1,235 for the years ended December 31, 2002, 2001, 2000, respectively.

In November 2002, the Company entered into a manufacturing agreement to purchase raw materials from a supplier beginning in 2003 and ending in 2008. The initial commitment is to purchase approximately \$405 thousand of product in the first quarter of 2003 for testing and regulatory approval. Assuming that the product proves satisfactory, the Company will be required to purchase an additional \$1.6 million of product in 2003 and a minimum total of \$3.8 million of product from 2004 through 2008.

#### Note 11. Income Taxes

Deferred income taxes result from differences in the recognition of expenses for tax and financial reporting purposes, as well as operating loss and tax credit carry forwards. Significant components of the Company's deferred income tax assets as of December 31, are as follows (in thousands):

	2002	2001
Deferred tax assets:		
Net operating loss carry forwards	\$ 18,717	\$ 15,451
Research and development credit carry forwards	5,649	5,044
Inventory reserve	2,775	2,854
Accruals and other	3,968	3,577
Depreciation	1,134	1,885
	32,243	28,811
Valuation allowance	(32,243)	(28,811)
	\$ —	\$ —

For federal and California income tax reporting purposes, respective net operating loss, or NOL, carry forwards of approximately \$52.9 million and \$5.4 million are available to reduce further taxable income, if any. For federal and California income tax reporting purposes, respective credit carry forwards of approximately \$3.8 million and \$2.8 million are available to reduce future taxable income, if any. The carry forwards, except for the California research and development credit, expire on various dates through 2022. The Internal Revenue Code of 1986, as amended, contains provisions that may limit the net operating loss and credit carry forwards available for use in any given period upon the occurrence of certain events, including a significant change in ownership interest.

A valuation allowance has been recorded for the entire deferred tax asset as a result of uncertainties regarding the realization of the asset balance due to the history of losses and the variability of operating results. The net change in the valuation allowance from December 31, 2001 to December 31, 2002 was \$3.4 million. As of December 31, 2002 and 2001, the Company had no significant deferred tax liabilities.

The (benefit)/provision for income taxes attributable to continuing operations is based upon (loss)/income before (benefit)/provision for income taxes as follows, for the years ended December 31, 2002, 2001 and 2000:

	2002	2001	2000
(Loss) income before income taxes:			
Domestic	\$ (6,386)	\$ (3,751)	\$ 9,374
International	(5,098)	(5,048)	(828)
	\$ (11,484)	\$ (8,799)	\$ 8,546

The (benefit)/provision for income taxes consists of the following components for the years ended December 31, 2002, 2001 and 2000:

	2002	2001	2000
Current			
Federal	\$ (842)	\$ (1,681)	\$ 805
State	(85)	(59)	40
Foreign	9	11	10



Total (benefit)/provision for income taxes \$ (918)    \$ (1,729)    \$ 855

The (benefit)/provision for income taxes differs from the amount computed by applying the statutory federal income tax rates as follows, for the years ended December 31, 2002, 2001 and 2000:

	2002	2001	2000
(Benefit) provision computed at federal statutory rates	(35)%	(35)%	35%
State income taxes, net of federal tax effect	(3)	(3)	6
Net operating losses utilized	—	—	(36)
Tax credits	(5)	(2)	(5)
Change in valuation allowance	30	12	5
Loss/(income) not subject to federal and state taxation	17	22	4
Refund of taxes	(5)	—	—
Adjustment of income tax payable	(3)	(14)	—
Other	(4)	—	1
(Benefit)/provision for income taxes	(8)%	(20)%	10%

The 2002 tax benefit relates primarily to a filing for a refund of previously paid alternative minimum taxes which became available due to a 2002 tax law change, as well as an updated estimate of net tax liabilities. The 2001 tax benefit was based on an updated estimate of net tax liabilities.

#### Note 12. Concentration of Customers and Suppliers

Sales to significant customers as a percentage of total revenues are as follows:

	2002	2001	2000
Customer A	30%	19%	15%
Customer B	20%	17%	17%
Customer C	17%	24%	18%
Customer D	17%	12%	10%
Customer E	5%	8%	6%

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Accounts receivable by significant customer as a percentage of the total gross accounts receivable balance are as follows:

	2002	2001
Customer A	43%	24%
Customer B	15%	21%
Customer C	14%	29%
Customer D	14%	11%
Customer E	11%	9%

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

#### Note 13. 401(k) Plan

All of the Company's employees are eligible to participate in the VIVUS 401(k) Plan. Employer-matching contributions for the year ended December 31, 2002, 2001 and 2000, in thousands, were \$246, \$240, and \$97, respectively. The employer-matching portion of the 401(k) plan began on July 1, 2000.

#### Note 14. Selected Financial Data

Selected Quarterly Financial Data (unaudited)

	Quarter Ended,			
	March 31	June 30	September 30	December 31
2002				
Net sales	\$ 6,383	\$ 4,547	\$ 3,530	\$ 7,889
Gross profit	\$ 3,029	\$ 2,997	\$ 1,238	\$ 3,878
Net income (loss)	\$ (1,857)	\$ (3,341)	\$ (3,722)	\$ (1,646)
Net income (loss) per share:				
Basic	\$ (0.06)	\$ (0.10)	\$ (0.11)	\$ (0.05)
Diluted	\$ (0.06)	\$ (0.10)	\$ (0.11)	\$ (0.05)
2001				
Net sales	\$ 6,359	\$ 6,370	\$ 5,553	\$ 5,319
Gross profit	\$ 2,726	\$ 3,206	\$ 2,267	\$ 2,469
Net income (loss)	\$ (4,884)	\$ (914)	\$ (1,122)	\$ (150)

Net income (loss) per share:

Basic	\$ (0.15)	\$ (0.03)	\$ (0.03)	\$ (0.00)
Diluted	\$ (0.15)	\$ (0.03)	\$ (0.03)	\$ (0.00)

#### Note 15. Legal Matters

On November 3, 1999, the Company filed a demand for arbitration against Janssen Pharmaceutica International with the American Arbitration Association pursuant to the terms of the Distribution Agreement entered into on January 22, 1997. The Company sought compensation for inventory manufactured in 1998 in reliance on contractual forecasts and orders submitted by Janssen Pharmaceutica. The Company also sought compensation for forecasts and order shortfalls attributed to Janssen Pharmaceutica in 1998, pursuant to the terms of the Distribution Agreement. The Company amended its arbitration demand in August 2000 to include claims for lost profits due to Janssen Pharmaceutica's failure to use the requisite diligence and reasonable efforts to gain regulatory approval for and launch MUSE in China. A full hearing on the merits was conducted before a three-member arbitration panel in Chicago on March 18 – 20, 2002. On July 17, 2002, an Interim Award was issued awarding the Company the purchase price of 332,880 units manufactured for Janssen Pharmaceutica and lost profits on an additional 421,704 forecasted units. The Panel denied any relief on claims related to diligence in China. The dollar value of the claim will be determined by an audit of VIVUS' cost of goods sold by an independent accountant. Fieldwork for the audit was completed in mid-August 2002 and a final report is expected shortly. In the meantime, a Second Interim Award denied the Company interest on the amounts that will be owed, but awarded it \$231,711 for reimbursement of attorney's fees and \$91,738 for reimbursement of costs and expenses related to the arbitration.

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

#### Note 16. Subsequent Event (Unaudited)

In February 2003, the Company executed a distribution and supply agreement with Meda AB to distribute our medical device, ACTIS, an adjustable constriction loop for the treatment of male erectile dysfunction, in certain countries in Europe.

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#### FINANCIAL STATEMENT SCHEDULE

The financial statement Schedule II — VALUATION AND QUALIFYING ACCOUNTS is filed as part of the Form 10-K.

VIVUS, Inc.

#### SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS (in thousands)

	Balance at Beginning of Period	Charged to Operations	Charges Utilized	Other	Balance at End of Period
Allowance for Doubtful Accounts					
Fiscal year ended December 31, 2000	147	266	(109)	—	304
Fiscal year ended December 31, 2001	304	13	(85)	—	232
Fiscal year ended December 31, 2002	232	33	(120)	—	145
Inventory Reserve					
Fiscal year ended December 31, 2000	14,969	(2,256)(2)	(6,678)	1,707(1)	7,742
Fiscal year ended December 31, 2001	7,742	252	(510)	—	7,484
Fiscal year ended December 31, 2002	7,484	192	(455)(3)	—	7,221
Product Returns					
Fiscal year ended December 31, 2000	4,300	1,181	(3,473)	—	2,008
Fiscal year ended December 31, 2001	2,008	1,204	(1,689)	—	1,523
Fiscal year ended December 31, 2002	1,523	2,020	(1,263)	—	2,280

(1) During the third quarter of 1998, as part of the Company's plan to restructure its operations, the Company recorded restructuring reserves related to

commitments to buy raw materials. As the Company purchased raw materials under these commitments, the Company reclassified the purchase commitment restructuring reserves to inventory reserves.

- (2) Based on subsequent sales activity and purchases made under inventory purchase commitments, the Company determined that a portion of the inventory purchase commitment reserves recorded in 1998 was not needed. Accordingly, the Company reversed reserves with a corresponding reduction in cost of goods sold in the amount of \$3,127. This amount is included in the year 2000 charged to operations.
- (3) The Company estimates that at least some portion of the fully reserved inventory will now be used in production. The Company used \$163 thousand of its fully reserved raw materials inventory and expects to continue to use the fully reserved raw materials inventory in future periods. The fully reserved raw materials were charged to cost of goods sold at a zero basis when used, which had a favorable impact of gross profit.

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None.

**PART III**

**Item 10. Executive Officers and Directors of the Registrant**

The information required by this item is hereby incorporated by reference from the information under the captions "Election of Directors" and "Executive Officers" contained in the Company's definitive Proxy Statement, to be filed with the Securities and Exchange Commission no later than 120 days from the end of the Company's last fiscal year in connection with the solicitation of proxies for its 2003 Annual Meeting of Stockholders. The information required by Section 16(a) is incorporated by reference from the information under the caption "Compliance with Section 16(a) of the Securities Exchange Act of 1934" in the Proxy Statement.

**Item 11. Executive Compensation**

The information required by this item is incorporated by reference from the information under the caption "Executive Officer Compensation" in the Company's Proxy Statement.

**Item 12. Security Ownership of Certain Beneficial Owners and Management**

**Securities Authorized for Issuance under Equity Compensation Plans**

The following table gives information about our common stock that may be issued upon the exercise of options, warrants and rights under all of our existing equity compensation plans as of December 31, 2002, including the 1991 Incentive Stock Option Plan, the 1994 Employee Stock Purchase Plan, the 1994 Directors Option Plan and the 2001 Stock Option Plan.

Plan Category	(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights	(b) Weighted average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))(1) (2)
Equity compensation plans approved by security holders	4,281,059	3.96	3,198,744
Equity compensation plans not approved by security holders (3)	None	None	None
Total	4,281,059	3.96	3,198,744

- (1) Includes shares of our common stock reserved under our 2001 Stock Option Plan. The maximum aggregate number of shares that may be optioned and sold under the 2001 Stock Option Plan is 1,000,000 shares plus (a) any shares that have been reserved but not issued under the Company's 1991 Incentive Stock Option Plan, or the 1991 Plan; (b) any shares returned to the 1991 Plan as a result of termination of options or repurchase of shares issued under the 1991 Plan; and (c) an annual increase to be added on the first day of the Company's fiscal year beginning 2003, equal to the lesser of (i) 1,000,000 shares, (ii) 2.5% of the outstanding shares on such date, or (iii) a lesser amount determined by the Board. 2,278,874 shares of common stock were not issued under the 1991 Plan and were transferred to the 2001 Plan upon stockholder approval in June 2002, and 26,884 shares were returned to the 1991 Plan as a result of termination of options and were subsequently transferred to the 2001 Stock Option Plan. In addition, 185,000 shares from the 1994 Director Option Plan were also transferred to the 2001 Stock Option Plan in June 2002. See Note 8 of Notes to Consolidated Financial Statements for additional information.
- (2) The 2001 Stock Option Plan is intended to replace the 1991 Plan, which terminated in November 2001, and the 1994 Director Stock Option Plan, which terminated in June 2002.
- (3) All of equity compensation plans have been approved by our security holders.

The other information required by this item is incorporated by reference from the information under the caption “Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters” in the Company’s Proxy Statement.

**Item 13. *Certain Relationships and Related Transactions***

The information required by this item is incorporated by reference from the information under the caption “Certain Relationships and Related Transactions” in the Company’s Proxy Statement.

**Item 14. *Disclosure Controls and Procedures***

(a) Evaluation of disclosure controls and procedures

Based on an evaluation of the Company’s disclosure controls and procedures as of a date within 90 days of the filing date of this Annual Report on Form 10-K, the Company’s Chief Executive Officer and Chief Financial Officer have concluded that the Company’s disclosure controls and procedures (as defined in Rules 13a-14(c) and 15d-14(c) under the Securities Exchange Act of 1934 (the “Exchange Act”)) are effective to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

(b) Changes in internal controls

There have been no significant changes in our internal controls or in other factors that could significantly affect internal controls subsequent to the date we carried out this evaluation.

**Item 15. *Audit Committee Financial Expert***

[Reserved]

**Item 16. *Accountants’ Fees and Services***

The information required by this item is incorporated by reference from the information under the caption “Accountants’ Fees and Services” in the Company’s Proxy Statement.

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**PART IV**

**Item 17. *Exhibits, Financial Statement Schedules and Reports on Form 8-K***

**(A) Exhibits, Financial Statement Schedules and Reports**

**1. Financial Statements**

The following Financial Statements of VIVUS, Inc. and Independent Auditors’ Reports, have been filed as part of this Form 10-K. See index to Financial Statements under Item 8, above:

**Index to Consolidated Financial Statements**

Independent Auditors’ Reports  
Consolidated Balance Sheets as of December 31, 2002 and 2001  
Consolidated Statements of Operations and Other Comprehensive (Loss) Income for the years ended December 31, 2002, 2001 and 2000  
Consolidated Statements of Stockholders’ Equity for the years ended December 31, 2002, 2001 and 2000  
Consolidated Statements of Cash Flows for the years ended December 31, 2002, 2001 and 2000  
Notes to Consolidated Financial Statements

**2. Financial Statement Schedules**

The following financial statement schedule of VIVUS, Inc. as set forth on page 50 is filed as part of this report on Form 10-K and should be read in conjunction with the Financial Statements of VIVUS, Inc. incorporated by reference herein:

Schedule II — Valuation and Qualifying Accounts

All other schedules are omitted because they are not applicable or the required information is shown in the Financial Statements or the notes thereto.

### 3. Exhibits

Exhibit Number	Description
3.2(7)	Amended and Restated Certificate of Incorporation of the Company
3.3(4)	Bylaws of the Registrant, as amended
3.4(8)	Certificate of Designations of Rights, Preferences and Privileges of Series A Participating Preferred Stock
4.1(7)	Specimen Common Stock Certificate of the Registrant
4.2(7)	Registration Rights, as amended
4.4(1)	Form of Preferred Stock Purchase Warrant issued by the Registrant to Invemed Associates, Inc., Frazier Investment Securities, L.P., and Cristina H. Kepner
4.5(8)	Second Amended and Restated Preferred Shares Rights Agreement, dated as of April 15, 1997 by and between the Registrant and Harris Trust Company of California, including the Certificate of Determination, the form of Rights Certificate and the Summary of Rights attached thereto as Exhibits A, B, and C, respectively
10.1(1)†	Assignment Agreement by and between Alza Corporation and the Registrant dated December 31, 1993
10.2(1)†	Memorandum of Understanding by and between Ortho Pharmaceutical Corporation and the Registrant dated February 25, 1992
10.3(1)†	Assignment Agreement by and between Ortho Pharmaceutical Corporation and the Registrant dated June 9, 1992
10.4(1)†	License Agreement by and between Gene A. Voss, MD, Allen C. Eichler, MD, and the Registrant dated December 28, 1992
10.5A(1)†	License Agreement by and between Ortho Pharmaceutical Corporation and Kjell Holmquist AB dated June 23, 1989
10.5B(1)†	Amendment by and between Kjell Holmquist AB and the Registrant dated July 3, 1992
10.5C(1)	Amendment by and between Kjell Holmquist AB and the Registrant dated April 22, 1992
10.5D(1)†	Stock Purchase Agreement by and between Kjell Holmquist AB and the Registrant dated April 22, 1992
10.6A(1)†	License Agreement by and between Amsu, Ltd., and Ortho Pharmaceutical Corporation dated June 23, 1989
10.6B(1)†	Amendment by and between Amsu, Ltd., and the Registrant dated July 3, 1992
10.6C(1)	Amendment by and between Amsu, Ltd., and the Registrant dated April 22, 1992
10.6D(1)†	Stock Purchase Agreement by and between Amsu, Ltd., and the Registrant dated July 10, 1992
10.11(4)	Form of Indemnification Agreements by and among the Registrant and the Directors and Officers of the Registrant
10.12(2)	1991 Incentive Stock Plan and Form of Agreement, as amended
10.13(1)	1994 Director Option Plan and Form of Agreement
10.14(1)	Form of 1994 Employee Stock Purchase Plan and Form of Subscription Agreement
10.17(1)	Letter Agreement between the Registrant and Leland F. Wilson dated June 14, 1991 concerning severance pay
10.21(3)†	Distribution Services Agreement between the Registrant and Synergy Logistics, Inc. (a wholly-owned subsidiary of Cardinal Health, Inc.) dated February 9, 1996
10.22(3)†	Manufacturing Agreement between the Registrant and CHINOIN Pharmaceutical and Chemical Works Co., Ltd. dated December 20, 1995
10.22A(11)†	Amendment One, dated as of December 11, 1997, to the Manufacturing Agreement by and between VIVUS and CHINOIN Pharmaceutical and Chemical Works Co., Ltd. dated December 20, 1995

10.23(6)†	Distribution and Services Agreement between the Registrant and Alternate Site Distributors, Inc. dated July 17, 1996
10.24(5)†	Distribution Agreement made as of May 29, 1996 between the Registrant and ASTRAZ AB
10.24A(14)†	Amended Distribution Agreement dated December 22, 1999 between AstraZeneca and the Registrant
10.27(11)†	Distribution Agreement made as of January 22, 1997 between the Registrant and Janssen Pharmaceutica International, a division of Cilag AG International
10.27A(11)†	Amended and Restated Addendum 1091, dated as of October 29, 1997, between VIVUS International Limited and Janssen Pharmaceutica International

Exhibit Number	Description
10.28(7)	Lease Agreement made as of January 1, 1997 between the Registrant and Airport Associates
10.29(7)	Lease Amendment No. 1 as of February 15, 1997 between Registrant and Airport Associates
10.29A(10)	Lease Amendment No. 2 dated July 24, 1997 by and between the Registrant and Airport Associates
10.29B(10)	Lease Amendment No. 3 dated July 24, 1997 by and between the Registrant and Airport Associates
10.31(9)†	Manufacture and Supply Agreement between Registrant and Spolana Chemical Works, A.S. dated May 30, 1997
10.32A(11)	Agreement between ADP Marshall, Inc. and the Registrant dated December 19, 1997
10.32B(11)	General Conditions of the Contract for Construction
10.32C(11)	Addendum to General Conditions of the Contract for Construction
10.34(12)†	Agreement dated as of June 30, 1998 between Registrant and Alza Corporation
10.35(12)†	Sales Force Transition Agreement dated July 6, 1998 between Registrant and Alza Corporation
10.36(13)	Form of, "Change of Control Agreements," dated July 8, 1998 by and between the Registrant and certain Executive Officers of the Company.
10.30A(13)	Amendment of lease agreement made as of October 19, 1998 by and between Registrant and 605 East Fairchild Associates, L.P.
10.37(13)	Sublease agreement made as of November 17, 1998 between Caliper Technologies, Inc. and Registrant
10.22B(13)†	Amendment Two, dated as of December 18, 1998 by and between VIVUS, Inc. and CHINOIN Pharmaceutical and Chemical Works Co.
10.31A(13)†	Amendment One, dated as of December 12, 1998 by and between VIVUS, Inc. and Spolana Chemical Works, A.S.
10.38(14)†	License Agreement by and between ASIVI, LLC, AndroSolutions, Inc., and the Registrant dated February 29, 2000
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10.42(16)†	Development, License and Supply Agreement made as of January 22, 2001 between the Registrant and TANABE SEIYAKU CO., LTD.
10.43(17)†	Settlement and Modification Agreement made as of July 12, 2001 between ASIVI, LLC, AndroSolutions, Inc. Gary W. Neal and the Registrant.
10.44(18)	2001 Stock Option Plan and Form of Agreement
10.45(19)†	Supply Agreement made as of September 3, 2002 between the Registrant and Meda AB.

10.46††	Amendment Three, dated November 21, 2002 by and between VIVUS, Inc. and CHINOIN Pharmaceutical and Chemical Works, Ltd.
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10.48††	Exclusive Distribution Agreement dated October 1, 2002 between the Registrant and Cord Logistics
10.49††	Distribution and Supply Agreement made as of February 18, 2003 between the Registrant and Meda AB.
21.2	List of Subsidiaries

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† Confidential treatment granted.

†† Confidential treatment requested.

(1) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Registration Statement on Form S-1 No. 33-75698, as amended.

(2) Incorporated by reference to the same numbered exhibit filed with the Registrant's Registration Statement on Form S-1 No. 33-90390, as amended.

(3) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1995, as amended.

(4) Incorporated by reference to the same numbered exhibit filed with the Registrant's Form 8-B filed with the Commission on June 24, 1996.

(5) Incorporated by reference to the same numbered exhibit filed with the Registrant's Current Report on Form 8-K/A filed with the Commission on June 21, 1996.

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- (18) Incorporated by reference to the same numbered exhibit filed with the Registrant's Registration Statement on Form S-8 filed with the Commission on November 15, 2001.
- (19) Incorporated by reference to the same numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended November 30, 2002.

(b) **Reports on Form 8-K**

None.

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**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/ RICHARD WALLISER

Richard Walliser  
*Vice President of Finance and  
Chief Financial Officer*  
(Principal Financial and Accounting Officer)

Date: March 17, 2003

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CERTIFICATION OF CHIEF EXECUTIVE OFFICER  
PURSUANT TO SECTION 302(a) OF THE SARBANES-OXLEY ACT OF 2002

I, Leland F. Wilson, certify that:

1. I have reviewed this annual report on Form 10-K of VIVUS, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a. designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b. evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - c. presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and



- b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were any significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 17, 2003

By: /s/ LELAND F. WILSON

Name: Leland F. Wilson  
Title: President and Chief Executive Officer

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CERTIFICATION OF CHIEF FINANCIAL OFFICER  
PURSUANT TO SECTION 302(a) OF THE SARBANES-OXLEY ACT OF 2002

I, Richard Walliser, certify that:

1. I have reviewed this annual report on Form 10-K of VIVUS, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a. designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b. evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - c. presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were any significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 17, 2003

By: /s/ RICHARD WALLISER

Name: Richard Walliser  
Title: Vice President and Chief Financial Officer

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I, Leland F. Wilson, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of VIVUS, Inc. on Form 10-K for the period ending December 31, 2002 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report on Form 10-K fairly presents in all material respects the financial condition and results of operations of VIVUS, Inc.

March 17, 2003

By: /s/ Leland F. Wilson

\_\_\_\_\_  
Leland F. Wilson  
President and Chief Executive Officer

I, Richard Walliser, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of VIVUS, Inc. on Form 10-K for the period ending December 31, 2002 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report on Form 10-K fairly presents in all material respects the financial condition and results of operations of VIVUS, Inc.

March 17, 2003

By: /s/ Richard Walliser

\_\_\_\_\_  
Richard Walliser  
Vice President and Chief Financial Officer

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Leland F. Wilson and Richard Walliser as his attorney-in-fact for him, in any and all capacities, to sign each amendment to this Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact or his substitute or substitutes may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

Signature	Title	Date
<p>/s/ LELAND F. WILSON</p> <p>_____ Leland F. Wilson</p>	<p>President, Chief Executive Officer (Principal Executive Officer) and Director</p>	<p>March 17, 2003</p>
<p>/s/ VIRGIL A. PLACE</p> <p>_____ Virgil A. Place</p>	<p>Chairman of the Board and Chief Scientific Officer and Director</p>	<p>March 17, 2003</p>
<p>/s/ RICHARD WALLISER</p> <p>_____ Richard Walliser</p>	<p>Vice President of Finance and Chief Financial Officer (Principal Financial and Accounting Officer)</p>	<p>March 17, 2003</p>
<p>/s/ GRAHAM STRACHAN</p> <p>_____ Graham Strachan</p>	<p>Director</p>	<p>March 17, 2003</p>
<p>/s/ MARIO M. ROSATI</p> <p>_____ Mario M. Rosati</p>	<p>Director</p>	<p>March 17, 2003</p>
<p>/s/ MARK B. LOGAN</p> <p>_____ Mark B. Logan</p>	<p>Director</p>	<p>March 17, 2003</p>
<p>/s/ LINDA M. DAIRIKI SHORTLIFFE, M.D.</p> <p>_____ Linda M. Dairiki Shortliffe, M.D.</p>	<p>Director</p>	<p>March 17, 2003</p>

## VIVUS, INC.

**REPORT ON FORM 10-K FOR  
THE YEAR ENDED DECEMBER 31, 2002**

**INDEX TO EXHIBITS**

Exhibit Number	Exhibit Name	Sequentially Numbered Page
3.2(7)	Amended and Restated Certificate of Incorporation of the Company	
3.3(4)	Bylaws of the Registrant, as amended	
3.4(8)	Certificate of Designations of Rights, Preferences and Privileges of Series A Participating Preferred Stock	
4.1(7)	Specimen Common Stock Certificate of the Registrant	
4.2(7)	Registration Rights, as amended	
4.4(1)	Form of Preferred Stock Purchase Warrant issued by the Registrant to Invemed Associates, Inc., Frazier Investment Securities, L.P., and Cristina H. Kepner	
4.5(8)	Second Amended and Restated Preferred Shares Rights Agreement, dated as of April 15, 1997 by and between the Registrant and Harris Trust Company of California, including the Certificate of Determination, the form of Rights Certificate and the Summary of Rights attached thereto as Exhibits A, B, and C, respectively	
10.1(1)†	Assignment Agreement by and between Alza Corporation and the Registrant dated December 31, 1993	
10.2(1)†	Memorandum of Understanding by and between Ortho Pharmaceutical Corporation and the Registrant dated February 25, 1992	
10.3(1)†	Assignment Agreement by and between Ortho Pharmaceutical Corporation and the Registrant dated June 9, 1992	
10.4(1)†	License Agreement by and between Gene A. Voss, MD, Allen C. Eichler, MD, and the Registrant dated December 28, 1992	
10.5A(1)†	License Agreement by and between Ortho Pharmaceutical Corporation and Kjell Holmquist AB dated June 23, 1989	
10.5B(1)†	Amendment by and between Kjell Holmquist AB and the Registrant dated July 3, 1992	
10.5C(1)	Amendment by and between Kjell Holmquist AB and the Registrant dated April 22, 1992	
10.5D(1)†	Stock Purchase Agreement by and between Kjell Holmquist AB and the Registrant dated April 22, 1992	
10.6A(1)†	License Agreement by and between Amsu, Ltd., and Ortho Pharmaceutical Corporation dated June 23, 1989	
10.6B(1)†	Amendment by and between Amsu, Ltd., and the Registrant dated July 3, 1992	
10.6C(1)	Amendment by and between Amsu, Ltd., and the Registrant dated April 22, 1992	
10.6D(1)†	Stock Purchase Agreement by and between Amsu, Ltd., and the Registrant dated July 10, 1992	
10.11(4)	Form of Indemnification Agreements by and among the Registrant and the Directors and Officers of the Registrant	
10.12(2)	1991 Incentive Stock Plan and Form of Agreement, as amended	
10.13(1)	1994 Director Option Plan and Form of Agreement	
10.14(1)	Form of 1994 Employee Stock Purchase Plan and Form of Subscription Agreement	
10.17(1)	Letter Agreement between the Registrant and Leland F. Wilson dated June 14, 1991 concerning severance pay	
10.21(3)†	Distribution Services Agreement between the Registrant and Synergy Logistics, Inc. (a wholly-owned subsidiary of Cardinal Health, Inc.) dated February 9, 1996	
10.22(3)†	Manufacturing Agreement between the Registrant and CHINOIN Pharmaceutical and Chemical Works Co., Ltd. dated December 20, 1995	
10.22A(11)†	Amendment One, dated as of December 11, 1997, to the Manufacturing Agreement by and between VIVUS and CHINOIN Pharmaceutical and Chemical Works Co., Ltd. dated December 20, 1995	

10.23(6)†	Distribution and Services Agreement between the Registrant and Alternate Site Distributors, Inc. dated July 17, 1996
10.24(5)†	Distribution Agreement made as of May 29, 1996 between the Registrant and ASTRAZ AB
10.24A(14)†	Amended Distribution Agreement dated December 22, 1999 between AstraZeneca and the Registrant
10.27(11)†	Distribution Agreement made as of January 22, 1997 between the Registrant and Janssen Pharmaceutica International, a division of Cilag AG International
10.27A(11) †	Amended and Restated Addendum 1091, dated as of October 29, 1997, between VIVUS International Limited and Janssen Pharmaceutica International
10.28(7)	Lease Agreement made as of January 1, 1997 between the Registrant and Airport Associates
10.29(7)	Lease Amendment No. 1 as of February 15, 1997 between Registrant and Airport Associates

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10.29A(10)	Lease Amendment No. 2 dated July 24, 1997 by and between the Registrant and Airport Associates
10.29B(10)	Lease Amendment No. 3 dated July 24, 1997 by and between the Registrant and Airport Associates
10.31(9)†	Manufacture and Supply Agreement between Registrant and Spolana Chemical Works, A.S. dated May 30, 1997
10.32A(11)	Agreement between ADP Marshall, Inc. and the Registrant dated December 19, 1997
10.32B(11)	General Conditions of the Contract for Construction
10.32C(11)	Addendum to General Conditions of the Contract for Construction
10.34(12)†	Agreement dated as of June 30, 1998 between Registrant and Alza Corporation
10.35(12)†	Sales Force Transition Agreement dated July 6, 1998 between Registrant and Alza Corporation
10.36(13)	Form of,“Change of Control Agreements,” dated July 8, 1998 by and between the Registrant and certain Executive Officers of the Company.
10.30A(13)	Amendment of lease agreement made as of October 19, 1998 by and between Registrant and 605 East Fairchild Associates, L.P.
10.37(13)	Sublease agreement made as of November 17, 1998 between Caliper Technologies, Inc. and Registrant
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AMENDMENT THREE  
TO THE MANUFACTURING AGREEMENT  
BY AND BETWEEN VIVUS AND CHINOIN

This Amendment Three ("Amendment Three"), effective as of November 21, 2002 ("Amendment Date"), by and between VIVUS, Inc., having a principal place of business at Mountain View, CA United States of America ("VIVUS"), and CHINOIN Pharmaceutical and Chemical Works, Ltd., having a principal place of business at H-1045, Budapest, To u. 1-5 Hungary ("CHINOIN") (VIVUS and CHINOIN collectively, the "Parties"), amends (i) that certain Manufacturing Agreement by and between the Parties dated December 20, 1995 (the "Agreement") and (ii) Amendment One to the Agreement dated December 11, 1997 ("Amendment One") and (iii) Amendment Two to the Agreement dated December 18, 1998 ("Amendment Two")

The Parties desire to amend the Agreement, the Amendment One and Amendment Two as set forth herein below;

NOW, THEREFORE, the Parties agree as follows:

1. AMENDMENT. This Amendment Three hereby amends the Agreement to incorporate the terms and conditions set forth in this Amendment Three. The relationship of the Parties shall continue to be governed by the terms and conditions of the Agreement, the Amendments One and Two, as amended herein; and in the event that there is any conflict between the terms and conditions of the Agreement or Amendment One or Two and this Amendment Three, the terms and conditions of this Amendment Three shall control. As used in this Amendment Three, all capitalized terms shall have the meanings defined for such terms in this Amendment Three or, if not defined in this Amendment Three, the meanings defined in the Agreement.

2. MODIFICATION TO THE AGREEMENT.

2.1 The Parties hereby acknowledge the change of the principal place of business of VIVUS from 605 East Fairchild Drive, Mountain View, CA 94043, to 1172 Castro Street, Mountain View, CA 94040.

2.2 The Parties hereby confirm that in the frame of the Agreement VIVUS has firmly ordered from CHINOIN under PO# [\*] the supply of [\*] Product for the year 1998. After CHINOIN having delivered [\*], VIVUS has requested CHINOIN to stop manufacturing and to postpone all further shipments. According to Amendment Two and further discussion of the Parties, [\*] of Product was delivered in 1999 and 2000 to VIVUS. A further [\*] of Product ordered for 1998 and the [\*] minimum purchasing obligation of VIVUS for the calendar year of 1999, for a total of [\*], the only obligation of VIVUS until December 31, 2002 according to Amendment Two, has not been ordered by VIVUS and has not been manufactured by CHINOIN.

2.3 The Parties hereby agree to prolong the validity of the Agreement for calendar years 2003 to 2008, being considered as seventh, eighth, ninth, tenth, eleventh and twelfth Agreement Years, respectively.

2.4 CHINOIN agrees to update its manufacturing process to meet the EAEMP Recommendation July 1999 on the compliance with the CPMP guideline on residual solvents.

2.4.1. Chinoin will manufacture [\*] of Product, approximately [\*] each, in a campaign starting in 2002. The [\*] will be completed no later than January 31, 2003. The [\*] and [\*] [\*] will follow thereafter and will be completed no later than February 28, 2003. During this campaign, CHINOIN will apply a change of manufacturing process characterized with the replacement of [\*] to a more desirable [\*] in manufacturing step 9 of the Product as numbered in CHINOIN's DMF and other changes deemed necessary by CHINOIN in connection with such change.

2.4.2. CHINOIN agrees to carry out all tests and studies necessary to prove the equivalence of Product manufactured with the modified process using these [\*], including stability studies, and submit the description of the changes and all related results as required by the regulatory authorities in a schedule set forth below:

- a. To the US FDA with three (3) month stability results no later than May 31, 2003;
- b. To the European and other regulatory authorities no later than thirty (30) days after receipt of a written request from VIVUS, such written request to occur no

earlier than May 31, 2003, such submission to include the latest stability results available at the time of submission.

2.4.3. CHINOIN agrees to provide VIVUS with a detailed analytical report on its findings on these batches of Product at the time of their qualification and results of its stability studies at the time such results are available.

2.4.4. CHINOIN agrees to carry out similar necessary tests and studies including stability study on at least its [\*] of the Product manufactured in [\*] size with its modified process following the [\*] in [\*] size as described above. Testing results on such additional [\*] will be submitted to the regulatory authorities in the customary manner with due advance consultation with VIVUS.

2.5 CHINOIN agrees to amend its current Specification:

- a) To meet the EAEMP Recommendation July 1999 on the compliance with the CPMP guideline on residual solvents;
- b) To meet the requirements of USP 25 Suppl.1 (April 1, 2002);
- c) To meet the requirements of the European Pharmacopeia, 2001:1448 FOR ALPROSTADIL;
- d) To meet additional VIVUS requirements.

2.5.1. These future requirements are set forth in Exhibit A to this Amendment Three.

2.5.2. CHINOIN agrees to submit its updated Specification as a part of its regulatory submissions set forth in Section 2.4.2 of this Amendment Three.



2.5.3. The updated Specification shall be applicable for the first time to batches manufactured by CHINOIN with the modified process set forth in Section 2.4.1 of this Amendment Three.

2.6 VIVUS agrees to carry out all tests and studies necessary to acquire the approval of the US, EU and other regulatory authorities for its use of Product manufactured with the modified process of CHINOIN as active ingredient in its finished product MUSE.

2.6.1. VIVUS agrees that these tests and studies shall include manufacture and stability studies of validation batches of MUSE using each of the [\*] of Product received from CHINOIN as the first shipment in 2003 as set forth in Section 2.7.1 below.

2.6.2. VIVUS agrees to submit a supplement to its NDA for approval by the US FDA no later than July 31, 2003 or as soon as such studies are completed.

2.6.3. VIVUS agrees to provide to its European Union licensed distributor, as expeditiously as possible, any and all assistance, information and/or materials in VIVUS possession to submit a Type I Variation to its European Product License upon completion of studies necessary for such submission to the European regulatory authorities.

2.6.4. VIVUS agrees to inform CHINOIN about its main findings on these validation batches of MUSE as well as to notify CHINOIN in a timely manner regarding regulatory submissions and their outcome.

2.7 The Parties agree that VIVUS shall not be required to purchase from CHINOIN any amount of the Product in the remainder of calendar year 2002 and VIVUS shall have only the following firm commitments to purchase the Product from CHINOIN during the validity of the Agreement as extended according to Section 2.3 of this Amendment Three:

2.7.1. VIVUS agrees to take delivery of [\*] of the Product during the seventh Agreement Year in the following schedule and under the conditions stipulated herein.

1. [\*] immediately upon availability in January/February 2003
2. Approximately [\*] in October 2003
3. Approximately [\*], up to [\*]total in December 2003

The first delivery to VIVUS in 2003 will consist of [\*] from each of the [\*] of Product manufactured by CHINOIN with the modified process as described in Section 2.4.1 of this Amendment Three. The second delivery may contain further quantities of these [\*] still on stock at CHINOIN at the time of shipment or from further [\*] or [\*] manufactured with the same modified process of CHINOIN. CHINOIN agrees to refrain from shipping residual tails of [\*] below [\*].

2.7.2. Parties agree that the obligation of VIVUS to take the [\*] deliveries is subject to European approval as set forth in Section 2.6.3 and to US FDA approval of the supplement to VIVUS' NDA of MUSE as set forth in Section 2.6.2 of this Amendment Three.

- 2.7.3. Within five (5) working days after execution of this Amendment Three, VIVUS agrees to issue a Purchase Order for the delivery of [\*] of Product with reference to conditions stipulated in this Amendment Three.
- 2.7.4. VIVUS will place with CHINOIN [\*] of its orders for the Product (based on mass) until VIVUS accepts delivery from CHINOIN the [\*] of the Product referred to in Section 2.7.1. In no event will CHINOIN be obligated to supply more than [\*] of Product in the seventh Agreement Year.
- 2.7.5. From the eighth Agreement Year of this Amendment Three onward, VIVUS agrees to place not less than [\*] of its orders for the Product (based on mass) from CHINOIN after having completed all of its purchasing obligations as detailed above in Sections 2.7.1, 2.7.2, 2.7.3 and 2.7.2 of this Amendment Three. In no event will CHINOIN be obligated to supply more than [\*] of Product annually.
- 2.7.6. Section 2.12 of the Agreement is hereby restated to read as follows:

#### 2.12 Minimum Quantities

- 2.12.1 VIVUS agrees that the quantity of Product purchased from CHINOIN shall in no event fall below the minimum quantity of [\*] in the eighth and ninth Agreement Years. This undertaking is not subject to any waiver due to decrease of the consumption of the Product.
- 2.12.2 The Parties will negotiate the minimum purchasing stipulations for the tenth, eleventh and twelfth Agreement Years at the end of ninth Agreement Year. Should the Parties fail to reach new minimum purchasing stipulations at the end of ninth Agreement Year, the purchasing stipulations valid in the ninth Agreement Year shall remain in force for the tenth, eleventh and twelfth Agreement Years.

#### 2.8 Non-fulfillment

- 2.8.1. In the event CHINOIN is unable to fulfil its obligations within three (3) months from the deadline indicated in Section 2.4.2 of this Amendment Three, VIVUS will have the right to place orders with other supplier(s) in quantities not exceeding the quantity scheduled for the time in question stipulated in Section 2.7.1 of this Amendment Three until the time CHINOIN completes the fulfillment of its referred obligations.

Thereafter, VIVUS will place with CHINOIN [\*] of its orders for the Product until the [\*] stipulated in Section 2.7.1 is delivered in full.

The delay of VIVUS taking deliveries of the [\*] stipulated in Section 2.4.1 for any reason will create no right for either of the Parties to change the price of this [\*] as stipulated for the seventh Agreement Year in Section 2.9 of this Amendment Three.

VIVUS agrees that the measures to postpone taking delivery from CHINOIN and/or to order quantities from other suppliers proportionally as stipulated in Section 2.8.1 will satisfy in full any and all of CHINOIN's obligations and VIVUS will not be entitled to claim compensations or losses due to the above delay, if any.

- 2.8.2. Notwithstanding Section 2.7.2 of this Amendment Three, in the event VIVUS is unable to acquire the approval of its supplement to its NDA, as described in Section 2.6 of this Amendment Three, due to reasons

unquestionably not attributable to CHINOIN, VIVUS shall be obligated to take the [\*] and pay their value in full.

Parties agree that the lack of any question on the Product by the FDA during the Amendment approval procedure or the lack of reasons referring to the Product in a regulatory decision denying the approval are reasons unquestionably not attributable to CHINOIN without any further evidence in case of inability of VIVUS to acquire the approval in question.

2.9 Section 2.7 of the Agreement as modified by Amendment One is hereby amended in its entirety to read as follows:

2.7 Price The price to be paid by VIVUS per gram of the Product ordered by VIVUS shall be based upon the quantities of the Product ordered by VIVUS for delivery during the particular Agreement Year, as follows:

2.7.1 Quantity Ordered for Delivery

During the seventh Agreement Year	U.S. \$/[*]
-----	-----
All quantities up to [*]	\$[*]
Quantities in excess of [*], if any up to [*]	\$[*]
Quantities in excess of [*], if any up to [*]	\$[*]

2.7.2 Quantity Ordered for Delivery

During the eight and ninth Agreement Year	U.S. \$/[*]
-----	-----
First [*] "Minimum Annual Quantity"	\$[*]
Quantities in excess of [*], up to [*]	\$[*]
Quantities in excess of [*], up to [*]	\$[*]
Quantities in excess of [*], up to [*]	\$[*]
Quantities in excess of [*], up to [*]	\$[*]
Quantities in excess of [*], if any	\$[*]

2.7.3 The Parties will negotiate the price stipulations for the tenth, eleventh and twelfth Agreement Years at the end of ninth Agreement Year. Should the Parties fail to reach new price stipulations at the end of ninth Agreement Year, the price stipulations valid in the ninth Agreement Year shall remain in force for the tenth, eleventh and twelfth Agreement Years.

It is understood that the foregoing prices are based upon the total cumulative quantities ordered by VIVUS for delivery during the particular Agreement Year, and not only on the size of the particular order or delivery. It is also understood that the prices are for the incremental quantities.

3. ENTIRE AGREEMENT. The Agreement and any Exhibits and Addenda thereto together with this Amendment Three and Amendment One and Amendment Two constitute the entire agreement between the Parties with respect to the subject matter thereof and supersede all prior and contemporaneous communications, representations, agreements or understandings, either written or oral, between the Parties.

IN WITNESS WHEREOF, the parties hereto have executed this Amendment Three.

VIVUS, INC.

CHINOIN PHARMACEUTICAL AND  
CHEMICAL WORKS CO., LTD.

By: /s/  
-----

By: /s/  
-----

Name: Terry Nida  
-----

Name: Patrick CHOCAT  
-----

Title: Vice President  
-----

Title: Managing Director  
-----

By: /s/  
-----

Name: Eric-Yves LILLE  
-----

Title: VP Administration & Finance  
-----

\* Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has already been granted with respect to the omitted portions.

CHINOIN - VIVUS  
AMENDMENT THREE TO THE  
MANUFACTURING AGREEMENT

EXHIBIT A

CHINOIN.DOC  
F-OCTOBER 8, 2002

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[\*]

LEASE AMENDMENT NO. 4  
AND SETTLEMENT AGREEMENT

THIS LEASE AMENDMENT NO. 4 AND SETTLEMENT AGREEMENT (this "Agreement") is made as of the 25th day of October, 2000, by and between AIRPORT ASSOCIATES, a New Jersey general partnership ("Landlord"), and VIVUS, INC., a Delaware corporation ("Tenant").

## RECITALS:

WHEREAS, Landlord and Tenant are parties to a certain Lease dated as of January 1, 1997 (the "Original Lease"), as amended by Lease Amendment No. 1 dated as of February 15, 1997 (the "First Amendment"), Lease Amendment No. 2 dated as of July 24, 1997 (the "Second Amendment"), and Lease Amendment No. 3 dated as of July 24, 1997 (the "Third Amendment") (the Original Lease, as amended by the First Amendment, Second Amendment and Third Amendment, is hereinafter referred to as the "Lease"); and

WHEREAS, the initially capitalized terms used, but not defined, in this Amendment shall have the same meanings as the terms defined in the Lease, directly or by cross-reference, unless the context requires otherwise; and

WHEREAS, Tenant has made certain Alterations to the Premises described in the drawings listed on Exhibit A attached hereto (the "Subject Alterations"); and

WHEREAS, Landlord made a demand on Tenant to provide the Removal Security for the Subject Alterations; and

WHEREAS, a dispute arose between Landlord and Tenant regarding the Removal Security for the Subject Alterations; and

WHEREAS, Landlord instituted an action against Tenant in the Superior Court of New Jersey, Chancery Division (the "Court"): Ocean County venue bearing Docket No.: C-225-98 (the "Litigation"); and

WHEREAS, an Order was entered by the Court in the Litigation which provided for the Landlord and Tenant to arbitrate their dispute and dismissed the Litigation; and

WHEREAS, in lieu of submitting the dispute between Landlord and Tenant regarding the Removal Security for the Subject Alterations to arbitration as permitted pursuant to the Lease and Court Order, Landlord and Tenant have reached an agreement with respect to the Removal Security for the Subject Alterations and certain other matters, as set forth below in this Agreement;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged by each of the parties hereto, Landlord and Tenant agree as follows:

1. Landlord and Tenant agree that the amount of the Removal Security for the Subject Alterations shall be \$3,324,143.00.

2. Simultaneously with the execution of this Agreement, Tenant shall deliver to and deposit with Landlord the Removal Security set forth in Paragraph 1 consisting of an irrevocable standby letter of credit, substantially in the form of Exhibit B attached hereto and incorporated herein (such letter of credit and any replacement or additional letters of credit are hereinafter referred to as the "Letter of Credit"). Any additional Letter of Credit that may be delivered to Landlord as Removal Security in connection with future Alterations shall also be substantially in the form of Exhibit B. With respect to the initial Letter of Credit, and any replacement or additional Letter of Credit, Tenant and Landlord agree as follows:

(a) Any Letter of Credit shall have a stated duration of and shall be effective for a period of not less than one (1) year.

(b) If any Letter of Credit is scheduled to expire prior to one (1) month after the later of: (i) the expiration of the Term of the Lease, plus any Renewal Terms; (ii) the expiration of any Deferral Period (as defined below); or (iii) the expiration of any Completion Period (as defined below), Tenant shall deliver to Landlord a replacement Letter of Credit no later than thirty (30) days prior to the expiration date of the expiring Letter of Credit, and if

Tenant fails to do so, Landlord may draw the entire amount of the expiring Letter of Credit, less any sums previously paid out of the expiring Letter of Credit, and hold the proceeds (the "Expiration Proceeds") in cash as Removal Security until such time as Tenant provides Landlord with a replacement Letter of Credit, or Landlord expends any portion of the Expiration Proceeds to perform any Restoration (as defined below). Any such cash proceeds that are not expended on Restoration shall be deposited with a financial institution selected by Landlord and satisfactory to Tenant, in its reasonable judgment, in a segregated, interest-bearing account, labeled "VIVUS Removal Security Account," and shall be held in trust for the purposes set forth herein and in the Lease. Any replacement Letter of Credit shall be in the same amount as the Expiration Proceeds, less any amounts expended by Landlord to perform any Restoration, and shall contain the same conditions as the expiring Letter of Credit. Upon delivery of the replacement Letter of Credit to Landlord, Landlord shall surrender the entire amount of the Expiration Proceeds, together with all interest accrued thereon, less any amounts expended by Landlord to perform any Restoration, to Tenant or Tenant's designee(s).

(c) If the issuer of the Letter of Credit shall admit in writing its inability to pay its debts generally as they become due, or shall file a petition or otherwise become a debtor in bankruptcy or take advantage of or become subject to any insolvency, reorganization, receivership or similar laws or remedies, or shall consent to or be subject to the appointment of a receiver or a conservator of itself or the whole or any substantial part of its property, or shall file a petition or answer seeking reorganization or arrangement under the United States Bankruptcy Code, or shall have a receiver or conservator appointed or shall become subject to operational supervision by any Federal or State regulatory authority, then Tenant within thirty (30) days after written demand by Landlord shall obtain a replacement Letter of Credit from another financial institution satisfactory to Landlord, in its reasonable judgment.

(d) If the Tenant shall become a debtor or debtor in possession in any bankruptcy case under the United States Bankruptcy Code or shall be subject to any receivership or insolvency proceeding, including but not limited to an assignment for the benefit of creditors, Tenant acknowledges that any Letter of Credit provided to the Landlord under the Lease or this Agreement is not and shall not constitute property of the estate under 11 U.S.C. ss. 541 and/or similar provisions under State receivership, assignment for the benefit of creditors and/or other insolvency laws or proceedings. Additionally, Tenant acknowledges that any draw on any Letter of Credit will not be subject to 11 U.S.C. ss. 362 (a) or constitute a preference or fraudulent conveyance under 11 U.S.C. ss. 547, 548 or otherwise be prohibited by 11 U.S.C. ss. 549, 550 or any other applicable State receivership, assignment for the benefit of creditors and/or other insolvency laws or proceedings. Tenant also acknowledges that in the event that it shall become a debtor or debtor in possession under the United States Bankruptcy Code, receivership, assignment for the benefit of creditors and/or other insolvency laws or proceedings, it shall timely perform all obligations under the Lease and this Agreement, and any amendments thereto arising from and after the order for relief, until the Lease, this Agreement and any amendments thereto are assumed or rejected as required by 11 U.S.C. ss. 365 (d) (3), as well as all other duties and performances required of a debtor and/or debtor in possession under the Bankruptcy Code without prejudice to any and all other rights, claims, remedies and interests the Landlord may possess.

3. Notwithstanding the provisions of the first sentence of Section 9.4 and the first sentence of Section 18 of the Lease, Landlord and Tenant agree as follows with respect to any Alterations:

(a) If (i) no Event of Default shall have occurred and be continuing, and (ii) prior to the scheduled expiration date of the Term, including any Renewal Term (the "Expiration Date"), Landlord shall not have entered into one or more leases for the Premises (each, a "New Lease"), Tenant may defer its obligations to remove the Alterations, repair any damage caused by such removal, and restore the portion of the Premises in question to substantially its condition immediately preceding the construction of such Alterations (collectively the "Restoration") for a period not to exceed six (6) months from and after the Expiration Date (the "Deferral Period"), provided that: (A) at least sixty (60) days prior to the Expiration Date, Tenant shall give Landlord written notice that Tenant desires to so defer its Restoration obligations; (B) Tenant shall pay to Landlord, in consideration of each one (1) month (or part thereof) period during the Deferral Period, and any subsequent period until the delivery to Landlord of Tenant's Initial Completion Notice (as defined in Section 3(g) below) (the "Initial Completion Period"), in advance on the first day of each one (1) month period during the Deferral Period and the Initial Completion Period (except that the first such payment shall be paid by Tenant together with Tenant's notice described in clause (A)) an amount equal to two (2) times Tenant's monthly rent, taxes, assessments and other charges, as defined in Sections 2 and 5.1 of the Lease, and (C) except as otherwise provided to the contrary in this Agreement, during the Deferral Period and any subsequent Completion Period Tenant shall be responsible for complying with all obligations required to be complied with during the Term and any Renewal Term (except that Tenant's payment obligations under Sections 2 and 5.1 of the Lease during the Deferral Period



and any subsequent Completion Period shall be as set forth in clause (B) above). In no event shall the Initial Completion Period extend beyond six months from the expiration of the Deferral Period. In the event Tenant fails to deliver Tenant's Initial Completion Notice (as defined in Section 3(g) below) within six months from the expiration of the Deferral Period, Tenant shall be deemed a holdover tenant in accordance with Section 18 of the Lease from that date until the date Landlord receives Tenant's Initial Completion Notice. Notwithstanding the provisions of Section 18 of the Lease, Tenant shall not be deemed to be a holdover tenant, and shall not be liable for holdover damages pursuant to Section 18, during the Deferral Period, any subsequent Completion Period and the Arbitration Period (as defined below). Tenant may, at its option, perform any or all of its Restoration obligations during the Deferral Period.

(b) If on or before the expiration of the Deferral Period, Landlord enters into a New Lease that does not expressly require or permit the Landlord to maintain any or all Alterations in place, Tenant shall promptly (and in any case within six (6) months after receipt of written notice from Landlord) perform its Restoration obligations with respect to such Alterations set forth in Landlord's notice to Tenant. In the event Tenant fails to perform its Restoration obligations with respect to such Alterations within such time limit, then Landlord shall be authorized to draw on the Letter of Credit in an amount sufficient to perform any Restoration obligations that Tenant has failed to perform, subject to the provisions of this Section 3.

(c) If, prior to the Expiration Date or the expiration of the Deferral Period, Landlord shall enter into a New Lease, pursuant to which Landlord is expressly required or permitted to maintain any or all Alterations in place (the "Designated Alterations"), then, in that event, Landlord shall promptly provide Tenant with written notice (the "Notice of New Lease") and a copy of the relevant portions of the New Lease, and Tenant shall not be required to remove the Designated Alterations, shall relinquish the Designated Alterations in place and shall, without further action, release to Landlord all right, title and interest in and to such Designated Alterations. Tenant shall have no liability to Landlord for the reinstallation of any Designated Alterations that were removed by Tenant prior to receipt of a Notice of New Lease. Nothing in this subsection shall impact Tenant's obligations under the Lease and this Agreement to remove all Alterations other than the Designated Alterations.

(d) Notwithstanding anything to the contrary contained in this Agreement, if, upon the expiration of the Deferral Period, Landlord has not entered into a New Lease pursuant to which Landlord is expressly required or permitted to maintain in place some or all Alterations, Tenant agrees that it shall, within six (6) months after the expiration of the Deferral Period, at its sole expense, perform the Restoration. In the event Tenant fails to complete the Restoration within such time limit, then Landlord shall be authorized to draw on the Letter of Credit in an amount sufficient to perform any Restoration obligations that Tenant has failed to perform, subject to the provisions of Section 3(g) below.

(e) Notwithstanding anything to the contrary herein contained, any New Lease shall be on terms acceptable to Landlord in its sole and absolute discretion, and Landlord shall have no obligation to attempt to negotiate the terms of any New Lease which would expressly require or permit the maintenance of some or all Alterations in place, and Landlord shall have no liability whatsoever to Tenant if Landlord shall not enter into a New Lease or if a New Lease shall not expressly require or permit the maintenance in place of some or all Alterations.

(f) Notwithstanding anything to the contrary herein contained, on or before the Expiration Date, Tenant shall remove from the Premises, in the manner required by the Lease, all trade fixtures, equipment and personalty of Tenant. From and after the Expiration Date, Tenant shall have no right to occupy the Premises or any part thereof, or any similar possessory rights, except as otherwise provided herein. After the Expiration Date, Tenant shall be granted access to the Premises solely for the purpose of performing the Restoration and conducting any inspections permitted pursuant to this Agreement.

(g) Upon the completion by Tenant of whatever Restoration obligations it reasonably believes are required pursuant to the Lease and this Agreement, Tenant shall promptly notify Landlord in writing of such completion ("Tenant's Initial Completion Notice"). Within fifteen (15) days of Landlord's receipt of Tenant's Initial Completion Notice, Landlord shall either notify Tenant in writing of any required Restoration obligations that it believes have not yet been performed (the "Deficiency Notice"), or shall notify the issuer of the Letter of Credit that the Letter of Credit is to be released in its entirety. If within fifteen (15) days of Tenant's receipt of a Deficiency Notice, Landlord and Tenant are unable to agree in writing on the scope and identity of any additional Restoration obligations, Landlord and Tenant shall submit the issue to arbitration in accordance with the procedures set forth in Section 3(i) below. During the pendency of the arbitration, Landlord shall have the right to draw on the Letter of Credit in an amount sufficient to perform the Restoration obligations identified in the Deficiency Notice; provided, however that if the arbitration panel subsequently determines that Tenant was not required to perform all or a portion of the Restoration obligations identified in the Deficiency Notice, and that the full amount of the Letter of Credit proceeds exceeds the estimated cost of the Restoration work that was required to be performed, then Landlord shall, within ten (10) days of the issuance of the arbitration panel's determination, submit to Tenant by wire transfer or by certified or bank check an amount equal to that portion of the Letter of Credit proceeds that the panel estimates are attributable to the portion of the Restoration obligations that the arbitrators determined were not required. Upon submission of the issue to arbitration, Tenant shall then have no further access to the Premises, except that Tenant and a contractor and/or licensed architect chosen by Tenant shall be granted reasonable access to the Premises for the sole purpose of inspecting the Premises in order to prepare a report regarding the nature, status and scope of Tenant's Restoration. In the event the arbitration panel determines that Tenant is required to perform some or all of the Restoration obligations identified in the Deficiency Notice, then Tenant shall promptly commence such additional Restoration work within thirty (30) days of Tenant's receipt of a copy of the arbitration panel's determination, and shall make reasonable efforts to complete all additional Restoration work within four (4) months of the date of Tenant's receipt of a copy of the arbitration panel's determination (the "Additional Completion Period"). If the cost of such additional Restoration work is estimated by the arbitrators to exceed 5% of the total amount of Removal Security posted by Tenant, then Tenant shall pay to Landlord, within thirty (30) days of Tenant's receipt of a copy of the arbitration panel's determination, an amount equal to the monthly payments provided for in Sections 2 and 5.1 of the Lease allocable to the period commencing thirty (30) days after the delivery to the Landlord of Tenant's Initial Completion Notice and ending thirty (30) days after Tenant's receipt of a copy of the arbitration panel's determination (the "Arbitration Period"); provided, however, that if Landlord enters into a new lease prior to the expiration of that period for all or some portion of the Premises, Tenant's obligation to make such monthly payments attributable to the

square footage covered by the new lease shall cease on the date Landlord first receives rent under such new lease. Tenant shall be obligated to make monthly payments to Landlord in accordance with Section 3(a)(B) of this Agreement from the date the Arbitration Period expires until the delivery of a written notice by Tenant to Landlord ("Tenant's Additional Completion Notice") stating that such additional work has been completed; provided, however, that if Landlord enters into a new lease prior to the expiration of the Additional Completion Period for all or some portion of the Premises, Tenant's obligation to make such monthly payments attributable to the square footage covered by the new lease shall cease on the date Landlord first receives rent under such new lease. Upon receipt by Landlord of Tenant's Additional Completion Notice, the parties shall follow the same procedures as are set forth above in this Section 3(g) with respect to Tenant's Initial Completion Notice.

(h) Landlord agrees that it shall use reasonable efforts to complete all Restoration obligations assumed by it within six (6) months of the date of the Deficiency Notice. Upon the completion by Landlord of any Restoration obligations, Landlord shall promptly notify Tenant in writing of such completion ("Landlord's Completion Notice"), and shall set forth in such notice an itemized list of each element of the Restoration work that was performed by or on behalf of the Landlord and the actual cost expended by the Landlord on each such element. Upon receipt of Landlord's Completion Notice, Tenant and a contractor and/or licensed architect chosen by Tenant shall be granted reasonable access to the Premises for the sole purpose of inspecting and evaluating the nature, status and scope of the Restoration obligations performed by or on behalf of the Landlord. Within thirty (30) days of the receipt of Landlord's Completion Notice, Tenant may object in writing to the reasonableness of the cost of the Restoration work performed by Landlord. If, within fifteen (15) days of Landlord's receipt of Tenant's objection, Landlord and Tenant are unable to agree on the reasonableness of the cost of Landlord's Restoration work, Landlord and Tenant shall submit the issue to arbitration in accordance with the procedures set forth in Section 3(i) below. In the event the arbitration panel determines that the reasonable cost of the Restoration work performed by Landlord is less than the actual cost expended as identified in Landlord's Completion Notice, and that the full amount of the Letter of Credit proceeds exceeds the reasonable cost of the Restoration work performed by Landlord, then Landlord shall, within ten (10) days of the issuance of the arbitration panel's determination, submit to Tenant by wire transfer or by certified or bank check an amount equal to the portion of the Restoration costs that the arbitrators determined were not reasonable. In the event the arbitration panel determines that the full amount of the Letter of Credit proceeds does not exceed the reasonable cost of the Restoration work performed by Landlord, then, under Section 18 of the Lease, Tenant shall only be obligated to pay Landlord an amount equal to the difference between the reasonable cost of the Restoration work performed by Landlord and the full amount of the Letter of Credit proceeds.

(i) If within fifteen (15) days of: (i) Tenant's receipt of a Deficiency Notice under Section 3(g) hereof, or (ii) Landlord's receipt of an objection to Landlord's Completion Notice under Section 3(h) hereof, Landlord and Tenant are unable to agree in writing, then within ten (10) days after that date, Landlord and Tenant shall each select a single arbitrator who shall have at least ten (10) years experience in the construction of commercial warehouse, assembly and manufacturing buildings in the Central New Jersey area. Within fifteen (15) days thereafter, the two selected arbitrators shall select a third arbitrator, and all three arbitrators shall constitute the panel of arbitrators. If the two arbitrators selected by Landlord and Tenant fail to agree upon and

appoint a third arbitrator within such fifteen (15) day period, then the parties shall immediately contact the American Arbitration Association ("AAA") in writing and request that the AAA appoint the third arbitrator within twenty (20) days of the AAA's receipt of such written request. None of the arbitrators shall have been affiliated with, or ever worked with or been hired by, either the Landlord or the Tenant. Within fifteen (15) days of the selection of the first two arbitrators, the parties shall agree on a written discovery schedule. The discovery schedule shall provide that all discovery, including expert discovery, shall be completed within thirty (30) days of the date of the schedule. The determination of the arbitration panel shall be limited solely to: (i) in the case of a reference pursuant to Section 3(g) of this Agreement, the issue of whether under the Lease and this Agreement Tenant is required to perform any or all of the Restoration obligations identified in the Deficiency Notice, and (ii) in the case of a reference pursuant to Section 3(h) of this Agreement, the issue of the reasonableness of the cost of the Restoration work performed by Landlord. The arbitration panel shall hold a hearing within thirty (30) days of the discovery deadline, and shall require submission of such further information as the panel, in its sole discretion, determines to be necessary. Within five (5) business days of the hearing, the arbitration panel shall inspect the Premises, and shall issue its determination in writing to both parties within thirty (30) days of the inspection. The determination by the arbitration panel shall be binding upon Landlord and Tenant. Each party shall bear the cost of its arbitrator, experts and attorneys. The cost of the third arbitrator, and any other fees and expenses incurred in connection with the arbitration, shall be paid by Landlord and Tenant equally.

(j) Landlord shall not be entitled to draw on the Letter of Credit unless either: (a) Tenant has failed timely to renew the expiring Letter of Credit in accordance with the provisions of Section 2(b) of this Agreement; or (b) Tenant has failed to perform its Restoration obligations under the Lease and this Agreement, and the cash Removal Security, if any, held by Landlord is not sufficient to cover the damages likely to be incurred by Landlord as a result of such failure. In the event Landlord is entitled to draw on the Letter of Credit, Landlord shall only be entitled to draw up to the net amount required by Landlord to perform that portion of the Restoration work that Tenant failed to perform, after application by Landlord of any cash security deposit (provided such cash security deposit is not required to cure any other default by Tenant) or cash Removal Security (including accrued interest) held by Landlord.

(k) Landlord agrees that upon the submission of any documentation to the issuer of the Letter of Credit, Landlord shall simultaneously provide copies of all such documentation to Tenant.

(l) Any proceeds of the Letter of Credit held by Landlord that are not expended on Restoration pursuant to the terms hereof shall be promptly delivered to Tenant after the Restoration is complete.

4. (a) The parties agree that the Superior Court of New Jersey shall have exclusive jurisdiction over any subsequent proceeding arising out of, or relating to, the enforcement of this Agreement, and the parties consent to venue in Ocean County, New Jersey. The laws of the State of New Jersey shall govern and apply to such subsequent proceeding, without regard to any conflict of laws provision.

(b) Each of the parties to this Agreement represents and warrants to and agrees with each other party hereto as follows:

(i) Each party has received independent legal advice from its attorneys with respect to the advisability of executing this Agreement.

(ii) No party, officer, agent, employee, representative or attorney of or for any party, has made any statement or representation to any other party regarding any fact relied upon in entering into this Agreement, nor does any party rely upon any statement, representation or promise of any other party, officer, agent, employee, representative or attorney of or for any other party in executing this Agreement, except as expressly stated in this Agreement.

(iii) Each of the individuals executing this Agreement on behalf of their respective entities is empowered to do so and thereby binds such respective entity.

(c) Except as modified hereby, the Lease is hereby ratified and shall remain in full force and effect in accordance with its terms. In the event of any conflict between the terms of this Agreement and the Lease, the terms of this Agreement shall control. Landlord and Tenant each represent to the other that to the best of its knowledge neither party is in default of its obligations under the Lease as of the effective date of this Fourth Amendment. This Fourth Amendment shall become effective and binding upon the parties as of the date both Landlord and Tenant have executed this Fourth Amendment.

IN WITNESS WHEREOF, Landlord and Tenant have executed this Agreement as of the day and year first above written.

LANDLORD:

WITNESS:

AIRPORT ASSOCIATES

/s/ June Langebin  
-----  
Name: June Langbein

By: /s/ Edmund Bennett, Jr.  
-----  
Edmund Bennett, Jr., Partner

WITNESS:

/s/ June Langebin  
-----  
Name: June Langbein

By: /s/ Edmund Bennett, Jr.  
-----  
Ronald Bennett, Jr., Partner

TENANT:

ATTEST:

VIVUS, INC.

/s/ Lori Forrest

By: /s/ Guy P. Marsh

-----  
Name: Lori Forrest  
Title: Assistant Corporate  
Controller

-----  
Name: Guy P. Marsh  
Title: Vice President and General  
Manager

EXHIBIT A

SUBJECT ALTERATIONS

Hand Delivered: Project Manual #96-081, dated 4/9/97 - 745 Airport Road,  
Lakewood, NJ

Drawings as listed:

Drawings	Issued	Revisions	Revisions	Revisions	
-----	-----	-----	-----	-----	
LA.1	4/23/97	6/12/97	7/24/97		
4A.1	4/29/97	6/12/97	6/20/97	7/14/97	8/11/97
4A.2	4/29/97	6/12/97	6/20/97	7/14/97	
4A.3	4/29/97	6/12/97			
4A.4	4/29/97	6/12/97	7/31/97	8/11/97	9/8/97
4A.5	4/29/97	6/12/97			
4A.6	4/29/97	6/12/97	6/20/97	6/23/97	7/14/97
4A.7	4/29/97	6/12/97	7/9/97		
4A.8	4/29/97	6/12/97	7/3/97		
4A.9	6/28/97	8/11/97			
4A.10	6/28/97				
4S.1	3/19/97	4/21/97			
4S.2	3/19/97	4/21/97	4/27/97		
4S.3	3/19/97	4/21/97	4/27/97		
FP.1	5/6/97				
4PO.1	4/29/97	5/5/97	5/27/97	6/6/97	
4P1.0	4/29/97	6/9/97	6/20/97	7/2/97	
4P1.1	4/29/97	6/9/97	6/20/97	7/1/97	
4P1.2	4/29/97	6/9/97	9/20/97		
4P2.0	4/29/97	6/9/97	6/20/97	7/2/97	
4P2.1	4/29/97	6/9/97	6/20/97	7/1/97	
4P3.0	4/29/97				
4P3.1	4/29/97	6/9/97	6/27/97	7/2/97	
4P4.0	4/29/97				
4HVAC.1	4/29/97				
4HVAC1.1	4/29/97	6/12/97	7/15/97		
4HVAC1.2	4/29/97	6/12/97			
4HVAC2.1	4/29/97	6/12/97			
4HVAC2.2	4/29/97	6/12/97			
4HVAC3.1	4/29/97				
4HVAC3.2	4/29/97				
4HVAC3.3	4/29/97				
4HVAC4.1	4/29/97	6/12/97	7/15/97		
4HVAC4.2	4/29/97	6/12/97			
4HVAC5.1	4/12/97	6/12/97	7/15/97		
4E.1	4/29/97	6/12/97			
4E.2	4/29/97	9/12/97			
4E.3	4/29/97	6/12/97	8/27/97		
4E.4	4/29/97	6/12/97	8/27/97		
4E.5	4/29/97	8/27/97			
4E.7	4/29/97	6/12/97	8/27/97		
4E.8	4/29/97	6/12/97	8/27/97		

Hand Delivered: Project Manual #96-081, dated 3/20/97 - 735 Airport Road,  
Lakewood, NJ

Drawings as listed:

Drawings	Issued	Revisions	Revisions	Revisions	
-----	-----	-----	-----	-----	
3A.1	5/23/97	6/23/97			
3A.2	5/7/97	6/23/97			
3A.3	5/7/97	6/23/97			
3A.4	5/7/97	6/23/97			
3A.5	5/7/97	6/23/97			
3A.6	5/13/97	6/23/97	9/8/97		
3A.7	5/7/97	6/23/97			
3A.8	5/13/97	6/23/97	7/3/97		
3D.1	5/13/97				
3P0.1	7/23/97	7/31/97			
3P1.0	7/23/97	5/27/97	6/9/97	7/31/97	
3P1.1	7/23/97	5/27/97	6/9/97	7/31/97	
3P1.1	7/23/97	5/27/97	6/9/97	8/19/97	9/16/97
3P2.0	7/23/97	7/31/97			
3P2.1	7/23/97	7/31/97			
3P2.2	7/23/97	7/31/97			
3P3.0	7/23/97	7/31/97			
3P3.1	7/23/97	7/31/97			
3P4.0	7/23/97				
3HVAC0.1	5/21/97	5/21/97			
3HVAC1.1	5/21/97	7/15/97			
3HVAC1.2	5/21/97	5/21/97			
3HVAC2.1	5/21/97	7/15/97			
3HVAC2.2	5/21/97	7/15/97			
3HVAC3.1	5/21/97				
3HVAC3.2	5/21/97	7/15/97			
3HVAC3.3	5/21/97				
3HVAC4.1	5/21/97	7/15/97			
3HVAC4.2	5/21/97	7/15/97			
3HVAC5.1	5/21/97	7/15/97			
3E.1	5/7/97	8/12/97			
3E.2	5/7/97	8/12/97			
3E.4	5/7/97	8/12/97			
3E.5	5/7/97	8/12/97			
3E.6	5/7/97	8/12/97			
3E.7	5/7/97	8/12/97			
3E.8	5/7/97	8/12/97			
3E.9	5/7/97	8/12/97			



## BANK OF AMERICA

## IRREVOCABLE STANDBY LETTER OF CREDIT NO.

Date of Issue: October 25, 2000

Applicant: VIVUS, Inc.  
1172 Castro Street  
Mountain View, CA 94040

AMOUNT: \$3,324,143.00

BENEFICIARY: Airport Associates  
1245 Airport Road  
Lakewood, New Jersey 08701

At the request and for the account of Vivus, Inc. (the "Account Party") we hereby establish in your favor our irrevocable standby Letter of Credit No.

("Letter of Credit") in the aggregate amount of THREE MILLION THREE HUNDRED TWENTY FOUR THOUSAND ONE HUNDRED FORTY THREE DOLLARS (\$3,324,143.00).

We are advised that this Letter of Credit is issued with respect to that certain Lease Agreement dated as of January 1, 1997, as the same has been and may in the future be amended, between you, as Landlord, and the Account Party, as Tenant. Said Lease Agreement, and any amendments or modifications thereof, is hereinafter referred to as the "Lease".

Funds under this Letter of Credit are available to you by wire transfer of funds to an account or accounts designated by you within one (1) business day after presentation of the following documents at our office at 333 S. Beaudry, 19th Floor, Mail Code: CA9-703-19-23, Los Angeles, Ca 90017 Attn: Standby Letter of Credit Dept. in person, or by delivery by a reputable overnight courier, prior to the close of business on the expiration date set forth below:

1. Your sight draft drawn on us in an amount not exceeding the amount of this Letter of Credit (less sums previously paid by us hereunder) executed by the person executing the Certification (as defined below) and bearing the number of this Letter of Credit; and
2. A written certification (the "Certification") executed by a natural person, specifically certifying that: (a) such person is your duly authorized representative; (b) pursuant to the Lease, Landlord is entitled to draw on this Letter of Credit; (c) the amount available to be drawn under this Letter of Credit by you; and (d) the wire transfer

instructions for the account or accounts designated by you to which the funds drawn under this Letter of Credit are to be delivered.

The amount available to be drawn under this Letter of Credit shall be irrevocably reduced by the amount of each draw hereunder.

The expiration of this Letter of Credit is February 15, 2002, but such expiration date shall be automatically extended without amendment for a period of one (1) year from the present expiration date and any future expiration dates, but in no event later than August 31, 2013, unless, at least 60 days before any expiration date, we notify you by registered mail or overnight courier service at the above address, that this letter of credit is not extended beyond the current expiration date.

This Letter of Credit may be drawn upon in one or more drafts not exceeding, in the aggregate, the amount available hereunder.

We hereby issue this Letter of Credit in your favor, and we hereby undertake to honor all drafts drawn under and in compliance with the terms of this Letter of Credit.

This Letter of Credit shall be governed by and construed in accordance with the Uniform Customs and Practices for Documentary Credits (1993 revision) International Chamber of Commerce Publication 500.

BANK OF AMERICA, N.A.

By: /s/ Lawrence Banales  
Authorized Signature

By: /s/ Michael Boriboon  
Authorized Signature

EXCLUSIVE DISTRIBUTION AGREEMENT  
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This Exclusive Distribution Agreement ("Agreement") is made as of October 1, 2002 (the "Effective Date"), between, VIVUS, Inc., a Delaware corporation, having its principal place of business at 745 Airport Road, Lakewood, NJ 08701 ("Client"), and CORD Logistics, Inc., an Ohio corporation, having its principal place of business at 15 Ingram Blvd LaVergne, TN 37086 ("CORD").

A. Client is, among other things, in the business of developing and marketing pharmaceutical products in the United States, the District of Columbia and Puerto Rico (the "Territory").

B. CORD is, among other things, in the business of distributing pharmaceutical products to wholesalers, specialty distributors, physicians, clinics, hospitals, pharmacies, and other health care providers in the Territory, and of providing Information Systems and other services that support its customers' use of its distribution capabilities.

C. Client desires to engage CORD as its exclusive distribution agent for commercial sales of MUSE in all formulations, and such other pharmaceutical products agreed to by the parties (collectively, the "Product") in the Territory and to perform certain other services described in this Agreement, all upon the terms and conditions set forth in this Agreement.

THEREFORE, in consideration of the mutual conditions and covenants set forth herein, CORD and Client (collectively referred to as "Party" or "Parties") agree as follows:

1. APPOINTMENT/AUTHORIZATION.  
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1.1 Upon the terms and conditions set forth in this Agreement, Client appoints CORD as its exclusive distribution agent of Product in the Territory to Client's customers, including, but not limited to, wholesalers, specialty distributors, physicians, clinics, hospitals, pharmacies and other health care providers in the Territory (collectively, "Customers").

1.2 Subject to the terms and conditions set forth in this Agreement, CORD accepts the appointment to represent Client as its authorized exclusive distribution agent of Product to Customers in the Territory.

2. SERVICES.  
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2.1 CORD shall provide the services set forth in the Operating Guidelines, which include, without limitation, storage, distribution, returns, customer support, financial support, EDI and system access support ("Services"). A copy of the Operating Guidelines is attached hereto as Exhibit A and incorporated by reference.

2.2 The Operating Guidelines may be amended from time to time upon the mutual written agreement of the Parties; provided, however, that any change, modification or amendment to the Operating Guidelines may result in an increase in the fees charged by CORD in Section 5.

2.3 CORD's services shall comply with the Operating Guidelines, provided Client's shipments of Product to CORD are within twenty-five percent (25%) of its Forecast (as hereinafter defined).

2.4 All Product Returns shall be processed and handled by CORD in accordance with the Operating Guidelines; and, any customization or additional return services requested by Client shall be performed at an additional fee as agreed by the Parties.

2.5 Client is solely responsible for all Product recalls. In the event Product is subject to recall, or Client, on its own initiative, recalls any Product, CORD shall provide assistance to Client as set forth in the Operating Guidelines, provided that Client shall pay to CORD an amount equal to CORD's actual costs incurred with any such recall services. Such cost shall be in addition to the Service Fees described in Section 5 below.

3. PRODUCT SUPPLY/CLIENT RESPONSIBILITIES.  
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3.1 Client shall deliver Product to CORD at CORD's facility located at

15 Ingram Boulevard, Suite 100, LaVergne, TN 37086, or such other distribution facility as may be mutually agreed to in writing by Client and CORD ("Facility").

3.2 Client shall be responsible for delivery of Product to the Facility, including all costs, expenses and risk of loss associated with such delivery. Title to Product shall remain with Client at all times, even when Product is stored or warehoused at the Facility. Client shall at all times insure the Product for damage, loss, destruction, theft or any such other property damage ("Loss") as further set forth in Section 15 below. Except for Loss resulting solely from the gross negligence or willful misconduct of CORD, Client shall bear all risk of loss or damage with respect to the Product stored or warehoused at the Facility.

3.3 Client shall provide CORD with a forecast of the volume of Product to be handled by CORD under this Agreement, not less often than semi-annually ("Forecast"). Upon execution of this Agreement, Client shall deliver to CORD a customer list, which sets forth the Product prices (the "Customer Price List"). Client shall notify CORD of any change in the Customer Price List not less than seventy-two (72) hours prior to the effective date of any such change. CORD shall use commercially reasonable efforts to implement such price change in accordance with Client's instruction.

3.4 CORD shall visually inspect each shipment of Product for external damage or loss in transit and notify Client of any such damage or loss within a commercially reasonable period of time following discovery.

4. INFORMATION SYSTEM ACCESS.  
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4.1 CORD shall provide Client access to an Operating System Base, which consists of the software used by CORD to support the services provided to Client, including the server and other components needed to execute the software and certain support services associated therewith, as further set forth in the Operating Guidelines (collectively, the "System"), upon the terms and conditions set forth in the System Access Agreement. A copy of the System Access Agreement is attached as Exhibit C and incorporated herein by reference. The software releases are (i) EliteSeries 6.1.2, as modified by CORD, supplied by Tecsys, Inc., a Montreal, Quebec, Canadian company, and any upgrades, maintenance releases or modifications implemented by CORD to support distribution services provided by CORD; (ii) BACCS 3.0 as modified by CORD and any upgrades implemented by CORD to support financial services provided by CORD; and (iii) Impromptu 6.0, supplied by Cognos Inc., a Canadian company, and any upgrades, maintenance releases or modifications implemented by CORD to support reporting services provided by CORD.

4.2 The System shall be made available to Client at the fees set forth in the Fee Schedule, except that any custom enhancements requested by Client shall be billed separately based on an hourly rate set forth in the Fee Schedule (as defined in Section 5).

4.3 In addition to the terms set forth in the System Access Agreement, Client shall maintain (i) a local area network sufficient to support Client's terminals and personal computers that have access to the System, all such personal computers shall meet the minimum specifications necessary to support software needed to access the system; (ii) a centralized server sufficient for data storage, if data export requirements exist; and (iii) a connection to the internet sufficient to support system access. Client shall also assign knowledgeable and qualified employees or representatives to facilitate access to the System.

5. FEES.  
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5.1 As compensation for the Services, Client shall pay to CORD the fees (the "Fees") set forth on Exhibit B (the "Fee Schedule").

5.2 CORD shall issue an invoice to Client for the Services rendered under this Agreement or for any other amounts due on a monthly basis. Payment is due within twenty-eight (28) days of the invoice date. If the Invoice is not paid within such twenty-eight (28) day period, a service charge on the unpaid amount calculated at the rate of 1.5% per month (or the maximum rate permitted by law if such rate is less than 1.5% per month) shall be imposed until such amount is paid in full.

5.3 The Fees shall be held firm for the first contract year. Thereafter, CORD shall adjust the price not more often than once per contract year by the greater of (i) the increase in the Producer Price Index - All Commodities published by the United States Department of Labor, Bureau of Statistics, as amended from time to time, or (ii) [\*]. For purposes of sub-Section (i), the base point shall be the index level on the first day of the contract year.

5.4 Notwithstanding the terms set forth above in Section 5.3, if CORD can reasonably demonstrate that the costs for providing the Services have materially increased, or are likely to materially increase in the coming year due to the adoption of any applicable law or regulation (or any material change in the interpretation or administration thereof), or due to unforeseen circumstances beyond CORD's reasonable control, then upon notice from CORD, the Parties agree to meet in good faith and negotiate a mutually acceptable adjustment to the Fees.

6. TERM AND TERMINATION.  
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6.1 The initial term of this Agreement shall begin on the Effective Date and shall continue for a period of three (3) years (the "Initial Term"), unless terminated earlier pursuant to this Agreement. Thereafter, this Agreement shall automatically renew for additional terms of one (1) year each, unless written notice of termination is given by either Party at least ninety (90) days prior to the end of the Initial Term, or such other term, in which case this Agreement shall terminate at the end of the then current term.

6.2 Either Party shall have the right to terminate this Agreement:

(a) upon one hundred eighty (180) days prior written notice to the other Party, provided that in the event Client terminates this Agreement, without cause, prior to the end of the Initial Term, such termination shall be effective only upon payment to CORD of all remaining fixed Fees set forth on the Fee Schedule for the remainder of the Initial Term;

(b) upon the breach by the other Party of a material provision of this Agreement and that Party's failure to cure such breach within thirty (30) days following written notice thereof from the non-breaching Party, provided that, with respect to any failure to make any payment when due under this Agreement, such period to cure shall be reduced to ten (10) days; or

(c) immediately upon notice to the other Party following the commencement of any bankruptcy or insolvency proceeding (whether voluntary or involuntary) with respect to such other Party or its assets, which in the event of an involuntary proceeding, is not dismissed within sixty (60) days, the general assignment for the benefit of creditors by such other Party, or the appointment of a receiver, trustee or liquidator by or for such other Party.

6.3 Client shall have the right to terminate this Agreement upon thirty (30) days written notice if CORD is unable to provide the services set forth in the Operating Guidelines at the Facility for a period of five (5) days or more, and provided the parties are unable to mutually agree in writing to the use of another distribution facility within such thirty day notice period.

6.4 Termination or expiration of this Agreement shall not relieve either Party from any liability or obligation that accrued prior to such termination or expiration. Upon termination or expiration of this Agreement, all Product shall be returned to Client or a designee of Client, at Client's sole cost and expense. Sections 11,12, 13 and 14 shall survive termination or expiration of this Agreement.

7. AUDITS. Client or its designee shall have the right to conduct the following audits each calendar year: (a) one audit to confirm compliance with all relevant Federal Drug Administration regulations ("Regulations"), including applicable Current Good Manufacturing Practices ("CGMPs"); (b) one physical audit of such portions of the Facility that relate solely to Product stored and warehoused at the Facility under this Agreement; and (c) one audit of CORD's financial records as they relate to the storage and distribution of the Product. In addition to the audits described above, Client shall have the right to conduct such additional audits as are necessary to investigate issues of noncompliance with applicable Regulations and CGMPs, and to investigate apparent discrepancies in data relating to the storage and distribution of the Product. All audits permitted by this Section 7 shall be conducted during normal business hours (i.e., 8:00 a.m. to 5:00 p.m. local time), upon five (5) business days prior written notice to CORD.

8. COMPLIANCE WITH LAWS. Each Party shall conduct its activities in connection with this Agreement in compliance with all applicable laws, rules, regulations, and orders of governmental entities.

9. REPRESENTATIONS AND WARRANTIES.  
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9.1 Each Party represents and warrants to the other that:

(a) it has full power and authority to enter into this Agreement and perform all obligations and conditions to be performed by it under this Agreement without any restriction by any other Agreement or otherwise;

(b) the execution, delivery and performance of this Agreement have been duly authorized by all necessary corporate action of that Party; and

(c) this Agreement constitutes the legal, valid and binding obligation of that Party.

9.2 Client further represents and warrants to CORD that the Product:

(a) is and shall be manufactured in conformity with the Food, Drug and Cosmetic Act, as amended from time to time, and all other applicable laws, rules, regulations and orders of governmental entities relating to the manufacture, promotion, sale or distribution of the Product;

(b) does not violate or infringe any patent, trademark, tradename or other interest of any person or entity.

10. TAXES. Client shall pay when due all sales, use, gross receipts, excise, personal property taxes associated with the Product (excluding any personal property tax associated with CORD's equipment used in connection with the Services), and other taxes now or hereafter imposed as a result of the transactions contemplated by this Agreement, none of which have been included in the fees payable to CORD under this Agreement; provided that the amounts payable by Client under this section shall not include taxes based on the net income of CORD.

11. TRADEMARKS. Neither Party shall have the right to use the name of the other Party or any Affiliate of the other Party, or the other Party's or such Affiliates' trademarks, service marks, logos, or other similar marks in any manner except with the prior written approval of that Party; provided that the foregoing shall not prohibit CORD's use of Client's names or marks in connection with the performance of the Services in a manner consistent with this Agreement. "Affiliate," as used in this Agreement, means any legal entity which, during the Term hereof, controls, is controlled by, or is under common control with, such Party. For purposes of this definition, an entity shall be deemed to control another entity if it owns or controls, directly or indirectly, at least fifty percent (50%) of the voting interest of all equity interests of the other entity (or other such comparable ownership interest for an entity other than a corporation).

12. CONFIDENTIALITY.

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12.1 Each Party acknowledges that as a result of this Agreement it may learn and have access to trade secrets and other confidential and proprietary information of the other Party through employees, representatives and/or agents acting on behalf of or subcontracted to either Party (collectively the "Representatives"), including without limitation, financial information, information regarding business practices and techniques, and systems and technology information, or any information identified as confidential in writing by either Party (the "Confidential Information"). For purposes of this Agreement, Confidential Information shall not include information disclosed by one Party to the other Party to the extent that such information can be proven by written evidence: (a) to be in the public domain or generally available in the industry in which the disclosing Party engages in business without any violation of this Agreement by the other Party; (b) is already legally known to the other Party or any of its Affiliates at the time of its disclosure by the disclosing Party; (c) becomes known to the other Party or any of its Affiliates from a third party without any obligation of confidentiality or limitation on use; or (d) is independently developed by the other Party or any of its Affiliates prior to the date of its disclosure. The specific material terms of this Agreement shall be deemed to be the Confidential Information of each Party. Confidential Information shall not be deemed to be in the public domain or publicly known or in the receiving Party's possession because it is embraced by more general information in the receiving Party's possession or because it is embraced in general terms in publications.

12.2 Neither Party shall, directly or indirectly, at any time: (a) disclose to any third person or entity any Confidential Information of the other Party (whether learned before or after the date of this Agreement), or (b) use, or permit or assist any third person or entity to use, any such Confidential Information, excepting only: (i) disclosures required by law, rule, regulation or order, as reasonably determined by the disclosing Party or its legal counsel, and (ii) disclosures on a confidential basis to

directors, officers, employees, and agents of that Party or its Affiliates who have a reasonable need to know such Confidential Information in the normal course of business of that Party or any of that Party's Affiliates.

12.3 The obligations of confidentiality hereunder shall survive the termination of this Agreement for a period of three (3) years. Upon termination of this Agreement (for any reason) each Party shall promptly: (i) return to the other Party all documentation and other materials (including copies of original documentation or other materials) containing any Confidential Information of the other Party; or (ii) with the other Party's consent, which consent will not be unreasonably withheld, certify to the other Party, pursuant to a certificate in form and substance reasonably satisfactory to the other Party, as to the destruction of all such documentation and other materials.

13. INDEMNIFICATION. Each Party shall indemnify and hold harmless the other Party and its parent and Affiliates, and each of their directors, officers, employees, agents, and representatives from and against all claims, liabilities, losses, damages, costs, and expenses, including, without limitation, reasonable attorneys' fees ("Liability") by a third party arising directly or indirectly out of any failure of that Party to perform fully all obligations and conditions to be performed by that Party pursuant to this Agreement or any breach of any warranty made by that Party in this Agreement. Client further agrees to indemnify and hold harmless CORD, its parent and Affiliates and each of their directors, officers, employees, agents and representatives from any and all Liability arising directly or indirectly out of injury or death to person or property alleged to have been caused by Client's Product, unless such Liability arose in whole or part as a result of the negligence, gross negligence or willful misconduct of CORD.

14. LIMITATION OF LIABILITY. NOTWITHSTANDING THE FOREGOING PROVISIONS OF SECTION 13, OR ANY OTHER PROVISION OF THIS AGREEMENT TO THE CONTRARY, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY CONSEQUENTIAL (SPECIFICALLY EXCEPTING THOSE CONSEQUENTIAL DAMAGES ARISING FROM EACH PARTY'S OBLIGATION TO INDEMNIFY THE OTHER FOR LIABILITY ARISING OUT OF OR RELATING TO THIRD PARTY CLAIMS IN ACCORDANCE WITH SECTION 13 ABOVE), INCIDENTAL, INDIRECT, SPECIAL, OR OTHER SIMILAR DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT.

15. INSURANCE. During the term of this Agreement and for as long thereafter as necessary to cover claims resulting from this Agreement, Client shall maintain: (i) product liability and commercial general liability insurance having a limit of not less than [\*] ; and (ii) property damage insurance at replacement value for the Product located at the CORD Facility or in transit to or from the CORD Facility, pursuant to one or more insurance policies with reputable insurance carriers. Cardinal Health, Inc. and its subsidiaries shall be designated as "additional insureds" under the product liability and commercial general liability insurance policy(ies) and as "loss payees" under the property damage insurance policy(ies). Prior to the Commencement Date, Client shall deliver to CORD certificates evidencing such insurance. Client shall not cause or permit such insurance to be canceled or modified to materially reduce its scope or limits of coverage during the term of this Agreement or thereafter as provided above. Except for any losses resulting solely from the gross negligence or intentional misconduct of CORD, Client shall bear all risk of loss or damage with respect to the Product, whether located at the Facility or otherwise.

16. DISPUTE RESOLUTION. The Parties agree to use good faith efforts to resolve all disputes within sixty (60) days of written notice that such a dispute exists. If dispute under this Agreement cannot be resolved by the Parties within such sixty (60) day period, the Parties agree to refer the matter to one executive from each Party not directly involved in the dispute for review and resolution. A copy of the



terms of this Agreement, agreed upon facts and areas of disagreement, and a concise summary of the basis for each side's contentions will be provided to both executives who shall review the same, confer, and attempt to reach a mutual resolution of the issue within forty-five (45) days after receipt of the materials referenced above. If the matter has not been resolved within such forty-five (45) day period, either or both Parties may pursue resolution of the matter through a binding, non-reviewable and non-appealable alternative dispute resolution process conducted within the State of New Jersey by a sole arbitrator in accordance with the Non-Administered Arbitration Rules of the CPR Institute for Dispute Resolution. The existence of the dispute, the dispute resolution process and the arbitrator's award shall be maintained confidential, provided that the arbitrator's award may be entered as a final judgment in any court having jurisdiction.

17. MISCELLANEOUS.

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17.1 Independent Contractor. The relationship of the Parties is that of independent contractors, and neither Party shall incur any debts or make any commitments for the other Party except to the extent expressly provided in this Agreement. Nothing in this Agreement is intended to create or shall be construed as creating between the Parties the relationship of joint venturers, co-partners, employer/employee or principal and agent.

17.2 Notices. Any notice or other communication required or desired to be given to any Party under this Agreement shall be in writing and shall be deemed given: (a) three business days after such notice is deposited in the United States mail, first-class postage prepaid, and addressed to that Party at the address for such Party set forth at the end of this Agreement; (b) one business day after delivered to Federal Express, Airborne, or any other similar express delivery service for next-day delivery to that Party at that address; or (c) when sent by facsimile transmission, with electronic confirmation, to that Party at its facsimile number set forth at the end of this Agreement. Any notice delivered by facsimile transmission will be deemed delivered upon electronic confirmation provided the notice is also deposited in the U.S. mail, first-class postage prepaid. Any Party may change its address or facsimile number for notices under this Agreement by giving the other Parties written notice of such change.

17.3 Governing Law. This Agreement shall be construed under the laws of the State of Tennessee, without regard to its conflicts of laws provisions.

17.4 Severability. If any term of this Agreement is declared invalid or unenforceable by a court or other body of competent jurisdiction, the remaining terms of this Agreement will continue in full force and effect.

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

17.6 Force Majeure. If the performance of any part of this Agreement by either Party shall be prevented, restricted, interfered with or affected for any length of time by fire or other casualty, government restrictions, war, riots, strikes or labor disputes, lock out, transportation delays, acts of God, or any other causes which are beyond the reasonable control of such Party, such Party shall not be responsible for delay or failure of performance of this Agreement for such length of time, provided, however, that the obligation of one Party to pay amounts due to the other Party shall not be subject to the provisions of this Section.

17.7 Complete Agreement. This Agreement constitutes the entire understanding between the Parties and supersedes any contracts, agreements or understanding (oral or written) of the Parties with respect to the subject matter hereof. No term of this Agreement may be amended except upon written agreement of both Parties, unless provided otherwise in this Agreement.

17.8 Assignment. Except as set forth herein, neither Party shall have the right to assign this Agreement, or any of such Party's rights or obligations under this Agreement, without the prior written consent of the other Party, provided, however, that CORD may assign its rights under this Agreement to any parent, subsidiary or affiliate without obtaining such consent. This Agreement shall be binding upon, inure to the benefit of, and be enforceable by and against the respective successors and assigns of the Parties.

IN WITNESS WHEREOF, the undersigned acknowledge and accept the terms of this Agreement and have duly executed this Agreement.

CORD LOGISTICS, INC.

VIVUS, INC.

By /s/ Frank C. Wegerson

By /s/ Guy P. Marsh

-----  
Frank C. Wegerson  
Vice President and General Manager  
1135 Heil Quaker Blvd, #100  
LaVergne, TN 37086

-----  
Guy P. Marsh  
V.P. U.S. Operations  
745 Airport Road  
Lakewood, NJ 08701

Facsimile No. (615) 793-4783

Facsimile No. (732) 942-4821

EXHIBITS  
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Exhibit A	Operating Guidelines
Exhibit B	Fee Schedule
Exhibit C	System Access Agreement

## OPERATING GUIDELINES

In performing its obligations under the Distribution Services Agreement ("Agreement"), CORD Logistics, Inc. ("CORD") will follow the Operating Guidelines as developed jointly with VIVUS, Inc. ("CLIENT"). These Operating Guidelines are in addition to CORD Standard Operating Procedures ("SOPs"). Copies of these documents are maintained by both parties and will be reviewed, and updated if necessary, from time to time as mutually agreed, but not less than once per calendar year.

## 1.0 WAREHOUSING

- 1.1 CORD will maintain its warehouse facility in accordance and comply with all federal, state and local laws, rules and regulations, including the Prescription Drug Marketing Act and current Good Manufacturing Practices ("cGMP") as promulgated under the FDA.
- 1.2 CORD will maintain Standard Operating Procedures appropriate for a pharmaceutical distribution center operating environment.
- 1.3 CORD will maintain documented training programs.
- 1.4 CORD will comply with storage, handling and shipping conditions designated by CLIENT for the "Products".
- 1.5 Products with specific storage requirements must be identified by CLIENT and the storage requirements must be expressly communicated by CLIENT to CORD. The specific requirements must be identified on the package label in accordance with NWDA bar coding standards. Product so identified by CLIENT will be stored in areas designed, continuously monitored and periodically validated for the temperature range specified for each product. CORD will maintain daily temperature recordings. CORD will provide such records to the CLIENT upon written request.
  - 1.5.1 Frozen - [\*]
  - 1.5.2 Refrigerated - [\*]
  - 1.5.3 Controlled ambient - [\*]
  - 1.5.4 Controlled ambient - [\*]
- 1.6 CORD will report temperature excursions to the CLIENT within two (2) business days of occurrence.
- 1.7 Products will be stored in an area with secured access, accessible only to authorized CORD personnel as agreed to by CLIENT and CORD.

## 2.0 RECEIVING

- 2.1 CLIENT or CLIENT's contract manufacturing agent will arrange transportation services to transfer the product to CORD. CLIENT will notify CORD of the specific delivery schedule.
- 2.2 CLIENT's carrier will contact CORD to arrange a delivery appointment.
- 2.3 CLIENT retains title to the goods at all times. CORD's signature on the carrier's bill of lading is an acknowledgement only of CORD's receipt of product.
- 2.4 CLIENT will provide CORD with Material Safety Data Sheets for each product stored at CORD.
- 2.5 CLIENT's product must meet the following standards for carton identification, documentation, palletization, and uniformity:
  - 2.5.1 Each shipping carton and inner packaging of CLIENT product must be labeled to meet NWDA standards for bar coding and human readable markings.
  - 2.5.2 CLIENT will provide the bill of lading, certificate of analysis and other documentation necessary. CORD and CLIENT will mutually agree upon the receiving process.
  - 2.5.3 Pallets will meet GMA standards for 40" x 48" dimensions with four-way entry; will be free of broken boards, treated for pests, and clean.
  - 2.5.4 Receipt of product on non-standard pallets may require restacking onto conforming pallets at CLIENT's expense.
  - 2.5.5 Palletized product must be uniform and consistent with specifications set up in the product master for the number of cartons and eaches.
- 2.6 CORD will receive each shipment into a secure Receiving area.

- 2.7 CORD will count and inspect the exterior packaging of the product, noting any shortages, overages or damage on the carrier bill of lading. CORD will obtain the carrier's signature on the bill of lading acknowledging the condition of the product upon receipt by CORD.
- 2.8 CORD will compare the CLIENT's documentation to CORD's receiving report. Discrepancies will be noted. CORD Quality Assurance will investigate and report all discrepancies to CLIENT within 24 hours of receipt. CLIENT and CORD will determine corrective actions, if any.
- 2.9 CORD will post receipts in the computer inventory system within one business day of delivery unless count discrepancies, missing paperwork, damage investigation, and other receiving anomalies interfere with efficient receiving and documentation. CORD will use commercially reasonable efforts to receive product accurately and efficiently.
- 2.10 CORD reserves the right to assess a fee for services required to hold non-conforming product in receiving, and to investigate, reconcile and report discrepancies to the CLIENT. Fees for receiving services are listed in the Fee Schedule, Exhibit C.
- 2.11 CORD will return partial case quantities - defined as less than a saleable quantity - to the CLIENT at CLIENT's expense.
- 2.12 CLIENT product in unapproved or quarantine status will be physically segregated and CORD's computer system will be flagged accordingly to prevent unapproved product from entering approved picking areas of the warehouse. CLIENT will provide written documentation to CORD to change quarantine product to approved status.
- 2.13 CORD will move product from the Receiving area to bulk storage following CORD SOPs.

### 3.0 INVENTORY

- 3.1 Inventory will be received, tracked and controlled on CORD's computerized inventory system by item number, lot number, expiration date, quantity, and status. CORD system will meet all cGMP requirements for lot traceability and accountability, from receipt of product at CORD to shipment of product to CLIENT's customer.
- 3.2 Quarantined product will be physically segregated and appropriately labeled. Quarantined Product will be released from quarantine status in CORD's inventory system upon written authorization by CLIENT.
- 3.3 CORD will assign unique locations for each product and lot in storage.
- 3.4 Inventory will be routinely verified by CORD through periodic cycle counts. CORD will use its best efforts to maintain accurate and timely inventory records.
- 3.5 Inventory deviations will be investigated by CORD and reported to CLIENT. Corrective actions will be determined jointly by CORD and CLIENT.
- 3.6 CORD will notify CLIENT of all expired or short dated Product (as specified by CLIENT to be "6" number of months prior to expiry date).
- 3.7 Disposition of returned, rejected or expired Product will be handled according to CLIENT's specific written direction.

### 4.0 DISTRIBUTION

- 4.0 Orders approved and available for processing (pick & pack) by 2:00 p.m. Central Time will be shipped before the close of business the same day, Monday through Friday. Orders received by EDI and approved for inventory allocation by 12:00 noon will be shipped by close of business the same day. Orders received and processed after the cutoff times will be shipped the following business day.
- 4.1 Recognizing that order volume may fluctuate from time to time, CORD will staff to meet 125% of the rolling average number of CLIENT orders processed over the previous two (2) calendar months. CORD will use commercially reasonable efforts to meet the shipping schedule outlined herein when order or unit volume exceeds 125% of the rolling average number of orders or units; provided, however, that CORD cannot guarantee daily on-time shipping standards will be achieved during such increased activity periods.

- 4.2 CORD will measure the timeliness of shipments and will report this attribute periodically according to Section 19 of the Operating Guidelines.
- 4.3 Emergency shipments and other exceptions will be authorized in writing by CLIENT. CORD will separately invoice CLIENT for emergency shipments, which are defined as shipments occurring on weekends, holidays, and non-standard hours, as defined in the Fee Schedule, Exhibit C.
- 4.4 CORD's inventory system will comply with First-to-Expire, First-Out (FEFO) inventory allocation. Any exceptions from FEFO must be approved by CLIENT in writing prior to shipment.
- 4.5 CORD will provide the system, equipment and procedures, along with trained personnel and supervision to services related to picking product for CLIENT's customer orders.
- 4.6 CORD will perform quality verification on all CLIENT shipments by an individual other than the employee who picked the order. CORD will use commercially reasonable efforts to pick, check and ship accurately all CLIENT customer orders.
- 4.7 CORD and CLIENT will mutually determine and agree in writing on the packaging requirements for shipping CLIENT's finished product(s). CORD's Quality Assurance will assist CLIENT and CORD will issue appropriate guidelines and training to the Distribution department to assure compliance with CLIENT specifications.
- 4.8 CLIENT and CORD will mutually determine and agree on special shipping conditions, such as for refrigerated product, which may be limited to Monday through Thursday shipping, or as otherwise instructed by the Client.
- 4.9 CORD will provide shipment confirmation information to CLIENT through CORD's information system on the same business day on which the shipment occurs.
- 4.10 CORD will manage shipping supplies - including vendor selection, ordering, inventory record keeping, and storage. CORD will invoice CLIENT for all shipping materials - corrugated cartons, insulated coolers (if specified), address labels, inner packing - as may be required by CLIENT's packing specifications, per CORD's proposal.
- 4.11 All Products will be shipped utilizing packaging and shipping carton(s) as per CLIENT's packaging instructions, or as deemed appropriate by CORD in the absence of CLIENT specifications. Unless instructed otherwise by CLIENT, shipping will occur based on the shipping procedures provided by CLIENT.
- 4.12 CORD personnel will be available for emergency product shipments, via phone request, 24 hours per day, 365 days per year. For emergency shipments called in after the carrier's cutoff time (approximately 8:00 p.m. for overnight airfreight), CORD will ship the product the following day, except Sunday, unless otherwise directed by the CLIENT. CORD's fees for emergency shipments are set forth in the Fee Schedule, Exhibit B.

## 5.0 TRANSPORTATION

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- 5.1 CORD and CLIENT will mutually agree upon a common carrier (s) based on shipment size, destination, freight rates, availability of standard and special services, reliability of delivery, and claim history among other requirements.
- 5.2 CORD shall provide, if CLIENT agrees, carriers under contract with Cardinal-Allegiance for discounted rates. The CLIENT and CORD will share the savings according to a formula acceptable to both parties, or, if CLIENT so chooses and CORD agrees, CORD shall charge a freight management fee according to the Fee Schedule, Exhibit B.
- 5.3 Shipping charges, including all special charges for insurance, proof of delivery, hazardous materials, service upgrades, and so forth, will be billed directly to CORD's account with the carrier and passed through to CLIENT per terms of the Distribution Agreement, inclusive of CORD's transportation management fees as defined in the Fee Schedule, Exhibit B.
- 5.4 Freight terms will be F.O.B. Origin, Freight Prepaid where title passes to the customer when the shipment is tendered to the common carrier.
- 5.5 CORD, at the request of the CLIENT, will provide proof of delivery for specific customer shipments. Fees charged by carriers for proofs of delivery, if any, will be passed directly to the CLIENT.
- 5.6 CLIENT will approve payment of all credits to CLIENT customers for overage, shortage and damage claims related to transportation. CORD, if handling Accounts Receivable for CLIENT, will issue a credit to CLIENT's customer accordingly, or CORD will provide freight claim documentation to the CLIENT when the CLIENT is responsible for the Accounts Receivable.

## 6.0 CUSTOMER SERVICE

- 6.1 CORD will provide a dedicated inbound phone line (or lines) for CLIENT's customers to phone in purchase orders, for inquiries, and for general information.
- 6.2 CORD will staff the CLIENT Customer Service inbound phone line from 7:00 a.m.- 6:00 p.m. central standard time, Monday through Friday, except for the following holidays: Christmas Day, New Year's Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day.
- 6.3 CORD will be responsible for the training of the customer service representative and backup representative(s). CLIENT will provide company and product specific information for training of customer service representatives assigned to the CLIENT.
- 6.4 CORD will be responsible for initial set up and on-going maintenance of customer master files. The initial customer master file will be approved and signed by CLIENT. CLIENT may add customers by completing the customer profile form and forwarding to CORD for system entry.
- 6.5 CORD will accept customer orders by electronic data interchange (EDI), phone, mail or fax.
- 6.6 CORD will use commercially reasonable efforts to answer inbound phone calls within the first thirty (30) seconds, and enter orders accurately.
- 6.7 Orders received by phone, mail or fax that are entered and approved for shipment by 2:00 p.m. Central Time will be shipped the same day. Orders received by EDI and approved for inventory allocation by 12:00 noon will be shipped the same day. Orders received and processed after the cutoff times will be shipped the following business day.
- 6.8 As a backup to the customer service representatives, a voice mail system will be maintained to accept telephone orders and to collect messages from customers.
- 6.9 CORD's dedicated customer service line for CLIENT will incorporate programming to forward calls to a CLIENT designated clinical service phone number if calls of a clinical nature are received outside of regular customer service hours.

## 7.0 ORDER ENTRY

- 7.1 CLIENT will determine minimum order and order line quantity and CORD will enter orders accordingly.
- 7.2 CLIENT will instruct its customers and trading partners to place orders based on the CLIENT's Distribution Agreement.
- 7.3 CLIENT will determine when customers shall pay for premium freight, special handling, and emergency order processing.
- 7.4 CLIENT reserves the right to limit quantities, to hold or to refuse orders. These decisions will be executed by CORD.
- 7.5 CORD will use commercially reasonable effort to enter orders accurately. CORD measures the accuracy of orders entered and will report this attribute periodically according to the conditions set forth in Section 19 of the Operating Guidelines.

## 8.0 CUSTOMER CREDIT

- 8.1 CLIENT will determine the customers to whom it will sell on a direct basis and will assign each to a customer class, sales territory, and other sort classifications, as applicable, based on definitions mutually acceptable to CLIENT and CORD.
- 8.2 CLIENT will establish credit limits for each customer or groups of customers.
- 8.3 CORD's system will monitor orders and outstanding account receivable against the customer's credit limit and hold orders where credit limits are exceeded.
- 8.4 CLIENT may elect to place a customer's account on credit hold so that all orders are reviewed prior to shipment.
- 8.5 CLIENT will review and approve all customer orders held for credit limits prior to shipment.

## 9.0 PRICING AND TERMS

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- 9.1 CLIENT will publish terms and conditions of sale to wholesalers and warehouse chains. Standard terms are 2% -30 days, net 31 days. Contracted customers may have non-standard terms.
  - 9.2 CLIENT will publish list prices for wholesalers and warehouses chains and are subject to change from time to time at the sole discretion of CLIENT.
  - 9.3 CLIENT will determine contract prices on a contract by contract basis. CLIENT will notify CORD of such price changes with seven-(7) days notice for update of the CORD system files. CLIENT will develop and forward customer notifications to CORD and CORD will provide printing and mailing services on behalf of CLIENT.
  - 9.4 CORD will perform system maintenance of pricing and terms. CLIENT will provide to CORD in writing any changes to prices or terms. CORD will be responsible for updating the CORD system within 48 hours of receipt of such notice or as CLIENT may otherwise instruct.
  - 9.5 CORD employees are bound by the confidentiality provisions of the Agreement between CORD and CLIENT and, as such, shall not disclose CLIENT sales data or pricing information outside the specific CORD employees who have a need to know of this information in the course of performing their routine job responsibilities.
  - 9.6 CORD will provide the necessary reports within stipulated time frames to ensure CLIENT can comply with the reporting requirements of Medicaid (OBRA), Veterans HealthCare Act, PHS Covered Entities, and state rebate programs. CLIENT will define reporting requirements against which CORD will produce the required reports.

## 10.0 INVOICING

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- 10.1 CORD Customer Service will use commercially reasonable efforts to mail invoices the morning following shipment of product, or transmit by electronic data interchange (EDI), where installed, the same day of shipment of product, to customer's billing address.
  - 10.2 For any order shipped after the close of business, the invoice will be prepared and mailed the following business day.
  - 10.3 CORD will make its best effort to process invoices as timely and accurately as possible. CORD measures invoice accuracy and processing timeliness and will report this attribute periodically according to the conditions set forth in Section 19 of the Operating Guidelines.

## 11.0 CHARGEBACKS

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- 11.1 CLIENT may enter into prime vendor arrangements for select contract or government mandated pricing arrangements.
  - 11.2 CLIENT will select a wholesaler with full EDI capabilities, including but not limited to purchase orders chargeback submission, chargeback reconciliation and credit, invoicing and bid award notification.
  - 11.3 CORD, on behalf of CLIENT, will process chargebacks daily with reconciliation of chargeback discrepancies within 5 working days. CORD's chargeback SOP will define the parameters available to CORD to resolve discrepancies between the CLIENT's contract terms and conditions and the chargeback submitted by the wholesaler.
  - 11.4 All chargebacks will be processed according to the chargeback policy for CLIENT.
  - 11.5 All validated chargeback submissions will be settled via credit invoice. CLIENT will not make advance payments or authorize advance deductions of chargebacks.
  - 11.6 Prime vendors will be instructed to report all returns from CLIENT's contract customers as a reverse chargeback.
  - 11.7 CORD will make its best effort to process chargebacks as timely and accurately as possible. CORD measures the chargeback discrepancy rate and timeliness of chargebacks processed and will report this attribute periodically according to the conditions set forth in Section 19 of the Operating Guidelines.



## 12.0 ACCOUNTS RECEIVABLE

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- 12.1 CLIENT will open and maintain a bank lockbox. The bank will receive customer remittances invoice information on behalf of CLIENT.
  - 12.2 The CLIENT's bank will forward information about lockbox deposits along with the customer's remittance information to CORD.
  - 12.3 CORD will reconcile and apply the cash receipt to the outstanding account receivable within 24 hours of receipt from the bank.
  - 12.4 To aid the cash application process, CLIENT will authorize accounts receivable payment terms of one day past published terms. This grace period will not be communicated to customers.
  - 12.5 CORD will disallow discounts for payments received beyond the payment terms grace period, as indicated by the postmark. CORD will handle the amount of the discount as a balance due on the Accounts Receivable account.
  - 12.6 Accounts Receivable will be monitored by CORD with appropriate collection actions taken as directed below:
    - 12.6.1 Notify by phone all customers with payments that have reached 10 days past due.
    - 12.6.2 Initiate second phone call at 17 to 20 days past due.
    - 12.6.3 Send letter (including documentation for item) to customer at thirty (30) days past due.
    - 12.6.4 Second letter at sixty (60) days past due. Follow up with third phone call.
    - 12.6.5 Give all documentation relating to item to CLIENT so third letter may be sent by CLIENT at ninety (90) days past due.
    - 12.6.6 CORD and CLIENT will discuss strategy for items still open after the above actions have been taken.  
(The term "item" will include invoices, deductions taken for charge backs and returns, and discounts not allowed.)
  - 12.7 CORD will maintain notes related to collection activities in an Accounts Receivable system file that will be accessible to CLIENT's authorized personnel.
  - 12.8 CORD will use commercially reasonable efforts to process accounts receivable as timely and accurately as possible. CORD, at CLIENT's option, may measure accounts receivable and collections activity and report these attributes periodically according to the conditions to be defined and mutually agreed upon by CORD and CLIENT.

## 13.0 GOVERNMENT REPORTING

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- 13.1 CORD personnel will provide the following Government reports to CLIENT by the fifth business day following the close of a business quarter.
    - 13.1.1 IFF Direct Sales Report
    - 13.1.2 IFF Indirect Sales Report
    - 13.1.3 AMP Report
    - 13.1.4 Non FAMP Report
    - 13.1.5 Best Price Report
    - 13.1.6 Most Favored Price Report
  - 13.2 CORD will also provide supporting schedules and source documents to be used by CLIENT to perform verification of the Government reports.

## 14.0 MONTH-END CLOSE

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- 14.1 CORD will comply with month-end reporting requirements as specified by CLIENT.
  - 14.2 CLIENT will complete its close by the 5th working day after the last day of the month being closed.

## 15.0 RETURN GOODS

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- 15.1 Returns will be processed according to the Return Procedures defined by CLIENT.
  - 15.2 CORD will complete the processing of all returns and issue credits within 5 business days of receipt of the return.
  - 15.3 CORD will use commercially reasonable efforts to process return goods as timely and accurately as possible.

## 16.0 RECALL ASSISTANCE

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- 16.1 CLIENT is responsible for management of a recall event, including but not limited to preparation of the letter of notification to customers, coordination and reporting with FDA, tracking of recalled product by customer, follow up letters to customers, and final disposition of product.
  - 16.2 CORD will provide the necessary recall reports within two hours of notification by CLIENT. Reports will contain, but not be limited to, the following information for each recalled product and lot number: all customer shipments by date, item number, quantity, lot number, and ship to address.
  - 16.3 CORD will provide a secure area for the receipt of recalled product. CORD will assist CLIENT with inventory reconciliation.
  - 16.4 CORD will provide destruction services for recalled product as may be required by CLIENT.

## 17.0 SYSTEMS

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- 17.1 CLIENT retains ownership to all data in the CORD system related to CLIENT's business.
  - 17.2 CORD will maintain security of the CLIENT's data in files segregated and inaccessible to other CORD clients, to CORD's parent organization Cardinal Health, or to any other entity as determined by the CLIENT.
  - 17.3 CORD will provide CLIENT with on-line access to sales information, inventory records, lot tracking, customer profiles, item maintenance, pricing and terms, and other business critical data as defined in CORD's standard reports output.
  - 17.4 Reporting and interfaces will be defined by CLIENT and jointly agreed upon with CORD.
  - 17.5 CORD will maintain all systems within the change control SOPs.
  - 17.6 CORD's system will be accessible by CLIENT 7:30 a.m. - 7:30 p.m. Central Time, Monday through Friday except for routine, scheduled maintenance.
  - 17.7 Unscheduled system downtime per calendar quarter shall not exceed 2% of the normally accessible access hours. CORD will immediately notify CLIENT of any system problem that might affect services and an estimated time for restoration of system access.
  - 17.8 Full system backups will be generated on a nightly basis in conjunction with SOP IS-005 `Backup and Recovery'. These backup tapes will be sorted either off-site or in a fireproof cabinet as indicated by the SOP.

## 18.0 AUDITS / INVENTORIES

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- 18.1 Upon not less than ten (10) days prior written notice, CLIENT personnel and their representatives will have access to CORD facilities for review and audit of CORD's facility and records to assure compliance with cGMP's, standard operating procedures, guidelines, and CLIENT specific agreements.
  - 18.2 CLIENT may request one complete physical inventory of CLIENT products every 12 months.
  - 18.3 CORD will assist CLIENT with inspections/audits ordered by the Federal Food & Drug Administration or other governmental or official agencies.
  - 18.4 CORD will notify CLIENT immediately of any inspection activity by FDA, DEA or other government agency, as applicable to the CLIENT or CLIENT's product.

## 19.0 QUALITY COUNCIL REPORT

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- 19.1 CORD will provide CLIENT with a periodic report on measurable attributes, as identified in preceding sections, to be used to track and benchmark performance. The frequency of the report will be determined jointly by CORD and CLIENT.
  - 19.2 CLIENT and CORD will agree to meet periodically to review performance and to develop methods, policies, practices, and procedures that may improve the quality and efficiency of the CORD - CLIENT relationship.
  - 19.3 CORD will use its best efforts to meet or exceed the CLIENT's expectation for performance based on the measured attributes.
  - 19.4 Measured attributes and standards:

SECTION	PERFORMANCE ATTRIBUTE	PERFORMANCE STANDARD	REPORTING FREQUENCY
1.0	Temperature excursions	[*] excursion -free	Upon occurrence
2.0	On-time receipts and data entry	[*] within [*] business hours for all conforming receipts	Monthly
3.0	Cycle count accuracy	[*]	Monthly
4.0	On-time shipping	[*] same day for orders received by the standard cut-off time	Monthly
4.0	Picking / shipping accuracy	[*] for all orders processed with carton markings meeting NWDA bar code standards	Monthly
6.0	Answer inbound phone calls within thirty [*] seconds	[*] answered within [*] seconds	Monthly
7.0	Order entry accuracy	[*]	Monthly
10.0	Invoicing accuracy and timeliness	[*]	Monthly
11.0	Chargeback processing time	[*] processed in 2 days or less from receipt of chargeback from wholesaler	Monthly
11.0	Chargeback discrepancy rate	[*] or less	Monthly
12.0	Accounts receivable	Based on CLIENT specifications; standard TBD.	TBD
14.0	Return goods processing cycle time	[*] processed in [*] business days or less	Monthly
17.0	System availability	[*] of normal accessible hours	Upon occurrence

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VIVUS, INC.  
FEE SCHEDULE EXHIBIT B  
(effective August 1, 2002)

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DISTRIBUTION SERVICES

MONTHLY PER PALLET REFRIGERATED STORAGE (5)	\$	[*]
REFRIGERATED PRODUCT PICK/PACK/STAGE - FIRST PICK (1)	\$	[*]
REFRIGERATED PRODUCT PICK/PACK/STAGE - EACH ADD'L PICK (1)	\$	[*]
PER LINE RETURN PROCESSING	\$	[*]
MONTHLY DISTRIBUTION SYSTEM ACCESS AND USE (2)	\$	[*]
MONTHLY ACCOUNT MANAGEMENT FEE (6)	\$	[*]
EMERGENCY/INTERNATIONAL ORDERS	\$	[*]
PACKING/SHIPPING SUPPLIES (3) (INCLUDES ORDERING, RECEIVING, STORAGE)	Cost plus [*]% handling fee	
SHIPPING CHARGES (4)	Published Rate minus [*]%	

CUSTOMER SERVICE

MONTHLY FIXED FEE	\$	[*]
PER ORDER FEE	\$	[*]

FINANCIAL SERVICES

MONTHLY FIXED FEE ACCOUNTS RECEIVABLE MANAGEMENT	\$	[*]
PER ORDER FEE ACCOUNTS RECEIVABLE MANAGEMENT	\$	[*]
MONTHLY FIXED FEE CHARGEBACK MANAGEMENT	\$	[*]
PER SUBMISSION CHARGEBACK PROCESSING & GOVERNMENT REPORTING	\$	[*]

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NOTE (1): This proposal is based on the distribution of Muse and Actis only, any additional products requiring distribution services will be quoted separately.

NOTE (2): System access fee includes licenses for four concurrent users. Any additional licenses required by VIVUS will increase the monthly fee by \$[\*] per concurrent user.

NOTE (3): Supplies include boxes, tape, labels, bubble pack, etc (approx. \$[\*] to \$[\*] per shipment), pallets if necessary (\$[\*] per pallet), and any other VIVUS requirements.

NOTE (4): This is based on FedEx shipments and may change as FedEx changes its pricing.

NOTE (5): The pallet fee (\$[\*]) is based on a three month inventory on hand. Pallet storage greater than three months on hand will be assessed a charge of twice the standard fee (\$[\*]) per month.

NOTE (6): The account management fee includes the following: logistics management, inventory management, quality assurance (QA), regulatory, receiving, supply control, process set-ups, and process set-ups, and process scheduling.

## SYSTEM ACCESS AGREEMENT

This System Access Agreement ("Agreement") is made as of October 1, 2002 between CORD Logistics, Inc., an Ohio corporation ("Licensor"), and, VIVUS, Inc., a Delaware corporation ("Licensee"), who hereby agree as follows:

1. Distribution Services Agreement. Licensor and Licensee have entered into a Distribution Services Agreement ("Distribution Agreement") of even date with this Agreement, the terms of which are incorporated by reference.

2. System Access; Maintenance Obligations. Licensor hereby grants to Licensee a nonexclusive, nontransferable limited license (the "License") to utilize Licensor's Operating System Base Package, consisting of the computer hardware (as set forth below), software, and other components described in the Distribution Agreement as well as future upgrades and maintenance of the base package (collectively, the "System"), for the information processing needs of Licensee in connection with the Services to be provided by Licensor under the Distribution Agreement. Licensee shall maintain during the term of this Agreement the local area network (including without limitation centralized server) and desktop processing requirements for the System as further described in the Distribution Agreement or the Operating Guidelines, a copy of which are attached to the Distribution Agreement as Exhibit A.

During the term of this Agreement, Licensor shall employ reasonable security measures and policies designed to safeguard the integrity, accessibility, and confidentiality of all of Licensee's data resident on the System and establish and maintain reasonable disaster and emergency recovery plans designed to minimize disruption from System operation interruptions. Licensee shall have the right to review the operation of the System from time to time during regular business hours, upon reasonable prior notice and at a time mutually agreeable by the parties; provided that such reviews shall be conducted in a manner to avoid disruption of Licensor's business operations.

3. Lease of Hardware. Licensee shall have the right to lease a router ("Hardware") from Licensor during the term of this Agreement, at no additional cost to Licensee, other than the Fee set forth in the Distribution Agreement. The Hardware shall be kept by Licensee (a) subject to inspection by Licensor during regular business hours, upon reasonable prior notice and at a time mutually agreeable by the parties; (b) at Licensee's address, as stated at the end of this Agreement, which Hardware shall not be relocated without the prior written consent of Licensor, which consent shall not be unreasonably withheld; (c) free of all security interests of any kind whatsoever, liens, encumbrances and other claims; (d) marked with Licensor's identification marks or numbers and if requested by Licensor, conspicuously labeled "supplied by Licensor"; and (e) maintained in good and efficient working order, condition and repair, reasonable wear and tear accepted.

Licensee shall use the equipment with due care to prevent injury thereto, and to any person or property and in conformity with all applicable laws, ordinances, rules, regulations and other requirements of any insurer or governmental body and with all requirements of the manufacturer with respect to use, maintenance and operation of the Hardware. Licensee shall not modify any hardware without the prior written consent of Licensor, which may be granted or withheld in its sole discretion. It is the intention and understanding of both Licensor and Licensee that the Hardware shall be, and at all times remain, separately identifiable personal property of Licensor. Licensee shall not permit any Hardware to be installed in or used, stored or maintained with, any of Licensee's personal property in such manner or under such circumstances that such Hardware might be or become an accession to or confused with such other personal property. Licensee shall not permit such Hardware to be installed in or used, stored or maintained with, any real property in such manner or under such circumstances that any person might acquire any rights in such Hardware paramount to the rights of the Licensor by reason of such Hardware being deemed to be real property or a fixture thereon.

Licensee shall at all times during the term of this Agreement and until the Hardware has been returned to Licensor, at its own expense, maintain physical damage insurance in the amount of not less than the replacement value of the Hardware. All insurance so maintained shall provide for a thirty (30) day prior written notice to Licensor or its assignees of any cancellation or reduction of coverages; (ii) an option in Licensor or its assignees to prevent cancellation by payment of premiums, (iii) cover the interest of the Licensor and (iv) provide that all insurance proceeds shall be payable to the Licensee and Licensor, as their respective interests may appear at the time of any such payment. Licensor shall be named as an additional insured on any public liability insurance policy so maintained. Upon the request of Licensor, Licensee shall furnish to Licensor satisfactory evidence of any insurance so maintained.

4. Proprietary Rights. Licensee shall have the right to use the System during the term of this Agreement as expressly provided in paragraphs 1 and 2 of this Agreement, but not otherwise. Licensee shall not assign or otherwise transfer, disclose, copy, modify, re-engineer, sell, license, disassemble, or decompile the System or disclose or permit access to the System or related documentation to any other person or entity. The System and all parts thereof, in all of their tangible and intangible manifestations, all existing or new enhancements, developments, derivative works, and other adaptations or modifications to the System (or any part thereof), and all related proprietary rights, are and shall remain the exclusive property of Licensor. Except for the License and Lease, Licensee shall have no right, title, or interest in or to the System or any part thereof. Upon termination of this Agreement, Licensee shall promptly return to Licensor all portions of the System then in Licensee's possession or under its control in accordance with the term set forth in Section 6 below.

5. Warranties. Licensee acknowledges that it has had adequate opportunity to review the System and its features and operation, and Licensee accepts the System "AS IS" for its use as contemplated in the Distribution Agreement. LICENSOR MAKES NO REPRESENTATIONS OR WARRANTIES, AND HEREBY EXPRESSLY DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED, RELATING DIRECTLY OR INDIRECTLY TO THE SYSTEM OR ANY PART THEREOF, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF QUALITY, PERFORMANCE, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE.

6. Limitation On Liability. LICENSOR SHALL NOT BE LIABLE FOR ANY CONSEQUENTIAL, INDIRECT, SPECIAL, OR OTHER SIMILAR DAMAGES ARISING DIRECTLY OR INDIRECTLY OUT OF THE USE OR INABILITY TO USE THE SYSTEM OR ANY PART THEREOF, EVEN IF INFORMED OF THE POSSIBILITY OF SUCH DAMAGES, WHETHER CLAIMED UNDER CONTRACT, TORT, OR ANY OTHER LEGAL THEORY.

IF ANY OF THE LIMITATIONS ON THE LIABILITY OF LICENSOR CONTAINED IN THIS AGREEMENT ARE FOUND TO BE INVALID OR UNENFORCEABLE FOR ANY REASON, THEN LICENSOR AND LICENSEE EXPRESSLY AGREE THAT THE MAXIMUM AGGREGATE LIABILITY OF LICENSOR FOR ALL CLAIMS RELATING TO THE SYSTEM SHALL NOT EXCEED 100% OF THE AGGREGATE BASE PACKAGE FEES PAID BY LICENSEE TO LICENSOR FOR LICENSEE'S USE OF THE SYSTEM UNDER THE DISTRIBUTION AGREEMENT.

7. Taxes. Licensee shall pay when due all sales, use, gross receipts, excise, property, and other taxes (other than taxes based upon Licensor's net income) now or hereafter imposed as a result of the transactions contemplated by this Agreement.

8. System Availability. The System shall be available for access twenty-four (24) hours a day, seven (7) days a week, except for scheduled maintenance periods.

9. Term. The term of this Agreement shall begin upon Licensee's initial use of the System as evidenced by the first entry of inventory into the System (which may be a date earlier than the Commencement Date specified for the Distribution Agreement) and shall end: (a) automatically upon the termination of the Distribution Agreement (for any reason), or (b) on any earlier date specified by Licensee in notice to Licensor given not less than ninety (90) days prior to the specified termination date; provided that: (i) paragraphs 4 through 10 inclusive shall survive the termination of this Agreement, and (ii) no termination of this Agreement shall affect any liabilities arising from, or based upon, acts or omissions occurring prior to such termination.

10. Expiration/Termination. Licensee shall continue to have access to the System for a reasonable period of time (not to exceed ninety (90) days) following termination of this Agreement solely for purposes of retrieving and transferring to a separate system Licensee's data relating to its pre-termination operations, and Licensor shall reasonably cooperate with Licensee to preserve the integrity and accessibility of Licensee's data during such period; provided that, during such period, Licensee shall continue to pay the full Base Package and other fees payable by Licensee under the Distribution Agreement and comply with all other requirements imposed upon Licensee under this Agreement.

Upon the expiration of this Agreement, Licensee shall return the Hardware to Licensor in the same condition and configuration as received, reasonable wear and tear accepted.

11. Notices. Any notice or other communication required or desired to be given to either Party under this Agreement shall be in writing and shall be deemed given: (a) five (5) days after mailing, if deposited in the United States mail, first-class postage prepaid, and addressed to that Party at its address set forth at the end of this Agreement; (b) when received if delivered to Federal Express or any other similar overnight delivery service for delivery to that Party at that address; or (c) when sent by facsimile transmission, with electronic confirmation, to that Party at its facsimile number set forth at the end of this Agreement. Either Party may change its address or facsimile number for notices under this Agreement by giving the other Party written notice of such change.

12. Remedies. Licensee shall indemnify Licensor and its affiliates, directors, officers, employees, agents, and representatives against all claims, liabilities, losses, damages, costs, and expenses (including without limitation reasonable attorneys' fees) arising directly or indirectly out of any failure of Licensee to perform fully all obligations and conditions to be performed by Licensee pursuant to this Agreement. Licensee acknowledges that in the event of any violation by it of any of the provisions of paragraph 4 (Proprietary Rights) of this Agreement, Licensor would suffer irreparable harm and its remedies at law would be inadequate. Accordingly, in the event of any violation or attempted violation of any such provisions by Licensee, Licensor shall be entitled, in addition to any other rights or remedies which may be available to Licensor, to a temporary restraining order, temporary and/or permanent injunctions, specific performance, and other equitable relief, without the showing of irreparable harm, injury, damage or the inadequacy of damages, and without the necessity of the posting of any bond.

13. Force Majeure. Notwithstanding any other provisions of this Agreement or the Distribution Agreement to the contrary, each Party's obligations under this Agreement (exclusive of payment obligations) shall be excused if and to the extent that any delay or failure to perform such obligations is due to fire or other casualty, government restrictions, war, riot, strikes or labor disputes, acts of God, or other causes beyond the reasonable control of that Party; provided, however, that any party hindered by such condition beyond its reasonable control must employ reasonable efforts to overcome such hindrance as promptly as practicable.

14. Successors. Licensee shall not assign or otherwise transfer this Agreement or any of its rights or obligations under this Agreement without the prior written consent of Licensor, which consent

shall not be unreasonably withheld. Subject to the preceding sentence, this Agreement shall be binding upon, inure to the benefit of, and be enforceable by and against the respective successors and assigns of each Party.

15. Interpretation. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware. If and to the extent that any court of competent jurisdiction determines that it is impossible to construe any provision of this Agreement consistently with any law or public policy and consequently holds that provision to be invalid, such holding shall in no way affect the validity of the other provisions of this Agreement, which shall remain in full force and effect.

16. Complete Agreement. This Agreement (together with the Distribution Agreement, which is hereby incorporated herein by reference) constitutes the entire Agreement between the Parties with respect to the subject matter of this Agreement and supersedes all prior or contemporaneous discussions, negotiations, representations, warranties, or agreements relating to the subject matter of this Agreement. This Agreement may not be amended or otherwise modified except by a written instrument signed by each Party.

IN WITNESS WHEREOF, the undersigned acknowledge and accept the terms of this Agreement and have duly executed this Agreement.

CORD LOGISTICS, INC.

VIVUS, INC.

By /s/ Frank C. Wegerson

By /s/ Guy P. Marsh

-----  
Frank C. Wegerson  
Vice President and General Manager

-----  
V.P. U.S. Operations

15 Ingram Blvd, Suite 100  
LaVergne, TN 37086

745 Airport Road  
Lakewood, NJ 08701

Facsimile No. (615) 793-4783

Facsimile No. (732) 942-4821



DISTRIBUTION AND SUPPLY AGREEMENT

This Agreement is made as of this 18th day of February 2003, by and between MEDA AB (publ), a company organized under the laws of Sweden, with its principal offices at Box 906 170 S-170 09 Solna, Sweden ("MEDA"), and VIVUS International, Ltd., a company organized under the laws of Bermuda, with its principal offices at Clarendon House, Church Street, Hamilton, Bermuda. ("VIVUS").

RECITALS

WHEREAS, VIVUS has developed the medical device, ACTIS(R), an Adjustable Constriction Loop for the treatment of male erectile dysfunction; and

WHEREAS, MEDA is interested in obtaining distribution rights to ACTIS(R), and VIVUS is interested in granting such rights to MEDA; and

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

ARTICLE 1 - DEFINITIONS  
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For purposes of this Agreement, the following terms shall have the following respective meanings:

- 1.1 Affiliate means any corporation, firm, partnership or other entity, whether de jure or de facto, that directly or indirectly owns, is owned by or is under common ownership with a party to the extent of in excess of fifty percent (50%) of the outstanding securities or assets having the power to vote on or direct the affairs of the entity.
- 1.2 CE Marking means products regulated by the European Commissions Health, Safety and Environmental Protection Legislation, which indicates the manufacturer has conformed to all obligations required by the legislation.
- 1.3 Confidential Information means any information, data or business plans relating to the Product or otherwise to the subject of this Agreement, which a party discloses to the other party, except any portion thereof which:
  - (i) is known to the receiving party at the time of disclosure and documented by written records made prior to the date of this Agreement;
  - (ii) is disclosed to the receiving party by a third person who has a right to make such disclosure;
  - (iii) becomes patented, published or otherwise part of the public domain through no fault of the receiving party; or
  - (iv) is independently developed by the receiving party as evidenced by its written records.
- 1.4 Effective Date means the date of this Agreement first written above.
- 1.5 First Commercial Sale means the first sale of Product (as defined below) in the Territory by MEDA or any MEDA Affiliate or sublicensee to any unaffiliated third party.
- 1.6 Product means the medical device ACTIS(R), an Adjustable Constriction Loop for the treatment of male erectile dysfunction.
- 1.7 Regulatory Approval means all governmental approvals and authorizations necessary for the commercial marketing and sale of the Product in the Territory including the CE Marking.
- 1.8 Supply Price means the price as set forth in Article 3.2 below.

1.9 Territory means Austria, Belgium, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Norway, Poland, Portugal, Spain, Sweden, Switzerland, The Netherlands, Turkey and the United Kingdom.

1.10 Trademark means the trademark ACTIS.

ARTICLE 2 - GRANT OF RIGHTS

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2.1 Appointment. VIVUS hereby grants to MEDA exclusive distribution rights (exclusive even as to VIVUS) to use, market and sell the Product in the Territory. MEDA may sublicense these rights to any one or more of its Affiliates at MEDA's sole discretion, and may sublicense third parties with VIVUS's prior written consent, such consent not to be unreasonably withheld.

ARTICLE 3 - PURCHASE AND SALE

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3.1 Purchases and Sale of Product. Subject to the terms and conditions of this Agreement, VIVUS shall exclusively to MEDA, sell the volumes of the Product required by MEDA for further sale in the Territory and MEDA shall purchase its requirements of Product exclusively from VIVUS, at the Supply Price. All sales of Product to MEDA are final.

- 3.2 Supply Price. The Product shall be sold to MEDA at a price of \$[\*] in year one and shall be adjusted by a [\*] increase each year thereafter.
- 3.3 Payments. Any payments due VIVUS or MEDA under this Agreement shall be made by remitting to the bank account designated by the party to whom payment is to be made. Any such payments shall be made in U.S. Dollars.
- 3.4 Taxes. Where any sum due to be paid to VIVUS hereunder is subject to any withholding or similar tax, the parties shall use their best efforts to do all such acts and things and to sign all such documents as will enable them to take advantage of any applicable double taxation agreement or treaty. In the event there is no applicable double taxation agreement or treaty, or if an applicable double taxation agreement or treaty reduces but does not eliminate such withholding or similar tax, MEDA shall pay such withholding or similar tax to the appropriate government authority, deduct the amount paid from the amount due VIVUS and secure and send to VIVUS the best available evidence of such payment.

ARTICLE 4 - FORECASTS, ORDERS, INVOICES AND TITLE

- 4.1 Initial Forecast. Within thirty (30) days of the Effective Date, MEDA shall provide to VIVUS its then current best forecast of the quantity of Product that MEDA will require from VIVUS, by month for the next two calendar quarters.
- 4.2 Rolling Forecasts. No later than ninety (90) days prior to the first day of each calendar quarter after the initial calendar quarter, MEDA shall provide to VIVUS its then current best forecast of the quantity of Product that MEDA will require from VIVUS during each of the next four (4) calendar quarters. MEDA shall break down the forecast for the first two such calendar quarters of the forecast by month.
- 4.3 Order and Acceptance. Firm binding orders must be made at least two (2) months in advance of delivery date, and VIVUS is obliged to confirm these orders within seven (7) days of receipt. If MEDA does not receive such notice, the order is deemed to have been accepted. MEDA shall not increase or decrease its forecast, for the second calendar quarter in each of MEDA's rolling forecasts made pursuant to Article 4.2 above, by more than twenty percent (20%). VIVUS shall accept all firm orders from MEDA for quantities of Product up to and including one hundred twenty percent (120%) of the quantity of Product previously forecasted by MEDA for such calendar quarter, and shall use its best efforts to accept all firm orders from MEDA for quantities of Product in excess of that quantity of Product. Once an order has been accepted by VIVUS, then VIVUS shall be obligated to sell, and MEDA shall be obligated to purchase, the ordered Product.

- 4.4 Invoices. VIVUS shall invoice MEDA for the Supply Price in United States Dollars for the Product shipped on the day of shipment. MEDA shall pay VIVUS such invoiced amount within thirty (30) days from the date of the receipt of the Product.
- 4.5 Delivery. VIVUS shall deliver the Product via sea freight to MEDA, CIF, MEDA's designated warehouses in the respective countries in the Territory. All shipping costs, liability, ownership and logistics of Product up to MEDA's designated warehouses discharging dock, are the responsibility of VIVUS. In the event MEDA requests delivery of Product via air freight, then all such shipping costs shall be the responsibility of MEDA.
- 4.6 Conflicting Terms and Conditions. Except as otherwise provided in this Agreement, the terms and conditions of this Agreement shall govern, notwithstanding any additional or inconsistent terms or conditions in MEDA's form of purchase order or similar document or in VIVUS's acknowledgment, invoice, or similar documents.
- 4.7 Initial Start-up and At Risk Costs. MEDA will be responsible for reimbursing VIVUS for VIVUS' actual costs incurred and expenses paid to third parties to modify the packaging for the Product in order to incorporate MEDA trade dress (including, but not limited to, artwork changes, typesetting charges and plate charges), to otherwise modify the packaging for the Product to meet MEDA's requirements (including, but not limited to, packaging materials). MEDA shall not repackage or re-label Product supplied to MEDA by VIVUS hereunder without the prior written consent of VIVUS.

ARTICLE 5 - SAMPLING, TESTING AND ANALYSIS  
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- 5.1 Defective Product. MEDA shall notify VIVUS in writing of any claim relating to damaged or defective Product or any shortage in quantity of any shipment of the Product within thirty (30) days of receipt of such Product or, if the defect is not readily apparent based upon a reasonable inspection (a "Hidden Defect"), within thirty (30) days after which the Hidden Defect becomes known to MEDA. A Hidden Defect is defined as a defect that existed at the time Product is delivered and, for avoidance of doubt, a Hidden Defect does not include any defect that might be caused in the storage or transportation of the Product. If MEDA fails to give such written claim notice to VIVUS within said thirty (30) day period, the Product shipped shall be deemed to be sufficient in quantity and not damaged nor defective at the time of delivery. If MEDA gives such written claim notice to VIVUS within said thirty (30) day period, then MEDA and VIVUS shall, in an appropriate manner to be agreed, jointly inspect the Product to see if claimed damage or defect actually exists in the Product shipped. If existence of claimed damage, defect or shortage is reasonably verified through such inspection, VIVUS shall replace the rejected Product or make up the shortage as soon as practicable but no later than ninety (90) days after such verification, at no extra cost to MEDA, and shall make arrangements with MEDA for the destruction of any rejected Product, at VIVUS's expense.

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- 6.1 VIVUS Responsibilities. VIVUS shall be responsible for, and shall bear all costs of the following:
- a. VIVUS shall provide to MEDA, as expeditiously as possible, appropriate assistance, information and/or materials in VIVUS's possession or control in order to enable or facilitate MEDA's filing for a CE Marking to market and sell the Product in the Territory.
  - b. VIVUS shall be responsible for filing trademark applications for, and for the maintenance and upkeep of, the Trademark in the Territory.
  - c. VIVUS shall provide Product to MEDA in final packaging for distribution in the Territory
- 6.2 MEDA Responsibilities. During the term of this Agreement, MEDA shall be responsible for, and shall bear all cost of, the following:
- a. MEDA shall, at its own expense, be responsible for
    - (i) Preparing, filing and maintaining a CE Marking and/or other Marketing or Regulatory Authorizations necessary for distribution of the Product in the Territory; and
    - (ii) Providing VIVUS with camera-ready artwork for the final packaging of Product including MEDA's trade dress.
  - b. MEDA shall own all registrations and Regulatory Approvals for the Product in the Territory.
  - c. In fulfilling its obligations under this Agreement, MEDA shall use its reasonable best efforts to ensure that the Product is entitled to and receives the maximum available benefit of any regulatory market exclusivity periods or other safeguards or extensions of proprietary status, which are or may be applicable in the Territory.
- 6.3 Pharmacovigilance. MEDA will have overall responsibility for Pharmacovigilance in the Territory. Promptly after the Effective Date and prior to Product distribution by MEDA, the respective pharmacovigilance groups of VIVUS and MEDA shall enter into a separate agreement covering adverse event information exchange relating to the Product. Such agreement will permit the inclusion of the respective pharmacovigilance

groups of other third parties to whom VIVUS has granted or will grant (during the term of this Agreement) similar rights to make, have made, use and sell the Product outside the Territory.

- 6.4 Regulatory Communications. MEDA and VIVUS shall promptly inform each other of any material communications to or from governmental authorities or agencies relating to the Product that affect marketing and/or sale of Product in the Territory. With the exception of product recalls, which are to be handled pursuant to Article 8 below, and adverse event reporting, which is to be handled pursuant to Article 6.3 above, the parties shall consult with each other regarding any issues raised in such communications, and shall attempt in good faith to agree upon any action to be taken or response to be made in connection with such communications. If the parties are unable to agree within a reasonable time prior to when the action is to be taken or the response is to be made, the party receiving the material communication for the Product shall decide what action to take or response to make.

#### ARTICLE 7 - MARKETING AND SALES

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- 7.1 MEDA Diligence. MEDA shall use its diligent efforts to market and/or sell the Product in the Territory, consistent with the efforts that MEDA expends on pursuing commercialization of other products MEDA markets in the Territory of similar market potential. MEDA agrees that neither MEDA nor its Affiliates or Authorized Distributors will market or distribute any medical device products for the treatment of Erectile Dysfunction in the Territory other than the Product.

#### ARTICLE 8 - PRODUCT RECALL

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- 8.1 Recall in the Territory. In the event that in the Territory (i) any government authority issues a request, directive or order that the Product be recalled, or (ii) a court of competent jurisdiction orders such a recall, or (iii) MEDA and VIVUS jointly determine that the Product should be recalled, MEDA shall take all appropriate corrective actions. If such recall results from any cause or event attributable solely to VIVUS's negligence or fault, VIVUS shall be responsible for the direct expenses of the recall. If such recall results from any cause or event attributable solely to MEDA's negligence or fault, MEDA shall be responsible for the direct expenses of the recall. If such recall results from any other cause or event (including attribution to the negligence or fault of both VIVUS and MEDA), the parties shall share equally the direct expenses of the recall. For the purposes of this Agreement, the direct expenses of recall shall include, without limitation, the expenses of notification and return of the recalled Product and MEDA's costs for the Product, and shall not include the cost of any re-launch by MEDA of the Product in the Territory subsequent to a recall.
- 8.2 Recall Outside the Territory. In the event that outside the Territory (i) any government authority issues a request, directive or order that the Product be recalled, or (ii) a court of competent jurisdiction orders such a recall, or (iii)

VIVUS (or its Affiliates or sublicensees, as the case may be) decides that the Product should be recalled, VIVUS shall notify MEDA as expeditiously as possible and shall provide MEDA with all information and assistance as MEDA may reasonably request in order to enable MEDA to determine any appropriate actions relating to the Product in the Territory arising from such recall.

ARTICLE 9 - REPRESENTATIONS AND WARRANTIES  
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Each party hereby represents and warrants for itself as follows:

- 9.1 Organized. It is a corporation duly organized, validly existing and is in good standing under the laws of the jurisdiction of its incorporation, is qualified to do business and is in good standing as a foreign corporation in each jurisdiction in which the conduct of its business or the ownership of its properties requires such qualification and failure to have such would prevent it from performing its obligations under this Agreement and has all requisite corporate power and authority to conduct its business as now being conducted, to own, lease and operate its properties and to execute, deliver and perform this Agreement.
- 9.2 Due Execution. The execution, delivery and performance by it of this Agreement have been duly authorized by all necessary corporate action and do not and will not (i) require any consent or approval of its stockholders; (ii) violate any provision of any law, rule, regulation, order, writ, judgment, injunction, decree, determination or award presently in effect having applicability to it or any provision of its charter or by-laws; or (iii) result in a breach of or constitute a default under any material agreement, mortgage, lease, license (including any license from a third party which is necessary for the full performance of this Agreement), permit or other instrument or obligation to which it is a party or by which it or its properties may be bound or affected.
- 9.3 No Third Party Approval. No authorization, consent, approval, license, exemption of, or filing or registration with, any court or governmental authority or regulatory body (other than health regulatory authorities) is required for the due execution, delivery or performance by it of this Agreement, except as provided herein.
- 9.4 Binding Agreement. This Agreement is a legal, valid and binding obligation of such party, enforceable against it in accordance with its terms and conditions. It is not under any obligation to any person, contractual or otherwise, that is in conflict with the terms of this Agreement.
- 9.5 Full Disclosure. Each Party has disclosed to the other in good faith all material information relevant to the subject matter of this Agreement and to such party's ability to observe and perform its obligations hereunder.

VIVUS covenants, represents and warrants to MEDA that:

- 10.1 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.
- 10.2 Specifications. All quantities of the Product will comply with, and VIVUS shall only release Product for shipment to MEDA which comply with (i) all specifications of the Product in the Regulatory Approvals granted by the regulatory authorities in the Territory; (ii) all Specifications; and (iii) all applicable legal and regulatory requirements relating to the manufacture of the Product for sale in the Territory, including but not limited to Good Manufacturing Practices.
- 10.3 Current Good Manufacturing Practices ("cGMP")/Regulatory Requirements. All manufacturing and quality control methods utilized by VIVUS and/or VIVUS's third-party contract manufacturer(s) in the manufacture of the Product shall be carried out in accordance with all applicable rules governing medical devices in the Good Manufacturing Practice for medical devices and regulations issued by the health regulatory authorities in the Territory for which such Product is to be sold as in effect at the time and the applicable standards in effect at the time (collectively, the "Manufacturing Standards").
- 10.4 Documentation. VIVUS shall keep and maintain, for a minimum of five (5) years after the date of distribution, (i) reference samples and quality control records for each batch of starting materials and packaging material used in the manufacture of the Product, and (ii) manufacturing and quality control records for each batch of the Product. Each shipment of the Product shall be accompanied by the following written documentation:
- a. the date of final packaging;
  - b. delivered amount of Product units; and
  - c. a certificate of compliance pursuant to Article 6.
- 10.5 Product Liability Insurance. The Parties shall maintain product liability insurance consistent with their normal business practices from time to time to cover risks related to the Product and, upon either Party's request, to provide the other Party with certificates of insurance attesting to the existence of such insurance.
- 10.6 Coverage. During the Term and for a period of two (2) years thereafter, each Party shall obtain and maintain insurance coverage from a reputable arm's-length insurer in respect of its respective obligations under Article 10.5 and in respect of third-person liability in an amount of not less than [\*]. Each Party shall add the other Party as a co-insured under its respective insurance policy



ARTICLE 11 - FORCE MAJEURE

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

ARTICLE 12 - ALLOCATION OF SUPPLY

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12.1 Allocation of Supply. In the event of VIVUS's inability to supply the Product ordered by MEDA, VIVUS shall allocate its available supply between MEDA, VIVUS and VIVUS's licensee(s) outside the Territory on a fair and equitable basis based on a pro-rata share of worldwide Product sales for the six (6) months preceding and the forecasted worldwide Product sales for the next six (6) months following such allocation. SUCH ALLOCATION SHALL BE MEDA'S SOLE REMEDY FOR VIVUS'S FAILURE TO SUPPLY MEDA QUANTITIES OF PRODUCT VIVUS IS OTHERWISE OBLIGATED TO SUPPLY UNDER ARTICLE 4 OF THIS AGREEMENT.

ARTICLE 13 - TRADEMARKS

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13.1 Trademark Rights. VIVUS hereby grants to MEDA the exclusive right, exclusive even as to VIVUS, to use the Trademarks in connection with the Product in the Territory during the term of this Agreement. MEDA acknowledges that such Trademarks shall be and are the sole property of VIVUS.

13.2 Electronic Address. VIVUS hereby grants to MEDA a non-exclusive right to use VIVUS's registered electronic address, [www.vivus.com](http://www.vivus.com), for the purpose of linking electronic users with MEDA's relevant web pages, web sites or other electronic addresses relating to the Product in the Territory. MEDA hereby grants to VIVUS a non-exclusive right to use MEDA's registered electronic address, [www.meda.se](http://www.meda.se) for the purpose of linking electronic users with VIVUS's relevant web pages, web sites or other electronic addresses relating to the Product.

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

14.2 Litigation.

- a. If the efforts of the parties are not successful in abating the alleged infringement, then VIVUS shall have the right, but not the obligation, to bring an appropriate suit or action against such infringement, at its own expense. MEDA agrees to cooperate in any such infringement action and agrees to execute all papers and perform such other acts as may be reasonably requested by VIVUS at MEDA's expense. VIVUS shall consult with MEDA and take into account MEDA's recommendations regarding the conduct of such action, provided that VIVUS shall have full right and authority to determine the strategy and tactics for such action and to settle, consent to judgment, or otherwise resolve any such action or suit. The provisions of the foregoing notwithstanding, no such resolution shall be binding on MEDA without its prior written consent (which consent shall not be unreasonably withheld) unless such resolution does not (i) impose any liability, loss, cost or obligation upon MEDA, and (ii) adversely affect MEDA's rights under this Agreement.
- b. If VIVUS does not elect to bring suit against the alleged infringer, MEDA shall have the right, but not the obligation, to bring an appropriate suit or action against such infringer in the Territory, at MEDA's own expense. VIVUS agrees to cooperate in any such infringement action and agrees to execute all papers and perform such other acts as may be reasonably requested by MEDA (including but not limited to consent to be joined as a nominal party plaintiff in such action), at VIVUS's expense. MEDA shall consult with VIVUS and take into account VIVUS's recommendations regarding the conduct of such action, provided that MEDA shall have full right and authority to determine the strategy and tactics for such action and to settle, consent to judgment, or otherwise resolve any such action or suit. The provisions of the foregoing notwithstanding, no such resolution shall be binding on VIVUS without its prior written consent (which consent shall not be unreasonably withheld) unless such resolution does not (i) impose any liability, loss, cost or obligation upon VIVUS and (ii) adversely affect VIVUS's rights under this Agreement.
- c. If VIVUS or MEDA brings an infringement action pursuant to this Article 14, any amount recovered in any action or suit against a third party infringer shall be allocated as follows: first, to the party bringing such action in order to reimburse such party for the costs and expenses of such action; second, with respect to any remaining amount, [\*]  
of that portion of such amount resulting from infringement within the Territory to MEDA, and the rest of any remaining amount to VIVUS.

ARTICLE 15 - TERM AND TERMINATION

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- 15.1 Term. The term of this Agreement shall commence on the Effective Date and shall, unless earlier terminated pursuant to this Article 15 or other express termination provisions in this Agreement, expire on the tenth (10th) anniversary of the First Commercial Sale of Product.
- 15.2 Breach. Either party may, in addition to any other remedies available to it by law or in equity, terminate this Agreement upon sixty (60) days' written notice in the event that the other party commits a material breach of this Agreement and fails to cure such breach within sixty (60) days of notice of the breach. The party giving notice of breach may withhold any payments otherwise due and owing to the breaching party, to be used as a setoff against any loss or damage arising from the breach, and said withholding shall not constitute breach of this Agreement. Any amounts so withheld shall be deposited by the withholding party into an interest-bearing escrow account. If the breaching party cures the breach within the sixty (60) day cure period and this Agreement is not terminated, then the withholding party shall promptly pay to the other party the withheld amount, less that portion of such amount which was applied as a setoff. Notwithstanding the foregoing provision, if MEDA gives notice of breach to VIVUS, MEDA may withhold other payments pursuant to this Article 15.2 but shall not be entitled to withhold payment for Product actually ordered by and delivered to MEDA pursuant to Article 4 of this Agreement.
- 15.3 Insolvency or Bankruptcy. Either party may, in addition to any other remedies available to it by law or in equity, terminate this Agreement, upon thirty (30) days' written notice to the other party in the event the other party shall have become insolvent or bankrupt, or shall have made an assignment for the benefit of its creditors, or there shall have been appointed a trustee or receiver of the other party or for all or a substantial part of its property, or any case or proceeding shall have been commenced or other action taken by or against the other party in bankruptcy or seeking reorganization, liquidation, dissolution, winding-up, arrangement, composition or readjustment of its debts or any relief under any bankruptcy, insolvency, reorganization or other similar act or law of any jurisdiction now or hereinafter in effect.
- 15.4 Serious Events. Should there occur serious and unexpected events which, from a reasonable pharmaceutical company's point of view, would make it impossible or impracticable to pursue the commercialization of the Product, including but not limited to a serious adverse event associated with the Product, either party may, with full consultation with the other party, terminate this Agreement upon thirty (30) days' written notice. Termination by a party in good faith pursuant to this Article 15.4 shall not, in itself, constitute a basis

for any claim for compensation or other remedies by the other party. In the event of termination by VIVUS under this Article 15.4, VIVUS shall be restricted from commercializing the Product, either directly or indirectly, for a period of two (2) years in the Territory.

- 15.5 Change of Control or Ownership. Either party may terminate this Agreement upon thirty (30) days' written notice if the ownership or control of at least fifty percent (50%) of the assets or voting securities of the other party are transferred and, in the non-changing party's reasonable judgment, the other party's new owner or controlling entity is a competitor of the non-changing party in the field of erectile dysfunction in the Territory.
- 15.6 Survival of Liability. Except as expressly provided otherwise in this Agreement, termination, expiration, cancellation or abandonment of this Agreement through any means and for any reason shall not relieve the parties of any obligation accruing prior thereto and shall be without prejudice to the rights and remedies of either party with respect to any antecedent breach of any provision of this Agreement.
- 15.7 Remaining Inventory. MEDA shall maintain a normal level of inventory of the Product prior to expiration or termination of this Agreement, and shall have a period of six (6) months from the date of termination of this Agreement during which it may sell its remaining inventory of Product, provided it sell such inventory in a manner substantially similar to the manner in which it was selling Product prior to the termination.
- 15.8 Survival. Upon expiration or termination of this Agreement, all rights and obligations of the parties under this Agreement shall terminate except those rights and obligations described in ARTICLES 1, 8.1, 10.4, 15, 16, 17 AND 18.

#### ARTICLE 16 - INDEMNITY

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- 16.1 By VIVUS. In addition to indemnification expressly provided elsewhere in this Agreement, VIVUS shall indemnify, defend and hold MEDA, its directors, employees, agents and representatives (including but not limited to MEDA's Affiliates) harmless from and against all claims, causes of action, settlement costs (including but not limited to reasonable attorney's fees and expenses) losses or liabilities of any kind which:
- (a) arise from or are attributable to any negligent act or omission or willful misconduct on the part of VIVUS or its Affiliates, or its or their directors, employees, agents or representatives relating to any of VIVUS' obligations under this Agreement, including but not limited to any breach of a representation or warranty;
  - (b) arise from or are attributable to the manufacture of the Product and which in either case are not otherwise attributable to any negligent act or

omission or willful misconduct on the part of MEDA, its directors, employees, agents or representatives (including, but not limited to, MEDA's Affiliates);

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

- (a) arise from or are attributable to any negligent act or omission or willful misconduct on the part of MEDA, its directors, employees, agents or representatives relating to any of its obligations under this Agreement; or
- (b) arise from or are attributable to the storage, use, sale, marketing and promotion of the Product by MEDA in the Territory and which in either case are not otherwise attributable to the manufacture of a Product and which in either case are not otherwise attributable to any negligent act or omission or willful misconduct on the part of VIVUS, its directors, employees, agents or representatives.

16.3 Condition of Indemnification. If either party expects to seek indemnification under this Section, it shall promptly give notice pursuant to Section 18.5 below to the indemnifying party of the basis for such claim of indemnification. If indemnification is sought as a result of any third party claim or suit, such notice to the indemnifying party shall be within fifteen (15) days after receipt by the other party of such claim or suit; provided, however, that the failure to give notice within such time period shall not relieve the indemnifying party of its obligation to indemnify unless it shall be materially prejudiced by the failure. The indemnifying party shall have full control over the defense of such claim or suit; provided that the indemnified party shall have the right to participate, at its own expense, with counsel of its own choosing, in such defense. The indemnified party shall fully cooperate with the indemnifying party in the defense of all such claims or suits. The indemnifying party shall make no offer of settlement, settlement or compromise without the prior written consent of the indemnified party (which consent shall not be unreasonably withheld) unless such settlement fully releases the indemnified party without any liability, loss, cost or obligation.

16.4 Term of Indemnification. The obligations of the parties set forth in this Article 16 shall apply during the term of this Agreement and for a period of five (5) years after the date of termination in whole or expiration of this Agreement or any extension thereof.

ARTICLE 17 - CONFIDENTIALITY AND DISCLOSURE

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- 17.1 Confidentiality. Neither party shall use or disclose any Confidential Information received by it pursuant to this Agreement without the prior written consent of the other. This obligation shall continue for a period of seven (7) years after expiration or termination of this Agreement.
- 17.2 Disclosure. Nothing contained in this Article 17 shall be construed to restrict the parties from disclosing Confidential Information as required: (i) for regulatory, tax, securities or customs reasons, (ii) by court or other government order, (iii) for confidential audit purposes; or (iv) from using such Confidential Information as is reasonably necessary to perform acts permitted by this Agreement, including the registration, marketing, sale or use of the Product.

ARTICLE 18 - MISCELLANEOUS

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- 18.1 Assignment. This Agreement may not be assigned or otherwise transferred, nor, except as expressly provided hereunder, may any right or obligation hereunder be assigned or transferred by either party without the prior written consent of the other party; provided, however, that either VIVUS or MEDA may, without such consent, assign this Agreement and its rights and obligations hereunder in connection with the transfer or sale of all or substantially all of its assets, its merger or consolidation or any similar transaction, and that MEDA may, without such consent, assign this Agreement and its rights and obligations hereunder to one or more of its Affiliates. Any permitted assignee shall assume all obligations of its assignor under this Agreement.
- 18.2 Sublicensees. In the event that MEDA grants sublicenses under Article 2, MEDA shall ensure that such sublicensees abide by all the obligations of MEDA contained in this Agreement to the extent that such obligations are relevant to and applicable to such sublicensees.
- 18.3 Damages. Notwithstanding any provision in this Agreement to the contrary, in no event shall a party hereto be liable to the other party for any indirect or consequential damages, including but not limited to loss of profits or business opportunity.
- 18.4 Severability. Each party intends not to violate any public policy, statutory or common law, rule, regulation, treaty or decision of any government agency or executive body thereof of any country or community or association of countries. If any term or provision of this Agreement is held to be invalid, illegal or unenforceable by a court or other governmental authority of competent jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Agreement, which shall remain in full force and effect. The holding of a term or provision to be invalid, illegal or unenforceable in a jurisdiction shall not have any effect on the application of the term or provision in any other jurisdiction.

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

If to VIVUS: VIVUS International Limited  
c/o VIVUS, Inc.  
1172 Castro Street  
Mountain View, CA 94040  
Attention: Legal Department  
Fax: (650) 934-5389

If to MEDA: MEDA AB  
Pipers vag 2  
Box 906, SE-170 09 Solna,  
Attention: CEO  
Fax: +46 8 630 19 19

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

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

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

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

- 18.10 Waiver. The waiver by either party of any right hereunder or of a failure to perform or breach by the other party shall not be deemed a waiver of any other right hereunder or of any other failure or breach whether of a similar nature or otherwise.
- 18.11 Dispute Resolution. Prior to either party initiating any court proceedings against the other party, the parties shall first attempt to resolve any disputes arising out of or related to this Agreement as follows. Either party may initiate the dispute resolution process by delivering written notice to the other party setting forth the matter in dispute. Such matter shall be referred to a joint committee comprised of at least one (1) member nominated by each party. The joint committee shall meet within ten (10) business days of receipt of such notice. The joint committee shall have a period of ten (10) business days to attempt to resolve the matter in dispute. If the joint committee is unable to resolve the dispute by unanimous resolution within such time, the joint committee will escalate the dispute to the chief executive officers of the parties for resolution. If the respective chief executive officers cannot resolve the dispute within fifteen (15) business days after the date such dispute was escalated, then either party may refer such dispute for resolution by court proceedings
- 18.12 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

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

MEDA AB

VIVUS INTERNATIONAL, LTD.

By: /s/ Anders Lonner

By: /s/ Leland Wilson

Title: CEO

Title: President and CEO

Date: 2/18/03

Date: 2/21/03



LIST OF SUBSIDIARIES

The following is a list of subsidiaries of VIVUS, Inc.

1. VIVUS International Limited, a wholly owned subsidiary of VIVUS, Inc.
2. VIVUS UK Limited, a wholly owned subsidiary of VIVUS International Limited
3. VIVUS BV Limited, a wholly owned subsidiary of VIVUS International Limited
4. VIVUS Ireland Limited, a wholly owned subsidiary of VIVUS International Limited