SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2003

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	**94-3136179**
(State or other jurisdiction of incorporation or organization)	**(IRS employer identification number)**
1172 Castro Street	**(650) 934-5200**
Mountain View, California 94040	**(Registrant's telephone number, including area code)**
(Address of principal executive offices and zip 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 [X] No [ ]

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

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

The aggregate market value of the voting and non-voting Common Stock held by non-affiliates of the Registrant on June 30, 2003, the last business day of Registrant's most recently completed second fiscal quarter, was approximately $182,632,437, which is based upon the closing price of the common stock on the Nasdaq National Market. There were 36,164,839 shares of the Registrant's common stock, par value $.001, issued and outstanding held by non-affiliates of the Registrant as of June 30, 2003.

There were 37,989,065 shares of the Registrant's common stock outstanding as of February 27, 2004.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information is incorporated by reference from the Proxy Statement for the Registrant's 2004 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Annual Report on 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 specialty pharmaceutical company focused on the research, development and commercialization of products to restore sexual function in men and women. In addition to its currently marketed therapies, VIVUS has a pipeline that includes both new chemical entities and existing compounds that are being developed to address unmet medical needs. VIVUS' business strategy is to apply its scientific and medical expertise to identify, develop and commercialize therapies that restore sexual function. In the United States, VIVUS markets MUSE® (alprostadil) and ACTIS®, two products for the treatment of erectile dysfunction. We have entered into supply agreements with Meda AB (Stockholm:MEDAa.ST) to market and distribute MUSE and ACTIS in all Member States of the European Union, the Baltic States, the Czech Republic, Hungary, Iceland, Norway, Poland, Switzerland and Turkey. In Canada, we have entered into a license and supply agreement with Paladin Labs, Inc. (TSE:PLB) for the marketing and distribution of MUSE.

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

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

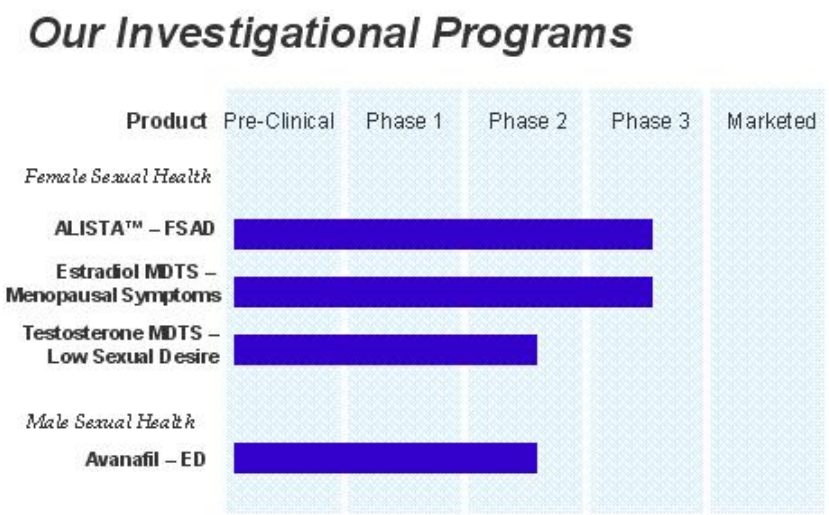
The first two programs are in Phase 3 clinical development and the second two are in Phase 2 clinical development. We believe that each of these programs addresses either established markets with sales in excess of $1.0 billion annually or potential markets with sales that could exceed $1.0 billion annually.

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

VIVUS was incorporated in California on April 16, 1991, effected its initial public offering of common stock in 1994, 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** 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 Future

It is our objective to become a global leader in the development and commercialization of products that help to restore sexual health in men and women. VIVUS has strong intellectual property supporting many opportunities in sexual health. Our future growth will come from further development and approval of our products as well as in-licensing and product line extensions. Consistent with our in-licensing strategy, two of our four investigational programs, Testosterone MDTS and Estradiol MDTS, were licensed in the first quarter of 2004 from Acrux Ltd., a specialty pharmaceutical company located in Melbourne, Australia.



Female Sexual Health

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

Our investigational programs in female sexual health are as follows:

- **ALISTA** to treat female sexual arousal disorder;
- **Testosterone MDTS** for treating women with low sexual desire; and
- **Estradiol MDTS,** a therapy for woman experiencing symptoms associated with menopause.

ALISTA

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

Our first Phase 2 clinical study, which was an in-clinic, single dose, multi-center trial designed to evaluate the safety of and response to ALISTA in postmenopausal women with female sexual arousal disorder, was completed in 2001. The study demonstrated a significant increase in ALISTA-treated women versus placebo in sexual response associated with visual sexual stimulation. ALISTA was well tolerated and associated with a rapid and sustained improvement in sexual response.

In the first quarter of 2003, we completed a separate, larger Phase 2 study designed to evaluate the efficacy and safety of ALISTA when used by postmenopausal women with female sexual arousal disorder in an at–home setting. The study demonstrated a statistically significant improvement in satisfactory sexual arousal and/or orgasm in postmenopausal women who were treated with the 400 mcg dose of ALISTA. ALISTA was well tolerated, with some women reporting transient discomfort. In the fourth quarter of 2003, the data from this Phase 2 study was presented at the International Society for the Study of Women's Sexual Health (ISSWSH) meeting in Amsterdam.

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

VIVUS plans to begin Phase 3 clinical development of ALISTA in 2004.

Metered Dose Transdermal Spray, or MDTS

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

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

- **Testosterone MDTS –** This proprietary spray product is designed to address the female low sexual desire market. The clinical name for low sexual desire is hypoactive sexual desire disorder, or HSDD. There are estimated to be over 10 million women in the United States afflicted with low sexual desire and there are currently no FDA approved therapies for this condition. In published literature testosterone has been shown to be effective in treating women with low sexual desire, whose ovaries had been removed through surgery, as reported in the *New England Journal of Medicine* in 2000.

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

  The data published in the *New England Journal of Medicine*, as mentioned above, was from a clinical trial sponsored by Procter & Gamble (NYSE:PG), or P&G. P&G is developing a testosterone patch and is currently in Phase 3 clinical development. The P&G patch, called Intrinsa®, is a twice-weekly patch and may likely be the first testosterone product approved by the FDA for the treatment of low sexual desire in women.

- **Estradiol MDTS —** This spray product utilizes the same spray technology as the testosterone spray. This product is simple to use and apply, has the safety of transdermal delivery, and is patented. The estradiol spray is a low-dose estrogen-only treatment addressing the symptoms associated with menopause, primarily hot flashes. The overall market for estrogen therapy exceeds $1.0 billion annually and today's market for transdermal delivery of estradiol is approximately $275 to $300 million. During Phase 2 clinical development, the estradiol spray produced comparable plasma levels of estrogen as a transdermal patch currently on the market.

  VIVUS plans to conduct Phase 3 clinical development of the estradiol spray in 2004.

  VIVUS currently plans to commercialize the estradiol spray, if approved, through a 40 to 50 person sales force calling on the top 15% to 20% high prescribing OB/GYN doctors. There are approximately 40,000 OB/GYN doctors in the United States. We believe that launching the estradiol spray would provide two advantages for VIVUS. First, it would establish relationships between VIVUS and the OB/GYN community of physicians. Second, it would introduce the VIVUS spray technology to the OB/GYN doctors so they are familiar with the technology in the event the testosterone spray product comes to the market.

Male Sexual Health

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

A survey of 2,900 men with erectile dysfunction, titled *Assessing Men's Attitudes Towards ED Pharmacotherapy*, was conducted by Eardly et. al. with data presented at the European Society of Sexual Medicine Congress in Istanbul, Turkey in 2003. The top attribute men sought in erectile dysfunction therapy was for the drug to work every time. The next three attributes dealt with safety issues.

Avanafil

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

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

VIVUS 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 avanafil in men with erectile dysfunction. This in-clinic, single-dose trial began in the first quarter of 2002. Subjects with mild to moderate erectile dysfunction were treated with placebo, avanafil or Viagra (sildenafil) prior to visual sexual stimulation, and their penile rigidity response was measured over a two-hour period. Patient enrollment was completed during the third quarter of 2002. The trial results demonstrated that avanafil caused a rapid increase in penile rigidity that was statistically significantly greater than placebo. Avanafil appeared to be safe and well tolerated in this trial.

In July 2003, we began enrolling patients in an at-home, prospective, randomized, double blind, direct comparator clinical trial to evaluate the safety, efficacy, and onset of action of avanafil versus Viagra in men with erectile dysfunction. Subjects in the clinical trial had erections sufficient to achieve vaginal penetration on approximately 80% of the attempts with both avanafil and Viagra. The attempts with both products occurred within an average of 20 minutes of dosing. We are planning to present the full peer-reviewed data at the American Urological Association, or AUA, sectional meeting in August 2004.

Our research and development expenses for the years ended December 31, 2003, 2002 and 2001, in thousands, were $7,724, $13,281, and $12,324, respectively. We anticipate that our research and development expenses will increase from 2003 levels 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.

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 21 in erectile dysfunction and 14 in female sexual dysfunction.

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 Urological 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 international supply agreements with Meda AB in September 2002 and February 2003. Under these supply agreements, Meda AB purchases MUSE and ACTIS 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.

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

MUSE — VIVUS' Transurethral System for Erection

Administration of MUSE 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 MUSE, a patient urinates, shakes the penis to remove excess urine, inserts the transurethral applicator 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 active pharmacologic agent used in MUSE. 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.

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 for Erectile Dysfunction

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. Three additional oral medications have since been approved by various worldwide regulatory authorities for the treatment of erectile dysfunction: Uprima®, approved and launched in Europe by Abbott Laboratories; Cialis®, approved and launched in Europe and the United States by Lilly ICOS LLC and the rest of the world by Eli Lilly and Company; and Levitra®, approved and launched by Bayer and GlaxoSmithKlineBeecham. These oral medications account for more than 95% of all prescriptions written for pharmaceutical products to treat ED.

- *Needle Injection Therapy.* This form of treatment involves the needle injection of pharmacologic agents directly into the penis. The most commonly prescribed pharmacologic agent that is currently approved for this indication is alprostadil (which is also the active ingredient in MUSE). European regulatory authorities have approved in France the use of an alpha blocker (Erecnos®) and in Denmark a combination of phetolamine with certain vasoactive intestinal polypeptides (Invicorp®) for the treatment of erectile dysfunction. 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 and Healthcare products Regulatory Agency, formerly the Medicines Control Agency, the regulatory authority in the United Kingdom, authorized us to begin commercial production and shipment of MUSE from this facility in June and March 1998, respectively. 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 and Healthcare products Regulatory Agency, formerly 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.

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 supply agreements with Meda AB for the international marketing and distribution of MUSE and ACTIS. In Canada, we have entered into a license and supply agreement with Paladin Labs for the marketing and distribution of MUSE.

All transactions are denominated in United States dollars and we operate 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*.

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

Employees

As of February 27, 2004, VIVUS had 119 employees, including 80 of which are located at our manufacturing facility in Lakewood, New Jersey and 39 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.

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 Annual Report on Form 10-K. 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 are 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 product candidates currently under development. Once we submit our potential products for review, we cannot assure you that the United States Food and Drug Administration or other regulatory agencies will grant approvals for any of our proposed products on a timely basis or at all. Further, even if we receive regulatory approval for a product, there can be no assurance that such product will prove to be commercially successful or profitable.

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

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

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

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

Competition in the pharmaceutical and medical products industries is intense and is characterized by extensive research efforts and rapid technological progress. The most significant competitive therapy for MUSE is an oral medication marketed by Pfizer under the name Viagra, which received regulatory approvals in the United States in March 1998 and in the European Union in September 1998. The commercial launch of Viagra in the United States in April 1998

significantly decreased demand for MUSE. Another oral medication under the name Uprima was approved and launched in Europe by Abbott Laboratories and Takeda in May 2001. In February 2003, a new oral medication under the name Cialis was launched in Europe by Lilly ICOS LLC and in Australia and New Zealand by Eli Lilly and Company. Cialis was launched in the United States in January 2004. Bayer AG and GlaxoSmithKline plc launched Levitra in the European Union and the United States in March and September 2003, respectively.

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

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

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

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

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

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

Failure of our third-party manufacturers to maintain satisfactory compliance with current Good Manufacturing Practices, or cGMPs, could have a material adverse effect on our ability to continue to market and distribute our products and, in the most serious cases, could result in the issuance of warning letters, seizure or recall of products, civil penalties or closure of our manufacturing facility until such cGMP compliance is achieved. We obtain the necessary raw materials and components for the manufacture of MUSE as well as certain services, such as testing and sterilization, from third parties. We currently contract with suppliers and service providers, including foreign manufacturers that are required to comply with strict standards established by us. Certain suppliers and service providers are required to follow cGMP requirements and are subject to routine unannounced periodic inspections by the United States Food and Drug Administration and by certain state and foreign regulatory agencies for compliance with cGMP requirements and other applicable regulations. Certain of our suppliers were inspected for cGMP compliance as part of the approval process. However, upon routine re-inspection of these facilities, there can be no assurance that the United States Food and Drug Administration and other regulatory agencies will find the manufacturing process or facilities to be in compliance with cGMP requirements and other regulations.

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

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

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

- ineffectiveness of the study compound, or perceptions by physicians that the compound is not effective for a particular indication;
- inability to manufacture sufficient quantities of compounds for use in clinical trials;

- failure of the United States Food and Drug Administration to approve our clinical trial protocols;
- slower than expected rate of patient recruitment;
- inability to adequately follow patients after treatment;
- unforeseen safety issues; or
- government or regulatory delays.

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

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

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

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

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

Our success depends in large part on the strength of our current and future patent positions to restore sexual function in men and women.

VIVUS holds various patents and patent applications targeting male and female sexual health.

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 transurethrally.

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 transurethrally administering an active agent. Patents have also been granted in Australia, Austria, Belgium, Canada, Finland, France, Germany, Great Britain, Greece, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Romania, Spain, Sweden and South Africa. A patent application is pending in Denmark. 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 transurethrally 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, Japan, Mexico, New Zealand, Norway, Portugal, South Africa and South Korea, and a foreign application is pending in Canada.

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 the prevention and/or treatment of other types of sexual dysfunction in men and women. 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 field of sexual health in men and women. 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 inventions. There can be no assurance that our patents will not be successfully challenged or designed around by others.

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

We are required to initially receive regulatory approval for suppliers and we obtained our current supply of alprostadil from two approved sources. The first is NeraPharm, formerly Spolana Chemical Works a.s., in Neratovice, Czech Republic. The second is Chinoin Pharmaceutical and Chemical Works Co., Ltd. We entered into manufacturing agreements with Chinoin and NeraPharm in November 2002 and December 2003, respectively, to produce additional quantities of alprostadil for us. We are currently in the process of assuring the new material meets testing and regulatory specifications. There can be no guarantees the material will pass these requirements and be usable material in our manufacturing process. We are currently in the process of investigating additional sources for our future alprostadil supplies. However, there can be no assurance that we will be able to identify and qualify additional suppliers of alprostadil, in a timely manner, if at all.

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

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

We entered into a distribution agreement with Cardinal Health (formerly CORD Logistics, Inc.). Under this agreement, Cardinal Health takes the following actions:

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

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

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

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

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

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

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

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

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

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

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

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

We have an accumulated deficit of $101.0 million at December 31, 2003 and expect to continue to incur substantial operating losses for the foreseeable future.

We have generated a cumulative net loss of $101.0 million for the period from our inception through December 31, 2003 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 approved therapeutic approach to treat erectile dysfunction.

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

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 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 position, are often uncertain and involve complex legal and factual questions. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. We apply for patents covering our technologies and products, as we deem appropriate. However,

we may not obtain patents on all inventions for which we seek patents, and any patents we obtain may be challenged and may be narrowed in scope or extinguished as a result of such challenges. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Others may independently develop similar or alternative technologies or design around our patented technologies or products. These companies would then be able to develop, manufacture and sell products that compete directly with our products. In that case, our revenues and operating results would decline.

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

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

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

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

MUSE and ACTIS 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.

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

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

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

The healthcare industry is undergoing fundamental changes that are the result of political, economic and regulatory influences. The levels of revenue and profitability of pharmaceutical companies may be affected by the continuing efforts of governmental and third party payors to contain or reduce healthcare costs through various means. Reforms that have been and may be considered include mandated basic healthcare benefits, controls on healthcare spending through limitations on the increase in private health insurance premiums and Medicare and Medicaid spending, the creation of large insurance purchasing groups and fundamental changes to the

healthcare delivery system. Due to uncertainties regarding the outcome of healthcare reform initiatives and their enactment and implementation, we cannot predict which, if any, of the reform proposals will be adopted or the effect such adoption may have on us. There can be no assurance that future healthcare legislation or other changes in the administration or interpretation of government healthcare or third party reimbursement programs will not have a material adverse effect on us. Healthcare reform is also under consideration in some other countries.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The Financial Accounting Standards Board is considering whether to require all companies to treat the value of stock options granted to employees as an expense. The United States Congress and other governmental and regulatory authorities have also considered requiring companies to expense stock options. If this change were to become mandatory, we and other companies would be required to record a compensation expense equal to the fair market value of each stock option granted. This expense would be spread over the vesting period of the stock option. Currently, we account for stock compensation under Accounting Principles Board, or APB, No. 25, *Accounting for Stock Issued to Employees*, which results in no compensation expenses recorded in connection with stock options granted to our employees. If we were required to expense stock option grants, it would reduce the attractiveness of granting stock options because of the additional expense associated with these grants, which would reduce our profitability. However, stock options are an important employee recruitment and retention tool, and we may not be able to attract and retain key personnel if we reduce the scope of our employee stock option program. Accordingly, in the event we are required to expense stock option grants, our profitability would be reduced, as would our ability to use stock options as an employee recruitment and retention tool.

Item 2. ***Properties***

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 and Healthcare products Regulatory Agency, formerly the Medicines Control Agency, the regulatory authority in the United Kingdom, authorized us to begin commercial production and shipment of MUSE from this facility in June and March 1998, respectively. We have met all market demands for the supply of MUSE utilizing this manufacturing facility and we currently have the capacity to manufacture more MUSE if required.

VIVUS leases 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***

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, 2003.

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
2003				
High	$ 4.48	$ 5.69	$ 4.60	$ 4.18
Low	3.15	4.19	3.30	3.52
2002				
High	$ 9.83	$ 8.50	$ 6.07	$ 4.45
Low	5.10	5.76	3.40	3.21

As of February 27, 2004, there were 37,989,065 shares of outstanding common stock that were held by 4,591 shareholders of record. As of February 27, 2004, 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.

On May 23, 2003, we completed a private placement of 4,375,000 shares of common stock for aggregate net proceeds of $16.4 million. The shares of common stock were sold at $4.00 per share, an approximate 9% discount to the five-day trailing average ended May 21, 2003, to approximately [30] accredited investors. CE Unterberg Towbin acted as our placement agent in the transaction.

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 this Annual Report on 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,				
	2003	2002	2001	2000	1999
Income Statement Data:					
Product revenue-- United States	$ 20,768	$ 22,982	$ 20,764	$ 22,474	$ 21,168
Product revenue-- International	3,452	1,387	4,041	5,200	19,996
Other revenue	5,033	—	—	—	3,142
Milestone revenue	—	—	—	—	8,000
Returns provision	(1,815)	(2,020)	(1,204)	(1,181)	(9,118)
Total revenue	27,438	22,349	23,601	26,493	43,188
Gross profit	16,445	11,142	10,668	18,427	30,819
Operating expenses:					
Research and development	7,724	13,281	12,324	4,670	7,884
Selling, general and administrative	9,839	10,556	9,314	8,655	6,332
Other restructuring (income)	—	—	—	(903)	(1,193)
Total operating expenses	17,563	23,837	21,638	12,422	13,023
Income (loss) from operations	(1,118)	(12,695)	(10,970)	6,005	17,796
Interest and other income	773	1,211	2,171	2,541	1,994
Income (loss) before taxes	$ (345)	$ (11,484)	$ (8,799)	$ 8,546	$ 19,790

Net income (loss)	$ (26)	$ (10,566)	$ (7,070)	$ 7,691	$ 18,801
Net income (loss) per diluted share	$ (0.00)	$ (0.32)	$ (0.22)	$ 0.23	$ 0.58
Shares used in per share computation	35,884	32,907	32,572	33,428	32,507
Balance Sheet Data (at year end):					
Working capital	$ 30,099	$ 18,974	$ 14,898	$ 32,981	$ 26,616
Total assets	$ 65,697	$ 49,681	$ 58,574	$ 69,174	$ 68,760
Accumulated deficit	$(100,960)	$(100,934)	$ (90,368)	$ (83,298)	$ (90,989)
Stockholders' equity	$ 51,235	$ 34,385	$ 43,975	$ 50,187	$ 41,496
Other Financial Data:					
Common shares outstanding	37,788	32,999	32,693	32,461	32,211
Number of employees	122	119	127	136	125

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, 2003, 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, Inc. is a specialty pharmaceutical company focused on the research, development and commercialization of products to restore sexual function in men and women. In addition to its currently marketed therapies, VIVUS has a pipeline that includes both new chemical entities and existing compounds that are being developed to address unmet medical needs. VIVUS' business strategy is to apply its scientific and medical expertise to identify, develop and commercialize therapies that restore sexual function. In the United States, VIVUS markets MUSE® (alprostadil) and ACTIS®, two products for the treatment of erectile dysfunction. We have entered into supply agreements with Meda AB (Stockholm:MEDAa.ST) to market and distribute MUSE and ACTIS in all Member States of the European Union, the Baltic States, the Czech Republic, Hungary, Iceland, Norway, Poland, Switzerland and Turkey. In Canada, we have entered into a license and supply agreement with Paladin Labs, Inc. (TSE:PLB) for the marketing and distribution of MUSE.

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

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

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

We made progress in our development programs in 2001. Our first Phase 2 clinical study to evaluate the safety of and response to ALISTA, our product for the treatment of female sexual arousal disorder, 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 avanafil in men with erectile dysfunction. 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.

Our development programs continued in 2002. An expanded Phase 2 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 avanafil in men with erectile dysfunction. Clinical data from this study demonstrated that avanafil was capable of restoring penile function in men with erectile dysfunction. We also began pre-clinical development work on a transurethral formulation of avanafil, alone and in combination with alprostadil, for the treatment of erectile dysfunction. 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.

In 2003, we strengthened our cash position to support upcoming clinical trials by completing a private placement of 4,375,000 shares of common stock for aggregate net proceeds of $16.4 million. Our cash position also increased by an additional $4.0 million as a result of the resolution in the third quarter of our arbitration claim against Janssen Pharmacuetica International with the American Arbitration Association. Although United States MUSE sales units declined 12%

from 2002 levels, international sales units increased 126% during 2003, resulting in equivalent product revenue in 2003 as compared to 2002. The results of our expanded Phase 2 ALISTA study discussed previously demonstrated a statistically significant improvement in satisfactory sexual arousal and/or orgasm in postmenopausal women who were treated with the 400 mcg dose of ALISTA. We initiated a second at-home clinical study for ALISTA designed to evaluate the efficacy and safety of ALISTA when used at home by pre-menopausal women with female sexual arousal disorder. In July 2003, we began enrolling patients in an at-home, prospective, randomized, double blind, direct comparator clinical trial to evaluate the safety, efficacy, and onset of action of avanafil versus Viagra in men with erectile dysfunction. Subjects in the clinical trial had erections sufficient to achieve vaginal penetration on approximately 80% of the attempts with both avanafil and Viagra. The attempts with both products occurred within an average of 20 minutes of dosing.

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, 2003, the remaining inventory reserve balance is $5.6 million. This remaining balance is related to the raw materials inventory that the Company previously estimated would not be used. 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.

- Available-for-Sale Securities: Available-for-sale securities represent investments in debt securities that are stated at fair value. We restrict our cash investments to:

  - Direct obligations of the United States Treasury;

  - Federal Agency securities which carry the direct or implied guarantee of the United States government; and

  - Corporate securities, including commercial paper, rated A1/P1 or better.

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 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 original maturities beyond one year from the balance sheet date are classified as non-current.

- 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.

Results of Operations

Years Ended December 31, 2003 and 2002

For the year ended December 31, 2003, the Company reported a net loss of ($26,000), or ($0.00) net loss per share as compared to a net loss of ($10.6) million or ($0.32) net loss per share for the year ended December 31, 2002. The decrease in the net loss in 2003 is due primarily to revenue recognized as the result of the resolution of our arbitration claim against Janssen Pharmaceutica in the third quarter of 2003. Reduced operating expenses also contributed to the lower loss.

The Company anticipates losses over the next several years. The Company generally does not expect increases in MUSE sales, and the Company will continue to invest in clinical development of its current research and development pipeline in an attempt to bring those potential products to market.

Revenue. United States product revenue for the year ended December 31, 2003 was $20.8 million, as compared to $23.0 million for the year ended December 31, 2002. The decrease was primarily due to a 12.3% decrease in the number of MUSE units sold in 2003 versus 2002.

International revenue was $3.5 million for the year ended December 31, 2003, compared to $1.4 million for the same period in 2002. Higher international product revenue in 2003 was due to a full year of sales to our international distribution partner, Meda. Initial shipments to Meda began in the fourth quarter of 2002.

Other revenue was $5.0 million due to the resolution of the Company's arbitration claim against Janssen Pharmaceutica with the American Arbitration Association related to payments owing to VIVUS under a previously terminated distribution agreement between the companies. $3.7 million represents amounts due from Janssen Pharmaceutica under the arbitration award. The remaining $1.3 million results from recognizing Janssen Pharmaceutica related revenue that was previously deferred pending the outcome of the arbitration.

In 2003 and 2002, the charge for actual and anticipated returns of product was $1.8 million and $2.0 million, respectively. The decrease in 2003 was due to lower United States revenue as discussed above. Product return data through the first quarter of 2002 indicated an increase to the returns reserve was warranted. Approximately $403,000 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. Cost of goods sold for the year ended December 31, 2003 was $11.0 million, compared to $11.2 million for the same period in 2002. During 2003, we used certain raw material inventory, the cost basis of which had been reduced to zero in prior years. This had a favorable impact on our gross profit during 2003 of $1.2 million. The 2002 amount includes a reduction in cost of goods sold of $802,000 as a result of settlements of previously recognized purchase commitment liabilities for our major raw material, alprostadil. Adjusting for these items, comparative gross margins, excluding "other revenue" from the calculation, for the twelve months ended December 31, 2003 versus 2002 were 45.6% and 46.3%, respectively. The slight decline in margins year over year was attributable to an increase in international sales in 2003 which carried lower margins than United States sales.

Research and development expenses. Research and development expenses for the year ended December 31, 2003 were $7.7 million, $5.6 million lower than the same period in the previous year. The decrease is due to greater clinical trial activity in 2002 as compared to 2003. The Company currently does not expect to recognize revenues from sales of any new products being developed through research and development efforts until 2007 at the earliest.

Selling, general and administrative expenses. Selling, general and administrative expenses for the year ended December 31, 2003 were $9.8 million, compared to $10.6 million in the year ended December 31, 2002. The decrease is primarily due to the reimbursement in 2003 by Janssen Pharmaceutica of legal fees and other expenses totaling $323,000 related to the Janssen Pharmaceutica arbitration that were previously expensed in 2002.

Interest income. Interest income for the year ended December 31, 2003 was $708,000, as compared to $1.3 million for the year ended December 31, 2002. Despite the increase in our investments, lower interest rates contributed to the reduction in interest income.

Income before taxes. We recorded a tax benefit of $319,000 for 2003 based on an updated estimate of our net tax liabilities. In 2002, we recorded a tax benefit of $918,000 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.

Years Ended December 31, 2002 and 2001

For the year ended December 31, 2002, the Company reported a net loss of ($10.6) million, or ($0.32) net loss per share as compared to a net loss of ($6.9) million, or a ($0.22) net loss per share for the year ended December 31, 2001. Lower international revenue, decreased interest income and spending for research and development contributed to the higher loss in 2002.

Revenue. 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 $724,000 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 distribution partner, Meda AB.

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 $403,000 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. 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 2002 amount includes a reduction in cost of goods sold of $802,000 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. 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 avanafil, formerly known as TA-1790. If not for this $5.0 million expense, 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. 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.

Interest income. Interest income for the year ended December 31, 2002 was $1.3 million as compared to $2.1 million in the year ended December 31, 2001. The $6.9 million reduction in cash and lower interest rates contributed to the reduction in interest income.

Income before taxes. We recorded a tax benefit of $918,000 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.

Liquidity and Capital Resources

Cash. Unrestricted cash, cash equivalents and available-for-sale securities totaled $48.3 million at December 31, 2003, compared with $29.8 million at December 31, 2002. The increase during 2003 was primarily due to the net proceeds of $16.4 million from the sale of our common stock in a private placement in May 2003. Additionally, VIVUS received $4.0 million of cash in November 2003 as a result of the resolution of our arbitration claim against Janssen Pharmaceutica. The $4.0 million consisted of $3.7 million for manufactured inventory and lost profits, and $323,000 for legal fees and other related expenses.

Since inception, we have financed operations primarily from the issuance of equity securities. Through December 31, 2003, VIVUS raised $173.0 million from financing activities and had an accumulated deficit of $101.0 million.

Available-for-sale securities. The Company focuses on liquidity and capital preservation in its investments in available-for-sale securities. The Company restricts its cash investments to:

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

The Company sequences the maturities of its investments consistent with its cash forecasts. The weighted average maturity of the portfolio is not to exceed 18 months. As investments mature, the Company re-invests the money by purchasing additional securities. As the Company needs cash for its operating expenses, it sells such investment securities. Because the Company sequences maturities consistent with its cash forecasts, realized gains and losses on the sales of securities are typically insignificant.

Accounts receivable. Accounts receivable (net of allowance for doubtful accounts) at December 31, 2003 was $1.6 million, as compared to $3.6 million at December 31, 2002. The 55.8% decrease in the accounts receivable balance at December 31, 2003 is due to a 53.2% decrease in the number of units sold in December 2003 as compared to December 2002. Currently, the Company does not have any significant concerns related to accounts receivable or collections.

Liabilities. Total liabilities were $14.5 million at December 31, 2003, compared with $15.3 million at December 31, 2002. Accounts payable increased $1.1 million primarily due to a shipment of alprostadil received in mid-December. Accrued liabilities decreased $1.3 million due to recognizing Janssen Pharmacuetica related revenue that was previously deferred pending the outcome of the arbitration and by $905,000 due to a decrease in research and clinical activities during 2003. These decreases were offset slightly by an overall $652,000 increase in the product returns liability due to less product being returned during 2003.

Operating activities. Our operating activities provided $1.9 million of cash during the twelve months ended December 31, 2003 and used $7.6 million of cash during the twelve months ended December 31, 2002. The cash provided in 2003 can be attributed to a $2.1 million decrease in our accounts receivable balance and $2.1 million of non-cash depreciation expense included in our $26,000 net loss, offset by an increase in our inventories due to the purchase of $2.1 million worth of alprostadil. In 2002, operating expenses, particularly research and development expenses, were higher than revenues from product sales accounting for the use of cash.

Investing activities. Net cash used for investing activities was $18.1 million during the twelve months ended December 31, 2003. This related primarily to the investment of the proceeds from our private placement of stock. Net cash provided by investing activities was $7.4 million for the same period in 2002 as we used invested funds to offset cash used in operations.

Financing activities. Financing activities provided cash of $17.1 million and $913,000 during the years ended December 31, 2003 and 2002, respectively. These amounts include the proceeds from the exercise of stock options and the sale of stock under our Employee Stock Purchase Plan in both 2003 and 2002. Additionally, during the second quarter of 2003, VIVUS completed a private placement of 4,375,000 shares of common stock for aggregate net proceeds of $16.4 million. The shares of common stock were sold at $4.00 per share, an approximate 9% discount to the five-day trailing average ended May 21, 2003.

We anticipate that our existing capital resources combined with anticipated future cash flows will be sufficient to support our operating needs for at least the coming year. However, we anticipate that we will be required to obtain additional financing to fund the development of our research and development pipeline in future periods as well as to support the possible launch of any future products. In particular, other substantial payments will be made in accordance with the agreement for licensing from Acrux Ltd. and for licensing the compound avanafil, formerly known as 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;
- 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. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities* and SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity* as well as Staff Accounting Bulletin No. 104, *Revenue Recognition, corrected copy* in 2003. Adoption of these pronouncements did not impact our financial statements.

Overview of Contractual Obligations

Contractual Obligations	Payments Due by Period (in thousands)				
	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Operating Leases (1)	4,074	1,280	2,794	—	—
Purchases (2)	6,120	1,530	3,825	765	—
Other Long Term Liabilities (3)	3,021	—	—	3,021	—
Total	13,215	2,810	6,619	3,786	—

(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. In 2003, the Company purchased $2.1 million of product and is committed to purchase a minimum total of $3.8 million of product from 2004 through 2008.

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

(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 2003 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, 2003 and 2002, 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 all of our investments in cash equivalents and available-for-sale securities are in money market funds that hold short-term investment grade commercial paper, treasury bills or other United States government obligations. Currently, this reduces our exposure to long-term interest rate changes.

Item 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:

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, 2003 and 2002, and the related consolidated statements of operations and other comprehensive (loss), stockholders' equity, and cash flows for the years then ended. In connection with our audits of the consolidated financial statements, we also have audited the 2003 and 2002 financial statement schedule as listed in Item 15(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 audits. The 2001 consolidated financial statements and financial statement schedule of VIVUS, Inc. and subsidiaries were audited by other auditors who have ceased operations. Those auditors expressed an unqualified opinion on those financial statements and financial statement schedule in their report dated January 17, 2002.

We conducted our audits 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 audits provide a reasonable basis for our opinion.

In our opinion, the 2003 and 2002 consolidated financial statements referred to above present fairly, in all material respects, the financial position of VIVUS Inc. and subsidiaries as of December 31, 2003 and 2002, and the results of their operations and their cash flows for the years then ended in conformity with

accounting principles generally accepted in the United States of America. Also in our opinion, the related 2003 and 2002 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 Francisco, California
January 22, 2004

The following is a copy of the audit report previously issued by Arthur Andersen LLP in connection with the Company's filing on Form 10-K for the fiscal year ended December 31, 2001. This audit report has not been reissued by Arthur Andersen LLP.

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

VIVUS, INC.

CONSOLIDATED BALANCE SHEETS
(In thousands, except par value)

ASSETS

	DECEMBER 31, 2003	2002
Current assets:		
Cash and cash equivalents	$ 13,097	$ 12,296
Available-for-sale securities	21,488	11,206
Accounts receivable (net of allowance for doubtful accounts of $68 and $145 at December 31, 2003 and 2002, respectively)	1,588	3,592
Inventories, net	3,109	1,358
Prepaid expenses and other assets	1,108	1,497
Total current assets	40,390	29,949
Property and equipment, net	8,220	10,084
Restricted cash	3,324	3,324
Available-for-sale securities, non-current	13,763	6,324
Total assets	$ 65,697	$ 49,681

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable	$ 2,917	$ 1,866
Accrued and other liabilities	7,374	9,109
Total current liabilities	10,291	10,975
Accrued and other long-term liabilities	4,171	4,321
Total liabilities	14,462	15,296
Stockholders' equity:		
Preferred stock; $1.00 par value; shares authorized— 5,000 at December 31, 2003 and 2002; shares issued and outstanding— 0 at December 31, 2003 and 2002	—	—
Common stock; $.001 par value; shares authorized— 200,000 at December 31, 2003 and 2002; shares issued and outstanding— 37,788 at December 31, 2003 and 32,999 at December 31, 2002	38	33
Additional paid-in capital	152,093	135,005
Accumulated other comprehensive income	64	281
Accumulated deficit	(100,960)	(100,934)
Total stockholders' equity	51,235	34,385
Total liabilities and stockholders' equity	$ 65,697	$ 49,681

See accompanying notes to consolidated financial statements.

VIVUS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND OTHER COMPREHENSIVE (LOSS)

(In thousands, except per share data)

	YEAR ENDED DECEMBER 31		
	2003	2002	2001
Revenue			
United States product	$ 20,768	$ 22,982	$ 20,764
International product	3,452	1,387	4,041
Other revenue	5,033	—	—
Returns provision	(1,815)	(2,020)	(1,204)
Total revenue	27,438	22,349	23,601
Cost of goods sold	10,993	11,207	12,933
Gross profit	16,445	11,142	10,668
Operating expenses:			
Research and development	7,724	13,281	12,324
Selling, general and administrative	9,839	10,556	9,314
Total operating expenses	17,563	23,837	21,638
(Loss) from operations	(1,118)	(12,695)	(10,970)
Interest and other income:			
Interest income	708	1,312	2,092
Gain (loss) on disposal of property and equipment	26	(134)	87
Foreign exchange gain (loss)	39	33	(8)
(Loss) before benefit for income taxes	(345)	(11,484)	(8,799)
Benefit for income taxes	319	918	1,729
Net (loss)	$ (26)	$ (10,566)	$ (7,070)
Other comprehensive (loss):			
Unrealized (loss) gain on securities, net of taxes	(217)	(41)	157
Comprehensive (loss)	$ (243)	$ (10,607)	$ (6,913)
Net (loss) per share:			

Basic	$ (0.00)	$ (0.32)	$ (0.22)
Diluted	$ (0.00)	$ (0.32)	$ (0.22)
Shares used in per share computation:			
Basic	35,884	32,907	32,572
Diluted	35,884	32,907	32,572

See accompanying notes to consolidated financial statements.

VIVUS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amount				
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, net of taxes				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 gain on securities, net of taxes				(41)		(41)
Net (loss)					(10,566)	(10,566)
Balances, December 31, 2002	32,999	33	135,005	281	(100,934)	34,385
Sale of common stock through employee stock purchase plan	108		325			325
Exercise of common stock options for cash	306		312			312
Stock compensation costs			39			39
Proceeds from private placement of common stock	4,375	5	17,500			17,505
Issue costs for private placement of common stock			(1,088)			(1,088)
Change in unrealized gain on securities, net of taxes				(217)		(217)
Net (loss)					(26)	(26)
Balances, December 31, 2003	37,788	38	$152,093	$ 64	$(100,960)	$ 51,235

See accompanying notes to consolidated financial statements.

VIVUS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,		
	2003	2002	2001
Cash flows from operating activities:			
Net (loss)	$ (26)	$(10,566)	$ (7,070)
Adjustments to reconcile net (loss) to net cash provided by (used for) operating activities:			
Provision for doubtful accounts	(77)	(87)	(72)
Depreciation and amortization	2,074	2,288	2,252
Stock compensation costs	39	104	61
(Gain) loss on disposal of property and equipment	(26)	134	(87)
Changes in assets and liabilities:			
Accounts receivable	2,081	(1,191)	1,192
Inventories	(1,751)	1,742	1,945
Prepaid expenses and other assets	389	(717)	363
Accounts payable	1,051	625	(534)

Accrued and other liabilities	(1,885)	72	(3,854)
Net cash provided by (used for) operating activities	1,869	(7,596)	(5,804)
Cash flows from investing activities:			
Property and equipment purchases	(225)	(169)	(336)
Proceeds from sale of property and equipment	41	41	87
Investment purchases	(42,798)	(10,567)	(34,958)
Proceeds from sale/maturity of securities	24,860	18,129	22,680
Net cash (used for) provided by investing activities	(18,122)	7,434	(12,527)
Cash flows from financing activities:			
Sale of common stock through employee stock purchase plan	325	289	320
Exercise of common stock options	312	624	320
Proceeds of issuance of common stock	16,417	—	—
Net cash provided by financing activities	17,054	913	640
Net increase (decrease) in cash and cash equivalents	801	751	(17,691)
Cash and cash equivalents:			
Beginning of year	12,296	11,545	29,236
End of year	$ 13,097	$ 12,296	$ 11,545
Non-cash investing and financing activities:			
Unrealized (loss) gain on securities	$ (217)	$ (41)	$ 157
Supplemental cash flow disclosure:			
Income taxes paid (received)	$ (494)	$ (6)	$ (342)

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 products to restore sexual function 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 and Healthcare products Regulatory Agency, formerly 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, 2003, the Company's accumulated deficit was approximately $101.0 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. On February 20, 2004, VIVUS Ireland was officially dissolved.

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 (losses) gains on investments included in accumulated other comprehensive (loss) income for 2003, 2002 and 2001, in thousands, are $(217), $(41), and $157, 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 and other comprehensive (loss). Available-for-sale securities with original maturities beyond one year from the balance sheet date are classified as non-current.

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, 2003, the remaining inventory reserve balance is $5.6 million. This remaining balance is related to the raw materials inventory that the Company previously estimated would not be used.

Some portion of the fully reserved inventory will now be used in production. In 2003, the Company used $1.2 million 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 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 and other comprehensive (loss) .

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.

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.

Revenue Recognition

The Company recognizes revenue when the following four criteria are met:

- persuasive evidence of an arrangement exists;
- delivery has occurred;
- the sales price is fixed or determinable; and
- collectibility is reasonably assured.

The Company recognizes revenue upon shipment when title passes to the customer and risk of loss is transferred to the customer. The Company does not have any post shipment obligations.

United States

The Company primarily sells its products through the wholesale channel in the United States. The Company provides for discounts, rebates, returns and other adjustments in the same period the related product sales are recorded. Provisions for discounts, rebates, returns and other adjustments are based upon analysis of historical data. Each period the Company reviews its reserves for discounts, rebates, returns and other adjustments based on data available at that time. Any adjustment to these reserves results in changes to the amount of product sales revenue recognized in the period.

International

The Company has supply agreements with Meda AB to market and distribute MUSE® and ACTIS® 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. for the marketing and distribution of MUSE. Sales to our distribution partner, who supplies MUSE in the European marketplace, for the twelve months ended December 31, 2003, 2002 and 2001 were 92.1%, 81.4% and 95.3% of international sales, respectively. The balance of international sales was made to our Canadian distribution partner.

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 its customers. The Company recognizes revenue at the lowest possible price, upon shipment, in accordance with contractual formulas. The Company recognizes additional revenue, if any, upon finalization of pricing with its international distributors. International distributors generally do not have the right to return products unless the products are damaged or defective.

The Company initially recorded $1.5 million of unearned revenue related to an upfront payment in accordance with 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. Through December 31, 2003, $200,000 has been recognized as revenue. As of December 31, 2003, the Company had also recorded deferred revenue of $131,000 representing amounts billed and received in excess of revenue recognized, related to sales to the Company's previous international distributor.

In 2003, we recorded other revenue of $5.0 million due to the resolution of the Company's arbitration claim against Janssen Pharmaceutica with the American Arbitration Association related to payments owing to VIVUS under a previously terminated distribution agreement between the companies. $3.7 million represents amounts due from Janssen Pharmaceutica under the arbitration award. The remaining $1.3 million results from recognizing Janssen Pharmaceutica related revenue that was previously deferred pending the outcome of the arbitration.

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 the net loss if the fair-value-based method has been applied to all outstanding and unvested awards in each period.

	2003	2002	2001
Net (loss), as reported	$ (26)	$ (10,566)	$ (7,070)
Deduct total stock-based employee compensation expense determined under fair-value-based method for all rewards, net of tax	(1,763)	(1,820)	(916)
Pro forma net (loss)	$ (1,789)	$ (12,386)	$ (7,986)
Pro forma net (loss) per share:			
Basic	$ (0.05)	$ (0.38)	$ (0.25)
Diluted	$ (0.05)	$ (0.38)	$ (0.25)

The weighted-average fair value of options granted in 2003, 2002 and 2001 was $2.63, $5.64 and $2.10, 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 2003, 2002 and 2001: no dividend yield, expected volatility of 66%, 75% and 86%, respectively, risk-free interest rates of between 1% to 4%, 2% to 6% and 3% to 5%, 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, 2003, 2002 and 2001 are as follows:

	2003	2002	2001
	(In thousands, except per share data)		
Net (loss)	$ (26)	$(10,566)	$ (7,070)
Net (loss) per share — basic	$ (.00)	$ (.32)	$ (.22)
Effect of dilutive securities (stock options)	—	—	—
Net (loss) per share — diluted	$ (.00)	$ (.32)	$ (.22)
Shares used in the computation of net (loss) per share — basic	35,884	32,907	32,572
Effect of dilutive securities (stock options)	—	—	—
Diluted shares	35,884	32,907	32,572

Potentially dilutive options outstanding of 481,437, 1,153,276 and 589,655 at December 31, 2003, 2002 and 2001, respectively, are excluded from the computation of diluted EPS for 2003, 2002 and 2001 because the effect would have been antidilutive.

Recent Pronouncements

We adopted Statement of Financial Accounting Standards, or SFAS, No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities* and SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity* as well as Staff Accounting Bulletin No. 104, *Revenue Recognition, corrected copy* in 2003. Adoption of these pronouncements did not impact our financial statements.

Note 2. Available-for-Sale Securities

The fair value and the amortized cost of available-for-sale securities at December 31, 2003 and 2002 are presented in the tables that follow. 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.

As of December 31, 2003 (in thousands):

	Amortized Cost	Fair Market Value	Unrealized Holding Gains	Unrealized Holding Losses
United States government securities	$ 25,520	$ 25,587	$ 68	$ (1)
Corporate debt	9,667	9,664	4	(7)
Total	35,187	35,251	72	(8)
Amount classified as short-term	(21,428)	(21,488)	(68)	8
Amount classified as long-term	$ 13,759	$ 13,763	$ 4	$ (0)

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)

Maturity dates for long-term investments range from February 2005 through May 2006.

Note 3. Inventories

Inventories are recorded net of reserves of $5.6 million and $7.2 million as of December 31, 2003 and 2002, respectively, and consist of (in thousands):

	2003	2002
Raw materials	$ 2,370	$ 393
Work in process	81	32
Finished goods	658	933
Inventory, net	$ 3,109	$ 1,358

Inventory balances at December 31, 2003 were $3.1 million as compared to $1.4 million at December 31, 2002. The increase is attributable to the purchase of $2.1 million worth of alprostadil during 2003.

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. Some portion of the fully reserved inventory will now be used in production. In 2003, the Company used $1.2 million 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, 2003 and 2002, respectively, consist of (in thousands):

	2003	2002
Machinery and equipment	$ 18,168	$ 18,144
Computers and software	2,523	2,414
Furniture and fixtures	1,251	1,249
Building improvements	11,941	11,916
	33,883	33,723
Accumulated depreciation	(25,663)	(23,639)
Property and equipment, net	$ 8,220	$ 10,084

For the years ended December 31, 2003, 2002 and 2001, depreciation expense was $2,074, $2,288 and $2,252, respectively.

Note 5. Accrued and Other Liabilities

Accrued and other liabilities as of December 31, 2003 and 2002, respectively, consist of (in thousands):

	2003	2002
Short-term accrued and other liabilities		
Product returns	$ 2,932	$ 2,280
Income taxes	1,216	1,554
Research and clinical expenses	458	1,363
Royalties	629	539
Deferred revenue	281	1,644
Employee compensation and benefits	1,249	1,129
Other	609	600
Total short-term accrued and other liabilities	$ 7,374	$ 9,109

	2003	2002
Long-term accrued and other liabilities		

Restructuring	$ 3,021	$ 3,021
Deferred revenue	1,150	1,300
Total long-term accrued and other liabilities	$ 4,171	$ 4,321

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.

Activity in the restructuring and related reserves accounts in fiscal 2003 and 2002 (in thousands):

	Inventory and Related Commitments	Property and Related Commitments	Total
Balance at December 31, 2001	$ 902	$ 3,021	$ 3,923
Activity in 2002	(902)	—	(902)
Balance at December 31, 2002	0	3,021	3,021
Activity in 2003	—	—	—
Balance at December 31, 2003	$ 0	$ 3,021	$ 3,021

In 2002, the Company paid $100,000 and reversed $508,000 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 $294,000 of the restructuring reserve as a result of settlements of a liability for alprostadil purchase commitments. Accordingly, cost of goods sold was reduced by $802,000 as a result of these reserve reversals.

There was no activity in 2003.

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, 2003 and 2002, there were 37,788,365 and 32,999,167 shares, respectively, issued and outstanding.

Preferred Stock

The Company is authorized to issue 5 million shares of undesignated preferred stock with a par value of $1.00 per share. As of December 31, 2003 and 2002, 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 2001 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, 2003, 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.

Details of option activity under these plans are as follows:

	Number of Shares	Weighted Average Exercise Price
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
Granted	642,526	4.04
Exercised	(306,631)	1.02
Cancelled	(31,344)	4.95
Outstanding, December 31, 2003	3,976,426	$ 4.38

Options Outstanding				Options Exercisable	
Range of Exercise Prices	Number Outstanding at December 31, 2003	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable December 31, 2003	Weighted-Average Exercise Price
$2.00 — $3.88	1,592,620	4.7 years	$3.08	1,453,460	$3.02
$3.94 — $4.50	1,359,815	5.9 years	$4.17	744,411	$4.33
$4.59 — $8.08	1,023,991	6.1 years	$6.67	796,254	$6.33
$2.00 — $8.08	3,976,426	5.5 years	$4.38	2,994,125	$4.23

At December 31, 2003, 3,205,657 options remain available for grant.

During 2003, an option to purchase 15,000 shares of common stock was granted to a research consultant. The fair value of the 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 72%, risk-free interest rate of 2.93% and an expected life of 10 years.

During 2002, an option to purchase 15,000 shares of common stock was granted to a research consultant. The fair value of the 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 expense recognized for options granted to research consultants as discussed above, no compensation cost has been recognized because the exercise price equaled 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.

At the annual meeting held on June 4, 2003, the stockholders approved amendments to the Stock Purchase Plan to (i) extend the original term of the Stock Purchase Plan by an additional 10 years such that the Stock Purchase Plan will now expire in April 2014

(subject to earlier termination as described in the Stock Purchase Plan) and (ii) increase the number of shares of Common Stock reserved for issuance under the Stock Purchase Plan by 600,000 shares to a new total of 1,400,000 (collectively referred to herein as the 1994 Purchase Plan Amendments).

As of December 31, 2003, 716,751 shares have been issued to employees and there are 683,249 available for issuance under the Stock Purchase Plan. During 2003, the weighted average fair market value of shares issued under the Stock Purchase Plan was $3.02 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 through 2003, as the Company has not reached 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 ED. 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 2003, 2002 and 2001, the Company recorded royalty expenses, in thousands, of $952, $978, and $959, respectively, as cost of goods sold based on product sales.

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):

2004	1,280
2005	1,318
2006	1,359
2007	117
	$ 4,074

Rent expense, in thousands, under operating leases totaled $1,252, $1,342, and $1,263 for the years ended December 31, 2003, 2002, 2001, 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. In 2003, the Company purchased $2.1 million of product and is committed to purchase a minimum total of $3.8 million of product from 2004 through 2008.

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

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):

	2003	2002
Deferred tax assets:		
Net operating loss carry forwards	$ 21,164	$ 18,717
Research and development credit carry forwards	5,955	5,649
Inventory reserve	2,166	2,775
Accruals and other	4,048	3,968
Depreciation	706	1,134
	34,039	32,243
Valuation allowance	(34,039)	(32,243)
Total	$ —	$ —

For federal and California income tax reporting purposes, respective net operating loss, or NOL, carry forwards of approximately $60.0 million and $4.4 million are available to reduce further taxable income, if any. For federal and California income tax reporting purposes, respective credit carry forwards of approximately $4.0 million and $3.1 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 2023. The California research and development credits do not expire. 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, 2002 to December 31, 2003 was $1.8 million. As of December 31, 2003 and 2002, 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, 2003, 2002 and 2001:

	2003	2002	2001
(Loss) income before income taxes:			
Domestic	$ (2,188)	$ (6,386)	$ (3,751)
International	1,842	(5,098)	(5,048)
Total	$ (346)	$ (11,484)	$ (8,799)

The (benefit)/provision for income taxes consists of the following components for the years ended December 31, 2003, 2002 and 2001:

	2003	2002	2001
Current			
Federal	$ (311)	$ (842)	$ (1,681)
State	(14)	(85)	(59)
Foreign	6	9	11
Total (benefit)/provision for income taxes	$ (319)	$ (918)	$ (1,729)

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, 2003, 2002 and 2001:

	2003	2002	2001
(Benefit) provision computed at federal statutory rates	(35)%	(35)%	(35)%
State income taxes, net of federal tax effect	(4)	(3)	(3)
Change in valuation allowance	39	30	12
Refund of taxes	(2)	(5)	—
Adjustment of income tax payable	(90)	(3)	(14)
Tax credits	—	(5)	(2)
Loss/(income) not subject to federal and state taxation	—	17	22
Other	—	(4)	—
(Benefit)/provision for income taxes	(92)%	(8)%	(20)%

The 2003 tax benefit was based on an updated estimate of net tax liabilities. 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:

	2003	2002	2001
Customer A	23%	17%	24%
Customer B	21%	30%	19%
Customer C	18%	17%	12%
Customer D	16%	20%	17%
Customer E	11%	0%	0%

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

	2003	2002
Customer A	45%	43%
Customer B	18%	15%
Customer C	15%	14%
Customer D	15%	14%

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 years ended December 31, 2003, 2002 and 2001, in thousands were $241, $246, and $240, respectively. The employer-matching portion of the 401(k) plan began on July 1, 2000.

Note 14. Legal Matters

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

Note 15. Subsequent Event (Unaudited)

In February 2004, the Company entered into exclusive licensing agreements with Acrux, a specialty pharmaceutical company located in Melbourne, Australia under which VIVUS will develop and commercialize Testosterone MDTS® and Estradiol MDTS® in the United States for treatment of low sexual desire and menopausal symptoms, respectively. Under the terms of the agreements, VIVUS will pay to Acrux combined licensing fees of $3.0 million to be paid over the next 17 months, payments up to $4.3 million for achievement of certain clinical development milestones, product approval milestone payments of $6.0 million, and royalties on net sales in the United States upon commercialization of each product.

Note 16. Selected Financial Data (Unaudited)

Selected Quarterly Financial Data

	Quarter Ended,			
	March 31	June 30	September 30	December 31
2003				
Total revenue	$ 4,269	$ 3,648	$ 10,530	$ 8,991
Gross profit	$ 1,485	$ 1,224	$ 7,528	$ 6,208
Net income (loss)	$ (3,191)	$ (2,925)	$ 3,873	$ 2,217
Net income (loss) per share:				
Basic	$ (0.10)	$ (0.08)	$ 0.10	$ 0.06
Diluted	$ (0.10)	$ (0.08)	$ 0.10	$ 0.06
2002				
Total revenue	$ 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)

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	Balance at End of Period
Allowance for Doubtful Accounts				
Fiscal year ended December 31, 2001	304	13	(85)	232
Fiscal year ended December 31, 2002	232	33	(120)	145
Fiscal year ended December 31, 2003	145	(24)	(53)	68
Inventory Reserve				
Fiscal year ended December 31, 2001	7,742	252	(510)	7,484
Fiscal year ended December 31, 2002	7,484	192	(455)(1)	7,221
Fiscal year ended December 31, 2003	7,221	56	(1,724)(2)	5,553
Product Returns				
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
Fiscal year ended December 31, 2003	2,280	1,815	(1,163)	2,932

(1) The Company used $163,000 of its fully reserved raw materials inventory in production 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.

(2) The Company used $1.2 million of its fully reserved raw materials inventory in production 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.

Item 9A. 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.

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 2004 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 referred to in Item 10 above.

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

The information required by this item is incorporated by reference from the information under the caption "Security Ownership of Certain Beneficial Owners and Management" in the Company's Proxy Statement referred to in Item 10 above.

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 referred to in Item 10 above.

Item 14. ***Principal Accounting Fees and Services***

The information required by this item is incorporated by reference from the information under the caption "Principal Accounting Fees and Services" in the Company's Proxy Statement referred to in Item 10 above.

PART IV

Item 15. ***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

2. Financial Statement Schedules

The following financial statement schedule of VIVUS, Inc. as set forth on page 48 is filed as part of this 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.

(B) Reports on Form 8-K

On October 22, 2003, we furnished a current report on Form 8-K that disclosed our financial results for the third quarter ended September 30, 2003 and certain other information. The Form 8-K included our unaudited financial statements for the third quarter ended September 30, 2003.

On October 28, 2003, we filed a current report on Form 8-K that announced the resolution of our arbitration claim against Janssen Pharmaceutica International with the American Arbitration Association related to payments owing to the Company under a previously terminated distribution agreement between the companies and revised financial statements for the third quarter ended September 30, 2003 based on the resolution of the arbitration.

(C). Exhibits

Exhibit Number	Description
3.2(4)	Amended and Restated Certificate of Incorporation of the Company
3.3(3)	Bylaws of the Registrant, as amended
3.4(5)	Certificate of Designations of Rights, Preferences and Privileges of Series A Participating Preferred Stock
4.1(4)	Specimen Common Stock Certificate of the Registrant
4.5(5)	Second Amended and Restated Preferred Shares Rights Agreement, dated as of April 15, 1997 by and between the Registrant and Harris Trust Company of California, including the Certificate of Determination, the form of Rights Certificate and the Summary of Rights attached thereto as Exhibits A, B, and C, respectively
10.1(1)+	Assignment Agreement by and between Alza Corporation and the Registrant dated December 31, 1993
10.2(1)+	Memorandum of Understanding by and between Ortho Pharmaceutical Corporation and the Registrant dated February 25, 1992
10.3(1)+	Assignment Agreement by and between Ortho Pharmaceutical Corporation and the Registrant dated June 9, 1992
10.4(1)+	License Agreement by and between Gene A. Voss, MD, Allen C. Eichler, MD, and the Registrant dated December 28, 1992
10.5A(1)+	License Agreement by and between Ortho Pharmaceutical Corporation and Kjell Holmquist AB dated June 23, 1989
10.5B(1)+	Amendment by and between Kjell Holmquist AB and the Registrant dated July 3, 1992
10.5C(1)	Amendment by and between Kjell Holmquist AB and the Registrant dated April 22, 1992
10.5D(1)+	Stock Purchase Agreement by and between Kjell Holmquist AB and the Registrant dated April 22, 1992

10.6A(1)+	License Agreement by and between Amsu, Ltd., and Ortho Pharmaceutical Corporation dated June 23, 1989
10.6B(1)+	Amendment by and between Amsu, Ltd., and the Registrant dated July 3, 1992
10.6C(1)	Amendment by and between Amsu, Ltd., and the Registrant dated April 22, 1992
10.6D(1)+	Stock Purchase Agreement by and between Amsu, Ltd., and the Registrant dated July 10, 1992
10.11(3)	Form of Indemnification Agreements by and among the Registrant and the Directors and Officers of the Registrant
10.12(2)	1991 Incentive Stock Plan and Form of Agreement, as amended
10.13(1)	1994 Director Option Plan and Form of Agreement
10.14(1)	Form of 1994 Employee Stock Purchase Plan and Form of Subscription Agreement
10.17(1)	Letter Agreement between the Registrant and Leland F. Wilson dated June 14, 1991 concerning severance pay
10.28(4)	Lease Agreement made as of January 1, 1997 between the Registrant and Airport Associates
10.29(4)	Lease Amendment No. 1 as of February 15, 1997 between Registrant and Airport Associates
10.29A(6)	Lease Amendment No. 2 dated July 24, 1997 by and between the Registrant and Airport Associates
10.29B(6)	Lease Amendment No. 3 dated July 24, 1997 by and between the Registrant and Airport Associates
10.36(7)	Form of, “Change of Control Agreements,” dated July 8, 1998 by and between the Registrant and certain Executive Officers of the Company.
10.39(8)	Sublease agreement between KVO Public Relations, Inc. and the Registrant dated December 21, 1999
10.41(9)+	License and Supply Agreement made as of November 20, 2000 between the Registrant and Paladin Labs, Inc.
10.42(9)+	Development, License and Supply Agreement made as of January 22, 2001 between the Registrant and TANABE SEIYAKU CO., LTD.
10.43(10)+	Settlement and Modification Agreement made as of July 12, 2001 between ASIVI, LLC, AndroSolutions, Inc. Gary W. Neal and the Registrant.
10.44(11)	2001 Stock Option Plan and Form of Agreement
10.45(12)+	Supply Agreement made as of September 3, 2002 between the Registrant and Meda AB.
10.46(13)+	Amendment Three, dated November 21, 2002 by and between VIVUS, Inc. and CHINOIN Pharmaceutical and Chemical Works, Ltd.

Exhibit Number	**Description**
10.47(13)	Lease Amendment No. 4 and Settlement Agreement dated October 25, 2000 by and between the Registrant and Airport Associates
10.48(13)+	Exclusive Distribution Agreement dated October 1, 2002 between the Registrant and Cord Logistics
10.49(13)+	Distribution and Supply Agreement made as of February 18, 2003 between the Registrant and Meda AB.
21.2	List of Subsidiaries
23.1	Consent of Independent Public Accountants
31.1	Certification of Chief Executive Officer, dated March 9, 2004, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer, dated March 9, 2004, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended.
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 18 U.S.C. 1350, as adopted

pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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† Confidential treatment granted.

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

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

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

(4) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1996, as amended.

(5) Incorporated by reference to exhibit 99.1 filed with Registrant's Amendment Number 2 to the Registration Statement of Form 8-A (File No. 0-23490) filed with the Commission on April 23, 1997.

(6) Incorporated by reference to the same numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1997.

(7) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1998.

(8) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1999.

(9) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 2000.

(10) Incorporated by reference to the same numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.

(11) Incorporated by reference to the same numbered exhibit filed with the Registrant's Registration Statement on Form S-8 filed with the Commission on November 15, 2001.

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

(13) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002.

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/ LARRY J. STRAUSS

Larry J. Strauss
Vice President of Finance and
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: March 9, 2004

VIVUS, INC.

INDEX TO EXHIBITS*

EXHIBIT	DESCRIPTION
21.2	List of Subsidiaries
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32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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 Larry J. Strauss 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
/s/ LELAND F. WILSON Leland F. Wilson	President, Chief Executive Officer (Principal Executive Officer) and Director	March 9, 2004
/s/ VIRGIL A. PLACE Virgil A. Place	Chairman of the Board and Chief Scientific Officer and Director	March 9, 2004
/s/ LARRY J. STRAUSS Larry J. Strauss	Vice President of Finance and Chief Financial Officer (Principal Financial and Accounting Officer)	March 9, 2004
/s/ GRAHAM STRACHAN Graham Strachan	Director	March 9, 2004
/s/ MARIO M. ROSATI Mario M. Rosati	Director	March 9, 2004
/s/ MARK B. LOGAN Mark B. Logan	Director	March 9, 2004
/s/ LINDA M. DAIRIKI SHORTLIFFE, M.D. Linda M. Dairiki Shortliffe, M.D.	Director	March 9, 2004

VIVUS, INC.

REPORT ON FORM 10-K FOR
THE YEAR ENDED DECEMBER 31, 2003

INDEX TO EXHIBITS

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10.1(1)+	Assignment Agreement by and between Alza Corporation and the Registrant dated December 31, 1993
10.2(1)+	Memorandum of Understanding by and between Ortho Pharmaceutical Corporation and the Registrant dated February 25, 1992
10.3(1)+	Assignment Agreement by and between Ortho Pharmaceutical Corporation and the Registrant dated June 9, 1992
10.4(1)+	License Agreement by and between Gene A. Voss, MD, Allen C. Eichler, MD, and the Registrant dated December 28, 1992
10.5A(1)+	License Agreement by and between Ortho Pharmaceutical Corporation and Kjell Holmquist AB dated June 23, 1989
10.5B(1)+	Amendment by and between Kjell Holmquist AB and the Registrant dated July 3, 1992
10.5C(1)	Amendment by and between Kjell Holmquist AB and the Registrant dated April 22, 1992
10.5D(1)+	Stock Purchase Agreement by and between Kjell Holmquist AB and the Registrant dated April 22, 1992
10.6A(1)+	License Agreement by and between Amsu, Ltd., and Ortho Pharmaceutical Corporation dated June 23, 1989
10.6B(1)+	Amendment by and between Amsu, Ltd., and the Registrant dated July 3, 1992
10.6C(1)	Amendment by and between Amsu, Ltd., and the Registrant dated April 22, 1992
10.6D(1)+	Stock Purchase Agreement by and between Amsu, Ltd., and the Registrant dated July 10, 1992
10.11(3)	Form of Indemnification Agreements by and among the Registrant and the Directors and Officers of the Registrant
10.12(2)	1991 Incentive Stock Plan and Form of Agreement, as amended
10.13(1)	1994 Director Option Plan and Form of Agreement
10.14(1)	Form of 1994 Employee Stock Purchase Plan and Form of Subscription Agreement
10.17(1)	Letter Agreement between the Registrant and Leland F. Wilson dated June 14, 1991 concerning severance pay
10.28(4)	Lease Agreement made as of January 1, 1997 between the Registrant and Airport Associates
10.29(4)	Lease Amendment No. 1 as of February 15, 1997 between Registrant and Airport Associates
10.29A(6)	Lease Amendment No. 2 dated July 24, 1997 by and between the Registrant and Airport Associates
10.29B(6)	Lease Amendment No. 3 dated July 24, 1997 by and between the Registrant and Airport Associates
10.36(7)	Form of, “Change of Control Agreements,” dated July 8, 1998 by and between the Registrant and certain Executive Officers of the Company.
10.39(8)	Sublease agreement between KVO Public Relations, Inc. and the Registrant dated December 21, 1999
10.41(9)+	License and Supply Agreement made as of November 20, 2000 between the Registrant and Paladin Labs, Inc.
10.42(9)+	Development, License and Supply Agreement made as of January 22, 2001 between the Registrant and TANABE SEIYAKU CO., LTD.

Exhibit Number	Description
10.43(10)+	Settlement and Modification Agreement made as of July 12, 2001 between ASIVI, LLC, AndroSolutions, Inc. Gary W. Neal and the Registrant.
10.44(11)	2001 Stock Option Plan and Form of Agreement
10.45(12)+	Supply Agreement made as of September 3, 2002 between the Registrant and Meda AB.
10.46(13)+	Amendment Three, dated November 21, 2002 by and between VIVUS, Inc. and CHINOIN Pharmaceutical and Chemical Works, Ltd.
10.47(13)	Lease Amendment No. 4 and Settlement Agreement dated October 25, 2000 by and between the Registrant and Airport Associates
10.48(13)+	Exclusive Distribution Agreement dated October 1, 2002 between the Registrant and Cord Logistics
10.49(13)+	Distribution and Supply Agreement made as of February 18, 2003 between the Registrant and Meda AB.
21.2	List of Subsidiaries
23.1	Consent of Independent Public Accountants

† Confidential treatment granted.

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

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

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

(4) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1996, as amended.

(5) Incorporated by reference to exhibit 99.1 filed with Registrant's Amendment Number 2 to the Registration Statement of Form 8-A (File No. 0-23490) filed with the Commission on April 23, 1997.

(6) Incorporated by reference to the same numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1997.

(7) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1998.

(8) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1998.

(9) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1999.

(10) Incorporated by reference to the same numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 2000.

(11) Incorporated by reference to the same numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.

(12) 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.

(13) 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.

(14) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002.

EXHIBIT 21.2

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

EXHIBIT 23.1

Consent of KPMG LLP, Independent Auditors

We consent to the incorporation by reference in (i) the Registration Statements on Form S-8 (Files Nos. 000-23490, 333-06486, 333-29934, 333-57374, 333-73394, 333-104287, and 333-107006) and (ii) the Registration Statement on Form S-3 (File No. 333-105985) of VIVUS, Inc., of our report dated January 22, 2004 with respect to the consolidated balance sheets of VIVUS, Inc. and subsidiaries as of December 31, 2003 and 2002, and the related consolidated statements of operations and other comprehensive (loss), stockholder's equity and cash flows for the years then ended, which report appears in the December 31, 2003 Annual Report on Form 10-K of VIVUS, Inc..

/S/ KPMG LLP

San Jose, California

March 9, 2004

EXHIBIT 31.1

CERTIFICATION

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 report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 9, 2004

By: /s/ LELAND F. WILSON

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

EXHIBIT 31.2

CERTIFICATION

I, Larry J. Strauss, certify that:

1. I have reviewed this annual report on Form 10-K of VIVUS, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 9, 2004

By: /s/ LARRY J. STRAUSS

Name: Larry J. Strauss
Title: Vice President and Chief Financial Officer

EXHIBIT 32

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Leland F. Wilson, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of VIVUS, Inc. on Form 10-K for the period ending December 31, 2003 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-Q fairly presents in all material respects the financial condition and results of operations of VIVUS, Inc.

March 9, 2004

By: /s/ Leland F. Wilson

Leland F. Wilson
President and Chief Executive Officer

I, Larry J. Strauss, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of VIVUS, Inc. on Form 10-K for the period ending December 31, 2003 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-Q fairly presents in all material respects the financial condition and results of operations of VIVUS, Inc.

March 9, 2004

By: /s/ Larry J. Strauss

Larry J. Strauss
Vice President and Chief Financial Officer