SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended
December 31, 2001

Commission File Number
0-23490

VIVUS, INC.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

94-3136179
(IRS employer identification number)

1172 Castro Street, Mountain View, California 94040

(Address of principal executive offices and zip code)

(650) 934-5200

(Registrant's telephone number, including area code)

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

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, $.001 Par Value

Preferred Share Purchase Rights

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [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. [X]

As of February 21, 2002, the aggregate market value of the voting stock held by non-affiliates of the Registrant was $235,977,943 (based upon the closing sales price of such stock as reported by The Nasdaq Stock Market on such date). Shares of Common Stock held by each officer, director, and holder of 5 percent or more of the outstanding Common Stock on that date have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 21, 2002, the number of outstanding shares of the Registrant's Common Stock was 32,820,298.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required by Items 10, 11, 12 and 13 of Part III of this report on Form 10-K is incorporated by reference from the Registrant's proxy statement for the 2002 Annual Stockholders' Meeting (the "Proxy Statement"), which will be filed with the Securities and Exchange Commission within 120 days after the close of the Registrant's fiscal year ended December 31, 2001.

TABLE OF CONTENTS

VIVUS, INC.

FISCAL 2001 FORM 10-K

INDEX

This Form 10-K contains "forward-looking" statements about future financial results, future products and other events that have not yet occurred. For example, statements like we "expect," we "anticipate" or we "believe" are forward-looking statements. Investors should be aware that actual results may differ materially from our expressed expectations because of risks and uncertainties about the future. We will not necessarily update the information in this Form 10-K if any forward-looking statement later turns out to be inaccurate. Details about risks affecting various aspects of our business are discussed throughout this Form 10-K. Investors should read all of these risks carefully, and should pay particular attention to risks affecting the following areas: new product development and uncertainty of product approvals (pages 9 and 10); clinical trial testing (page 10); intense competition (pages 10 and 11); patent positions (pages 11 and 12); future capital needs and uncertainty of additional financing (page 12); raw materials and dependence on third parties (pages 12 and 13); single manufacturing facility (page 13); and other risk factors as stated (pages 13 through 17).

PART I

Item 1. *Business*

Company Overview

VIVUS, Inc. ("VIVUS," also referred to herein as "we," "us" and "our") is a pharmaceutical company developing innovative products to improve quality of life disorders in men and women, with a focus on sexual dysfunction. We are a Delaware corporation that was organized in 1991. We developed and market in the United States ("U.S.") MUSE® (alprostadil) and ACTIS®, two innovations in the treatment of erectile dysfunction ("ED"). We have entered into a license and supply agreement with Abbott Laboratories ("Abbott") (NYSE:ABT) for the international marketing and distribution of our male transurethral ED products. In Canada, we have entered into a license and supply agreement with Paladin Labs, Inc. ("Paladin") (TSE:PLB) for the marketing and distribution of MUSE. We have ongoing research and development ("R&D") programs, including projects in ED, female sexual dysfunction ("FSD"), and premature ejaculation ("PE").

VIVUS Strategy

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

Targeted Research and Development (R&D) Efforts

We will exploit our expertise and patent portfolio by focusing our R&D activities on sexual dysfunction, PE and other urologic disorders.

Focus on Development

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

Maintain Proprietary Technology

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

Marketing and Distribution Strategy

In the U.S., VIVUS markets MUSE through our own dedicated urology sales force. We have entered into a license and supply agreement with Abbott to market and distribute MUSE internationally. In addition, Abbott has the option to co-develop and license any future transurethral products we may develop for the treatment of ED. In Canada, we have entered into a distribution and supply agreement with Paladin to market and distribute MUSE. We will continue to evaluate distribution, marketing, licensing and other opportunities for our products, as well as out-licensing rights related to products in our pipeline to third parties.

2001 Highlights

First Quarter 2001

VIVUS signed a development, license and supply agreement with TANABE SEIYAKU CO., LTD. ("Tanabe"), a leading Japanese pharmaceutical company, for its proprietary phosphodiesterase type 5 (PDE5) inhibitor TA-1790. Under the terms of this agreement, we acquired worldwide rights, except Japan, China and certain Pacific Rim countries, to develop and commercialize TA-1790 for the oral and local treatments of male and female sexual dysfunction.

We reported a net loss of $4.9 million, for a $0.15 net loss per share. These results included up-front, non-refundable milestone payments totaling $5 million to Tanabe for licensing TA-1790.

We initiated a Phase II multi-center, double blind, placebo controlled clinical trial for our FSD product, ALISTA™, for female sexual arousal disorder ("FSAD").

Second quarter 2001

We reported a net loss of $914 thousand, for a $0.03 net loss per share. Increased spending for R&D and lower U.S. product revenue contributed to the loss.

VIVUS was awarded a new patent by the U.S. Patent & Trademark Office. This patent strengthens our proprietary protection in the field of PE, allowing for broad treatment claims for PE by administration of 5-HT4 agonists, alone or in combination with other agents.

We reported results from our Phase I safety study for ALISTA, which showed that a single dose of ALISTA topically applied in healthy volunteers was well tolerated both locally and systemically.

Third Quarter 2001

We reported a net loss of $1.1 million, for a $0.03 net loss per share. Contributing to the loss were increased R&D expenses partially offset by an income tax benefit.

We completed patient dosing in a Phase II study of ALISTA. The study was conducted to evaluate the safety and efficacy of topically applied ALISTA in subjects with FSAD. We also began the manufacture of clinical supplies and clinical site selection for our next Phase II/III ALISTA study, a multi-center, double-blind, placebo-controlled evaluation of topical alprostadil administered at home for the treatment of women with FSAD.

VIVUS was awarded a new patent by the U.S. Patent & Trademark Office in the area of FSD.

Fourth Quarter 2001

We reported a net loss of $150 thousand, for a $0.0 net loss per share. Increased R&D expenses were offset by an income tax benefit.

We successfully filed an Investigational New Drug ("IND") application with the U.S. Food & Drug Administration ("FDA") in December to initiate a clinical study to evaluate the erectile response to oral TA-1790 in men with ED.

We announced positive results from a Phase II trial evaluating ALISTA for the treatment of FSAD.

We were awarded a new patent by the U.S. Patent & Trademark Office covering the use of nitrovasodilators, either alone or in combination with other pharmacologic agents, for the treatment of FSD.

VIVUS announced the appointment of Carol Zoltowski, V.M.D. to the position of Vice President, Regulatory Affairs. Dr. Zoltowski brings over 11 years of experience in the pharmaceutical and biopharmaceutical industry to VIVUS and has coordinated regulatory filings for a variety of different drug candidates. Most recently, Dr. Zoltowski was Senior Director and Head, Regulatory Affairs at Shaman Pharmaceuticals, as well as acting Head of Quality Assurance.

Additional studies would have been required to meet European combination drug approval requirements. As a result, we withdrew the European marketing authorization application for ALIBRA®, our second-generation product for the treatment of ED, which was originally submitted to the European Agency for Medicinal Products ("EMEA") in May 2000.

Research and Development

In recent years we have invested in a number of R&D projects. The current status of certain R&D projects is depicted in the chart below.

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

Our R&D expenses for the years ended December 31, 2001, 2000 and 1999, in thousands, were $12,324, $4,670, and $7,884, respectively. We anticipate that our R&D expenses will continue to increase as we focus our efforts on clinical development of our current R&D pipeline, targeted acquisitions of new technologies and the development of patentable uses of known pharmacologic agents for which significant safety data already exists.

Recent progress and current plans in our R&D projects include:

- **ALISTA** - A proprietary formulation of alprostadil applied locally to the female genitalia to treat FSAD.

  —Our first Phase II clinical study, which was an in-clinic, multi-center trial designed to evaluate the safety of and response to ALISTA in subjects with FSAD, was completed. The study demonstrated a significant increase versus placebo and baseline in sexual response associated with visual sexual stimulation in women with FSAD. ALISTA was associated with a rapid and sustained improvement in sexual response.

  —Our expanded Phase II/III study, which is a trial designed to evaluate the efficacy and safety of ALISTA when used by women at home with their partner, is scheduled to begin in the first quarter of 2002.

- **TA-1790** - A relatively fast-acting, highly selective, potent phosphodiesterase type 5 (PDE5) inhibitor for the oral and local treatments of ED and FSD.

  —We successfully filed an IND with the FDA in December 2001 to initiate a clinical study to evaluate the safety and erectile response to oral TA-1790 in men with ED. This trial is scheduled to begin in the first quarter of 2002.

  —We began pre-clinical development work on the local administration of TA-1790, alone and in combination with alprostadil, for the treatment of ED. Our goal for the local administration of TA-1790 is to provide an effective therapy for patients who do not have success with oral treatments.

- **VI-0134** — An on demand, oral treatment for PE.

  —During the fourth quarter of 2001, we initiated a clinical trial to evaluate the pharmacokinetics (blood levels in relation to time) with our new oral formulation of VI-0134.

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 U.S., patents and patent applications licensed to and developed by VIVUS currently include 22 in ED, 16 in FSD and 7 in PE.

Clinical Studies

Clinical trial activity at VIVUS is currently focused on the development of ALISTA for the treatment of FSAD, the development of TA-1790 for the treatment of male ED, and the evaluation of VI-0134 for the treatment of PE.

During the third quarter of 2001, we completed a double blind, placebo-controlled, multi-center study to evaluate the safety and efficacy of ALISTA in women with FSAD. The study demonstrated a significant increase versus placebo and baseline in sexual response associated with visual sexual stimulation in women with FSAD. ALISTA was associated with a rapid and sustained improvement in sexual response. Results from these studies provided data that enabled us to design and initiate a larger-scale Phase II/III study required to obtain regulatory approval for this product. This study is scheduled to begin in the first quarter of 2002.

VIVUS has licensed from Tanabe TA-1790 for the oral and local treatment of sexual dysfunction in men and women. Tanabe conducted an initial Phase I study evaluating the safety of TA-1790 in normal subjects. In this study, healthy male volunteers received increasing single doses of TA-1790. We plan to begin additional clinical studies in the first quarter of 2002 to evaluate the safety and efficacy of this compound as an on-demand oral therapy for the treatment of male ED. In addition, TA-1790 will be evaluated for its potential for use as a transurethral therapy for ED either alone or in combination with other vasodilators, and as an oral and topical treatment for FSD.

In a proof-of-concept study previously completed, the effect of on-demand therapy with several classes of compounds for the treatment of PE was evaluated. This study demonstrated statistically significant effects on ejaculatory latency, and additional formulation work to optimize the drug product for this indication is ongoing. A clinical trial to evaluate the pharmacokinetics (blood levels in relation to time) with the new oral formulation of VI-0134 was initiated during the fourth quarter of 2001.

Sales and Marketing

Domestic

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

International

VIVUS signed an international distribution and marketing agreement with Abbott in June 2000. Abbott purchases MUSE from us for resale in all markets except the U.S. and Canada. To date, Abbott distributes MUSE in over 19 countries including the United Kingdom, Germany, France, Switzerland and Sweden.

In November of 2000, VIVUS granted Paladin the exclusive rights to distribute and market MUSE in Canada. Initial shipments of MUSE were made to Paladin in the first quarter 2001.

VIVUS' Transurethral System for Erection

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

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

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

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

Advantages of Transurethral Therapy

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

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

Ease of Administration. Our transurethral system for erection is easy to use with minimal instruction, unlike needle injection therapy that requires precise injection into the penis.

Minimally-invasive. Our transurethral system for erection utilizes urethral delivery, permitting topical application to the urethral lining.

Discreet. Our transurethral system for erection utilizes a small, single-use disposable applicator that can be discreetly applied and is easily integrated into the normal sexual life of the patient. Administration takes less than a minute.

Quality of Erection. Our transurethral system for erection therapy mimics the normal vasoactive process, producing an erection that is more natural than those resulting from needle injection therapy, vacuum constriction devices or penile implants.

Current Therapies

In addition to MUSE, the primary physiological therapies currently utilized for the treatment of ED include:

Oral Medications. In 1998, Pfizer Inc. received clearance from the FDA to market its oral treatment for ED, Viagra®. Commercial introduction of this new competitive product adversely affected VIVUS' business, financial condition and results of operations. Currently, Viagra accounts for over 91% of prescriptions for pharmaceutical products to treat ED. Yohimbine is another oral medication currently prescribed in the U.S. for the treatment of ED. Other large pharmaceutical companies are also actively engaged in the development of therapies for the treatment of ED.

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

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

Penile Implants. This therapy involves the surgical implantation of a semi-rigid, rigid or inflatable device into the penile structure to mechanically simulate an erection. In addition to the risks associated with surgical procedures, there is a significant rate of

complication with implants such as infection and mechanical failure of the device. This may necessitate a second surgical procedure to remove or reposition the device. In addition, due to the scarring associated with the implant procedure, the patient may no longer be a viable candidate for less radical therapies.

Manufacturing

VIVUS leases 90,000 square feet of space in Lakewood, New Jersey for its manufacturing operation, which includes formulation, filling, packaging, analytical laboratories, storage, distribution and administrative offices. The FDA and the Medicines Control Agency ("MCA") 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 U.S. 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 FDA and equivalent foreign regulatory agencies. The process of obtaining FDA and other required regulatory approvals is lengthy and expensive. In November 1996, VIVUS received final marketing clearance from the FDA for MUSE. In November 1997, we obtained regulatory marketing clearance by the MCA to market MUSE in the United Kingdom. MUSE has also been approved in more than 40 countries around the globe.

After regulatory approval is obtained, our products are subject to continual review. We submitted marketing applications for our second-generation product, ALIBRA, to the FDA in December 1999 and to the EMEA in May 2000. In October 2000, we withdrew our application from the FDA. VIVUS has met with the FDA to determine what additional data is required to obtain marketing clearance for ALIBRA in the U.S. We met with the Committee for Proprietary Medicine Products ("CPMP") in the fourth quarter of 2001 to discuss our European application. Additional studies would have been required to meet European combination drug approval requirements. As a result, we have withdrawn our European application from further consideration. There can be no assurance, however, that we will be successful in obtaining approvals for ALIBRA in the U.S.

Segments and Geographic Area Information

We primarily sell our products through the wholesale channel in the U.S. International sales are made only to our international distributors. We have entered into a license and supply agreement with Abbott for the international marketing and distribution of our male transurethal ED products. In Canada, we have entered into a license and supply agreement with Paladin for the marketing and distribution of MUSE. In 1999, MUSE was distributed internationally through license and supply agreements with AstraZeneca and Janssen Pharmaceutica International ("Janssen"). You can find this financial information in our Consolidated Statements of Operations and Other Comprehensive Income on page 27 and in the Notes to Consolidated Financial Statements, Note 1, "Business and Significant Accounting Policies — Revenue Recognition" on pages 31 and 32.

All transactions are denominated in U.S. dollars and we operate in a single segment reporting to the chief executive officer, based on the criteria of Statement of Financial Accounting Standards ("SFAS") No. 131, "Disclosures about Segments of an Enterprise and Related Information."

All material long-lived assets are located in the U.S.

Employees

As of February 21, 2002, VIVUS employed 124 persons. Of these employees, 87 are located at the manufacturing facility in Lakewood, New Jersey; and 37 are located at our corporate headquarters in Mountain View, California and other U.S. 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.

This Form 10-K contains "forward-looking" statements about future financial results, future products and other events that have not yet occurred. For example, statements like we "expect," we "anticipate" or we "believe" are forward-looking statements. Investors should be aware that actual results may differ materially from our expressed expectations because of risks and uncertainties about the future. We will not necessarily update the information in this Form 10-K if any forward-looking statement later turns out to be inaccurate. Details about risks affecting various aspects of our business are discussed throughout this Form 10-K. Investors should read all of these risks carefully, and should pay particular attention to risks affecting the following areas: new product development and uncertainty of product approvals (pages 9 and 10); clinical trial testing (page 10); intense competition (pages 10 and 11); patent positions (pages 11 and 12); future capital needs and uncertainty of additional financing (page 12); raw materials and dependence on third parties (pages 12 and 13); single manufacturing facility (page 13); and other risk factors as stated (pages 13 through 17).

RISK FACTORS

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 FDA 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 FDA can suspend clinical studies at any time if the agency believes that the subjects participating in such studies are being exposed to unacceptable health risks.

We cannot predict with certainty if or when we might submit for regulatory review those products currently under development. Once we submit our potential products for review, we cannot assure you that the FDA 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 FDA and international regulatory authorities approve a product, we must manufacture sufficient volumes to meet market demand. This is a process that requires accurate forecasting of market demand. There is no guarantee that there will be market demand for any future products or that we will be able to successfully manufacture or adequately support sales of any future products.

We are developing TA-1790 for the potential oral and local treatment of male and female sexual dysfunction. In January 2001, we licensed TA-1790, a proprietary phosphodiesterase type 5 (PDE5) inhibitor compound from Tanabe, a Japanese pharmaceutical company. Tanabe completed a Phase I clinical trial evaluating the safety of orally administered TA-1790 for male erectile dysfunction. We intend to initiate additional pre-clinical studies, and if promising results are observed, we intend to initiate clinical studies that would be required to obtain regulatory approval of TA-1790 for the treatment of sexual dysfunction. However, there are no guarantees that TA-1790 will prove to be safe and effective or receive regulatory approval for any indication. Further, even if we were to receive regulatory approval for a product, there could be no assurance that such a product would prove to be commercially successful or profitable.

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

We are developing VI-0134 for the potential treatment of premature ejaculation. We have completed certain pre-clinical and clinical trials and recently initiated a clinical trial to evaluate the pharmacokinetics (blood levels in relation to time) of VI-0134, our

re-formulated oral, on-demand treatment for premature ejaculation. However, there can be no assurance that this trial or future clinical studies, if performed, will be successful or that a product for the treatment of premature ejaculation, if approved, will prove to be commercially successful.

In December 1999, we submitted a New Drug Application ("NDA") to the FDA to market ALIBRA, which we subsequently withdrew in October 2000. We met with the FDA in December 2000 and continue to communicate with the agency to determine what additional data is required to obtain marketing clearance for ALIBRA. There can be no assurance that we will re-file an NDA for ALIBRA. Even if we re-file an NDA for ALIBRA, there can be no assurance that it will be approved or that ALIBRA will be successful in the marketplace.

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 and effective for human use, our business will suffer.

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

- ineffectiveness of the study compound, or perceptions by physicians that the compound is not effective for a particular indication;
- inability to manufacture sufficient quantities of compounds for use in clinical trials;
- failure of the FDA 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 FDA or physicians, our business, financial condition and results of operations will be harmed.

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

Competition in the pharmaceutical and medical products industries is intense and is characterized by extensive research efforts and rapid technological progress. Certain treatments for erectile dysfunction exist, such as oral medications, needle injection therapy, vacuum constriction devices and penile implants, and the manufacturers of these products will continue to improve these therapies. The most significant competitive therapy is an oral medication marketed by Pfizer under the name Viagra, which received regulatory approvals in the United States in March 1998 and in the European Union in September 1998. The commercial launch of Viagra in the United States in April 1998 significantly decreased demand for MUSE.

Additional competitive products in the erectile dysfunction market include needle injection therapy products from Pharmacia Upjohn and Schwartz Pharma, which were approved by the FDA in July 1995 and June 1997, respectively. Other large pharmaceutical companies are also actively engaged in the development of therapies for the treatment of erectile dysfunction. These companies have substantially greater research and development capabilities as well as substantially greater marketing, financial and human resources

abilities than VIVUS. In addition, many of these companies have significantly greater experience than us in undertaking pre-clinical testing, human clinical trials and other regulatory approval procedures. Both Lilly ICOS LLC and Bayer AG filed NDA's with the FDA in June and September 2001, respectively, for their oral erectile dysfunction medications. These entities may market commercial products either on their own or through collaborative efforts, such as Bayer AG, which has signed a worldwide co-promotion agreement with GlaxoSmithKline plc for its product. 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.

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

VIVUS holds various patents and patent applications in three major areas of sexual dysfunction: male erectile dysfunction, female sexual dysfunction and premature ejaculation. We are the exclusive licensee of United States and Canadian patents originally filed in the name of Dr. Gene Voss. These patents claim methods of treating erectile dysfunction with a vasodilator-containing ointment that is administered either topically or 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, Spain, Sweden and South Africa. Patent applications are pending in Denmark and Romania. The foreign patents and applications, like the United States patents, are directed to the treatment of erectile dysfunction by transurethral administration of certain active substances including alpha-receptor blockers, vasoactive polypeptides, prostaglandins or nitroglycerin dispersed in a hydrophilic vehicle.

VIVUS' license and assignment agreements for these 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 the ALZA Corporation ("ALZA"), 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, Mexico, New Zealand, Norway, Portugal, South Africa and South Korea, and foreign applications are pending in Canada and Japan.

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

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

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

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

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

Capital resources from operating activities are expected to decline over the next several quarters as the result of increased spending for research and development projects, including clinical trials. We expect that our existing capital resources combined with future cash flows will be sufficient to support operating needs throughout the next twelve to twenty-four months. Financing in future periods will most likely be required to fund development of our research and development pipeline and the possible launch of any future products. Our future capital requirements will depend upon numerous factors, including: (i) the progress of our research and development programs; (ii) the scope, timing and results of pre-clinical testing and clinical trials; (iii) the results of operations; (iv) the cost, timing and outcome of regulatory reviews; (v) the rate of technological advances; (vi) ongoing determinations of the potential commercial success of our products under development; (vii) the level of resources devoted to sales and marketing capabilities; and (viii) the activities of competitors.

To provide additional capital when needed, we will evaluate alternative financing sources, including, but not limited to, the issuance of additional equity or debt securities, corporate alliances, joint ventures, and licensing agreements. However, there can be no assurance that funding will be available on favorable terms, if at all, when needed.

If either of our two 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 Spolana Chemical Works a.s. in Neratovice, Czech Republic ("Spolana"). The second is CHINOIN Pharmaceutical and Chemical Works Co., Ltd. ("Chinoin"). Chinoin is the Hungarian subsidiary of the French pharmaceutical company Sanofi Synthelabo. At the present time, Spolana is the sole source of supply of alprostadil approved for use in the manufacture of product for distribution in Europe. Currently, we have a limited supply of alprostadil from Spolana. Certain restrictions have been put in place by the European regulatory authorities that would require a variation to be approved before VIVUS can use the Chinoin alprostadil supply for European manufacture, if at all. We have transferred marketing licenses in Europe to Abbott, and Abbott filed a variation with the European regulatory authorities for use of Chinoin alprostadil on September 26, 2001. There can be no assurance that this variation will be approved in a timely manner or at all, which could result in a material impact on our ability to supply MUSE to Abbott for distribution in Europe.

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

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

We entered into a distribution agreement with CORD Logistics, Inc. ("CORD"), a wholly owned subsidiary of Cardinal Health, Inc. Under this agreement, CORD (i) warehouses our finished goods for United States distribution; (ii) takes customer orders; (iii) picks, packs and ships our products; (iv) invoices customers; and (v) collects related receivables. As a result of this distribution agreement, we are heavily dependent on CORD'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 (“Gibraltar”) performs sterility testing on finished product manufactured by us to ensure that it complies with product specifications. Gibraltar also performs microbial testing on water and compressed gases used in the manufacturing process and microbial testing on environmental samples to ensure that the manufacturing environment meets appropriate current Good Manufacturing Practice, or cGMP regulations and cleanliness standards. As a result of this testing agreement, we are dependent on Gibraltar 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 (“WRB”) to handle patient and healthcare professional hotlines for us. WRB 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 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 (“ICS”), a subsidiary of Bergen Brunswig Corporation. ICS provides “direct-to-physician” distribution capabilities in support of United States marketing and sales efforts. As a result of this distribution agreement, we are dependent on ICS’s efforts to distribute product samples effectively. There can be no assurance that such efforts will be successful.

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

We rely on a single injection molding company, Porex Medical Products, Inc. (“Porex”) (formerly The Kipp Group), for our supply of plastic applicator components. In turn, Porex 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 FDA approval for suppliers. Until we secure and qualify additional sources of plastic components, we are entirely dependent upon Porex. If interruptions in this supply occur for any reason, including a decision by Porex to discontinue manufacturing, political unrest, labor disputes or a failure of Porex 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.

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

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

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

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

If we, or our suppliers, fail to comply with FDA and other government regulations, our manufacturing operations could be delayed, 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 FDA 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 FDA and equivalent foreign regulatory agencies, and we must also report certain adverse events involving our products to these agencies. Previously unidentified adverse events or an increased frequency of adverse events that occur post-approval could result in labeling modifications of approved products, which could adversely affect future marketing. Finally, approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing. The restriction, suspension or revocation of regulatory approvals or any other failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

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

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

We obtain the necessary raw materials and components for the manufacture of MUSE as well as certain services, such as testing and sterilization, from third parties. We currently contract with suppliers and service providers, including foreign manufacturers that are required to comply with strict standards established by us. Certain suppliers and service providers are required to follow cGMP requirements and are subject to routine unannounced periodic inspections by the FDA 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 FDA and other regulatory agencies will find the manufacturing process or facilities to be in compliance with cGMP requirements and other regulations.

Failure to achieve satisfactory cGMP compliance as confirmed by routine 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 efforts 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. Despite our sales efforts, prescriptions of MUSE have declined steadily from 1998 through December 2000. Although prescriptions increased by two percent (2%) in the last six (6) months of 2001 as compared to the first six (6) months of 2001, 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 depend exclusively on third-party distributors outside of the United States and we have very limited control over their activities.

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

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

We had an accumulated deficit of $90.4 million at December 31, 2001 and expect to continue to incur substantial operating losses for the foreseeable future.

We have generated a cumulative net loss of $90.4 million for the period from our inception through December 31, 2001 and we anticipate losses for the next several quarters due to increased investment in our research and development programs and limited revenues. We are subject to a number of risks, including our ability to develop and successfully commercialize products in our research and development pipeline, our ability to market, distribute and sell our products in the United States, our reliance on others to market and distribute MUSE in countries other than the United States, intense competition, and our reliance on a single therapeutic approach to erectile dysfunction. There can be no assurance that we will be able to achieve profitability on a sustained basis. Accordingly, there can be no assurance of our future success.

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

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

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

The rights and measures that we rely upon to protect our intellectual property may not be adequate and could reduce our ability to compete in the market.

We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, and nondisclosure, confidentiality agreements and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. For example, our patents may be challenged, invalidated or circumvented by third parties. Our patent applications, including those already allowed, may not be issued as patents in a form that will be advantageous to us. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by employees. Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. Even if our intellectual property rights are adequately protected, litigation may be necessary to enforce our intellectual property rights, which could result in substantial costs to us and result in a substantial diversion of management attention. If our intellectual property is not adequately protected, our competitors could use our intellectual property to enhance their products. This would harm our competitive position, decrease our market share or otherwise harm our business.

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

Our success is highly dependent upon the skills of a limited number of key management personnel. To reach our business objectives, we will need to retain and hire qualified personnel in the areas of manufacturing, research and development, regulatory affairs, clinical trial management and pre-clinical testing. There can be no assurance that we will be able to hire or retain such

personnel as we must compete with other companies, academic institutions, government entities and other agencies. The loss of any of our key personnel or the failure to attract or retain necessary new employees could have an adverse effect on our research, product development and business operations.

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

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

Our stock price is volatile.

The stock market has experienced significant price and volume fluctuations unrelated to the operating performance of particular companies. In addition, the market price of our common stock has been highly volatile and is likely to continue to be so. The market price of our common stock may fluctuate due to factors including, but not limited to: (i) announcements of technological innovations or new products by us or our competitors; (ii) our ability to increase demand for our products in the United States; (iii) our ability to successfully sell our products in the United States and internationally; (iv) actual or anticipated fluctuations in our financial results; (v) our ability to obtain needed financing; (vi) economic conditions in the United States and abroad; (vii) comments by or changes in Company assessments or financial estimates by security analysts; (viii) adverse regulatory actions or decisions; (ix) any loss of key management; (x) the results of our clinical trials or those of our competitors; (xi) changing governmental regulations, patents or other proprietary rights; (xii) developments or disputes concerning patents or other proprietary rights; (xiii) product or patent litigation; or (xiv) public concern as to the safety of products developed by us.

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

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

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

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

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

Item 2. *Properties*

VIVUS leases 90,000 square feet of space in New Jersey in which it has constructed manufacturing and testing facilities. The FDA and MCA authorized us to begin commercial production and shipment of MUSE from this facility in June and March 1998, respectively.

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

Item 3. ***Legal Proceedings***

On May 19, 2000 VIVUS was named, along with other defendants, in a civil action filed in the Superior Court of New Jersey. The Complaint in this action alleged that plaintiff was the victim of sexual harassment during the second quarter of 1998, while she was working as a temporary worker for VIVUS at a facility operated by PACO Pharmaceutical Services, Inc. ("PACO"). At the time, we were leasing space and workers from PACO to assist us with the manufacture of our product, MUSE. The complaint alleged hostile work environment and quid pro quo sexual harassment, and sought compensatory and punitive damages. VIVUS denied liability and in the fourth quarter of 2001 settled out of court for a nominal amount.

On November 3, 1999, VIVUS filed a demand for arbitration against Janssen with the American Arbitration Association pursuant to the terms of the Distribution Agreement entered into on January 22, 1997. We are seeking compensation for inventory manufactured in 1998 in reliance on contractual forecasts and orders submitted by Janssen. We are also seeking compensation for forecasts and order shortfalls attributed to Janssen in 1998, pursuant to the terms of the Distribution Agreement. We amended our arbitration demand in August 2000 to include claims for lost profits due to Janssen's failure to use the requisite diligence and reasonable efforts to gain regulatory approval for and launch MUSE in each country of the Territory. This amendment also includes claims based on Janssen's development of a competing product intended for use in the treatment of male ED, in violation of the Distribution Agreement. Our amended demand seeks an award of $7.9 million plus costs and interest. On October 20, 2000, Janssen submitted its response to VIVUS' amended arbitration demand denying liability on all claims, and asserting counterclaims against VIVUS for $1.8 million based on an alleged improper calculation of our cost of goods charged to Janssen pursuant to the Distribution Agreement. On November 20, 2000, we filed our response to the counterclaims, denying all liability. We believe that Janssen's counterclaims are without merit and intend to defend against them vigorously. Administration of the arbitration has been transferred to JAMS and a three-member arbitration panel has been selected. The parties are currently in the process of conducting discovery. The arbitration hearing in this matter is scheduled to occur in March 2002.

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***

No matters were submitted to a vote of VIVUS' stockholders during the quarter ended December 31, 2001.

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 stock market.

	Three Months Ended			
	March 31	June 30	September 30	December 31
2001				
High	$5.00	$4.84	$4.20	$5.46
Low	2.75	3.10	2.96	2.89
2000				
High	$9.56	$7.94	$7.41	$4.22
Low	3.88	4.53	4.25	1.88

As of February 21, 2002, there were 32,820,298 shares of outstanding common stock that were held by 689 shareholders of record. As of February 21, 2002, there were no outstanding shares of preferred stock. The Company has not paid any dividends since its inception and does not intend to declare or pay any dividends on its common stock in the foreseeable future. Declaration or payment of future dividends, if any, will be at the discretion of the Company's Board of Directors after taking into account various factors, including the Company's financial condition, operating results and current and anticipated cash needs.

Item 6. ***Selected Financial Data***

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

Selected Financial Data
(In thousands, except per share and employee data)

Selected Quarterly Financial Data (unaudited)

	Quarter Ended,			
	March 31	June 30	September 30	December 31
2001				
Net sales	$ 6,359	$6,370	$ 5,553	$ 5,319
Gross profit	$ 2,726	$3,206	$ 2,267	$ 2,469
Net income (loss)	$(4,884)	$ (914)	$(1,122)	$ (150)
Net income (loss) per share:				
Basic	$ (0.15)	$ (0.03)	$ (0.03)	$ (0.00)
Diluted	$ (0.15)	$ (0.03)	$ (0.03)	$ (0.00)
2000				
Net sales	$ 7,467	$6,747	$ 4,978	$ 7,301
Gross profit	$ 4,540	$3,883	$ 2,036	$ 7,968
Net income (loss)	$ 1,546	$ 890	$ 208	$ 5,047
Net income (loss) per share:				
Basic	$ 0.05	$ 0.03	$ 0.01	$ 0.16
Diluted	$ 0.05	$ 0.03	$ 0.01	$ 0.15
1999				
Net sales	$ 9,754	$5,811	$ 6,127	$21,496
Gross profit	$ 6,151	$2,739	$ 3,287	$18,642
Net income (loss)	$ 3,792	$ 292	$ 897	$13,820
Net income (loss) per share:				
Basic	$ 0.12	$ 0.01	$ 0.03	$ 0.43
Diluted	$ 0.12	$ 0.01	$ 0.03	$ 0.43

Selected Annual Financial Data

	Year Ended December 31,				
	2001	2000	1999	1998	1997
Income Statement Data:					
Product revenue — U.S.	$ 20,764	$ 22,474	$ 21,168	$ 39,041	$128,320
Product revenue — International	4,041	5,200	19,996	32,658	1,017
Milestone revenue	—	—	8,000	3,000	9,000
Other revenue	—	—	3,142	—	—
Returns provision	(1,204)	(1,181)	(9,118)	—	—
Total revenue	23,601	26,493	43,188	74,699	138,337
Gross profit	10,668	18,427	30,819	19,083	100,049
Operating expenses:					
Research and development	12,324	4,670	7,884	16,178	12,123
Selling, general and administrative	9,314	8,655	6,332	40,477	47,931
Write-downs and other charges	—	(903)	(1,193)	44,653	5,050
Total operating expenses	21,638	12,422	13,023	101,308	65,104
Income (loss) from operations	(10,970)	6,005	17,796	(82,225)	34,945
Interest and other income	2,171	2,541	1,994	1,972	4,856
Income (loss) before taxes	$ (8,799)	$ 8,546	$ 19,790	$ (80,253)	$ 39,801
Net income (loss)	$ (7,070)	$ 7,691	$ 18,801	$ (80,253)	$ 36,617
Net income (loss) per diluted share	$ (0.22)	$ 0.23	$ 0.58	$ (2.52)	$ 1.03
Shares used in per share computation	32,572	33,428	32,507	31,876	35,559
Balance Sheet Data (at year end):					
Working capital	$ 14,898	$ 32,981	$ 26,616	$ 10,324	$ 54,888
Total assets	$ 58,574	$ 69,174	$ 68,760	$ 54,108	$150,669
Accumulated deficit	$(90,368)	$(83,298)	$(90,989)	$(109,790)	$ (29,537)
Stockholders' equity	$ 43,975	$ 50,187	$ 41,496	$ 21,677	$123,930
Other Financial Data:					
Common shares outstanding	32,693	32,461	32,211	31,890	33,168
Number of employees	127	136	125	101	215

Item 7. ***Management's Discussion and Analysis of Financial Conditions and Results of Operations***

Overview

In the Management Discussion and Analysis section of the Form 10-K we are providing more detailed information about our operating results and changes in financial position over the past three years. This section should be read in conjunction with the Consolidated Financial Statements and related Notes beginning on page 24.

VIVUS, Inc. ("VIVUS," also referred to herein as "we," "us" and "our") is a pharmaceutical company developing innovative products to improve quality of life disorders in men and women, with a focus on sexual dysfunction. We developed and market in the United States ("U.S.") MUSE® (alprostadil) and ACTIS®, two innovations in the treatment of erectile dysfunction ("ED"), and have entered into a license and supply agreement with Abbott Laboratories ("Abbott") (NYSE:ABT) for the international marketing and distribution of our male transurethral ED products. In Canada, VIVUS has entered into a license and supply agreement with Paladin Labs, Inc. ("Paladin") (TSE:PLB) by which Paladin markets and distributes MUSE. We have ongoing research and development ("R&D") programs in male ED, female sexual dysfunction ("FSD"), and premature ejaculation ("PE").

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

During 1999, we continued to align our operations more closely with our current and expected revenues. We achieved profitability for all quarters in 1999, earning $0.58 per diluted share for the year. Cash, cash equivalents and available-for-sale securities at December 31, 1999 increased $16.5 million from December 31, 1998 to $40.4 million, while total liabilities decreased $5.1 million

during the same period. VIVUS was awarded five patents in the areas of FSD, ED and PE to further build and strengthen our patent portfolio. We established a targeted sales force in the U.S. to support our product, MUSE, in the marketplace. A New Drug Application ("NDA") was filed for ALIBRA®, our second-generation product for the treatment of ED, with the U.S. Food and Drug Administration ("FDA"), which was subsequently withdrawn in October 2000.

During 2000, we continued to strengthen our balance sheet, increasing working capital by $6.4 million, to enable investment in our R&D projects and to pursue targeted technology acquisitions to expand our pipeline. We filed an Investigational New Drug ("IND") application and began clinical studies for ALISTA™, our product for the treatment of FSD. VIVUS signed an agreement with Abbott for the marketing of MUSE internationally, except Canada, where Paladin is marketing and distributing MUSE. We were awarded several new patents for the treatment of ED and solidified our FSD intellectual property through an agreement with AndroSolutions. VIVUS also received 510(k) clearance from the FDA in December 2000, for over-the-counter (OTC) marketing of ACTIS, our adjustable constriction band used to improve erections in men with ED.

Significant progress was made in our development programs in 2001. Our first Phase II clinical study to evaluate the safety of and response to ALISTA was successfully completed and demonstrated a significant increase versus placebo and baseline in sexual response. Our expanded Phase II/III study designed to evaluate the efficacy and safety of ALISTA when used by women at home is scheduled to begin in the first quarter of 2002. We filed an IND application to initiate a clinical study to evaluate the safety and erectile response to oral TA-1790 in men with ED. This trial is also scheduled to begin in the first quarter of 2002. A clinical trial was initiated during the fourth quarter of 2001 to evaluate the pharmacokinetics (blood levels in relation to time) with our new oral formulation of VI-0134. Prescriptions for MUSE in the U.S. increased by 2% in the last six months of 2001, as compared to the first six months of 2001. We withdrew our European application for ALIBRA.

2001 Highlights

In January 2001, enrollment began in a multi-center Phase II study to evaluate the safety and efficacy of ALISTA in women with a primary diagnosis of female sexual arousal disorder ("FSAD"). Patient dosing in this trial was completed in the third quarter of 2001 and demonstrated a significant increase versus placebo and baseline in sexual response associated with visual sexual stimulation in women with FSAD. ALISTA was associated with a rapid and sustained improvement in sexual response.

We began the manufacture of clinical supplies and clinical site selection for our next Phase II/III study designed to evaluate the efficacy and safety of ALISTA when used by women at home with their partner. This trial is scheduled to begin in the first quarter of 2002.

In January 2001, VIVUS signed a development, license and supply agreement with TANABE SEIYAKU CO., LTD. ("Tanabe") for its proprietary phosphodiesterase type 5 (PDE5) inhibitor compound TA-1790 for the oral and local treatment of male and female sexual dysfunction. TA-1790 is a relatively fast acting, highly selective, potent PDE5 inhibitor.

VIVUS successfully filed an IND with the FDA in December 2001 to initiate a clinical study to evaluate the safety and erectile response to oral TA-1790 in men with ED. This trial is scheduled to begin in the first quarter of 2002.

We initiated a clinical trial to evaluate the pharmacokinetics (blood levels in relation to time) of VI-1034, our re-formulated oral, on-demand treatment for PE, in the fourth quarter of 2001.

VIVUS was awarded three new patents by the U.S. Patent & Trademark Office. The first patent strengthens our proprietary protection in the field of PE, allowing for broad treatment claims for PE by administration of 5-HT4 agonists, alone or with other agents. The second patent was awarded in the area of FSD. The third patent covers the use of nitrovasodilators, either alone or in combination with other pharmacologic agents, for the treatment FSD.

Additional studies would have been required to meet European combination drug approval requirements. As a result, in November 2001, we withdrew our European marketing authorization application for ALIBRA, our second-generation transurethral product for the treatment of ED, which was originally submitted to the European Agency for the Evaluation of Medicinal Products ("EMEA") in May 2000.

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 U.S. 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, inventories, income taxes, restructuring, 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:

- Product Returns: We record reserves for anticipated returns of expired or damaged product in the U.S. 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.

- 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.

- 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. We monitor the adequacy of these liabilities and have made periodic adjustments as conditions have changed.

- Contingencies and Litigation: We are periodically involved in disputes and litigation related to a variety of matters. When it is probable that we will experience a loss, and that loss is quantifiable, we record appropriate reserves. We are currently involved in a dispute with our former international distributor, for which arbitration is scheduled to occur in March 2002.

Results of Operations

Years Ended December 31, 2001 and 2000

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

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

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

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

R&D expenses for the year ended December 31, 2001 were $12.3 million, compared to $4.7 million in the year ended December 31, 2000. The $7.6 million increase in 2001 was primarily due to licensing and development expenses for TA-1790 as an oral treatment for male ED, clinical expenses for ALISTA, our product for the treatment of FSD, and development and clinical expenses for VI-0134 to treat PE.

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

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

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

Years Ended December 31, 2000 and 1999

U.S. product revenue for the year ended December 31, 2000 was $22.5 million, remaining relatively flat as compared to $21.2 million for the year ended December 31, 1999.

International revenue was $5.2 million for the year ended December 31, 2000, compared to $20.0 million for the same period in 1999. The $20.0 million in revenues reported in 1999 included $14.9 million associated with the termination of our distribution agreement with AstraZeneca.

In 1999, VIVUS recorded a $9.1 million charge for the actual and anticipated return of expired product in the U.S. These returns were primarily the result of shipments made during the fourth quarter of 1997 and the first quarter of 1998. Demand for MUSE declined following the launch of Viagra in April 1998, resulting in excess inventories at wholesalers and retailers. In 2000, the charge for actual and anticipated returns of product was $1.2 million, or five percent of gross sales.

Cost of goods sold for the year ended December 31, 2000 was $8.1 million, compared to $12.4 million for the same period in 1999. In 2000, we determined that a portion of the inventory purchase commitment reserves recorded in 1998 were not needed. Accordingly, in 2000, we reversed $3.1 million of reserves with a corresponding reduction in cost of goods sold. Additionally in 2000, we reversed an accrual for royalties of $2.0 million related to shipments to our previous international distributors due to the termination of those distribution agreements.

R&D expenses for the year ended December 31, 2000 were $4.7 million, compared to $7.9 million in the year ended December 31, 1999. The $3.2 million decrease is a result of lower spending in 2000 versus 1999 when we were completing our Phase III clinical studies and filing an NDA for ALIBRA.

Selling, general and administrative expenses for the year ended December 31, 2000 were $8.7 million, compared to $6.3 million in the year ended December 31, 1999. The increased expenses in 2000 were primarily a result of additional investment in our U.S. marketing and sales effort.

Operating expenses for the year ended December 31, 2000 includes a reversal of $903 thousand of restructuring reserve established in 1998 related primarily to inventory commitments and other manufacturing expenses that were not required. Operating expenses for the year ended December 31, 1999 include a non-cash charge of $600,000 for the issuance of 120,000 shares of common stock toward the settlement of shareholders class action lawsuits. VIVUS also reclassified $1.8 million in 1999 from other restructuring costs to the allowance for product returns during earlier quarters.

VIVUS recorded a tax provision of ten percent of net income before taxes for 2000. The effective tax rate calculation includes the effect of net operating losses ("NOLs") carried forward from prior periods. The tax rate would have been substantially higher if the NOLs had not been available to offset current income. We recorded a tax provision of five percent of net income before taxes for 1999.

Recent Accounting Pronouncements

Accounting for Asset Retirement Obligations. In October 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 143, "Accounting for Asset Retirement Obligations" to be effective for all fiscal years beginning after June 15, 2002, with early adoption permitted. SFAS No. 143 establishes accounting standards for the recognition and measurement of an asset retirement obligation and its associated asset retirement cost. It also provides accounting guidance for legal obligations associated with the retirement of tangible long-lived assets. VIVUS is currently assessing the impact of SFAS No. 143 on its financial position, results of operations and cash flows as well as the timing of its adoption, but does not believe the adoption will have any impact on its financial position, results of operations and cash flows.

Accounting for the Impairment or Disposal of Long-Lived Assets. In October 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," which establishes a single accounting model for the impairment or disposal of long-lived assets, including discontinued operations. SFAS No. 144 supersedes SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets to be Disposed of" and Accounting Principles Board ("APB") Opinion No. 30, "Reporting the Results of Operations-Reporting the Effects of Disposal of a Segment of a Business and Extraordinary, Unusual and Infrequently Occurring Events and Transactions for the Disposal of a Segment of a Business." The provisions of SFAS No. 144 are effective in fiscal years beginning after December 15, 2001, with early adoption permitted and, in general, are to be applied prospectively. VIVUS is currently assessing the impact of SFAS No. 144 on its financial position, results of operations and cash flows as well as the timing of its adoption, but does not believe the adoption will have any impact on its financial position, results of operations and cash flows.

Liquidity and Capital Resources

Since inception, we have financed operations primarily from the sale of preferred and common stock. Through December 31, 2001, VIVUS raised $155.1 million from financing activities and had an accumulated deficit of $90.4 million at December 31, 2001.

Unrestricted cash, cash equivalents and available-for-sale securities totaled $36.7 million at December 31, 2001, compared with $41.9 million at December 31, 2000. The decrease during 2001 was primarily due to payments totaling $5 million made to Tanabe during the first quarter of 2001 for licensing TA-1790.

Total liabilities were $14.6 million at December 31, 2001, compared with $19.0 million at December 31, 2000, a decrease of $4.4 million. This decrease relates primarily to a reduction in taxes payable based on an updated estimate of our net tax liability and total payments of $1.3 million for legal matters settled earlier in the year. The remainder of the decrease relates to timing differences of payments.

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

We expect to evaluate potential financing sources, including, but not limited to, the issuance of additional equity or debt securities, corporate alliances, joint ventures, and licensing agreements to fund the development and possible commercial launch of any future products. The sale of additional equity securities would result in additional dilution to VIVUS' stockholders. Our working capital and additional funding requirements will depend upon numerous factors, including: (i) the progress of our R&D programs; (ii) the timing and results of pre-clinical testing and clinical trials; (iii) results of operations; (iv) demand for MUSE; (v) technological advances; (vi) the level of resources that we devote to our sales and marketing capabilities; and (vii) the activities of competitors.

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

The SEC'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, 2001 and 2000, 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. Substantially 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 U.S. government obligations. Currently, this reduces our exposure to long-term interest rate changes.

This Form 10-K contains "forward-looking" statements about future financial results, future products and other events that have not yet occurred. For example, statements like we "expect," we "anticipate" or we "believe" are forward-looking statements. Investors should be aware that actual results may differ materially from our expressed expectations because of risks and uncertainties about the future. We will not necessarily update the information in this Form 10-K if any forward-looking statement later turns out to be inaccurate. Details about risks affecting various aspects of our business are discussed throughout this

Form 10-K. Investors should read all of these risks carefully, and should pay particular attention to risks affecting the following areas: new product development and uncertainty of product approvals (pages 9 and 10); clinical trial testing (page 10); intense competition (pages 10 and 11); patent positions (pages 11 and 12); future capital needs and uncertainty of additional financing (page 12); raw materials and dependence on third parties (pages 12 and 13); single manufacturing facility (page 13); and other risk factors as stated (pages 13 through 17).

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:

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,	
	2001	**2000**
Current assets:		
Cash and cash equivalents	$ 11,545	$ 29,236
Available-for-sale securities	7,835	9,187
Accounts receivable (net of allowance for doubtful accounts of $232 and $304 at December 31, 2001 and 2000, respectively)	2,314	3,434
Inventories, net	3,100	5,045
Prepaid expenses and other assets	780	1,143
Total current assets	25,574	48,045
Property and equipment, net	12,378	14,294
Restricted cash	3,324	3,324
Available-for-sale securities, non-current	17,298	3,511
Total assets	$ 58,574	$ 69,174

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable	$ 1,241	$ 1,775
Accrued and other liabilities	9,435	13,289
Total current liabilities	10,676	15,064
Accrued and other long-term liabilities	3,923	3,923
Total liabilities	14,599	18,987
Stockholders' equity:		
Common stock; $.001 par value; shares authorized — 200,000 at December 31, 2001 and 2000; shares outstanding — December 31, 2001, 32,693 December 31, 2000, 32,461	33	32
Paid in capital	133,988	133,288
Accumulated other comprehensive income	322	165
Accumulated deficit	(90,368)	(83,298)
Total stockholders' equity	43,975	50,187
Total liabilities and stockholders' equity	$ 58,574	$ 69,174

The accompanying notes are an integral part of these consolidated financial statements.

VIVUS, INC.

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

	Year Ended December 31,		
	2001	2000	1999
Revenue			
US product	$ 20,764	$22,474	$21,168
International product	4,041	5,200	19,996
Milestone	—	—	8,000
Other revenue	—	—	3,142
Returns provision	(1,204)	(1,181)	(9,118)
Total revenue	23,601	26,493	43,188
Cost of goods sold	12,933	8,066	12,369
Gross profit	10,668	18,427	30,819
Operating expenses:			
Research and development	12,324	4,670	7,884
Selling, general and administrative	9,314	8,655	6,332
Settlement of lawsuits	—	—	600
Other restructuring costs (income)	—	(903)	(1,793)
Total operating expenses	21,638	12,422	13,023
(Loss) income from operations	(10,970)	6,005	17,796
Interest and other income	2,171	2,541	1,994
(Loss) income before provision for income taxes	(8,799)	8,546	19,790
Benefit (provision) for income taxes	1,729	(855)	(989)
Net (loss) income	$ (7,070)	$ 7,691	$18,801
Other comprehensive (loss) income:			
Unrealized gain (loss) on securities	157	355	(159)
Income tax benefit (provision)	—	(36)	8
Comprehensive (loss) income	$ (6,913)	$ 8,010	$18,650
Net (loss) income per share:			
Basic	$ (0.22)	$ 0.24	$ 0.59
Diluted	$ (0.22)	$ 0.23	$ 0.58
Shares used in per share computation:			
Basic	32,572	32,328	32,085
Diluted	32,572	33,428	32,507

The accompanying notes are an integral part of these consolidated financial statements.

VIVUS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands)

	Common Stock and Paid In Capital		Accumulated Other		
	Shares	Amount	Comprehensive Income	Accumulated Deficit	Total
Balances, December 31, 1998	31,890	$131,498	$ (31)	$(109,790)	$21,677
Sale of common stock through employee stock purchase plan	97	208			208
Exercise of common stock options for cash	104	188			188
Settlement of lawsuits	120	600			600
Stock compensation costs		181			181
Unrealized loss on securities			(159)		(159)
Net income				18,801	18,801
Balances, December 31, 1999	32,211	132,675	(190)	(90,989)	41,496
Sale of common stock through employee stock purchase plan	117	276			276
Exercise of common stock options for cash	133	369			369
Unrealized gain on securities			355		355
Net income				7,691	7,691
Balances, December 31, 2000	32,461	133,320	165	(83,298)	50,187
Sale of common stock through employee stock purchase plan	117	320			320
Exercise of common stock options for cash	115	320			320
Stock compensation costs		61			61
Unrealized gain on securities			157		157
Net loss				(7,070)	(7,070)
Balances, December 31, 2001	32,693	$134,021	$ 322	$ (90,368)	$43,975

The accompanying notes are an integral part of these consolidated financial statements.

VIVUS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,		
	2001	**2000**	**1999**
Cash flows from operating activities:			
Net (loss) income	$ (7,070)	$ 7,691	$ 18,801
Adjustments to reconcile net (loss) income to net cash (used for) provided by operating activities:			
Depreciation and amortization	2,252	2,379	3,316
Stock compensation costs	61	—	181
Settlement of lawsuits	—	—	600
Changes in assets and liabilities:			
Accounts receivable	1,120	998	765
Inventories	1,945	(1,518)	1,745
Prepaid expenses and other assets	363	3,195	(3,804)
Accounts payable	(534)	(678)	(824)
Accrued and other liabilities	(3,854)	(7,599)	(4,344)
Net cash (used for) provided by operating activities	(5,717)	4,468	16,436
Cash flows from investing activities:			
Property and equipment purchases	(336)	(602)	(173)
Investment purchases	(34,958)	(120,941)	(134,860)
Proceeds from sale/maturity of securities	22,680	140,205	123,997
Investment in restricted certificate of deposit	—	(3,324)	—
Net cash (used for) provided by investing activities	(12,614)	15,338	(11,036)
Cash flows from financing activities:			
Sale of common stock through employee stock purchase plan	320	276	208
Exercise of common stock options	320	369	188
Net cash provided by financing activities	640	645	396
Net (decrease) increase in cash	(17,691)	20,451	5,796
Cash:			
Beginning of year	29,236	8,785	2,989
End of year	$ 11,545	$ 29,236	$ 8,785
Non-cash investing and financing activities:			
Unrealized gain (loss) on securities	$ 157	$ 355	$ (159)
Supplemental cash flow disclosure:			
Income taxes (received) paid	$ (342)	$ 532	$ 36

The accompanying notes are an integral part of these consolidated financial statements.

VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Business and Significant Accounting Policies

Business

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

The Company obtained clearance from the United States ("U.S.") Food and Drug Administration ("FDA") to manufacture and market MUSE, a transurethral applicator used for treating erectile dysfunction ("ED"), in the U.S. in November 1996. The Medicines Control Agency ("MCA") 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, 2001, the Company's accumulated deficit was approximately $90.4 million.

The Company primarily sells its products through wholesale channels in the U.S. International sales are made only to the Company's international distributors. All transactions are denominated in U.S. 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 ("SFAS") No. 131, "Disclosures about Segments of an Enterprise and Related Information."

Significant Accounting Policies

Principles of Consolidation

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

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles 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 Income," a separate component of stockholders' equity until realized. The unrealized gain (loss) on investments included in accumulated other comprehensive income in the accompanying consolidated balance sheets for 2001, 2000 and 1999, in thousands, are $156, $354, and ($158), respectively.

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

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 wrote down 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. Based on subsequent sales activity and purchases under inventory purchase commitments, the Company determined that a portion of the inventory purchase commitment reserves recorded in 1998 was not needed. Accordingly, in 2000, the Company reversed $3.1 million of reserves with a corresponding reduction in cost of goods sold.

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.

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable in accordance with SFAS No. 121, “Accounting for Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of.” An asset is considered impaired if its carrying amount exceeds the future net cash flow the asset is expected to generate. If such asset is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds its fair market value. Based on management’s assumption, the Company believes the carrying value of its long-lived assets is recoverable through future net cash flow as of December 31, 2001.

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

U.S.

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

International

The Company invoices its international distributors based on an agreed transfer price per unit which is subject to revision based on contractual formulas either up or down upon quarterly reconciliations. Final pricing for product shipments to international distributors is subject to contractual formulas based on the distributor's net realized price to their customers. At the time of shipment, the Company recognizes revenue at the lowest possible price in accordance with contractual formulas and recognizes additional revenue, if any, upon finalization of pricing with its international distributors. As of December 31, 2001, the Company had deferred revenue of $2.2 million representing amounts billed and received in excess of revenue recognized.

Income Taxes

The Company uses the liability method to calculate deferred taxes. The realization of deferred tax assets 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 and tax basis of assets and liabilities based on enacted tax laws and rates applicable to the period in which differences are expected to affect taxable income. 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 ("R&D"). 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 ("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, 2001, 2000 and 1999 are as follows:

	2001	2000	1999
	(In thousands, except per share data)		
Net (loss) income	$ (7,070)	$ 7,691	$18,801
Net (loss) income per share — basic	$ (.22)	$ .24	$ .59
Effect of dilutive securities (stock options)	—	(.01)	(.01)
Net (loss) income per share — diluted	$ (.22)	$ .23	$ .58
Shares used in the computation of net income (loss) per share — basic	32,572	32,328	32,085
Effect of dilutive securities (stock options)	—	1,100	422
Diluted shares	32,572	33,428	32,507

All options which were outstanding at December 31, 2001 are excluded from the computation of diluted EPS for 2001 because the effect would have been antidilutive. Options to purchase 290,041 shares at prices ranging from $5.81 to $25.88, which were outstanding at December 31, 2000, are not included in the computation of diluted EPS for 2000 because the option prices were greater than the average market price of common shares and the effect, therefore, would have been antidilutive. Options to purchase 964,879 shares at prices ranging from $3.25 to $25.88, which were outstanding at December 31, 1999, are not included in the computation of diluted EPS for 1999 because the option prices were greater than the average market price of common shares and the effect, therefore, would have been antidilutive.

Recent Pronouncements

Accounting for Asset Retirement Obligations. In October 2001, the Financial Accounting Standards Board ("FASB") issued SFAS No. 143, "Accounting for Asset Retirement Obligations" to be effective for all fiscal years beginning after June 15, 2002, with early adoption permitted. SFAS No. 143 establishes accounting standards for the recognition and measurement of an asset retirement obligation and its associated asset retirement cost. It also provides accounting guidance for legal obligations associated with the retirement of tangible long-lived assets. VIVUS is currently assessing the impact of SFAS No. 143 on its financial position, results of operations and cash flows as well as the timing of its adoption, but does not believe the adoption will have any impact on its financial position, results of operations and cash flows.

Accounting for the Impairment or Disposal of Long-Lived Assets. In October 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets", which establishes a single accounting model for the impairment or disposal of long-lived assets, including discontinued operations. SFAS No. 144 supersedes SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets to be Disposed of" and Accounting Principles Board ("APB") Opinion No. 30, "Reporting the Results of Operations-Reporting the Effects of Disposal of a Segment of a Business and Extraordinary, Unusual and Infrequently Occurring Events and Transactions for the Disposal of a Segment of a Business." The provisions of SFAS No. 144 are effective in fiscal years beginning after December 15, 2001, with early adoption permitted and, in general, are to be applied prospectively. VIVUS is currently assessing the impact of SFAS No. 144 on its financial position, results of operations and cash flows as well as the timing of its adoption, but does not believe the adoption will have any impact on its financial position, results of operations and cash flows.

Note 2. Available-for-Sale Securities

The fair value and the amortized cost of available-for-sale securities at December 31, 2001 and 2000 are presented in the table that follows. Fair values are based on quoted market prices obtained from an independent broker. For each category of investment securities, the table presents gross unrealized holding gains and losses.

As of December 31, 2001 (in thousands):

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

As of December 31, 2000 (in thousands):

	Amortized Cost	Fair Market Value	Unrealized Holding Gains	Unrealized Holding Losses
U.S. government securities	$ 4,484	$ 4,598	$ 114	$—
Corporate debt	8,049	8,100	51	—
Total	12,533	12,698	165	0
Amount classified as short-term	(9,064)	(9,187)	(123)	—
Amount classified as long-term	$ 3,469	$ 3,511	$ 42	$ 0

Note 3. Inventories

Inventories are recorded net of reserves of $7.5 million and $7.7 million as of December 31, 2001 and 2000, respectively, and consist of (in thousands):

	2001	2000
Raw materials	$1,845	$3,497
Work in process	44	61
Finished goods	1,211	1,487
Inventory, net	$3,100	$5,045

Note 4. Property and Equipment

Property and equipment as of December 31, 2001 and 2000, respectively, consist of (in thousands):

	2001	2000
Machinery and equipment	$ 19,125	$ 18,990
Computers and software	4,266	4,095
Furniture and fixtures	2,257	2,247
Building improvements	11,855	11,839
	37,503	37,171
Accumulated depreciation and amortization	(25,125)	(22,877)
Property and equipment, net	$ 12,378	$ 14,294

For the years ended December 31, 2001, 2000 and 1999, depreciation expense was $2,252, $2,379 and $3,316, respectively.

Note 5. Accrued and Other Liabilities

Accrued and other liabilities as of December 31, 2001 and 2000, respectively, consist of (in thousands):

	2001	2000
Restructuring	$ 3,923	$ 4,266
Product returns	1,523	2,008
Income taxes	1,952	3,332
Research and clinical expenses	1,118	2,076
Royalties	473	541
Deferred revenue	2,151	1,917
Employee compensation and benefits	1,485	1,670
Other	733	1,402
	13,358	17,212
Amount classified as short-term	(9,435)	(13,289)
Amount classified as long-term	$ 3,923	$ 3,923

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 ("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.

During first quarter, second quarter and third quarter 1999, the Company included expired products returns of $500 thousand, $1 million, and $293 thousand, respectively, against the "Other" restructuring. In the fourth quarter 1999, the Company reclassified these charges to returns reserve to offset product revenues, and reversed the "Other" restructuring reserve from operating expenses as such reserves were determined to be excess in 1999. The remainder of the activity in 1999 related to payments made against the reserve.

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

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

Restructuring and related charges in fiscal 2001, 2000 and 1999 (in thousands):

	Severance and Employee Costs	Inventory and Related Commitments	Property and Related Commitments	Marketing Commitments	Other	Total
Balance at December 31, 1998	$ 1,910	$ 5,384	$4,664	$ 1,307	$ 1,793	$15,058
Activity in 1999	(1,610)	(1,379)	(784)	(1,307)	(1,793)	(6,873)
Balance at December 31, 1999	300	4,005	3,880	0	0	8,185
Activity in 2000	(300)	(3,063)	(556)	—	—	(3,919)
Balance at December 31, 2000	0	942	3,324	0	0	4,266
Activity in 2001	—	(40)	(303)	—	—	(343)
Balance at December 31, 2001	$ 0	$ 902	$3,021	$ 0	$ 0	$ 3,923

The Company expects that during the fiscal year 2002 it will not make any cash payments related to the restructuring, with the remaining $3.9 million in cash payments to occur in later years.

Note 7. Stockholders' Equity

Common Stock

The Company is authorized to issue 200 million shares of common stock. As of December 31, 2001 and 2000, there were 32,693,205 and 32,461,457 shares, respectively, issued and outstanding.

During 1999, the Company reached a settlement of the shareholder class action lawsuits, in which the Company incurred a non-cash expense of $600,000 for the issuance of 120,000 shares of VIVUS, Inc. common stock.

Preferred Stock

The Company is authorized to issue 5,000,000 shares of undesignated preferred stock with a par value of $1.00 per share. As of December 31, 2001 and 2000, 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 Plans

Under the 2001 Stock Option Plan (the "2001 Plan"), upon stockholder approval, the Company may grant incentive or non-statutory stock options or stock purchase rights ("SPRs"). The maximum aggregate number of shares that may be optioned and sold under the Plan is 1,000,000 shares plus (a) any shares that have been reserved but not issued under the Company's 1991 Incentive Stock Option Plan (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 ("ISOs") 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 ("NSOs") 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, 2001, no SPRs have been granted under the 2001 Plan.

Under the 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 director shall receive an option to purchase 8,000 shares of the Company's common stock annually upon their reelection. These options are fully exercisable ratably over eight months.

Under the 1991 Plan, the Company may grant incentive or non-statutory stock options or stock purchase rights (SPRs). Up to 7,800,000 shares of common stock have been authorized for issuance under the 1991 Plan. The 1991 Plan allows the Company to grant ISOs 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 1991 Plan allows the Company to grant NSOs 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 1991 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 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, 2001, no SPRs have been granted under the 1991 Plan.

2,278,874 shares expired under the 1991 Plan in November 2001 and will be transferred to the 2001 Plan upon stockholder approval.

Under the 1994 Director Option Plan (the “Director Option Plan”), the Company reserved 400,000 shares of common stock for issuance to non-employee directors of the Company pursuant to non-statutory stock options issued at the fair market value of the Company’s common stock at the date of grant. Under the Director Option 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 director shall receive an option to purchase 8,000 shares of the Company’s common stock annually upon their reelection. These options are fully exercisable ratably over eight months after grant. The Director Option Plan will not be used once the 2001 Plan is approved by the stockholders because the 2001 Plan provides for annual option grants to non-employee directors.

Details of option activity under these plans are as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding, December 31, 1998	3,071,742	$3.90
Granted	300,783	3.36
Exercised	(103,623)	2.13
Cancelled	(324,626)	7.43
Outstanding, December 31, 1999	2,944,276	$3.52
Granted	579,660	4.90
Exercised	(133,166)	2.77
Cancelled	(155,815)	3.19
Outstanding, December 31, 2000	3,234,955	$3.81
Granted	527,961	3.84
Exercised	(115,181)	2.78
Cancelled	(201,836)	7.57
Outstanding, December 31, 2001	3,445,899	$3.63

Options Outstanding				Options Exercisable	
Range of Exercise Prices	Number Outstanding at December 31, 2001	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable December 31, 2001	Weighted-Average Exercise Price
$0.24 - $2.94	1,556,916	4.9 years	$2.45	1,392,382	$2.43
$3.13 - $4.41	1,238,006	6.7 years	$4.07	645,362	$4.29
$4.45 - $7.38	650,977	6.5 years	$5.60	434,639	$5.83
$0.24 - $7.38	3,445,899	5.9 years	$3.63	2,472,383	$3.51

At December 31, 2001, 1,185,000 options remain available for grant; 1,000,000 from the 2001 Plan and 185,000 from the Director Option Plan.

During 2001, options to purchase 20,000 shares of common stock were granted to research consultants with a strike price at the fair market value on the date of grant. Compensation expenses, including the impact of re-pricing using the Black-Scholes option-pricing model, in the amount of $61,000 were recorded as expenses in 2001.

During 1997, options to purchase 100,000 shares of common stock were granted to research consultants with a strike price at the fair market value on the date of grant. Compensation costs, including the impact of re-pricing, using the Black-Scholes option-pricing model were approximately $1.1 million over the options' vesting period, of which $181,000 was recorded as expense for the year ended December 31, 1999. These options were cancelled in July 1999, when the Company decided not to renew the contract with the research consultants. The research consultants exercised a total of 25,000 shares of these options during 1999.

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

Under SFAS No. 123, the estimated fair value of options is amortized to expense over the options' vesting period. In accordance with the disclosure requirements of SFAS No. 123, if the Company had elected to recognize this expense, (loss) income and (loss) income per share would have been reduced to the following pro forma amounts (in thousands, except per share data):

	2001	2000	1999
Pro forma net (loss) income	$(7,986)	$6,509	$17,341
Pro forma net (loss) income per share:			
Basic	$ (0.25)	$ 0.20	$ 0.54
Diluted	$ (0.25)	$ 0.19	$ 0.53

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions used for grants: risk-free rates ranging from 3% to 5% and corresponding to government securities with original maturities similar to the vesting periods; expected dividend yield of 0%; expected lives of .64 years beyond vest dates; and expected volatility of 86% in all years.

Stock Purchase Plan

Under the 1994 Employee Stock Purchase Plan (the "Stock Purchase Plan"), the Company reserved 1,200,000 shares of common stock for issuance to employees pursuant to the Stock Purchase Plan, under which eligible employees may authorize payroll deductions of up to 10% of their base compensation (as defined) to purchase common stock at a price equal to 85% of the lower of the fair market value as of the beginning or the end of the offering period. As of December 31, 2001, 503,462 shares have been issued to employees and there are 296,538 available for issuance. During 2001, the weighted average fair market value of shares issued under the Stock Purchase Plan was $2.75 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 R&D upon execution of this agreement. Other substantial payments are required to be made based on certain development, regulatory and sales milestones. 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 U.S. and Canadian product sales and 3% of sales elsewhere in the world). In 1999, 2000 and 2001, the Company recorded royalty expenses as cost of goods sold based on product sales. The Company reversed $2.0 million of accrued royalties in 2000 related to shipments to its previous international distributors due to the termination of those distribution agreements.

Note 10. Lease 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):

2002	$1,335
2003	1,285
2004	1,324
2005	1,375
2006	1,428
Thereafter	119
	$6,866

Rent expense, in thousands, under operating leases totaled $1,263, $1,235, and $994 for the years ended December 31, 2001, 2000, 1999, respectively.

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 carryforwards. Significant components of the Company's deferred income tax assets as of December 31, are as follows (in thousands):

	2001	2000
Deferred tax assets:		
Net operating loss carryforwards	$ 15,451	$ 11,606
Research and development credit carryforwards	5,044	5,255
Inventory reserve	2,854	3,063
Accruals and other	3,577	4,294
Depreciation	1,885	3,002
	28,811	27,220
Valuation allowance	(28,811)	(27,220)
Total	$ —	$ —

For federal and state income tax reporting purposes, respective net operating loss ("NOL") carryforwards of approximately $43.3 million and $8.4 million are available to reduce further taxable income, if any. The federal NOLs expire on various dates beginning in 2011 and ending in 2021. The state NOLs expire on various dates beginning in 2003 and ending in 2006. The Internal Revenue Code of 1986, as amended, contains provisions that may limit the net operating loss and credit carryforwards available for use in any given period upon the occurrence of certain events, including a significant change in ownership interest.

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, 2001, 2000 and 1999:

	2001	2000	1999
(Loss) income from continuing operations before income taxes:			
Domestic	$(3,751)	$9,374	$ 6,898
International	(5,048)	(828)	12,892
Total	$(8,799)	$8,546	$19,790

The (benefit)/provision for income taxes consists of the following components for the years ended December 31, 2001, 2000 and 1999:

	2001	2000	1999
Current			
Federal	$(1,681)	$805	$730
State	(59)	40	95
Foreign	11	10	164
Total (benefit)/provision for income taxes	$(1,729)	$855	$989

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, 2001, 2000 and 1999:

	2001	2000	1999

(Benefit) provision computed at federal statutory rates	(35)%	35%	35%
State income taxes, net of federal tax effect	(3)	6	6
Net operating losses utilized	—	(36)	(31)
Tax credits	(2)	(5)	—
Change in valuation allowance	12	5	—
Loss/(income) not subject to federal and state taxation	22	4	(4)
Tax reserves no longer needed	(14)		
Other	—	1	(1)
Provision for income taxes	(20)%	10%	5%

Note 12. Concentration of Customers and Suppliers

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

	2001	2000	1999
Customer A	24%	18%	10%
Customer B	19%	15%	9%
Customer C	18%	9%	—
Customer D	12%	17%	9%
Customer E	12%	10%	6%

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

Note 13. 401(k) Plan

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

Note 14. Legal Matters

On November 3, 1999, the Company filed a demand for arbitration against Janssen Pharmaceutica International ("Janssen") with the American Arbitration Association pursuant to the terms of the Distribution Agreement entered into on January 22, 1997. The Company seeks compensation for inventory manufactured in 1998 in reliance on contractual forecasts and orders submitted by Janssen. The Company also seeks compensation for forecasts and order shortfalls attributed to Janssen in 1998, pursuant to the terms of the Distribution Agreement. The Company amended its arbitration demand in August 2000 to include claims for lost profits due to Janssen's failure to use the requisite diligence and reasonable efforts to gain regulatory approval for and launch MUSE in each country of the Territory. This amendment also includes claims based on Janssen's development of a competing product intended for use in the treatment of male ED, in violation of the Distribution Agreement. The Company's amended demand seeks an award of $7.9 million plus costs and interest. On October 20, 2000, Janssen submitted its response to the Company's amended arbitration demand denying liability on all claims, and asserting counterclaims against the Company for $1.8 million based on the Company's alleged improper calculation of its cost of goods charged to Janssen pursuant to the Distribution Agreement. On November 20, 2000, the Company filed its response to the counterclaims, denying all liability. The Company believes that Janssen's counterclaims are without merit and intends to defend against them vigorously. Administration of the arbitration has been transferred to JAMS and a three-member arbitration panel has been selected. The parties are currently in the process of conducting discovery. The arbitration hearing in this matter has been re-scheduled to occur in March 2002.

During 2001, the Company settled certain legal matters resulting in payments of $1.3 million. Net (loss) income for the twelve months ended December 31, 2001 includes legal charges of approximately $300 thousand related to these matters. The remainder of the charges were accrued in prior periods.

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

FINANCIAL STATEMENT SCHEDULE

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

VIVUS, Inc.

SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS
(in thousands)

	Balance at Beginning of Period	Charged to Operations	Charges Utilized	Other (1)	Balance at End of Period
Allowance for Doubtful Accounts					
Fiscal year ended December 31, 1999	$ 341	$ 6,686	$(6,880)	—	$ 147
Fiscal year ended December 31, 2000	147	266	(109)	—	304
Fiscal year ended December 31, 2001	304	13	(85)	—	232
Inventory Reserve					
Fiscal year ended December 31, 1999	$14,795	1,575	(2,673)	1,272	$14,969
Fiscal year ended December 31, 2000	14,969	(2,256)(2)	(6,678)	1,707	7,742
Fiscal year ended December 31, 2001	7,742	252	(510)	—	7,484

(1) During the third quarter of 1998, as part of the Company's plan to restructure its operations, the Company recorded restructuring reserves related to commitments to buy raw materials. As the Company purchased raw materials under these commitments, the Company reclassified the purchase commitment restructuring reserves to inventory reserves.

(2) Based on subsequent sales activity and purchases made under inventory purchase commitments, the Company determined that a portion of the inventory purchase commitment reserves recorded in 1998 were not needed. Accordingly, the Company reversed reserves with a corresponding reduction in cost of goods sold in the amount of $3,127. This amount is included in the year 2000 charged to operations.

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

None.

PART III

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

The information required by this item is incorporated by reference from the discussion in the Company's Proxy Statement captioned "Proposal One: Election of Directors," to be filed with the Commission.

Item 11. ***Executive Compensation***

The information required by this item is incorporated by reference from the discussion in the Company's Proxy Statement captioned "Executive Compensation," to be filed with the Commission.

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

The information required by this item is incorporated by reference from the discussion in the Company's Proxy Statement captioned "Record Date and Share Ownership," to be filed with the Commission.

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

The information required by this item is incorporated by reference from the discussion in the Company's Proxy Statement captioned "Certain Transactions and Reports," to be filed with the Commission.

PART IV

Item 14. ***Exhibits, Financial Statement Schedules and Reports on Form 8-K***

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

1. **Financial Statements**

The financial statements of VIVUS, Inc. for the year ended December 31, 2001 together with the report of Independent Accountants, are set forth on pages 25 through 39 of this Form 10-K.

2. Financial Statement Schedules

The following financial statement schedule of VIVUS, Inc. as set forth on page 40 is filed as part of this report on Form 10-K and should be read in conjunction with the Financial Statements of VIVUS, Inc. incorporated by reference herein:

Schedule II — Valuation and Qualifying Accounts

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

3. **Exhibits**

Exhibit Number	Description
3.2(7)	Amended and Restated Certificate of Incorporation of the Company
3.3(4)	Bylaws of the Registrant, as amended
3.4(8)	Certificate of Designations of Rights, Preferences and Privileges of Series A Participating Preferred Stock
4.1(7)	Specimen Common Stock Certificate of the Registrant
4.2(7)	Registration Rights, as amended
4.4(1)	Form of Preferred Stock Purchase Warrant issued by the Registrant to Invemed Associates, Inc., Frazier Investment Securities, L.P., and Cristina H. Kepner

Exhibit Number	Description
4.5(8)	Second Amended and Restated Preferred Shares Rights Agreement, dated as of April 15, 1997 by and between the Registrant and Harris Trust Company of California, including the Certificate of Determination, the form of Rights Certificate and the Summary of Rights attached thereto as Exhibits A, B, and C, respectively
10.1(1)†	Assignment Agreement by and between Alza Corporation and the Registrant dated December 31, 1993
10.2(1)†	Memorandum of Understanding by and between Ortho Pharmaceutical Corporation and the Registrant dated February 25, 1992
10.3(1)†	Assignment Agreement by and between Ortho Pharmaceutical Corporation and the Registrant dated June 9, 1992
10.4(1)†	License Agreement by and between Gene A. Voss, MD, Allen C. Eichler, MD, and the Registrant dated December 28, 1992
10.5A(1)†	License Agreement by and between Ortho Pharmaceutical Corporation and Kjell Holmquist AB dated June 23, 1989
10.5B(1)†	Amendment by and between Kjell Holmquist AB and the Registrant dated July 3, 1992
10.5C(1)	Amendment by and between Kjell Holmquist AB and the Registrant dated April 22, 1992
10.5D(1)†	Stock Purchase Agreement by and between Kjell Holmquist AB and the Registrant dated April 22, 1992
10.6A(1)†	License Agreement by and between Amsu, Ltd., and Ortho Pharmaceutical Corporation dated June 23, 1989
10.6B(1)†	Amendment by and between Amsu, Ltd., and the Registrant dated July 3, 1992
10.6C(1)	Amendment by and between Amsu, Ltd., and the Registrant dated April 22, 1992
10.6D(1)†	Stock Purchase Agreement by and between Amsu, Ltd., and the Registrant dated July 10, 1992
10.11(4)	Form of Indemnification Agreements by and among the Registrant and the Directors and Officers of the Registrant
10.12(2)	1991 Incentive Stock Plan and Form of Agreement, as amended
10.13(1)	1994 Director Option Plan and Form of Agreement
10.14(1)	Form of 1994 Employee Stock Purchase Plan and Form of Subscription Agreement
10.17(1)	Letter Agreement between the Registrant and Leland F. Wilson dated June 14, 1991 concerning severance pay
10.21(3)†	Distribution Services Agreement between the Registrant and Synergy Logistics, Inc. (a wholly-owned subsidiary of Cardinal Health, Inc.)† dated February 9, 1996
10.22(3)†	Manufacturing Agreement between the Registrant and CHINOIN Pharmaceutical and Chemical Works Co., Ltd. dated December 20, 1995
10.22A(11)†	Amendment One, dated as of December 11, 1997, to the Manufacturing Agreement by and between VIVUS and CHINOIN Pharmaceutical and Chemical Works Co., Ltd. dated December 20, 1995
10.23(6)†	Distribution and Services Agreement between the Registrant and Alternate Site Distributors, Inc. dated July 17, 1996
10.24(5)†	Distribution Agreement made as of May 29, 1996 between the Registrant and ASTRAZ AB
10.24A(14)†	Amended Distribution Agreement dated December 22, 1999 between AstraZeneca and the Registrant
10.27(11)†	Distribution Agreement made as of January 22, 1997 between the Registrant and Janssen Pharmaceutica International, a division of Cilag AG International
10.27A(11)†	Amended and Restated Addendum 1091, dated as of October 29, 1997, between VIVUS International Limited and Janssen Pharmaceutica International
10.28(7)	Lease Agreement made as of January 1, 1997 between the Registrant and Airport Associates
10.29(7)	Lease Amendment No. 1 as of February 15, 1997 between Registrant and Airport Associates
10.29A(10)	Lease Amendment No. 2 dated July 24, 1997 by and between the Registrant and Airport Associates
10.29B(10)	Lease Amendment No. 3 dated July 24, 1997 by and between the Registrant and Airport Associates
10.31(9)†	Manufacture and Supply Agreement between Registrant and Spolana Chemical Works, A.S. dated May 30, 1997
10.32A(11)	Agreement between ADP Marshall, Inc. and the Registrant dated December 19, 1997
10.32B(11)	General Conditions of the Contract for Construction

Exhibit Number	Description
10.32C(11)	Addendum to General Conditions of the Contract for Construction
10.34(12)†	Agreement dated as of June 30, 1998 between Registrant and Alza Corporation
10.35(12)†	Sales Force Transition Agreement dated July 6, 1998 between Registrant and Alza Corporation
10.36(13)	Form of, "Change of Control Agreements," dated July 8, 1998 by and between the Registrant and certain Executive Officers of the Company.
10.30A(13)	Amendment of lease agreement made as of October 19, 1998 by and between Registrant and 605 East Fairchild Associates, L.P.
10.37(13)	Sublease agreement made as of November 17, 1998 between Caliper Technologies, Inc. and Registrant
10.22B(13)†	Amendment Two, dated as of December 18, 1998 by and between VIVUS, Inc. and CHINOIN Pharmaceutical and Chemical Works Co.
10.31A(13)†	Amendment One, dated as of December 12, 1998 by and between VIVUS, Inc. and Spolana Chemical Works, A.S.
10.38(14)†	License Agreement by and between ASIVI, LLC, AndroSolutions, Inc., and the Registrant dated February 29, 2000
10.38A(14)†	Operating Agreement of ASIVI, LLC, between AndroSolutions, Inc. and the Registrant dated February 29, 2000
10.39(14)	Sublease agreement between KVO Public Relations, Inc. and the Registrant dated December 21, 1999
10.40(15)†	License and Supply Agreement made as of May 23, 2000 between the Registrant and Abbott Laboratories, Inc.
10.41(16)†	License and Supply Agreement made as of November 20, 2000 between the Registrant and Paladin Labs, Inc.
10.42(16)†	Development, License and Supply Agreement made as of January 22, 2001 between the Registrant and TANABE SEIYAKU CO., LTD.
10.43(17)††	Settlement and Modification Agreement made as of July 12, 2001 between ASIVI, LLC, AndroSolutions, Inc. Gary W. Neal and the Registrant.
10.44(18)	2001 Stock Option Plan and Form of Agreement
21.2	List of Subsidiaries
23.1	Consent of Independent Public Accountants
24.1	Power of Attorney (see "Power of Attorney")

† Confidential treatment granted.
†† Confidential treatment requested.
(1) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Registration Statement on Form S-1 No. 33-75698, as amended.
(2) Incorporated by reference to the same numbered exhibit filed with the Registrant's Registration Statement on Form S-1 No. 33-90390, as amended.
(3) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1995, as amended.
(4) Incorporated by reference to the same numbered exhibit filed with the Registrant's Form 8-B filed with the Commission on June 24, 1996.
(5) Incorporated by reference to the same numbered exhibit filed with the Registrant's Current Report on Form 8-K/A filed with the Commission on June 21, 1996.
(6) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1996.

(7) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1996, as amended.
(8) Incorporated by reference to exhibit 99.1 filed with Registrant's Amendment Number 2 to the Registration Statement of Form 8-A (File No. 0-23490) filed with the Commission on April 23, 1997.
(9) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1997.
(10) Incorporated by reference to the same numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1997.
(11) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1997.
(12) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1998.
(13) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1998.
(14) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1999.
(15) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2000.
(16) 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.
(17) 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.
(18) Incorporated by reference to the same numbered exhibit filed with the Registrant's Registration Statement on Form S-8 filed with the Commission on November 15, 2001.

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

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized:

VIVUS, INC.,
a Delaware Corporation

By: /s/ RICHARD WALLISER

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

Date: February 28, 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 Richard Walliser as his attorney-in-fact for him, in any and all capacities, to sign each amendment to this Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact or his substitute or substitutes may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ LELAND F. WILSON Leland F. Wilson	President, Chief Executive Officer (Principal Executive Officer) and Director	February 28, 2002
/s/ VIRGIL A. PLACE Virgil A. Place	Chairman of the Board and Chief Scientific Officer and Director	February 28, 2002
/s/ RICHARD WALLISER Richard Walliser	Vice President of Finance and Chief Financial Officer (Principal Financial and Accounting Officer)	February 28, 2002
/s/ GRAHAM STRACHAN Graham Strachan	Director	February 28, 2002
/s/ MARIO M. ROSATI Mario M. Rosati	Director	February 28, 2002
/s/ MARK B. LOGAN Mark B. Logan	Director	February 28, 2002
/s/ LINDA M. DAIRIKI SHORTLIFFE, M.D. Linda M. Dairiki Shortliffe, M.D.	Director	February 28, 2002

VIVUS, INC.

REPORT ON FORM 10-K FOR
THE YEAR ENDED DECEMBER 31, 2001

INDEX TO EXHIBITS

Exhibit Number	Exhibit Name	Sequentially Numbered Page
21.2	List of Subsidiaries	
23.1	Consent of Independent Public Accountants	
24.1	Power of Attorney (see “Power of Attorney”)	

* Only exhibits actually filed are listed. Exhibits incorporated by reference are set forth in the exhibit listing included in Item 14 of the Report on Form 10-K.

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 INDEPENDENT PUBLIC ACCOUNTANTS

As independent public accountants, we hereby consent to the incorporation by reference of our report dated January 17, 2002 included in this Form 10-K, into the Company's previously filed Registration Statements on Form S-8 File Nos. 000-23490, 333-06486, 333-29934, 333-57374 and 333-73394.

/s/ ARTHUR ANDERSEN LLP

San Jose, California
February 28, 2002