VIVUS INC
Form 10-K
March 16, 2005

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2004

OR

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

For the transition period from to

Commission File Number 0-23490

VIVUS, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**94-3136179**
(State or other jurisdiction of incorporation or organization)	(IRS employer identification number)
1172 Castro Street Mountain View, California 94040	**(650) 934-5200**
(Address of principal executive offices and zip code)	(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 ý No o

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. o

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

The aggregate market value of the voting and non-voting Common Stock held by non-affiliates of the Registrant on June 30, 2004, the last business day of Registrant s most recently completed second fiscal quarter, was approximately $132,866,941, which is based upon the closing price of the common stock on the Nasdaq National Market. There were 36,501,907 shares of the Registrant s common stock, par value $.001, issued and outstanding held by non-affiliates of the Registrant as of June 30, 2004.

There were 38,223,488 shares of the Registrant s common stock outstanding as of February 25, 2005.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information is incorporated by reference from the Proxy Statement for the Registrant s 2005 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

VIVUS, INC.

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This Form 10-K contains forward-looking statements that involve risks and uncertainties. These statements typically may be identified by the use of forward-looking words or phrases such as believe, expect, intend, anticipate, should, planned, estimated, and potential, among o forward-looking statements included in this document are based on our current expectations, and we assume no obligation to update any such forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a safe harbor for such forward-looking statements. In order to comply with the terms of the safe harbor, we note that a variety of factors could cause actual results and experiences to differ materially from the anticipated results or other expectations expressed in such forward-looking statements. The risks and uncertainties that may affect the operations, performance, development, and results of our business include but are not limited to: (1) our history of losses and variable quarterly results; (2) substantial competition; (3) risks related to the clinical trial development of products not yet approved; (4) our reliance on sole source suppliers; (5) our limited sales and marketing efforts and our reliance on third parties; (6) failure to continue to develop innovative products; (7) risks related to noncompliance with United States Food and Drug Administration regulations; (8) risks related to the failure to protect our intellectual property and litigation in which we may become involved; and (9) other factors that are described from time to time in our periodic filings with the Securities and Exchange Commission, including those set forth in this filing as Risk Factors Affecting Operations and Future Results.

PART I

Item 1. *Business*

Overview

VIVUS, Inc. is a specialty pharmaceutical company focused on the research, development and commercialization of products to restore sexual function in women and men. Our product pipeline includes four clinical stage product candidates, each of which targets an estimated existing or potential market in excess of $1 billion annually. ALISTA®, currently in Phase 3 trials, is our product candidate for the treatment of female sexual arousal disorder. Testosterone-MDTS, which recently completed a positive Phase 2 trial, is our product candidate to treat hypoactive sexual desire disorder. Evamist®, currently in Phase 3 development, is our product candidate to alleviate symptoms associated with menopause. Avanafil, currently in Phase 2 trials, is our phosphodiesterase type 5, or PDE5, inhibitor product candidate for the treatment of erectile dysfunction.

In 1997, we launched MUSE® (alprostadil) in the United States and, together with our partners in 1998, internationally. We market MUSE as a prescription product for the treatment of erectile dysfunction. For international markets, we have entered into supply and distribution agreements with established pharmaceutical companies to market and distribute MUSE in various foreign countries. MUSE was the first minimally invasive therapy for erectile dysfunction available at a time when only more invasive therapies existed. Developing and bringing MUSE to the market provided us with experience in clinical and regulatory matters when the market for erectile dysfunction was in its infancy.

Our Product Pipeline

We currently have four research and development programs targeting female and male sexual health:

Product	Indication	Status

			Patent Expiry and Number
ALISTA			
(topical alprostadil)	Female sexual arousal disorder (FSAD)	Phase 3 ongoing	2017 (US 5,877,216)
Testosterone-MDTS	Hypoactive sexual desire disorder (HSDD)	Phase 2 completed	2017 (US 6,818,226)
Evamist (estradiol-MDTS)	Menopausal symptoms	Phase 3 ongoing	2017 (US 6,818,226)
Avanafil (PDE5 inhibitor)	Erectile dysfunction (ED)	Phase 2 ongoing	2020 (US 6,656,935)

Female Sexual Health

We believe the market for the treatment of female sexual health is large and underserved. Issues related to female sexual health include sexual disorders, such as FSAD and HSDD, as well as vasomotor symptoms associated with menopause. A paper published in the *Journal of the American Medical Association* in 1999 noted that 43% of women between the ages of 18 and 59 identified themselves as afflicted with a sexual disorder, reporting female sexual arousal disorder and hypoactive sexual desire disorder as the two most common conditions of female sexual dysfunction, or FSD. Currently, there are no pharmaceutical treatments on the market that have been approved by the United States Food and Drug Administration, or the FDA, for the treatment of these sexual disorders in women.

ALISTA

Female Sexual Arousal Disorder

FSAD, the persistent or recurrent inability to attain or maintain sufficient sexual excitement resulting in personal distress, occurs in 20 to 25% of women suffering from FSD. Sexual arousal in females involves vasodilation, or increased genital blood flow, which results in increased clitoral sensation and vaginal lubrication. Reduced vasodilation and lubrication resulting from atherosclerosis, diabetes and advancing age as well as surgeries such as hysterectomies can deleteriously affect a woman s ability to become sexually aroused.

There are no FDA-approved medical treatments for FSAD.

Our Clinical Candidate

ALISTA is a patented formulation of alprostadil that is intended for topical application to the female genitalia prior to sexual activity as an on-demand treatment for FSAD. ALISTA has been designed to increase blood flow in the genital region, allowing for greater sensitivity and sexual arousal. These positive effects have been observed as early as 5 to 15 minutes after application of ALISTA and may last up to two hours.

The active ingredient in ALISTA, alprostadil, is a synthetic version of a naturally occurring molecule found in humans. Alprostadil has been approved by the FDA for other indications, including erectile dysfunction in men. We believe the combination of alprostadil s ability to achieve vasodilation in genital tissues and its long-standing safety record and short half-life makes it an ideal agent for the treatment of FSAD.

Clinical Status

We have completed three double blind, randomized, placebo-controlled Phase 2 studies of ALISTA, all of which demonstrated statistically significant increases in arousal and/or satisfying sexual encounters in pre- and post-menopausal women with FSAD. We initiated a Phase 3 clinical trial of ALISTA in 2004 in post-menopausal women with FSAD. We anticipate that enrollment in this study will be completed by the end of 2005.

Testosterone-MDTS

Hypoactive Sexual Desire Disorder

Hypoactive sexual desire disorder, the persistent or recurrent lack of interest in sexual activity resulting in personal distress, is the most common type of female sexual dysfunction, affecting as many as 30% of women in the United States. Several studies over the last several decades have suggested that testosterone plays an important role in female sexual desire. As a woman ages, there is a decline in testosterone production. The administration of testosterone has been associated with an increase in sexual desire in both pre- and post-menopausal women. In addition to the gradual decline in testosterone that accompanies aging and natural menopause, the surgical removal of a woman s ovaries results in a decrease of approximately one half of the woman s testosterone production capability. Hence, HSDD can occur much faster, and at a younger age, in women who have undergone this type of surgically induced menopause. Furthermore, HSDD has been observed in pre-menopausal women with naturally occurring low levels of testosterone.

There are no FDA-approved medical treatments for HSDD.

Double blind, multicenter, placebo-controlled clinical trials conducted by The Procter & Gamble Company to assess the effects of a twice weekly testosterone patch demonstrated a statistically significant increase in the number of satisfying sexual events in surgically induced menopausal women. In addition, an independent clinical study has demonstrated that transdermally applied testosterone has the ability to improve sexual desire in pre-menopausal women with HSDD.

Our Clinical Candidate

Testosterone-MDTS is our patent protected, transdermal product for the treatment of HSDD in women. The active ingredient in testosterone-MDTS is the synthetic version of the testosterone that is present naturally in women and men.

Testosterone-MDTS utilizes a proprietary, metered-dose transdermal spray, or MDTS, applicator that delivers a precise amount of testosterone to the skin. We licensed the U.S. rights for this product from Acrux Limited in 2004. The metered spray enables patients to

apply a precise dose of testosterone for transdermal delivery. The applied dose dries in approximately 30 to 60 seconds and becomes invisible. Acrux studies have demonstrated that the testosterone-MDTS system delivers sustained levels of testosterone in women over a 24-hour period, achieves efficacy in increasing the number of satisfying sexual events and results in substantially lower rates of application site skin irritation than reported in women using testosterone patches.

We believe that our testosterone-MDTS product has significant advantages over patches and other transdermal gels that are being developed for this indication. The testosterone-MDTS spray allows for discreet application, unlike patches that are visible and topical gels that are messy. We believe that the patented MDTS delivery technology will prevent others from commercializing competitive therapies utilizing a spray delivery technology.

Clinical Status

In February 2005, along with Acrux, we announced positive Phase 2 results for testosterone-MDTS, which showed a statistically significant improvement in the number of satisfying sexual events in pre-menopausal patients with hypoactive sexual desire disorder.

Earlier clinical trials to assess the MDTS technology were conducted by Acrux. These studies demonstrated that application of testosterone-MDTS to the skin resulted in absorption of predictable amounts of testosterone. The amount absorbed was comparable to that absorbed on a daily basis from the Procter and Gamble transdermal testosterone patch that has been shown in Phase 3 trials to improve sexual desire in women with HSDD.

We are currently consulting with the FDA to draft protocols for our Phase 3 testosterone-MDTS trials.

Evamist

Menopausal Vasomotor Symptoms

Vasomotor symptoms such as hot flashes and vaginal atrophy are among the most common medical complaints of women going through menopause. Each year an estimated 1.5 million women in the United States enter menopause. As many as 75% of menopausal women experience vasomotor symptoms at some time during menopause, although the frequency and severity vary. The cause of vasomotor symptoms is related to a decrease in estrogen production by the ovaries that accompanies menopause. As a result, temperature regulation is altered, resulting in increased vasodilation of skin blood vessels and feelings of hot flashes and sweating. Estrogen and estradiol products are generally considered to be highly effective treatments for menopausal vasomotor symptoms. Sales of estrogen products in the United States in 2004 were estimated to be $1.4 billion.

Premarin®, an oral preparation of conjugated estrogens, is the most widely prescribed estrogen therapy in the United States. In 2004, a long-term, large-scale study that evaluated the effects of Premarin was terminated by the National Institutes of Health. This study, called the Women s Health Initiative, demonstrated an increase in the number of strokes and deep vein thromboses in women receiving Premarin as

compared to placebo. This finding may be explained by previously published studies which showed that conjugated estrogens are associated with potentially deleterious changes in triglycerides, inflammatory mediators, and certain clotting factors. We believe that these changes may be the result of the liver s metabolism of conjugated estrogens taken orally.

In contrast to orally administered conjugated estrogens, the use of transdermal estradiol, which avoids first pass metabolism by the liver, has been shown in studies to result in little or no significant changes in triglycerides, inflammatory mediators or clotting factors. Therefore, we believe transdermal estradiol may offer a safer means of treating vasomotor symptoms associated with menopause.

Our Clinical Candidate

Evamist is our patented estradiol spray being developed for the treatment of vasomotor symptoms associated with menopause. Evamist uses our proprietary, metered-dose transdermal spray applicator that delivers a precise amount of estradiol to the skin. We believe that the MDTS technology has significant advantages over patches and gels. The applied dose dries in approximately 30 to 60 seconds and becomes invisible. Acrux studies have demonstrated that the estradiol-MDTS system delivers sustained levels of estradiol in women over a 24-hour period.

Clinical Status

In December 2004, we initiated our Phase 3 study of Evamist in the United States to evaluate its safety and efficacy in menopausal women suffering from vasomotor symptoms. We have received a Special Protocol Assessment from the FDA, which is an official

agreement that designates the agreed upon terms and conditions under which we will conduct and analyze the data from our Phase 3 trial. The primary endpoint is to assess the decrease in the frequency and severity of hot flashes. We anticipate that enrollment for this trial will be complete by the end of 2005, with an anticipated NDA filing in 2006.

Male Sexual Health

Erectile dysfunction (ED), or the inability to attain or maintain an erection sufficient for intercourse, was reported by 35% of men between the ages of 40 to 70 in the United States, according to an independent study, with the incidence increasing with age. Erectile dysfunction, frequently associated with vascular problems, is particularly common in men with diabetes and in those who have had a radical prostatectomy for prostate cancer. PDE5 inhibitors such as sildenafil (Viagra®), vardenafil (Levitra®) and tadalafil (Cialis®), which inhibit the breakdown of cyclic guanosine monophosphate, have been shown to be effective treatments for ED.

The worldwide sales in 2004 of PDE5 inhibitor products for ED were in excess of $2.4 billion, including approximately $1.7 billion in sales of Viagra, approximately $550 million in sales of Cialis and approximately $150 million in sales of Levitra. Based on the aging baby boomer population and their desire to maintain an active sexual lifestyle, we believe the market for PDE5 inhibitors will continue to grow.

Avanafil

Our Clinical Candidate

We are developing avanafil, an orally administered PDE5 inhibitor, which we licensed from Tanabe Seiyaku Co., Ltd., or Tanabe, in 2001. We have exclusive worldwide development and commercialization rights for avanafil with the exception of certain Asian markets.

Pre-clinical and clinical data suggests that avanafil:

- is highly selective to PDE5, which we believe should result in a favorable side effect profile;
- has a shorter half-life than currently approved PDE5 inhibitors; and
- is comparably fast-acting to currently available PDE5 inhibitors.

While PDE5 inhibitors currently on the market are often effective in treating ED, newer drugs that possess better specificity for the PDE5 enzyme may be safer. In addition to PDE5, there are at least ten other types of PDE enzymes in the human body. Drugs that inhibit more than one of these enzymes can potentially cause significant adverse side effects, depending on the enzymes that are affected. In an internal study conducted by Tanabe comparing the activity of avanafil, sildenafil, tadalafil and vardenafil against all 11 of the known PDE enzymes, Tanabe found that avanafil demonstrated the best specificity for PDE5, with little activity against the other enzymes.

Avanafil possesses a shorter plasma half-life than other PDE5 inhibitors currently on the market. The plasma half-life of a drug is the amount of time required for 50% of the drug to be removed from the bloodstream. In general, the shorter the half-life of a drug, the less potential there is for the drug to interact with other drugs that may also be in the bloodstream. All approved PDE5 inhibitors are required by the FDA to include warnings against taking nitrates after administration. For example, Cialis s label warns patients not to take nitrates within 48 hours of administration. Approximately 5.5 million men take nitrates on a regular basis for angina pectoris and another half million annually will experience a heart attack and are potential candidates for nitrate therapy. Sildenafil and vardenafil possess plasma half-lives of approximately four hours, and tadalafil has an extended half-life of 17 to 18 hours. The plasma half-life of avanafil, however, is between approximately 60 and 90 minutes, which means that it is removed from the bloodstream faster than the other currently available PDE5 inhibitors. We believe avanafil s short half-life, high specificity and fast on-set of action are ideal characteristics for an on-demand treatment for ED.

Clinical Status

We have completed enrollment of a Phase 2, double blind, placebo-controlled, dose ranging study for avanafil and we anticipate data will be available in 2005. We anticipate that results from this study will allow us to finalize plans for Phase 3 studies.

We have conducted a number of clinical trials with avanafil, including pharmacokinetic and in-clinic studies as well as at-home efficacy trials in men with ED. These trials have demonstrated that avanafil has a fast onset of action, with activity apparent as soon as 15

to 20 minutes after administration. In an internal study comparing avanafil to Viagra in men with ED, the efficacy of the two PDE5 inhibitors was comparable.

Our Marketed Product

MUSE

In 1997, we commercially launched MUSE in the United States. MUSE was the first minimally invasive therapy for erectile dysfunction approved by the FDA. With MUSE, an erection is typically produced within 15 minutes of administration and lasts approximately 30 to 60 minutes. Alprostadil is the active pharmacologic agent used in MUSE. Alprostadil is the generic name for the synthetic version of prostaglandin E1, a naturally occurring vasodilator present in the human body and at high levels in seminal fluid.

MUSE is designed to overcome the limitations of other available therapies through its unique product attributes. Because therapeutic levels of drug are delivered locally to the erectile tissues with minimal systemic drug exposure, MUSE is a safe, local treatment that minimizes the chances of systemic interactions with other drugs or diseases. Because it mimics the normal vasoactive process, MUSE produces an erection that is more natural than those resulting from needle injection therapy, vacuum constriction devices or penile implants. Over 10 million units of MUSE have been sold since we introduced MUSE to the market.

Other Programs

We have licensed and will continue to license from third parties the rights to other products to treat various sexual and nonsexual disorders. We also sponsor early stage clinical trials at various research institutions. We will continue to use our expertise in designing clinical trials, formulation and product development to commercialize pharmaceuticals for unmet medical needs or for disease states that are underserved by currently approved products. We intend to develop products with a proprietary position or that complement our other products currently under development. We have several programs in early clinical development. Depending on the outcomes of these early studies, we may continue development of these products.

Government Regulations

FDA Regulation

Prescription pharmaceutical products are subject to extensive pre- and post-marketing regulation by the FDA, including regulations that govern the testing, manufacturing, safety, efficacy, labeling, storage, record-keeping, advertising and promotion of the products under the Federal Food, Drug and Cosmetic Act and the Public Health Services Act, and by comparable agencies in most foreign countries. The process required by the FDA before a new drug may be marketed in the U.S. generally involves the following: completion of pre-clinical laboratory and animal testing; submission of an investigational new drug application, or IND, which must become effective before clinical trials may begin; performance of adequate and well controlled human clinical trials to establish the safety and efficacy of the proposed drug s intended use; and approval by the

FDA of a New Drug Application, or NDA.

The activities required before a pharmaceutical agent may be marketed in the United States begin with pre-clinical testing. Pre-clinical tests include laboratory evaluation of potential products and animal studies to assess the potential safety and efficacy of the product and its formulations. The results of these studies and other information must be submitted to the FDA as part of an IND application, which must be reviewed and approved by the FDA before proposed clinical testing can begin. Clinical trials involve the administration of the investigational new drug to healthy volunteers or to patients under the supervision of a qualified principal investigator. Clinical trials are conducted in accordance with Good Clinical Practices under protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND application. Further, each clinical study must be conducted under the auspices of an independent institutional review board. The institutional review board will consider, among other things, ethical factors and the safety of human subjects.

Typically, human clinical trials are conducted in three phases that may overlap. In Phase 1, clinical trials are conducted with a small number of subjects to determine the early safety profile and pharmacology of the new therapy. In Phase 2, clinical trials are conducted with groups of patients afflicted with a specific disease in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety. In Phase 3, large scale, multicenter, comparative clinical trials are conducted with patients afflicted with a target disease in order to provide enough data for the statistical proof of efficacy and safety required by the FDA and others.

The results of the pre-clinical and clinical testing, together with chemistry and manufacturing information, are submitted to the FDA in the form of an NDA for a pharmaceutical product in order to obtain approval to commence commercial sales. In responding to an NDA, the FDA may grant marketing approvals, request additional information or further research, or deny the application if it determines that the application does not satisfy its regulatory approval criteria. Patient-specific therapies may be subject to additional risk with respect to the regulatory review process. FDA approval for a pharmaceutical product may not be granted on a timely basis, if at all, or if granted may not cover all the clinical indications for which approval is sought or may contain significant limitations in the form of warnings, precautions or contraindications with respect to conditions of use.

Satisfaction of FDA premarket approval requirements for new drugs typically takes several years, and the actual time required may vary substantially based upon the type, complexity and novelty of the product or targeted disease. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon our activities. Success in early stage clinical trials or with prior versions of products does not assure success in later stage clinical trials. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval.

Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require post-marketing studies, referred to as Phase 4 studies, to monitor the effect of an approved product, and may limit further marketing of the product based on the results of these post-market studies. The FDA has broad post-market regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, or withdraw approvals.

Facilities used to manufacture drugs are subject to periodic inspection by the FDA, DEA and other authorities where applicable, and must comply with the FDA s cGMP regulations. Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product or voluntary recall of a product. Adverse experiences with the product must be reported to the FDA and could result in the imposition of market restriction through labeling changes or in product removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval.

With respect to post-market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals, which include, among other things, standards and regulations relating to direct-to-consumer advertising, off-label promotion, industry sponsored scientific and educational activities, and promotional activities involving the Internet. The FDA has very broad enforcement authority under the Federal Food, Drug and Cosmetic Act, and failure to abide by these regulations can result in penalties including the issuance of a warning letter directing the entity to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and state and federal civil and criminal investigations and prosecutions.

We are subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the government has broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect upon us.

Other Government Regulations

In addition to laws and regulations enforced by the FDA, we are also subject to regulation under National Institutes of Health guidelines, as well as under the Controlled Substances Act, the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential future federal, state or local laws and regulations, as our research and development involves the controlled use of hazardous materials, chemicals, viruses and various radioactive compounds.

In addition to regulations in the United States, we are subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of MUSE and our product candidates. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Corporate Collaborations and Licenses from Third Parties

Tanabe

In January 2001, we entered into an exclusive development, license and supply agreement with Tanabe for the development and commercialization of avanafil, a PDE5 inhibitor compound for the oral and local treatment of male and female sexual dysfunction. Tanabe is one of Japan s leading pharmaceutical companies with revenues of over $1.6 billion in 2004.

Under the terms of the agreement, Tanabe agreed to grant an exclusive license to us for products containing avanafil outside of Japan, North Korea, South Korea, China, Taiwan, Singapore, Indonesia, Malaysia, Thailand, Vietnam and the Philippines. We agreed to grant Tanabe an exclusive, royalty-free license within those countries for oral products that we develop containing avanafil. In addition, we agreed to grant Tanabe an exclusive option to obtain an exclusive, royalty-bearing license within those countries for non-oral products that we develop containing avanafil. Further, we granted Tanabe the option to obtain co-promotional rights for oral products that we develop under our license for up to 25% of the promotional activity in our territory. Tanabe agreed to manufacture and supply us with avanafil for use in clinical trials, which will be our primary responsibility.

We have paid upfront licensing fees to Tanabe and have agreed to make additional payments upon the completion of certain development, regulatory and sales milestones. We have further agreed to pay royalties on net sales of products containing avanafil. During the first quarter of 2004, we initiated a Phase 2 clinical trial with avanafil, which meets one of the milestone criteria above. We intend to pay Tanabe $2.0 million in connection with this milestone in March 2006.

In the first quarter of 2004, we also entered into a secured line of credit agreement with Tanabe Holding America, Inc., a subsidiary of Tanabe, allowing us to borrow up to $8.5 million to be used for the development of avanafil. We can draw upon the line of credit quarterly, with a 48-month term on each drawdown bearing 2% annual interest. We are not obligated under any financial covenants in connection with this agreement. As of December 31, 2004, we had long-term notes payable to Tanabe Holding America, Inc. of $3.2 million, and $5.3 million available for future borrowing.

Acrux

In February 2004, we entered into exclusive licensing agreements with Acrux Limited and a subsidiary of Acrux under which we have agreed to develop and commercialize testosterone-MDTS and Evamist in the United States for various female health applications. Acrux s metered-dose transdermal spray, or MDTS, technology is a patented, simple to use spray that is being developed to deliver testosterone and estradiol effectively to women when applied to the skin. We agreed to grant Acrux s subsidiary a non-exclusive, royalty-free license outside the United States for any MDTS products containing improvements we have made to the licensed intellectual property and the option to obtain a non-exclusive, worldwide license for our intellectual property related to MDTS products.

Under the terms of the agreements, we agreed to pay to Acrux combined licensing fees of $3.0 million over the 17 month period beginning in February 2004, up to $4.3 million for the achievement of certain clinical development milestones, up to $6.0 million for achieving product approval milestones, and royalties on net sales in the United States upon commercialization of each product.

Patents and Proprietary Technology

We hold 31 patents and 9 patent applications in the United States and related patents and patent applications in major foreign jurisdictions. We intend to develop, maintain and secure intellectual property rights and to aggressively defend and pursue new patents to expand upon our current patent base.

We have developed and acquired exclusive rights to patented technology in support of our development and commercialization of our products, and we rely on trade secrets and proprietary technologies in developing potential products. 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.

Manufacturing

We lease 90,000 square feet of space in Lakewood, New Jersey for our manufacturing operation, which includes formulation, filling, packaging, analytical laboratories, storage, distribution and administrative offices. The facility is cGMP certified and includes class 10,000 clean rooms used in the sterile production of MUSE. The FDA and the Medicines and Healthcare Products Regulatory

Agency, the regulatory authority in the United Kingdom, authorized us to begin commercial production and shipment of MUSE from this facility in June and March 1998, respectively. We manufacture all of the worldwide demand for MUSE in this facility.

In addition to manufacturing, we have fully integrated manufacturing support systems including quality assurance, quality control and regulatory compliance. These support systems enable us to maintain high standards of quality for our products and simultaneously deliver reliable services and goods to our customers on a timely basis.

Sales and Marketing

We plan to market Evamist, if approved by the FDA, through a 40 to 50 person sales force calling on OB/GYN doctors, the primary prescribers of hormone therapies. We believe our direct marketing of Evamist will allow us to establish relationships with the OB/GYN physician community and to familiarize them with our MDTS technology in anticipation of testosterone-MDTS entering the market. We intend to use these relationships to promote testosterone-MDTS and ALISTA, our future product candidates in the female sexual health market.

For avanafil, we intend to enter into an agreement with a development and marketing partner that will provide commercial support for this primary care product, as well as financial support for future late-stage development activities. We plan to retain co-promotional rights and to use our existing specialty sales organization to market this product.

We support MUSE sales in the United States with a direct sales team comprised of regional sales managers and telesales personnel calling on specialist physicians. We participate in national urologic and sexual dysfunction forums and conferences, such as the American Urological Association annual meeting and the International Society for Impotence Research.

We signed an international distribution agreement with Meda in September 2002. According to the agreement, Meda will purchase MUSE from us for resale in member states of the European Union and certain other European countries. In November 2000, we granted Paladin Labs the exclusive rights to distribute and market MUSE in Canada.

Competition

Competition in the pharmaceutical and medical products industries is intense and is characterized by extensive research efforts and rapid technological progress. Several large pharmaceutical companies are also actively engaged in the development of therapies for the treatment of female sexual dysfunction and male erectile dysfunction.

The most significant competitive therapy for MUSE is an oral medication marketed by Pfizer under the name Viagra, which received regulatory approvals in the United States in March 1998 and in the European Union in September 1998. The commercial launch of Viagra in the United States in April 1998 significantly decreased demand for MUSE. In February 2003, an oral medication under the name Cialis was launched in Europe by Lilly ICOS LLC and in Australia and New Zealand by Eli Lilly and Company alone. Lilly ICOS LLC launched Cialis in the United States in November 2003. Bayer AG and GlaxoSmithKline plc launched Levitra in the European Union in March 2003 and in the United States

in September 2003.

Other treatments for erectile dysfunction exist, such as needle injection therapies, vacuum constriction devices and penile implants, and the manufacturers of these products will most likely continue to improve these therapies.

Several companies are developing products that could compete with our clinical candidates for the treatment of FSD.

NexMed, Inc. is developing Femprox, an alprostadil cream for the treatment of FSAD.

The Proctor & Gamble Company is developing a testosterone patch for the treatment of HSDD.

BioSante Pharmaceuticals, Inc., Cellegy Pharmaceuticals, Inc. and Novavax, Inc. are developing forms of testosterone gels and creams for HSDD.

Nastech Pharmaceutical Company Inc. and Palatin Technologies, Inc. are also developing various nasal sprays to treat FSD.

None of these products have been approved by the FDA.

Employees

As of February 28, 2005, we had 114 employees, including 79 of which are located at our manufacturing facility in Lakewood, New Jersey and 35 of which are located at our corporate headquarters in Mountain View, California and other United States and international locations. None of our current employees are represented by a labor union or are the subject of a collective bargaining agreement. We believe that we maintain good relations with our employees.

Legal Proceedings

We are not currently involved in any legal proceedings that are material to our business.

RISK FACTORS AFFECTING OPERATIONS AND FUTURE RESULTS

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

Risks Relating to our Product Development Efforts

We face significant risks in our product development efforts.

The process of developing new drugs and/or therapeutic products is inherently complex, time-consuming, expensive and uncertain. We must make long-term investments and commit significant resources before knowing whether our development programs will result in products that will receive regulatory approval and achieve market acceptance. Product candidates that may appear to be promising at early stages of development may not reach the market for a number of reasons. Product candidates may be found ineffective or may cause harmful side effects during clinical trials, may take longer to progress through clinical trials than had been anticipated, may fail to receive necessary regulatory approvals, may prove impracticable to manufacture in commercial quantities at reasonable cost and with acceptable quality or may fail to achieve market acceptance.

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

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

inability to manufacture sufficient quantities of compounds for use in clinical trials;

failure to receive approval by the United States Food and Drug Administration, or FDA, of our clinical trial protocols;

the effectiveness of our product candidates;

slower than expected rate of patient recruitment;

inability to adequately follow patients after treatment;

unforeseen safety issues; or

government or regulatory delays.

To date, the clinical results we have obtained 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 materially harmed.

We are exposed to risks related to collaborative arrangements or strategic alliances.

We are, and in the future expect to be, dependent upon collaborative arrangements or strategic alliances to complete the development and commercialization of some of our drug candidates particularly after the Phase 2 stage of clinical testing. These arrangements may place the development of our drug candidates outside of our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

We may be unable to locate and enter into favorable agreements with third parties, which could delay or impair our ability to develop and commercialize our drug candidates and could increase our costs of development and commercialization. Dependence on collaborative arrangements or strategic alliances will subject us to a number of risks, including the risk that:

we may not be able to control the amount and timing of resources that our collaborators may devote to the drug candidates;

our collaborators may experience financial difficulties;

we may be required to relinquish important rights such as marketing and distribution rights;

business combinations or significant changes in a collaborator s business strategy may also adversely affect a collaborator s willingness or ability to complete its obligations under any arrangement;

a collaborator could independently move forward with a competing drug candidate developed either independently or in collaboration with others, including our competitors; and

collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing our drug candidates.

We face significant governmental regulation during our product development activities.

The research, testing, manufacturing, selling and marketing of drug candidates are subject to extensive regulations by the FDA and other regulatory agencies in the United States and other countries. We cannot predict with certainty if or when we might submit for regulatory review those product candidates currently under development. 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.

Regulatory approval is never guaranteed, and the approval process typically takes several years and is extremely expensive. The FDA has substantial discretion in the drug approval process. Despite the time and expense involved, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional pre-clinical trials and clinical trials. The number of pre-clinical studies and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease condition that the drug candidate is designed to address and the regulations applicable to any particular drug candidate. The FDA could determine that additional studies are required before and after a product candidate will be approved.

For example, in December 2004, an FDA advisory panel recommended against approval of a testosterone patch being developed by another company to address female sexual dysfunction, specifically hypoactive sexual desire disorder, and indicated that more safety data would be required before it would be in a position to recommend approval. Subsequently, this company withdrew its New Drug Application, or NDA. We are also developing a transdermal testosterone product candidate, testosterone-MDTS, that is designed to address hypoactive sexual desire

disorder. In light of the FDA panel s recommendation, we may be required to undertake additional or expanded clinical trials, which could be expensive. As a result, we could experience delays in our ability to submit our product candidate to the FDA for consideration, and we may be unsuccessful in obtaining FDA approval of our product candidate.

We are not permitted to market any of our product candidates in the United States until we receive approval from the FDA. As a consequence, any failure to obtain or delay in obtaining FDA approval for our drug candidates would delay or prevent our ability to generate revenue from our product candidates, which would adversely affect our financial results and our business.

Our applications for regulatory approval could be delayed or denied due to problems with studies conducted before we licensed some of our product candidates from third parties.

We currently license some of our product candidates from third parties. Our present development programs involving these product candidates rely upon previous development work conducted by third parties over which we had no control and before we licensed the product candidates. In order to receive regulatory approval of a product candidate, we must present all relevant data and information obtained during research and development, including research conducted prior to our license of the product candidate. Although we are not currently aware of any such problems, any problems that emerge with research and testing conducted prior to our licensing a product candidate may affect future results or our ability to document prior research and to conduct clinical trials, which could delay, limit or prevent regulatory approval for our product candidates.

Following regulatory approval of any drug candidates, we would be subject to ongoing regulatory obligations and restrictions, which may result in significant expense and limit our ability to commercialize our potential drugs.

If one of our drug candidates is approved by the FDA or by another regulatory authority for a territory outside of the United States, we would be held to extensive regulatory requirements over product manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping. Regulatory approvals may also be subject to significant limitations on the indicated uses or marketing of the drug candidates. Potentially costly follow-up or post-marketing clinical studies may be required as a condition of approval to further substantiate safety or efficacy, or to investigate specific issues of interest to the regulatory authority. Previously unknown problems with the drug candidate, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the drug, and could lead to the withdrawal of the drug from the market.

In addition, the law or regulatory policies governing pharmaceuticals may change. New statutory requirements may be enacted or additional regulations may be enacted that could prevent or delay regulatory approval of our drug candidates. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or elsewhere. If we are not able to maintain regulatory compliance, we might not be permitted to market our drugs and our business could suffer.

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

Like many companies our size, we do not have the ability to conduct clinical studies for our product candidates by ourselves without the assistance of third parties who conduct the studies on our behalf. These third parties are usually clinical research organizations, or CROs, that have significant resources and experience in the conduct of clinical studies. The CROs typically perform patient recruitment, project management, data management, statistical analysis, and other reporting functions. We intend to use several different CROs for all of our clinical studies. If these third party CROs 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 on a timely basis, if at all, and we may not be able to successfully commercialize these proposed products. If these third party CROs do not perform satisfactorily, we may not be able to locate acceptable replacements or enter into favorable agreements with them, if at all.

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

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

Risks Relating to our Operations

If we, or our suppliers, fail to comply with FDA and other government regulations relating to our manufacturing operations, we may be prevented from manufacturing our products or may be required to undertake significant expenditures to become compliant with regulations.

After regulatory approval for a drug candidate is obtained, the candidate is subject to continual regulatory review. Manufacturing, labeling and promotional activities are continually regulated by the FDA and equivalent foreign regulatory agencies. For example, our third-party manufacturers are required to maintain satisfactory compliance with current Good Manufacturing Practices, or cGMPs. If these manufacturers fail to comply with applicable regulatory requirements, our ability to manufacture, market and distribute our products may be adversely affected. In addition, the FDA could issue warning letters or could require the seizure or recall of products. The FDA could also issue warning letters, impose civil penalties or require the closure of our manufacturing facility until 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. We and these suppliers and service providers are required to follow cGMP requirements and are subject to routine and unannounced inspections by the FDA and by state and foreign regulatory agencies for compliance with cGMP requirements and other applicable regulations. Upon

inspection of these facilities, the FDA or foreign regulatory agencies may find the manufacturing process or facilities are not in compliance with cGMP requirements and other regulations.

Failure to achieve satisfactory cGMP compliance as confirmed by routine and 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.

Our marketing activities for our products are subject to continued governmental regulation.

After product approval by the FDA, our labeling and marketing activities continue to be subject to FDA and other regulatory review. If products are marketed in contradiction with FDA mandates, the FDA may issue warning letters that require specific remedial measures to be taken, as well as an immediate cessation of the impermissible conduct. For example, the FDA issued a warning letter to us in May 2004 in which the FDA objected to a specific television commercial, as well as information contained on our website, promoting MUSE, our FDA approved product for the treatment of erectile dysfunction. The letter indicated that we had failed to disclose or had minimized certain risks associated with MUSE. Through discussions with the FDA, we agreed to produce and have released a television commercial that we believe addressed the FDA s concerns. We incurred costs in providing this corrective information, which would have otherwise been utilized by us in a different manner.

We must continue to monitor the use of our approved drugs and may be required to complete post-approval studies mandated by the FDA.

Even if we receive regulatory approval of our products, such approval may involve limitations on the indicated uses or marketing claims we may make for our products. Further, later discovery of previously unknown problems could result in additional regulatory restrictions, including withdrawal of products. The FDA may also require us to commit to perform lengthy post-approval studies, for which we would have to expend significant additional resources, which could have an adverse effect on our operating results and financial condition. Failure to comply with the applicable regulatory requirements can result in, among other things, civil penalties, suspensions of regulatory approvals, product recalls, operating restrictions and criminal prosecution. The 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.

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

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

Sales of our current and any future products are subject to continued governmental regulation, our ability to accurately forecast demand and our ability to produce sufficient quantities to meet demand.

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 have limited sales and marketing capabilities in the United States.

We support MUSE sales in the United States through a small direct sales force targeting major accounts. Telephone marketers also focus on urologists who prescribe MUSE. Physician and patient information/help telephone lines are available to answer additional

questions that may arise after reading the inserts or after actual use of the product. The sales force actively participates in national urologic and sexual dysfunction forums and conferences, such as the American Urological Association annual and regional meetings and the International Society for Impotence Research. There can be no assurance that our sales programs will effectively maintain or potentially increase current sales levels. There can be no assurance that demand for MUSE will continue or that we will be able to adequately support sales of MUSE in the United States in the future.

We have little or no control over our wholesalers buying patterns, which may impact future revenues, returns and excess inventory.

For domestic sales we sell our product primarily to major wholesalers located in the United States. Consistent with the pharmaceutical industry, most of our revenues are derived from the three major wholesalers. We rely solely on our wholesaler customers to effect the distribution allocation of our product. There can be no assurance that these customers will adequately manage their local and regional inventories to avoid outages, build-ups or result in excessive returns for expiration.

We do not control or significantly influence the purchasing patterns of wholesale customers. These are highly sophisticated customers that purchase our product in a manner consistent with their industry practices and perceived business interests. Our sales are subject to the purchasing requirements of our major customers, which presumably are based upon projected volume levels. Purchases by any customer, during any period may be above or below the actual prescription volumes of our product during the same period, resulting in increases or decreases in inventory existing in the distribution channel.

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

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

The most significant competitive therapy for MUSE is an oral medication marketed by Pfizer Inc. 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. In February 2003, a new oral medication under the name Cialis was launched in Europe by Lilly ICOS LLC and in Australia and New Zealand by Eli Lilly and Company alone. Lilly ICOS LLC launched Cialis in the United States in November 2003. Bayer AG and GlaxoSmithKline plc launched Levitra in the European Union and the United States in March and September 2003, respectively.

Worldwide product revenues from the sales of MUSE were $19.4 million in 2004, a decrease of $2.8 million, or 13%, from the worldwide sales of MUSE in 2003. The change in revenues is mainly due to decreased demand for MUSE. The launch of new PDE5 inhibitors and the associated direct-to-consumer advertising and aggressive sampling opportunities for all PDE5 inhibitors contributed to the decline in demand for MUSE. In addition, based on the current demand for MUSE, as measured by independent third party prescription data, we estimate purchases made by

wholesalers ahead of our annual price increase in the fourth quarter of 2004, represent approximately 6 to 7 months of demand. As a result of the decrease in demand and the strategic buying in the fourth quarter by our wholesalers, combined with the promotional efforts of all PDE5 inhibitors, we anticipate worldwide revenues of MUSE will decline in 2005.

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

We are required to receive regulatory approval for suppliers. We obtained our current supply of alprostadil from two approved sources, NeraPharm, s.r.o., in the Czech Republic and Chinoin Pharmaceutical and Chemical Works Co., Ltd., in Hungary. We have manufacturing agreements with Chinoin and NeraPharm to produce additional quantities of alprostadil for us. We are currently in the process of investigating additional

sources for our future alprostadil supplies. However, there can be no assurance that we will be able to identify and qualify additional suppliers of alprostadil in a timely manner, or at all.

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

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

Under our outsourcing agreement with Cardinal Health, Inc. related to MUSE, Cardinal Health warehouses our finished goods for United States distribution; takes customer orders; picks, packs and ships our products; invoices customers; and collects related receivables. As a result of this distribution agreement, we are heavily dependent on Cardinal Health s efforts to fulfill orders and warehouse our products effectively in the United States. There can be no assurance that such efforts will continue to be successful.

Under our testing agreement, Gibraltar Laboratories performs sterility testing on finished product manufactured by us to ensure that it complies with product specifications. Gibraltar Laboratories also performs microbial testing on water and compressed gases used in the manufacturing process and microbial testing on environmental samples to ensure that the manufacturing environment meets appropriate cGMP regulations and cleanliness standards. As a result of this testing agreement, we are dependent on Gibraltar Laboratories to perform testing and issue reports on finished product and the manufacturing environment in a manner that meets cGMP regulations.

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

We entered into a distribution agreement with Integrated Commercialization Services, or ICS, a subsidiary of AmerisourceBergen Corporation. ICS provides direct-to-physician distribution of product samples 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.

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

We rely on a single injection molding company, Medegen Medical Products, LLC, for our supply of plastic applicator components. In turn, Medegen obtains its supply of resin, a key ingredient of the applicator, from a single source, Huntsman Corporation. There can be no assurance that we will be able to identify and qualify additional sources of plastic components or that Medegen will be able to identify and qualify additional sources of resin. We are required to receive FDA approval for new suppliers. Until we secure and qualify additional sources of plastic components, we are entirely dependent upon Medegen. If interruptions in this supply occur for any reason, including a decision by Medegen to

discontinue manufacturing, labor disputes or a failure of Medegen to follow regulations, the manufacture and 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 or results of operations.

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

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

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

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

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, sales and marketing, research and development, regulatory affairs, clinical trial management and pre-clinical testing. There can be no assurance that we will be able to hire or retain such personnel, as we must compete with other companies, academic institutions, government entities and other agencies. The loss of any of our key personnel or the failure to attract or retain necessary new employees could have an adverse effect on our research, product development and business operations.

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

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

Defending against claims relating to improper handling, storage or disposal of hazardous materials could be time consuming and expensive.

Our research and development involves the controlled use of hazardous materials and our operations produce hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from those materials. Various laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. We may be sued for any injury or contamination that results from our use or the use by third parties of these materials. Compliance with environmental laws and regulations may be expensive, and current

or future environmental regulations may impair our research, development and production efforts.

Risks Relating to our Intellectual Property

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

There can be no assurance that our products do not or will not infringe on the patent or proprietary rights of others. Third parties may assert that we are employing their proprietary technology without authorization. For example, in October 2002, the PTO issued to Pfizer a method of use U.S. Patent No. 6,469,012. Pfizer immediately initiated litigation against competitors who were selling PDE5 inhibitors, including ICOS, the maker of Cialis. In September 2003, the PTO ordered the reexamination of the patent. In a related action, the European Patent Office revoked Pfizer s European patent. However, if the claims under the method of use patent are upheld by the PTO, we may be prevented from commercializing avanafil, our PDE5 inhibitor.

In addition, third parties may obtain patents in the future and claim that use of our technologies infringes these patents. We could incur substantial costs and diversion of the time and attention of management and technical personnel in defending ourselves against any such claims. Furthermore, parties making claims against us may be able to obtain injunctive or other equitable relief that could effectively block our ability to further develop, commercialize and sell products, and such claims could result in the award of substantial damages against us. In the event of a successful claim of infringement against us, we may be required to pay damages and obtain one or more licenses from third parties. We may not be able to obtain these licenses at a reasonable cost, if at all. In that case, we could encounter delays in product introductions while we attempt to develop alternative methods or products or be required to cease commercializing affected products and our operating results would be harmed.

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

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

The patent positions of pharmaceutical companies, including our patent position, are often uncertain and involve complex legal and factual questions. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. We apply for patents covering our technologies and products, as we deem appropriate. However, we may not obtain patents on all inventions for which we seek patents, and any patents we obtain may be challenged and may be narrowed in scope or extinguished as a result of such challenges. We could incur substantial costs in proceedings before the United States Patent and Trademark Office, including interference proceedings. These proceedings could also result in adverse decisions as to the priority of our inventions. There can be no assurance that our patents will not be successfully challenged or designed around by others.

Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Others may independently develop similar or alternative technologies or design around our patented technologies or products. These companies would then be able to develop, manufacture and sell products that compete directly with our products. In that case, our revenues and operating results would decline.

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

Risks Relating to our Financial Position and Need for Financing

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

Our capital resources are expected to continue to decline over the next several quarters as the result of increased spending on research and development projects, including clinical trials. On March 15, 2005, we sold 6,250,000 shares of our common stock at a price of $3.40 per share providing us with net proceeds of $19.6 million. We also granted the underwriters a 30-day option to purchase up to an additional 937,500 shares to cover over-allotments. We expect that our existing capital resources combined with future cash flows will be sufficient to support our operating activities through the end of 2006. However, we anticipate that we will be required to obtain additional financing to fund the development of our research and development pipeline in future periods as well as to support the possible launch of any future products. Our future capital requirements will depend upon numerous factors, including:

the progress and costs of our research and development programs;

the scope, timing and results of clinical trials;

patient recruitment and enrollment in current and future clinical trials;

the results of operations;

the cost, timing and outcome of regulatory reviews;

the rate of technological advances;

ongoing determinations of the potential commercial success of our products under development;

the level of resources devoted to sales and marketing capabilities; and

the activities of competitors.

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

We have an accumulated deficit of $122.5 million as of December 31, 2004 and expect to continue to incur substantial operating losses for the foreseeable future.

We have generated a cumulative net loss of $122.5 million for the period from our inception through December 31, 2004 and we anticipate losses for the next several years due to increased investment in our research and development programs and limited revenues. There can be no assurance that we will be able to achieve profitability or that we will be successful in the future.

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

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

Risks Relating to an Investment in our Common Stock

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

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

announcements of technological innovations or new products by us or our competitors;

announcements by licensors of our technology;

our ability to increase demand for our products in the United States and internationally;

our ability to successfully sell our products in the United States and internationally;

actual or anticipated fluctuations in our financial results;

our ability to obtain needed financing;

economic conditions in the United States and abroad;

comments by or changes in assessments of us or financial estimates by security analysts;

adverse regulatory actions or decisions;

any loss of key management;

the results of our clinical trials or those of our competitors;

developments or disputes concerning patents or other proprietary rights;

product or patent litigation; and

public concern as to the safety of products developed by us.

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

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

Volatility in the stock prices of other companies may contribute to volatility in our stock price.

The stock market in general, and the Nasdaq National Market and the market for life sciences companies in particular, have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Further, there has been particular volatility in the market prices of securities of early stage and development stage life sciences companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance.

Our share ownership is concentrated, and our officers, directors and principal stockholders can exert significant control over matters requiring stockholder approval.

Due to their combined stock holdings, our officers, directors and principal stockholders (stockholders holding greater than 5% of our common stock) acting collectively may have the ability to exercise significant influence over matters requiring stockholder approval including the election of directors and approval of significant corporate transactions. In addition, this concentration of ownership may delay or prevent a change in control of the Company and may make some transactions more difficult or impossible to complete without the support of these stockholders.

Our operating results may fluctuate from quarter to quarter and this fluctuation may cause our stock price to decline.

Our quarterly operating results have fluctuated in the past and are likely to fluctuate in the future. Factors contributing to these fluctuations include, among other items, the timing and enrollment rates of clinical trials for our drug candidates, the timing of significant purchases of MUSE by distributors, our need for clinical supplies and the re-measurement of certain deferred stock compensation. Thus, quarter-to-quarter comparisons of our operating results are not indicative of what we might expect in the future. As a result, in some future quarters our operating results may not meet the expectations of securities analysts and investors, which could result in a decline in the price of our stock.

There may not be an active, liquid trading market for our common stock.

There is no guarantee that an active trading market for our common stock will be maintained on the Nasdaq National Market. Investors may not be able to sell their shares quickly or at the latest market price if trading in our stock is not active.

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

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

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

authorize the issuance of preferred stock by the Board of Directors without prior stockholder approval, commonly referred to as blank check preferred stock, with rights senior to those of common stock;

prohibit stockholder actions by written consent;

specify procedures for director nominations by stockholders and submission of other proposals for consideration at stockholder meetings; and

eliminate cumulative voting in the election of directors.

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

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

Effective June 30, 2005, the Financial Accounting Standards Board requires all companies to treat the value of stock options granted to employees as an expense. This expense would be spread over the vesting period of the stock option. Currently, we account for stock compensation under Accounting Principles Board, or APB, No. 25, Accounting for Stock Issued to Employees, which results in no compensation expenses recorded in connection with stock options granted to our employees. When we are required to expense stock option grants, it will reduce the attractiveness of granting stock options because of the additional expense associated with these grants, which will reduce our profitability. However, stock options are an important employee recruitment and retention tool, and we may not be able to attract and retain key personnel if we reduce the scope of our employee stock option program. Accordingly, when we are required to expense stock option grants, our profitability would be reduced, as would our ability to use stock options as an employee recruitment and retention tool.

In December 2004, the Financial Accounting Standards Board (FASB) issued revised statement No. 123 (FAS 123R), *Share-Based Payment*, which requires companies to expense the estimated fair value of employee stock options and similar awards. The accounting provisions of FAS 123R will be effective for the third quarter of fiscal 2005. We will adopt the provisions of FAS 123R using a modified prospective application. Under modified prospective application, FAS 123R, which provides certain changes to the method for valuing stock-based compensation among other changes, will apply to new awards and to awards that are outstanding on the effective date and are subsequently modified or cancelled. Further compensation expense for outstanding awards for which the requisite service had not been rendered as of the effective date will be recognized over the remaining service period using the compensation cost calculated for pro forma disclosure purposes under FAS 123. We are in the process of determining how the new method of valuing stock-based compensation as prescribed in FAS 123R will be applied to valuing stock-based awards granted after the effective date and the impact the recognition of compensation expense related to such awards will have on our consolidated financial statements.

Item 2. ***Properties***

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

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

Item 3. ***Legal Proceedings***

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

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

We did not submit any matters to a vote of security holders during the fourth quarter of the fiscal year ended December 31, 2004.

PART II

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

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

	Three Months Ended			
	March 31	**June 30**	**September 30**	**December 31**
2004				
High	$ 7.20	$ 6.50	$ 5.10	$ 6.18
Low	4.13	3.61	3.61	4.27
2003				
High	$ 4.48	$ 5.69	$ 4.60	$ 4.18
Low	3.15	4.19	3.30	3.52

As of February 25, 2005, there were 38,223,488 shares of outstanding common stock that were held by 4,445 shareholders of record. As of February 25, 2005, 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.

Stock Options

Our stock option plans are part of a broad-based, long-term retention program that is intended to attract and retain talented employees and directors and align stockholder and employee interests.

Pursuant to our 2001 Stock Option Plan, or the 2001 Plan, we may grant incentive or non-statutory stock options or stock purchase rights, or SPRs. The 2001 Plan allows us to grant incentive stock options to employees at not less than 100% of the fair market value of the stock (110% of fair market value for individuals who control more than 10% of the Company stock) at the date of grant, as determined by the Board of Directors. The 2001 Plan allows the Company to grant non-statutory stock options to employees, directors and consultants at a price to be determined by the Board of Directors. The term of the option is determined by the Board of Directors on the date of grant but shall not be longer than ten years. The 2001 Plan allows the Company to grant SPRs to employees and consultants. Sales of stock under SPRs are made pursuant to restricted stock purchase agreements containing provisions established by the Board of Directors. The Company has a right, but not the obligation, to repurchase the shares at the original sale price, which expires at a rate to be determined by the Board of Directors. As of December 31, 2004, no SPRs have been granted under the 2001 Plan.

Additional information regarding our stock option plans and plan activity for fiscal 2004, 2003 and 2002 is provided in our consolidated financial statements. See Notes to Consolidated Financial Statements, Note 8 Stock Option and Purchase Plans .

Equity Compensation Plans Approved by Stockholders

Information about our equity compensation plans at December 31, 2004 that were approved by our stockholders was as follows:

Plan Category	Number of Shares to be issued Upon Exercise of Outstanding Options		Weighted Average Exercise Price of Outstanding Options	Number of Shares Remaining Available for Future Issuance
Equity compensation plans approved by stockholders (a)	4,114,785	$	4.56	2,532,198
Equity compensation plans not approved by stockholders (b)		$		
Total	4,114,785	$	4.56	2,532,198

(a) Consists of three plans: our 1991 Stock Option Plan, our 1994 Stock Option Plan and our 2001 Stock Option Plan.

(b) We do not have any plans that have not been approved by our stockholders.

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

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

Selected Financial Data
(In thousands, except per share)

Selected Annual Financial Data

	Year Ended December 31				
	2004	**2003**	**2002**	**2001**	**2000**
Income Statement Data:					
Product revenue United States, net	$ 16,419	$ 18,953	$ 20,962	$ 19,560	$ 21,293
Product revenue International	3,030	3,302	1,237	4,041	5,200
Milestone and other revenue	152	5,183	150		
Total revenue	19,601	27,438	22,349	23,601	26,493
Operating expenses:					
Cost of goods sold	11,283	10,993	11,207	12,933	8,066
Research and development	18,676	7,724	13,281	12,324	4,670
Selling, general and administrative	11,730	9,839	10,556	9,314	8,655
Other restructuring (income)					(903)
Total operating expenses	41,689	28,556	35,044	34,571	20,488
Income (loss) from operations	(22,088)	(1,118)	(12,695)	(10,970)	6,005
Interest and other income, net	511	773	1,211	2,171	2,541
Income (loss) before taxes	$ (21,577)	$ (345)	$ (11,484)	$ (8,799)	$ 8,546
Net income (loss)	$ (21,583)	$ (26)	$ (10,566)	$ (7,070)	$ 7,691
Net income (loss) per diluted share	$ (0.57)	$ (0.00)	$ (0.32)	$ (0.22)	$ 0.23
Shares used in per share computation	38,010	35,884	32,907	32,572	33,428
Balance Sheet Data (at year end):					
Working capital	$ 25,466	$ 30,099	$ 18,974	$ 14,898	$ 32,981
Total assets	$ 54,389	$ 66,732	$ 49,681	$ 58,574	$ 69,174
Accumulated deficit	$ (122,543)	$ (100,960)	$ (100,934)	$ (90,368)	$ (83,298)
Stockholders equity	$ 30,722	$ 51,235	$ 34,385	$ 43,975	$ 50,187

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

Forward Looking Statement

This Management s Discussion and Analysis of Financial Conditions and Results of Operations and other parts of this Form 10-K contain forward-looking statements that involve risks and uncertainties. These statements typically may be identified by the use of forward-looking words or phrases such as believe, expect, intend, anticipate, should, planned, estimated, and potential, among others. All forward-statements included in this document are based on our current expectations, and we assume no obligation to update any such forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a safe harbor for such forward-looking statements. In order to comply with the terms of the safe harbor, we note that a variety of factors could cause actual results and experiences to differ materially from the anticipated results or other expectations expressed in such forward-looking statements. The risks and uncertainties that may affect the operations, performance, development, and results of our business include but are not limited to: (1) our history of losses and variable quarterly results; (2) substantial competition; (3) risks related to the clinical trial development of products not yet approved; (4) our reliance on sole source suppliers; (5) our limited sales and marketing efforts and our reliance on third parties; (6) failure to continue to develop innovative products; (7) risks related to noncompliance with United States Food and Drug Administration regulations; (8) risks related to the failure to protect our intellectual property and litigation in which we may become involved; and (9) other factors that are described from time to time in our periodic filings with the Securities and Exchange Commission, including those set forth in this filing as Risk Factors Affecting Operations and Future Results.

All percentage amounts and ratios were calculated using the underlying data in thousands. Operating results for the year ended December 31, 2004, are not necessarily indicative of the results that may be expected for future fiscal years. The following discussion and analysis should be read in conjunction with our historical financial statements and the notes to those financial statements that are included in Item 8. of Part II of this Form 10-K.

Overview

VIVUS, Inc. is a specialty pharmaceutical company focused on the research, development and commercialization of products to restore sexual function in women and men. Our product pipeline includes four clinical stage product candidates, each of which targets an estimated existing or potential market in excess of $1 billion annually. ALISTA, currently in Phase 3 trials, is our product candidate for the treatment of female sexual arousal disorder. Testosterone-MDTS, which recently completed a positive Phase 2 trial, is our product candidate to treat hypoactive sexual desire disorder. Evamist, currently in Phase 3 development, is our product candidate to alleviate symptoms associated with menopause. Avanafil, currently in Phase 2 trials, is our phosphodiesterase type 5, or PDE5, inhibitor product candidate for the treatment of erectile dysfunction.

In 1997, we launched MUSE (alprostadil) in the United States and, together with our partners in 1998, internationally. We market MUSE as a prescription product for the treatment of erectile dysfunction. For international markets, we have entered into supply and distribution agreements with established pharmaceutical companies to market and distribute MUSE in various foreign countries. MUSE was the first minimally invasive therapy for erectile dysfunction available at a time when only more invasive therapies existed. Developing and bringing MUSE to the market provided us with experience in clinical and regulatory matters when the market for erectile dysfunction was in its infancy.

Our Product Pipeline

We currently have four research and development programs targeting female and male sexual health:

Product	Indication	Status	Patent Expiry and Number
ALISTA (topical alprostadil)	Female sexual arousal disorder (FSAD)	Phase 3 ongoing	2017 (US 5,877,216)
Testosterone-MDTS	Hypoactive sexual desire disorder (HSDD)	Phase 2 completed	2017 (US 6,818,226)
Evamist (estradiol-MDTS)	Menopausal symptoms	Phase 3 ongoing	2017 (US 6,818,226)
Avanafil (PDE5 inhibitor)	Erectile dysfunction (ED)	Phase 2 ongoing	2020 (US 6,656,935)

Our Corporate Strategy

Our goal is to become a leader in the development and commercialization of innovative proprietary products for the treatment of female and male sexual health. We intend to achieve this by:

capitalizing on our clinical and regulatory expertise and experience in the field of sexual health to advance the development of product candidates in our pipeline;

establishing strategic relationships with marketing partners to maximize sales potential for our products that require significant commercial support; and

licensing complementary clinical stage products or technologies with competitive advantages from third parties for new and established markets.

Critical Accounting Policies and Estimates

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

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

Revenue Recognition: We recognize revenue when persuasive evidence of an arrangement exists, delivery has occurred, the sales price is fixed or determinable and collectibility is reasonably assured.

Product Returns: We record reserves for anticipated returns of expired or damaged product in the United States. We follow this method since reasonably dependable estimates of product returns can be made based on historical experience and our monitoring of inventory levels in the wholesale distribution channel. Revisions in returns

estimates are charged to income in the period in which the facts that give rise to the revision become known. There is no right-of-return on product sold internationally subsequent to shipment, thus no returns reserve is needed.

Allowance for Doubtful Accounts: We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances could be required.

Income Taxes: We record a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized. For all periods presented, we have recorded a full valuation allowance against our net deferred tax asset. While we have considered future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for the valuation allowance, in the event we were to determine that we would be able to realize our deferred tax assets in the future in excess of our net recorded amount, an adjustment to the deferred tax asset would increase income in the period such determination was made. We have also recorded income taxes payable for estimated current tax liabilities. We monitor these estimated liabilities and adjust them as conditions warrant.

Restructuring: In 1998, we experienced a significant restructuring and recorded restructuring related reserves for severance and employee costs, inventory obsolescence, raw material purchase commitments, property and related commitments, marketing commitments and other commitments. We monitor the adequacy of these liabilities and have made periodic adjustments as conditions have changed.

Inventories: We record inventory reserves for estimated obsolescence or unmarketable inventory equal to the difference between the cost of inventory and the estimated market value based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required. During the quarter ended September 30, 1998, we established significant reserves against its inventory to align with new estimates of expected future demand for MUSE. VIVUS had built up its inventory level prior to and after the launch of Viagra and had not anticipated the impact that Viagra would have on the demand for MUSE. As of December 31, 2004, the remaining inventory reserve balance is $3.9 million. This remaining balance is related to the raw materials inventory that we previously estimated would not be used. Some portion of the fully reserved inventory was used in production in 2004, 2003 and 2002. In the fourth quarter of 2004, we stopped using this fully reserved inventory in production and determined that we would not likely use this inventory in future production. To the extent that this inventory was used in production in 2003 and 2004, it was charged to cost of goods sold at a zero basis, which had a favorable impact on cost of goods sold.

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

Direct obligations of the United States Treasury;

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

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

The difference between amortized cost (cost adjusted for amortization of premiums and accretion of discounts which are recognized as adjustments to interest income) and fair value, representing unrealized holding gains or losses, are recorded in Accumulated Other Comprehensive (Loss) Income, a separate component of stockholders equity until realized.

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

Contingencies and Litigation: We are periodically involved in disputes and litigation related to a variety of matters. When it is probable that we will experience a loss, and that loss is quantifiable, we record appropriate reserves.

Results of Operations

Years Ended December 31, 2004 and 2003

For the year ended December 31, 2004, we reported a net loss of $21.6 million, or $0.57 net loss per share as compared to a net loss of $26,000, or no net loss per share, during the same period in 2003. The net loss was higher in 2004 as compared to 2003 primarily due to lower product sales of MUSE in the United States and internationally and higher research and development expenses including an aggregate $5.1 million in one time charges for licensing and milestone payments associated with three of the development programs in the pipeline, increased clinical trial and project activity for ALISTA, avanafil, estradiol and testosterone, as well as the lack of the $5.0 million in other revenue resulting from the 2003 settlement of the Janssen Pharmaceutica arbitration claim.

We anticipate continued losses over the next several years because we expect MUSE sales to continue to decline, and we plan to continue to invest in clinical development of our current research and development product candidates to bring those potential products to market.

Revenue. Product revenue from the sales of MUSE in the United States for the year ended December 31, 2004 was $16.4 million compared to $19.0 million last year, a decrease of $2.6 million. International product revenue was $3.0 million for the year ended December 31, 2004, a decrease of $272,000 compared to last year.

Worldwide product revenues from the sales of MUSE were $19.4 million in 2004, a decrease of $2.8 million, or 13%, from the worldwide sales of MUSE in 2003. The change in revenues is mainly due to decreased demand for MUSE. The launch of new PDE5 inhibitors and the associated direct-to-consumer advertising and aggressive sampling opportunities for all PDE5 inhibitors contributed to the decline in demand for MUSE. In addition, based on the current demand for MUSE, as measured by independent third party prescription data, we estimate purchases made by wholesalers ahead of our annual price increase in the fourth quarter of 2004, represent approximately 6 to 7 months of

demand. As a result of the decrease in demand and the strategic buying in the fourth quarter by our wholesalers, combined with the promotional efforts of all PDE5 inhibitors, we anticipate worldwide revenues of MUSE will decline in 2005.

Cost of goods sold. Cost of goods sold for 2004 was $11.3 million, as compared to $11.0 million for 2004, an increase of $300,000. In accordance with GAAP, in 1998 we reduced the carrying cost of alprostadil, the active ingredient in MUSE, to zero due to excess quantities on hand at that time. Although the cost basis for alprostadil was reduced to zero we continued to use this active ingredient as allowed by the FDA in the production of MUSE, in 2004 and 2003. By utilizing the inventory that had previously been written down to zero, we lowered our cost of sales for 2004 and 2003 by $844,000 and $1.2 million, respectively. In the fourth quarter of 2004 we stopped using the alprostadil that had previously been reduced to a zero cost basis. The increase in cost of goods sold in 2004 as compared to 2003 is primarily due to use of recently purchased alprostadil that is expensed at its full cost of acquisition. We expect cost of goods sold to increase in 2005 as we are no longer using the zero cost basis alprostadil in production.

Research and development expenses. Research and development expenses for the year ended December 31, 2004 were $18.7 million, as compared to $7.7 million for the same period in 2003. During 2004, we entered into exclusive licensing agreements with a subsidiary of Acrux under which we will develop and commercialize, in the United States, an estradiol spray for the alleviation of the symptoms of menopause and a testosterone spray for the treatment of hypoactive sexual desire disorder in women. We expensed a total $3.3 million of licensing fees under the terms of the agreements in 2004. A portion of these licensing fees was paid in February and September 2004, with the remainder, $972,000, to be paid in June 2005. In addition, during the first half of 2004, we initiated a Phase 2 clinical trial with avanafil, our oral phosphodiesterase type 5 (PDE5) inhibitor being studied for the treatment of erectile dysfunction. Under the terms of our 2001 development, licensing and supply agreement with Tanabe we expensed a $1.9 million milestone obligation to Tanabe in 2004. We intend to pay this milestone obligation in March 2006. The expenses associated with the avanafil Phase 2 clinical trials in 2004 resulted in an additional $1.2 million expense. Increased clinical trial and project activity for ALISTA, estradiol and testosterone resulted in incremental spending for these projects of $1.9 million during 2004. Additionally, salary, benefit and consulting expenses increased in support of our ongoing projects. We anticipate that our research and development expenditures will continue to increase in 2005 and we do not expect to recognize revenue from sales of any new product candidates being developed through our research and development efforts for several years.

Selling, general and administrative expenses. Selling, general and administrative expenses for 2004 were $11.7 million as compared to $9.8 million for 2003, or $1.9 million higher than last year primarily due to an increase in spending for investor and public relations activities and marketing programs, as well as the absence of the reimbursement of previously incurred legal fees and other expenses related to the settlement of the Janssen Pharmaceutica arbitration claim in the third quarter of 2003.

Interest income and expense. Interest income for 2004 was $622,000 as compared to $708,000 for 2003. Declining balances of cash, cash equivalents and available-for-sale securities contributed to the reduction in interest income. Interest expense of $143,000 in 2004 was related to the Acrux and Tanabe milestone liabilities. We did not have any interest expense in 2003.

Provision for income taxes. In 2004, we recorded a net tax provision of $6,000 for minimum state income taxes and U.K. income taxes, both due for 2004. For the year ended December 31, 2003, we recorded a tax benefit based on an updated estimate of our tax liabilities.

Years Ended December 31, 2003 and 2002

For 2003, we reported a net loss of $26,000, or no net loss per share as compared to a net loss of $10.6 million or $0.32 net loss per share for 2002. The decrease in the net loss in 2003 was due primarily to revenue recognized as the result of the resolution of our arbitration claim against Janssen Pharmaceutica in the third quarter of 2003. Reduced operating expenses also contributed to the lower loss.

Revenue. United States product revenue for 2003 was $19.0 million, as compared to $21.0 million for 2002. The decrease in revenue was due to a decrease in the number of MUSE units sold in 2003 versus 2002 due to declining demand.

International revenue was $3.3 million for 2003, compared to $1.2 million for 2002. Higher international product revenue in 2003 was due to a full year of sales to our international distribution partner, Meda. Initial shipments to Meda began in the fourth quarter of 2002.

Milestone and other revenue was $5.2 million primarily due to $5.0 million of other revenue resulting from the resolution of our arbitration claim against Janssen Pharmaceutica with the American Arbitration Association related to payments owing to VIVUS under a previously terminated distribution agreement between the companies. $3.7 million of other revenue represented amounts due

from Janssen Pharmaceutica under the arbitration award. The remaining $1.3 million resulted from recognizing Janssen Pharmaceutica related revenue that was previously deferred pending the outcome of the arbitration.

Cost of Goods Sold. Cost of goods sold for 2003 was $11.0 million, compared to $11.2 million for the 2002. During 2003, we used certain raw material inventory of alprostadil, the cost basis of which had been reduced to zero in prior years. The use of this raw material which had a zero cost basis had a favorable impact on our cost of goods sold during 2003 of $1.2 million. The 2002 amount includes a reduction in cost of goods sold of $802,000 as a result of settlements of previously recognized purchase commitment liabilities for our major raw material, alprostadil.

Research and development expenses. Research and development expenses for the year ended December 31, 2003 were $7.7 million, $5.6 million lower than the same period in the previous year. The decrease was due to greater clinical trial activity in 2002 as compared to 2003.

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

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

Benefit for income taxes. We recorded a tax benefit of $319,000 for 2003 based on an estimate of our net tax liabilities. In 2002, we recorded a tax benefit of $918,000 based on an estimate of our net tax liabilities as well as filing for a refund of previously paid alternative minimum taxes which became available due to a 2002 tax law change.

Liquidity and Capital Resources

Cash. Unrestricted cash, cash equivalents and available-for-sale securities totaled $29.8 million at December 31, 2004, compared with $48.3 million at December 31, 2003. The decrease was primarily due to decreased revenues in 2004 as well as increased research and development spending.

Since inception, we have financed operations primarily from the issuance of equity securities. Through December 31, 2004, we raised $174.2 million from financing activities and had an accumulated deficit of $122.5 million.

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

Direct obligations of the United States Treasury;

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

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

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

Accounts receivable. Accounts receivable (net of allowance for doubtful accounts) at December 31, 2004 was $9.5 million, as compared to $2.6 million at December 31, 2003. The increase in the accounts receivable balance at December 31, 2004 is due to 38% of the 2004 sales occurring in the month of December. Currently, the Company does not have any significant concerns related to accounts receivable or collections. As of February 25, 2005, we had collected all of the December 31, 2004 accounts receivable.

Liabilities. Total liabilities were $23.7 million at December 31 2004, $8.2 million higher than at December 31, 2003. Accrued research and clinical expenses and accrued licensing fees increased $3.6 million due to liabilities for the future payment of milestones totaling $2.8 million to Acrux and Tanabe and to increased liabilities for clinical trial expense in 2004. Notes payable increased $3.2 million due to borrowing under the agreement we signed with Tanabe in the first quarter of 2004 for a line of credit of up to $8.5 million to be used for the development of avanafil, and accrued chargeback reserves increased $1.0 million due to the increase in December 2004 sales of MUSE as compared to December 2003.

Operating Activities. Our operating activities used $22.7 million of cash during 2004 and provided $1.9 million of cash in 2003. The cash used in 2004, can be attributed to our net operating loss of $21.6 million, an increase in our accounts receivable balance of $7.0 million offset by a $3.6 million increase in accrued research and development expenses, non-cash depreciation expense of $1.9 million, and a $1.0 million increase in accrued chargeback reserves. The cash provided by operations in 2003 was due to a $2.0 million decrease in our accounts receivable balance and $2.1 million of non-cash depreciation expenses included in our $26,000 net loss, offset by an increase in our inventories due to the purchase of $2.1 million of alprostadil.

Investing Activities. Net cash provided by investing activities was $13.5 million in 2004 as compared to the use of $18.1 million in 2003, respectively. The fluctuations from period to period are due primarily to the timing of purchases, sales and maturity of investment securities.

Financing Activities. Financing activities provided cash of $4.4 million and $17.1 million during 2004 and 2003, respectively. These amounts include the proceeds from the exercise of stock options in 2004 and 2003, borrowings from Tanabe during 2004 and the private placement of 4,375,000 shares of common stock for aggregate net proceeds of $16.4 million in 2003.

We anticipate that our existing capital resources combined with anticipated future cash flows will be sufficient to support our operating needs for at least the next two years. However, we anticipate that we will be required to obtain additional financing to fund the development of our research and development pipeline in future periods as well as to support the possible launch of any future products. In particular, we expect to make other substantial payments to Acrux and Tanabe in accordance with our agreements with them in connection with the licensing of certain compounds. These payments are based on certain development, regulatory and sales milestones. In addition, we are required to make royalty payments on any future product sales.

In the first quarter of 2004, we signed an agreement for a secured line of credit with Tanabe, allowing us to borrow up to $ 8.5 million to be used for the development of avanafil (formerly TA-1790), our erectile dysfunction compound currently in Phase 2 clinical trials. The secured line of credit may be drawn upon quarterly and each quarterly borrowing has a 48-month term and bears interest at the annual rate of 2%. There are no financial covenants associated with this secured line of credit. As of December 31, 2004 we had long-term notes payable to Tanabe of $3.2 million, and $5.3 million of available credit under this agreement.

On December 21, 2004, we filed a shelf registration statement on Form S-3 with the Securities and Exchange Commission (SEC) which allows us to offer and sell up to an aggregate of $50 million of common stock from time to time in one or more offerings. The terms of any such future offering would be established at the time of such offering. On February 22, 2005, we filed a prospectus supplement with the Securities and Exchange Commission relating to an underwritten public offering of 7,500,000 shares of common stock under the existing shelf registration statement and supplement thereto. On March 15, 2005, we sold 6,250,000 shares of our common stock at a price of $3.40 per share providing us with net proceeds of $19.6 million. We also granted the underwriters a 30-day option to purchase up to an additional 937,500 shares to cover over-allotments.

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

reduce cash used by operating activities, including the termination of research and development efforts that may appear to be promising to us, the sale of certain assets and the reduction in overall operating activities. Our future capital requirements will depend upon numerous factors, including:

the progress of our research and development programs;

the scope, timing and results of pre-clinical testing and clinical trials;

patient recruitment and enrollment in current and future clinical trials;

results of operations;

the cost, timing and outcome of regulatory reviews;

the rate of technological advances;

ongoing determinations of the potential commercial success of our products under development;

the level of resources devoted to sales and marketing capabilities; and

the activities of competitors.

Future Accounting Requirements

In December 2004, the Financial Accounting Standards Board (FASB) issued revised statement No. 123 (FAS 123R) which requires companies to expense the estimated fair value of employee stock options and similar awards. The accounting provisions of FAS 123R will be effective for the third quarter of fiscal 2005. We will adopt the provisions of FAS 123R using a modified prospective application. Under modified prospective application, FAS 123R, which provides certain changes to the method for valuing stock-based compensation among other changes, will apply to new awards and to awards that are outstanding on the effective date and are subsequently modified or cancelled. Further compensation expense for outstanding awards for which the requisite service had not been rendered as of the effective date will be recognized over the remaining service period using the compensation cost calculated for pro forma disclosure purposes under FAS 123. We are in the process of determining how the new method of valuing stock-based compensation as prescribed in FAS 123R will be applied to valuing stock-based awards granted after the effective date and the impact the recognition of compensation expense related to such awards will have on our consolidated financial statements.

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs, an amendment of ARB No. 43, Chapter 4*. This Statement is meant to eliminate any differences existing between the FASB standards and the standards issued by the International Accounting Standards Board by clarifying that any abnormal idle facility expense, freight, handling costs and spoilage be recognized as current-period charges. This Statement is required to be adopted by VIVUS, Inc. in the first quarter of 2006; however, early application is permitted. VIVUS, Inc. does not expect the adoption of this Statement to have a material impact on results of operations, financial position or cash flows as we currently do expense a portion of our manufacturing overhead as period cost due to excess capacity.

Overview of Contractual Obligations

Contractual Obligations	Payments Due by Period (in thousands)				
	Total	Less than 1 year	1 - 3 years	3 5 years	More than 5 years
Operating Leases (1)	$ 2,793	$ 1,318	$ 1,475	$	$
Purchases (2)	4,590	1,530	3,060		
Notes Payable (3)	3,239		3,239		
Other Long Term Liabilities (4)	6,293	300	2,350	325	3,318
Total	$ 16,915	$ 3,148	$ 10,124	$ 325	$ 3,318

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

(2) In November 2002, we entered into a manufacturing agreement to purchase raw materials from a supplier beginning in 2003 and ending in 2008. In 2003 we purchased $2.1 million of product and in 2004 we purchased $762,000 of product. We are committed to purchase a minimum total of $3.1 million of product from 2005 through 2008

In January 2004, we entered into a manufacturing agreement to purchase raw materials from an additional supplier beginning in 2004 and ending in 2006. As of December 31, 2004, we have purchased $475,000 of product from this supplier. We will be required to purchase a minimum total of $1.8 million of product from 2005 through 2006.

(3) In the first quarter of 2004, we signed an agreement for a secured line of credit with Tanabe, allowing us to borrow up to $8.5 million to be used for the development of avanafil (formerly TA-1790), our erectile dysfunction compound currently in Phase 2 clinical trials. The secured line of credit may be drawn upon quarterly and each quarterly borrowing will have a 48-month term and will bear interest at the annual rate of 2%. There are no financial covenants associated with this secured line of credit. As of December 31, 2004 we have $5.3 million of available credit under this agreement.

(4) Other Long Term Liabilities includes the restoration liability of $3.0 million for our leased manufacturing facilities. This liability will remain in effect through the end of the lease term, including any renewals. We have exercised our first option to renew the original lease, thereby extending any cash payments to be made relating to this liability out to 2007. The second renewal term, if

exercised, would then extend the liability out an additional five years, to 2012. We initially recorded $1.5 million of unearned revenue related to an upfront payment in accordance with the international supply agreement signed with Meda AB in September 2002. This amount is being recognized as income ratably over the term of the supply agreement. Through December 31, 2004, $1,000,000 of long-term revenue remains deferred under this agreement. We will recognize $150,000 of revenue under this agreement in 2005.

During the first quarter of 2004, we initiated a Phase 2 clinical trial with avanafil. Under the terms of our 2001 development, licensing and supply agreement with Tanabe we accrued an expense of $1.9 million for a milestone obligation to Tanabe during 2004. We intend to pay the entire milestone obligation, with a future value of $2.0 million, in March 2006.

Off-Balance Sheet Financing and Related Party Transactions

VIVUS has not entered into any off-balance sheet financing arrangements and has not established any special purpose entities. VIVUS has not guaranteed any debt or commitments of other entities or entered into any options on non-financial assets. The only transaction between VIVUS and a related party during 2004 was Mario M. Rosati, one of our directors, who is also a member of Wilson Sonsini Goodrich & Rosati, Professional Corporation, which has served as our outside corporate counsel since our formation and has received compensation at normal commercial rates for these services.

Dividend Policy

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

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

The Securities and Exchange Commission s rule related to market risk disclosure requires that we describe and quantify our potential losses from market risk sensitive instruments attributable to reasonably possible market changes. Market risk sensitive instruments include all financial or commodity instruments and other financial instruments that are sensitive to future changes in interest rates, currency exchange rates, commodity prices or other market factors. VIVUS is not exposed to market risks from changes in foreign currency exchange rates or commodity prices. We do not hold derivative financial instruments nor do we hold securities for trading or speculative purposes. At December 31, 2004, we had drawn $3.2 million of the $8.5 million secured line of credit with Tanabe. Each quarterly borrowing will have a 48-month term and will bear interest at the annual rate of 2%. We, however, are exposed to changes in interest rates on our investments in cash equivalents and available-for-sale securities. A significant portion of all of our investments in cash equivalents and available-for-sale securities are in money market funds that hold short-term investment grade commercial paper, treasury bills or other United States government obligations. Currently, this reduces our exposure to long-term interest rate changes.

Item 8. ***Financial Statements and Supplementary Data***

VIVUS, INC.

1. Index to Consolidated Financial Statements

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

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of

Vivus Inc.:

We have audited the accompanying consolidated balance sheets of Vivus Inc. and subsidiaries as of December 31, 2004 and 2003, and the related consolidated statements of operations and other comprehensive (loss), stockholders equity, and cash flows for each of the years in the three-year period ended December 31, 2004. In connection with our audits of the consolidated financial statements, we also have audited financial statement schedule II. These consolidated financial statements and schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. Our audit included 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, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Vivus Inc. and subsidiaries as of December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles. Also in our opinion, the related financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, present fairly, in all material respects, the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Vivus Inc. s internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 15, 2005 expressed an unqualified opinion on management s unqualified opinion on management s assessment of, and the effective operation of, internal control over financial reporting.

/s/KPMG LLP

San Francisco, California
March 15, 2005

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of

Vivus Inc.:

We have audited management s assessment, included in the accompanying Management s Report on Internal Control Over Financial Reporting, that Vivus Inc. maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Vivus Inc. s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management s assessment and an opinion on the effectiveness of the Company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management s assessment that Vivus Inc. maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Also, in our opinion, Vivus Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Vivus Inc. and subsidiaries as of December 31, 2004 and 2003, and the related consolidated statements of operations and other comprehensive (loss), stockholders equity, and cash flows for each of the years in the three-year period ended December 31, 2004, and our report dated March 15, 2005 expressed an unqualified opinion on those consolidated financial statements.

/s/KPMG LLP

San Francisco, California
March 15, 2005

VIVUS, INC.

CONSOLIDATED BALANCE SHEETS
(In thousands, except par value)

	December 31	
	2004	**2003**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 8,304	$ 13,097
Available-for-sale securities	16,739	21,488
Accounts receivable (net of allowance for doubtful accounts of $104 and $68 at December 31, 2004 and 2003, respectively)	9,544	2,623
Inventories, net	3,855	3,109
Prepaid expenses and other assets	1,459	1,108
Total current assets	39,901	41,425
Property and equipment, net	6,394	8,220
Restricted cash	3,324	3,324
Available-for-sale securities, non-current	4,770	13,763
Total assets	$ 54,389	$ 66,732
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 3,120	$ 2,917
Product returns	2,848	2,932
Accrued research and clinical expenses	2,164	458
Accrued chargeback reserve	1,989	1,035
Accrued employee compensation and benefits	1,442	1,249
Income taxes payable	1,214	1,216
Accrued royalties	764	629
Accrued and other liabilities	894	890
Total current liabilities	14,435	11,326
Notes payable	3,239	
Accrued restructuring reserve	3,021	3,021
Deferred revenue	1,110	1,150
Accrued licensing fees	1,862	
Total liabilities	23,667	15,497
Stockholders equity:		
Preferred stock; $1.00 par value; shares authorized 5,000 at December 31, 2004 and 2003; shares issued and outstanding 0 at December 31, 2004 and 2003		
Common stock; $.001 par value; shares authorized 200,000 at December 31, 2004 and 2003; shares issued and outstanding 38,127 at December 31, 2004 and 37,788 at December 31, 2003	38	38
Additional paid-in capital	153,275	152,093
Accumulated other comprehensive income (loss)	(48)	64
Accumulated deficit	(122,543)	(100,960)
Total stockholders equity	30,722	51,235
Total liabilities and stockholders equity	$ 54,389	$ 66,732

See accompanying notes to consolidated financial statements.

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VIVUS, INC.

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

	Year Ended December 31		
	2004	2003	2002
Revenue			
United States product, net	$ 16,419	$ 18,953	$ 20,962
International product	3,030	3,302	1,237
Milestone and other revenue	152	5,183	150
Total revenue	19,601	27,438	22,349
Operating expenses:			
Cost of goods sold	11,283	10,993	11,207
Research and development	18,676	7,724	13,281
Selling, general and administrative	11,730	9,839	10,556
Total operating expenses	41,689	28,556	35,044
Loss from operations	(22,088)	(1,118)	(12,695)
Interest and other income:			
Interest income	622	708	1,312
Gain (loss) on disposal of property and equipment	(7)	26	(134)
Foreign exchange gain	39	39	33
Interest expense	(143)		
Loss before benefit for income taxes	(21,577)	(345)	(11,484)
Benefit (provision) for income taxes	(6)	319	918
Net loss	$ (21,583)	$ (26)	$ (10,566)
Other comprehensive loss:			
Unrealized loss on securities, net of taxes	(112)	(217)	(41)
Comprehensive loss	$ (21,695)	$ (243)	$ (10,607)
Net loss per share:			
Basic and diluted	$ (0.57)	$ (0.00)	$ (0.32)
Shares used in per share computation:			
Basic and diluted	38,010	35,884	32,907

See accompanying notes to consolidated financial statements.

VIVUS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY
(In thousands)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Capital	Income (Loss)	Deficit	Total
Balances, December 31, 2001	32,693	$ 33	$ 133,988	$ 322	$ (90,368)	$ 43,975
Sale of common stock through employee stock purchase plan	106		289			289
Exercise of common stock options for cash	200		624			624
Stock compensation costs			104			104
Change in unrealized gain on securities, net of taxes				(41)		(41)
Net loss					(10,566)	(10,566)
Balances, December 31, 2002	32,999	33	135,005	281	(100,934)	34,385
Sale of common stock through employee stock purchase plan	108		325			325
Exercise of common stock options for cash	306		312			312
Stock compensation costs			39			39
Proceeds from private placement of common stock	4,375	5	17,500			17,505
Issue costs for private placement of common stock			(1,088)			(1,088)
Change in unrealized gain on securities, net of taxes				(217)		(217)
Net loss					(26)	(26)
Balances, December 31, 2003	37,788	38	152,093	64	(100,960)	51,235
Sale of common stock through employee stock purchase plan	84		283			283
Exercise of common stock options for cash	255		859			859
Stock compensation costs			40			40
Change in unrealized gain on securities, net of taxes				(112)		(112)
Net loss					(21,583)	(21,583)
Balances, December 31, 2004	38,127	$ 38	$ 153,275	$ (48)	$ (122,543)	$ 30,722

See accompanying notes to consolidated financial statements.

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VIVUS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31		
	2004	**2003**	**2002**
Cash flows from operating activities:			
Net loss	$ (21,583)	$ (26)	$ (10,566)
Adjustments to reconcile net loss to net cash provided by (used for) operating activities:			
Provision for doubtful accounts	36	(77)	(87)
Depreciation	1,936	2,074	2,288
Stock compensation costs	40	39	104
(Gain) loss on disposal of property and equipment	7	(26)	134
Changes in assets and liabilities:			
Accounts receivable	(6,957)	1,955	(1,766)
Inventories	(746)	(1,751)	1,742
Prepaid expenses and other assets	(351)	389	(717)
Accounts payable	203	1,051	625
Accrued research and clinical expenses	1,706	(905)	245
Accrued chargeback reserve	954	126	575
Accrued employee compensation and benefits	193	120	(356)
Accrued and other liabilities	1,875	(1,100)	183
Net cash provided by (used for) operating activities	(22,687)	1,869	(7,596)
Cash flows from investing activities:			
Property and equipment purchases	(118)	(225)	(169)
Proceeds from sale of property and equipment	1	41	41
Investment purchases	(20,451)	(42,798)	(10,567)
Proceeds from sale/maturity of securities	34,081	24,860	18,129
Net cash provided by (used for) investing activities	13,513	(18,122)	7,434
Cash flows from financing activities:			
Sale of common stock through employee stock purchase plan	283	325	289
Borrowing under note agreements	3,239		
Exercise of common stock options	859	312	624
Proceeds of issuance of common stock		17,500	
Common stock issuance costs		(1,083)	
Net cash provided by financing activities	4,381	17,054	913
Net increase (decrease) in cash and cash equivalents	(4,793)	801	751
Cash and cash equivalents:			
Beginning of year	13,097	12,296	11,545
End of year	$ 8,304	$ 13,097	$ 12,296
Non-cash investing and financing activities:			
Unrealized loss on securities	$ (112)	$ (217)	$ (41)
Supplemental cash flow disclosure:			
Income taxes paid (received)	$ 13	$ (494)	$ (6)

See accompanying notes to consolidated financial statements.

VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Business and Significant Accounting Policies

Business

VIVUS, Inc. is a specialty pharmaceutical company, incorporated in 1991, focused on the research, development and commercialization of products to restore sexual function in women and men. The Company s product pipeline includes four clinical stage product candidates. ALISTA, currently in Phase 3 trials, is a product candidate for the treatment of female sexual arousal disorder. Testosterone-MDTS, which recently completed a positive Phase 2 trial, is a product candidate to treat hypoactive sexual desire disorder. Evamist, currently in Phase 3 development, is a product candidate to alleviate symptoms associated with menopause. Avanafil, currently in Phase 2 trials, is a phosphodiesterase type 5, or PDE5, inhibitor product candidate for the treatment of erectile dysfunction. The Company also markets MUSE (alprostadil), a transurethral applicator used for treating erectile dysfunction, in the United States and internationally through distribution partners.

At December 31, 2004, the Company s accumulated deficit was approximately $122.5 million. Based on current plans, management expects to incur further losses for the foreseeable future. Management believes that the Company s cash, cash equivalents, and short-term investments at December 31, 2004, will be sufficient to meet the Company s obligations through at least the end of 2006. Until the Company can generate sufficient levels of cash from its operations, the Company expects to continue to finance future cash needs primarily through proceeds from equity or debt financing, loans and collaborative agreements with corporate partners.

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

Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of VIVUS, Inc., VIVUS International Limited, a wholly owned subsidiary, and VIVUS Ireland Limited, VIVUS U.K. Limited and VIVUS B.V. Limited, wholly owned subsidiaries of VIVUS International Limited. All significant inter-company transactions and balances have been eliminated in consolidation. On February 20, 2004, VIVUS Ireland was officially dissolved.

Use of Estimates

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

Cash and Cash Equivalents

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

Available-for-Sale Securities

Available-for-sale securities represent investments in debt securities that are stated at fair value. The difference between amortized cost (cost adjusted for amortization of premiums and accretion of discounts which are recognized as adjustments to interest income) and fair value, representing unrealized holding gains or losses, are recorded in Accumulated Other Comprehensive (Loss) Income, a separate component of stockholders equity until realized. The change in unrealized (losses) gains on investments included in accumulated other comprehensive loss for 2004, 2003 and 2002, in thousands, are $112, $217, and $41, respectively.

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

Inventories

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

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

As of December 31, 2004, the remaining inventory reserve balance is $3.9 million. This remaining balance is related to the raw materials inventory that the Company previously estimated would not be used.

Some portion of the fully reserved inventory has been used in production. In 2004, 2003 and 2002, the Company used $844,000, $1.2 million and $163,000 of its fully reserved raw materials inventory. The fully reserved raw materials are charged to cost of goods sold at a zero basis when used, which has a favorable impact on gross profit. In the fourth quarter of 2004, the Company determined that it will likely not use the fully reserved inventory in future production.

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 is 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, which may include option renewal periods if the Company determines that it is likely that the renewal options will be exercised. 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, and leasehold improvements are reflected as a component of other income, net in the accompanying consolidated statements of operations and other comprehensive (loss).

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

Restricted Cash

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

Revenue Recognition

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

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

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

United States

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

International

The Company has supply agreements with Meda AB to market and distribute MUSE® internationally in some Member States of the European Union. In Canada, we have entered into a license and supply agreement with Paladin Labs, Inc. for the marketing and distribution of MUSE. Sales to our distribution partner, who supplies MUSE in the European marketplace, for 2004, 2003 and 2002 were 96.7%, 92.1%, and 81.4% of international sales, respectively. The balance of international sales was made to our Canadian distribution partner.

The Company invoices its international distributors based on an agreed transfer price per unit, which is subject to revision based on contractual formulas upon quarterly reconciliations. Final pricing for product shipments to international distributors is subject to contractual formulas based on the distributor s net realized price to its customers. The Company recognizes revenue at the lowest possible price, upon shipment, in accordance with contractual formulas. The Company recognizes additional revenue, if any, upon finalization of pricing with its international distributors. International distributors generally do not have the right to return products unless the products are damaged or defective.

The Company initially recorded $1.5 million of unearned revenue related to an upfront payment in accordance with the international supply agreement signed with Meda AB in September 2002. This amount is being recognized as income ratably over the term of the supply agreement. Through December 31, 2004, $350,000 has been recognized as revenue.

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

In November 2004, the Company recorded $123,000 of unearned revenue related to an upfront licensing payment in accordance with an amendment to its international supply and distribution agreement with Paladin Labs, Inc. This amount is being recognized as

income ratably over the term of the supply and distribution agreement. Through December 31, 2004, $2,000 has been recognized as revenue.

Stock Option Plans

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

	2004	2003	2002
	(In thousands, except per share data)		
Net (loss), as reported	$ (21,583)	$ (26)	$ (10,566)
Deduct total stock-based employee compensation expense determined under fair-value-based method for all rewards, net of tax	(1,970)	(1,763)	(1,820)
Pro forma net (loss)	$ (23,553)	$ (1,789)	$ (12,386)
Pro forma net (loss) per share:			
Basic and diluted	$ (0.62)	$ (0.05)	$ (0.38)

The weighted-average fair value of options granted in 2004, 2003 and 2002 was $3.17, $2.63 and $5.64, respectively.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions used for grants in 2004, 2003 and 2002: no dividend yield, expected volatility of 64%, 66% and 75%, respectively, risk-free interest rates of between 2% to 4%, 1% to 4% and 2% to 6%, respectively and an expected life of 5 years for all years.

Effective February 28, 2005, the vesting of the 359,682 outstanding stock options granted on January 21, 2002, of which 82,479 were unvested options, was accelerated to that date. The options were originally scheduled to vest during the period from January 2002 to January 2012. On the accelerated vesting date, the per share market value of VIVUS stock of $3.98 was less than the strike price of the options, which was $8.08 per share.

Income Taxes

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

License Agreements

The Company has obtained rights to patented technologies under several licensing agreements. Non-refundable licensing payments made on technologies that are yet to be proven are expensed to research and development. Royalties paid associated with existing products are expensed to cost of goods sold when the liability is generated upon sale of product. We incurred royalty expense of $952,000 in 2004 and $950,000 in 2003.

Net (Loss) Income Per Share

Basic (loss) earnings per share, or EPS, is computed using the weighted average number of common shares outstanding during the periods. Diluted EPS is based on the weighted average number of common and common equivalent shares, which represent shares that may be issued in the future upon the exercise of outstanding stock options under the treasury stock method. The computation of basic and diluted EPS for the years ended December 31, 2004, 2003 and 2002 are as follows:

	2004	2003	2002
	(In thousands, except per share data)		
Net (loss)	$ (21,583)	$ (26)	$ (10,566)
Net (loss) per share basic	$ (.57)	$ (.00)	$ (.32)
Effect of dilutive securities (stock options)			
Net (loss) per share diluted	$ (.57)	$ (.00)	$ (.32)
Shares used in the computation of net (loss) per share basic	38,010	35,884	32,907
Effect of dilutive securities (stock options)			
Diluted shares	38,010	35,884	32,907

Potentially dilutive options outstanding of 696,815, 481,437 and 1,153,276 at December 31, 2004, 2003 and 2002, respectively, are excluded from the computation of diluted EPS for 2004, 2003 and 2002 because the effect would have been antidilutive.

Future Accounting Requirements

In December 2004, the FASB revised Statement No. 123 (FAS 123R), *Share-Based Payment*, which requires companies to expense the estimated fair value of employee stock options and similar awards. The accounting provisions of FAS 123R will be effective for the third quarter of fiscal 2005.

The Company will adopt the provisions of FAS 123R using a modified prospective application. Under modified prospective application, FAS 123R, which provides certain changes to the method for valuing stock-based compensation among other changes, will apply to new awards and to awards that are outstanding on the effective date and are subsequently modified or cancelled. Further compensation expense for outstanding awards for which the requisite service had not been rendered as of the effective date will be recognized over the remaining service period using the compensation cost calculated for pro forma disclosure purposes under FAS 123 (Note 1). The Company is in the process of determining how the new method of valuing stock-based compensation as prescribed in FAS 123R will be applied to valuing stock-based awards granted after the effective date and the impact the recognition of compensation expense related to such awards will have on its consolidated financial statements.

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs, an amendment of ARB No. 43, Chapter 4*. This Statement is meant to eliminate any differences existing between the FASB standards and the standards issued by the International Accounting Standards Board by clarifying that any abnormal idle facility expense, freight, handling costs and spoilage be recognized as current-period charges. This Statement is required to be adopted by VIVUS, Inc. in the first quarter of 2006; however, early application is permitted. VIVUS, Inc. does not expect the adoption of this Statement to have a material impact on results of operations, financial position or cash flows.

Reclassifications

Certain reclassifications have been made to the Company s 2003 and 2002 consolidated financial statements to conform to the current period presentations.

Note 2. Available-for-Sale Securities

The fair value and the amortized cost of available-for-sale securities at December 31, 2004 and 2003 are presented in the tables that follow. Fair values are based on quoted market prices obtained from an independent broker. For each category of investment securities, the table presents gross unrealized holding gains and losses.

As of December 31, 2004 (in thousands):

	Amortized Cost	Fair Market Value	Unrealized Holding Gains	Unrealized Holding Losses
United States government securities	$ 16,646	$ 16,600	$ 0	$ (46)
Corporate debt	4,911	4,909	0	(2)
Total	21,557	21,509	0	(48)
Amount classified as short-term	(16,756)	(16,739)	0	17
Amount classified as long-term	$ 4,801	$ 4,770	$ 0	$ (31)

As of December 31, 2003 (in thousands):

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

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

Note 3. Inventories

Inventories are recorded net of reserves of $3.9 million and $5.6 million as of December 31, 2004 and 2003, respectively, and consist of (in thousands):

	2004	2003
Raw materials	$ 3,260	$ 2,370
Work in process	22	81
Finished goods	573	658
Inventory, net	$ 3,855	$ 3,109

Inventory balances at December 31, 2004 were $3.8 million as compared to $3.1 million at December 31, 2003. The increase is attributable to increased purchases of alprostadil, the active ingredient in MUSE.

As noted above, the Company has recorded significant reserves against the carrying value of its inventory of raw material. The reserves relate primarily to raw materials inventory that the Company previously estimated would not be used. Some portion of the fully reserved inventory has been used in production. In 2004, 2003 and 2002, the Company used $844,000, $1.2 million and $163,000 of its fully reserved raw materials inventory, respectively. The fully reserved raw materials are charged to cost of goods sold at a zero basis when used, which has a favorable impact on gross profit. In the fourth quarter of 2004, the Company determined that it will likely not use the fully reserved inventory in future production.

Note 4. Property and Equipment

Property and equipment as of December 31, 2004 and 2003, respectively, consist of (in thousands):

	2004	2003
Machinery and equipment	$ 18,160	$ 18,168
Computers and software	2,504	2,523
Furniture and fixtures	1,254	1,251
Building improvements	11,947	11,941
	33,865	33,883
Accumulated depreciation	(27,471)	(25,663)
Property and equipment, net	$ 6,394	$ 8,220

For the years ended December 31, 2004, 2003 and 2002, depreciation expense was $1,936, $2,074 and $2,288, respectively.

Note 5. Notes Payable

In the first quarter of 2004, the Company signed an agreement for a secured line of credit with Tanabe Holding America, Inc., a subsidiary of Tanabe Seiyaku Co., Ltd., or Tanabe, allowing it to borrow up to $8.5 million to be used for the development of avanafil (formerly TA-1790), an erectile dysfunction compound currently in Phase 2 clinical trials. The secured line of credit may be drawn upon quarterly and each quarterly borrowing has a 48-month term and bears interest at the annual rate of 2%. There are no financial covenants associated with this secured line of credit. As of December 31, 2004 we had long-term notes payable to Tanabe of $3.2 million, and $5.3 million of available credit under this agreement. All the assets of the Company serve as collateral for this line of credit.

The amount of each quarterly borrowing and its due date are (in thousands):

Date of Note	Amount of Note	Due Date
March 31, 2004	$ 315	March 31, 2008
June 30, 2004	883	June 30, 2008
September 30, 2004	1,007	September 30, 2008
December 31, 2004	1,034	December 31, 2008
Total	$ 3,239	

Note 6. Restructuring and Related Charges

In 1998, the Company restructured its operations and recorded related costs and write-downs in accordance with Emerging Issues Task Force, or EITF, 94-3. 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.

Restructuring reserve and related balances at December 31, 2004 were $3.0 million. There was no change in the restructuring and related reserves accounts in 2004 and 2003.

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

Note 7. Stockholders Equity

Common Stock

The Company is authorized to issue 200 million shares of common stock. As of December 31, 2004 and 2003, there were 38,126,962 and 37,788,365 shares, respectively, issued and outstanding.

Preferred Stock

The Company is authorized to issue 5 million shares of undesignated preferred stock with a par value of $1.00 per share. As of December 31, 2004 and 2003, there are no preferred shares issued or outstanding. The Company may issue shares of preferred stock in the future, without stockholder approval, upon such terms as the Company s management and Board of Directors may determine.

Note 8. Stock Option and Purchase Plans

Stock Option Plan

Under the 2001 Stock Option Plan, or the 2001 Plan, which was approved by the stockholders at the annual meeting held on June 5, 2002, the Company may grant incentive or non-statutory stock options or stock purchase rights, or SPRs. The maximum aggregate number of shares that may be optioned and sold under the 2001 Plan is 1,000,000 shares plus (a) any shares that have been reserved but not issued under the Company s 1991 Incentive Stock Option Plan, or the 1991 Plan; (b) any shares returned to the 1991 Plan as a result of termination of options or repurchase of shares issued under the 1991 Plan; and (c) an annual increase to be added on the first day of the Company s fiscal year beginning 2003, equal to the lesser of (i) 1,000,000 shares, (ii) 2.5% of the outstanding shares on such date, or (iii) a lesser amount determined by the Board. The 2001 Plan allows the Company to grant incentive stock options to employees at not less than 100% of the fair market value of the stock (110% of fair market value for individuals who control more than 10% of the Company stock) at the date of grant, as determined by the Board of Directors. The 2001 Plan allows the Company to grant non-statutory stock options to employees, directors and consultants at a price to be determined by the Board of Directors. The term of the option is determined by the Board of Directors on the date of grant but shall not be longer than ten years. The 2001 Plan allows the Company to grant SPRs to employees and consultants. Sales of stock under SPRs are made pursuant to restricted stock purchase agreements containing provisions established by the Board of Directors. The Company has a right, but not the obligation, to repurchase the shares at the original sale price, which expires at a rate to be determined by the Board of Directors. As of December 31, 2004, no SPRs have been granted under the 2001 Plan.

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

Details of option activity under these plans are as follows:

	Number of Shares	Weighted-Average Exercise Price
Outstanding, December 31, 2001	3,445,899	$ 3.63
Granted	503,645	7.59
Exercised	(200,240)	3.12
Cancelled	(77,429)	5.03
Outstanding, December 31, 2002	3,671,875	$ 4.16
Granted	642,526	4.04
Exercised	(306,631)	1.02
Cancelled	(31,344)	4.95
Outstanding, December 31, 2003	3,976,426	$ 4.38
Granted	868,126	4.82
Exercised	(251,212)	3.41
Cancelled	(478,555)	4.14
Outstanding, December 31, 2004	4,114,785	$ 4.56

Options Outstanding				Options Exercisable	
Range of Exercise Prices	Number Outstanding at December 31,	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable December 31,	Weighted-Average Exercise Price

		2004				2004		
$2.00	$4.00	1,854,653	5.1 years	$	3.38	1,592,992	$	3.28
$4.03	$5.23	1,387,090	5.9 years	$	4.57	841,954	$	4.57
$5.67	$8.08	873,042	6.1 years	$	7.04	566,502	$	7.35
$2.00	$8.08	4,114,785	5.5 years	$	4.56	3,001,448	$	4.41

At December 31, 2004, 2,532,198 options remain available for grant.

During 2004, an option to purchase 15,000 shares of common stock was granted to a research consultant. The fair value of the option was estimated on the date of grant using the Black-Scholes option-pricing model with the following assumptions: no dividend yield, expected volatility of 46%, risk-free interest rate of 3.02% and an expected life of 10 years.

During 2003, an option to purchase 15,000 shares of common stock was granted to a research consultant. The fair value of the option was estimated on the date of grant using the Black-Scholes option-pricing model with the following assumptions: no dividend yield, expected volatility of 72%, risk-free interest rate of 2.93% and an expected life of 10 years.

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

As permitted under SFAS No. 123, the Company accounts for these plans under APB Opinion No. 25. Except for compensation expense recognized for options granted to research consultants as discussed above, no compensation cost has been recognized because the exercise price equaled the market value of stock on the date of grant. Options under these plans generally vest over four years, and all options expire after ten years.

Stock Purchase Plan

Under the 1994 Employee Stock Purchase Plan, or the Stock Purchase Plan, the Company reserved 800,000 shares of common stock for issuance to employees pursuant to the Stock Purchase Plan, under which eligible employees may authorize payroll deductions of up to 10% of their base compensation (as defined) to purchase common stock at a price equal to 85% of the lower of the fair market value as of the beginning or the end of the offering period.

At the annual meeting held on June 4, 2003, the stockholders approved amendments to the Stock Purchase Plan to (i) extend the original term of the Stock Purchase Plan by an additional 10 years such that the Stock Purchase Plan will now expire in April 2014 (subject to earlier termination as described in the Stock Purchase Plan) and (ii) increase the number of shares of Common Stock reserved for issuance under the Stock Purchase Plan by 600,000 shares to a new total of 1,400,000 (collectively referred to herein as the 1994 Purchase Plan Amendments).

As of December 31, 2004, 800,549 shares have been issued to employees and there are 599,451 available for issuance under the Stock Purchase Plan. During 2004, the weighted average fair market value of shares issued under the Stock Purchase Plan was $3.90 per share.

Note 9. License Agreements

During the first quarter of 2004, we initiated a Phase 2 clinical trial with avanafil, our oral PDE5 inhibitor being studied for the treatment of erectile dysfunction. Under the terms of our 2001 development agreement, we accrued a $1.9 million milestone obligation to Tanabe for the year ended December 31, 2004. We intend to pay this milestone obligation, with a future value of $2.0 million, in March 2006. We expect to make other substantial payments to Tanabe in accordance with our agreements with them. These payments are based on certain development, regulatory and sales milestones. In addition, we are required to make royalty payments on any future product sales.

In February 2004, the Company entered into exclusive licensing agreements with Acrux Limited and a subsidiary of Acrux under which it has agreed to develop and commercialize testosterone-MDTS and Evamist in the United States for various female health applications. Under the terms of the agreements, VIVUS agreed to pay to Acrux combined licensing fees of $3.0 million over the 17 month period beginning in February 2004, up to $4.3 million for the achievement of certain clinical development milestones, up to $6.0 million for achieving product approval milestones, and royalties on net sales in the United States upon commercialization of each product. The Company expensed a total $3.3 million of licensing fees under the terms of the agreements in 2004. A portion of these licensing fees was paid in February and September 2004, with the remainder, $972,000, to be paid in June 2005.

The Company has entered into several agreements to license patented technologies that are essential to the development and production of the Company s transurethral products for the treatment of ED. These agreements generally required milestone payments during the development period. In connection with these agreements, the Company is obligated to pay royalties on product sales covered by the license agreements (4% of United States and Canadian product sales and 3% of sales elsewhere in the world). In 2004, 2003 and 2002, the Company recorded royalty expenses, in thousands, of $949, $952, and $978, respectively, as cost of goods sold based on product sales.

Note 10. Commitments

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

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

2005	$	1,318
2006		1,359
2007		116
	$	2,793

Rent expense, in thousands, under operating leases totaled $1,486, $1,252, and $1,342 for the years ended December 31, 2004, 2003, and 2002, respectively.

In November 2002, the Company entered into a manufacturing agreement to purchase raw materials from a supplier beginning in 2003 and ending in 2008. In 2004, the Company purchased $762,000 of product. The Company is committed to purchase a minimum total of $3.1 million of product from 2005 through 2008.

In January 2004, the Company entered into a manufacturing agreement to purchase raw materials from an additional supplier beginning in 2004 and ending in 2006. As of December 31, 2004, the Company had purchased $475,000 of product from this supplier and will be required to purchase a minimum total of $1.8 million of product from 2005 through 2006.

Note 11. Income Taxes

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

		2004		2003
Deferred tax assets:				
Net operating loss carry forwards	$	26,718	$	21,164
Research and development credit carry forwards		6,033		5,955
Inventory reserve		1,528		2,166
Accruals and other		5,853		4,048
Depreciation		1,979		706
		42,111		34,039
Valuation allowance		(42,111)		(34,039)
Total	$		$	

For federal and California income tax reporting purposes, respective net operating loss, or NOL, carry forwards of approximately $74.9 million and $8.4 million are available to reduce further taxable income, if any. For federal and California income tax reporting purposes, respective credit carry forwards of approximately $4.1 million and $2.9 million are available to reduce future taxable income, if any. The carry forwards, except for the California research and development credit, expire on various dates through 2024. The California research and development credits do not expire. The Internal Revenue Code of 1986, as amended, contains provisions that may limit the net operating loss and credit carry forwards available for use in any given period upon the occurrence of certain events, including a significant change in ownership interest.

A valuation allowance has been recorded for the entire deferred tax asset as a result of uncertainties regarding the realization of the asset balance due to the history of losses and the variability of operating results. The net change in the valuation allowance from December 31, 2003 to December 31, 2004 was $8.1 million. As of December 31, 2004 and 2003, the Company had no significant deferred tax liabilities.

The (benefit)/provision for income taxes attributable to continuing operations is based upon (loss)/income before (benefit)/provision for income taxes as follows, for the years ended December 31, 2004, 2003 and 2002 (in thousands):

	2004	2003	2002
Loss before income taxes:			
Domestic	$ (20,388)	$ (2,188)	$ (6,386)
International	(1,189)	1,843	(5,098)
Total	$ (21,577)	$ (345)	$ (11,484)

The (benefit)/provision for income taxes consists of the following components for the years ended December 31, 2004, 2003 and 2002 (in thousands):

	2004	2003	2002
Current			
Federal	$	$ (311)	$ (842)
State	2	(14)	(85)
Foreign	4	6	9
Total (benefit)/provision for income taxes	$ 6	$ (319)	$ (918)

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, 2004, 2003 and 2002:

	2004	2003	2002
(Benefit) provision computed at federal statutory rates	(35)%	(35)%	(35)%
State income taxes, net of federal tax effect	(4)	(4)	(3)
Change in valuation allowance	38	39	30
Refund of taxes		(2)	(5)
Adjustment of income tax payable		(90)	(3)
Tax credits	1		(5)
Loss/(income) not subject to federal and state taxation			17
Other			(4)
(Benefit)/provision for income taxes	0%	(92)%	(8)%

The 2003 tax benefit was based on updated estimate of net tax liabilities. The 2002 tax benefit relates primarily to a filing for a refund of previously paid alternative minimum taxes which became available due to a 2002 tax law change, as well as an updated estimate of net tax liabilities.

Note 12. Concentration of Customers and Suppliers

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

	2004	2003	2002
Customer A	46%	23%	17%
Customer B	27%	21%	30%
Customer C	0%	18%	17%
Customer D	12%	16%	20%
Customer E	12%	11%	0%

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

	2004	2003
Customer A	51%	45%
Customer B	36%	18%
Customer C	0%	15%
Customer D	4%	15%

Customer C merged with Customer A in 2004. The Company did not have any suppliers making up more than 10% of operating costs.

Note 13. 401(k) Plan

All of the Company s employees are eligible to participate in the VIVUS 401(k) Plan. Employer-matching contributions for the years ended December 31, 2004, 2003 and 2002, in thousands were $261, $241, and $246, respectively. The employer-matching portion of the 401(k) plan began on July 1, 2000.

Note 14. Legal Matters

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

Note 15. Subsequent Events (Unaudited)

On January 7, 2005, the Securities and Exchange Commission (SEC) declared effective the shelf Registration Statement the Company filed on Form S-3 on December 21, 2004. The shelf Registration Statement (File Number 333-12159) allows the Company to offer and sell up to an aggregate of $50 million of common stock from time to time in one or more offerings. The terms of any such future offering would be established at the time of such offering.

On February 22, 2005, the Company filed a prospectus supplement with the Securities and Exchange Commission relating to an underwritten public offering of 7,500,000 shares of common stock under the existing shelf Registration Statement (File Number 333-12159) and supplement thereto. On March 15, 2005, we sold 6,250,000 shares of our common stock at a price of $3.40 per share providing us with net proceeds of $19.6 million. We also granted the underwriters a 30-day option to purchase up to an additional 937,500 shares to cover over-allotments.

Effective February 28, 2005, the vesting of the 359,682 outstanding stock options granted on January 21, 2002, of which 82,479 were unvested options, was accelerated. The options were originally scheduled to vest during the period from January 2002 to January 2012. On the accelerated vesting date, the per share market value of VIVUS stock of $3.98 was less than the strike price of the options, which was $8.08 per share. When considering this action, the Compensation Committee took into account that accelerating the vesting of these out-of-the money options prior to June 30, 2005, when the Company currently expects to adopt SFAS 123R, will further reduce the amount of compensation expense that the Company will be required to record in 2005 and beyond as a result of the previously granted equity incentive awards. In addition, by accelerating these options before the implementation of SFAS 123R the expenses associated with the implementation of SFAS123R will be lower in future periods. The acceleration of these out-of-the money options will not cause any additional compensation expense in 2005. Under SFAS 123R the compensation expense associated with these out-of-the-money options would have been significant.

Note 16. Selected Financial Data (Unaudited)

Selected Quarterly Financial Data (in thousands)

	Quarter Ended,			
	March 31	June 30	September 30	December 31
2004				
Total revenue	$ 1,942	$ 3,202	$ 4,331	$ 10,126
Net loss	$ (10,899)	$ (4,880)	$ (4,917)	$ (887)
Net loss per share:				
Basic and diluted	$ (0.29)	$ (0.13)	$ (0.13)	$ (0.02)
2003				
Total revenue	$ 4,269	$ 3,648	$ 10,530	$ 8,991
Net income (loss)	$ (3,191)	$ (2,925)	$ 3,873	$ 2,217
Net income (loss) per share:				
Basic and diluted	$ (0.10)	$ (0.08)	$ 0.10	$ 0.08

FINANCIAL STATEMENT SCHEDULE

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

VIVUS, Inc.

SCHEDULE II - VALUATION AND QUALIFYING ACCOUNTS

(in thousands)

	Balance at Beginning of Period	Charged to Operations	Charges Utilized	Balance at End of Period
Allowance for Doubtful Accounts				
Fiscal year ended December 31, 2002	$ 232	$ 33	$ (120)	$ 145
Fiscal year ended December 31, 2003	145	(24)	(53)	68
Fiscal year ended December 31, 2004	68	42	(6)	104
Inventory Reserve				
Fiscal year ended December 31, 2002	7,484	192	(455)(1)	7,221
Fiscal year ended December 31, 2003	7,221	56	(1,724)(2)	5,553
Fiscal year ended December 31, 2004	5,553	158	(1,794)(3)	3,917
Product Returns				
Fiscal year ended December 31, 2002	1,523	2,020	(1,263)	2,280
Fiscal year ended December 31, 2003	2,280	1,815	(1,163)	2,932
Fiscal year ended December 31, 2004	$ 2,932	$ 1,640	$ (1,724)	$ 2,848

(1) The Company used $163,000 of its fully reserved raw materials inventory in production. The fully reserved raw materials are charged to cost of goods sold at a zero basis when used, which has a favorable impact on gross profit. In the fourth quarter of 2004, the Company determined that it will likely not use the fully reserved inventory in future production.

(2) The Company used $1.2 million of its fully reserved raw materials inventory in production. The fully reserved raw materials are charged to cost of goods sold at a zero basis when used, which has a favorable impact on gross profit. In the fourth quarter of 2004, the Company determined that it will likely not use the fully reserved inventory in future production.

(3) The Company used $844,000 of its fully reserved raw materials inventory in production. The fully reserved raw materials are charged to cost of goods sold at a zero basis when used, which has a favorable impact on gross profit. In the fourth quarter of 2004, the Company determined that it will likely not use the fully reserved inventory in future production.

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

None.

Item 9A. ***Controls and Procedures***

(a) Evaluation of disclosure controls and procedures

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act). Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this annual report.

Management s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2004.

Our management s assessment of the effectiveness of our internal control over financial reporting as of December 31, 2004 has been attested to by KPMG LLP, an independent registered public accounting firm, as stated in their report which is included herein.

(b) Changes in internal controls

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

PART III

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

The information required by this item is hereby incorporated by reference from the information under the captions Election of Directors and Executive Officers contained in the Company s definitive Proxy Statement, to be filed with the Securities and Exchange Commission no later than 120 days from the end of the Company s last fiscal year in connection with the solicitation of proxies for its 2004 Annual Meeting of Stockholders. The information required by Section 16(a) is incorporated by reference from the information under the caption Compliance with Section 16(a) of the Securities Exchange Act of 1934 in the Proxy Statement.

Item 11. ***Executive Compensation***

The information required by this item is incorporated by reference from the information under the caption Executive Officer Compensation in the Company s Proxy Statement referred to in Item 10 above.

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

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

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

The information required by this item is incorporated by reference from the information under the caption Certain Relationships and Related Transactions in the Company s Proxy Statement referred to in Item 10 above.

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

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

PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

(A)

1. Financial Statements

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

Index to Consolidated Financial Statements

2. Financial Statement Schedules

The following financial statement schedule of VIVUS, Inc. as set forth on page 48 is filed as part of this Form 10-K and should be read in conjunction with the Financial Statements of VIVUS, Inc. incorporated by reference herein:

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

(b). Exhibits

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

Exhibit Number	Description
10.6A(1)	License Agreement by and between Amsu, Ltd., and Ortho Pharmaceutical Corporation dated June 23, 1989
10.6B(1)	Amendment by and between Amsu, Ltd., and the Registrant dated July 3, 1992
10.6C(1)	Amendment by and between Amsu, Ltd., and the Registrant dated April 22, 1992
10.6D(1)	Stock Purchase Agreement by and between Amsu, Ltd., and the Registrant dated July 10, 1992
10.11(3)	Form of Indemnification Agreements by and among the Registrant and the Directors and Officers of the Registrant
10.12(2)	1991 Incentive Stock Plan and Form of Agreement, as amended
10.13(1)	1994 Director Option Plan and Form of Agreement
10.14(1)	Form of 1994 Employee Stock Purchase Plan and Form of Subscription Agreement
10.17(1)	Letter Agreement between the Registrant and Leland F. Wilson dated June 14, 1991 concerning severance pay
10.28(4)	Lease Agreement made as of January 1, 1997 between the Registrant and Airport Associates
10.29(4)	Lease Amendment No. 1 as of February 15, 1997 between Registrant and Airport Associates
10.29A(6)	Lease Amendment No. 2 dated July 24, 1997 by and between the Registrant and Airport Associates
10.29B(6)	Lease Amendment No. 3 dated July 24, 1997 by and between the Registrant and Airport Associates
10.36(7)	Form of, Change of Control Agreements, dated July 8, 1998 by and between the Registrant and certain Executive Officers of the Company.
10.39(8)	Sublease agreement between KVO Public Relations, Inc. and the Registrant dated December 21, 1999
10.41(9)	License and Supply Agreement made as of November 20, 2000 between the Registrant and Paladin Labs, Inc.
10.42(9)	Development, License and Supply Agreement made as of January 22, 2001 between the Registrant and TANABE SEIYAKU CO., LTD.
10.42A(14)	Amendment One to Agreement, dated January 9, 2004 between Registrant and TANABE SEIYAKU CO., LTD.
10.43(10)	Settlement and Modification Agreement made as of July 12, 2001 between ASIVI, LLC, AndroSolutions, Inc. Gary W. Neal and the Registrant.
10.44(11)	2001 Stock Option Plan and Form of Agreement
10.45(12)	Supply Agreement made as of September 3, 2002 between the Registrant and Meda AB.
10.46(13)	Amendment Three, dated November 21, 2002 by and between VIVUS, Inc. and CHINOIN Pharmaceutical and Chemical Works, Ltd.
10.47(13)	Lease Amendment No. 4 and Settlement Agreement dated October 25, 2000 by and between the Registrant and Airport Associates
10.48(13)	Exclusive Distribution Agreement dated October 1, 2002 between the Registrant and Cord Logistics
10.49(13)	Distribution and Supply Agreement made as of February 18, 2003 between the Registrant and Meda AB.
10.50(14)	Testosterone Development and Commercialization Agreement made as of February 7, 2004 between the Registrant, Fempharm Pty Ltd. and Acrux DDS Pty Ltd.
10.51(14)	Estradiol Development and Commercialization Agreement made as of February 12, 2004 between the Registrant, Fempharm Pty Ltd. and Acrux DDS Pty Ltd.
10.52(14)	Note Purchase Agreement, dated January 8, 2004 between Registrant and Tanabe Holding America, Inc.
10.53(14)	Manufacture and Supply Agreement, dated December 22, 2003 between Registrant and NeraPharm spol., s.r.o. and signed by the Company on January 7, 2004.
10.54	Amendment One, dated November 20, 2004 to License and Supply Agreement made between the Registrant and Paladin Labs, Inc.
21.2	List of Subsidiaries
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer, dated March 16, 2005, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended.

Exhibit Number	Description
31.2	Certification of Chief Financial Officer, dated March 16, 2005, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended.
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Confidential treatment granted.

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

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

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

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

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

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

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

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SIGNATURES

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

VIVUS, INC.,
a Delaware Corporation

By: /s/ TIMOTHY E. MORRIS
Timothy E. Morris
Vice President, Finance and Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: March 16, 2005

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

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

Signature	Title	Date
/s/ LELAND F. WILSON Leland F. Wilson	President, Chief Executive Officer (Principal Executive Officer) and Director	March 16, 2005
/s/ VIRGIL A. PLACE Virgil A. Place	Chairman of the Board and Chief Scientific Officer and Director	March 16, 2005
/s/ TIMOTHY E. MORRIS Timothy E. Morris	Vice President of Finance and Chief Financial Officer (Principal Financial and Accounting Officer)	March 16, 2005
/s/ GRAHAM STRACHAN Graham Strachan	Director	March 16, 2005
/s/ MARIO M. ROSATI Mario M. Rosati	Director	March 16, 2005
/s/ MARK B. LOGAN Mark B. Logan	Director	March 16, 2005
/s/ LINDA M. DAIRIKI SHORTLIFFE, M.D. Linda M. Dairiki Shortliffe, M.D.	Director	March 16, 2005

VIVUS, INC.

REPORT ON FORM 10-K FOR

THE YEAR ENDED DECEMBER 31, 2004

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