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Filed Pursuant to Rule 424(b)(5)
Registration No. 333-121519

SUBJECT TO COMPLETION, DATED FEBRUARY 22, 2005

The information in this prospectus supplement and the accompanying prospectus is not complete and may be changed. A registration statement relating to these securities has been filed with the Securities and Exchange Commission and has been declared effective. This prospectus supplement and the accompanying prospectus are not an offer to sell these securities, and we are not soliciting offers to buy these securities, in any jurisdiction where the offer or sale is not permitted.

PROSPECTUS SUPPLEMENT
(to Prospectus dated January 7, 2005)

7,500,000 Shares

VIVUS, INC.

Common Stock

We are offering 7,500,000 shares of our common stock.

Our common stock is quoted on the Nasdaq National Market under the symbol "VVUS." On February 18, 2005, the last reported sale price of our common stock on the Nasdaq National Market was $4.04 per share.

An investment in our common stock involves signif icant risks. These risks are described under the caption "Risk Factors" beginning on page S-4 of this prospectus supplement and supersede in their entirety the risk factors set forth beginning on page 4 of the accompanying prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement or the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share	Total
Public offering price	**$**	**$**
Underwriting discounts and commissions	**$**	**$**
Proceeds, before expenses, to us	**$**	**$**

The underwriters may also purchase up to an additional 1,125,000 shares of our common stock from us at the public offering price, less the underwriting discounts and commissions, to cover over-allotments.

The underwriters expect to deliver the shares in New York, New York on , 2005.

SG Cowen & Co. **Wachovia Securities**

, 2005

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Prospectus Supplement

Prospectus

You should rely only on the information contained in this prospectus supplement, the accompanying prospectus and the documents we incorporate by reference in this prospectus supplement and the accompanying prospectus. We have not, and the underwriters have not, authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus supplement and the accompanying prospectus. If anyone provides you with different or inconsistent information, you should not rely on it. You should assume that the information contained in this prospectus supplement and the accompanying prospectus, as well as the information that we have filed with the Securities and Exchange Commission, or the SEC, and incorporated by reference herein and therein, is accurate only as of the date of the applicable document. This prospectus supplement and the accompanying prospectus do not constitute an offer or solicitation by anyone in any jurisdiction in which an offer or solicitation is not authorized or in which the person making an offer or solicitation is not qualified to do so, or to anyone to whom it is unlawful to make an offer or solicitation.

This prospectus supplement contains the terms of this offering. This prospectus supplement, along with the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, may add, update or change information in the accompanying prospectus. If information in this prospectus supplement, or the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, is inconsistent with the accompanying prospectus, this prospectus supplement, or the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, will apply and will supersede the information in the accompanying prospectus.

This prospectus supplement contains references to a number of our trademarks that are registered or are subject to pending applications or to which we have common law rights. These include, but are not limited to, the following: VIVUS®, ALISTA™, Evamist™ and MUSE®. Each trademark, trade name or service mark of any other company appearing in this prospectus supplement or the accompanying prospectus belongs to its holder.

PROSPECTUS SUPPLEMENT SUMMARY

This summary only highlights the more detailed information appearing elsewhere in this prospectus supplement and the documents incorporated by reference herein. It may not contain all of the information that may be important to you. To fully understand the investment you are contemplating, you should read carefully this entire prospectus supplement, the accompanying prospectus and the detailed information incorporated into each of them by reference before you decide to make an investment. You should pay special attention to the "Risk Factors" section of this prospectus supplement beginning on page S-4 to determine whether an investment in our common stock is appropriate for you. Unless otherwise indicated, all information in this prospectus supplement assumes no exercise of the over-allotment option to purchase additional shares of common stock that we have granted to the underwriters. Unless the context otherwise requires, the terms "we," "us," "our," the "Company" and "VIVUS" refer to VIVUS, Inc., a Delaware corporation, and its predecessors and subsidiaries.

Our Company

VIVUS, Inc. is a specialty pharmaceutical company focused on the research, development and commercialization of products to restore sexual function in women and men. We currently are developing four clinical stage product candidates, as described below, each of which targets an estimated existing or potential market in excess of $1 billion annually. In 1997, we launched MUSE (alprostadil) in the United States and, together with our partners, internationally. We market MUSE as a prescription product for the treatment of erectile dysfunction.

Our Product Pipeline

We are currently conducting clinical trials on four product candidates:

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	2021 (US 6,818,226)
Evamist (estradiol-MDTS)	Menopausal symptoms	Phase 3 ongoing	2021 (US 6,818,226)
Avanafil (PDE5 inhibitor)	Erectile dysfunction (ED)	Phase 2 ongoing	2021 (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.

Recent Developments

Since the beginning of the fourth quarter of 2004, we have announced a number of important developments.

- In November 2004, the United States Patent and Trademark Office, or the PTO, granted a key patent relating to the metered-dose transdermal spray, or MDTS, delivery system to which we hold an exclusive license for the U.S. market. We believe this patent will provide long-term protection for the MDTS system, which we are currently developing for the treatments of menopausal symptoms and hypoactive sexual desire disorder.

- In December 2004, after we were granted a Special Protocol Assessment from the Food and Drug Administration on the design of our trial, we initiated a pivotal Phase 3 trial for Evamist for the treatment of menopausal symptoms.

- In February 2005, along with Acrux Limited, the company from which we licensed the testosterone-MDTS technology, 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 women with hypoactive sexual desire disorder.

- In February 2005, we completed the enrollment of a Phase 2 dose ranging study for avanafil for the treatment of erectile dysfunction.

Corporate Information

VIVUS, Inc. was incorporated in the state of California on April 16, 1991 and completed a re-incorporation in the state of Delaware in May 1996. Our corporate headquarters and mailing address is 1172 Castro Street, Mountain View, California 94040, and the telephone number at that location is (650) 934-5200. Our website address is www.vivus.com. We make our periodic and current reports that we file with the SEC available on our web site, free of charge, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information contained on our website is not a part of this prospectus supplement or the accompanying prospectus. Our common stock trades on the Nasdaq National Market under the symbol "VVUS."

The Offering

Shares of common stock we are offering	7,500,000 shares
Shares of common stock to be outstanding immediately after this offering	45,716,421 shares
Use of proceeds	We currently intend to use the net proceeds from this offering to continue to fund clinical trials of our product candidates, to fund general corporate purposes and as further described in this prospectus supplement under the heading "Use of Proceeds."
Nasdaq National Market symbol	VVUS

The number of shares of common stock outstanding immediately after this offering in the table above is based on 38,216,421 shares of our common stock outstanding as of February 14, 2005 and does not include the following, each stated as of that date:

- 3,999,235 shares of our common stock issuable upon the exercise of outstanding stock options; and
- up to 1,125,000 shares of our common stock issuable upon the exercise of the underwriters' over-allotment option.

Unless otherwise stated, all information contained in this prospectus supplement reflects an assumed public offering price of $4.04 per share, which was the last reported sale price of our common stock on the Nasdaq National Market on February 18, 2005.

RISK FACTORS

An investment in our securities involves a high degree of risk. You should carefully consider the following risk factors related to the securities offered in this prospectus supplement and to our business and operations. You should also carefully consider the other information contained or incorporated by reference in this prospectus supplement and the accompanying prospectus before you decide to purchase our securities. Some of these factors have affected our financial condition and operating results in the past or are currently affecting us. All of these factors could affect our future financial condition and operating results. The risks and uncertainties described below are not the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. If any of the following risks actually occur, our business, results of operations and financial condition could be harmed, the trading price of our securities could decline and you may lose all or part of your investment. The risks set forth below replace and supersede in their entirety the risks set forth beginning on page 4 of the accompanying prospectus. The risks discussed below also include forward-looking statements and our actual results may differ substantially from those discussed in these forward-looking statements.

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 some 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's 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.

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. Cialis was launched in the United States in January 2004. Bayer AG and GlaxoSmithKline plc launched Levitra in the European Union and the United States in March and September 2003, respectively.

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 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, spol. 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 assuring the new material from NeraPharm meets testing and regulatory specifications. There can be no guarantees the material will pass these requirements and be usable in our manufacturing process. We are currently in the process of investigating additional sources for our future alprostadil supplies. However, there can be no assurance that we will be able to identify and qualify additional suppliers of alprostadil in a timely manner, 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 Bergen Brunswig 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

Our inability to adequately protect our proprietary technologies could harm our competitive position.

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.

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 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.

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. We expect that our existing capital resources combined with future cash flows will be sufficient to support our operating activities through the end of 2005. Financing in future periods will most likely be required to fund development of our research and development pipeline and the possible launch of any future products. Our future capital requirements will depend upon numerous factors, including:

- the progress 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 $123 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 $123 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. The United States Congress and other governmental and regulatory authorities have also considered requiring companies to expense stock options. We and other companies are required to record a compensation expense equal to the fair market value of each stock option granted. This expense would be spread over the vesting period of the stock option. Currently, we account for stock compensation under Accounting Principles Board, or APB, No. 25, Accounting for Stock Issued to Employees, which results in no compensation expenses recorded in connection with stock options granted to our employees. 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.

SPECIAL NOTE ON FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus and the documents we have filed with the Securities and Exchange Commission, or SEC, that are incorporated herein by reference and that are referenced under the sections entitled "Where You Can Find More Information" on pages S-38 and "Information Incorporated by Reference into this Prospectus Supplement" on pages S-38, contain forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements represent our management's judgment regarding future events. In many cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "could," "plan," "expect," "anticipate," "estimate," "believe," "predict," "intend," "potential," or "continue" or the negative of these terms or other words of similar import, although some forward-looking statements are expressed differently. All statements, other than statements of historical fact, included in this prospectus supplement and the accompanying prospectus regarding our financial position, business strategy and plans or objectives for future operations are forward-looking statements. Without limiting the broader description of forward-looking statements above, we specifically note that statements regarding timelines for initiating new clinical trials, planned announcements of clinical data, the possibility of obtaining regulatory approval, our ability to manufacture and sell any products, potential drug candidates, their potential therapeutic effect, market acceptance or our ability to earn a profit from sales or licenses of any drug candidate, our ability to discover new drugs in the future, and our ability to establish future collaborative arrangements are all forward-looking in nature. We cannot guarantee the accuracy of the forward-looking statements, and you should be aware that results and events could differ materially and adversely from those contained in the forward-looking statements.

You should also consider carefully the statements set forth in the section entitled "Risk Factors" and other sections of this prospectus supplement, in the accompanying prospectus, and in the other documents we have filed with the SEC and that are incorporated herein by reference, which address these and additional factors that could cause results or events to differ from those set forth in the forward-looking statements. All subsequent written and oral forward-looking statements attributable to us or to persons acting on our behalf are expressly qualified in their entirety by the applicable cautionary statements. We have no plans to update these forward-looking statements.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables set forth our summary consolidated statement of operations data for the years ended December 31, 2004, 2003, 2002 and 2001 and our actual and as adjusted summary consolidated balance sheet data as of December 31, 2004. The summary consolidated statement of operations data for the years ended December 31, 2003, 2002 and 2001 have been derived from our audited consolidated financial statements. Our audited consolidated financial statements as of December 31, 2003 and 2002 and for the years ended December 31, 2003, 2002 and 2001 are incorporated by reference into this prospectus supplement and the accompanying prospectus. The summary consolidated statement of operations data for the year ended December 31, 2004 and the actual summary consolidated balance sheet data as of December 31, 2004 have been derived from our unaudited consolidated financial statements. This summary consolidated financial data should be read in conjunction with the information in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our audited consolidated financial statements, including the notes thereto, set forth in our Annual Report on Form 10-K for the year ended December 31, 2003 and other periodic filings with the SEC, including our most recent Form 10-Q. The historical and pro forma results presented here are not necessarily indicative of future results.

Summary Consolidated Financial Data

	Year ended December 31,			
	2004	2003	2002	2001
	(unaudited)			
	(in thousands, except per share amounts)			
Consolidated Statements of Operations Data:				
Revenue	$ 19,601	$ 27,438	$ 22,349	$ 23,601
Operating Expenses:				
Cost of goods sold	11,283	10,993	11,207	12,933
Research and development	18,676	7,724	13,281	12,324
Selling, general and administrative	11,730	9,839	10,556	9,314
Total operating expenses	41,689	28,556	35,044	34,571
Loss from operations	(22,088)	(1,118)	(12,695)	(10,970)
Interest and other income	511	773	1,211	2,171
Loss before taxes	(21,577)	(345)	(11,484)	(8,799)
(Provision) benefit for income taxes	(6)	319	918	1,729
Net loss	$ (21,583)	$ (26)	$ (10,566)	$ (7,070)
Basic loss per common share	$ (0.57)	$ (0.00)	$ (0.32)	$ (0.22)
Diluted loss per common share	$ (0.57)	$ (0.00)	$ (0.32)	$ (0.22)
Weighted average shares of common stock outstanding—basic	38,010	35,884	32,907	32,572
Weighted average shares of common stock outstanding—diluted	38,010	35,884	32,907	32,572

	As of December 31, 2004	
	Actual	As Adjusted[1]
	(unaudited)	
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash, cash equivalents and available-for-sale securities, including restricted cash	$ 33,137	$ 61,218
Total assets	54,389	82,470
Long-term obligations	9,232	9,232
Accumulated deficit	(122,543)	(122,543)
Stockholders' equity	30,722	58,802

(1) The As Adjusted column in the Consolidated Balance Sheet Data gives effect to the sale of 7,500,000 shares of our common stock in this offering at an assumed offering price of $4.04 per share after deducting underwriting discounts and commissions and estimated offering expenses.

USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of our common stock in this offering (assuming an offering price of $4.04 per share) will be approximately $28.1 million, or approximately $32.3 million if the underwriters' over-allotment option is exercised in full, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us in connection with this offering.

We currently intend to use the net proceeds we receive from the sale of our common stock in this offering to fund clinical trials of our product candidates and for general corporate purposes.

At this time, we have not determined the approximate amount of net proceeds that will be allocated to each of the uses of proceeds stated above. In addition, we may use the net proceeds we receive from this offering for a variety of other corporate uses, including in-licenses or acquisitions of other products, technologies or companies, although we currently have no commitments or agreements for any such transactions. Our management will retain broad discretion as to the allocation of the net proceeds from this offering. Pending application of the net proceeds as described above, we intend to invest the proceeds in highly liquid, investment-grade securities and money market funds.

DILUTION

If you invest in our common stock, your interest will be diluted to the extent of the difference between the public offering price per share you pay in this offering and the net tangible book value per share of our common stock immediately after this offering. Our net tangible book value of our common stock as of December 31, 2004 was approximately $30.7 million, or approximately $0.81 per share of common stock based upon 38,123,381 shares outstanding. Net tangible book value per share is equal to our total tangible assets, less our total liabilities, divided by the total number of shares of our common stock outstanding as of December 31, 2004. After giving effect to the sale by us of the 7,500,000 shares of our common stock we are offering, and after deducting underwriting discounts and commissions and our estimated offering expenses, our as-adjusted net tangible book value would have been approximately $58.8 million, or approximately $1.29 per share of common stock based upon 45,623,381 shares outstanding. This represents an immediate increase in net tangible book value of $0.48 per share to our existing stockholders and an immediate dilution in net tangible book value of $2.75 per share to new investors. The following table illustrates this calculation on a per share basis:

Assumed public offering price per share		$ 4.04
Net tangible book value per share as of December 31, 2004	$ 0.81	
Increase in net tangible book value per share attributable to the offering	0.48	
As-adjusted net tangible book value per share after giving effect to the offering		1.29
Dilution in net tangible book value per share to new investors		$ 2.75

The foregoing table excludes the following, each stated as of December 31, 2004:

- 3,000,619 shares of our common stock issuable upon the exercise of exercisable stock options at a weighted average exercise price of $4.41 per share;
- 1,114,166 shares of our common stock issuable upon the exercise of outstanding stock options that are not exercisable; and
- 2,532,198 shares of common stock reserved for future issuance under our stock plans.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of December 31, 2004:

- on an actual basis; and
- on an adjusted basis to give effect to our receipt of an estimated $28.1 million of net proceeds from the sale of our common stock in this offering (assuming an offering price of $4.04 per share), after deducting underwriting discounts and commissions and estimated offering expenses.

	As of December 31, 2004	
	Actual	As Adjusted
	(unaudited)	
Cash, cash equivalents and available-for-sale securities	$ 29,813	$ 57,893
Notes payable	3,239	3,239
Stockholders' equity		
Common stock, $.001 par value: 200,000,000 shares authorized; 38,123,381 and 45,623,381 shares issued and outstanding, actual and as adjusted, respectively	38	46
Preferred stock, $1.00 par value: 5,000,000 shares authorized; no shares issued or outstanding, actual and as adjusted	0	0
Additional paid-in capital	153,275	181,347
Accumulated other comprehensive income	(48)	(48)
Accumulated deficit	(122,543)	(122,543)
Total stockholders' equity	30,722	58,802
Total capitalization	$ 33,961	$ 62,041

The table above excludes the following, each stated as of December 31, 2004:

- 3,000,619 shares of our common stock issuable upon the exercise of exercisable stock options at a weighted average exercise price of $4.41 per share;
- 1,114,166 shares of our common stock issuable upon the exercise of outstanding stock options that are not exercisable; and
- 2,532,198 shares of our common stock reserved for future issuance under our stock plans.

PRICE RANGE OF OUR COMMON STOCK

Our common stock is quoted on the Nasdaq National Market under the symbol "VVUS." The following table sets forth the high and low last reported sales prices of our common stock as reported on the Nasdaq National Market for the periods indicated:

	High	Low
2003		
First quarter	$ 4.48	$ 3.15
Second quarter	5.69	4.19
Third quarter	4.60	3.30
Fourth quarter	4.18	3.52
2004		
First quarter	$ 7.20	$ 4.38
Second quarter	6.50	3.61
Third quarter	5.10	3.61
Fourth quarter	6.18	4.27
2005		
First quarter (through February 18, 2005)	$ 4.54	$ 3.99

Computershare Limited is the transfer agent for our common stock. As of February 18, 2005, we had approximately 4,454 record holders of our common stock.

DIVIDEND POLICY

We have never declared or paid cash dividends on our common stock. We currently intend to use all available funds and retain any future earnings for use in our business and do not anticipate declaring or paying any cash dividends on our common stock in the foreseeable future. Future dividends, if any, will be at the discretion of our Board of Directors.

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, 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 needle penile injection and penile implants were the main treatment options for ED. 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	2021 (US 6,818,226)
Evamist (estradiol-MDTS)	Menopausal symptoms	Phase 3 ongoing	2021 (US 6,818,226)
Avanafil (PDE5 inhibitor)	Erectile dysfunction (ED)	Phase 2 ongoing	2021 (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, 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 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 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 in the United States 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 completed 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 increases in triglycerides, inflammatory mediators, and certain clotting factors. We believe that these increases 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 increases 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, 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 onset 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 little 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. The administration of MUSE for erection is a relatively easy and painless procedure which typically takes less than a minute. 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. In addition, MUSE is easy to use, minimally invasive and discrete. 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 at the institution at which the study will be conducted. 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 some 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. Cialis was launched in the United States in January 2004. 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 14, 2005, we had 114 employees, including 78 of which are located at our manufacturing facility in Lakewood, New Jersey and 36 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.

MANAGEMENT

The following table sets forth information regarding our executive officers and directors as of February 18, 2005.

Name	Age	Position(s)
Virgil A. Place, M.D.	80	Chairman of the Board, Chief Scientific Officer and Director
Leland F. Wilson	60	President, Chief Executive Officer and Director
Peter Y. Tam	41	Sr. Vice President, Product and Corporate Development
John Dietrich, Ph.D.	58	Vice President, Research and Development
Neil Gesundheit, M.D.	52	Vice President, Clinical Research
Guy P. Marsh	51	Vice President, U.S. Operations and General Manager
Timothy E. Morris	43	Vice President, Finance and Chief Financial Officer
Terry M. Nida	56	Vice President, Corporate Development and International Marketing
Mark B. Logan(1)(2)	65	Director
Mario M. Rosati(2)(3)	57	Secretary and Director
Linda M. Dairiki Shortliffe, M.D.(1)(2)(3)	55	Director
Graham Strachan(1)	66	Director

(1) Member of the audit committee of the board of directors.

(2) Member of the compensation committee of the board of directors.

(3) Member of the nominating and governance committee of the board of directors.

Virgil A. Place, M.D. is the founder of VIVUS and has been its Chief Scientific Officer and Chairman of the Board since VIVUS was formed in April 1991. Before joining VIVUS, Dr. Place was Principal Scientist and held a variety of executive positions including Vice President of Medical and Regulatory Affairs at ALZA Corporation from 1969 to 1991. In addition, Dr. Place served nine years on the ALZA Corporation Board of Directors. He received a B.A. in Chemistry from Indiana University and an M.D. from The Johns Hopkins University. He is Board Certified in Internal Medicine, with specialty training at the Mayo Clinic.

Leland F. Wilson has been President and a director of VIVUS since it was formed in April 1991 and Chief Executive Officer since November 1991. Prior to joining VIVUS, Mr. Wilson was Vice President of Marketing and Corporate Development of Genelabs Technologies, Inc. from 1989 to 1991. Mr. Wilson was Group Product Director, later promoted to Director of Marketing, at LifeScan, a Johnson & Johnson company, from 1986 to 1989. From 1973 to 1986, Mr. Wilson served in several research, marketing and sales positions for Syntex Research and Syntex Laboratories, Inc. Mr. Wilson received a B.S. and an M.S. from Pennsylvania State University and was a Lieutenant in the United States Army.

Peter Y. Tam has been Senior Vice President of Product and Corporate Development of VIVUS since July 2004. Prior to that time, Mr. Tam was Vice President of Strategic Planning and Corporate Development at VIVUS. Mr. Tam joined VIVUS in 1993 as Manager of Clinical Research, and in 1999 he assumed the responsibilities of Director of Clinical and Corporate Development. Prior to joining VIVUS, Mr. Tam held various research and clinical development positions at Genentech, Inc. from 1991 through 1993 and XOMA Corporation from 1987 to 1991. Mr. Tam received a B.S. in Chemistry from University of California Berkeley in 1986 and his M.B.A. at Santa Clara University in 2000.

John Dietrich, Ph.D. has been Vice President of Research and Development for VIVUS since October 2000. Prior to that time, he held a similar position at Cellegy Pharmaceuticals. From 1991 until

1999, Dr. Dietrich was Vice President of R&D at Allelix Biopharmaceuticals in Toronto, Canada, where he was responsible for all pre-clinical and clinical departments and managed a staff of 125 people. Dr. Dietrich received a B.S. from LeMoyne College, an M.S. from the University of Dayton and a Ph.D. in Pharmacology from the University of North Carolina and was an Assistant Professor at the University of Illinois School of Medicine.

Neil Gesundheit, M.D., M.P.H. has been Vice President, Clinical Research for VIVUS since January 1994. In August 1999, Dr. Gesundheit transitioned to part-time status to assume the position of Associate Dean for Medical Education at the Stanford University School of Medicine. Dr. Gesundheit has also held the position of Associate Professor of Medicine at Stanford University School of Medicine since 1999. Dr. Gesundheit previously served as Vice President, Clinical and Regulatory Affairs at VIVUS from January 1994 to September 1997 and as Chief Medical Officer from August 1998 to August 1999. From 1989 to 1993, Dr. Gesundheit was Associate Director of Clinical Research (Endocrinology) at Genentech, Inc. and from 1989 to 1999, he was an attending physician (Endocrinology) at Santa Clara Valley Medical Center, a Stanford affiliate. He holds an A.B. degree from Harvard College, an M.D. from the University of California, San Francisco, and an M.P.H. from the University of California, Berkeley. Dr. Gesundheit is Board Certified in Internal Medicine and in the subspecialty of endocrinology and metabolism.

Guy P. Marsh has been Vice President of U.S. Operations and General Manager for VIVUS since July 2000. In 2001, Mr. Marsh assumed responsibilities for U.S. Sales and Marketing of MUSE. Mr. Marsh joined VIVUS in May 1998 in the position of Senior Director, U.S. Operations, and assumed the responsibilities of General Manager, Operations in April 1999. Prior to joining VIVUS, Mr. Marsh served as Vice President Technical Operations for Copley Pharmaceutical, Inc. from April 1994 to April 1998. Also during this period, Mr. Marsh served as a liaison between Copley Pharmaceutical and Copley's majority stockholder, Hoechst-Celanese Corporation. From November 1987 to April 1994, Mr. Marsh served in various manufacturing, sales and business management roles for Hoechst-Roussel Pharmaceuticals, Inc. Mr. Marsh received a B.S. in Engineering from New Jersey Institute of Technology, holds a New Jersey State Professional Engineering License, and received an M.B.A. from Seton Hall University.

Timothy E. Morris has been Vice President, Finance and Chief Financial Officer since November 2004. Prior to joining VIVUS, Mr. Morris served as Chief Financial Officer and Senior Vice President of Finance & Administration at Questcor Pharmaceuticals Inc. from September 2001 to November 2004. Prior to this position, Mr. Morris served as Vice President of Finance & Administration and Chief Financial Officer at InterPro Business Solutions from October 2000 to September 2001, at utility.com from October 1999 to October 2000 and at RiboGene, Inc., the predecessor company to Questcor, from May 1995 to October 1999. Prior to RiboGene, Mr. Morris was at Glycomed Incorporated from May 1992 to May 1995 most recently as Chief Accounting Officer, Acting Chief Financial Officer and Senior Director, Finance. Mr. Morris earned a B.S. degree, cum laude, in Business with an emphasis in Accounting from California State University, Chico, and in 1996 Mr. Morris became a Certified Public Accountant.

Terry M. Nida has been Vice President, Corporate Development and International Marketing for VIVUS since August 1998. From November 1995 to August 1998, Mr. Nida was Vice President, Europe, and effective March 28, 1996 was appointed as an executive officer. Prior to joining VIVUS, Mr. Nida was Vice President, Sales, Marketing and Business Development at Carrington Laboratories, with responsibility for all sales, marketing and business development activities. Mr. Nida was Senior Director, Worldwide Sales, Marketing and Business Development for Centocor, Inc. from 1993 to 1994, and Director of Sales and Marketing in Europe for Centocor, Inc. from 1990 to 1993. He received a B.A and M.A. from Wichita State University.

Mark B. Logan has been a director of VIVUS since March 1999. From 1994 until his retirement in May 2001, Mr. Logan was Chairman of the Board, President and Chief Executive Officer of VISX Inc., a medical device company. From January 1992 to October 1994, he was Chairman of the Board and Chief Executive Officer of INSMED Pharmaceuticals, Inc. Previously, Mr. Logan was Senior Vice President & Chief Operating Officer and a member of the Board of Directors of Baush & Lomb, Inc., and has held senior executive positions with Becton, Dickinson and Co. and Wyeth, Inc. Mr. Logan serves as a director of Abgenix, a publicly traded biotechnology company. He is also a director of the University of Virginia Heart Center, and a trustee of the Southern Environmental Law Center. Mr. Logan received a B.A. from Hiram College and a P.M.D. from Harvard Business School.

Mario M. Rosati has been a director of VIVUS since March 1999. Mr. Rosati has been with the Palo Alto, California law firm of Wilson Sonsini Goodrich & Rosati, Professional Corporation, since 1971. Mr. Rosati also serves as a director of Aehr Test Systems, Genus, Inc., Sanmina-SCI Corporation and Symyx Technologies, Inc. Mr. Rosati holds a B.A. from the University of California, Los Angeles and a J.D. from the University of California, Berkeley, Boalt Hall School of Law.

Linda M. Dairiki Shortliffe, M.D. has been a director of VIVUS since June 1999. Dr. Shortliffe has been Professor of Urology at Stanford University School of Medicine since 1993 and Chair of the Department of Urology since 1995. She has also been Chief of Pediatric Urology of Lucile Salter Packard Children's Hospital at Stanford since 1991. She is a Fellow of the American College of Surgeons and the American Academy of Pediatrics and serves as a Trustee to the American Board of Urology. Dr. Shortliffe has authored numerous publications and her works appear in prominent medical journals and books. Dr. Shortliffe received an A.B. from Radcliffe/Harvard College and an M.D. from Stanford University.

Graham Strachan has been a director of VIVUS since June 2001. From 1987 to 1999, he was President and CEO of Allelix Biopharmaceuticals Inc., now NPS Allelix Pharmaceuticals Inc., which is engaged in the discovery and development of novel, small molecule drugs and recombinant therapeutic proteins. Between 1982 and 1986, Mr. Strachan held other executive level positions within Allelix, of which he was a co-founder in 1981. He has also been active in community service, particularly in life science organizations, and is currently chair of the Ontario Mental Health Research Foundation and the Canadian Biotechnology Human Resource Council. Mr. Strachan holds a B.Sc. Honours Chemistry degree from the University of Glasgow, is a Qualified Patent Agent in Canada and in the United States, and he completed an Advanced Management Program at the University of Western Ontario in 1972.

PRINCIPAL STOCKHOLDERS

The following table sets forth information known to us with respect to the beneficial ownership of our outstanding common stock as of February 14, 2005 by:

- each person or entity who is known by us to beneficially own more than 5% of our common stock;
- each of our directors;
- each of our named executive officers; and
- all of our directors and executive officers as a group.

Except as otherwise noted, the stockholders named in the table have sole voting and investment power with respect to all shares of common stock shown as beneficially owned by them, subject to applicable community property laws.

	Beneficially Owned Stock[2]		
Name and Address of Beneficial Owner[1]	**Number of Shares**	**Percent before offering**	**Percent after offering[4]**
Royce & Associates LLC 1414 Avenue of the Americas New York, New York 10019	3,996,400	10.46%	8.74%
Chilton Investment Co., Inc. 1266 E. Main Street Stamford, Connecticut 06902	2,645,000	6.92%	5.79%
Virgil A. Place, M.D.[3][5]	659,893	1.73%	1.44%
Leland F. Wilson[3][6]	1,529,500	4.00%	3.35%
Mark B. Logan[3]	76,750	*	*
Mario M. Rosati[3]	75,539	*	*
Linda M. Dairiki Shortliffe, M.D[3]	76,750	*	*
Graham Strachan[3]	52,750	*	*
Terry M. Nida[3]	416,687	1.09%	*
John Dietrich, Ph.D.[3]	163,375	*	*
Guy P. Marsh[3]	171,617	*	*
Peter Y. Tam[3]	159,033	*	*
All directors and executive officers as a group (11 persons)	3,381,894	8.85%	7.40%

* Less than 1%

(1) Unless otherwise indicated, the address of each person in this table is c/o Vivus, Inc., 1172 Castro Street, Mountain View, CA 94040.

(2) Applicable percentage ownership is based on 38,216,421 shares of common stock as of February 14, 2005. Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission. In computing the number of shares beneficially owned by a person and the percentage of ownership of that person, shares of common stock subject to options held by that person that are currently exercisable or exercisable within 60 days of February 14, 2005 are deemed outstanding. Those shares, however, are not deemed outstanding for the purpose of computing the percentage ownership of any other person.

(3) Includes options to purchase shares of common stock currently exercisable or exercisable within 60 days after February 14, 2005, which are deemed outstanding for computing the percentage ownership of the person holding such options, but are not deemed outstanding for computing the percentage of any other person.

(4) The percent after offering column assumes 7,500,000 shares of common stock issued in connection with this offering. This calculation also assumes the listed beneficial owners do not purchase shares of common stock sold in this offering.

(5) Includes 31,600 shares of common stock held by Dr. Place as Custodian for V. Aristophanes Kamehameha A.H. Place under the Hawaii Uniform Transfers to Minors Act, of which Dr. Place is the beneficial owner.

(6) Includes 25,000 shares of common stock held by the Leland F. Wilson Living Trust.

UNDERWRITING

We and the underwriters named below have entered into an underwriting agreement with respect to the shares being offered. Subject to the terms and conditions of the underwriting agreement, the underwriters named below have severally agreed to purchase from us the number of shares of our common stock set forth opposite their names on the table below at the public offering price, less the underwriting discounts and commissions, as set forth on the cover page of the prospectus supplement as follows:

Name	Number of Shares
SG Cowen & Co., LLC	
Wachovia Capital Markets, LLC	
Total	7,500,000

The underwriting agreement provides that the obligations of the several underwriters to purchase the shares of common stock offered hereby on a firm commitment basis may be terminated at their discretion in the event of a material adverse change in economic, political or financial conditions or based on their assessment of the state of the financial markets. The obligations of the underwriters may also be terminated upon the occurrence of other events specified in the underwriting agreement. The underwriters are severally committed to purchase all of the shares of common stock being offered by us if any shares are purchased.

The underwriters propose to offer the shares of common stock to the public at the public offering price set forth on the cover page of this prospectus supplement. The underwriters may offer the common stock to securities dealers at the price to the public less a concession not in excess of $ per share. Securities dealers may reallow a concession not in excess of $ per share to other dealers. After the shares of common stock are released for sale to the public, the underwriters may vary the offering price and other selling terms from time to time.

We have granted to the underwriters an option, exercisable not later than 30 days after the date of this prospectus supplement, to purchase up to an aggregate of 1,125,000 additional shares of common stock at the public offering price set forth on the cover page of the prospectus supplement less the underwriting discounts and commissions. The underwriters may exercise this option only to cover over-allotments, if any, made in connection with the sale of the common stock offered hereby. If the over-allotment option is exercised in full, the underwriters will purchase additional shares of common stock from us in approximately the same proportion as shown in the table above.

The following table summarizes the compensation to be paid to the underwriters by us and the proceeds, before expenses, payable to us:

		Total	
	Per Share	Without Over-Allotment	With Over-Allotment
Public offering price			
Underwriting discounts and commissions			
Proceeds, before expenses, to us			

We estimate that our total expenses for this offering, excluding underwriting discounts and commissions, will be approximately $250,000.

We have agreed to indemnify the underwriters against certain civil liabilities, including liabilities under the Securities Act of 1933 and liabilities arising from breaches of representations and warranties contained in the underwriting agreement, and to contribute to payments the underwriters may be required to make in respect of any such liabilities.

We, our directors and our executive officers have agreed with the underwriters (or pursuant to agreements with us) that, for a period of 90 days following the date of this prospectus supplement, they will not offer, sell, assign, transfer, pledge, contract to sell or otherwise dispose of or hedge any shares of common stock or any securities convertible into or exchangeable for shares of common stock. In addition, so long as the transferee agrees to be bound by the terms of the lock-up agreement, a director or executive officer may transfer his or her securities by gift. SG Cowen & Co., LLC may, in its sole discretion, at any time without prior notice, release all or any portion of the shares from the restrictions in any such agreement to which SG Cowen & Co., LLC is a party.

The underwriters may engage in over-allotment, stabilizing transactions, syndicate covering transactions, penalty bids and passive market making in accordance with Regulation M under the Securities Exchange Act of 1934. Over-allotment involves syndicate sales in excess of the offering size, which creates a syndicate short position. Covered short sales are sales made in an amount not greater than the number of shares available for purchase by the underwriters under their over-allotment option. The underwriters may close out a covered short sale by exercising their over-allotment option or purchasing shares in the open market. Naked short sales are sales made in an amount in excess of the number of shares available under the over-allotment option. The underwriters must close out any naked short sale by purchasing shares in the open market. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Syndicate covering transactions involve purchases of the shares of common stock in the open market after the distribution has been completed in order to cover syndicate short positions. Penalty bids permit the representatives to reclaim a selling concession from a syndicate member when the shares of common stock originally sold by such syndicate member are purchased in a syndicate covering transaction to cover syndicate short positions. Penalty bids may have the effect of deterring syndicate members from selling to people who have a history of quickly selling their shares.

In passive market making, market makers in the shares of common stock who are underwriters or prospective underwriters may, subject to certain limitations, make bids for or purchases of the shares of common stock until the time, if any, at which a stabilizing bid is made.

These stabilizing transactions, syndicate covering transactions and penalty bids may cause the price of the shares of our common stock to be higher than it would otherwise be in the absence of these transactions. These transactions may be effected on the Nasdaq National Market or otherwise and, if commenced, may be discontinued at any time.

SG Cowen & Co., LLC may provide financial advisory services to us from time to time in the ordinary course of its business.

LEGAL MATTERS

Wilson Sonsini Goodrich & Rosati, Professional Corporation of Palo Alto, California will issue an opinion about the validity of the issuance of the shares of common stock issued hereby. Certain legal matters will be passed upon for the underwriters by Brown Raysman Millstein Felder & Steiner LLP of New York, New York.

EXPERTS

The consolidated financial statements and schedules of VIVUS, Inc. and subsidiaries as of December 31, 2003 and 2002 and for each of the years in the two-year period ended December 31, 2003 have been incorporated by reference herein in reliance upon the reports of KPMG LLP, independent accountants, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

Our consolidated financial statements as of and for the year ended December 31, 2001, incorporated by reference in this prospectus and in the registration statement (of which this prospectus is a part) from our Annual Report on Form 10-K of and for the year ended December 31, 2003 have been audited by Arthur Andersen LLP, independent accountants, as stated in their report with respect thereto and incorporated by reference herein. After reasonable efforts, we have been unable to obtain Arthur Andersen's consent to the incorporation by reference of their audit report on the financial statements and schedule from our Annual Report on Form 10-K as of and for the year ended December 31, 2001. Accordingly, Arthur Andersen LLP has not consented to the inclusion of their report in this prospectus, and we have dispensed with the requirement to file their consent in reliance on rule 437a under the Securities Act. Because Arthur Andersen LLP has not consented to the inclusion of their report in this prospectus, you will not be able to recover against Arthur Andersen LLP under Section 11 of the Securities Act for any untrue statements of a material fact contained in the financial statements audited by Arthur Andersen LLP incorporated by reference in this prospectus or any omissions to state a material fact required to be stated therein. Additionally, due to Arthur Andersen's current financial and legal circumstances, the ability of Arthur Andersen LLP to satisfy claims will be limited as a practical matter.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus supplement is part of a registration statement on Form S-3 that we filed with the SEC registering the securities that may be offered and sold hereunder. The registration statement, including the exhibits and schedules, contains additional relevant information about us and these securities that, as permitted by the rules and regulations of the SEC, we have not included in this prospectus supplement. A copy of the registration statement can be obtained at the address set forth below. You should read the registration statement for further information about us and these securities.

We file reports, proxy statements and other information with the SEC, in accordance with the Securities Exchange Act of 1934. You may read and copy any materials that we file with the SEC at the following address:

Public Reference Room 450 Fifth Street, N.W.
Room 1024
Washington, D.C. 20549

Please call the SEC at 1-800-SEC-0330 for further information about the public reference rooms. Our reports, proxy statements and other information filed with the SEC are available to the public over the Internet at the SEC's World Wide Web site at http://www.sec.gov.

INFORMATION INCORPORATED BY REFERENCE INTO THIS PROSPECTUS SUPPLEMENT

The SEC allows us to "incorporate by reference" information into this prospectus. This means that we can disclose important information about us and our financial condition to you by referring you to another document filed separately with the SEC. The information incorporated by reference is considered to be a part of this prospectus supplement, and information that we file later with the SEC will automatically update and supersede this information.

We incorporate by reference the documents listed below and any future filings made by us with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act until the sale of all securities registered hereunder or termination of the registration statement. Nothing in this prospectus supplement shall be deemed to incorporate information furnished but not filed with the SEC:

- Annual Report on Form 10-K for the fiscal year ended December 31, 2003;

- Definitive Proxy Statement on Schedule 14A for our annual meeting of stockholders held on June 14, 2004, filed on April 28, 2004.
- Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2004, June 30, 2004 and September 30, 2004.
- Current Reports on Form 8-K filed with the SEC on January 30, 2004, February 9, 2004, February 12, 2004, April 29, 2004, July 15, 2004, July 22, 2004, August 13, 2004, October 22, 2004, November 4, 2004, November 10, 2004, January 27, 2005 and February 10, 2005; and
- The description of the common stock of the Registrant that is contained in the Registration Statement on Form 8-A filed pursuant to Section 12 of the Exchange Act that became effective on April 7, 1994, including any amendments or reports filed for the purpose of updating such description.

We will provide to each person who so requests, including any beneficial owner to whom a prospectus supplement is delivered, a copy of these filings excluding exhibits except to the extent such exhibits are specifically incorporated by reference. You may request a copy of these filings, at no cost, by writing or telephoning us at the following address:

Christina Weisgerber
VIVUS, Inc.
1172 Castro Street
Mountain View, CA 94040
(650) 934-5200

You should rely only on the information incorporated by reference or provided in this prospectus supplement and the accompanying prospectus. We have not authorized anyone else to provide you with different information. We are not making an offer of these securities in any state where such an offer is not permitted. You should not assume the information in this prospectus supplement and the accompanying prospectus is accurate as of any date other than the date on the front of those documents.

PROSPECTUS

$50,000,000

COMMON STOCK

VIVUS, Inc. may offer shares of its common stock from time to time. We will specify in an accompanying prospectus supplement the terms of any offering. Our common stock is listed on the Nasdaq National Market under the symbol "VVUS." On January 7, 2005, the last reported sale price of our common stock on the Nasdaq National Market was $4.19 per share.

You should read this prospectus, any prospectus supplement and the documents incorporated by reference in this prospectus or any prospectus supplement carefully before you invest. THIS PROSPECTUS MAY NOT BE USED TO OFFER AND SELL SECURITIES UNLESS ACCOMPANIED BY A PROSPECTUS SUPPLEMENT.

INVESTING IN OUR COMMON STOCK INVOLVES A HIGH DEGREE OF RISK. YOU SHOULD CAREFULLY CONSIDER THE RISK FACTORS BEGINNING ON PAGE 4 OF THIS PROSPECTUS BEFORE YOU MAKE AN INVESTMENT DECISION.

The common stock offered by this prospectus may be offered in amounts, at prices and at terms determined at the time of the offering and may be sold directly by us to investors, through agents designated from time to time or to or through underwriters or dealers. We will set forth the names of any underwriters or agents in the accompanying prospectus supplement. For additional information on the methods of sale, you should refer to the section entitled "Plan of Distribution." The net proceeds we expect to receive from such sale will also be set forth in a prospectus supplement.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

This prospectus is dated January 7, 2005

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No person has been authorized to give any information or make any representations in connection with this offering other than those contained or incorporated by reference in this prospectus and any accompanying prospectus supplement in connection with the offering described herein and therein, and, if given or made, such information or representations must not be relied upon as having been authorized by us. Neither this prospectus nor any prospectus supplement shall constitute an offer to sell or a solicitation of an offer to buy offered securities in any jurisdiction in which it is unlawful for such person to make such an offering or solicitation. Neither the delivery of this prospectus or any prospectus supplement nor any sale made hereunder shall under any circumstances imply that the information contained or incorporated by reference herein or in any prospectus supplement is correct as of any date subsequent to the date hereof or of such prospectus supplement.

SUMMARY

THE FOLLOWING SUMMARY IS QUALIFIED IN ITS ENTIRETY BY THE MORE DETAILED INFORMATION, INCLUDING OUR CONSOLIDATED FINANCIAL STATEMENTS AND RELATED NOTES, INCLUDED IN THIS PROSPECTUS OR INCORPORATED BY REFERENCE IN THIS PROSPECTUS. YOU SHOULD CAREFULLY CONSIDER THE INFORMATION SET FORTH IN THIS ENTIRE PROSPECTUS, INCLUDING THE "RISK FACTORS" SECTION, THE APPLICABLE PROSPECTUS SUPPLEMENT FOR SUCH SECURITIES AND THE OTHER DOCUMENTS WE REFER TO OR THAT WE INCORPORATE BY REFERENCE. UNLESS THE CONTEXT OTHERWISE REQUIRES, THE TERMS "VIVUS," "WE," "US," THE COMPANY AND "OUR" REFER TO VIVUS, INC., A DELAWARE CORPORATION.

This prospectus is part of a Registration Statement on Form S-3 that we filed with the Securities and Exchange Commission, or SEC, utilizing a "shelf" registration process. Under this shelf process, we may, from time to time, sell up to an aggregate of $50,000,000 of our common stock in one or more offerings. This prospectus provides you with a general description of the securities we may offer. Each time we sell securities, we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may also add, update or change information contained in this prospectus. You should read both this prospectus and any prospectus supplement, including the risk factors, together with additional information described below under the heading "Where You Can Find More Information" and "Information Incorporated by Reference."

VIVUS, INC.

VIVUS, Inc. is a specialty pharmaceutical company focused on the research, development and commercialization of products to restore sexual function in women and men. In addition to our currently marketed therapies, we have a pipeline that includes both new chemical entities and existing compounds that are being developed to address unmet medical needs. Our business strategy is to apply our scientific and medical expertise to identify, develop and commercialize therapies that restore sexual function. In the United States, we market MUSE® (alprostadil) 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 certain foreign countries.

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

- ALISTA™ to treat female sexual arousal disorder;
- Evamist™ (Estradiol MDTS®), a short-term therapy to alleviate symptoms associated with menopause;
- Testosterone MDTS® to treat hypoactive sexual desire disorder; and
- Avanafil for the treatment of erectile dysfunction.

ALISTA entered Phase 3 clinical development in the third quarter of 2004 and Evamist entered Phase 3 clinical development in the fourth quarter of 2004. The other two research and development programs are in Phase 2 clinical development.

When we were founded in 1991, our sole purpose was to develop a therapy for men suffering from erectile dysfunction. In 1997, we commercially launched MUSE in the United States. At that time, MUSE revolutionized erectile dysfunction therapy at a time when few effective therapies existed. Developing and bringing MUSE to the market provided us experience in clinical and regulatory matters when no intra-urethral drugs had been approved for this indication. This experience serves us well

today in making progress towards developing and commercializing product candidates in our research and development programs for the treatment of sexual disorders.

OUR FUTURE

It is our objective to become a global leader in the development and commercialization of products that help to restore sexual health in women and men. We believe that we have strong intellectual property supporting many opportunities in sexual health. Our future growth will come from further development and approval of our product candidates as well as in-licensing and product line extensions.

FEMALE SEXUAL HEALTH

We believe that the market for the treatment of sexual disorders in women is large and underserved. Today, there are no treatments on the market that have been approved by the United States Food and Drug Administration, or the FDA, for the treatment of sexual disorders in women. A paper published in the JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION in 1999, noted 43% of women between the ages of 18 and 65 identified themselves as afflicted with a sexual disorder, with two prevalent conditions being low sexual desire and arousal disorder. VIVUS' research and development programs in female sexual health address both of these conditions.

ALISTA

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

In the second quarter of 2004, we completed an at-home Phase 2 study to assess the efficacy and safety of ALISTA when used by pre-menopausal women with female sexual arousal disorder. The study demonstrated that ALISTA significantly increased the percentage of satisfying sexual events in pre-menopausal women when compared with placebo. Results from this Phase 2 clinical trial were similar to the results from earlier clinical trials in post-menopausal women.

At the end of the third quarter of 2004, we began a Phase 3 study of ALISTA.

METERED DOSE TRANSDERMAL SPRAY, OR MDTS

In the first quarter of 2004, we entered into license agreements with a subsidiary of Acrux Limited, a specialty pharmaceutical company based in Melbourne, Australia, pursuant to which we have the exclusive rights to market two drugs in the United States, estradiol and testosterone, using Acrux's Metered Dose Transdermal Spray, or MDTS. The MDTS is a small, easy-to-use, handheld spray that delivers either estradiol or testosterone topically to the skin. It dries in approximately 30 seconds, and when dry, is invisible. Data generated to date suggests that, once dry, there is little chance for transfer or removal by washing.

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

- Evamist—The estradiol spray is a low-dose estrogen-only treatment addressing the symptoms associated with menopause, primarily hot flashes. This proprietary spray product utilizes the MDTS technology, which is patented. This transdermal spray product is simple to apply and may have safety benefits compared to certain oral estrogen pills.

At the end of the fourth quarter of 2004, we began a phase 3 study of Evamist.

- Testosterone MDTS—This proprietary spray product is designed to treat females with low sexual desire, or Hypoactive Sexual Desire Disorder ("HSDD"). There are estimated to be over 10 million women in the United States afflicted with HSDD and there are no FDA approved therapies for this condition.

In October 2004, Acrux completed a Phase 2 clinical trial, which enrolled approximately 260 patients for the evaluation of the safety and efficacy of the testosterone spray. This study was completed under an Investigational New Drug application on file with the FDA. We expect the results of this Phase 2 study to be available in early 2005.

MALE SEXUAL HEALTH

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

Avanafil

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

- Highly selective to PDE5, which we believe should result in a favorable side effect profile; and

- Faster acting than the currently available PDE5 inhibitors.

In March 2004, we began enrolling patients in an at-home, double blind, randomized, parallel design Phase 2 clinical study to evaluate the safety and efficacy of avanafil. One of the primary goals of this study is to confirm the appropriate dose range in a large group of patients. Enrollment is anticipated to be completed during the first half of 2005 and data from this study should be available during the second half of 2005. VIVUS has initiated drug interaction studies with avanafil during 2004 and anticipates completing Phase 2 development in 2005.

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

THE SECURITIES WE MAY OFFER

We may offer up to an aggregate of $50,000,000 of common stock in one or more offerings. A prospectus supplement, which we will provide to you each time we offer securities, will describe the specific amounts, prices and terms of these securities.

We may sell the common stock to or through underwriters, dealers or agents or directly to purchasers. Our agents and we reserve the sole right to accept and to reject in whole or in part any proposed purchase of securities. Each prospectus supplement will set forth the names of any underwriters, dealers or agents involved in the sale of the common stock described in that prospectus supplement and any applicable fee, commission or discount arrangements with them.

Common stock holders are entitled to receive dividends declared by the board of directors out of funds legally available for the payment of dividends, subject to rights, if any, of preferred stock holders. We have never paid a cash dividend and do not anticipate paying any cash dividends in the foreseeable future. Each holder of common stock is entitled to one vote per share. The holders of common stock have no preemptive rights or cumulative voting rights. A prospectus supplement will describe the specific amounts, prices and terms of any common stock to be issued.

RISK FACTORS

An investment in our securities involves a high degree of risk. You should carefully consider the risks described below before making an investment decision. You should also refer to the other information in this prospectus, including our financial statements and the related notes incorporated by reference into this prospectus. The risks and uncertainties described below are not the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. If any of the following risks actually occur, our business, results of operations and financial condition could suffer. In that event, the trading price of our common stock could decline, and you may lose all or part of your investment in our common stock. The risks discussed below also include forward-looking statements and our actual results may differ substantially from those discussed in these forward-looking statements.

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 commencement and rate of completion of clinical trials may be delayed by many factors, including:

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

The clinical results we have obtained to date do not necessarily predict that the results of further testing, including later stage controlled human clinical testing, will be successful. If our trials are not

successful or are perceived as not successful by the FDA or physicians, our business, financial condition and results of operations will be materially harmed.

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. Our product candidates address sexual dysfunction and any observed or perceived side effects may receive heightened scrutiny by the FDA based on a perception that these drug candidates are lifestyle-enhancing rather than life-saving in nature. 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 exerted, 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 a product candidate will be approved.

For example, an FDA advisory panel recently 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 study would be required before it would be in a position to recommend approval. These additional studies will be time consuming and may significantly delay the introduction of this product to the marketplace. 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.

WE RELY ON THIRD PARTIES TO CONDUCT CLINICAL TRIALS FOR OUR PRODUCT CANDIDATES IN DEVELOPMENT AND THOSE THIRD PARTIES MAY NOT PERFORM SATISFACTORILY.

We do not have the ability to independently conduct clinical studies for any of our products currently in development, and we rely on third parties to perform this function. The third parties used to perform this function are usually Clinical Research Organizations ("CRO's") that have significant resources and experience in the conduct of clinical studies. The CRO's will usually perform project management, data management, statistical analysis, and other reporting functions. We will use several different CRO's for all of our clinical studies. If third parties do not successfully carry out their contractual duties or meet expected timelines, we may not be able to obtain regulatory approvals for our proposed products and may not be able to successfully commercialize these proposed products. If third parties do not perform satisfactorily, we may not be able to locate acceptable replacements or enter into favorable agreements with them, if at all.

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

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 is obtained, products are 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, 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 unannounced periodic 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 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 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 marketing activities continue to be subject to FDA and other regulatory review. The labeling and other marketing information that may permissibly be provided are subject to FDA 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 provide or had minimized certain risks associated with MUSE. Through discussions with the FDA, we agreed to produce and have released a

television commercial correcting the earlier information. We incurred costs in providing this corrective information, which would have likely 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 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 HAVE LIMITED SALES AND MARKETING CAPABILITIES IN THE UNITED STATES.

We support MUSE sales in the United States through a small sales support group targeting major accounts that include the top prescribers of MUSE. 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 DEPEND EXCLUSIVELY ON THIRD-PARTY DISTRIBUTORS OUTSIDE OF THE UNITED STATES AND WE HAVE VERY LIMITED CONTROL OVER THEIR ACTIVITIES.

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

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

SALES OF OUR CURRENT AND ANY FUTURE PRODUCTS ARE SUBJECT TO CONTINUED GOVERNMENTAL REGULATION.

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.

THE MARKETS IN WHICH WE OPERATE ARE HIGHLY COMPETITIVE AND WE MAY BE UNABLE TO COMPETE SUCCESSFULLY AGAINST NEW ENTRANTS OR ESTABLISHED COMPANIES WITH GREATER RESOURCES.

Competition in the pharmaceutical and medical products industries is intense and is characterized by extensive research efforts and rapid technological progress. Several large pharmaceutical companies are also actively engaged in the development of therapies for the treatment of erectile dysfunction and female sexual dysfunction. These companies have substantially greater research and development capabilities as well as substantially greater marketing, financial and human resources abilities than 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 under the name Viagra, which received regulatory approvals in the United States in March 1998 and in the European Union in September 1998. The commercial launch of Viagra in the United States in April 1998 significantly decreased demand for MUSE. Another oral medication under the name Uprima was approved and launched in Europe by Abbott Laboratories and Takeda in May 2001. In February 2003, a new oral medication under the name Cialis was launched in Europe by Lilly ICOS LLC and in Australia and New Zealand by Eli Lilly and Company. Cialis was launched in the United States in January 2004. Bayer AG and GlaxoSmithKline plc launched Levitra in the European Union and the United States in March and September 2003, respectively.

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

IF OUR RAW MATERIAL SUPPLIERS FAIL TO SUPPLY US WITH ALPROSTADIL WE MAY EXPERIENCE DELAYS IN OUR PRODUCT DEVELOPMENT AND COMMERCIALIZATION.

We are required to initially receive regulatory approval for suppliers and we obtained our supply of alprostadil from two approved sources. The first is NeraPharm, formerly Spolana Chemical Works a.s., in Neratovice, Czech Republic. The second is Chinoin Pharmaceutical and Chemical Works Co., Ltd. We have manufacturing agreements with Chinoin and NeraPharm respectively, to produce quantities of alprostadil for us. We must assure that any new receipts of alprostadil meet regulatory specifications. There can be no guarantees the new material will pass these requirements and be usable material in our manufacturing process.

Furthermore, alprostadil is subject to periodic re-testing to ensure it continues to meet specifications. There can be no guarantees that our 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. There can be no assurance that we will be able to identify and qualify additional suppliers of alprostadil, if necessary, in a timely manner, if at all.

WE OUTSOURCE SEVERAL KEY PARTS OF OUR OPERATIONS AND ANY INTERRUPTION IN THE SERVICES PROVIDED COULD HARM OUR BUSINESS.

We entered into a distribution agreement with Cardinal Health. Under this agreement, Cardinal Health takes the following actions:

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

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

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

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

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

WE CURRENTLY DEPEND ON A SINGLE SOURCE FOR THE SUPPLY OF PLASTIC APPLICATOR COMPONENTS, AND AN INTERRUPTION TO THIS SUPPLY SOURCE COULD HARM OUR BUSINESS.

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

ALL OF OUR MANUFACTURING OPERATIONS ARE CURRENTLY CONDUCTED AT A SINGLE LOCATION, AND A PROLONGED INTERRUPTION TO OUR MANUFACTURING OPERATIONS COULD HARM OUR BUSINESS.

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

WE ARE DEPENDENT UPON A SINGLE APPROVED THERAPEUTIC APPROACH TO TREAT ERECTILE DYSFUNCTION.

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

IF WE FAIL TO RETAIN OUR KEY PERSONNEL AND HIRE, TRAIN AND RETAIN QUALIFIED EMPLOYEES, WE MAY NOT BE ABLE TO COMPETE EFFECTIVELY, WHICH COULD RESULT IN REDUCED REVENUES.

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

WE ARE SUBJECT TO ADDITIONAL RISKS ASSOCIATED WITH OUR INTERNATIONAL OPERATIONS.

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

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.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY

WE MAY BE SUED FOR INFRINGING ON THE INTELLECTUAL PROPERTY RIGHTS OF OTHERS.

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

OUR INABILITY TO ADEQUATELY PROTECT OUR PROPRIETARY TECHNOLOGIES COULD HARM OUR COMPETITIVE POSITION AND HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS.

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

IF WE REQUIRE ADDITIONAL CAPITAL FOR OUR FUTURE OPERATING PLANS, WE MAY NOT BE ABLE TO SECURE THE REQUISITE ADDITIONAL FUNDING ON ACCEPTABLE TERMS, IF AT ALL.

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

launch of any future products. Our future capital requirements will depend upon numerous factors, including:

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

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

WE HAVE AN ACCUMULATED DEFICIT OF $121.7 MILLION AS OF SEPTEMBER 30, 2004 AND EXPECT TO CONTINUE TO INCUR SUBSTANTIAL OPERATING LOSSES FOR THE FORESEEABLE FUTURE.

We have generated a cumulative net loss of $121.7 million for the period from our inception through September 30, 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 on a sustained basis. Accordingly, there can be no assurance of our future success.

IF WE BECOME SUBJECT TO PRODUCT LIABILITY CLAIMS, WE MAY BE REQUIRED TO PAY DAMAGES THAT EXCEED OUR INSURANCE COVERAGE.

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

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;

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

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

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

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 technology 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. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. A securities class action suit against us could result in substantial costs, potential liabilities and the diversion of management's attention and resources.

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, 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.

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

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

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

CHANGES IN ACCOUNTING STANDARDS REGARDING STOCK OPTION PLANS COULD LIMIT THE DESIRABILITY OF GRANTING STOCK OPTIONS, WHICH COULD HARM OUR ABILITY TO ATTRACT AND RETAIN EMPLOYEES, AND COULD ALSO REDUCE OUR PROFITABILITY.

The Financial Accounting Standards Board is considering whether to require all companies to treat the value of stock options granted to employees as an expense. The United States Congress and other governmental and regulatory authorities have also considered requiring companies to expense stock options. If this change were to become mandatory, we and other companies would be required to

record a compensation expense equal to the fair market value of each stock option granted. This expense would be spread over the vesting period of the stock option. Currently, we account for stock compensation under Accounting Principles Board, or APB, No. 25, Accounting for Stock Issued to Employees, which results in no compensation expenses recorded in connection with stock options granted to our employees. If we were required to expense stock option grants, it would reduce the attractiveness of granting stock options because of the additional expense associated with these grants, which would reduce our profitability. However, stock options are an important employee recruitment and retention tool, and we may not be able to attract and retain key personnel if we reduce the scope of our employee stock option program. Accordingly, in the event we are required to expense stock option grants, our profitability would be reduced, as would our ability to use stock options as an employee recruitment and retention tool.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

In addition to this other information contained or incorporated by reference in this prospectus, you should carefully consider the risk factors disclosed in this prospectus or any prospectus supplement when evaluating an investment in our common stock. This prospectus contains forward-looking statements that are based upon current expectations that are within the meaning of the Private Securities Reform Act of 1995. It is our intent that such statements be protected by the safe harbor created thereby.

Forward-looking statements involve risks and uncertainties and our actual results and timing of events may differ significantly from the results discussed in the forward-looking statements. Examples of such forward-looking statements include, but are not limited to:

- statements about our history of losses and variable quarterly results;
- statements about the potential benefits of our drug candidates;
- statements relating to the timing, substance and sufficiency of materials required for or anticipated results of our clinical development of our drug candidates;
- statements about the size of the potential market for our products;
- statements about upcoming announcements by the Company;
- statements about future market acceptance of our drug candidates;
- statements about future expectations regarding trade secrets, technological innovations, licensing agreements and outsourcing of certain business functions;
- statements about potential competitors or products;
- statements about risks related to the failure to protect our intellectual property and litigation in which we may become involved;
- statements about our reliance on sole source suppliers;
- statements about our limited sales and marketing efforts and our reliance on third parties;
- statements about failure to continue to develop innovative products;
- statements about risks related to noncompliance with United States Food and Drug Administration regulations development of our internal systems and infrastructure; and
- statements about other factors that are described from time to time in our periodic filings with the Securities and Exchange Commission.

USE OF PROCEEDS

Unless otherwise indicated in the prospectus supplement, the net proceeds from the sale of securities offered by this prospectus will be used for general corporate purposes and working capital requirements. We may also use a portion of the net proceeds to fund possible investments in and acquisitions of complimentary businesses, partnerships, minority investments, products or technologies. Currently, there are no commitments or agreements regarding such acquisitions or investments that are material. Pending their ultimate use, we intend to invest the net proceeds in money market funds, commercial paper and governmental and non-governmental debt securities with maturities of up to three years.

DESCRIPTION OF COMMON STOCK

Our certificate of incorporation authorizes us to issue up to 200,000,000 shares of common stock, $0.001 par value. As of December 10, 2004, there were 38,123,381 shares of common stock issued and outstanding.

The holders of shares of our common stock are entitled to one vote per share on all matters to be voted on by stockholders. Common stock holders are entitled to receive dividends declared by the board of directors out of funds legally available for the payment of dividends, subject to the rights, if any, of preferred stock holders. We have never paid a dividend and we do not anticipate paying a dividend in the foreseeable future. Upon any liquidation, dissolution or winding up of our business, the holders of common stock are entitled to share equally in all assets available for distribution after payment of all liabilities and provision for liquidation preference of shares of preferred stock then outstanding. The holders of common stock have no preemptive rights and no rights to convert their common stock into any other securities. There are also no redemption or sinking fund provisions applicable to our common stock. All outstanding shares of common stock are fully paid and nonassessable.

The transfer agent and registrar for the common stock is Computershare Investor Services, 2 N LaSalle, 2nd Floor, Chicago, Illinois 60602.

ANTI-TAKEOVER EFFECTS OF DELAWARE LAW

We are subject to the provisions of Section 203 of the Delaware General Corporation Law, which, subject to certain exceptions, prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the time that such stockholder became an interested stockholder, unless:

(1) prior to such time, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder,

(2) upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding those shares owned:

- by persons who are directors and also officers, and
- by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer, or

(3) at or subsequent to such time, the business combination is approved by the board of directors and is authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least $66^{2}/_{3}\%$ of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines "business combination" to include:

(1) any merger or consolidation involving the corporation and the interested stockholder,

(2) any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder,

(3) subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder,

(4) any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder, or

(5) the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an "interested stockholder" as any entity or person who or which beneficially owns (or within three years did own) 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by such entity or person.

The existence of this provision would be expected to have an anti-takeover effect with respect to transactions not approved in advance by our board of directors, including discouraging attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

PLAN OF DISTRIBUTION

We may sell the securities:

- through one or more underwriters or dealers,
- directly to purchasers,
- through agents, or
- through a combination of any of these methods of sale.

We may distribute the securities:

- from time to time in one or more transactions at a fixed price or prices, which may be changed from time to time,
- at market prices prevailing at the times of sale,
- at prices related to such prevailing market prices, or at negotiated prices.

We will describe the method of distribution of the securities in the applicable prospectus supplement.

We may determine the price or other terms of the securities offered under this prospectus by use of an electronic auction. We will describe how any auction will determine the price or any other terms, how potential investors may participate in the auction and the nature of the obligations of the underwriter, dealer or agent in the applicable prospectus supplement.

If underwriters are used in the sale, they will acquire the common stock for their own account and may resell the stock from time to time in one or more transactions at a fixed public offering price. The obligations of the underwriters to purchase the common stock will be subject to the conditions set forth in the applicable underwriting agreement. We may offer the common stock to the public through underwriting syndicates represented by managing underwriters or by underwriters without a syndicate. Underwriters, dealers or agents may receive compensation in the form of discounts, concessions or commissions from us or our purchasers (as their agents in connection with the sale of securities). These underwriters, dealers or agents may be considered to be underwriters under the Securities Act. As a result, discounts, commissions, or profits on resale received by the underwriters, dealers or agents may be treated as underwriting discounts and commissions. Each prospectus supplement will identify any such underwriter, dealer or agent, and describe any compensation received by them from us. Any initial public offering price and any discounts or concessions allowed or reallowed or paid to dealers may be changed from time to time.

Underwriters, dealers and agents may be entitled to indemnification by us against certain civil liabilities, including liabilities under the Securities Act, or to contribution with respect to payments made by the underwriters, dealers or agents, under agreements between us and the underwriters, dealers and agents.

We may grant underwriters who participate in the distribution of securities an option to purchase additional securities to cover over-allotments, if any, in connection with the distribution.

Underwriters or agents and their associates may be customers of, engage in transactions with or perform services for us in the ordinary course of business.

In connection with the offering of the common stock, certain persons participating in such offering may engage in transactions that stabilize, maintain or otherwise affect the market price, including over-allotment, stabilizing transactions, short covering transactions and penalty bids in accordance with Regulation M under the Exchange Act. Over-allotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Short covering transactions involve purchases of the common stock in the open market after the distribution is completed to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the common stock originally sold by the dealer is purchased in a covering transaction to cover short positions. Those activities may cause the price of the common stock to be higher than it would otherwise be. If commenced, the underwriters may discontinue any of the activities at any time.

Any underwriters who are qualified market makers on the Nasdaq National Market may engage in passive market making transactions in the common stock on the Nasdaq National Market in accordance with Rule 103 of Regulation M, during the business day prior to the pricing of the offering, before the commencement of offers or sales of the common stock. Passive market makers must comply with applicable volume and price limitations and must be identified as passive market makers. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for such security; if all independent bids are lowered below the passive market maker's bid, however, the passive market maker's bid must then be lowered when certain purchase limits are exceeded.

To the extent required, this prospectus may be amended and supplemented from time to time to describe a specific plan of distribution.

LEGAL MATTERS

Wilson Sonsini Goodrich & Rosati, Professional Corporation, Palo Alto, California, will pass upon the validity of the issuance of the securities offered by this prospectus.

EXPERTS

The consolidated financial statements and schedules of VIVUS, Inc. and subsidiaries as of December 31, 2003 and 2002 and for each of the years in the two-year period ended December 31, 2003 have been incorporated by reference herein in reliance upon the reports of KPMG LLP, independent accountants, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

Our consolidated financial statements as of and for the year ended December 31, 2001, incorporated by reference in this prospectus and in the registration statement (of which this prospectus is a part) from our Annual Report on Form 10-K of and for the year ended December 31, 2003 have been audited by Arthur Andersen LLP, independent accountants, as stated in their report with respect thereto and incorporated by reference herein. After reasonable efforts, we have been unable to obtain Arthur Andersen's consent to the incorporation by reference of their audit report on the financial statements and schedule from our Annual Report on Form 10-K as of and for the year ended

December 31, 2001. Accordingly, Arthur Andersen LLP has not consented to the inclusion of their report in this prospectus, and we have dispensed with the requirement to file their consent in reliance on rule 437a under the Securities Act. Because Arthur Andersen LLP has not consented to the inclusion of their report in this prospectus, you will not be able to recover against Arthur Andersen LLP under Section 11 of the Securities Act for any untrue statements of a material fact contained in the financial statements audited by Arthur Andersen LLP incorporated by reference in this prospectus or any omissions to state a material fact required to be stated therein. Additionally, due to Arthur Andersen's current financial and legal circumstances, the ability of Arthur Andersen LLP to satisfy claims will be limited as a practical matter.

WHERE YOU CAN FIND MORE INFORMATION

We file reports, proxy statements and other information with the Securities and Exchange Commission, in accordance with the Securities Exchange Act of 1934. You may read and copy any materials that we file with the Securities and Exchange Commission at the following address:

Public Reference Room
450 Fifth Street, N.W.
Room 1024
Washington, D.C. 20549

Please call the Commission at 1-800-SEC-0330 for further information about the public reference rooms. Our reports, proxy statements and other information filed with the Commission are available to the public over the Internet at the Commission's World Wide Web site at http://www.sec.gov.

INFORMATION INCORPORATED BY REFERENCE

The Commission allows us to "incorporate by reference" the information into this prospectus. This means that we can disclose important information to you by referring you to another document filed separately with the Securities and Exchange Commission. The information incorporated by reference is considered to be a part of this prospectus, and information that we file later with the Commission will automatically update and supersede this information.

We incorporate by reference the documents listed below and any future filings made by us with the Commission under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act until our offering is complete:

- Annual Report on Form 10-K for the fiscal year ended December 31, 2003;
- Definitive Proxy Statement on Schedule 14A for our annual meeting of stockholders held on June 14, 2004, filed on April 28, 2004.
- Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2004, June 30, 2004 and September 30, 2004.
- Current Reports on Form 8-K filed with the Securities and Exchange Commission on January 30, 2004, February 9, 2004, February 12, 2004, April 29, 2004, July 15, 2004, July 22, 2004, August 13, 2004, October 22, 2004, November 4, 2004 and November 10, 2004; and
- The description of the Common Stock of the Registrant that is contained in the Registration Statement on Form 8-A filed pursuant to Section 12 of the Exchange Act that became effective on April 7, 1994, including any amendments or reports filed for the purpose of updating such description.

We will provide to each person who so requests, including any beneficial owner to whom a prospectus is delivered, a copy of these filings excluding exhibits except to the extent such exhibits are

specifically incorporated by reference. You may request a copy of these filings, at no cost, by writing or telephoning us at the following address:

Christina Weisgerber
VIVUS, Inc.
1172 Castro Street
Mountain View, CA 94040
(650) 934-5200

You should rely only on the information incorporated by reference or provided in this prospectus or any prospectus supplement. We have not authorized anyone else to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume the information in this prospectus or any prospectus supplement is accurate as of any date other than the date on the front of those documents.

7,500,000 Shares

VIVUS, INC.

Common Stock

PROSPECTUS SUPPLEMENT

SG Cowen & Co.
Wachovia Securities

, 2005

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