VIVUS INC
Form S-3
December 22, 2004

AS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION ON DECEMBER 21, 2004
REGISTRATION NO. 333-

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SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM S-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

VIVUS, INC.
(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

DELAWARE	94-3136179
(STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION)	(I.R.S. EMPLOYER IDENTIFICATION NUMBER)

1172 CASTRO STREET
MOUNTAIN VIEW, CA 94040
(650) 934-5200
(ADDRESS, INCLUDING ZIP CODE, AND TELEPHONE NUMBER, INCLUDING AREA CODE, OF REGISTRANT'S PRINCIPAL EXECUTIVE OFFICES)

LELAND F. WILSON
PRESIDENT, CHIEF EXECUTIVE OFFICER AND DIRECTOR
VIVUS, INC.
1172 CASTRO STREET
MOUNTAIN VIEW, CA 94040
(650) 934-5200
(NAME, ADDRESS, INCLUDING ZIP CODE, AND TELEPHONE NUMBER, INCLUDING AREA CODE, OF AGENT FOR SERVICE)

COPIES TO:
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PROFESSIONAL CORPORATION
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PALO ALTO, CA 94304
(650) 493-9300

APPROXIMATE DATE OF COMMENCEMENT OF PROPOSED SALE TO THE PUBLIC: From time to time after the effective date of this Registration Statement. [ ]

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. [ ]

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. [X]

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]_____

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration

statement for the same offering. [ ]_____

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. [ ]

CALCULATION OF REGISTRATION FEE

TITLE OF EACH CLASS OF SECURITIES TO BE REGISTERED	PROPOSED MAXIMUM OFFERING PRICE (1)	AMOUNT OF REGISTRATION FEE
Common Stock, $0.001 par value.....	$50,000,000	$5,885

(1) This figure is an estimate made solely for the purpose of calculating the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended.

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(A) OF THE SECURITIES ACT OF 1933 OR UNTIL THIS REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(A) MAY DETERMINE.

SUBJECT TO COMPLETION, DATED DECEMBER 21, 2004

PROSPECTUS

$50,000,000

VIVUS, INC.

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 December 21, 2004, the last reported sale price of our common stock on the Nasdaq National Market was $4.62 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 5 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 December 21, 2004

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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(R) (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 TM to treat female sexual arousal disorder;
- Evamist TM (Estradiol MDTS(R)), a short-term therapy to alleviate symptoms associated with menopause;
- Testosterone MDTS(R) 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(R), 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(R), launched by Bayer and GlaxoSmithKlineBeecham, and Cialis(R), 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 o 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.

PART II

INFORMATION NOT REQUIRED IN THE PROSPECTUS

ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

The aggregate estimated (other than the registration fee) expenses to be paid by the Registrant in connection with this offering are as follows:

Securities and Exchange Commission registration fee.....	$ 5,885
Accounting fees and expenses.....	25,000
Legal fees and expenses of the registrant.....	45,000
Printing fees.....	15,000
Miscellaneous.....	9,115

Total.....	$ 100,000

ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS OF VIVUS, INC.

Section 145 of the Delaware General Corporation Law ("Delaware Law") authorizes a court to award or a corporation's board of directors to grant indemnification to directors and officers in terms that are sufficiently broad to permit indemnification under certain circumstances for liabilities (including reimbursement for expenses incurred) arising under the Securities Act of 1933, as amended. Our bylaws provide for the mandatory indemnification of our directors and officers to the maximum extent permitted by Delaware law. Our bylaws also provide (i) that we may modify the scope of indemnification by individual contracts with our directors and officers, and (ii) that we shall not be required to indemnify any director or officer unless the indemnification is required by law, the proceeding in which indemnification is sought was authorized in advance by our board of directors, the indemnification is provided by us, in our sole discretion pursuant to powers vested in us under the General Corporation Law of Delaware or the indemnification is required by individual contract. In addition our bylaws give us the power to indemnify our employees and agents to the maximum extent permitted by Delaware law.

Our amended and restated certificate of incorporation provides for the indemnification of directors to the fullest extent permitted under Delaware law.

We refer you to the form of underwriting agreement to be filed as an exhibit to this Registration Statement as incorporated by reference as an exhibit to a current Report on Form 8-K for certain provisions regarding indemnification of our officers and directors by the underwriters.

We have entered into indemnification agreements with our directors and executive officers, in addition to indemnification provided for in our bylaws, and we intend to enter into indemnification agreements with any new directors and executive officers in the future.

ITEM 16. EXHIBITS

The following exhibits are filed herewith or incorporated by reference herein:

EXHIBIT INDEX

EXHIBIT NUMBER	DESCRIPTION OF DOCUMENT
1.1	Form of Underwriting Agreement.*
5.1	Opinion of Wilson Sonsini Goodrich & Rosati, Professional Corporation.*
23.1	Consent of KPMG, LLP, independent auditors.
23.2	Consent of Wilson Sonsini Goodrich & Rosati, Professional Corporation (included in Exhibit 5.1).
24.1	Power of Attorney of certain directors and officers of VIVUS, Inc. (see page II-4 of this Form S-3).

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* To be filed by amendment or as an exhibit to a current report of the

registrant and incorporated herein by reference.

ITEM 17. UNDERTAKINGS

The undersigned Registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement:

(a) To include any prospectus required by Section 10(a)(3) of the Securities Act,

(b) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the Registration Statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement,

(c) To include any material information with respect to the plan of distribution not previously disclosed in the Registration Statement or any material change to such information in the Registration Statement;

provided, however, that clauses (a) and (b) do not apply if the information required to be included in a post-effective amendment by such clauses is contained in periodic reports filed with or furnished to the Securities and Exchange Commission by the Registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act") that are incorporated by reference in the Registration Statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for purposes of determining any liability under the Securities Act, each filing of the Registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act

that is incorporated by reference in this Registration Statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the provisions described under Item 15 above, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities, other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding, is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement on Form S-3 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Mountain View, State of California, on December 21, 2004.

VIVUS, INC.

By: /s/ LELAND F. WILSON

Leland F. Wilson
President and
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Leland F. Wilson and Timothy E. Morris and each of them individually, as his true and lawful attorneys-in-fact and agents with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities to sign the Registration Statement filed herewith and any or all amendments to said Registration Statement (including post-effective amendments and registration statements filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and otherwise), and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission granting unto said attorneys-in-fact and agents the full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the foregoing, as full to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or his or her substitute, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated:

SIGNATURE	TITLE	DATE
/S/ LELAND F. WILSON Leland F. Wilson	President and Chief Executive Officer (principal executive officer)	December 21, 2004
/S/ VIRGIL A. PLACE Virgil A. Place	Chairman of the Board Director and Chief Scientific Officer and Director	December 21, 2004
/S/ TIMOTHY E. MORRIS Timothy E. Morris	Vice President of Finance and Chief Financial Officer (principal financial and accounting officer)	December 21, 2004
/S/ MARIO M. ROSATI Mario M. Rosati	Director and Secretary	December 21, 2004
/S/ GRAHAM STRACHAN Graham Strachan	Director	December 21, 2004

SIGNATURE	TITLE	DATE

/S/ MARK B. LOGAN Mark B. Logan	Director	December 21, 2004
/S/ LINDA M. DAIRIKI SHORTLIFFE, M.D. Linda M. Dairiki Shortliffe, M.D.	Director	December 21, 2004

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* To be filed by amendment or as an exhibit to a current report of the registrant and incorporated herein by reference.