VIVUS INC
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Registration No. 333-135793

PROSPECTUS SUPPLEMENT

(To Prospectus dated July 14, 2006)

9,600,000 Shares

VIVUS, INC.

COMMON STOCK

We are offering directly to certain investors an aggregate of 9,600,000 shares of our common stock.

Our common stock is listed on the NASDAQ Global Market under the symbol VVUS. On November 15, 2006, the last reported sale price of our common stock on the NASDAQ Global Market was $3.60 per share.

Investing in our common stock involves a high degree of risk. You should carefully consider the *Risk Factors* beginning on page S-4 of this prospectus supplement, which supersede in their entirety the risk factors set forth beginning on page 7 of the accompanying prospectus, before you make an investment decision.

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.

	Per Share	Total
Public offering price	$ 3.50	$ 33,600,000
Proceeds, before expenses, to us	$ 3.50	$ 33,600,000

Dated November 17, 2006

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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 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®, Qnexa , 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 it s holder.

The information contained in this prospectus supplement and the accompanying prospectus is correct only as of the date on the cover, regardless of the date this prospectus supplement was delivered to you or the date on which you acquired any of the shares.

Information that we file with the SEC subsequent to the date on the cover will automatically update and supersede the information contained in this prospectus supplement and the accompanying prospectus. We incorporate by reference the documents listed in the accompanying prospectus and any future filings made with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, until we issue all of the common stock offered pursuant to this prospectus supplement and the accompanying prospectus.

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 section entitled Where You Can Find More Information on page 31 of the accompanying prospectus, 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 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.

PROSPECTUS SUPPLEMENT SUMMARY

This summary only highlights the more detailed information appearing elsewhere in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein and therein. 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 the context otherwise requires, the terms VIVUS, we, us, the Company and our refer to VIVUS, Inc., a Delaware corporation.

VIVUS, Inc.

VIVUS, Inc. is a pharmaceutical company dedicated to the development and commercialization of therapeutic products for large underserved markets using patented proprietary formulations and novel delivery systems and by seeking new indications for previously approved pharmaceutical products. We have employed this strategy and, currently, we have development candidates addressing obesity and sexual health. Both of these sectors are rapidly growing as patients seek more effective treatment options with fewer side effects. With respect to obesity, analysts estimate that this potential market ranges from $5 billion to $10 billion annually. The indications targeted by VIVUS sexual health products each represent a projected market greater than $1 billion annually.

We are currently advancing four late-stage clinical products, each addressing specific components of these significant markets. Three of these products are being prepared to enter Phase 3 clinical trials, and one product has completed Phase 3 evaluation, for which we submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the third quarter of 2006. 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 investigational product pipeline includes:

- **Qnexa**TM for treating obesity, for which a Phase 2 study has been completed;

- **EvaMist**TM to treat vasomotor symptoms associated with menopause, for which we submitted an NDA to the FDA in the third quarter of 2006;

- **Testosterone MDTS®** is being developed to treat hypoactive sexual desire disorder, for which a Phase 2 study has been completed; a Special Protocol Assessment (SPA) request was submitted at the end of the second quarter of 2006; and

- **Avanafil** is being developed for the treatment of erectile dysfunction, for which Phase 2 studies have been completed and an end of Phase 2 meeting with the FDA has been held.

Our Future

Our goal is to build a successful pharmaceutical company through the development and commercialization of innovative proprietary products for the treatment of obesity and sexual health. We intend to achieve this by:

- capitalizing on our clinical and regulatory expertise and experience 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.

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

Year-to-Date 2006 Update

Highlights year to date include:

- Grant of Key Patent for MDTS® Delivery System An additional patent relating to the Metered Dose Transdermal Spray (MDTS) was granted by the U.S. Patent and Trademark Office to Acrux (ASX: ACR). This patent, which expires July 31, 2022, provides protection for the MDTS applicator, which is currently used in two of VIVUS women s health investigational product candidates under clinical development: Testosterone MDTS for the treatment of decreased libido and EvaMist (Estradiol MDTS) for the treatment of menopausal symptoms. VIVUS licensed the U.S. rights to these products from Acrux in 2004.

- Purchase of Manufacturing Facility In January 2006, VIVUS financed the purchase of land and buildings previously leased by VIVUS by entering into a mortgage note agreement with Crown Bank, N.A. of New Jersey. In December 2005, VIVUS purchased the land and buildings for $7.1 million funded by $3.3 million, which had previously been classified as restricted cash, and the remainder from its general cash account. In January 2006, VIVUS received proceeds from the mortgage note of $5.4 million. Together, the note and the previously restricted cash allowed VIVUS to purchase the facility without using any cash from its general cash account.

- Receipt of Milestone Payment from European Distributor In January 2006, VIVUS received a milestone payment from its European distributor, MEDA AB of $2.0 million, which is included in deferred revenue as of September 30, 2006 and is being recognized as income ratably over the term of the distribution agreement. The milestone payment provides MEDA with the right to continue to sell and distribute MUSE in its European territories. VIVUS and MEDA entered into a ten-year distribution agreement in 2002.

- Positive Phase 2 Clinical Trial Results with Qnexa In May 2006, we announced positive results from a Phase 2 study of Qnexa. The trial, which was conducted by Duke University Medical Center, was a double blind, randomized, placebo controlled study. Findings from the study included:

- Over 50% of patients on Qnexa experienced 10% or more total body weight loss in 24 weeks.

- Patients on Qnexa achieved a placebo-adjusted weight loss of 20.3 pounds at week 24.

- Weight loss with Qnexa had not plateaued by 24 weeks.

- Qnexa was well-tolerated. Four patients (8%) dropped out of the Qnexa study arm for any reason, versus 19 patients (38%) on placebo. This trial involved 200 subjects, 159 women and 41 men with an average age of 40 and a mean body mass index (BMI) of 38. (A BMI of >30.0 is classified as obese per guidelines from the U.S. Department of Health and Human Services.)

- Key Patent Issuance for Qnexa In June 2006, the U.S. Patent and Trademark Office issued VIVUS s first patent for Qnexa. This patent, number US 7,056,890 B2, broadly covers Qnexa and its use in the treatment of obesity. The term of this patent extends into 2019. Qnexa is the subject of multiple additional U.S. and foreign patent applications.

- Raised $12.0 million in Registered Direct Offering of Common Stock In May 2006, VIVUS entered into a purchase agreement for the sale of $12.0 million of its common stock in a registered direct offering. The financing was led by new investor, OrbiMed Advisors, LLC. We intend to use the proceeds from the financing to fund on-going and future clinical trials, including certain studies required prior to the initiation of a Phase 3 clinical trial of Qnexa and for general operating purposes.

- Positive Phase 3 Clinical Trial Results for EvaMist In May 2006, we announced positive results from the pivotal Phase 3 clinical trial of EvaMist. EvaMist is a novel, once-a-day, transdermal spray that delivers estradiol, a naturally occurring estrogen, for the treatment of hot flashes in women. The study showed a statistically significant reduction in the number and severity of moderate and severe hot flashes. The Phase 3 trial, which was conducted at 43 clinical sites in the United States, was a 12-week, randomized, double-blind, placebo controlled study of 457 menopausal women.

- Special Protocol Assessment (SPA) request for Testosterone MDTS was submitted to the FDA In June 2006, we submitted a request for SPA for the Phase 3 study for Testosterone MDTS for the treatment of Hypoactive Sexual Desire Disorder (HSDD).

- Submitted a New Drug Application (NDA) with the FDA In September 2006, we submitted an NDA for our investigational estradiol drug, EvaMist, being developed for the treatment of vasomotor symptoms associated with menopause.

Our Product Pipeline

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

Product	Indication	Status	Patent Expiry and Number
Qnexa (phentermine and topiramate)	Obesity	Phase 2 completed	2019 (US 7,056,890 B2)
EvaMist (Estradiol-MDTS)	Menopausal symptoms	Phase 3 completed, NDA submitted with FDA	2017 (US 6,818,226)
Testosterone MDTS	Hypoactive sexual desire disorder (HSDD)	Phase 2 completed, SPA submitted with FDA	2017 (US 6,818,226)
Avanafil (PDE5 inhibitor)	Erectile dysfunction (ED)	Phase 2 completed	2020 (US 6,656,935)

Corporate Information

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 Global Market under the symbol VVUS.

The Offering

Shares of common stock we are offering	9,600,000 shares
Shares of common stock to be outstanding immediately after this offering	58,052,250 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 Global Market symbol	VVUS

The number of shares of common stock outstanding immediately after this offering in the table above is based on 48,452,250 shares of our common stock outstanding as of November 14, 2006 and excludes up to 4,764,605 shares of our common stock issuable upon the exercise of outstanding stock options and up to 62,500 shares of restricted stock units subject to vesting issuable to one of our officers.

Unless otherwise stated, all information contained in this prospectus supplement reflects a public offering price of $3.50 per share.

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 7 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 not be able to achieve the pre-defined clinical endpoint due to statistical anomalies even though clinical benefit was achieved, 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. To date, our development efforts have been focused on products for sexual health. Qnexa is our product candidate to treat obesity. While we have experience in running clinical trials in general, we have no experience in running large scale clinical trials for obesity. There can be no assurance that we will be successful with the limited obesity knowledge and resources we have available at the present time.

The results of pre-clinical studies and completed clinical trials are not necessarily predictive of future results, and our current product candidates may not have favorable results in later studies or trials.

Pre-clinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a product candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the product candidate s side effects at various doses and schedules. Success in pre-clinical studies or completed clinical trials does not ensure that later studies or trials, including continuing pre-clinical studies and large-scale clinical trials, will be successful nor does it necessarily predict future results. Favorable results in early studies or trials may not be repeated in later studies or trials, and product candidates in later stage trials may fail to show acceptable safety and efficacy despite having progressed through initial-stage trials. In addition, the placebo rate in larger studies may be higher than expected.

Our product candidates, Qnexa, Testosterone MDTS and avanafil, have not completed the large, pivotal Phase 3 trials for efficacy and safety that are required for FDA approval. Pre-clinical data and the limited clinical results that we have obtained for these investigational products may not predict results from studies in larger numbers of subjects drawn from more diverse populations treated for longer periods of time. They also may not predict the ability of these investigational products to achieve or sustain the desired effects in the intended population or to do so safely. We may also decide to not conduct smaller Phase 2 studies prior to the initiation of pivotal Phase 3 studies. In addition, we may elect to enter into pivotal Phase 3 studies with a new formulation, delivery system or choose to study different populations than had been used or studied in previous clinical trials.

Qnexa is a proprietary capsule formulation containing the active ingredients phentermine and topiramate. Phentermine was approved for the short-term treatment of obesity by the FDA in 1959. Topiramate is approved for seizures and migraine prevention. Topiramate has been reported in published studies to produce weight loss. By combining the activity of each of these compounds, Qnexa attempts to simultaneously address excessive appetite and a high threshold for satiety, the two main mechanisms believed to impact eating behavior. Although we believe Qnexa affects both of the two major causes of overeating, excessive hunger and the inability to feel satisfied, we may not be correct in our assessment of the impact the combination of these two ingredients may have on weight loss or their mechanism of action. Our Phase 2 study was a single center trial conducted by Duke University in only 200 patients. The twice-a-day dose and timing of the administration of the active ingredients was determined by the inventor through the treatment of patients in his private practice. We are continuing the formulation development of Qnexa and expect to initiate the Phase 3 studies of Qnexa with a once-a-day formulation. We intend to complete a pharmacokinetic study of the once-a-day formulation prior to entering the Phase 3 trials to ensure adequate plasma level of Qnexa; however, there can be no assurance that we will be able to achieve any weight loss effects with the once-a-day formulation. The FDA has also asked us to study the effects of a lower dose of Qnexa, which we plan to do in the Phase 3 trials. We are unable to predict the effect of the inclusion of a lower dose group in the Phase 3 trials on the overall development program of Qnexa.

We will be required to demonstrate through larger-scale clinical trials that these product candidates are safe and effective for use in a broader population before we can seek regulatory approvals for their commercial sale. There is typically a high rate of attrition from the failure of product candidates proceeding through clinical trials. To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our product candidates, except EvaMist for which a Phase 3 clinical trial was completed. If any of our investigational products fails to demonstrate sufficient safety and efficacy in any clinical trial, we will experience potentially significant delays in, or decide to abandon development of, that product candidate. If we abandon or are delayed in our development efforts related to any of our investigational products we may not be able to generate sufficient revenues to continue our operations and clinical studies at the current level or become profitable, our reputation in the industry and in the investment community would likely be significantly damaged, it may not be possible for us to complete financings, and our stock price would likely decrease significantly.

If the results of current pre-clinical studies and/or clinical trials indicate that our proposed products are not safe or effective for human use, our business will suffer.

Unfavorable results from ongoing pre-clinical studies and/or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials. For example, we are currently conducting pre-clinical animal studies with phentermine and topiramate combined and with phentermine alone. Should the results of these pre-clinical studies show serious toxicity, we might choose to terminate or modify the development program and FDA approval of Qnexa could be delayed or denied. In addition, we may report top-line data from our pre-clinical studies and clinical trials from time to time. Top-line data is based on preliminary analysis of selected efficacy and safety data, and is subject to change.

A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after promising results in initial-stage trials. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated, modified or terminated. In addition, failure to construct appropriate clinical trial protocols could result in the test or control group experiencing a disproportionate number of adverse events and could cause a clinical trial to be delayed, repeated, modified or terminated.

Once a clinical trial has begun, it may be delayed, suspended or terminated due to a number of factors, including:

- ongoing discussions with regulatory authorities regarding the scope or design of our clinical trials or requests by them for supplemental information with respect to our clinical trial results;

- failure to conduct clinical trials in accordance with regulatory requirements;

- lower than anticipated retention rate of patients in clinical trials;
- serious adverse events or side effects experienced by participants; and
- insufficient supply or deficient quality of drug candidates or other materials necessary for the conduct of our clinical trials.

Many of these factors may also ultimately lead to denial of regulatory approval of a current or potential drug candidate. If we experience delays, suspensions or terminations in our clinical trials, the commercial prospects for that drug candidate will be harmed, and we may be unable to generate product revenues from that drug candidate or revenues would be delayed.

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/or clinical testing before we can submit any application for regulatory approval. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through pre-clinical testing and/or 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, but not limited to:

- 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;
- changes in clinical trial protocols imposed by the FDA;
- the effectiveness of our product candidates;
- slower than expected rate of and higher than expected cost of patient recruitment;
- inability to adequately follow patients after treatment;
- unforeseen safety issues; or
- government or regulatory delays.

One of the active ingredients in Qnexa, phentermine, had previously been used in combination with fenfluramine and dexfenfluramine. Phentermine is the most commonly prescribed anti-obesity product. As phentermine is an older drug, no new efficacy trials have been conducted with the exception of several trials on the combination of phentermine and fenfluramine in the early and mid 1990s. The combination of fenfluramine or PONDIMIN (the fen) and phentermine (the phen) is known as fen-phen . Fenfluramine received FDA approval in 1973 for the short-term treatment of obesity. Together, phentermine and fenfluramine were used by doctors to treat obesity. The FDA never approved the fen-phen combination; however, since the FDA approved fenfluramine, doctors were able to prescribe it as needed. The use of these drugs together for treatment of obesity was considered an off-label use. In 1992, a published study cited fen-phen as a more effective method than dieting or exercise in reducing the weight of the chronically obese. The fen-phen combination was successful and in 1996, 6.6 million prescriptions of fen-phen were written in the U.S. Dexfen-phen refers to the combination of dexfenfluramine or Redux (the dexfen) and phentermine (the phen). Dexfenfluramine received FDA approval in 1996 for use as an appetite suppressant in the management of obesity.

Like fen-phen, dexfen-phen, too, was successful. Neither combination, however, was ever tested for safety. By the summer of 1997, the Mayo Clinic reported 24 cases of heart valve disease in patients that had taken the fen-phen cocktail. The cluster of unusual cases of heart valve disease in fen-phen users suggested a co-relation between fen-phen use and heart valve disease. On July 8, 1997, the FDA issued a Public Health Advisory to report the Mayo findings. The FDA continued to receive additional reports of heart disease, including reports from patients who had taken only fenfluramine or dexfenfluramine. Further evaluations of patients taking

fenfluramine or dexfenfluramine showed that approximately 30% had abnormal valve findings. This figure was much higher than expected for abnormal test results and suggests fenfluramine and dexfenfluramine as the likely causes of Primary Pulmonary Hypertension (PPH) and valvular heart disease.

In September 1997, the FDA requested drug manufacturers to voluntarily withdraw fenfluramine and dexfenfluramine. At the same time, the FDA recommended that patients using either fenfluramine or dexfenfluramine stop taking them. The FDA did not, however, request the withdrawal of the third drug involved in the drug combination, phentermine. While previous studies have shown that phentermine did not cause PPH and valvular heart disease, there can be no assurance that Qnexa will not have any cardiovascular or other detrimental side effects. In the Phase 2 study, echocardiograms and cardiovascular monitoring were performed and no abnormalities were noted. The FDA has requested we provide our plans regarding the collection of echocardiograms and cardiovascular monitoring of some patients in the Phase 3 studies. Moreover, the adverse history of fen-phen and dexfen-phen combinations for obesity may result in increased FDA regulatory scrutiny of the safety of Qnexa and may raise potential adverse publicity in the marketplace, which could affect clinical enrollment or ultimately market acceptance if Qnexa is approved for sale.

Previous published studies suggested that the administration of topiramate alone in conjunction with diet and a behavioral modification program results in weight reduction in obese patients. The most prominent side effect seen in the published studies was paresthesia, (tingling of the extremities) experienced by 42% to 59% of patients. Drop outs due to paresthesia were 5% or less. In the Phase 2 Duke study, paresthesia was experienced in 38% of the patients on Qnexa. There were no drop outs in the Qnexa group due to paresthesia. The other common adverse events experienced in the topiramate monotherapy studies were also Central Nervous System (CNS) related including fatigue, difficulty with attention, memory and concentration and depression. In the Phase 2 study, these CNS related side effects were also experienced but the difference was not significant when compared to placebo. The pharmaceutical company performing research of topiramate alone announced they had discontinued development of a time-release formulation due to side effects at high doses. We believe that the addition of phentermine to topiramate may help alleviate some of the CNS side effects seen in the topiramate alone studies; however, we may not be correct in this belief and Qnexa may not avoid or exhibit a significant reduction in these undesired side effects.

The FDA has also recently begun the review of the correlation of certain centrally acting drugs on suicidal ideations. The agency has requested that as part of our Phase 3 trials for Qnexa, a standard suicidality analysis be performed. While we do not expect a negative impact from the completion of this analysis on the ultimate approval of Qnexa, the labeled use of Qnexa may exclude patients with suicidal tendencies.

To date, the clinical results we have obtained do not necessarily predict that the results of further testing, including larger, late-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.

Our product candidate, Qnexa, is a combination of approved drugs that are commercially available and marketed by other companies. As a result, our product may be subject to substitution and competition.

We anticipate that the approved drugs that are combined to produce our product candidate, Qnexa, are likely to be commercially available at prices lower than the prices at which we would seek to market our product candidate. We cannot be sure that physicians will view our products as sufficiently superior to a treatment regime of the individual active pharmaceutical ingredients as to justify the significantly higher cost we expect to seek for Qnexa, and they may prescribe the individual drugs already approved and marketed by other companies instead of our combination product. Even though our U.S. patent contains composition, product formulation and method-of-use claims that should protect Qnexa, that patent may be ineffective as a practical matter to protect against physicians prescribing the individual drugs marketed by other companies instead of our combination product. To the extent that the price of our product is significantly higher than the prices of the individual components as marketed by other companies, physicians may have a greater incentive to write prescriptions for the individual components instead of for our combination product, and this may limit how we price Qnexa. Similar concerns could also limit the reimbursement amounts private health insurers or government agencies in the United States are prepared to pay for Qnexa, which could also limit market and patient acceptance of our product, and could

negatively impact our revenues and net income, if any. Physicians might also prescribe the individual components of a product candidate prior to Qnexa s approval, which could adversely affect our development of the product candidate due to our lack of control over the administration to patients of the combination of active pharmaceutical ingredients in our product candidate, the occurrence of adverse effects, and other reasons. Such pre-approval use could also adversely affect our ability to market and commercialize Qnexa.

In many countries where we may plan to market Qnexa, including Europe, Japan and Canada, the pricing of prescription drugs is controlled by the government or regulatory agencies. Regulatory agencies in these countries could determine that the pricing for Qnexa should be based on prices for its active pharmaceutical ingredients when sold separately, rather than allowing us to market Qnexa at a premium as a new drug.

The FDA and other regulatory agencies may require more extensive or expensive trials for our combination investigational product candidate, Qnexa, than may be required for single agent pharmaceuticals.

To obtain regulatory approval for Qnexa, we will be required to show that each active pharmaceutical ingredient in the product candidate makes a contribution to the combined product candidate s claimed effects and that the dosage of each component, including amount, frequency and duration, is such that the combination is safe and effective for a significant patient population requiring such concurrent therapy. As a result, we may be required to conduct clinical trials for each component drug as well as for the component drug in combination. This would require us to conduct more extensive and more expensive clinical trials than would be the case for many single agent pharmaceuticals. The need to conduct such trials could make it more difficult and costly to obtain regulatory approval of Qnexa than of a new drug containing only a single active pharmaceutical ingredient.

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

We have and will continue to in-license product candidates from third parties. The United States rights to EvaMist and Testosterone MDTS were licensed from Acrux Limited and its related affiliates. The rights to avanafil were licensed from Tanabe Seiyaku Co, LTD., a Japanese corporation. Each of these agreements contains certain obligations. Failure to comply with the terms of the agreements could result in the early termination of these agreements. We believe we are in compliance with all the material terms of these agreements, however there can be no assurance that this compliance will continue or that the licensees would not have a differing interpretation of the material terms of the agreements. If the license agreements were terminated early or if the terms of the license were contested for any reason it would have a material adverse impact on our ability to commercialize products subject to these agreements, our ability to raise funds to finance the company, our stock price and our overall financial condition.

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 product candidates, particularly after the Phase 2 stage of clinical testing. These arrangements may place the development of our product 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 product 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 product 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 product 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 product candidates.

We face significant governmental regulation during our product development activities.

The research, testing, manufacturing, selling and marketing of product 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 studies and clinical trials. The number of pre-clinical studies and clinical trials that will be required for FDA approval varies depending on the product candidate, the disease condition that the product candidate is designed to address, and the regulations applicable to any particular product 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 under development by another company to address female sexual dysfunction, specifically hypoactive sexual desire disorder. The FDA 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 developing a transdermal testosterone product candidate, Testosterone MDTS, which 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 significant 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 investigational 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 product 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 investigational product candidates from third parties. Our present development programs involving these product candidates rely in part 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 to the FDA for its review 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 investigational product 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 investigational product 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 product 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 product 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 product 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 products and our business could suffer.

We rely on third parties to conduct pre-clinical and clinical trials and studies 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 pre-clinical or clinical studies for our product candidates without the assistance of third parties who conduct the studies on our behalf. These third parties are usually toxicology facilities and clinical research organizations, or CROs, that have significant resources and experience in the conduct of pre-clinical and clinical studies. The toxicology facilities conduct the pre-clinical safety studies as well as all associated tasks connected with these studies. The CROs typically perform patient recruitment, project management, data management, statistical analysis, and other reporting functions. We intend to use several different toxicology facilities and CROs for all of our pre-clinical and clinical studies. If these third party toxicology facilities or 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 product candidates on a timely basis, if at all, and we may not be able to successfully commercialize these proposed product candidates. If these third party toxicology facilities or 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 product candidates and may not be able to successfully commercialize these proposed product candidates.

The Phase 3 clinical studies of EvaMist were conducted using the first generation MDTS applicator. We have improved on the design of the housing used in the MDTS applicator, which we believe will allow us to manufacture EvaMist more efficiently than with the previous design. The New Drug Application (NDA) for EvaMist includes the new MDTS applicator. Since this applicator was not used in the pivotal Phase 3 study the FDA may require additional data before it approves our NDA. If additional data are required we would delay the approval of the NDA for EvaMist, which in turn could delay the launch of the product into the marketplace. A material delay in the approval of the NDA for EvaMist or the ultimate commercial launch of EvaMist would have a material adverse impact on our stock price and financial condition.

We are continuing the formulation development of Qnexa. To date, we have not created a once-a-day formulation. We are currently evaluating the capabilities of several contract manufacturers to develop a once-a-day formulation. While we anticipate these contract manufacturers will be successful in developing a once-a-day formulation there can be no assurance that a once-a-day formulation can be developed, that it can be developed on a timely basis, or if it is developed that it will result in sufficient safety and efficacy for approval. A failure to

develop a once-a-day formulation may have a material adverse impact on our stock price, financial condition and, if approved, future revenues.

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 product 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 cGMP. 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 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.

We are required to obtain FDA approval for any change in suppliers or service providers. For example, MUSE is supplied to the market with the MUSE applicator, containing the MUSE dosage, enclosed within a sealed foil pouch. Our supplier that produces the MUSE laminated foil has closed its business. The laminated foil is used to make the sealed foil pouch, described above, which is used to make the MUSE primary product container. Before the supplier closed its business, the supplier produced a bulk-quantity of foil that, at this time, is expected to be sufficient to support MUSE production through the end of the first quarter of 2007. There can be no assurance that as this bulk supply is used through the end of the first quarter of 2007 there will be a sufficient yield in the final quantity of foil with acceptable quality to support MUSE demand through the first quarter of 2007. Although the foil supplier produced this bulk unprinted foil, the label printing will be done periodically. As a consequence, if there are unacceptable quality issues with the bulk foil, they may not be discovered as the bulk material is used through the first quarter of 2007. If such foil quality issues do occur, we may be unable to meet MUSE demand in 2006 and 2007.

We have identified a new potential vendor for the MUSE laminated foil. As this laminated foil is used to make the MUSE primary product container, there are significant qualifications and regulatory approvals that must be obtained prior to using the new vendor to produce foil to meet MUSE demand. These include, but are not limited to, vendor qualification, foil material qualification, MUSE product suitability studies, electron beam irradiation suitability, FDA approval, and European Medicines and Healthcare products Regulatory Agency approval. There can be no assurance that these qualifications and approvals will be successfully obtained, or that they will be obtained within the time needed to support MUSE demand before our current supply of foil is exhausted.

Failure to receive adequate supplies of foil, failure to receive appropriate regulatory approvals for the change in materials and vendors, and any unforeseen quality or production issues due to the use of the new materials or vendors could have a material adverse effect on our business, financial condition and results of operations.

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. The FDA may also order that all future promotional materials receive prior agency review and approval before use. 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 corrected the prior message and 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. In March 2005, we received a letter from the FDA indicating that the matter had been closed.

Results from a single center study reported in mid-2005 show a potential benefit from the therapeutic use of MUSE following radical prostatectomy. We are sponsoring clinical trials to study the effects of MUSE therapy following radical prostatectomy. We believe physicians are beginning to prescribe MUSE for use following radical prostatectomy. All promotional materials and efforts are subject to FDA review. If our promotional materials and efforts are altered, modified, or halted by the FDA for any reason, future sales of MUSE could be negatively affected.

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

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

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

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

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

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

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

future products or that we will be able to successfully manufacture or adequately support sales of any future products.

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

We support MUSE sales in the United States through a small direct sales force targeting major accounts. Telephone marketers also focus on urologists who prescribe MUSE. Physician and patient information/help telephone lines are available to answer additional questions that may arise after reading the inserts or after actual use of the product. The sales force actively participates in national urologic and sexual dysfunction forums and conferences, such as the American Urological Association annual and regional meetings and the International Society for Impotence Research. There can be no assurance that our sales programs will effectively maintain or potentially increase current sales levels. There can be no assurance that demand for MUSE will continue or that we will be able to adequately support sales of MUSE in the United States in the future.

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

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

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

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

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

Current anti-obesity products include Xenical (orlistat), marketed by Roche, and Meridia (sibutramine), marketed by Abbott Labs. Phentermine is the largest selling anti-obesity therapeutic and is available in several generic forms. Topamax, marketed by Johnson and Johnson, is not approved for the treatment of obesity but analysts estimate Topamax is used for this indication. ACOMPLIA (rimonabant) is a small-molecule central cannabinoid antagonist being developed by Sanofi-Aventis. We believe ACOMPLIA will be marketed under the trade name Zimulti in the United States. ACOMPLIA received an approval letter from the FDA in February 2006. Analysts estimate that peak sales of ACOMPLIA for obesity could exceed $2.0 billion.

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

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

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 product candidates for the treatment of FSD including: The Proctor & Gamble Company is developing Intrinsa, a testosterone patch for the treatment of HSDD; BioSante Pharmaceuticals, Inc. is developing forms of testosterone gels for HSDD and Palatin Technologies, Inc. is developing a nasal spray to treat FSD. None of these products has been approved by the FDA. In July 2006, the European Medicines Agency (EMEA) granted marketing authorization of Intrinsa for the treatment of HSDD in bilaterally oophorectomized and hysterectomized women.

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

We are required to receive regulatory approval for suppliers. We obtained our current supply of alprostadil from two approved sources, NeraPharm, s.r.o., in the Czech Republic and Chinoin Pharmaceutical and Chemical Works Co., Ltd., in Hungary. We have manufacturing agreements with Chinoin and NeraPharm to produce additional quantities of alprostadil for us. We are currently in the process of investigating additional sources for our future alprostadil supplies. However, there can be no assurance that we will be able to identify and qualify additional suppliers of alprostadil in a timely manner, or at all.

Furthermore, our current supply of alprostadil is subject to periodic re-testing to ensure it continues to meet specifications. There can be no guarantees that our existing inventory of alprostadil will pass these re-testing procedures and continue to be usable material. There is a long lead-time for manufacturing alprostadil. A shortage in 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 to answer questions and inquiries about MUSE. Calls to these hotlines may include complaints about our products due to efficacy or quality, as well as the reporting of adverse events. As a result of this agreement, we are dependent on WRB Communications to effectively handle these calls and inquiries. There can be no assurance that such efforts will be successful.

We entered into a distribution agreement with Integrated Commercialization Services, or ICS, a subsidiary of AmerisourceBergen Corporation. ICS provides direct-to-physician distribution of product samples in support of United States marketing and sales efforts. As a result of this distribution agreement, we are dependent on ICS s efforts to distribute product samples effectively.

We rely on two companies, E-Beam Services, Inc. (E-Beam) and Beam One, LLC (Beam One), for the sterilization of MUSE. However, for some international markets, the MUSE Product License includes approval to use only one of the above listed vendors. If interruptions in these services occur for any reason, including a decision by E-Beam or Beam One to discontinue manufacturing or services, political unrest, labor disputes or a failure of E-Beam or Beam One to follow regulations, the commercial marketing of MUSE and the development of other potential products could be prevented or delayed. An extended interruption in sterilization services would have a material adverse effect on our business, financial condition and results of operations.

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 (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 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 purchased two buildings with a total combined 90,000 square feet in Lakewood, New Jersey, which we previously leased, on December 22, 2005. This facility is used 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 government and other third-party payors may limit our ability to market and sell our products or limit our product revenues and delay profitability.

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 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 the types of drugs eligible for reimbursement 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.

The continuing efforts of government and third-party payors to contain or reduce the costs of health care through various means may reduce our potential revenues. These payors efforts could decrease the price that we receive for any products we may develop and sell in the future. In addition, third-party insurance coverage may not be available to patients for any products we develop. If government and third-party payors do not provide adequate coverage and reimbursement levels for our products, or if price controls are enacted, our product revenues will suffer.

Congress passed legislation that ended federal Medicaid and Medicare payments for erectile dysfunction drugs beginning January 1, 2006 and January 1, 2007, respectively. We are currently assessing the impact that this legislation will have on our business. However, historically the volume of MUSE sales to Medicaid and Medicare patients has not been a significant portion of our overall MUSE sales volume. We believe there is increasing political pressure to reduce or eliminate reimbursement by the U.S. government for MUSE. A reduction or elimination in the reimbursement by the U.S. government would have a material adverse impact on our revenues and business operations.

One of the active ingredients in Qnexa, phentermine is available as a generic. The other, topiramate, is subject to several patents, the first of which is set to expire in 2008. Based on the research we have completed to date, we have no reason to believe Qnexa would not be subject to reimbursement by third party payors. The exact doses of the active ingredients in the final formulation of Qnexa will be different than those currently available. State pharmacy law prohibits pharmacists from substituting drugs with differing doses and formulations. The safety and efficacy of Qnexa is highly dependent on the titration, dosing and formulation which we believe could not be easily duplicated, if at all, with the use of generic substitutes. However, there can be no assurance that we will be able to provide for optimal reimbursement of Qnexa for obesity from third party payors or the U.S. Government. Furthermore, there can be no assurance that healthcare providers would not actively seek to provide patients generic versions of the active ingredients in Qnexa in order to treat obesity at a potential lower cost.

Federal legislation may increase the pressure to reduce prices of pharmaceutical products paid for by Medicare, which could adversely affect our revenues, if any.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, expanded Medicare coverage for drug purchases by the elderly and disabled beginning in 2006. Under the MMA, private insurance plans subsidized by the government offer prescription drug coverage to Medicare beneficiaries who elect to enroll in their plans. Although almost all prescription drugs are potentially available to plan enrollees, the plans are allowed to use formularies, preferred drug lists and similar mechanisms to favor selected drugs and limit access to other drugs except in certain circumstances. The price of a drug as negotiated between the manufacturer and a plan is a factor that the plan can consider in determining its availability to enrollees.

As a result, we expect that there will be increased pressure to reduce prices for drugs to obtain favorable status for them under the plans offering prescription drug coverage to Medicare beneficiaries. This pressure could decrease the coverage and price that we receive for our products in the future and could seriously harm our business. It is possible that our product, Qnexa, if successfully developed, could be particularly subject to price reduction initiatives because it is based on combinations of lower priced existing drugs.

In addition, some members of Congress advocate that the federal government should negotiate directly with manufacturers for lower prices for drugs in the Medicare program, rather than rely on private plans. If the law were changed to allow or require such direct negotiation, there could be additional reductions in the coverage of and prices that we receive for our products.

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.

Natural disasters or resource shortages could disrupt our operations and adversely affect results.

Our manufacturing operation is conducted in a single location in Lakewood, New Jersey. In the event of a natural disaster in that region, such as a storm, drought or flood, or localized extended outages of critical utilities or transportation systems, we do not have a formal business continuity or disaster plan, and could therefore experience a significant business interruption.

Furthermore, our clinical trials could be delayed or disrupted indefinitely upon the occurrence of a natural disaster. For example, our clinical trials in the New Orleans area were interrupted by Hurricane Katrina. Future natural disasters could further delay our clinical trials process, thus adversely affecting our business and financial results.

Risks Relating to our Intellectual Property

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

There can be no assurance that our products do not or will not infringe on the patent or proprietary rights of others. Third parties may assert that we are employing their proprietary technology without authorization. For example, in October 2002, the United States Patent and Trademark Office (USPTO) issued to Pfizer a method of use patent, 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 USPTO 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 USPTO, we may be prevented from commercializing avanafil, our PDE5 inhibitor.

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

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

We hold various patents and patent applications in the United States and abroad targeting obesity and male and female sexual health among other products. Qnexa is our product candidate involving low doses of topiramate and phentermine. On June 6, 2006, U.S. Patent No. 7,056,890 B2 was issued by the USPTO. This patent contains composition, product, and other claims that should protect Qnexa as a proprietary product for the treatment of obesity. The term of this patent extends into 2019. The corresponding European patent with similar claims has been approved for grant. We are in the process of prosecuting patent applications in other countries as well, to obtain significant foreign patent coverage for both Qnexa and future generations of Qnexa. Furthermore, we have filed additional patent applications in the United States to expand the coverage that will be provided by the initial U.S. patent. The primary focus of the patent applications is on combination therapy using a sympathomimetic agent (such as phentermine) and an anticonvulsant (such as topiramate) for the treatment of obesity and other related disorders. We have worked closely with our patent counsel to put together a cogent patent strategy and are building a strong patent portfolio, ensuring exclusivity for many years to come.

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 positions, 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 USPTO, 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.

We may be subject to claims that we, or our employees, have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ individuals who were previously employed at other pharmaceutical companies, including our competitors or potential competitors. Although we have no knowledge of any pending claims, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

We may not be able to develop or commercialize our product candidates due to intellectual property rights held by third parties.

If a third party holds a patent to a composition or method of use of an approved drug that is a component of one or more of our product candidates, we may not be able to develop or commercialize such product candidates without first obtaining a license to such patent, or waiting for the patent to expire. Our business will be harmed if we are unable to use the optimal formulation or methods of use of the component drugs that comprise our product candidates. This may occur because the formulations or methods of use are covered by one or more third party patents, and a license to such patents is unavailable or is available on terms that are unacceptable to us.

We may be unable to in-license intellectual property rights or technology necessary to develop and commercialize our products.

Depending on its ultimate formulation and method of use, before we can develop, clinically test, make, use, or sell a particular product candidate, we may need to obtain a license from one or more third parties who have patent or other intellectual property rights covering components of our product candidate or its method of use. There can be no assurance that such licenses will be available on commercially reasonable terms, or at all. If a third party does not offer us a necessary license or offers a license only on terms that are unattractive or unacceptable to us, we might be unable to develop and commercialize one or more of our product candidates.

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 spending on research and development projects, including clinical trials. On July 14, 2006, VIVUS, Inc. filed with the Securities and Exchange Commission (SEC) a shelf Registration Statement on Form S-3. The shelf Registration Statement (File Number 333-135793) was declared effective by the SEC on August 16, 2006, providing us with the ability to offer and sell up to an aggregate of $80.0 million of common stock from time to time in one or more offerings. The terms of any such future offering would be established at the time of such offering. On May 10, 2006, we raised $12.0 million in a registered direct offering of our common stock to two

institutional investors. Under the terms of this financing, we sold 3,669,725 shares of VIVUS common stock at a price of $3.27 per share. On January 4, 2006, we obtained a $5.4 million loan from Crown Bank, N.A. (Crown), secured by the land and buildings, among other assets, located at our principal manufacturing facility and a $700,000 Certificate of Deposit held by Crown. The loan is payable over a 10-year term and the interest rate will be fixed at 8.25%, which is the prime rate plus 1% at the time of funding and then will be adjusted annually to a fixed rate for the year equal to the prime rate plus 1% with a floor of 7.5%. On December 22, 2005, we purchased from our landlord our principal manufacturing facility, which was previously leased, for $7.1 million. The purchase price was funded in part by $3.3 million of restricted cash, which was being held by the landlord as cash collateral for renovations to the facility upon the termination of the lease and the remainder with cash. On March 15, 2005, we sold 6,250,000 shares of our common stock at a price of $3.40 per share, providing us with net proceeds of $19.6 million.

We expect that our existing capital resources combined with future anticipated cash flows will be sufficient to support our operating activities into 2007. However, we anticipate that we will be required to obtain additional financing to fund the development of our research and development pipeline in future periods as well as to support the possible launch of any future products. Our future capital requirements will depend upon numerous factors, including:

- the progress and costs of our research and development programs;
- the scope, timing and results of pre-clinical testing and clinical trials;
- patient recruitment and enrollment in current and future clinical trials;
- the costs involved in seeking regulatory approvals for our product candidates;
- the costs involved in filing and pursuing patent applications and enforcing patent claims;
- the establishment of collaborations and strategic alliances;
- the cost of manufacturing and commercialization activities and arrangements;
- the results of operations;
- demand for MUSE;
- 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. We are continually evaluating our existing portfolio and we may choose to divest or spin-off one or more of our products or product candidates at any time. We cannot assure you that we will successfully develop our products under development or that our products, if successfully developed, will generate revenues sufficient to enable us to earn a profit. 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 $167.9 million as of September 30, 2006 and expect to continue to incur substantial operating losses for the foreseeable future.

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We have generated a cumulative net loss of $167.9 million for the period from our inception through September 30, 2006, 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 Global 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 VIVUS 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, and our need for clinical supplies. 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 Global 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.

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

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

In addition, we are governed by the provisions of Section 203 of Delaware General Corporate Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us. These and other provisions in our 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 financial accounting standards related to share-based payments are expected to continue to have a significant effect on our reported results.

On January 1, 2006, we adopted the revised statement of Financial Accounting Standards No. SFAS 123R (SFAS 123(R)), *Share-Based Payment*, which requires that we record compensation expense in the statement of operations for share-based payments, such as employee stock options, using the fair value method. The adoption of this new standard is expected to continue to have a significant effect on our reported earnings, although it will not affect our cash flows, and could adversely impact our ability to provide accurate guidance on our future reported financial results due to the variability of the factors used to estimate the values of share-based payments. If factors change and we employ different assumptions or different valuation methods in the application of SFAS 123(R) in future periods, the compensation expense that we record under SFAS 123(R) may differ significantly from what we have recorded in the current period, which could negatively affect our stock price and our stock price volatility.

Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and NASDAQ Global Market rules, are creating uncertainty for companies such as ours. These new or changed laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, our efforts to comply with evolving laws, regulations and standards have resulted in, and are likely to continue to result in, increased general and administrative expenses and management time related to compliance activities. In particular, our efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002 and the related regulations regarding our required assessment of our internal controls over financial reporting and our external auditors audit of that assessment has required the commitment of significant financial and managerial resources. We expect these efforts to require the continued commitment of significant resources. If we fail to comply with new or changed laws, regulations and standards, our reputation may be harmed and we might be subject to sanctions or investigation by regulatory authorities, such as the Securities and Exchange Commission. Any such action could adversely affect our financial results and the market price of our common stock.

USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of our common stock in this offering will be approximately $33.6 million.

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 September 30, 2006 was approximately $19.6 million, or approximately $0.41 per share of common stock based upon 48,402,517 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 September 30, 2006. After giving effect to the sale by us of the 9,600,000 shares of our common stock we are offering, our as-adjusted net tangible book value would have been approximately $53.2 million, or approximately $0.92 per share of common stock based upon 58,002,517 shares outstanding. This represents an immediate increase in net tangible book value of $0.51 per share to our existing stockholders and an immediate dilution in net tangible book value of $2.58 per share to new investors. The following table illustrates this calculation on a per share basis:

Public offering price per share		$ 3.50
Net tangible book value per share as of September 30, 2006	$ 0.41	
Increase in net tangible book value per share attributable to the offering	0.51	
As-adjusted net tangible book value per share after giving effect to the offering		0.92
Dilution in net tangible book value per share to new investors		$ 2.58

The foregoing table excludes the following, each stated as of September 30, 2006:

- 3,310,279 shares of our common stock issuable upon the exercise of exercisable stock options at a weighted average exercise price of $4.38 per share;
- 1,439,379 shares of our common stock issuable upon the exercise of outstanding stock options that are not exercisable;
- 1,806,588 shares of common stock reserved for future issuance under our stock plans; and
- 62,500 shares of restricted stock units issuable subject to vesting requirements.

PLAN OF DISTRIBUTION

We will enter into securities purchase agreements directly with the investors in connection with this offering. Assuming all of the purchase agreements are executed by the investors as currently contemplated and subject to the terms and conditions of the purchase agreements, the investors will agree to purchase, and we will agree to sell, an aggregate of 9,600,000 shares of our common stock, as provided on the cover of this prospectus supplement.

The shares of common stock sold in this offering will be listed on the NASDAQ Global Market. We expect that the shares of common stock will be delivered only in book-entry form through The Depository Trust Company, New York, New York on or about November 17, 2006.

The expenses directly related to this offering are estimated to be approximately $50,000 and will be paid by us. Expenses of the offering include our legal and accounting fees, printing expenses, transfer agent fees, NASDAQ Global Market listing fees and miscellaneous fees.

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, 2005 and for the one-year period ended December 31, 2005 have been incorporated by reference herein in reliance upon the reports of Odenberg, Ullakko, Muranishi & Co. LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

The consolidated financial statements and schedules of VIVUS, Inc. and subsidiaries as of December 31, 2004 and for each of the years in the two-year period ended December 31, 2004 have been incorporated by reference herein in reliance upon the reports of KPMG LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

RECENT DEVELOPMENTS

On November 14, 2006, we received a letter from Manatt, Phelps & Phillips LLP on behalf of Acrux DDS Pty Ltd., FemPharm PTY Ltd. and Acrux Limited (collectively Acrux) notifying us of an alleged dispute under the Testosterone and Estradiol Development Agreements between Vivus and Acrux. We believe we are in compliance with all material aspects of both of these agreements and have communicated this belief to Acrux. If we are unable to resolve the matter with Acrux, we intend to seek to enforce our rights under these agreements. Development and commercialization of EvaMist and Testosterone MDTS continues as planned and we believe that we have a meritorious defense to any actual claims made by Acrux in connection with the alleged dispute. We believe the resolution of this dispute will not have a material impact on our financial position.

LIMITATION OF LIABILITY AND INDEMNIFICATION

Our Amended and Restated Certificate of Incorporation provides that, to the fullest extent permitted by the Delaware General Corporation Law, our directors will not be liable for monetary damages to us or our stockholders for breach of fiduciary duty as a director. Our Amended and Restated Bylaws authorize us to indemnify our directors, officers, employees and agents to the fullest extent permitted by applicable law, except for any legal proceeding that is initiated by such directors, officers, employees or agents without authorization of the Board of Directors. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the SEC s opinion, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

PROSPECTUS

$80,000,000

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 Global Market under the symbol VVUS. On July 11, 2006, the last reported sale price of our common stock on the NASDAQ Global Market was $3.33 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 7 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 July 14, 2006

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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 $80 million 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 pharmaceutical company dedicated to the development and commercialization of therapeutic products for large underserved markets using patented proprietary formulations and novel delivery systems and by seeking new indications for previously approved pharmaceutical products. We have employed this strategy and, currently, we have development candidates addressing obesity and sexual health. Both of these sectors are rapidly growing as patients seek more effective treatment options with fewer side effects. With respect to obesity, analysts estimate that this potential market ranges from $5 billion to $10 billion annually. The indications targeted by VIVUS sexual health products each represent a projected market greater than $1 billion annually.

We are currently advancing five late-stage clinical products, each addressing these significant markets. Four of these products are being prepared to enter Phase 3 clinical trials, and one product has completed Phase 3 evaluation, for which we anticipate submitting a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the second half of 2006. 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 pipeline includes:

- **Qnexa**TM for treating obesity, for which a Phase 2 study has been completed;
- **Evamist**TM to treat vasomotor symptoms associated with menopause for which a Phase 3 study has been completed; we anticipate submitting an NDA to the FDA in the second half of 2006;
- **Testosterone MDTS®** is being developed to treat hypoactive sexual desire disorder, for which a Phase 2 study has been completed;
- **ALISTA**TM for which a Phase 2B study is on-going, is being developed to treat female sexual arousal disorder; and
- **Avanafil** is being developed for the treatment of erectile dysfunction; a Phase 2 study has been completed.

Our Future

Our goal is to build a successful pharmaceutical company through the development and commercialization of innovative proprietary products for the treatment of obesity and sexual health. We intend to achieve this by:

- capitalizing on our clinical and regulatory expertise and experience 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.

It is our objective to become a global leader in the development and commercialization of products that help to treat obesity and restore sexual health in women and men. We believe that we have strong intellectual property supporting several opportunities in obesity treatment and 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.

Obesity

In 2004, the U.S. Centers for Disease Control and Prevention ranked obesity as the number one health threat in America. Obesity is a chronic condition that affects millions of people and often requires long-term or invasive treatment to promote and sustain weight loss. Obesity is the second leading cause of preventable death in the United States. The American Obesity Association estimates that approximately 127 million, or 64.5 percent, of adults in the U.S. are overweight, and an estimated 60 million, or 30.5 percent, are obese. An estimated 400,000 deaths a year in the U.S. may be attributable to poor diet and physical inactivity. The total direct and indirect costs attributed to overweight and obesity amounted to $117 billion in 2000. Additionally, Americans spend more than $33 billion annually on weight-loss products and services.

Qnexa

Qnexa is a proprietary treatment involving low doses of active ingredients from two previously approved products, topiramate and phentermine. By combining each of these compounds, we believe Qnexa simultaneously addresses excessive appetite and high threshold for satiety, the two main mechanisms that impact eating behavior. We believe Qnexa is the first product to treat obesity in this manner. In a recent Phase 2 clinical trial involving 200 patients and conducted at Duke University, over 50% of obese patients experienced 10% or more total body weight loss in a 24-week study. Our first patent covering Qnexa was issued June 6, 2006. In addition, Qnexa is the subject of multiple U.S. and International patent applications.

The Phase 2 clinical trial was performed with a twice a day dosing formulation. We are continuing development with the intention of entering into Phase 3 clinical trials with a once-a-day dosing formulation.

Female Sexual Health

We believe that the market for the treatment of sexual disorders in women is large and underserved. 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, 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 Food and Drug Administration, or FDA, for the treatment of these sexual disorders in women.

Evamist

Evamist is our patented estradiol spray being developed for the treatment of vasomotor symptoms associated with menopause. Vasomotor symptoms such as hot flashes and vaginal atrophy are reported to be among the most common medical complaints of women going through menopause. Evamist uses our proprietary,

metered-dose transdermal spray, or MDTS, 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 60 seconds. It is not messy. It is easy to apply and becomes invisible. We licensed the U.S. rights for this product from Acrux Limited (Acrux) in 2004. Acrux s studies have demonstrated that the Estradiol-MDTS system delivers sustained levels of estradiol to women over a 24-hour period.

In December 2004, we initiated our Phase 3 study of Evamist in the United States, under a Special Protocol Assessment (SPA) from the FDA to evaluate its safety and efficacy in menopausal women suffering from vasomotor symptoms, the primary endpoint of which is to assess the decrease in the frequency and severity of hot flashes at 4 and 12 weeks of treatment. In May 2006, we announced positive results from this pivotal Phase 3 clinical trial of Evamist. The study showed a statistically significant reduction in the number and severity of moderate and severe hot flashes for all three doses tested. We anticipate submitting the New Drug Application (NDA) for Evamist in the second half of 2006.

Testosterone MDTS

Hypoactive sexual desire disorder, the persistent or recurrent lack of interest in sexual activity resulting in personal distress, is reported to be the most common type of female sexual dysfunction, affecting as many as 30% of women in the United States. There are no FDA-approved pharmaceutical treatments for HSDD. Testosterone MDTS is our patent protected, transdermal product candidate 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. 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 should prevent others from commercializing competitive therapies utilizing a spray delivery technology.

In February 2005, we announced, along with Acrux, 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. In September 2005, we met with the FDA to share results from our Phase 2 clinical study and to discuss the Phase 3 study requirements for obtaining approval for this indication. Although final Phase 3 protocols have not been agreed upon, the FDA provided guidance to us on the size of and endpoints for the Phase 3 study. We have submitted a request for a Special Protocol Assessment (SPA) for our Phase 3 safety and efficacy protocol.

ALISTA

ALISTA is a patented formulation of alprostadil that is intended for topical application to the female genitalia prior to sexual activity as a treatment for female sexual arousal disorder, or FSAD. There are no FDA-approved pharmaceutical treatments 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 its short half-life makes ALISTA an ideal agent for the treatment of FSAD.

In December 2005, we announced that we had completed enrollment in a multi-center, randomized, double-blind, placebo-controlled Phase 2B study in over 300 patients. Patients are expected to complete the trial late in the third quarter of 2006. Pending completion of the study, the data will be compiled and analyzed, and the results announced before the end of 2006. Assuming positive results from the Phase 2B study, our development plan for ALISTA calls for subsequent large-scale confirmatory studies. For regulatory approval, the FDA now requires co-primary endpoints that must include statistically significant increases in both the number of Satisfactory Sexual Events (SSEs) and improvement in the self-assessed level of sexual arousal using validated questionnaires.

Male Sexual Health

The worldwide sales in 2005 of PDE5 inhibitor products for ED were in excess of $2.7 billion, including approximately $1.6 billion in sales of Viagra, approximately $747 million in sales of Cialis and approximately $313 million in sales of Levitra. Based on the aging baby boomer population and the desire to maintain an active sexual lifestyle, we believe the market for PDE5 inhibitors will continue to grow.

Avanafil

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 may result in a favorable side effect profile;
- has a shorter plasma half-life than currently approved PDE5 inhibitors; and
- is fast-acting.

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. We believe avanafil s short half-life and fast onset of action are ideal characteristics for treatment for ED. An End-of-Phase 2 meeting with the FDA for avanafil took place in November 2005. We discussed the Phase 2 results and the proposed protocol for the Phase 3 trials. Based on feedback from the FDA at this meeting, we anticipate completing several non-clinical and one clinical Phase 1 study prior to the initiation of Phase 3. In addition, it is our intention to request a Special Protocol Assessment for our Phase 3 protocol from the FDA.

Corporate Information

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 Global Market under the symbol VVUS.

The Securities We May Offer

We may offer up to an aggregate of $80 million 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. We and our agents 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.

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 about the timing, substance, 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 regulation; and
- statements about other factors that are described from time to time in our periodic filings with the Securities and Exchange Commission.

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 not be able to achieve the pre-defined clinical endpoint due to statistical anomalies even though clinical benefit was achieved, 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. To date, our development efforts have been focused on products for sexual health. Qnexa is our product candidate to treat obesity. While we have experience in running clinical trials in general, we have no experience in running large scale clinical trials for obesity. There can be no assurance that we will be successful with the limited obesity knowledge and resources we have available at the present time.

The results of pre-clinical studies and completed clinical trials are not necessarily predictive of future results, and our current product candidates may not have favorable results in later studies or trials.

Pre-clinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a product candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the product candidate s side effects at various doses and schedules. Success in pre-clinical studies or completed clinical trials does not ensure that later studies or trials, including continuing pre-clinical studies and large-scale clinical trials, will be successful nor does it necessarily predict future results. Favorable results in early studies or trials may not be repeated in later studies or trials, and product candidates in later stage trials may fail to show desired safety and efficacy despite having progressed through initial-stage trials. Unfavorable results from ongoing pre-clinical studies or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials. In addition, we may report top-line data from time to time. Top-line data is based on preliminary analysis of key efficacy and safety data, and is subject to change.

A number of companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials, even after promising results in initial-stage trials. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated, modified or terminated. In addition, failure to construct appropriate clinical trial protocols could result in the test or control group experiencing a disproportionate number of adverse events and could cause a clinical trial to be delayed, repeated, modified or terminated.

Our product candidates, Qnexa, ALISTA, Testosterone MDTS and avanafil, have not completed the large, pivotal Phase 3 trials for efficacy and safety that are required for FDA approval. Pre-clinical data and the limited clinical results that we have obtained for these investigational products may not predict results from studies in

larger numbers of subjects drawn from more diverse populations treated for longer periods of time. They also may not predict the ability of these investigational products to achieve or sustain the desired effects in the intended population or to do so safely. We may also decide to not conduct smaller Phase 2 studies prior to the initiation of pivotal Phase 3 studies. In addition, we may elect to enter into pivotal Phase 3 studies with a new formulation, delivery system or choose to study different populations than had been used or studied in previous clinical trials.

Qnexa is a proprietary capsule formulation containing the active ingredients phentermine and topiramate. Phentermine was approved for the short-term treatment of obesity by the FDA in 1959. Topiramate is approved for seizures and migraine prevention. Topiramate has been shown to produce weight loss. By combining the activity of each of these compounds, Qnexa attempts to simultaneously address excessive appetite and high threshold for satiety, the two main mechanisms believed to impact eating behavior. Although we believe Qnexa affects both of the two major causes of overeating, excessive hunger and the inability to feel satisfied, we may not be correct in our assessment of the impact the combination of these two ingredients may have on weight loss or their mechanism of action. Our Phase 2 study was a single center trial conducted by Duke University in only 200 patients. The twice-a-day dose and timing of the administration of the active ingredients was determined by the inventor through the treatment of patients in his private practice. We continue the formulation development of Qnexa and expect to initiate the Phase 3 studies of Qnexa with a once-a-day formulation. We intend to complete a pharmacokinetic study of the once-a-day formulation prior to entering the Phase 3 trials to ensure adequate plasma level of Qnexa; however, there can be no assurance that we will be able to achieve any weight loss results with the once-a-day formulation. The FDA has also asked us to study the effects of a lower dose of Qnexa, which we plan to do in the Phase 3 trials. We are unable to predict the effect of the inclusion of a lower dose group in the Phase 3 trials on the overall development program of Qnexa.

We will be required to demonstrate through larger-scale clinical trials that these product candidates are safe and effective for use in a diverse population before we can seek regulatory approvals for their commercial sale. There is typically a high rate of attrition from the failure of product candidates proceeding through clinical trials. To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our product candidates, except Evamist for which a Phase 3 clinical trial was recently completed. If any of our investigational products fails to demonstrate sufficient safety and efficacy in any clinical trial, we will experience potentially significant delays in, or decide to abandon development of, that product candidate. If we abandon or are delayed in our development efforts related to any of our investigational products we may not be able to generate sufficient revenues to continue our operations and clinical studies at the current level or become profitable, our reputation in the industry and in the investment community would likely be significantly damaged, it may not be possible for us to complete financings, and our stock price would likely decrease significantly.

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 product candidates, 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, but not limited to:

- 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;
- changes in clinical trial protocols imposed by the FDA;
- the effectiveness of our product candidates;
- slower than expected rate of and higher than expected cost of patient recruitment;

- inability to adequately follow patients after treatment;
- unforeseen safety issues; or
- government or regulatory delays.

One of the active ingredients in Qnexa, phentermine, had previously been used in combination with fenfluramine and dexfenfluramine. Phentermine is the most commonly prescribed prescription appetite suppressant. As phentermine is an older drug, no new efficacy trials have been conducted with the exception of several trials on the combination of phentermine and fenfluramine in the early and mid 1990s. The combination of fenfluramine or PONDIMIN (the fen) and phentermine (the phen) is known as fen-phen . Fenfluramine received FDA approval in 1973 for the short-term treatment of obesity. Together, phentermine and fenfluramine were used by doctors to treat obesity. The FDA never approved the fen-phen combination; however, since the FDA approved fenfluramine, doctors were able to prescribe it as needed. The use of these drugs together was considered off-label. In 1992, a published study cited fen-phen as a more effective method than dieting or exercise in reducing the weight of the chronically obese. The fen-phen combination was successful and in 1996 6.6 million prescriptions of fen-phen were written in the U.S. Dexfen-phen refers to the combination of dexfenfluramine or Redux (the dexfen) and phentermine (the phen). Dexfenfluramine received FDA approval in 1996 for use as an appetite suppressant in the management of obesity.

Like fen-phen, dexfen-phen, too, was successful. Neither combination, however, was ever tested for safety. By the summer of 1997, the Mayo Clinic reported 24 cases of heart valve disease in patients that had taken the fen-phen cocktail. The cluster of unusual cases of heart valve disease in fen-phen users suggested a co-relation between fen-phen use and heart valve disease. On July 8, 1997, the FDA issued a Public Health Advisory to report the Mayo findings. The FDA continued to receive additional reports of heart disease, including reports from patients who had taken only fenfluramine or dexfenfluramine. Further evaluations of patients taking fenfluramine or dexfenfluramine showed that approximately 30% had abnormal valve findings. This figure was much higher than expected for abnormal test results and suggests fenfluramine and dexfenfluramine as the likely causes of Primary Pulmonary Hypertension (PPH) and valvular heart disease.

In September 1997, the FDA requested drug manufacturers to voluntarily withdraw fenfluramine and dexfenfluramine. At the same time, the FDA recommended that patients using either fenfluramine or dexfenfluramine stop taking them. The FDA did not, however, request the withdrawal of the third drug involved in the drug combination, phentermine. While previous studies have shown that phentermine did not cause PPH and valvular heart disease, there can be no assurance that Qnexa will not have any cardiovascular or other detrimental side effects. In the Phase 2 study, echocardiograms and cardiovascular monitoring were performed and no abnormalities were noted. The FDA will require echocardiograms and cardiovascular monitoring of patients in the Phase 3 studies. Moreover, the potential relationship between the activity of Qnexa and the activity of fenfluramine and dexfenfluramine may result in increased FDA regulatory scrutiny of the safety of Qnexa and may raise potential adverse publicity in the marketplace, which could affect clinical enrollment or ultimately market acceptance if Qnexa is approved for sale.

Previous published studies suggested that the administration of topiramate alone in conjunction with diet and a behavioral modification program is effective for weight reduction in obese patients. The most prominent side effect seen in the studies was paresthesia, (tingling of the skin) experienced by 42% to 59% of patients. Drop outs due to paresthesia were 5% or less. In the Phase 2 Duke study, paresthesia was experienced in 38% of the patients on Qnexa. There were no drop outs in the Qnexa group due to paresthesia. The other common adverse events experienced in the topiramate monotherapy studies were also CNS related including fatigue, difficulty with attention, memory and concentration and depression. In the Phase 2 study, these CNS related side effects were also experienced but the difference was not significant when compared to placebo. The pharmaceutical company performing research of topiramate alone announced they had discontinued development of a time-release formulation due to side effects at high doses. We believe that the addition of phentermine to topiramate may help alleviate some of the CNS side effects seen in the topiramate alone studies; however, we may not be correct in this belief and Qnexa may not avoid or exhibit a significant reduction in these undesired side effects.

The FDA has also recently begun the review of the correlation of certain centrally acting drugs on suicidal ideations. The agency has requested that as part of our Phase 3 trials for Qnexa, a standard suicidality analysis be performed. While we do not expect a negative impact from the completion of this analysis on the ultimate approval of Qnexa, there can be no assurance that the labeled use of Qnexa would exclude patients with suicidal tendencies.

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.

Our product candidate, Qnexa, is a combination of approved drugs that are commercially available and marketed by other companies. As a result, our product may be subject to substitution and competition.

We anticipate that the approved drugs that are combined to produce our product candidate, Qnexa, are likely to be commercially available at prices lower than the prices at which we would seek to market our product candidate. We cannot be sure that physicians will view our products as sufficiently superior to a treatment regime of the individual active pharmaceutical ingredients as to justify the significantly higher cost we expect to seek for Qnexa, and they may prescribe the individual drugs already approved and marketed by other companies instead of our combination product. Even though the U.S. patent contains composition, product formulation and method-of-use claims that should protect Qnexa, a patented proprietary product, that patent may be ineffective as a practical matter to protect against physicians prescribing the individual drugs marketed by other companies instead of our combination product. To the extent that the price of our product is significantly higher than the prices of the individual components as marketed by other companies, physicians may have a greater incentive to write prescriptions for the individual components instead of for our combination product, and this may limit how we price Qnexa. Similar concerns could also limit the reimbursement amounts private health insurers or government agencies in the United States are prepared to pay for Qnexa, which could also limit market and patient acceptance of our product, and could negatively impact our revenues and net income, if any. Physicians might also prescribe the individual components of a product candidate prior to Qnexa s approval, which could adversely affect our development of the product candidate due to our lack of control over the administration to patients of the combination of active pharmaceutical ingredients in our product candidate, the occurrence of adverse effects, and other reasons. Such pre-approval use could also adversely affect our ability to market and commercialize Qnexa.

In many countries where we may plan to market Qnexa, including Europe, Japan and Canada, the pricing of prescription drugs is controlled by the government or regulatory agencies. Regulatory agencies in these countries could determine that the pricing for Qnexa should be based on prices for its active pharmaceutical ingredients when sold separately, rather than allowing us to market Qnexa at a premium as a new drug.

The FDA and other regulatory agencies may require more extensive or expensive trials for our combination product candidate, Qnexa, than may be required for single agent pharmaceuticals.

To obtain regulatory approval for Qnexa, we may be required to show that each active pharmaceutical ingredient in the product candidate makes a contribution to the combined product candidate s claimed effects and that the dosage of each component, including amount, frequency and duration, is such that the combination is safe and effective for a significant patient population requiring such concurrent therapy. As a result, we may be required to conduct clinical trials for each component drug as well as for the component drug in combination. This would require us to conduct more extensive and more expensive clinical trials than would be the case for many single agent pharmaceuticals. The need to conduct such trials could make it more difficult and costly to obtain regulatory approval of Qnexa than of a new drug containing only a single active pharmaceutical ingredient.

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

We have and will continue to in-license product candidates from third parties. The United States rights to Evamist and Testosterone MDTS were licensed from Acrux Limited and its related affiliates. The rights to avanafil were licensed from Tanabe Seiyaku Co, LTD., a Japanese corporation. Each of these agreements contains certain obligations. Failure to comply with the terms of the agreements could result in the early termination of these agreements. We believe we are in compliance with all the material terms of these agreements, however there can be no assurance that this compliance will continue or that the licensees would not have a differing interpretation of the material terms of the agreements. If the license agreements were terminated early or if the terms of the license were contested for any reason it would have a material adverse impact on our ability to commercialize products subject to these agreements, our ability to raise funds to finance the company, our stock price and our overall financial condition.

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 product candidates, particularly after the Phase 2 stage of clinical testing. These arrangements may place the development of our product 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 product 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 product 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 product 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 product candidates.

We face significant governmental regulation during our product development activities.

The research, testing, manufacturing, selling and marketing of product 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 product candidate, the disease condition that the product candidate is designed to address, and the regulations applicable to any particular product 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. The FDA 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 developing a transdermal testosterone product candidate, Testosterone MDTS, which 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 significant 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 in part 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 to the FDA for its review 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 product 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 product 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 product 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 product 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 product 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 products and our business could suffer.

We rely on third parties to conduct pre-clinical and clinical trials and studies 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 pre-clinical or clinical studies for our product candidates without the assistance of third parties who conduct the studies on our behalf. These third parties are usually toxicology facilities and clinical research organizations, or CROs, that have significant resources and experience in the conduct of pre-clinical and clinical studies. The toxicology facilities conduct the pre-clinical safety studies as well as all associated tasks connected with these studies. The CROs typically

perform patient recruitment, project management, data management, statistical analysis, and other reporting functions. We intend to use several different toxicology facilities and CROs for all of our pre-clinical and clinical studies. If these third party toxicology facilities or 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 product candidates on a timely basis, if at all, and we may not be able to successfully commercialize these proposed product candidates. If these third party toxicology facilities or 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 product candidates and may not be able to successfully commercialize these proposed product candidates.

The Phase 3 clinical studies of Evamist were conducted using the first generation MDTS applicator. We have improved on the design of the MDTS applicator, which we believe will allow us to manufacture Evamist more efficiently than with the previous design. The New Drug Application (NDA) for Evamist will include the new MDTS applicator. Since this applicator was not used in the pivotal Phase 3 study the FDA may require additional data before it accepts our NDA. If additional data are required we would delay the submission of the NDA for Evamist, which in turn could delay approval and the launch of the product into the marketplace. A material delay in the submission of the NDA for Evamist or the ultimate approval of Evamist would have a material adverse impact on our stock price and financial condition.

We are continuing the formulation development of Qnexa. To date, we have not created a once-a-day formulation. We are currently evaluating the capabilities of several contract manufacturers to develop a once-a-day formulation. While we anticipate our contract manufacturer will be successful in developing a once-a-day formulation there can be no assurance that a once-a-day formulation can be developed, that it can be developed on a timely basis, or if it is developed that it will result in sufficient safety and efficacy for approval. A failure to develop a once-a-day formulation may have a material adverse impact on our stock price, financial condition and, if approved, future revenues.

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 product 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 cGMP. 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 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.

We are required to obtain FDA approval for any change in suppliers or service providers. For example, MUSE is supplied to the market with the MUSE applicator, containing the MUSE dosage, enclosed within a sealed foil pouch. Our supplier that produces the MUSE laminated foil has closed its business. The laminated foil is used to make the sealed foil pouch, described above, which is used to make the MUSE primary product container. Before the supplier closed its business, the supplier produced a bulk-quantity of foil that, at this time, is expected to be sufficient to support MUSE production through the end of 2006. There can be no assurance that as this bulk supply is used over the next year there will be a sufficient yield in the final quantity of foil with acceptable quality to support MUSE demand through 2006. Although the foil supplier produced this bulk unprinted foil, the label printing will be done periodically during 2006. As a consequence, if there are unacceptable quality issues with the bulk foil, they may not be discovered until sometime in 2006. If such foil quality issues do occur, we may be unable to meet MUSE demand during 2006.

We have identified a new potential vendor for the MUSE laminated foil. As this laminated foil is used to make the MUSE primary product container, there are significant qualifications and regulatory approvals that must be obtained prior to using the new vendor to produce foil to meet MUSE demand. These include, but are not limited to, vendor qualification, foil material qualification, MUSE product suitability studies, electron beam

irradiation suitability, FDA approval, and European Medicines and Healthcare products Regulatory Agency approval. There can be no assurance that these qualifications and approvals will be successfully obtained, or that they will be obtained within the time needed to support MUSE demand before our current supply of foil is exhausted.

Failure to receive adequate supplies of foil, failure to receive appropriate regulatory approvals for the change in materials and vendors, and any unforeseen quality or production issues due to the use of the new materials or vendors could have a material adverse effect on our business, financial condition and results of operations.

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. The FDA may also order that all future promotional materials receive prior agency review and approval before use. 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 corrected the prior message and 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. In March 2005, we received a letter from the FDA indicating that the matter had been closed.

Results from a single center study reported in mid-2005 show a potential benefit from the therapeutic use of MUSE following radical prostatectomy. MUSE is not indicated for the treatment of erectile dysfunction caused by trauma, including surgeries such as a radical prostatectomy. We are sponsoring clinical trials to study the effects of MUSE therapy following radical prostatectomy. We believe physicians are beginning to prescribe MUSE for use following radical prostatectomy. All promotional materials and efforts are subject to FDA review. If our promotional materials and efforts are altered, modified, or halted by the FDA for any reason, future sales of MUSE could be negatively affected.

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

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

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

We entered into an agreement granting Meda AB exclusive marketing and distribution rights for MUSE in member states of the European Union, the Baltic States, the Czech Republic, Hungary, Iceland, Norway, Poland, Switzerland and Turkey. This agreement does not have minimum purchase commitments and we are entirely

dependent on Meda s efforts to distribute and sell MUSE effectively in all these markets. There can be no assurance that such efforts will be successful or that Meda will continue to support MUSE.

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

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

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

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

We support MUSE sales in the United States through a small direct sales force targeting major accounts. Telephone marketers also focus on urologists who prescribe MUSE. Physician and patient information/help telephone lines are available to answer additional questions that may arise after reading the inserts or after actual use of the product. The sales force actively participates in national urologic and sexual dysfunction forums and conferences, such as the American Urological Association annual and regional meetings and the International Society for Impotence Research. There can be no assurance that our sales programs will effectively maintain or potentially increase current sales levels. There can be no assurance that demand for MUSE will continue or that we will be able to adequately support sales of MUSE in the United States in the future.

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

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

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

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

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

Current antiobesity products include Xenical, marketed by Roche, and Meridia, marketed by Abbott Labs. Phentermine is the largest selling antiobesity therapeutic and is available in several generic forms. Topamax, marketed by Johnson and Johnson, is not approved for the treatment of obesity but analysts estimate Topamax is used for this indication. Acomplia (rimonabant) is a small-molecule central cannabinoid antagonist being developed by Sanofi-Aventis. Acomplia received an approval letter from the FDA in February 2006. Analysts estimate that peak sales of Acomplia for obesity could exceed $2.0 billion. The most significant competitive therapy for MUSE is an oral medication marketed by Pfizer, Inc. under the name Viagra®, which received regulatory approvals in the United States in March 1998 and in the European Union in September 1998. The commercial launch of Viagra in the United States in April 1998 significantly decreased demand for MUSE. In February 2003, a new oral medication under the name Cialis® was launched in Europe by Lilly ICOS LLC and in Australia and New Zealand by Eli Lilly and Company alone. Lilly ICOS LLC launched Cialis in the United States in November 2003. Bayer AG and GlaxoSmithKline plc launched Levitra® in the European Union and the United States in March and September 2003, respectively.

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 product candidates for the treatment of FSD including: 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. is developing forms of testosterone gels for HSDD and Palatin Technologies, Inc. is developing a various nasal spray to treat FSD. None of these products has been approved by the FDA.

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

We are required to receive regulatory approval for suppliers. We obtained our current supply of alprostadil from two approved sources, NeraPharm, s.r.o., in the Czech Republic and Chinoin Pharmaceutical and Chemical Works Co., Ltd., in Hungary. We have manufacturing agreements with Chinoin and NeraPharm to produce additional quantities of alprostadil for us. We are currently in the process of investigating additional sources for our future alprostadil supplies. However, there can be no assurance that we will be able to identify and qualify additional suppliers of alprostadil in a timely manner, or at all.

Furthermore, our current supply of alprostadil is subject to periodic re-testing to ensure it continues to meet specifications. There can be no guarantees that our existing inventory of alprostadil will pass these re-testing procedures and continue to be usable material. There is a long lead-time for manufacturing alprostadil. A shortage in 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 to answer questions and inquiries about MUSE. Calls to these hotlines may include complaints about our products due to efficacy or quality, as well as the reporting of adverse events. As a result of this agreement, we are dependent on WRB Communications to effectively handle these calls and inquiries. There can be no assurance that such efforts will be successful.

We entered into a distribution agreement with Integrated Commercialization Services, or ICS, a subsidiary of AmerisourceBergen Corporation. ICS provides direct-to-physician distribution of product samples in support of United States marketing and sales efforts. As a result of this distribution agreement, we are dependent on ICS s efforts to distribute product samples effectively.

We rely on two companies, E-Beam Services, Inc. (E-Beam) and Beam One, LLC (Beam One), for the sterilization of MUSE. However, for some international markets, the MUSE Product License includes approval to use only one of the above listed vendors. If interruptions in these services occur for any reason, including a decision by E-Beam or Beam One to discontinue manufacturing or services, political unrest, labor disputes or a failure of E-Beam or Beam One to follow regulations, the commercial marketing of MUSE and the development of other potential products could be prevented or delayed. An extended interruption in sterilization services would have a material adverse effect on our business, financial condition and results of operations.

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 (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 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 purchased two buildings with a total combined 90,000 square feet in Lakewood, New Jersey, which we previously leased, on December 22, 2005. This facility is used 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 government and other third-party payors may limit our ability to market and sell our products or limit our product revenues and delay profitability.

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 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 the types of drugs eligible for reimbursement 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.

The continuing efforts of government and third-party payors to contain or reduce the costs of health care through various means may reduce our potential revenues. These payors efforts could decrease the price that we receive for any products we may develop and sell in the future. In addition, third-party insurance coverage may not be available to patients for any products we develop. If government and third-party payors do not provide adequate coverage and reimbursement levels for our products, or if price controls are enacted, our product revenues will suffer.

Congress passed legislation that ended federal Medicaid and Medicare payments for erectile dysfunction drugs beginning January 1, 2006 and January 1, 2007, respectively. We are currently assessing the impact that this legislation will have on our business. However, historically the volume of MUSE sales to Medicaid and Medicare patients has not been a significant portion of our overall MUSE sales volume. We believe there is increasing political pressure to reduce or eliminate reimbursement by the U.S. government for MUSE. A reduction or elimination in the reimbursement by the U.S. government would have a material adverse impact on our revenues and business operations.

One of the active ingredients in Qnexa, phentermine is available as a generic. The other, topiramate, is subject to several patents, the first of which is set to expire in 2008. Based on the research we have completed to date, we have no reason to believe Qnexa would not be subject to reimbursement by third party payors. The exact doses of the active ingredients in the final formulation of Qnexa will be different than those currently available. State pharmacy law prohibits pharmacists from substituting drugs with differing doses and formulations. The safety and efficacy of Qnexa is highly dependent on the titration, dosing and formulation which we believe could not be easily duplicated, if at all, with the use of generic substitutes. However, there can be no assurance that we will be able to provide for optimal reimbursement of Qnexa for obesity from third party payors or the U.S. Government. Furthermore, there can be no assurance that healthcare providers would not actively seek to provide patients generic versions of the active ingredients in Qnexa in order to treat obesity at a potential lower cost.

Federal legislation may increase the pressure to reduce prices of pharmaceutical products paid for by Medicare, which could adversely affect our revenues, if any.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, expanded Medicare coverage for drug purchases by the elderly and disabled beginning in 2006. Under the MMA, private insurance plans subsidized by the government offer prescription drug coverage to Medicare beneficiaries who elect to enroll in their plans. Although almost all prescription drugs are potentially available to plan enrollees, the plans are allowed to use formularies, preferred drug lists and similar mechanisms to favor selected drugs and limit access to other drugs except in certain circumstances. The price of a drug as negotiated between the manufacturer and a plan is a factor that the plan can consider in determining its availability to enrollees.

As a result, we expect that there will be increased pressure to reduce prices for drugs to obtain favorable status for them under the plans offering prescription drug coverage to Medicare beneficiaries. This pressure could decrease the coverage and price that we receive for our products in the future and could seriously harm our business. It is possible that our product, Qnexa, if successfully developed, could be particularly subject to price reduction initiatives because it is based on combinations of lower priced existing drugs.

In addition, some members of Congress advocate that the federal government should negotiate directly with manufacturers for lower prices for drugs in the Medicare program, rather than rely on private plans. If the law were changed to allow or require such direct negotiation, there could be additional reductions in the coverage of and prices that we receive for our products.

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.

Natural disasters or resource shortages could disrupt our operations and adversely affect results.

Our manufacturing operation is conducted in a single location in Lakewood, New Jersey. In the event of a natural disaster in that region, such as a storm, drought or flood, or localized extended outages of critical utilities or transportation systems, we do not have a formal business continuity or disaster plan, and could therefore experience a significant business interruption.

Furthermore, our clinical trials could be delayed or disrupted indefinitely upon the occurrence of a natural disaster. For example, our clinical trials in the New Orleans area were interrupted by Hurricane Katrina. Future natural disasters could further delay our clinical trials process, thus adversely affecting our business and financial results.

Risks Relating to our Intellectual Property

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

There can be no assurance that our products do not or will not infringe on the patent or proprietary rights of others. Third parties may assert that we are employing their proprietary technology without authorization. For example, in October 2002, the United States Patent and Trademark Office (USPTO) issued to Pfizer a method of use patent, 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 USPTO 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 USPTO, we may be prevented from commercializing avanafil, our PDE5 inhibitor.

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

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

We hold various patents and patent applications in the United States and abroad targeting obesity and male and female sexual health among other products. Qnexa is our product candidate involving low doses of topiramate and phentermine. On June 6, 2006, U.S. Patent No. 7,056,890 B2 was issued by the USPTO. This patent contains composition, product, and other claims that should protect Qnexa as a proprietary product for the treatment of obesity. The term of this patent extends into 2019. The corresponding European patent with similar claims has been approved for grant. We are in the process of prosecuting patent applications in other countries as well, to obtain significant foreign patent coverage for both Qnexa and future generations of Qnexa. Furthermore, we have filed additional patent applications in the United States to expand the coverage that will be provided by the initial U.S. patent. The primary focus of the patent applications is on combination therapy using a sympathomimetic agent (such as phentermine) and an anticonvulsant (such as topiramate) for the treatment of obesity and other related disorders. We have worked closely with our patent counsel to put together a cogent patent strategy and are building a strong patent portfolio, ensuring exclusivity for many years to come.

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 positions, 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 USPTO, 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.

We may be subject to claims that we, or our employees, have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ individuals who were previously employed at other pharmaceutical companies, including our competitors or potential competitors. Although we have no knowledge of any pending claims, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

We may not be able to develop or commercialize our product candidates due to intellectual property rights held by third parties.

If a third party holds a patent to a composition or method of use of an approved drug that is a component of one or more of our product candidates, we may not be able to develop or commercialize such product candidates without first obtaining a license to such patent, or waiting for the patent to expire. Our business will be harmed if we are unable to use the optimal formulation or methods of use of the component drugs that comprise our product candidates. This may occur because the formulations or methods of use are covered by one or more third party patents, and a license to such patents is unavailable or is available on terms that are unacceptable to us.

We may be unable to in-license intellectual property rights or technology necessary to develop and commercialize our products.

Depending on its ultimate formulation and method of use, before we can develop, clinically test, make, use, or sell a particular product candidate, we may need to obtain a license from one or more third parties who have patent or other intellectual property rights covering components of our product candidate or its method of use. There can be no assurance that such licenses will be available on commercially reasonable terms, or at all. If a

third party does not offer us a necessary license or offers a license only on terms that are unattractive or unacceptable to us, we might be unable to develop and commercialize one or more of our product candidates.

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 spending on research and development projects, including clinical trials. On May 10, 2006, we raised $12 million in a registered direct offering of our common stock to two institutional investors. Under the terms of this financing, we sold 3,669,725 shares of VIVUS common stock at a price of $3.27 per share. On January 4, 2006, we obtained a $5.4 million loan from Crown Bank, N.A. (Crown), secured by the land and buildings, among other assets, located at our principal manufacturing facility and a $700,000 Certificate of Deposit held by Crown. The loan is payable over a 10-year term and the interest rate will be fixed at 8.25%, which is the prime rate plus 1% at the time of funding and then will be adjusted annually to a fixed rate for the year equal to the prime rate plus 1% with a floor of 7.5%. On December 22, 2005, we purchased from our landlord our principal manufacturing facility, which was previously leased, for $7.1 million. The purchase price was funded in part by $3.3 million of restricted cash, which was being held by the landlord as cash collateral for renovations to the facility upon the termination of the lease and the remainder with cash. On March 15, 2005, we sold 6,250,000 shares of our common stock at a price of $3.40 per share, providing us with net proceeds of $19.6 million.

We expect that our existing capital resources combined with future anticipated cash flows will be sufficient to support our operating activities into 2007. However, we anticipate that we will be required to obtain additional financing to fund the development of our research and development pipeline in future periods as well as to support the possible launch of any future products. Our future capital requirements will depend upon numerous factors, including:

- the progress and costs of our research and development programs;
- the scope, timing and results of pre-clinical testing and clinical trials;
- patient recruitment and enrollment in current and future clinical trials;
- the costs involved in seeking regulatory approvals for our product candidates;
- the costs involved in filing and pursuing patent applications and enforcing patent claims;
- the establishment of collaborations and strategic alliances;
- the cost of manufacturing and commercialization activities and arrangements;
- the results of operations;
- demand for MUSE;
- 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. We cannot assure you that we will successfully develop our products under development or that our products, if successfully developed, will generate revenues sufficient to enable us to earn a profit. 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 $155.9 million as of March 31, 2006 and expect to continue to incur substantial operating losses for the foreseeable future.

We have generated a cumulative net loss of $155.9 million for the period from our inception through March 31, 2006, 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 Global 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 VIVUS 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, and our need for clinical supplies. 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 Global 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.

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

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

In addition, we are governed by the provisions of Section 203 of Delaware General Corporate Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us. These and other provisions in our 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 financial accounting standards related to share-based payments are expected to continue to have a significant effect on our reported results.

On January 1, 2006, we adopted the revised statement of Financial Accounting Standards No. SFAS 123R (SFAS 123(R)), *Share-Based Payment*, which requires that we record compensation expense in the statement of operations for share-based payments, such as employee stock options, using the fair value method. The adoption of this new standard is expected to continue to have a significant effect on our reported earnings, although it will not affect our cash flows, and could adversely impact our ability to provide accurate guidance on our future reported financial results due to the variability of the factors used to estimate the values of share-based payments. If factors change and we employ different assumptions or different valuation methods in the application of SFAS 123(R) in future periods, the compensation expense that we record under SFAS 123(R) may differ significantly from what we have recorded in the current period, which could negatively affect our stock price and our stock price volatility.

Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and NASDAQ Global Market rules, are creating uncertainty for companies such as ours. These new or changed laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, our efforts to comply with evolving laws, regulations and standards have resulted in, and are likely to continue to result in, increased general and administrative expenses and management time related to compliance activities. In particular, our efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002 and the related regulations regarding our required assessment of our internal controls over financial reporting and our external auditors audit of that assessment has required the commitment of significant financial and managerial resources. We expect these efforts to require the continued commitment of significant resources. If we fail to comply with new or changed laws, regulations and standards, our reputation may be harmed and we might be subject to sanctions or investigation by regulatory authorities, such as the Securities and Exchange Commission. Any such action could adversely affect our financial results and the market price of our common stock.

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.

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 Global Market may engage in passive market making transactions in the common stock on the NASDAQ Global 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.

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 June 30, 2006, there were 48,382,517 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 Street, 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 66⅔% 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.

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, 2005 and for the one-year period ended December 31, 2005 have been incorporated by reference herein in reliance upon the reports of Odenberg, Ullakko, Muranishi & Co. LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

The consolidated financial statements and schedules of VIVUS, Inc. and subsidiaries as of December 31, 2004 and for each of the years in the two-year period ended December 31, 2004 have been incorporated by reference herein in reliance upon the reports of KPMG LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

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
1-800-SEC-0330

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.

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, 2005;
- Definitive Proxy Statement on Schedule 14A for our annual meeting of stockholders held on June 14, 2006, filed on May 11, 2006;
- Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2006;
- Current Reports on Form 8-K filed with the Securities and Exchange Commission on January 6, 2006, February 23, 2006, February 27, 2006, March 3, 2006, April 27, 2006, May 8, 2006, May 10, 2006, May 11, 2006, May 12, 2006, May 17, 2006 and July 13, 2006; 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:

Attn: Chief Financial Officer
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.