

VIVUS INC
Form 424B5
April 15, 2008

Filed Pursuant to Rule 424(b)(5)

Registration No. 333-135793

PROSPECTUS SUPPLEMENT

(To Prospectus dated July 14, 2006)

1,626,017 Shares

VIVUS, INC.

COMMON STOCK

Edgar Filing: VIVUS INC - Form 424B5

We are offering directly to certain investors an aggregate of 1,626,017 shares of our common stock.

Our common stock is listed on the NASDAQ Global Market under the symbol VVUS. On April 3, 2008, the last reported sale price of our common stock on the NASDAQ Global Market was \$6.19 per share.

Investing in our common stock involves a high degree of risk. You should carefully consider the *Risk Factors* beginning on page S-5 of this prospectus supplement, which supersede in their entirety the risk factors set forth beginning on page 6 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	\$	6.15	\$	10,000,004.55

Dated April 7, 2008

TABLE OF CONTENTS

Prospectus Supplement

	Page
<u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	S-iii
<u>PROSPECTUS SUPPLEMENT SUMMARY</u>	S-1
<u>RISK FACTORS</u>	S-5
<u>USE OF PROCEEDS</u>	S-34
<u>DILUTION</u>	S-35
<u>PLAN OF DISTRIBUTION</u>	S-36
<u>LEGAL MATTERS</u>	S-37
<u>EXPERTS</u>	S-37
<u>RECENT DEVELOPMENTS</u>	S-37
<u>LIMITATION OF LIABILITY AND INDEMNIFICATION</u>	S-37
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	S-37

Prospectus

	Page
SUMMARY	1
SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS	5
RISK FACTORS	6
USE OF PROCEEDS	26
PLAN OF DISTRIBUTION	26
DESCRIPTION OF COMMON STOCK	27
LEGAL MATTERS	29
EXPERTS	29
WHERE YOU CAN FIND MORE INFORMATION	29

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®, Luramist®, Evamist®, MDTs® and MUSE®. Each trademark, trade name or service mark of any other company appearing in this prospectus supplement or the accompanying prospectus belongs to its holder.

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 this prospectus supplement, 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

Edgar Filing: VIVUS INC - Form 424B5

This prospectus supplement, the accompanying prospectus and the documents we have filed with the Securities and Exchange Commission, or the SEC, that are incorporated herein by reference and that are referenced under the section entitled “Where You Can Find More Information,” contain forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

Forward-looking statements represent our management's judgment regarding future events. In many cases, you can identify forward-looking statements by terminology such as may, will, should, could, plan, expect, anticipate, estimate, believe, predict, intend, possibly, or other words or phrases 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

Edgar Filing: VIVUS INC - Form 424B5

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-5 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.

Edgar Filing: VIVUS INC - Form 424B5

VIVUS, Inc. is a pharmaceutical company dedicated to the development and commercialization of therapeutic products for large underserved markets. The investigational products currently under development could serve the obesity, diabetes and sexual health markets. Our current and future products in development will encompass patented proprietary formulations and novel delivery systems and future products may be developed by seeking new indications for previously approved pharmaceutical products. To date, through employment of this strategy we have one commercial product and several development-stage products that address these markets. In these sectors, patients seek more effective treatment options with fewer negative side effects. With respect to obesity, analysts estimate that this potential market could exceed \$5 billion annually. Sales of approved drugs for diabetes exceed \$10 billion. The indications targeted by VIVUS' investigational sexual health products each represent a projected market greater than \$1 billion annually.

The current product pipeline includes three late-stage clinical products, each addressing specific components of the obesity, diabetes and sexual health markets. One of these investigational products, Qnexa, is in Phase 3 clinical trials for obesity and in Phase 2 clinical trials for diabetes.

All of the pivotal Phase 3 studies for Qnexa were initiated in the fourth quarter of 2007. The co-primary endpoints for these studies will evaluate the differences between treatments from baseline to the end of the treatment period, in mean percent weight loss and in the percentage of subjects achieving weight loss of 5% or more. All Phase 3 studies will utilize our novel once-a-day formulation of Qnexa, which at full strength contains 15 mg phentermine immediate release and 92 mg topiramate controlled release. Pharmacokinetic- Pharmacodynamic (PK/PD) studies indicated that the once-a-day formulation is comparable to the twice-a-day formulation used in the Phase 2 study.

Our late-stage investigational product pipeline includes:

- **Qnexa** for treating obesity, for which the pivotal Phase 3 studies have been initiated;
- **Qnexa** for treating diabetes, which is in Phase 2 clinical trials;
- **Luramist** (Testosterone MDTs®) is being developed to treat hypoactive sexual desire disorder in women, for which a Phase 2 study has been completed; and
- **Avanafil** is being developed for the treatment of erectile dysfunction, for which Phase 2 studies have been completed.

Our former investigational product, Evamist[®], a metered dose transdermal estradiol spray approved for the treatment of vasomotor symptoms associated with menopause, was sold to K-V Pharmaceutical Company ("K-V") on May 15, 2007. We had completed Phase 3 studies for Evamist in May 2006 and a New Drug Application ("NDA") was approved by the United States Food and Drug Administration (the "FDA") on July 27, 2007.

On March 30, 2007, we announced that we had entered into a definitive agreement with K-V to transfer certain of our assets and grant a sublicense under our exclusive rights to certain patents and know-how related to Evamist pursuant to our Estradiol Development and Commercialization Agreement with FemPharm Pty Ltd. and Acrux DDS Pty Ltd. (together, Acrux), dated February 12, 2004, as amended (the Acrux Agreement) to K-V (the Transaction).

On May 15, 2007, the transaction with K-V closed. Under the terms of the transaction, we received an upfront payment of \$10 million upon the closing. On August 1, 2007, we transferred and assigned the Evamist FDA submissions, and all files related thereto to K-V and on August 8, 2007, we received a \$140 million milestone payment from K-V. K-V also paid \$1.5 million of the \$3 million product approval milestone payment due to Acrux upon approval of Evamist. We are also eligible to receive certain one-time milestone payments from K-V totaling to \$30 million based on the achievement of certain annual net sales thresholds for Evamist.

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 Future

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

- capitalizing on our clinical and regulatory expertise and experience to advance the development of investigational product candidates in our pipeline;
- establishing strategic relationships with marketing partners to maximize sales potential for our products that require significant commercial support;
- licensing complementary clinical stage investigational product candidates or technologies with competitive advantages from third parties for new and established markets; and
- partnering our late-stage investigational product candidates with third parties.

It is our objective to become a leader in the development and commercialization of products for large underserved markets. We believe that we have strong intellectual property supporting several opportunities in obesity and diabetes treatment and sexual health. Our future growth will depend on our ability to further develop and obtain regulatory approval of our investigational product candidates as well as in-licensing and product line extensions.

We have funded operations primarily through private and public offerings of our common stock, the sale of the rights to Evamist and MUSE. We expect to generate future net losses due to increases in operating expenses as investigational product candidates are advanced through the various stages of clinical development. In connection with the sale of Evamist, we received \$150 million. The sale of Evamist was a unique transaction. As discussed in Note 12 to the financial statements for the year ended December 31, 2007: Sale of Evamist Product, an initial \$10 million was paid at closing and \$140 million was paid upon the FDA's approval of the Evamist NDA. These payments are non-refundable and have been recorded as deferred revenue and will be recognized as license and other revenue ratably over a 21.5-month period, from August 1, 2007 to May 15, 2009, which is the remaining term of a license to improvements to the MDTs applicator. As compared to revenues from product sales, license and other revenue will be significant on a quarterly basis until all of the revenue from

the sale of Evamist is recognized, currently expected to be May 2009. Since the \$150 million has been received and we have no related contingencies, the future recognition of revenue and the corresponding reduction of deferred revenue related to the Evamist sale will have no impact on our cash flows from operations in future periods through May 2009. As of December 31, 2007, we have incurred a cumulative deficit of \$169.8 million and expect to incur operating losses in future years.

Year-to-Date Update

Highlights since the end of 2007 include:

- **Extension Study with Qnexa for Diabetes** In January 2008, we announced the initiation of a six-month extension study for patients currently enrolled in the OB-202 diabetes study.
- **Completion of Enrollment in EQUIP (OB-301) trial** In March 2008, we announced that we reached our enrollment goals in the OB-301 trial with over 700 obese patients having been enrolled. We currently anticipate the data from this trial should be available in late 2008.
- **Completion of Enrollment in EQUATE (OB-302) trial** In March 2008, we announced that we reached our enrollment goals in the OB-302 trial and over 1,250 morbidly obese patients had been enrolled. Data from this trial should be available in the second half of 2009.
- **Special Protocol Assessment, or SPA, Granted and Agreement Reached on safety study for Luramist** In April 2008, we received an SPA and reached agreement on the safety requirements for Luramist (testosterone MDTs). The pivotal Phase 3 studies will include two six month studies in menopausal women and the events driven safety study will enroll 5,200 women over 50 with one cardiovascular risk factor.

Our Product Pipeline

Edgar Filing: VIVUS INC - Form 424B5

We currently have three research and development programs targeting obesity, diabetes and sexual health:

Product	Indication	Status	Patent Expiry and Number
Qnexa (phentermine and topiramate)	Obesity	Phase 3 initiated	2019 (US 7,056,890 B2)
Qnexa (phentermine and topiramate)	Diabetes	Phase 2 initiated	2019 (US 7,056,890 B2)
Luramist (Testosterone MDTs)	Hypoactive sexual desire disorder (HSDD)	Phase 2 completed	2017 (US 6,818,226)
Avanafil (PDE5 inhibitor)	Erectile dysfunction (ED)	Phase 2 completed	2020 (US 6,656,935)

Corporate Information

Edgar Filing: VIVUS INC - Form 424B5

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

Edgar Filing: VIVUS INC - Form 424B5

Shares of common stock we are offering	1,626,017 shares
Shares of common stock to be outstanding immediately after this offering	60,530,827 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

S-3

The number of shares of common stock outstanding immediately after this offering in the table above is based on 60,530,827 shares of our common stock outstanding as of March 31, 2008 and excludes up to 6,690,510 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 \$6.15 per share.

S-4

RISK FACTORS

Edgar Filing: VIVUS INC - Form 424B5

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 6 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. Investigational product candidates that may appear to be promising at all stages of development may not reach the market for a number of reasons. Investigational 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 may have been 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. Historically, our development efforts have been focused on products for sexual and postmenopausal health. While we have experience in managing Phase 1 through 3 clinical trials in support of various indications, we do not have any experience in managing Phase 3 clinical trials for obesity or clinical trials for diabetes. There can be no assurance that we will be successful with the limited experience and resources we have available at the present time relating to obesity or diabetes.

The results of pre-clinical studies and completed clinical trials are not necessarily predictive of future results, and our current investigational 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 an investigational product candidate in the general population, but rather to test initial safety, to study pharmacokinetics and pharmacodynamics, to study limited efficacy in a selected disease population, and to identify and attempt to understand the investigational 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 investigational 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 investigational product candidates, Qnexa, Luramist and avanafil, have not completed the large, pivotal Phase 3 trials for efficacy and safety that are required for approval by the FDA and other worldwide regulatory

authorities. 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 in multiple sites drawn from more diverse populations treated for longer periods of time. The smaller clinical trials also may not predict the ability of these investigational products to achieve or sustain the desired effects in the broad intended population or to do so safely. We may also decide to not conduct additional 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 our proprietary capsule formulation investigational product candidate 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 at 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 have completed the formulation development of Qnexa and have initiated Phase 3 studies of Qnexa with a once-a-day formulation. We have completed various pharmacokinetic studies of the once-a-day formulations to characterize the pharmacokinetic profile of the once-a-day formulation 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 or that we will be able to duplicate the weight loss seen in the Phase 2 study. 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 investigational product candidates are safe and effective for use in a broad population before we can seek regulatory approvals for their commercial sale. There is typically a high rate of attrition from the failure of investigational 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 investigational product candidates. 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 investigational 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 or future pre-clinical studies, clinical testing 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, clinical testing and/or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in late stage 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 design 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.

All of the investigational product 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 investigational product candidates, we must demonstrate through pre-clinical testing and/or clinical trials that our investigational 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 obtain or manufacture sufficient quantities of drugs for use in clinical trials;
- failure to receive approval by the FDA of our clinical trial protocols;
- changes in clinical trial protocols made by us or imposed by the FDA;
- the effectiveness of our investigational 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;
- government or regulatory delays; or
- our ability to raise the necessary cash to start or complete the trials.

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

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 (fen) and phentermine (phen) was 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 and unapproved 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 (dexfen) and phentermine. Dexfenfluramine received FDA approval in 1996 for use as an appetite suppressant in the management of obesity.

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 combination. 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 phentermine. Although studies to date have shown that phentermine does not cause PPH and valvular heart disease, there can be no assurance that Qnexa will not have any significant cardiovascular or other detrimental side effects. In the Phase 2 study, echocardiograms and cardiovascular monitoring were performed and no abnormalities were noted.

S-7

Moreover, the adverse clinical history of fen-phen and dexfen-phen combinations for obesity may result in increased FDA regulatory scrutiny of the safety or the risk/benefit profile 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 suggest 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.

On January 31, 2008, the FDA issued an alert to Healthcare Professionals on suicidality and antiepileptic drugs as a result of a meta analysis of various clinical studies on antiepileptic drugs, or AEDs. The analysis included trials from 11 AEDs, including topiramate (first approved for epilepsy in 1997). The meta analysis reported that patients on AEDs were at twice the risk as those on placebo. The study also went on to state that epileptics are at the greatest risk. Of the 43,892 patients included in the analysis there were 4 completed events. The actual incidence rates were 0.43% for all AEDs and 0.22% for patients on placebo. Suicide ideation is a serious issue for all patients on centrally acting drugs. The background suicide rate for epileptics is five times that of the normal population. The suicide rate for bipolar patients is 15 times higher than that of the normal population. Prior to the issuance of this alert, during our discussions with the FDA regarding the design of the Phase 3 protocols, VIVUS also became aware of the agency's concern regarding suicidality for the entire class of AEDs. Specific procedures and standard data collection requirements were included in protocols to monitor all neuro/psych events. In addition, bipolar patients and epileptics are excluded from our obesity studies. The FDA has requested that as part of our Phase 3 trials for Qnexa, a standard analysis of patients' suicidal tendencies 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. In addition, we do not know the impact this alert will have on the potential future use of Qnexa by healthcare professionals.

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

We anticipate that each of the approved drugs that are combined to produce our investigational product candidate, Qnexa, will be commercially available at prices lower than the price at which we would seek to market our investigational 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. A physician could seek to prescribe off-label generics in place of Qnexa. Off-label use occurs when a drug that is approved by the FDA for one indication is legally prescribed by physicians for a different, unapproved indication. Topiramate, one of the ingredients in Qnexa, is not approved for obesity treatment. With regard to off-label substitution at the pharmacy level, we expect to rely on the novel dose ratios and novel pharmacokinetic properties of our investigational product candidate, to provide sufficient distinction such that generic preparations are not considered therapeutic equivalents by the FDA. State pharmacy laws in many instances preclude pharmacists from substituting with generic preparations if the products are not therapeutic equivalents. We believe there will be no commercially available doses of the active ingredients in Qnexa, when and if approved. Therefore, the lack of therapeutic equivalency restricts generic substitution by pharmacies and/or pharmacy benefit managers. However, we cannot be certain that pharmacists and/or pharmacy benefit managers will not substitute generics in place of Qnexa, which could significantly diminish its market potential. Physicians might also prescribe the individual components of an investigational product candidate prior to Qnexa's approval, which could adversely affect our development of the investigational product candidate due to our lack of control over the administration to patients of the combination of active pharmaceutical ingredients in our investigational 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 will likely 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 investigational product candidate makes a contribution to the combined investigational 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. As a result, we will be required to include in our clinical trials an evaluation of each component drug as well as for the component drug in combination. This would likely 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. The OB-301, or EQUIP trial, is designed to meet the combination guidelines set by the FDA. This trial was fully enrolled in March 2008. Data from this study is expected to be available late in 2008.

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

We have and will continue to in-license investigational product candidates from third parties. The United States rights to Evamist and Luramist were licensed from Acrux and its related affiliates. The rights to avanafil were licensed from Tanabe. The rights to Evamist, under the Acrux Agreement, were sublicensed to K-V upon closing of the sale of Evamist to K-V. 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 licensors would not have a differing interpretation of the material terms of the agreements. If the license or sublicense agreements were terminated early or if the terms of the license or sublicense 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. In the event that the Acrux license was terminated, and at such time K-V was not in material breach of the sublicense, then we may be required to pay as liquidated damages an amount equal to the amounts paid by K-V for Evamist under our Asset Purchase Agreement with K-V.

On November 14, 2006, we received a letter from Manatt, Phelps & Phillips LLP (Manatt) on behalf of Acrux DDS Pty Ltd., FemPharm PTY Ltd., and Acrux Limited (collectively Acrux) notifying us of an alleged dispute under the Testosterone (Luramist) and Estradiol (Evamist) Development Agreements (the Acrux Agreements) between VIVUS and Acrux. Since that time VIVUS and Acrux have corresponded regarding the alleged dispute, with VIVUS having communicated its belief that it is in compliance with all material aspects of the Acrux Agreements. The claims relating to Evamist have not progressed further, but, to date, the claims have not been formally withdrawn. Per the terms of our Asset Purchase Agreement with K-V, the license with Acrux related to Evamist is sublicensed to K-V. Although we have sublicensed our rights under the Acrux Agreement related to Evamist to K-V, we will continue to have certain obligations under this license in the event that K-V does not satisfy the requirements under the sublicense agreement. We believe that we have a meritorious defense to the claims made by Acrux in connection with the alleged dispute; however, in the event that Acrux should prevail in this matter relating to Evamist it could have a material adverse effect on our business, financial condition and results of operations, including the possible payment of liquidated damages up to the amount paid by K-V for Evamist.

On November 5, 2007, our legal counsel received a demand for arbitration under the Acrux Agreements relating to Luramist. Acrux's demand seeks a reversion of all rights assigned to VIVUS regarding Luramist, monetary damages, a portion of a milestone payment for Luramist under the Acrux Agreements and declaratory relief. We believe that we are in compliance with all material aspects of the Acrux Agreements including those related to Luramist and that we currently do not owe monetary damages or any milestone payment under the Acrux Agreements. If we are unable to resolve these Luramist related claims with Acrux, we intend to seek to enforce our rights under the Acrux Agreements in arbitration. Development and commercialization of Luramist continues. We believe that we have a meritorious defense to the claims made by Acrux in connection with the alleged dispute concerning Luramist; however, in the event that Acrux should prevail in this matter, it could have a material adverse effect on our business, financial condition and results of operations.

The terms of the agreements with K-V included representations and warranties relating to the technology and the freedom to utilize such technology in the commercialization of Evamist. Other parties may attempt to interfere or infringe on the technology licensed to K-V. To the extent these other parties prevail, K-V may seek assistance, reimbursement or compensation from us in complete or partial resolution of these matters.

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 investigational product candidates, particularly after the Phase 2 stage of clinical testing. These arrangements may place the development of our investigational product candidates outside of our control, may require us to relinquish important rights, or may otherwise be on terms unfavorable to us.

In October 2007, Tanabe and Mitsubishi Pharma Corporation completed their merger and announced their name change to Mitsubishi Tanabe Pharma Corporation. It is unclear at this time what effect, if any, the merger will have on our agreement with Tanabe. There can be no guarantee that the merger of Tanabe and Mitsubishi will not have an adverse material effect on our agreement with Tanabe, which in turn could lead to a material adverse effect on our business, financial condition and results of operations.

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 investigational 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 investigational 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 investigational 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 investigational product candidates.

We face significant governmental regulation during our product development activities.

The research, testing, manufacturing, selling and marketing of investigational 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 investigational 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.

In June 2007, an FDA advisory panel recommended against approval of rimonabant, an oral obesity treatment targeting the CB1 receptor system being developed by another sponsor. Rimonabant is a centrally acting drug that reduces patients' desire to eat. The advisory panel expressed concerns about the impact of the drug on depressed patients and also expressed concerns about patients having thoughts about suicide. In addition, concerns about rimonabant's mechanism of action and interference with the CB1 receptor pathway were also voiced. The sponsor of rimonabant withdrew its NDA shortly after the advisory panel meeting.

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. We are developing an investigational transdermal testosterone product candidate, Luramist, 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 and the cause of significant delays in our ability to submit our investigational product candidate to the FDA for consideration. In April 2008 we received a Special Protocol Assessment on the pivotal Phase 3 studies and reached agreement with the FDA on the safety requirements necessary for approval for Luramist. While we believe the regulatory pathway has been defined, there can be no assurance that, in the end, we will be

successful in obtaining FDA approval of Luramist or any of our investigational product candidates.

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 investigational product candidates would delay or prevent our ability to generate revenue from our investigational 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 investigational product candidates from third parties.

We currently license some of our investigational product candidates from third parties. Our present development programs involving these investigational product candidates rely in part upon previous development work conducted by third parties over whom we had no control and before we licensed the investigational product candidates. In order to receive regulatory approval of an investigational 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 investigational 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 an investigational 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 investigational 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 will be held to extensive regulatory requirements over product manufacturing, labeling, packaging, adverse event reporting, storage, distribution, advertising, promotion and record keeping. Regulatory approvals may also be subject to significant limitations on the indicated uses or marketing of the investigational product candidates or who we may distribute to. Potentially costly 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. The safety study for Luramist will require us to follow patients for five years in order to assess potential cardiovascular risks and breast cancer. While we may submit an NDA for Luramist after patients have had an average exposure of 12 months and a minimum number of predefined cardiovascular incidences have occurred, there can be no assurance that Luramist will be approved or, if approved, that safety issues would not arise subsequent to such approval. Previously unknown problems with the investigational 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 investigational product candidates. We cannot predict the likelihood, nature, extent or effects of 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 investigational 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 investigational 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

S-12

investigational product candidates on a timely basis, if at all, and we may not be able to successfully commercialize these investigational 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 future commercial operations and an interruption to this service may harm our business.

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

We have completed the development of a once-a-day formulation of Qnexa. The contract manufacturer we have selected to develop a once-a-day formulation is supplying all product for the Phase 3 program. In addition, this contract manufacturer is our sole-source of clinical supplies for Qnexa. Stability data of the once-a-day capsule is limited. There can be no assurance that the final once-a-day formulation will result in sufficient safety and efficacy for approval. A failure on the stability or manufacturability of our once-a-day formulation or the inability of this contract manufacturer to carry out its contractual duties or meet expected timelines, our Qnexa clinical studies would be delayed which may have a material adverse impact on our development plan, stock price and financial condition.

We have requested Mitsubishi Tanabe to manufacture materials for the pivotal Phase 3 trials for avanafil. We do not expect the materials to be available before the third quarter of 2008. We would not be able to initiate the clinical trials of avanafil prior to the receipt of the materials from Mitsubishi Tanabe. The failure to receive the materials on the expected timeline would delay the start of the studies and could have a material adverse effect on our stock price, our ability to raise additional funds and on the estimated costs of the studies.

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 is obtained, the product 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.

Edgar Filing: VIVUS INC - Form 424B5

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.

S-13

We are required to obtain FDA, European Medicines and Healthcare products Regulatory Agency (MHRA), and other regulatory agency approvals 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 previous supplier of 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 this previous supplier closed its business, the supplier produced a bulk-quantity of foil that, at this time, is expected to be sufficient to support the production of MUSE for our international markets through the end of the third quarter of 2008. There can be no assurance that as this bulk supply is used through the end of the third quarter of 2008 for international product, that there will be a sufficient yield in the final quantity of foil with acceptable quality to support the international markets MUSE demand. 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 end of the third quarter of 2008. If such foil quality issues do occur, we may be unable to meet international MUSE demand through the end of the third quarter of 2008.

We have a new 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 MHRA approval. Although the FDA has granted approval for the use of foil from our new vendor for U.S. MUSE product, there can be no assurance that these qualifications and approvals will be successfully obtained from the MHRA or Canadian market regulatory agency, 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.

Non-conformance issues may occur in our manufacturing operations or in the operations of our vendors and suppliers which could have an adverse impact on our ability to manufacture our products and investigational product candidates. For example, in late March 2008, we identified a non-conformance issue in a bottle containing 250 grams of raw material for MUSE, as supplied by the raw material vendor. The MUSE units manufactured from this bottle were separated from our other inventory and will not be distributed. We filed the appropriate paperwork with the FDA in connection with the non-conforming raw material and we are in the process of testing the remaining quantities of raw material from the vendor. It is not yet possible to determine what impact the current non-conformance may have upon previously distributed product. While we do not expect any disruption in the normal supply of MUSE, there can be no assurance that the non-conformance and the subsequent investigation will not result in an interruption or possible recall of previously distributed MUSE. A long-term interruption in our ability to manufacture MUSE or a recall of MUSE previously distributed could have an adverse impact on the sales of MUSE and the resultant amounts collected or to be collected from the sales of MUSE. In addition, the costs associated with the interruption in supply could be great and our future financial results could be adversely affected.

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.

If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

As a manufacturer of pharmaceuticals, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third party payors, certain federal and state healthcare laws and regulations pertaining to fraud, abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud, abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The regulations that may affect our ability to operate include, but are not limited to:

- the federal healthcare program Anti-Kickback Law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third party payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers or promoting our commercial products for off-label use;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

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

After product approval by the FDA, our marketing activities will 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 resulting in adverse publicity. 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.

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. The safety study for Luramist requires that we follow subjects for five years in total to detect cardiovascular events and breast cancer. Further, later discovery of previously unknown problems for Luramist or any of our investigational products 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 exclusive marketing and distribution rights for MUSE in member states of the European Union. Meda currently sells MUSE in the United Kingdom, Ireland, Sweden, Norway, Germany, Switzerland, Denmark, Finland, France and the Netherlands. 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. 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.

S-16

If we are unable to establish capabilities to sell, market and distribute our investigational product candidates, either by developing our own capabilities or entering into agreements with others, we will not be able to successfully launch our investigational product candidates upon FDA approval. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need. We may not be able to enter into any marketing or distribution agreements with third party providers on acceptable terms, if at all. In that event, we will not be able to generate significant revenues.

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 demand for MUSE has declined and, given the loss of coverage under Medicare Part D, we are not able to anticipate if wholesalers will continue their historical pattern of making purchases in the fourth quarter that exceed expected quarterly demands. If wholesalers do not repeat this pattern of purchasing quantities of MUSE that exceed quarterly demands, revenues from the sale of MUSE in 2008 may be lower as compared to 2007.

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. We are aware of several pharmaceutical companies also actively engaged in the development of therapies for the treatment of obesity, diabetes 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 drugs include Xenical (orlistat), marketed by Roche, and Meridia (sibutramine), marketed by Abbott Labs. Orlistat works by inhibiting lipase, thus preventing digestion and absorption of dietary fat in the gastrointestinal tract. In 2007, Xenical accounted for approximately \$70 million in sales in the United States. Orlistat was launched over-the-counter in the United States by GlaxoSmithKline under the brand name Alli, in June 2007. 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 in an off-label manner. Sanofi-Aventis' Acomplia (rimonabant) was approved in the European Union in 2006 for the treatment of obesity (the drug is

Edgar Filing: VIVUS INC - Form 424B5

approved in a total of 51 countries worldwide). However, Sanofi withdrew the drug's NDA in the United States following an FDA advisory panel's recommendation against approval on the basis of safety concerns.

S-17

There are several drugs in development for obesity including 4 product candidates in Phase 3 clinical trials being developed by Merck & Co., Inc., Pfizer, Arena Pharmaceuticals, Inc., and Orexigen Therapeutics, Inc., and approximately 20 product candidates in Phase 2 clinical trials by companies including Amylin Pharmaceuticals, Inc., Alizyme plc, Neurosearch A/S, Novo Nordisk and GlaxoSmithKline, among others.

Prescription anti-diabetic drugs generate sales of more than \$10 billion per year in the United States. We estimate there are several hundred anti-diabetic drug candidates currently being evaluated in clinical trials. New classes of drugs are being developed for type 2 diabetes including Byetta, a GLP-1 analog developed and marketed by Amylin Pharmaceuticals and Eli Lilly, which was approved by the FDA in April 2005. Byetta generated about \$400 million in U.S. sales in 2006 and over \$600 million in 2007. Januvia, a DPP-4 inhibitor, developed and marketed by Merck, was approved by the FDA in October 2006 and is experiencing a dramatic market growth thanks to its once-a-day oral dosing and perceived clean safety profile. Analysts have projected its sales to reach approximately \$800 million in 2007. There are approximately 15 GLP-1 analogs/formulations and 25 DPP-4 inhibitors in clinical development today, dominated by large pharmaceutical companies. In addition, many companies are developing products against emerging drug targets in this therapeutic area.

All of these drugs are marketed by pharmaceutical companies with substantially greater resources than us. In addition, a number of generic pharmaceutical products are prescribed for obesity, including phentermine, phendimetrazine, mazindol, benzphetamine and diethylpropion. Some of these generic drugs, and others, are prescribed in combinations that have shown some level of efficacy. These products are sold at much lower prices than we intend to charge for our investigational product candidate, Qnexa, if approved. The availability of a large number of branded prescription products, generic products and over-the-counter products could limit the demand for, and the price we are able to charge for, our investigational obesity product candidate.

Significant competitive therapies exist for MUSE and avanafil in the form of oral medications marketed by Pfizer, Inc. under the name Viagra®, Cialis® marketed by Eli Lilly and Company and Levitra® which is co-marketed by GlaxoSmithKline plc and Schering-Plough Corp in the United States.

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 develop or improve these therapies. In November 2007, NexMed, Inc. announced that the NDA filed for its ED product, a topically applied alprostadil cream, was accepted for review by the FDA. NexMed has also announced that they have entered into a licensing arrangement with Warner Chilcott Company, Inc. (a subsidiary of Warner Chilcott, Ltd., Nasdaq:WCRX) granting Warner Chilcott the exclusive U.S. rights to NexMed's topically applied alprostadil cream for the treatment of erectile dysfunction (ED). Under the terms of the agreement, Warner Chilcott has exclusive U.S. rights to develop and market NexMed's product. NexMed received an initial, up-front payment and is eligible to receive additional payments upon achievement of certain development and regulatory approval milestones. Further, Warner Chilcott will pay a royalty to NexMed on sales of the product. Specific financial details of the agreement were not disclosed. If the NDA for the NexMed product is approved and Warner Chilcott is successful in commercializing this product, the sales of MUSE will decline which will have an adverse effect on the results of our operations and cash flows from sales of MUSE.

Several companies are developing products that could compete with our investigational 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 investigational 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 and in February 2007, Intrinsa was launched in France and Germany. In March 2007, Intrinsa became available through the National Health Service (NHS) in the United Kingdom.

New developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical and medical technology industries at a rapid pace. These developments may render our investigational product candidates obsolete or noncompetitive. Compared to us, many of our potential competitors have substantially greater:

- research and development resources, including personnel and technology;
- regulatory experience;
- drug development and clinical trial experience;
- experience and expertise in exploitation of intellectual property rights; and
- access to strategic partners and capital resources.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our investigational product candidates.

If our raw material suppliers fail to supply us with the Active Pharmaceutical Ingredients for our products and investigational product candidates, 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 Chinoïn Pharmaceutical and Chemical Works Private Co., Ltd., in Hungary. We have manufacturing agreements with Chinoïn and NeraPharm to produce additional quantities of alprostadil for us.

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.

Non-conformance issues may occur in our manufacturing operations or in the operations of our vendors and suppliers which could have an adverse impact on our ability to manufacture our products and investigational product candidates. For example, in late March 2008, we identified a non-conformance issue in a bottle containing 250 grams of raw material for MUSE, as supplied by the raw material vendor. The MUSE units manufactured from this bottle were separated from our other inventory and will not be distributed. We filed the appropriate paperwork with the FDA in connection with the non-conforming raw material and we are in the process of testing the remaining quantities of raw material from the vendor. It is not yet possible to determine what impact the current non-conformance may have upon previously distributed product. While we do not expect any disruption in the normal supply of MUSE, there can be no assurance that the non-conformance and the subsequent investigation will not result in an interruption or possible recall of previously distributed MUSE. A long-term interruption in our ability to manufacture MUSE or a recall of MUSE previously distributed could have an adverse impact on the sales of MUSE and the resultant amounts collected or to be collected from the sales of MUSE. In addition, the costs associated with the interruption in supply could be great and our future financial results could be adversely affected.

Edgar Filing: VIVUS INC - Form 424B5

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.

In addition, we currently do not have manufacturing agreements in place for topiramate or phentermine. There can be no guarantees that we will be able to enter into such agreements under reasonable terms, if at all. We cannot guarantee that should we be successful in entering into such agreements we will be able to obtain the necessary regulatory approvals for these suppliers.

S-19

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.

S-20

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, although one of the buildings is used for warehousing component parts. 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 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, cultural 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. Some third party payor benefit packages restrict reimbursement or do not provide coverage for specific drugs or drug classes. While a large percentage of prescriptions in the United States for MUSE have been reimbursed to some extent 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. Historically the volume of MUSE sales to Medicaid and Medicare patients was not 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 erectile dysfunction drugs. 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 are unable to determine if Qnexa, if approved, will be subject to reimbursement or at what level reimbursement may occur. 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, if approved, 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.

S-22

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 investigational product, Qnexa, if approved, 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.

Recent federal legislation and actions by state and local governments may permit re-importation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could adversely affect our operating results and our overall financial condition.

We may face competition for our products from lower priced products from foreign countries that have placed price controls on pharmaceutical products. The Medicare Prescription Drug Improvement and Modernization Act of 2003 contains provisions that may change United States importation laws and expand consumers' ability to import lower priced versions of our investigational product candidates and competing products from Canada, where there are government price controls. These changes to United States importation laws will not take effect unless and until the Secretary of Health and Human Services certifies that the changes will lead to substantial savings for consumers and will not create a public health safety issue. The Secretary of Health and Human Services has not yet announced any plans to make this required certification. As directed by Congress, a task force on drug importation conducted a comprehensive study regarding the circumstances under which drug importation could be safely conducted and the consequences of importation on the health, medical costs and development of new medicines for United States consumers. The task force issued its report in December 2004, finding that there are significant safety and economic issues that must be addressed before importation of prescription drugs is permitted. In addition, a number of federal legislative proposals have been made to implement the changes to the United States importation laws without any certification, and to broaden permissible imports in other ways. Even if the changes do not take effect, and other changes are not enacted, imports from Canada and elsewhere may continue to increase due to market and political forces, and the limited enforcement resources of the FDA, the United States Customs Service and other government agencies.

For example, Pub. L. No. 109-295, which was signed into law in October 2006 and provides appropriations for the Department of Homeland Security for the 2007 fiscal year, expressly prohibits the United States Customs Service from using funds to prevent individuals from importing from Canada less than a 90-day supply of a prescription drug for personal use, when the drug otherwise complies with the Federal Food, Drug, and Cosmetic Act.

Further, several states and local governments have implemented importation schemes for their citizens, and, in the absence of federal action to curtail such activities, we expect other states and local governments to launch importation efforts. The importation of foreign products that compete with our own products could negatively impact our financial condition.

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.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs and drug manufacturing operations. For example, the loss of clinical trial data from completed or ongoing clinical trials for our investigational product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our investigational product candidates could be delayed.

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 on-going or planned clinical trials could be delayed or disrupted indefinitely upon the occurrence of a natural disaster. For example, in 2005, 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 or others may infringe on our intellectual property rights.

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 (the USPTO) issued to Pfizer a method of use patent, U.S. Patent No. 6,469,012. Pfizer immediately initiated litigation against competitors who

S-24

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 already own or 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.

A recent Supreme Court ruling in *KSR International Co. vs. Teleflex, Inc.*, will raise the standards for patentability and ease the ability to show that a patent is obvious. This ruling will make it more difficult to obtain patents for combination pharmaceutical products. At the present time, we are unable to predict the impact, if any, that this recent ruling will have on our current or future patents. If we are unable to defend the patents currently issued on our commercial product and investigational drug candidates, or to obtain new patents for any reason, our ability to commercialize the current and future products would be at risk.

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, diabetes and male and female sexual health among other products. Qnexa is our investigational 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, if approved, 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 are aware of an issued patent for the use of topiramate for obesity. 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.

In November 2007, NexMed submitted an NDA for a transdermal formulation of alprostadil for ED. It is unclear if the NexMed product would infringe on the patents we hold for MUSE. If this NDA is approved and NexMed's commercialization partner, Warner Chilcott, is successful in commercializing this product we will likely incur significant expenses protect our MUSE business from this competition.

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 investigational 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 investigational product candidates, we may not be able to develop or commercialize such investigational 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 investigational 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 investigational 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 investigational 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 investigational 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 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 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 November 17, 2006, we raised \$33.6 million in a registered direct offering of our common stock pursuant to this shelf Registration Statement. Under the terms of this financing, we sold and issued a total of 6,750,000 shares of our common stock at a price of \$3.50 per share in an initial closing and an additional 2,850,000 shares in a second closing on December 8, 2006. On May 10, 2006, we raised \$12 million in a registered direct offering under an earlier shelf Registration Statement (File Number 333-121159) in which we sold and issued 3,669,725 shares of our common stock to two institutional investors 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). The land and buildings, among other assets, located at our principal manufacturing facility and a \$700,000 Certificate of Deposit held by Crown serve as collateral for this loan. The loan is payable over a 10-year term. The interest rate is 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.

We expect that our existing capital resources combined with future anticipated cash flows will be sufficient to support our operating activities at least through 2008. 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 planned and future clinical trials;

- the costs involved in seeking regulatory approvals for our investigational product candidates;
- the costs involved in filing and pursuing patent applications, defending and enforcing patent claims;
- the establishment of collaborations and strategic alliances and the related costs;
- the cost of manufacturing and commercialization activities and arrangements;
- the results of operations;
- demand for MUSE;
- the cost, timing and outcome of regulatory reviews;

S-27

- 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, sell or spin-off one or more of our products or investigational 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 \$169.8 million as of December 31, 2007 and we may continue to incur substantial operating losses for the future.

We have generated a cumulative net loss of \$169.8 million for the period from our inception through December 31, 2007, and we anticipate losses in future years due to increased investment in our research and development programs. There can be no assurance that we will be able to achieve or maintain profitability or that we will be successful in the future.

Our ability to utilize our net operating loss carryforwards to offset future taxable income may be limited.

As of December 31, 2007, we had approximately \$7 million of net operating loss (NOL) carryforwards with which to offset our future taxable income for federal and state income tax reporting purposes. We used \$121.6 million federal and \$38.7 million state NOLs to offset our year ended December 31, 2007 federal and state tax liabilities, which included the \$150 million in gain recognized from the Evamist sale. The Internal Revenue Code of 1986, as amended, contains provisions that may limit the net operating loss and credit carryforwards available for use in any given period upon the occurrence of certain events, including significant change in ownership interest. Should this occur, our future ability to use NOLs to offset taxable earnings would be limited in accordance with the Internal Revenue Code.

We may be unable to collect on our claim for reimbursement of product and establishment and NDA application fees from the FDA.

We believe we are due a refund pursuant to Section 736(d)(1)(C) of the Federal Food, Drug and Cosmetic Act (FDCA) from the FDA for product and establishment fees paid in 2006 and 2007 and for the NDA application fee for Evamist paid in 2006 on the basis that the fees paid exceed the anticipated present and future costs incurred by the FDA in conducting the process for the review of human drug applications

Edgar Filing: VIVUS INC - Form 424B5

for VIVUS, Inc. To date, we have been unsuccessful in our attempts to collect these amounts from the FDA. We believe that we will collect these refund amounts from the FDA; however, should we be unable to collect on these claims, we will be required to reverse all or some part of these receivables.

S-28

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:

- the Phase 3 program for Qnexa;
- the data from the current Phase 2 program for Qnexa in diabetes;
- 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;
- the volatility and liquidity of the financial markets;
- 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 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 acting collectively 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, the timing of recognition of deferred revenue, 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.

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

Some provisions of our Amended and Restated Certificate of Incorporation and Bylaws could 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;

Edgar Filing: VIVUS INC - Form 424B5

- 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.

S-30

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 123R), *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 123R in future periods, the compensation expense that we record under SFAS 123R may differ significantly from what we have recorded in the current period, which could negatively affect our stock price.

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 our internal control over financial reporting 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 SEC. Any such action could adversely affect our financial results and the market price of our common stock.

The investment of our cash balance and our investments in marketable debt securities are subject to risks which may cause losses and affect the liquidity of these investments.

At December 31, 2007, we had \$37.8 million in cash and cash equivalents and \$141.7 million in available for sale securities. We invest our excess cash balances in money market and marketable securities, primarily high quality corporate debt securities and asset-backed securities, in accordance with our investment policy approved by the Board of Directors. The investment policy has the primary investment objectives of preservation of principal while at the same time maximizing yields without significantly increasing risk; however, there may be times when certain of the securities in our portfolio will fall below the credit ratings required in the policy. If those securities are downgraded or impaired we would experience losses in the value of our portfolio which would have an adverse effect on our results of operations, liquidity and financial condition. Certain of these securities are subject to general credit, liquidity, market and interest rate risks, which may be exacerbated by U.S. sub-prime mortgage defaults that have affected various sectors of the financial markets and caused credit and liquidity issues.

From 2005 and until December 2007 the Company had an investment in Columbia Strategic Cash Portfolio (Strategic Cash) offered by the Company's investment advisor, Columbia Management LLC (Columbia), an affiliate of Bank of America. Strategic Cash is an enhanced money market fund in which the fund sought to maintain a \$1 per share net asset value. The Company used Strategic Cash for the investment of excess cash, and periodic transfers were made from Strategic Cash to the operating cash account to fund current operations.

In early December 2007, VIVUS was notified by Columbia that the Strategic Cash fund was closed and that the fund was to be liquidated. The fund no longer supported the \$1 per share net asset value and switched to a market value fund in which all investments were marked to market. VIVUS was given the option of staying in the fund and receiving cash proceeds from the fund as its holdings were liquidated or receiving a pro-rata share of the investments held by the fund. Upon advice from the investment advisor, the Company took a redemption-in-kind consisting of cash, interest receivable and a pro-rata distribution of the underlying securities, consisting principally of high quality corporate debt and asset-backed securities. Prior to the redemption the Company's investment in Strategic Cash was \$84.4 million. On December 20, 2007 and December 21, 2007, the Company received its redemption-in-kind consisting of securities with a market value of \$68.7 million, interest receivable of \$300,000 and cash of \$14.4 million. The difference between the Company's investment in Strategic Cash of \$84.4 million and the fair value of the securities, cash and interest receivable totaling \$83.4 million received in-kind resulted in a loss of \$1 million. This loss of \$1 million is reflected in interest income in the consolidated statement of operations and other comprehensive income (loss). We have reason to believe certain of these securities are in default and others have experienced a decline in market value. In addition, the active market for certain securities is extremely limited.

As a result of the distribution from Strategic Cash, we received securities that fell outside the investment policy at that time. The Audit Committee allowed the receipt of the securities and granted an exception to the policy for these specific securities. At the time of distribution, the Strategic Cash held \$35 billion in securities. Several other holders in Strategic Cash received a redemption-in-kind as well. Shareholders who remained in Strategic Cash will receive cash as the fund is liquidated. It is our belief that the investors in the Strategic Cash who did not take, or were not allowed to take, a redemption-in-kind will not realize 100% of their holdings. As a result of all of the redemptions-in-kind held by us and others, the liquidation of the fund itself and the general market conditions for these types of securities, the current market value of these securities may be negatively affected.

We currently believe we will be able to realize a significant portion of the par value of our investments without significant loss; however, it could take until the final maturity of the underlying securities or until market conditions improve to realize the par value. Based on our expected operating cash flows, and our other sources of cash, we do not anticipate the potential lack of liquidity on certain of these investments will affect our ability to execute our current business plan; however, these market risks associated with our investment portfolio could cause the loss of a significant portion of our investments which would have an adverse effect on our results of operations, liquidity and financial condition.

Risks Relating to our Proposed Transaction with Deerfield Capital Management and Affiliates

Background

Simultaneously with the sale of securities to funds affiliated with Deerfield Capital Management (DCM), we entered into a Funding and Royalty Agreement (FARA), an Option and Put Agreement (OPA) and a Security Agreement with ED, a corporation formed by funds affiliated with DCM. We also entered into a Security Agreement with the shareholders of ED. Under the terms of the FARA, ED will provide funding paid as installments after the closing of the transaction and continuing quarterly for 5 remaining quarters. As part of the funding arrangement, we have agreed to continue our development of avanafil, our oral PDE5i for ED. The FARA also provides that we will pay royalties on the net MUSE sales on a quarterly basis. Under the FARA the royalty payments continue for 10 years. There are no minimum royalties due, however, we have agreed to maintain the promotion of MUSE consistent with our prior efforts. The OPA provides that we may purchase all

the outstanding shares of ED, thus ending any further royalty payments. The OPA allows for the purchase of the shares of ED by us for \$23 million on a net basis through the first 3 years and \$26 million net from the third to fourth year. The purchase amounts are net of the premium paid to DCM upfront for the call option. We have no ability to repurchase the shares after the fourth year. We paid a purchase premium of \$2 million. The OPA provides that DCM can force a sale of the shares of ED to us beginning after the third year through the tenth year. The timing on the sale of the shares could be accelerated under certain conditions including a change-in-control, sale of MUSE or avanafil, sale of major assets and the sale of securities in a transaction or a series of related transactions by us that exceed 20% of our outstanding common stock at the date the OPA was signed if at the time of the sale our market capitalization is below \$300 million (each, a Major Transaction). Under these conditions, the cost of the shares of ED would be \$23 million before the third anniversary and \$26 million from the third to tenth anniversary. The sale of the shares of ED could also accelerate if our cash, cash equivalents and available for sale securities falls below \$15 million or our market capitalization falls below \$50 million. As security for the payment of royalties we have pledged certain unencumbered MUSE and avanafil assets to ED. As security for the payment under the forced sale of shares of ED to DCM we have pledged certain unencumbered MUSE and avanafil assets to DCM. The Company is evaluating the appropriate accounting treatment of this transaction under generally accepted accounting principles.

Risks Related to the FARA

Under the FARA, the payment of the royalties may result in the MUSE operations being unprofitable. If we fail to exercise the option to repurchase the shares of ED or if DCM does not force us to purchase the shares of ED, we will continue to pay royalties into 2018. We agreed to continue to promote MUSE at levels consistent with our current efforts. This requirement may force us to allocate resources that could be better utilized for other activities. If we decide to sell the MUSE business line or related assets, we will be forced to purchase the shares of ED. The royalty payments and required commitment under the FARA may have an adverse effect on our cash flows, stock price, ability to raise money, financial position and results of operations.

Risks Related to the OPA

Under the OPA, we only have four years to repurchase the shares of ED. If we do not exercise this option within this period of time we will pay royalties through 2018. If exercised by us, the OPA will require us to pay \$23 million or \$26 million. The payment of these amounts may have an adverse effect on our cash balances, stock price and operations at the time of payment. DCM has the ability to force us to buy the shares of ED for \$17 million, \$23 million or \$26 million. The payment of any one of these amounts would have a material adverse effect on our cash balance at the time. If our purchase of the ED shares is accelerated due to a Major Transaction, our ability to effectively negotiate and complete such a transaction could be adversely affected. The proceeds from such a transaction will also be reduced by the price paid for the ED shares.

Risks Related to the Security Agreement

We entered into a Security Agreement with ED to secure the royalty payments and with DCM to secure the forced sale of the ED shares. The Security Agreements severely limit our ability to commercialize the assets covered by the Security Agreement outside the ordinary course of business. These assets would also not be available to serve as collateral for any future purpose.

Risks Related to the Purchase of Shares of Common Stock

Edgar Filing: VIVUS INC - Form 424B5

Simultaneously with the entering into the FARA, OPA and the Security Agreements, DCM has agreed to purchase \$10 million of our common stock. The stock purchase requires us to pay a \$500,000 fee and reimburse expenses incurred by DCM up to \$250,000. If the FARA, OPA and Security Agreements are terminated, our development of avanafil is discontinued or sales of MUSE cease, DCM may continue to hold the common stock. Due to the complexity of the structure and the high costs of the transactions, investors may react negatively towards the transaction. It is difficult to predict the impact this transaction will have on our stock price or our ability to raise capital in the future.

S-33

USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of our common stock in this offering will be approximately \$9.0 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 December 31, 2007 was approximately \$60.2 million, or approximately \$1.02 per share of common stock based upon 58,872,905 shares outstanding. Net tangible book value per share is equal to our total tangible assets, less our total liabilities, divided by the total number of shares of our common stock outstanding as of December 31, 2007. After giving effect to the sale by us of the 1,626,017 shares of our common stock we are offering, our as-adjusted net tangible book value would have been approximately \$69.2 million, or approximately \$1.14 per share of common stock based upon 60,498,922 shares outstanding. This represents an immediate increase in net tangible book value of \$0.12 per share to our existing stockholders and an immediate dilution in net tangible book value of \$5.01 per share to new investors. The following table illustrates this calculation on a per share basis:

Public offering price per share	\$6.15
Net tangible book value per share as of December 31, 2007	\$1.02
Increase in net tangible book value per share attributable to the offering	0.12
As-adjusted net tangible book value per share after giving effect to the offering	1.14
Dilution in net tangible book value per share to new investors	\$5.01

The foregoing table excludes the following, each stated as of December 31, 2007:

- 3,226,260 shares of our common stock issuable upon the exercise of exercisable stock options at a weighted average exercise price of \$4.35 per share;
- 2,122,241 shares of our common stock issuable upon the exercise of outstanding stock options that are not exercisable;
- 1,753,871 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 entered into securities purchase agreements directly with the investors in connection with this offering. Subject to the terms and conditions of the purchase agreements, the investors agreed to purchase, and we agreed to sell, an aggregate of 1,626,017 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. 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 April 15, 2008.

The expenses directly related to this offering are estimated to be approximately \$500,000 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, has passed 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, 2007 and 2006 and for each of the three years in the period ended December 31, 2007 have been incorporated by reference from our Annual Report on Form 10-K for the fiscal year ended December 31, 2007, 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.

RECENT DEVELOPMENTS

- **Extension Study with Qnexa for Diabetes** In January 2008, we announced the initiation of a six-month extension study for patients currently enrolled in the OB-202 diabetes study.
- **Completion of Enrollment in EQUIP (OB-301) trial** In March 2008, we announced that we reached our enrollment goals in the OB-301 trial with over 700 obese patients having been enrolled. We currently anticipate the data from this trial should be available in late 2008.
- **Completion of Enrollment in EQUATE (OB-302) trial** In March 2008, we announced that we reached our enrollment goals in the OB-302 trial and over 1,250 morbidly obese patients had been enrolled. Data from this trial should be available in the second half of 2009.
- **Special Protocol Assessment, or SPA, Granted and Agreement Reached on safety study for Luramist** In April 2008, we received an SPA and reached agreement on the safety requirements for Luramist (testosterone MDTs). The pivotal phase 3 studies will include two six month studies in menopausal women and the events driven safety study will enroll 5,200 women over 50 with one cardiovascular risk factor.

LIMITATION OF LIABILITY AND INDEMNIFICATION

Edgar Filing: VIVUS INC - Form 424B5

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.

WHERE YOU CAN FIND MORE INFORMATION

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

Public Reference Room
450 Fifth Street, N.W.
Room 1024
Washington, D.C. 20549
1-800-SEC-0330

S-37

Edgar Filing: VIVUS INC - Form 424B5

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

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

We incorporate by reference the documents listed below and any future filings made by us with the 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, 2007;
- Current Reports on Form 8-K filed with the Securities and Exchange Commission on April 4, 2008, April 2, 2008, March 31, 2008, March 14, 2008, March 11, 2008, March 6, 2008, February 11, 2008, February 5, 2008, February 1, 2008, January 30, 2008, January 24, 2008, January 10, 2008 and January 3, 2008; and
- The description of the Common Stock of the Registrant that is contained in the Registration Statement on Form 8-A filed pursuant to Section 12 of the Exchange Act that became effective on April 7, 1994, including any amendments or reports filed for the purpose of updating such description.

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

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 supplement or the accompanying prospectus. We have not authorized anyone else to provide you with different information. We are not making an offer of these securities in any state where 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.

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 6 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

TABLE OF CONTENTS

	Page
<u>SUMMARY</u>	1
<u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	5
<u>RISK FACTORS</u>	6
<u>USE OF PROCEEDS</u>	26
<u>PLAN OF DISTRIBUTION</u>	26
<u>DESCRIPTION OF COMMON STOCK</u>	27
<u>LEGAL MATTERS</u>	29
<u>EXPERTS</u>	29
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	29

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

Edgar Filing: VIVUS INC - Form 424B5

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

Edgar Filing: VIVUS INC - Form 424B5

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 reallocated 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

Edgar Filing: VIVUS INC - Form 424B5

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

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

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

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

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

Section 203 defines business combination to include:

- (1) any merger or consolidation involving the corporation and the interested stockholder,
- (2) any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder,
- (3) subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder,
- (4) any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder, or
- (5) the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

Edgar Filing: VIVUS INC - Form 424B5

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.

Edgar Filing: VIVUS INC - Form 424B5

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.

Edgar Filing: VIVUS INC - Form 424B5

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.