

VIVUS INC
Form 10-K
March 14, 2007

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2006

OR

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

For the transition period from _____ to _____

Commission File Number 0-23490

VIVUS, INC.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation or organization)
1172 Castro Street
Mountain View, California
(Address of principal executive office)

94-3136179
(IRS employer
identification number)

94040
(Zip Code)

Registrant's telephone number, including area code: **(650) 934-5200**
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, \$.001 Par Value (Title of class)	The NASDAQ Global Market
Preferred Share Purchase Rights (Title of class)	

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Note- checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Exchange Act from their obligations under those Sections.

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for

Edgar Filing: VIVUS INC - Form 10-K

the past 90 days. Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

The aggregate market value of the common equity held by non-affiliates of the Registrant as of June 30, 2006 totaled approximately \$180,459,395 based on the closing stock price as reported by the Nasdaq National Market.

As of February 26, 2007, there were 58,258,296 shares of the Registrant's Common Stock, \$0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Document Description

Portions of the Registrant's notice of annual meeting of stockholders and proxy statement to be filed pursuant to Regulation 14A within 120 days after Registrant's fiscal year end of December 31, 2006 are incorporated by reference into Part III of this report.

10-K part

III, ITEMS 10, 11, 12, 13, 14

VIVUS, INC.
FISCAL 2006 FORM 10-K
INDEX

	<u>PART I</u>	3
<u>Item 1:</u>	<u>Business</u>	3
<u>Item 1A:</u>	<u>Risk Factors</u>	17
<u>Item 1B:</u>	<u>Unresolved Staff Comments</u>	42
<u>Item 2:</u>	<u>Properties</u>	43
<u>Item 3:</u>	<u>Legal Proceedings</u>	43
<u>Item 4:</u>	<u>Submission of Matters to a Vote of Security Holders</u>	43
	<u>PART II</u>	44
<u>Item 5:</u>	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	44
<u>Item 6:</u>	<u>Selected Financial Data</u>	46
<u>Item 7:</u>	<u>Management's Discussion and Analysis of Financial Conditions and Results of Operations</u>	48
<u>Item 7a:</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	67
<u>Item 8:</u>	<u>Financial Statements and Supplementary Data</u>	69
<u>Item 9:</u>	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	100
<u>Item 9A:</u>	<u>Controls and Procedures</u>	100
<u>Item 9B:</u>	<u>Other Information</u>	101
	<u>PART III</u>	102
<u>Item 10:</u>	<u>Directors, Executive Officers and Corporate Governance</u>	102
<u>Item 11:</u>	<u>Executive Compensation</u>	102
<u>Item 12:</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	102
<u>Item 13:</u>	<u>Certain Relationships, Related Transactions and Director Independence</u>	102
<u>Item 14:</u>	<u>Principal Accountant Fees and Services</u>	102
	<u>PART IV</u>	103
<u>Item 15:</u>	<u>Exhibits and Financial Statement Schedules.</u>	103
<u>Signatures</u>		108
<u>Power of Attorney</u>		108
<u>Index to Exhibits</u>		109
Certification of Chief Executive Officer		
Certification of Chief Financial Officer		
Certification of Chief Executive Officer and Chief Financial Officer		

PART I

FORWARD-LOOKING STATEMENTS

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

Item 1. *Business*

Overview

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, postmenopausal and sexual health. All 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 postmenopausal and sexual health products each represent a projected market greater than \$1 billion annually.

We are currently advancing four late-stage clinical products, each addressing specific components of these significant markets. One of these products has completed Phase 3 testing and we submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the third quarter of 2006. The remaining products are being prepared to enter Phase 3 clinical trials. In 1997, we launched MUSE (alprostadil) in the United States and, together with our partners, internationally. We market MUSE as a prescription product for the treatment of erectile dysfunction.

Our investigational product pipeline includes:

- **Qnexa**TM for treating obesity, for which a Phase 2 study has been completed;
- **EvaMist**TM to treat vasomotor symptoms associated with menopause, for which we submitted an NDA to the FDA in the third quarter of 2006;
- **Testosterone MDTs**[®] is being developed to treat hypoactive sexual desire disorder, for which a Phase 2 study has been completed; and
- **Avanafil** is being developed for the treatment of erectile dysfunction; for which Phase 2 studies have 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 leader in the development and commercialization of products that help to treat obesity and restore sexual health in women and men. We believe that we have strong intellectual property supporting several opportunities in obesity treatment and sexual health. Our future growth will come from further development and regulatory approval of our product candidates as well as in-licensing and product line extensions.

We have funded operations primarily through private and public offerings of our common stock and through product sales of MUSE. We expect to generate future net losses due to increases in operating expenses as product candidates are advanced through the various stages of clinical development. As of December 31, 2006, we have incurred a cumulative deficit of \$168.7 million and expect to incur operating losses in the near future.

Our Product Pipeline

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

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

Obesity

In 2004, the U.S. Centers for Disease Control and Prevention (CDC) 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. According to a study performed by the CDC, as reported in the Journal of the American Medical Association, an estimated 112,000 excess deaths a year in the U.S. is attributable to obesity. The total direct and indirect costs attributed to overweight and obesity amounted to \$117 billion

in 2000. Additionally, Americans spend approximately \$30 billion annually on weight-loss products and services.

Qnexa

Qnexa is a proprietary oral investigational pharmaceutical treatment for obesity that incorporates low doses of active ingredients from two products previously approved by the FDA, topiramate and phentermine. By combining each of these compounds, we believe Qnexa can simultaneously address excessive appetite and high threshold for satiety, or the feeling of being full, the two main mechanisms that impact eating behavior.

Previously, we reported results from a Phase 2 double blind, randomized, and placebo-controlled clinical trial conducted at Duke University, in which patients on Qnexa lost, on average, 25.1 pounds as compared to patients in the placebo group, which lost 4.8 pounds. This trial involved 200 subjects, 159 women and 41 men with an average approximate age of 40 and a mean body mass index (BMI) of 38.6. (A BMI of > 30.0 is classified as obese per guidelines from the U.S. Department of Health and Human Services.) Patients completing the 24-week treatment period lost on average approximately 11% of baseline body weight, as compared to an average 2.8% in the placebo group. The difference between the Qnexa arm and the placebo arm was statistically significant. Qnexa was well tolerated in this trial. The study completion rate for patients on Qnexa over the 24-week treatment period was 92%, as compared to 62% for patients in the placebo group. Adverse events occurring in greater than 10% in the Qnexa arm as compared to placebo included paresthesia (mild tingling of the extremities), altered taste and increased urinary frequency. There were no dropouts in the Qnexa arm due to serious or severe adverse events.

In addition, Qnexa treated subjects had a significant reduction of waist circumference, triglycerides, systolic blood pressure C-reactive protein and total cholesterol compared to patients in the placebo group. These findings suggest that Qnexa may improve several important metabolic disease risk factors in obese patients. According to the American Heart Association, The metabolic syndrome is characterized by a group of metabolic risk factors in one person. Such factors include but are not limited to abdominal obesity, and blood fat disorders that foster plaque buildup in artery walls including: high triglycerides, low HDL cholesterol, high LDL cholesterol, and elevated blood pressure. People with metabolic syndrome have an increased risk of coronary heart disease and other conditions that result from the buildup of plaque in artery walls (e.g., stroke and peripheral vascular disease) and type 2 diabetes. The current FDA guidelines state that on its own, metabolic syndrome represents a cluster of laboratory and clinical findings that serve as markers for increased risk for cardiovascular disease and type 2 diabetes, and is prevalent in as much as 25 percent of the adult American population. The FDA does not consider the metabolic syndrome to represent a distinct disease entity. Nonetheless, in addition to lifestyle modification, a host of drug therapies now exist to address individual or multiple components of the syndrome (e.g., lipid altering agents, antihypertensives, insulin sensitizers). We may, in the future, decide to study Qnexa, as a single agent, in a clinical trial that will look to impact the components of metabolic syndrome.

The Phase 2 clinical trial was performed with a twice-a-day dosing formulation. We are finalizing the development of our once-a-day controlled release formulation ahead of the planned Phase 3 clinical trials.

The primary efficacy endpoint for Phase 3 weight loss trials as required by the FDA is demonstration of a mean placebo-subtracted 1-year weight loss of greater than or equal to 5%. Recently issued FDA draft guidelines for obesity products set forth a primary efficacy endpoint in Phase 3 trials of at least 35% of patients achieving 5% weight loss. The weight loss in patients taking the obesity product should also be twice the weight loss of the placebo group. In our Phase 2 trial 82% of patients lost 5% of their baseline weight as compared to 14% in the placebo group. In Europe, The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended that demonstration of significant weight loss of at least 10% of baseline weight is considered to be a valid primary endpoint for anti-obesity drugs. In the Phase 2 study, 50% of the patients on Qnexa lost 10% of their baseline weight as

compared to 8% in the placebo group. The FDA and the Medicines and Healthcare products Regulatory Agency, the regulatory authority in the United Kingdom, require obesity studies to be conducted for at least one year. While the results from our single center Phase 2 trial for six months of treatment meet these guidelines, there can be no assurance that these results can be replicated in a multi-center, one-year, Phase 3 trial.

Our first patent covering Qnexa was issued June 6, 2006. In addition, Qnexa is the subject of multiple U.S. and International patent applications.

Female Sexual Health

We believe the market for the treatment of female sexual health is large and underserved. A paper published in the *Journal of the American Medical Association* in 1999 noted that 43% of women between the ages of 18 and 59 identified themselves as afflicted with a sexual disorder, reporting female sexual arousal disorder and hypoactive sexual desire disorder as the two most common conditions of female sexual dysfunction, or FSD. Currently, there are no pharmaceutical treatments on the market that have been approved by the FDA for the treatment of these sexual disorders in women.

EvaMist

Menopausal Vasomotor Symptoms

Vasomotor symptoms such as hot flashes and vaginal atrophy are reported to be among the most common medical complaints of women going through menopause. Each year an estimated 1.5 million women in the United States enter menopause. As many as 75% of menopausal women experience vasomotor symptoms at some time during menopause, although the frequency and severity may vary. The cause of vasomotor symptoms is related to a decrease in estrogen production by the ovaries that accompanies menopause. As a result, temperature regulation is altered, resulting in increased vasodilation of skin blood vessels and feelings of hot flashes and sweating. Estrogen and estradiol products are generally considered to be highly effective treatments for menopausal vasomotor symptoms. Sales of estrogen products in the United States in 2006 were estimated to be \$1.5 billion.

Premarin®, an oral preparation containing various conjugated estrogens, is the most widely prescribed estrogen therapy in the United States. In 2004, a long-term, large-scale study that evaluated the effects of Premarin was terminated by the National Institutes of Health. This study, called the Women's Health Initiative (WHI), demonstrated an increase in the number of strokes and deep vein thromboses in women receiving Premarin as compared to placebo. This finding may be explained by previously published studies, which showed that when given orally, conjugated equine estrogens (CEE's) are associated with potentially deleterious changes in the plasma concentration triglycerides, inflammatory mediators, and certain clotting factors. We and others believe that these changes may be the result of high oral doses, and possible compounds formed by the liver, as a result of the first pass metabolism of the conjugated equine estrogens.

In contrast to orally administered conjugated estrogens, the use of transdermal estradiol, which avoids first pass metabolism by the liver, has been shown in studies to result in little or no significant changes in triglycerides, inflammatory mediators or clotting factors. A recently published study in *Circulation* reported an increased risk of thrombotic events in patients taking oral CEE's. In the study, patients on CEE's had four times greater risk of venous thromboembolism (VTE) versus patients that had not taken CEE's. In patients using transdermal estrogen there was no increased risk of VTE's. EvaMist is a transdermal delivery of estradiol. EvaMist is not approved, and therefore was not included in this study. Recently published results from the Nurses' Health Study involving over 120,000 women, suggest that initiating hormone therapy at the onset of menopause resulted in an approximate 30% reduction in the risk of coronary heart disease compared to women who never used hormones. These results support that early initiation of hormone therapy in relation to the onset of menopause might have a positive influence on reducing the risk of coronary heart disease in women.

Our Clinical Candidate

EvaMist is our patent protected, estradiol spray investigational product candidate being developed for the treatment of vasomotor symptoms associated with menopause. Vasomotor symptoms (hot flashes) 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 easy to apply, is invisible, and does not wash off when dry. We licensed the U.S. rights for this product from Acrux Limited (Acrux) in 2004. Acrux 's early studies have demonstrated that the Estradiol-MDTS system delivers sustained levels of estradiol to women over a 24-hour period.

Clinical Status

In December 2004, we initiated our Phase 3 study of EvaMist in the United States, under an SPA with the FDA to evaluate its safety and efficacy in menopausal women suffering from vasomotor symptoms. The primary endpoints were 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. We submitted the New Drug Application (NDA) for EvaMist to the FDA in the third quarter of 2006 and the FDA accepted the filing for substantive review. We made a \$1.0 million clinical development milestone payment to Acrux in October 2006 under the terms of our licensing agreement, related to the submission of the NDA for EvaMist. Upon approval of the NDA for EvaMist, a \$3.0 million product approval milestone will be due to Acrux.

Testosterone MDTS

Hypoactive Sexual Desire Disorder

Hypoactive Sexual Desire Disorder (HSDD), 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. Several studies over the last several decades have demonstrated that testosterone is an important component of female sexual desire. As a woman ages, there is a decline in testosterone production. The administration of testosterone has been associated with an increase in sexual desire in both pre- and post-menopausal women. In addition to the gradual decline in testosterone that accompanies aging and natural menopause, the surgical removal of a woman 's ovaries rapidly results in a decrease of approximately one half of the woman 's testosterone production capability. Hence, HSDD can occur much faster, and at a younger age, in women who have undergone this type of surgically induced menopause. Furthermore, HSDD has been observed in pre-menopausal women with naturally occurring low levels of testosterone.

There are no FDA-approved medical treatments for HSDD; however, we noted that there were over 1.4 million units prescribed by OB/Gyns for AndroGel, an approved testosterone treatment for hypogonadism, in 2006. Intrinsa , a transdermal testosterone patch, is currently approved and available for sale in Europe.

Double-blind, multicenter, placebo-controlled clinical trials conducted by The Procter & Gamble Company to assess the effects of a twice-weekly testosterone patch demonstrated a statistically significant increase in the number of satisfying sexual events in surgically induced menopausal women. In addition, an independent clinical study, conducted by Acrux in 261 patients, demonstrated that transdermally applied testosterone has the ability to improve sexual desire in pre-menopausal women with HSDD.

Our Clinical Candidate

Testosterone MDTS is our patent protected, transdermal investigational product candidate being developed 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 humans.

Testosterone MDTS utilizes a proprietary, metered-dose transdermal spray, or MDTS, applicator that delivers a precise amount of testosterone to the skin. We licensed the U.S. rights for this product from Acrux in 2004. The metered spray enables patients to apply a precise dose of testosterone for transdermal delivery. The applied dose dries in approximately 60 seconds and becomes invisible. Secondary contact is not required to rub or spread the application. Acrux's studies have demonstrated that the Testosterone MDTS system delivers sustained levels of testosterone in women over a 24-hour period, achieves an increasing number of satisfying sexual events, and results in substantially lower rates of application site skin irritation than reported in women using testosterone patches.

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

Clinical Status

Previously, we announced positive Phase 2 results for Testosterone MDTS, which showed a statistically significant improvement in the number of satisfying sexual events in pre-menopausal patients with HSDD. In 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 marketing 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 studies. We submitted a Phase 3 safety and efficacy protocol under the SPA process and are currently in discussion with the FDA regarding the details of the protocol.

Male Sexual Health

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

The worldwide sales in 2006 of PDE5 inhibitor products for ED were in excess of \$3.0 billion, including approximately \$1.7 billion in sales of Viagra, approximately \$971 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

Our Clinical Candidate

Avanafil is our orally administered, PDE5 inhibitor investigational product candidate, 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 the current commercially available 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 the treatment of ED.

Clinical Status

We have conducted a number of clinical trials with avanafil, including pharmacokinetic and in-clinic studies as well as at-home efficacy trials in men with ED.

In 2005, we announced positive results from a Phase 2, multicenter, double-blind, randomized, parallel-design study conducted to assess the safety and efficacy of different doses of avanafil for the treatment of ED. Patients in this study were instructed to attempt sexual intercourse 30 minutes after taking avanafil, with no restrictions on food or alcohol consumption. Results showed that up to 84% of avanafil doses resulted in erections sufficient for vaginal penetration, as compared to those who received a dosage of placebo. No serious adverse events were reported during this study.

In 2005, we released the results from an open-label, pharmacokinetic study designed to evaluate the feasibility of allowing avanafil to be taken twice in a 24-hour period. This study compared blood levels of avanafil in healthy volunteer subjects after taking a single dose of avanafil and after taking avanafil every 12 hours for seven days. The results showed no significant plasma accumulation of avanafil after the twice-a-day treatment regimen when compared to the single dose.

In 2005, the results of a clinical pharmacology study conducted to evaluate the hemodynamic responses (blood pressure and heart rate) to glyceryl trinitrate (GTN) in subjects pretreated with placebo, avanafil, and sildenafil citrate (Viagra) were announced. Results revealed that avanafil had less impact on blood pressure and heart rate than Viagra.

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 December 2006, we filed a Special Protocol Assessment for a Phase 3 clinical trial to the FDA. We have received a response to our SPA and we consider the FDA's recommendations to be minor. We are currently making the requested changes to the Phase 3 protocol for resubmission to the FDA.

Our Marketed Product

MUSE

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

Because therapeutic levels of drug are delivered locally to the erectile tissues with minimal systemic drug exposure, MUSE is a relatively safe, local treatment that minimizes the chances of systemic interactions with other drugs or diseases. Over 12 million units of MUSE have been sold since we introduced MUSE to the market.

In May 2005, results were reported from a study, conducted by the Cleveland Clinic, which focused on an individual's ability to restore sexual function following radical prostatectomy, a common treatment for prostate cancer. The study showed that 74% of patients who completed six months of MUSE treatment were able to resume sexual activity and 39% were able to achieve natural erections sufficient for intercourse.

Other Programs

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

ALISTA is our patent protected, alprostadil investigational product that is intended for topical application to the female genitalia prior to sexual activity as a treatment for female sexual arousal disorder, or FSAD. We have completed a multi-center, randomized, double-blind, and placebo-controlled Phase 2b study in over 300 patients. In this study, patients with FSAD using ALISTA achieved a more than doubling over baseline in the number of satisfactory sexual events; however, the difference between the ALISTA treatment group and the placebo group did not achieve statistical significance for the primary endpoint of the study. Due to the outcome of this study, ALISTA will receive a lower development priority at VIVUS.

Government Regulations

FDA Regulation

Prescription pharmaceutical products are subject to extensive pre- and post-marketing regulation by the FDA, including regulations that govern the testing, manufacturing, safety, efficacy, labeling, storage, record-keeping, advertising and promotion of the products under the Federal Food, Drug and Cosmetic Act, and by comparable agencies in most foreign countries.

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

Typically, human clinical trials are conducted in three phases that may overlap. In Phase 1, clinical trials are conducted with a small number of subjects to determine the early safety profile and pharmacology of the new therapy. In Phase 2, clinical trials are conducted with groups of patients afflicted

with a specific disease or medical condition in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety. In Phase 3, large scale, multicenter clinical trials are conducted with patients afflicted with a target disease or medical condition in order to provide enough data for proof of efficacy and safety required by the FDA and others.

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

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

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

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

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

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

Other Government Regulations

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

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

The Medicines and Healthcare products Regulatory Agency (MHRA), the regulatory authority in the United Kingdom, authorized us to begin commercial production and shipment of MUSE from our New Jersey facility in March 1998. We are currently undergoing a routine inspection by the MHRA. Our licensee in Europe, Meda AB (Meda), is responsible for all direct communications with the MHRA, including those regarding any and all regulatory requirements; however, we are responsible for compliance with such requirements. Should the MHRA determine that we have not satisfactorily complied with these regulatory requirements, it could have a material adverse impact on our business, financial condition and results of operations.

Corporate Collaborations and Licenses from Third Parties

Tanabe

In January 2001, we entered into an exclusive Development, Licensing and Supply Agreement with Tanabe for the development of avanafil, a PDE5 inhibitor compound for the oral and local treatment of male and female sexual dysfunction. Tanabe is one of Japan's leading pharmaceutical companies with estimated revenues of over \$1.4 billion in 2006.

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

We paid a \$2.0 million license fee obligation to Tanabe during the year ended December 31, 2006, under the terms of this agreement. We expect to make other substantial payments to Tanabe in accordance with our agreements with Tanabe. These payments are based on certain development, regulatory and sales milestones. In addition, we are required to make royalty payments on any future product sales.

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

of December 31, 2006, we had long-term notes payable to Tanabe Holding America, Inc. of \$6.3 million, and \$2.2 million available for future borrowing.

In February 2007, Tanabe Seiyaku Co., Ltd. and Mitsubishi Pharma Corporation announced that they had reached an agreement in principle on a proposed merger between the two firms. Based on a press release from Tanabe, the merger is scheduled to close on October 1, 2007. It is unclear at this time, what effect, if any, the merger will have on our agreements with Tanabe. There can be no guarantee that the successful merger of Tanabe and Mitsubishi will not have an adverse material effect on our agreements with Tanabe, which in turn could lead to a material adverse effect on our business, financial condition and results of operations.

AcruX

In February 2004, we entered into exclusive licensing agreements with AcruX and its subsidiary under which we have agreed to develop and, if approved, commercialize Testosterone MDTS and EvaMist in the United States for various female health applications. Under the terms of the agreements, we agreed to pay to AcruX combined licensing fees of \$3.0 million, up to \$4.3 million for the achievement of certain clinical development milestones, up to \$6.0 million for achieving product approval milestones, and royalties on net sales in the United States following approval and commercialization of each product. We made a \$1.0 million milestone payment to AcruX in October 2006 related to the submission of a New Drug Application (NDA) to the FDA for EvaMist. We expensed \$1.0 million, \$375,000 and \$3.3 million of clinical development milestone fees under the terms of the agreements in the years ended December 31, 2006, 2005 and 2004, respectively. Upon approval of the NDA for EvaMist, a \$3.0 million product approval milestone will be due to AcruX.

On November 14, 2006, we received a letter from Manatt, Phelps & Phillips LLP on behalf of AcruX and its subsidiary notifying us of an alleged dispute under the Testosterone and Estradiol Development Agreements between VIVUS and AcruX. We believe we are in compliance with all material aspects of both of these agreements and have communicated this belief to AcruX. If we are unable to resolve the matter with AcruX, we intend to seek to enforce our rights under these agreements. The claims have not progressed further, but, to date, the claims have not been formally withdrawn. Development and commercialization of EvaMist and Testosterone MDTS continues as planned and we believe that we have a meritorious defense to claims made by AcruX in connection with the alleged dispute.

Patents and Proprietary Technology

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

We have developed and acquired exclusive rights to patented technology in support of our development and commercialization of our products, and we rely on trade secrets and proprietary technologies in developing potential products. We continue to place significant emphasis on securing global intellectual property rights and are aggressively pursuing new patents to expand upon our strong foundation for commercializing products in development.

Manufacturing

We own the Lakewood, New Jersey manufacturing facilities, which are primarily used for formulation, filling, packaging, analytical laboratories, storage, distribution and administrative offices. The facility is cGMP certified and includes class 10,000 clean rooms used in the sterile production of MUSE. The facilities include two buildings totaling 90,000 square feet, although one of the buildings is used for warehousing component parts. The FDA and the Medicines and Healthcare products Regulatory Agency

(MHRA), authorized us to begin commercial production and shipment of MUSE from this facility in June and March 1998, respectively. We are currently undergoing a routine inspection by the MHRA. We manufacture all of the worldwide demand for MUSE in this facility.

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

Sales and Marketing

We intend to market EvaMist, if approved by the FDA, through a partner, or through an internal sales force, calling on OB/GYN doctors, the primary prescribers of hormone therapies. We believe this intended direct marketing of EvaMist will allow us to establish relationships with the OB/GYN physician community and to familiarize them with our MDTS technology in anticipation of the FDA's approval of Testosterone-MDTS and its entering the market. We intend to use these relationships to promote Testosterone-MDTS, our future product candidate in the female sexual health market.

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

We anticipate that we will require additional funding to support internal sales and marketing efforts of our future products that we intend to market ourselves. We may seek to access the public or private equity markets whenever conditions are favorable. We may also seek additional funding through strategic alliances and other financing mechanisms. We cannot assure you that adequate funding will be available on terms acceptable to us, if at all. We cannot assure you that we will successfully market our products under development or that our products, if successfully marketed, will generate revenues sufficient to enable us to earn a profit.

We support MUSE sales in the United States with a direct sales team comprised of regional sales managers and telesales personnel calling on specialist physicians. We signed an international distribution agreement with Meda AB in 2002. According to the agreement, Meda will purchase MUSE from us for resale in member states of the European Union and certain other European countries. The agreement with Meda provides that Meda will earn a predetermined profit percentage on product sales. The transfer price at which we sell to Meda may change depending on the final price to the customer and the foreign exchange rate in the country where MUSE is sold. The current transfer price is in excess of the variable costs of manufacturing MUSE. Since our current facility is below maximum capacity, units sold to Meda contribute to reimbursement for the fixed costs of the manufacturing facilities. If the final selling price and/or the foreign exchange rate decreases, the gross profits on the sales of MUSE to Meda will decrease. In November 2000, we granted Paladin Labs the exclusive rights to distribute and market MUSE in Canada.

Competition

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

Current anti-obesity products include Xenical (orlistat), marketed by Roche, and Meridia (sibutramine), marketed by Abbott Labs. Orlistat works by inhibiting lipase, an enzyme that blocks the absorption of fat in the gastrointestinal tract. In 2005, Xenical accounted for approximately \$87 million in

sales in the United States, according to IMS Health. Orlistat was recently launched over-the-counter by GlaxoSmithKline under the brand name Alli. 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.

Despite the large market opportunity for anti-obesity agents, there are relatively few competitive products in late stage clinical development. Rimonabant, which has been developed by Sanofi-Aventis under the U.S. brand name Acomplia and in Europe as Zimulti, is the most advanced. It has been approved in certain countries outside of the United States and has received an approvable letter from the FDA relating to potential marketing in the United States. Rimonabant is the first in a new class of anti-obesity drugs that work as antagonists at the cannabinoid type 1, or CB-1, receptor. This is the same receptor that is stimulated by cannabis. While rimonabant has shown efficacy (average 4.7kg or 4.85%) across several large Phase III clinical trials at the highest dose tested, it has also been associated with significant CNS side effects, including depression and related symptoms, according to a 2006 report published in *Drugs*. The overall risk-to-benefit profile of rimonabant is yet to be defined. Analysts estimate that peak sales of Acomplia for obesity could exceed \$3.0 billion.

The most significant competitive therapy for MUSE is an oral medication marketed by Pfizer under the name Viagra, which received regulatory approvals in the United States in March 1998 and in the European Union in September 1998. The commercial launch of Viagra in the United States in April 1998 significantly decreased demand for MUSE. In February 2003, an oral medication under the name Cialis was launched in Europe by Lilly ICOS LLC. Lilly ICOS LLC launched Cialis in the United States in November 2003. Bayer AG and GlaxoSmithKline plc (GSK) launched Levitra in the European Union in March 2003 and in the United States in September 2003. In 2005, the co-promotion rights of GSK on Levitra were transferred back to Bayer in many markets outside of the U.S. and currently, GSK shares co-promotion rights on Levitra in the U.S. with Schering-Plough.

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

Several companies are developing products that could compete with our clinical candidates for the treatment of FSD. The Proctor & Gamble Company has developed a testosterone patch for the treatment of HSDD in Europe. BioSante Pharmaceuticals, Inc. is developing a testosterone gel for HSDD. Palatin Technologies, Inc. and others are also developing various nasal sprays to treat FSD. None of these products has been approved by the FDA. In July 2006, the European Medicines Agency (EMA) granted marketing authorization of Intrinsa for the treatment of HSDD in bilaterally oophorectomized and hysterectomized women. This product has launched in Germany and France.

Research and Development

We spent \$13.3 million in 2006, \$17.0 million in 2005, and \$18.7 million in 2004 on research, primarily to discover and develop our late-stage clinical products in obesity and to restore sexual function in men and women, to license from third parties the rights to products to treat various sexual and nonsexual disorders and to sponsor early stage clinical trials at various research institutions.

Employees

As of February 28, 2007, we had 114 employees, including 75 of which are located at our manufacturing facility in Lakewood, New Jersey and 39 of which are located at our corporate headquarters in Mountain View, California and other United States locations. None of our current employees are represented by a labor union or are the subject of a collective bargaining agreement. We believe that we maintain good relations with our employees.

Insurance

We maintain product liability insurance for our currently marketed product, MUSE, and our clinical trials. Insurance coverage is becoming increasingly expensive, and no assurance can be given that we will be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. There can also be no assurance that we will be able to obtain commercially reasonable product liability insurance for any products approved for marketing.

International Operations

We entered into an agreement granting Meda AB exclusive marketing and distribution rights for MUSE in member states of the European Union and we entered into an agreement granting Paladin Labs, Inc. exclusive marketing and distribution rights for MUSE in Canada. Meda currently sells MUSE in the United Kingdom, Ireland, Sweden, Norway, Germany, Switzerland, Denmark, Finland, France and the Netherlands. International product revenues from the sales of MUSE to these distributors is included in the financial statements and notes thereto appearing elsewhere in this Form 10-K. International sales are subject to certain additional risks inherent in conducting business outside the United States, including changes in overseas economic and political conditions, terrorism, currency exchange rates, foreign tax laws and tariffs and other governmental action.

Available Information

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to reports filed pursuant to Section 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, are available on our website at www.vivus.com, when such reports are available on the Securities and Exchange Commission website. Copies of our annual report will be made available, free of charge, upon written request.

The public may read and copy any materials filed by VIVUS with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at <http://www.sec.gov>. The contents of these websites are not incorporated into this filing. Further, VIVUS' references to the URLs for these websites are intended to be inactive textual references only.

In addition, information regarding our code of ethics and the charters of our Audit, Compensation and Nominating and Governance Committees, are available free of charge on our website listed above, or in print upon written request.

Item 1A. *Risk Factors*

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

Risks Relating to our Product Development Efforts

We face significant risks in our product development efforts.

The process of developing new drugs and/or therapeutic products is inherently complex, time-consuming, expensive and uncertain. We must make long-term investments and commit significant resources before knowing whether our development programs will result in products that will receive regulatory approval and achieve market acceptance. Product candidates that may appear to be promising at all 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 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, and may never have, any experience in managing Phase 3 clinical trials for obesity. 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.

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

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

We will be required to demonstrate through larger-scale clinical trials that these product candidates are safe and effective for use in a broad 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. EvaMist has completed a Phase 3 clinical trial program. If any of our investigational products fails to demonstrate sufficient safety and efficacy in any clinical trial, we will experience potentially significant delays in, or decide to abandon development of, that product candidate. If we abandon or are delayed in our development efforts related to any of our investigational products we may not be able to generate sufficient revenues to continue our operations and clinical studies at the current level or become profitable, our reputation in the industry and in the investment community would likely be significantly damaged, it may not be possible for us to complete financings, and our stock price would likely decrease significantly.

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

Unfavorable results from ongoing pre-clinical studies and/or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials. 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.

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

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

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

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

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

All of the drug candidates that we are currently developing require extensive pre-clinical and/or clinical testing before we can submit any application for regulatory approval. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through pre-clinical testing and/or clinical trials that our product candidates are safe and effective in humans. Conducting clinical trials is a lengthy, expensive and uncertain process. Completion of clinical trials may take several years or more. Our ability to complete clinical trials may be delayed by many factors, including, but not limited to:

- inability to manufacture sufficient quantities of compounds for use in clinical trials;
- failure to receive approval by the United States Food and Drug Administration, or FDA, of our clinical trial protocols;
- changes in clinical trial protocols imposed by the FDA;
- the effectiveness of our product candidates;
- slower than expected rate of and higher than expected cost of patient recruitment;
- inability to adequately follow patients after treatment;
- unforeseen safety issues;
- government or regulatory delays; or
- our ability to raise the necessary cash to start or complete the trials.

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) is known as fen-phen . Fenfluramine received FDA approval in 1973 for the short-term treatment of obesity. Together, phentermine and fenfluramine were used by doctors to treat obesity. The FDA never approved the fen-phen combination; however, since the FDA approved fenfluramine, doctors were able to prescribe it as needed. The use of these drugs together for treatment of obesity was considered an off-label 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 (phen). Dexfenfluramine received FDA approval in 1996 for use as an appetite suppressant in the management of obesity.

The dexfen-phen combination 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 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. The FDA has requested we provide our plans regarding the collection of echocardiograms and cardiovascular monitoring of some patients in the proposed Phase 3 studies. Moreover, the adverse clinical history of fen-phen and dexfen-phen combinations for obesity may result in increased FDA regulatory scrutiny of the safety of Qnexa and may raise potential adverse publicity in the marketplace, which could affect clinical enrollment or ultimately market acceptance if Qnexa is approved for sale.

Previous published studies 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.

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

To date, the clinical results we have obtained do not necessarily predict that the results of further testing, including larger, late-stage controlled human clinical testing, will be successful. If our trials are not successful or are perceived as not successful by the FDA or physicians, our business, financial condition and results of operations will be materially harmed.

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

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

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

To obtain regulatory approval for Qnexa, we will be required to show that each active pharmaceutical ingredient in the product candidate makes a contribution to the combined product candidate's claimed effects and that the dosage of each component, including amount, frequency and duration, is such that the combination is safe and effective for a significant patient population. 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 FDA revised guidelines for obesity set forth the Phase 2 requirements for combination products. While we believe we have met these requirements, there can be no assurance that the FDA will agree and that we can proceed with a Phase 3 clinical protocol that includes only a Qnexa and placebo comparison.

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.

On November 14, 2006, we received a letter from Manatt, Phelps & Phillips LLP on behalf of Acrux DDS Pty Ltd., FemPharm PTY Ltd. and Acrux Limited (collectively Acrux) notifying us of an alleged dispute under the Testosterone and Estradiol Development Agreements between Vivus and Acrux. We believe we are in compliance with all material aspects of both of these agreements and have communicated this belief to Acrux. If we are unable to resolve the matter with Acrux, we intend to seek to enforce our rights under these agreements. The claims have not progressed further, but, to date, the claims have not been formally withdrawn. Development and commercialization of EvaMist and Testosterone MDTS continues as planned. We believe that we have a meritorious defense to claims made by Acrux in connection with the alleged dispute; however, in the event that Acrux should prevail in this matter, it may have a material adverse effect on our business, financial condition and results of operations. 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.

In February 2007, Tanabe Seiyaku Co., Ltd. and Mitsubishi Pharma Corporation announced that they had reached an agreement in principle on a proposed merger between the two firms. Based on a press release from Tanabe, the merger is scheduled to close on October 1, 2007. It is unclear at this time, what effect, if any, the merger will have on our agreements with Tanabe. There can be no guarantee that the successful 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 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.

For example, in December 2004, an FDA advisory panel recommended against approval of a testosterone patch under development by another company to address female sexual dysfunction, specifically hypoactive sexual desire disorder. The FDA indicated that more safety data would be required before it would be in a position to recommend approval. Subsequently, this company withdrew its New Drug Application. 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 and the cause of significant delays in our ability to submit our product candidate to the FDA for consideration. In the end, we may be unsuccessful in obtaining FDA approval of our product candidate.

We are not permitted to market any of our investigational product candidates in the United States until we receive approval from the FDA. As a consequence, any failure to obtain or delay in obtaining FDA approval for our product candidates would delay or prevent our ability to generate revenue from our product candidates, which would adversely affect our financial results and our business. We submitted the New Drug Application (NDA) for EvaMist to the FDA in the third quarter of 2006. A material delay in the approval of the NDA for EvaMist, or in the ultimate commercial launch of EvaMist would have a material adverse impact on our stock price and financial condition.

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

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

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

If one of our investigational product candidates is approved by the FDA or by another regulatory authority for a territory outside of the United States, we will 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 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, 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 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 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 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 proposed product candidates and may not be able to successfully commercialize these proposed product candidates.

We have identified third party suppliers of the various components and materials, including API, of the EvaMist product; however, the contractual terms have not yet been finalized. If the NDA for EvaMist is approved, we will likely rely on single source suppliers for the EvaMist product in the commercial launch quantities. There can be no assurance that we will be able to finalize the contractual terms with these suppliers, or that once finalized, these suppliers will be successful in supplying product to our specifications within our launch timetable.

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

We are continuing the formulation development of Qnexa. Currently, we have not finalized the once-a-day formulation. We have selected the contract manufacturer to develop a once-a-day formulation. There can be no assurance that the final 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 and financial condition.

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, 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 the U.S. market through the end of the third quarter of 2007, as well as support the production of MUSE for our international markets through the end of 2008. There can be no assurance that as this bulk supply is used through the end of the third quarter of 2007 for U.S. product, and through the end of 2008 for international product, that there will be a sufficient yield in the final quantity of foil with acceptable quality to support the respective 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 2008. If such foil quality issues do occur, we may be unable to meet MUSE demand in 2007 and 2008.

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 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.

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.

We are currently undergoing a routine inspection by the MHRA. Our licensee in Europe, Meda AB (Meda), is responsible for all direct communications with the MHRA, including those regarding any and all regulatory requirements; however, we are responsible for compliance with such requirements. Should the MHRA determine that we have not satisfactorily complied with these regulatory requirements, it could have a material adverse impact on our business, financial condition and results of operations.

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 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.

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. 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.

If we are unable to establish capabilities to sell, market and distribute our products, either by developing our own capabilities or entering into agreements with others, we will not be able to successfully launch EvaMist or any of our other 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 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 and sexual health. These companies have substantially greater research and development capabilities as well as substantially greater marketing, financial and human resources than we do. In addition, many of these companies have significantly greater experience than us in undertaking pre-clinical testing, human clinical trials and other regulatory approval procedures. Our competitors may develop technologies and products that are more effective than those we are currently marketing or developing. Such developments could render our products less competitive or possibly obsolete. We are also competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have limited experience.

Current anti-obesity products include Xenical (orlistat), marketed by Roche, and Meridia (sibutramine), marketed by Abbott Labs. Orlistat is marketed in the United States by Roche Laboratories, Inc. under the brand name Xenical. Orlistat works by inhibiting lipase, an enzyme that blocks the absorption of fat in the gastrointestinal tract. In 2005, Xenical accounted for approximately \$87 million in sales, in the United States, according to IMS Health. Orlistat was recently launched over-the-counter in the United States by GlaxoSmithKline under the brand name Alli. 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 extensively used for this indication in an off-label manner.

Despite the large market opportunity for anti-obesity agents, there are relatively few competitive products in late stage clinical development. Rimonabant, which has been developed by Sanofi-Aventis under the U.S. brand name Acomplia and in Europe as Zimulti, is the most advanced. It has been approved in certain countries outside of the United States and has received an approvable letter from the FDA relating to potential marketing in the United States. Rimonabant is the first in a new class of anti-obesity drugs that work as antagonists at the cannabinoid type 1, or CB-1, receptor. This is the same receptor that is stimulated by cannabis. While rimonabant has shown efficacy (average 4.7kg or 4.85%) across several large Phase III clinical trials at the highest dose tested, it has also been associated with significant CNS side effects, including depression and related symptoms, according to a 2006 report published in *Drugs*. The overall risk-to-benefit profile of rimonabant is yet to be defined. Acomplia received an approval letter from the FDA in February 2006, but the PDUFA date has been pushed to July 2007. Analysts estimate that peak sales of Acomplia for obesity could exceed \$3.0 billion.

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 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 obesity product candidate.

Other products are also in development which could become successful competitors against our obesity product candidate, Qnexa. These include products being developed by Arena Pharmaceuticals, Inc., Amylin Pharmaceuticals, Inc., Alizyme plc, Merck & Co., Inc., Peptimmune, Inc. and Orexigen Therapeutics, Inc., among others. With the exception of Orexigen Therapeutics, Inc., most of these efforts are directed toward a monotherapeutic approach which we would expect to be subject to the same early weight loss plateau typically seen.

Significant competitive therapy for MUSE exists in the form of oral medications marketed by Pfizer, Inc. under the name Viagra®, Cialis® which was launched in Europe by Lilly ICOS LLC and Levitra® which is marketed by Bayer AG, GlaxoSmithKline plc and Schering-Plough Corp in the United States and the European Union.

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.

Several companies are developing products that could compete with our product candidates for the treatment of FSD including: The Proctor & Gamble Company is developing Intrinsa, a testosterone patch for the treatment of HSDD; BioSante Pharmaceuticals, Inc. is developing forms of testosterone gels for HSDD and Palatin Technologies, Inc. is developing a nasal spray to treat FSD. None of these products has been approved by the FDA. In July 2006, the European Medicines Agency (EMA) 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.

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 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
- 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 product candidates.

If our raw material suppliers fail to supply us with the Active Pharmaceutical Ingredients for our products and 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 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.

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.

In addition, we currently do not have manufacturing agreements in place for topiramate, phentermine or Estradiol. 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.

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 the individual plastic component parts and materials, including API, of the EvaMist product, and an interruption to these supply sources 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.

The Phase 3 clinical studies of EvaMist were conducted using the first generation MDTS applicator. We have improved on the design of the housing used in the MDTS applicator, which we believe will allow us to manufacture EvaMist more efficiently than with the previous design. Should the FDA approve our NDA for EvaMist, in the early stages of our commercial launch we intend to single source the individual component parts of the EvaMist MDTS applicator. An extended interruption in the supply of plastic components could have a material adverse impact on the commercialization of EvaMist and our financial condition and results of operations.

We have identified third party suppliers of the various components and materials, including API, of the EvaMist product; however, the contractual terms have not yet been finalized. If the NDA for EvaMist is approved, we will likely rely on single source suppliers for the EvaMist product in the commercial launch quantities. There can be no assurance that we will be able to finalize the contractual terms with these suppliers, or that once finalized, these suppliers will be successful in supplying product to our specifications within our launch timetable.

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 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 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.

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 U.S. importation laws and expand consumers' ability to import lower priced versions of our product candidates and competing products from Canada, where there are government price controls. These changes to U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 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 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 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Relating to our Financial Position and Need for Financing

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

Our capital resources are expected to continue to decline over the next several quarters as the result of spending on research and development projects, including clinical trials. On July 14, 2006, VIVUS, Inc. filed with the Securities and Exchange Commission (SEC) a shelf Registration Statement on Form S-3. The shelf Registration Statement (File Number 333-135793) was declared effective by the SEC on August 16, 2006, providing us with the ability to offer and sell up to an aggregate of \$80.0 million of common stock from time to time in one or more offerings. The terms of any such future offering would be established at the time of such offering. On 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 \$12.0 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 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 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 under shelf Registration Statement (File No. 333-121159), 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 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 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;
- 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 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 \$168.7 million as of December 31, 2006 and expect to continue to incur substantial operating losses for the foreseeable future.

We have generated a cumulative net loss of \$168.7 million for the period from our inception through December 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.

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

As of December 31, 2006, we had approximately \$186.6 million of net operating loss (NOL) carryforwards with which to offset our future taxable income for federal and California income tax reporting purposes. 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.

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.

Edgar Filing: VIVUS INC - Form 10-K

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

40

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.

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

Item 1B. *Unresolved Staff Comments*

None.

42

Item 2. *Properties*

We own two buildings with a combined 90,000 square feet in Lakewood New Jersey, although one of the buildings is used for warehousing component parts. These buildings are used for our MUSE manufacturing operation, which includes formulation, filling, packaging, analytical laboratories, storage, distribution and administrative offices. The United States Food and Drug Administration and the Medicines and Healthcare products Regulatory Agency, formerly the Medicines Control Agency, the regulatory authority in the United Kingdom, authorized us to begin commercial production and shipment of MUSE from this facility in June and March 1998, respectively. We have met all market demands for the supply of MUSE utilizing this manufacturing facility and currently have the capacity to manufacture additional quantities of MUSE if required.

In November 2006, we entered into a new 30-month lease for the existing Mountain View corporate headquarters location with our existing landlord. The new lease commenced on February 1, 2007. The base monthly rent is set at \$1.85 per square foot or \$26,000 per month. The new lease expires on July 31, 2009 and allows VIVUS one option to extend the term of the lease for a period of one year from the expiration of the lease.

In general, our existing facilities, owned or leased, are in good condition and adequate for all present and near term uses.

Item 3. *Legal Proceedings*

In the normal course of business, VIVUS receives and makes inquiries regarding patent infringement and other legal matters.

We have received notice from a former employee seeking payment due to their termination in 2005 and in the third quarter of 2006, we concluded this matter without a material impact on our financial position.

On November 14, 2006, we received a letter from Manatt, Phelps & Phillips LLP on behalf of Acrux DDS Pty Ltd., FemPharm PTY Ltd. and Acrux Limited (collectively Acrux) notifying VIVUS of an alleged dispute under the Testosterone and Estradiol Development Agreements between VIVUS and Acrux. We believe we are in compliance with all material aspects of both of these agreements and have communicated this belief to Acrux. If we are unable to resolve the matter with Acrux, we intend to seek to enforce our rights under these agreements. The claims have not progressed further, but, to date, the claims have not been formally withdrawn. Development and commercialization of EvaMist and Testosterone MDTS continues as planned. We believe that we have a meritorious defense to claims made by Acrux in connection with the alleged dispute; however, in the event that Acrux should prevail in this matter, it could have a material adverse effect on VIVUS' business, financial condition and results of operations.

We are not aware of any other asserted or unasserted claims against us where the resolution would have an adverse material impact on our operations or financial position.

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

None.

PART II**Item 5.** *Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.*

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

	Three Months Ended			
	March 31	June 30	September 30	December 31
2006				
High	\$ 3.72	\$ 5.34	\$ 4.30	\$ 4.20
Low	2.95	2.92	3.05	3.29
2005				
High	\$ 4.54	\$ 3.95	\$ 4.57	\$ 3.54
Low	2.81	2.32	3.44	2.87

Stockholders

As of February 26, 2007, there were 58,258,296 shares of outstanding common stock that were held by 4,251 shareholders of record and no outstanding shares of preferred stock. On February 26, 2007, the last reported sales price of our common stock on the NASDAQ National Market was \$4.00 per share.

Dividends

We have not paid any dividends since our inception and we do not intend to declare or pay any dividends on our common stock in the foreseeable future. Declaration or payment of future dividends, if any, will be at the discretion of our Board of Directors after taking into account various factors, including VIVUS' financial condition, operating results and current and anticipated cash needs.

Stock Options

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

Pursuant to our 2001 Stock Option Plan, or the 2001 Plan, which was approved by the stockholders at the annual meeting held on June 5, 2002, we may grant incentive or non-statutory stock options or stock purchase rights, or SPRs. The 2001 Plan allows us to grant incentive stock options to employees at not less than 100% of the fair market value of the stock (110% of fair market value for individuals who control more than 10% of our stock) at the date of grant, as determined by the Board of Directors. The 2001 Plan allows us to grant non-statutory stock options to employees, directors and consultants at a price to be determined by the Board of Directors. The term of the option is determined by the Board of Directors on the date of grant but shall not be longer than ten years. The 2001 Plan allows us to grant SPRs to employees and consultants. Sales of stock under SPRs are made pursuant to restricted stock purchase agreements containing provisions established by the Board of Directors. We have a right, but not the obligation, to repurchase the shares at the original sale price, which expires at a rate to be determined by the Board of Directors. As of December 31, 2006, no SPRs have been granted under the 2001 Plan.

On July 12, 2006, the Board of Directors adopted an amendment to the 2001 Plan to add the ability to issue Restricted Stock Units, or RSUs, under the 2001 Plan. In contrast to restricted stock awards, the newly permitted RSUs would represent an obligation of VIVUS to issue unrestricted shares of common stock or cash to the grantee only when and to the extent that the vesting criteria of the award are satisfied. As in the case of restricted stock awards, vesting criteria for RSUs can be based on time or other

conditions specified by the Board or an authorized committee of the Board. However, until vesting occurs, the grantee is not entitled to any stockholder rights with respect to the unvested shares. Upon vesting of an RSU, the recipient receives one share of VIVUS stock for each vested restricted stock unit or a cash payment for the value thereof. VIVUS, in its sole discretion, may pay earned RSUs in cash, shares, or a combination thereof. Shares represented by RSUs that are fully paid in cash again will be available for grant under the Plan. We issue new shares for settlement of vested restricted stock units and exercises of stock options. We do not have a policy of purchasing our shares relating to our share-based programs.

Additional information regarding our stock option plans and plan activity for fiscal 2006, 2005, and 2004 is provided in our consolidated financial statements. See Notes to Consolidated Financial Statements, Note 8 Stock Option and Purchase Plans .

Equity Compensation Plans Approved by Stockholders

Information about our equity compensation plans at December 31, 2006 that were approved by our stockholders was as follows:

Plan Category	Number of Shares to be issued Upon Exercise of Outstanding Options and Rights	Weighted Average Exercise Price of Outstanding Options	Number of Shares Remaining Available for Future Issuance
Equity compensation plans approved by stockholders(a)	4,612,652	\$ 4.21	1,914,080
Equity compensation plans not approved by stockholders(b)		\$	
Total	4,612,652	\$ 4.21	1,914,080

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

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

Corporate Performance Graph

The following graph shows a comparison of total stockholder return for holders of our Common Stock from December 31, 2001, through December 31, 2006 compared with the NASDAQ Stock Market (U.S.) Index and RDG Microcap Pharmaceutical Index. Total stockholder return assumes \$100 invested at the beginning of the period in our Common Stock, the stock represented in the NASDAQ Stock Market (U.S.) Index and the stock represented by the RDG Microcap Pharmaceutical Index, respectively. This graph is presented pursuant to SEC rules. We believe that while total stockholder return can be an important indicator of corporate performance, the stock prices of microcap pharmaceutical stocks like VIVUS are subject to a number of market-related factors other than company performance, such as competitive announcements, mergers and acquisitions in the industry, the general state of the economy, and the performance of other medical technology stocks.

Item 6. *Selected Financial Data*

The following selected financial data have been derived from our audited financial statements. The information set forth below is not necessarily indicative of the results of future operations and should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations and the financial statements and notes thereto included elsewhere in this Annual Report on Form 10-K. The selected data is not intended to replace the financial statements.

Selected Financial Data
(In thousands, except per share)

Selected Annual Financial Data

	Year Ended December 31				
	2006	2005	2004	2003	2002
<i>Income Statement Data:</i>					
Product revenue United States, net	\$ 14,280	\$ 11,697	\$ 16,419	\$ 18,953	\$ 20,962
Product revenue International	2,377	2,794	3,030	3,302	1,237
Other revenue	588	163	152	5,183	150
Total revenue	17,245	14,654	19,601	27,438	22,349
Operating expenses:					
Cost of goods sold and manufacturing expense	11,933	11,018	11,283	10,993	11,207
Research and development	13,316	17,005	18,676	7,724	13,281
Selling, general and administrative	14,579	11,916	11,730	9,839	10,556
Total operating expenses	39,828	39,939	41,689	28,556	35,044
Loss from operations	(22,583)	(25,285)	(22,088)	(1,118)	(12,695)
Interest and other income, net	979	826	511	773	1,211
Loss before taxes	\$ (21,604)	\$ (24,459)	\$ (21,577)	\$ (345)	\$ (11,484)
Net loss	\$ (21,624)	\$ (24,484)	\$ (21,583)	\$ (26)	\$ (10,566)
Net loss per basic and diluted share	\$ (0.45)	\$ (0.57)	\$ (0.57)	\$ (0.00)	\$ (0.32)
Shares used in per share computation	48,103	43,272	38,010	35,884	32,907
<i>Balance Sheet Data (at year end):</i>					
Working capital	\$ 57,564	\$ 23,569	\$ 25,466	\$ 30,099	\$ 18,974
Total assets	\$ 78,214	\$ 49,282	\$ 54,389	\$ 66,732	\$ 49,681
Long-term debt	\$ 11,488	\$ 5,164	\$ 3,239	\$	\$
Accumulated deficit	\$ (168,651)	\$ (147,027)	\$ (122,543)	\$ (100,960)	\$ (100,934)
Stockholders' equity	\$ 53,140	\$ 26,601	\$ 30,722	\$ 51,235	\$ 34,385

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

Forward Looking Statement

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

All percentage amounts and ratios were calculated using the underlying data in thousands. Operating results for the year ended December 31, 2006, are not necessarily indicative of the results that may be expected for future fiscal years. The following discussion and analysis should be read in conjunction with our historical financial statements and the notes to those financial statements that are included in Item 8. of Part II of this Form 10-K.

Overview

VIVUS, Inc. is a 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, postmenopausal and sexual health. All 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 postmenopausal and sexual health products each represent a projected market greater than \$1 billion annually.

We are currently advancing four late-stage clinical products, each addressing specific components of these significant markets. One of these products has completed Phase 3 testing and we submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the third quarter of 2006. The remaining products are being prepared to enter Phase 3 clinical trials. In 1997, we launched MUSE (alprostadil) in the United States and, together with our partners, internationally. We market MUSE as a prescription product for the treatment of erectile dysfunction.

Our investigational product pipeline includes:

- **Qnexa™** for treating obesity, for which a Phase 2 study has been completed;
- **EvaMist™** to treat vasomotor symptoms associated with menopause, for which we submitted an NDA to the FDA in the third quarter of 2006;

- **Testosterone MDTs®** is being developed to treat hypoactive sexual desire disorder, for which a Phase 2 study has been completed; and
- **Avanafil** is being developed for the treatment of erectile dysfunction; for which Phase 2 studies have 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 leader in the development and commercialization of products that help to treat obesity and restore sexual health in women and men. We believe that we have strong intellectual property supporting several opportunities in obesity treatment and sexual health. Our future growth will come from further development and regulatory approval of our product candidates as well as in-licensing and product line extensions.

We have funded operations primarily through private and public offerings of our common stock and through product sales of MUSE. We expect to generate future net losses due to increases in operating expenses as product candidates are advanced through the various stages of clinical development. As of December 31, 2006, we have incurred a cumulative deficit of \$168.7 million and expect to incur operating losses in the near future.

Critical Accounting Policies and Estimates

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

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

Revenue Recognition

Product Revenue: Product sales are recognized as revenues when persuasive evidence of an arrangement exists, shipment has occurred, the sales price is fixed or determinable and collectibility is reasonably assured.

Sales Allowances and Reserves: Revenues from product sales are recorded net of product sales allowances for expected returns of expired product, government chargebacks, other rebates, and cash discounts for prompt payment. These sales allowances are deducted from gross product revenues at the time such revenues are recognized along with the recording of a corresponding reserve, or liability. In making these estimates we take into consideration our historical information, current contractual and statutory requirements, shelf life of our products, estimated customer inventory levels and information received from outside parties. Significant judgments and estimates must be made and used in estimating the reserve balances in any accounting period. Our product sales allowances and reserves include:

- **Product Returns:** We have estimated reserves for product returns from wholesalers, hospitals and pharmacies in the United States in accordance with our product returns policy. Our returns policy allows product returns within the period beginning six months prior to and twelve months following product expiration. As of December 31, 2006 the shipments of MUSE in the United States made in 2006, 2005 and a portion of the shipments in 2004 remain subject to future returns.

We record reserves for anticipated returns of expired product in the United States. We follow this method since reasonably dependable estimates of product returns can be made based on historical experience. There is no right-of-return on expired product sold internationally subsequent to shipment; thus, no returns reserve is needed.

We estimate our return reserve by utilizing historical information and data obtained from external sources, along with the shelf life of the product. We track the actual returns on a lot-by-lot basis along with date of production and date of expiration. We review the actual returns experience for trends. We calculate our returns reserve by applying an estimated return rate to the quantity of units sold that are subject to future return. We routinely assess our experience with product returns and adjust the reserves accordingly. Revisions in returns estimates are charged to income in the period in which the information that gives rise to the revision becomes known.

- **Government Chargebacks:** Government chargebacks are contractual commitments by us to provide MUSE to Federal government organizations including the Veterans Administration at specified prices. Government chargeback allowances are recorded at the time of sale and accrued as a reserve. In estimating the government chargeback reserve, we analyze actual chargeback amounts and apply chargeback rates to estimates of the quantity of units subject to chargeback. We routinely reassess the chargeback estimates and adjust the reserves accordingly.
- **Other Rebates:** We estimate amounts payable by us for Medicare Part D rebates, Medicaid rebates to states for goods purchased by patients covered by Medicaid, and other rebate programs, primarily with managed care organizations, for the reimbursement of portions of the prescriptions filled that are covered by these programs. Rebate allowances are estimated and reserved at the time of sale. We estimate this reserve by utilizing historical information, contractual and statutory requirements, estimated quantities sold to these organizations and estimated customer inventory levels. Effective January 1, 2006, MUSE no longer qualifies for Medicaid reimbursement, which has not had a significant impact on our business. Effective January 1, 2007, MUSE will no longer qualify for Medicare Part D, which we do not believe will have a significant impact on our business.

- **Cash Discounts:** We offer cash discounts to wholesaler distributors, generally 2% of the sales price as an incentive for prompt payment. The estimate of cash discounts is recorded at the time of sale. We account for the cash discounts by reducing accounts receivable by the full amount of the discounts we expect wholesaler distributors to take.

All of the aforementioned categories of sales allowances are evaluated each reporting period and adjusted when trends or significant events indicate that a change in estimate is appropriate. Changes in actual experience or changes in other qualitative factors could cause our sales allowance

adjustments to fluctuate. If actual returns, government chargebacks, Medicare rebates, other rebates and cash discounts are greater than our estimates, additional reserves may be required which could have an adverse effect on financial results in the period of adjustment. Revisions to estimates are charged to income in the period in which the facts that give rise to the revision become known.

Other Revenue: Revenue from non-refundable, upfront license fees where we have continuing involvement is recognized ratably over the development or agreement period. Revenue associated with performance milestones is recognized based upon the achievement of the milestones, as defined in the respective agreements.

Research and Development Expenses

Research and development (R&D) expenses include license fees, related compensation, contractor fees, facilities costs, administrative expenses and clinical trials at other companies and research institutions under agreements which are generally cancelable, among other related R&D costs. We also record accruals for estimated clinical study costs. Clinical study costs represent costs incurred by clinical research organizations, or CROs, and clinical sites. These costs are recorded as a component of R&D expenses. We analyze the progress of the clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of accrued liabilities. Significant judgments and estimates must be made and used in determining the accrued balance in any accounting period. Actual results could differ from those estimates under different assumptions. Revisions are charged to expense in the period in which the facts that give rise to the revision become known.

Accounts Receivable and Allowance for Doubtful Accounts

We extend credit to our customers for product sales resulting in accounts receivable. For qualified customers, we grant payment terms of 2%, net 30 days. Customer accounts are monitored for past due amounts. Past due accounts receivable, determined to be uncollectible, are written off against the allowance for doubtful accounts. Allowances for doubtful accounts are estimated based upon past due amounts, historical losses and existing economic factors, and are adjusted periodically. The accounts receivable are reported on the balance sheet, net of the allowance for doubtful accounts.

Income Taxes

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

Inventories

We record inventory reserves for estimated obsolescence, unmarketable or excess inventory equal to the difference between the cost of inventory and the estimated market value based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required. In 2006, we recorded a \$764,000 inventory write-down related to the purchase of alprostadil, considered to be in excess of projected production needs. During the quarter ended September 30, 1998, we established significant

reserves against our inventory to align with new estimates of expected future demand for MUSE. As of December 31, 2006, the remaining inventory reserve balance is \$4.4 million relating to raw materials and components. Some portion of the fully reserved inventory was used in production in 2004, 2005 and 2006. In the fourth quarter of 2004, we stopped using the fully reserved raw materials inventory in production and determined that we would not likely use this inventory in future production. In the first quarter of 2005, we determined that we likely would continue to use some portion of the fully reserved component parts in production. When we record inventory reserves, we establish a new, lower cost basis for the inventory for accounting purposes. Accordingly, to the extent that this fully reserved inventory was used in production in 2004, 2005 and 2006, it was charged to cost of goods sold at a zero basis, which had a favorable impact on cost of goods sold.

Available-for-Sale Securities

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

- Direct obligations of the United States Treasury;
- Federal Agency securities which carry the direct or implied guarantee of the United States government; and
- Corporate securities, including commercial paper, rated A1/P1/F1 or better.

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

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

Contingencies and Litigation

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

Share-Based Payments

We grant options to purchase our common stock to our employees and directors under our stock option plans. Eligible employees can also purchase shares of our common stock at 85% of the lower of the fair market value on the first or the last day of each six-month offering period under our employee stock purchase plans. In the third quarter of 2006, we added the ability to issue restricted stock units to our 2001 Plan. The benefits provided under these plans are share-based payments subject to the provisions of revised Statement of Financial Accounting Standards No. 123 (SFAS 123(R)), *Share-Based Payment*. Effective January 1, 2006, we use the fair value method to apply the provisions of SFAS 123(R) with a modified prospective application which provides for certain changes to the method for valuing share-based compensation. The valuation provisions of SFAS 123(R) apply to new awards and to awards that are outstanding on the effective date and subsequently modified or cancelled. Under the modified prospective application, prior periods are not revised for comparative purposes.

On November 10, 2005, the FASB issued FASB Staff Position No. SFAS 123(R)-3, *Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards*. We have elected to adopt the alternative transition method provided in this FASB Staff Position for calculating the tax effects of share-based compensation pursuant to SFAS 123(R). The alternative transition method includes a simplified method to establish the beginning balance of the additional paid-in capital pool (APIC pool) related to the tax effects of employee share-based compensation, which is available to absorb tax deficiencies recognized subsequent to the adoption of SFAS 123(R).

Prior to the adoption of SFAS 123(R)

Prior to the adoption of SFAS 123(R), as permitted by SFAS No. 123, *Accounting for Stock-Based Compensation*, (SFAS 123) and SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*, we applied the existing accounting rules under APB Opinion No. 25, *Accounting for Stock Issued to Employees*, (APB 25) which provided that no compensation expense was charged for options granted at an exercise price equal to or greater than the market value of the underlying common stock on the date of grant.

At December 31, 2006, a total of 4,550,152 stock options were outstanding under our stock option plans. Stock-based compensation expense recognized for the year ended December 31, 2006 included compensation expense for stock options granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the pro forma provisions of SFAS 123. Included in stock-based compensation expense for the year ended December 31, 2006 was \$1.9 million related to stock options, \$142,000 related to the employee stock purchase plan, and \$16,000 related to restricted stock units, net of the estimated forfeitures.

As of December 31, 2006, unrecognized estimated compensation expense totaled \$1.6 million related to non-vested stock options, \$49,000 related to the employee stock purchase plan, and \$113,000 related to restricted stock units. The weighted average remaining requisite service period of the non-vested options was 1.3 years, of the employee stock purchase plan was 4.5 months, and of the restricted stock units was 4.7 years.

Valuation Assumptions

The fair value of stock options granted in the year ended December 31, 2006 was estimated using a Black-Scholes Model with the following weighted average assumptions:

	Twelve months ended December 31, 2006
Expected term (in years)	6.18
Volatility	75.41 %
Risk-free interest rate	4.88 %
Dividend yield	0.00 %

Expected Term: VIVUS expected term represents the period that our stock-based awards are expected to be outstanding based on the simplified method provided in Staff Accounting Bulletin No. 107 (SAB 107) which averages an award s weighted average vesting period and expected term for plain vanilla share options. Under SAB 107, options are considered to be plain vanilla if they have the following basic characteristics: granted at-the-money ; exercisability is conditioned upon service through the vesting date; termination of service prior to vesting results in forfeiture; limited exercise period following termination of service; and options are non-transferable and non-hedgeable. The range of expected terms used in the Black-Scholes Model in 2006 was 5.19 years to 6.25 years.

Expected Volatility: We estimated volatility using the historical share price performance over the expected term of the option. We also considered other factors such as our current clinical trials and other company activities that may affect volatility of our stock in the future but determined that at this time, the historical volatility was more indicative of our expected future stock performance. The range of expected volatility used in the Black-Scholes Model in 2006 was 68% to 77%.

Expected Dividend: The Black-Scholes Model requires a single expected dividend yield as an input. We do not anticipate paying any dividends in the near future.

Risk-Free Interest Rate: We base the risk-free interest rate used in the Black-Scholes Model on the implied yield available on U.S. Treasury zero-coupon issues with an equivalent remaining term, in effect during the period of the grant. The range of risk-free interest rates used in the Black-Scholes Model in 2006 was 4.60% to 5.11%.

Estimated Pre-vesting Forfeitures: We develop pre-vesting forfeiture assumptions based on an analysis of historical data.

The fair value of employee stock purchases made under the ESPP in the year ended December 31, 2006 was also estimated using the Black-Scholes option pricing model. The following assumptions were used: expected term ranging from .49 years to .53 years, expected volatility ranging from 62.60% to 64.84%, no dividend yield and risk free rates ranging from 4.25% to 5.16%. The weighted average assumptions used in 2006 were: expected term of .51 years, expected volatility of 63.95%, no dividend yield and a risk free rate of 4.76%.

During the third quarter of 2006, we granted 62,500 restricted stock units to an officer with a weighted average grant date fair value of \$2.04 per restricted stock unit. This grant contains a market condition and was valued using a binomial model. The following assumptions were used for valuing this grant: no dividend yield, expected volatility of 60.60%, risk-free interest rate of 4.70% and an expected term of 5 years.

The determination of the fair value of share-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, our expected stock price volatility over the term of the awards, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends.

If factors change and we employ different assumptions 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. Therefore, we believe it is important for investors to be aware of the high degree of subjectivity involved when using option pricing models to estimate share-based compensation under SFAS 123(R). Option-pricing models were developed for use in estimating the value of traded options that have no vesting or hedging restrictions, are fully transferable and do not cause dilution. Because our share-based payments have characteristics significantly different from those of freely traded options, and because changes in the subjective input assumptions can materially affect our estimates of fair values, in our opinion, existing valuation models, including the Black-Scholes and lattice binomial models, may not provide reliable measures of the fair values of our share-based compensation. Consequently, there is a risk that our estimates of the fair values of our share-based compensation awards on the grant dates may bear little resemblance to the actual values realized upon the exercise, expiration, early termination or forfeiture of those share-based payments in the future. Certain share-based payments, such as employee stock options, may expire worthless or otherwise result in zero intrinsic value as compared to the fair values originally estimated on the grant date and reported in our financial statements. Alternatively, value may be realized from these instruments that is significantly in excess of the fair values originally estimated on the grant date and reported in our financial statements. There is currently no

market-based mechanism or other practical application to verify the reliability and accuracy of the estimates stemming from these valuation models, nor is there a means to compare and adjust the estimates to actual values. Although the fair value of employee share-based awards is determined in accordance with SFAS 123(R) and the Securities and Exchange Commission's Staff Accounting Bulletin No. 107 (SAB 107) using an option-pricing model, that value may not be indicative of the fair value observed in a willing buyer/willing seller market transaction.

Estimates of share-based compensation expenses are significant to our financial statements, but these expenses are based on option valuation models and will never result in the payment of cash by us. For this reason, and because we do not view share-based compensation as related to our operational performance, we exclude estimated share-based compensation expense when evaluating our business performance.

The guidance in SFAS 123(R) and SAB 107 is relatively new, and best practices are not well established. The application of these principles may be subject to further interpretation and refinement over time. There are significant differences among valuation models, and there is a possibility that we will adopt different valuation models in the future. This may result in a lack of consistency in future periods and materially affect the fair value estimate of share-based payments. It may also result in a lack of comparability with other companies that use different models, methods and assumptions.

Theoretical valuation models and market-based methods are evolving and may result in lower or higher fair value estimates for share-based compensation. The timing, readiness, adoption, general acceptance, reliability and testing of these methods is uncertain. Sophisticated mathematical models may require voluminous historical information, modeling expertise, financial analyses, correlation analyses, integrated software and databases, consulting fees, customization and testing for adequacy of internal controls. Market-based methods are emerging that, if employed by us, may dilute our earnings per share and involve significant transaction fees and ongoing administrative expenses. The uncertainties and costs of these extensive valuation efforts may outweigh the benefits to investors.

RESULTS OF OPERATIONS

Executive Overview

For the year ended December 31, 2006, we reported a net loss of \$21.6 million, or \$0.45 net loss per share, as compared to a net loss of \$24.5 million, or \$0.57 net loss per share, during the same period in 2005. The decreased net loss in the year ended December 31, 2006, as compared to the year ended December 31, 2005, was primarily due to higher domestic product revenue and decreased clinical activities related to VIVUS four clinical development programs for sexual health, partially offset by increased spending related to the Qnexa program.

For the year ended December 31, 2005, we reported a net loss of \$24.5 million, or \$0.57 net loss per share as compared to a net loss of \$21.6 million, or \$0.57 net loss per share, during the same period in 2004. The increased net loss in the year ended December 31, 2005, as compared to the year ended December 31, 2004, was primarily due to lower product revenues both in the United States and internationally, partially offset by lower research and development costs in 2005 as compared to 2004.

Effective January 1, 2006 VIVUS implemented SFAS 123(R), which requires companies to expense the estimated fair value of employee stock options and similar awards. Stock compensation expense under SFAS 123(R) is \$2.1 million for the year ended December 31, 2006. This amount has been allocated to cost of goods sold and manufacturing, research and development, and selling, general and administrative expenses, accordingly. There were no comparable stock compensation charges in the years ended December 31, 2005 or 2004.

Edgar Filing: VIVUS INC - Form 10-K

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

Revenue

	Years Ended December 31,			% Change	
	2006	2005	2004	Increase/(Decrease) 2006 vs 2005	2005 vs 2004
	(In thousands, except percentages)				
United States product, net	\$ 14,280	\$ 11,697	\$ 16,419	22 %	(29)%
International product	2,377	2,794	3,030	(15)%	(8)%
Other revenue	588	163	152	261 %	7 %
Total revenues	\$ 17,245	\$ 14,654	\$ 19,601	18 %	(25)%

Worldwide product revenues from the sales of MUSE were \$16.7 million in 2006, an increase of \$2.2 million, or 15%, from the worldwide sales of MUSE in 2005. Product revenue in the United States for the year ended December 31, 2006 was \$14.3 million, as compared to \$11.7 million in 2005. The increase in revenues in 2006 is mainly due to increases in both domestic prices and volume, partially offset by the timing of orders from our international distributors. Domestic demand for MUSE at the retail and government level remains consistent with the prior period, averaging approximately 200,000 units per quarter. Similar to prior years, wholesalers made purchases in the fourth quarter of 2006 that were greater than the current demand. Based on the fourth quarter demand for MUSE, we estimate purchases made by wholesalers in the fourth quarter of 2006 represent approximately 3 to 4 months of excess demand. The increase in other revenue is primarily due to the amortization of a \$2.0 million milestone payment from our European Distributor, Meda AB that we received in the first quarter of 2006.

Worldwide product revenues from the sales of MUSE were \$14.5 million in 2005, a decrease of \$5.0 million, or 25%, from the worldwide sales of MUSE in 2004. Product revenue in the United States for the year ended December 31, 2005 was \$11.7 million, compared to \$16.4 million for the year ended December 31, 2004. International product revenue was \$2.8 million for the year ended December 31, 2005, compared to \$3.0 million in the same period in 2004.

Domestic sales of MUSE were lower in the year ended December 31, 2005, as compared to the year ended December 31, 2004, mainly due to a decline in the demand for MUSE, decreased purchases made by wholesalers in advance of the December 2005 price increase as compared to purchases in advance of the December 2004 price increase, and new U.S. government pricing which resulted in higher chargebacks. Similar to prior years, wholesalers made purchases in the fourth quarter that were greater than demand. International revenue also decreased as a result of lower shipments of MUSE to our international distribution partners in the year ended December 31, 2005 as compared to the prior year; however, 63% of the shipments made in 2005 to our international partners took place in the fourth quarter of 2005.

Given the stabilization of demand and the strategic buying in the fourth quarter of 2006, we anticipate worldwide revenues of MUSE in 2007 will remain consistent with those seen in 2006.

Cost of goods sold and manufacturing.

	Years Ended December 31,			% Change	
	2006	2005	2004	Increase/(Decrease) 2006 vs 2005	2005 vs 2004
	(In thousands, except percentages)				
Cost of goods sold and manufacturing	\$ 11,933	\$ 11,018	\$ 11,283	8 %	(2)%

Cost of goods sold and manufacturing (cost of goods sold) in the year ended December 31, 2006 increased \$915,000, or 8%, to \$11.9 million, as compared to \$11.0 million for the year ended December 31, 2005. The increase in cost of goods sold and manufacturing expense is the result of a \$764,000 inventory write-down related to the purchase of alprostadil in excess of projected production needs, \$348,000 of stock compensation expense from the adoption of SFAS 123(R), partially offset by other cost of goods sold and manufacturing expense net decreases of \$195,000 in the year ended December 31, 2006. As a result of excess manufacturing capacity at our New Jersey facility, we expensed approximately \$6.2 million in manufacturing overhead costs expensed as period costs in the year ended December 31, 2006, as compared to \$6.8 million the prior year. This accounting treatment is based on the determination made during the 1998 restructuring that the manufacturing capacity of the New Jersey plant far exceeds the level of production required to meet estimated future market demand.

Cost of goods sold and manufacturing (cost of goods sold) in the year ended December 31, 2005 decreased \$265,000, or 2%, to \$11.0 million, as compared to \$11.3 million for the year ended December 31, 2004. We expensed approximately \$6.8 million of manufacturing overhead costs in the year ended December 31, 2005, as compared to \$5.9 million during the same period in 2004 as period costs because of excess manufacturing capacity at our New Jersey facility.

In accordance with GAAP, in 1998 we reduced the carrying cost of alprostadil, the active ingredient in MUSE, and its component parts to zero due to excess quantities on hand at that time. Although the cost basis for alprostadil was reduced to zero, we continued to use this active ingredient as allowed by the FDA in the production of MUSE in 2004. By utilizing the inventory that had previously been written down to zero, we lowered our cost of sales for the year ended December 31, 2004 by \$844,000. In the fourth quarter of 2004, we determined that we would likely not use the fully reserved raw materials inventory in future production. In the years ended December 31, 2006 and 2005, we used component parts of this fully reserved inventory resulting in a favorable impact on our cost of goods sold of \$99,000 and \$76,000, respectively.

We anticipate that cost of goods sold in 2007 will remain consistent with 2006 costs.

Research and development.

	Years Ended December 31,			% Change	
	2006	2005	2004	Increase/(Decrease) 2006 vs 2005	2005 vs 2004
Research and development	\$ 13,316	\$ 17,005	\$ 18,676	(22)%	(9)%

Research and development expenses in the year ended December 31, 2006 decreased \$3.7 million, or 22%, to \$13.3 million, as compared to \$17.0 million for the year ended December 31, 2005. Decreased clinical trial and project activity for EvaMist, avanafil, and ALISTA resulted in decreased spending for these projects of \$6.4 million in 2006 as compared to 2005. These decreases were partially offset by increased Qnexa project expenses of \$2.0 million, the recording of \$613,000 of stock compensation expense and an incremental increase in other research and development related spending in 2006 as compared to the prior year.

Research and development expenses in the year ended December 31, 2005 were \$17.0 million, as compared to \$18.7 million in the year ended December 31, 2004. Increased clinical trial and project activity for ALISTA and EvaMist resulted in incremental spending for these projects of \$7.1 million in the year ended December 31, 2005, as compared to the same period last year. This increase was more than offset by a decrease of \$2.8 million in avanafil, Testosterone MDTS and other related clinical trial and project spending, a decrease of \$1.0 million in non-project related research and development expenses, primarily lower compensation expense due to reduced headcount, and \$5.1 million in milestone and licensing fees

which were incurred in 2004. During 2004, we entered into exclusive licensing agreements with a subsidiary of Acrux under which we will develop and, if approved, commercialize, in the United States, an estradiol spray (now known as EvaMist) for the alleviation of the symptoms of menopause and a testosterone spray for the treatment of hypoactive sexual desire disorder in women. During the year ended December 31, 2004, we expensed a total of \$3.3 million of licensing fees incurred under the terms of the agreements. In addition, during the year ended December 31, 2004, we initiated a Phase 2 clinical trial with avanafil, which we completed in 2005. Under the terms of our 2001 Development, Licensing and Supply Agreement with Tanabe, we expensed a \$1.8 million licensing fee obligation to Tanabe in the year ended December 31, 2004. We paid the entire obligation to Tanabe, totaling \$2.0 million with imputed interest, in March 2006.

We anticipate that our research and development expenses will increase significantly in 2007, as we continue to advance the clinical program for Qnexa for the treatment of obesity and our other programs. Our research and development expenses may fluctuate from period to period due to the timing and scope of our development activities and the results of clinical and preclinical studies. Based upon results of our Phase 2b study, ALISTA will receive a lower development priority than the other investigational product candidates in our pipeline. If we are successful in obtaining FDA regulatory approval for any new product candidates being developed through our research and development efforts, we do not expect to recognize revenue from sales of any such new products, if any, for several years.

We filed a New Drug Application (NDA) for EvaMist with the FDA in the third quarter of 2006 and made a \$1.0 million clinical development milestone payment to Acrux under the terms of our licensing agreement in October 2006 related to this filing, which was expensed in the third quarter of 2006. Upon approval of the NDA, a \$3.0 million product approval milestone payment will be due to Acrux.

Selling, general and administrative.

	Years Ended December 31,			% Change	
	2006	2005	2004	Increase	
	(In thousands, except percentages)			2006 vs 2005	2005 vs 2004
Selling, general and administrative	\$ 14,579	\$ 11,916	\$ 11,730	22 %	2 %

Selling, general and administrative expenses in the year ended December 31, 2006 of \$14.6 million increased \$2.7 million, or 22% as compared to the year ended December 31, 2005. In the year ended December 31, 2006, the increase is primarily due to recording of \$1.1 million in stock compensation expense, and incremental net increases in MUSE related sales and marketing expenses of \$1.0 million and legal fees of \$514,000, as compared to the year ended December 31, 2005.

Selling, general and administrative expenses in the year ended December 31, 2005 of \$12.0 million were \$186,000 higher than the same period last year due to several factors. In the first quarter of 2005, two of our largest wholesalers commenced charging us a distribution service fee based upon either the quantity of product purchased or sold by the respective wholesaler. We recorded expense of \$229,000 for this distribution service fee in the year ended December 31, 2005 to selling, general and administrative expenses. In addition, we recorded \$196,000 of incremental accounting and audit fees expense and \$153,000 in other professional consulting fees in the year ended December 31, 2005 primarily related to compliance with the requirements of Sarbanes-Oxley. These increases were partially offset by a \$384,000 reduction in MUSE advertising and promotion related expenses in the twelve months ended December 31, 2005 as compared to 2004.

We anticipate that our selling, general and administrative expenses in 2007 will be similar to 2006.

Interest income and expense.

Interest income for the year ended December 31, 2006 was \$1.6 million, as compared to \$1.1 million for the year ended December 31, 2005. The increase in 2006 is primarily due to an increase in our cash balances due to increased financing in 2006 and related investment yields from the year ended December 31, 2005 to December 31, 2006. Interest expense for the year ended December 31, 2006 was \$593,000 as compared to \$221,000 during the same period in 2005. The increased interest expense is primarily due to the Crown Bank loan, which was obtained on January 4, 2006, and a higher loan balance outstanding for the Tanabe loan.

Interest income for 2005 was \$1.1 million, as compared to \$622,000 for the year ended December 31, 2004. The increase is primarily due to an increase in our cash balances and related investment yields from the year ended December 31, 2004 to December 31, 2005. Interest expense for the year ended December 31, 2005 was \$221,000 as compared to \$143,000 during the same period in 2004. This interest expense is related to the Acrux milestone liabilities and Tanabe license fees and loan. The increased interest expense is primarily due to a higher loan balance outstanding for the Tanabe loan.

Liquidity and Capital Resources

Cash. Unrestricted cash, cash equivalents and available-for-sale securities totaled \$58.9 million at December 31, 2006, as compared to \$27.0 million at December 31, 2005. The increase in cash, cash equivalents and available-for-sale securities of \$31.9 million is the result of the \$45.4 million in net proceeds from our registered direct public offerings in 2006, the \$5.4 million loan obtained from Crown Bank, N.A. in 2006, the collection of amounts owed at December 31, 2005 from customers as measured by a decrease of \$3.4 million in accounts receivable partially offset by cash used in operations, investment and other financing activities of \$22.3 million for the year.

Since inception, we have financed operations primarily from the issuance of equity securities and revenues. Through December 31, 2006, we raised \$221.7 million from financing activities and had an accumulated deficit of \$168.7 million at December 31, 2006.

Available-for-sale securities. We focus on liquidity and capital preservation in our investments in available-for-sale securities. We restrict our cash investments to:

- Direct obligations of the United States Treasury;
- Federal Agency securities which carry the direct or implied guarantee of the United States government; and
- Corporate securities, including commercial paper, rated A1/P1/F1 or better.

The weighted average maturity of our portfolio is not to exceed 18 months.

Accounts Receivable. Accounts receivable (net of allowance for doubtful accounts) at December 31, 2006 was \$4.4 million, as compared to \$7.6 million at December 31, 2005. The 43% decrease in the accounts receivable balance at December 31, 2006 is primarily due to a \$3.6 million decrease in sales in December 2006, as compared to the same period in 2005. Currently, we do not have any significant concerns related to accounts receivable or collections. As of February 15, 2007, we had collected 95% of the December 31, 2006 accounts receivable.

Liabilities. Total liabilities were \$25.1 million at December 31, 2006, \$2.4 million higher than at December 31, 2005. The change in total liabilities is primarily due to the \$5.4 million loan received from Crown Bank on January 4, 2006, and receipt of the \$2.0 million MEDA milestone payment, recorded as deferred revenue in the first quarter of 2006. These increases were partially offset by the reduction of liabilities, including a \$3.4 million reduction in accrued research, clinical and licensing fees, primarily due

to the payment of accrued licensing fees to Tanabe of \$2.0 million in 2006, and a \$1.7 million reduction in accounts payable, due to the timing of payments.

We have entered into manufacturing agreements with suppliers to purchase raw materials. As of December 31, 2006, our remaining commitment under these agreements is to purchase a minimum of \$3.1 million of product from 2007 through 2008. In 2006, we recorded a \$764,000 inventory write-down related to the purchase of alprostadil considered to be in excess of projected production needs. Should our inventory of raw materials exceed our future production needs, it may be necessary to write-off additional excess inventory.

In February 2004, we entered into exclusive licensing agreements with Acrux Limited and a subsidiary of Acrux under which we have agreed to develop and, if approved, commercialize Testosterone MDTs (metered-dose transdermal spray) and EvaMist in the United States for various female health applications. Under the terms of the agreements, we agreed to pay to Acrux combined licensing fees of \$3.0 million, up to \$4.3 million for the achievement of certain clinical development milestones, up to \$6.0 million for achieving product approval milestones, and royalties on net sales in the United States following approval and commercialization of each product. We made a \$1.0 million clinical development milestone payment to Acrux in October 2006 related to the submission of an NDA to the FDA for EvaMist and we will owe an additional \$3.0 million product approval milestone payment upon approval of this NDA.

Operating Activities. Our operating activities used \$19.5 million and \$21.1 million of cash during the years ended December 31, 2006 and 2005, respectively. During the year ended December 31, 2006, our net operating loss of \$21.6 million was partially offset by a \$3.4 million reduction in our accounts receivable, due to the collection of monies owed to us, and the recording of \$2.1 million in non-cash stock-based compensation expense, due to the adoption of FAS 123R in 2006. These operating cash flow sources were offset by a \$3.4 million reduction in accrued research, clinical and licensing fees, primarily due to the payment of accrued licensing fees to Tanabe of \$2.0 million in 2006.

Investing Activities. Our investing activities used \$10.6 million and provided \$12.8 million in cash during the years ended December 31, 2006 and 2005, respectively. The fluctuations from period to period are due primarily to the timing of purchases, sales and maturity of investment securities and the purchase of land and buildings for \$7.1 million offset by the release of restricted cash of \$3.3 million in 2005. In addition, during the first quarter of 2006, we provided Crown Bank with a \$700,000 Certificate of Deposit as collateral for the loan agreement we entered into with them on January 4, 2006.

Financing Activities. Financing activities provided cash of \$52.5 million and \$22.2 million during the years ended December 31, 2006 and 2005, respectively. In 2006, the cash provided by financing activities is primarily due to the \$45.4 million net proceeds from the registered direct sales of 3,669,725 shares of common stock on May 10, 2006 at a price of \$3.27 per share, 6,750,000 shares of common stock on November 17, 2006 at a price of \$3.50 per share, and 2,850,000 shares of common stock on December 8, 2006 at a price of \$3.50 per share, in addition to the \$5.3 million net proceeds from the Crown Bank loan we entered into on January 4, 2006. In both 2006 and 2005, these amounts also include borrowings under our Tanabe line of credit, proceeds from the exercise of stock options, and employee stock purchase plan (ESPP) purchases.

In the first quarter of 2004, we signed an agreement for a line of credit with Tanabe, allowing us to borrow up to \$8.5 million to be used for the development of avanafil. The secured line of credit may be drawn upon quarterly and each quarterly borrowing will have a 48-month term and will bear interest at the annual rate of 2%. As of December 31, 2006, we had a long-term notes payable balance of \$6.3 million and \$2.2 million remaining available on the credit line. We borrowed an additional \$1.1 million under this credit line during 2006.

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, 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 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 these Agreements. 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, 2004, we filed a shelf registration statement on Form S-3 with the SEC, which allowed us to offer and sell up to an aggregate of \$50 million of common stock from time to time in one or more offerings. The terms of any such future offering would be established at the time of such offering. On February 22, 2005, we filed a prospectus supplement with the SEC relating to an underwritten public offering of 7,500,000 shares of common stock under the existing shelf Registration Statement and supplement thereto. On March 15, 2005, we sold 6,250,000 shares of our common stock at a price of \$3.40 per share, providing us with net proceeds of \$19.6 million.

On May 10, 2006, we sold \$12.0 million of our common stock in a registered direct offering. Under the terms of the financing, we sold 3,669,725 shares of VIVUS common stock at a price of \$3.27 per share to two institutional investors. On May 11, 2006, we filed a prospectus supplement with the SEC relating to this registered direct offering under the existing shelf Registration Statement on Form S-3 and supplement thereto.

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 \$80.0 million of common stock from time to time in one or more offerings. The terms of any such future offering would be established at the time of such offering. This shelf Registration Statement (File Number 333-135793) replaces shelf Registration Statement (File Number 333-12159).

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. All of the shares of Common Stock were offered pursuant to an effective Registration Statement on Form S-3 filed with the SEC on July 14, 2006.

The funding necessary to execute our business strategies is subject to numerous uncertainties, which may adversely affect our liquidity and capital resources. Completion of clinical trials may take several years or more, but the length of time generally varies substantially according to the type, complexity, novelty and intended use of a product candidate. It is also important to note that if a clinical candidate is identified, the further development of that candidate can be halted or abandoned at any time due to a number of factors. These factors include, but are not limited to, funding constraints, lack of efficacy or safety or change in market demand.

The nature and efforts required to develop our product candidates into commercially viable products include research to identify a clinical candidate, preclinical development, clinical testing, FDA approval and commercialization. This process is very costly and can take in excess of 10 years to complete for each product candidate. The duration and the cost of clinical trials may vary significantly over the life of a project as a result of differences arising during the clinical studies, including, among others, the following:

- we or the FDA may suspend trials;
- we may discover that a product candidate may cause harmful side effects or is not effective;

- patient recruitment may be slower than expected; and
- patients may drop out of the trials.

For each of our programs, we periodically assess the scientific progress and the merits of the programs to determine if continued research and development is economically viable. Certain of our programs have been terminated due to the lack of scientific progress and lack of prospects for ultimate commercialization. As such, the ultimate timeline and costs to commercialize a product cannot be accurately estimated.

Our product candidates have not yet achieved FDA regulatory approval, which is required before we can market them as therapeutic products. In order to achieve regulatory approval, the FDA must conclude that our clinical data establish safety and efficacy. The results from preclinical testing and early clinical trials may not be predictive of results in later clinical trials. It is possible for a candidate to show promising results in clinical trials, but subsequently fail to establish safety and efficacy data necessary to obtain regulatory approvals.

As a result of the uncertainties discussed above, among others, the duration and completion of our research and development projects are difficult to estimate and are subject to considerable variation. Our inability to complete our research and development projects in a timely manner or our failure to enter into collaborative agreements, when appropriate, could significantly increase our capital requirements and could adversely impact our liquidity. These uncertainties could force us to seek additional, external sources of financing from time to time in order to continue with our business strategy. Our inability to raise capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business.

We may also be required to make further substantial expenditures if unforeseen difficulties arise in other areas of our business. In particular our future capital and additional funding 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.

Edgar Filing: VIVUS INC - Form 10-K

We anticipate that our existing capital resources combined with anticipated future cash flows will be sufficient to support our operating needs into 2008. However, we anticipate that we will require additional funding to continue our research and product development programs, to conduct preclinical studies and

62

trials, for operating expenses, to pursue regulatory approvals for our product candidates, for the costs involved in filing and prosecuting patent applications and enforcing or defending our patent claims, if any, and we may require additional funding to establish additional manufacturing and marketing capabilities in the future. In particular, we expect to make other substantial payments to Acrux and Tanabe in accordance with our agreements with them in connection with the licensing of certain compounds. These payments are based on certain development, regulatory and sales milestones. In addition, we are required to make royalty payments on any future product sales. We may seek to access the public or private equity markets whenever conditions are favorable. The sale of additional equity securities would result in additional dilution to our stockholders. We may also seek additional funding through strategic alliances and other financing mechanisms. We cannot assure you that adequate funding will be available on terms acceptable to us, if at all. If adequate funds are not available, we may be required to curtail significantly one or more of our research or development programs or obtain funds through arrangements with collaborators or others. This may require us to relinquish rights to certain of our technologies or product candidates. To the extent that we are unable to obtain third party funding for such expenses, we expect that increased expenses will result in increased losses from operations. We are continually evaluating our existing portfolio and we may choose to divest or spin-off one or more of our products or product candidates at any time. We cannot assure you that we will successfully develop our products under development or that our products, if successfully developed, will generate revenues sufficient to enable us to earn a profit.

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2006 and the effect such obligations are expected to have on our liquidity and cash flow in future fiscal years. These do not include milestones or future interest expense and assume non-termination of agreements. These obligations, commitments and supporting arrangements represent payments based on current operating forecasts, which are subject to change:

Contractual obligations	Payments Due by Period (in thousands)				
	Total	2007	2008-2010	2011-2012	Thereafter
Operating leases	\$ 1,493	\$ 586	\$ 907		
Purchases	6,486	4,191	2,295		
Notes payable	11,605	117	6,740	\$ 341	\$ 4,407
Total contractual obligations	\$ 19,584	\$ 4,894	\$ 9,942	\$ 341	\$ 4,407

Operating Leases

We purchased our previously leased manufacturing facilities in Lakewood, New Jersey on December 22, 2005. In January 2000, we entered into a seven-year lease for our corporate headquarters in Mountain View, California, which expired in January 2007. In November 2006, we entered into a new 30-month lease for our existing Mountain View corporate headquarters location with our existing landlord. The new lease commenced on February 1, 2007. The lease expires on July 31, 2009 and allows us one option to extend the term of the lease for a period of one year from the expiration of the lease.

Purchases

Purchase obligations consist of agreements to purchase goods or services that are enforceable and legally binding on us and that specify all significant terms, including: fixed or minimum quantities to be purchased; fixed, minimum or variable price provisions; and the approximate timing of the transaction. These include obligations for minimum inventory purchase contracts, clinical data management, research and development and media/market research contracts.

Manufacturing Agreements

In November 2002, we entered into a manufacturing agreement to purchase raw materials from a supplier beginning in 2003 and ending in 2008. Our remaining commitment is to purchase a minimum total of \$2.3 million of product from 2007 through 2008. In 2005, we purchased \$765,000 of product from this supplier. We did not purchase any product from this supplier in 2006.

In January 2004, we entered into a manufacturing agreement to purchase raw materials from an additional supplier beginning in 2004 and ending in 2006. In February 2006, we amended the terms of this agreement to require the purchase of a minimum total of \$1.5 million of product from 2006 through 2008. In 2005 we purchased \$240,000 of product. We purchased \$751,000 of product from this supplier in 2006 and our remaining commitment under this agreement is \$765,000.

Other Agreements

We have entered into various agreements with clinical consultants and clinical research organizations to perform clinical studies on our behalf and, at December 31, 2006, our remaining commitment under these agreements totaled \$750,000. We have also entered into various agreements with research consultants and other contractors to perform drug research, testing and manufacturing including animal studies and, at December 31, 2006, our remaining commitment under these agreements totaled \$1.6 million. In addition, in December 2006, we entered into a marketing promotion agreement for our erectile dysfunction product, MUSE. At December 31, 2006, our remaining commitment under this agreement totaled \$1.1 million.

Notes Payable

In 2004, we signed an agreement for a secured line of credit with Tanabe, allowing us to borrow up to \$8.5 million to be used for the development of avanafil. The secured line of credit may be drawn upon quarterly and each quarterly borrowing will have a 48-month term and will bear interest at the annual rate of 2%. There are no financial covenants associated with this secured line of credit. Under certain conditions, at our option, payments on this secured line of credit may be made, in whole or in part, in common stock. As of December 31, 2006, we have long term notes payable of \$6.3 million, and \$2.2 million of available credit under this agreement.

On January 4, 2006, we obtained a \$5.4 million loan from 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 these Agreements. 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%. As of December 31, 2006, we have a principal balance of \$5.3 million remaining on the Crown loan.

Additional Payments

We have entered into development, license and supply agreements which contain provisions for payments upon completion of certain development, regulatory and sales milestones. Due to the uncertainty concerning when and if these milestones may be completed, we have not included these potential future obligations in the above table.

Tanabe

In January 2001, we entered into an exclusive development, license and supply agreement with Tanabe for the development and commercialization of avanafil, a PDE5 inhibitor compound for the oral and local treatment of male and female sexual dysfunction. Under the terms of the agreement, Tanabe agreed to grant an exclusive license to us for products containing avanafil outside of Japan, North Korea, South Korea, China, Taiwan, Singapore, Indonesia, Malaysia, Thailand, Vietnam and the Philippines. We agreed to grant Tanabe an exclusive, royalty-free license within those countries for oral products that we develop containing avanafil. In addition, we agreed to grant Tanabe an exclusive option to obtain an exclusive, royalty-bearing license within those countries for non-oral products that we develop containing avanafil. Further, we granted Tanabe the option to obtain co-promotional rights for oral products that we develop under our license for up to 25% of the promotional activity in our territory. Tanabe agreed to manufacture and supply us with avanafil for use in clinical trials, which will be our primary responsibility.

We have paid upfront licensing fees of \$5.0 million to Tanabe and have agreed to make additional payments upon the completion of certain development, regulatory and sales milestones. During the first quarter of 2004, we initiated a Phase 2 clinical trial with avanafil, which meets one of the clinical development milestone criteria above. We paid Tanabe \$2.0 million in connection with this milestone in 2006. We have further agreed to pay royalties on net sales of products containing avanafil.

Acrux

In February 2004, we entered into exclusive licensing agreements with Acrux Limited (Acrux) and its subsidiary under which we have agreed to develop and, if approved, commercialize Testosterone-MDTS and EvaMist in the United States for various female health applications. Acrux 's metered-dose transdermal spray, or MDTS, technology is a patented, simple to use spray that is being developed to deliver testosterone and estradiol effectively to women when applied to the skin. We agreed to grant Acrux 's subsidiary a non-exclusive, royalty-free license outside the United States for any MDTS products containing improvements we have made to the licensed intellectual property and the option to obtain a non-exclusive, worldwide license for our intellectual property related to MDTS products. We have paid \$3.0 million in upfront licensing fees to Acrux and have agreed to make additional payments upon the completion of certain development, regulatory and sales milestones. Under the terms of the agreements, we agreed to pay to Acrux combined licensing fees up to \$4.3 million for the achievement of certain clinical development milestones, up to \$6.0 million for achieving product approval milestones, and royalties on net sales in the United States following approval and commercialization of each product. We have paid \$1.8 million in clinical development milestones payments to date, including the \$1.0 million milestone payment we made to Acrux in October 2006 related to the submission of an NDA to the FDA for EvaMist. In addition, we will owe a \$3.0 million product approval milestone payment upon approval of this NDA.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet financing arrangements and have not established any special purpose entities. We have not guaranteed any debt or commitments of other entities or entered into any options on non-financial assets.

Indemnifications

In the normal course of business, we provide indemnifications of varying scope to customers against claims of intellectual property infringement made by third parties arising from the use of our products. Historically, costs related to these indemnification provisions have not been significant and we are unable to estimate the maximum potential impact of these indemnification provisions on our future results of operations.

To the extent permitted under Delaware law, we have agreements whereby we indemnify our officers and directors for certain events or occurrences while the officer or director is, or was, serving at our request in such capacity. The indemnification period covers all pertinent events and occurrences during the officer's or director's lifetime. The maximum potential amount of future payments we could be required to make under these indemnification agreements is unlimited; however, we have director and officer insurance coverage that reduces our exposure and enables us to recover a portion of any future amounts paid. We believe the estimated fair value of these indemnification agreements in excess of applicable insurance coverage is minimal.

Recent Accounting Pronouncements

In February 2007, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115*. SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value. This statement provides entities the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. This Statement is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. Management is currently evaluating the impact of adopting this Statement.

In September 2006, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) 157, *Fair Value Measurements*. SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles (GAAP) and expands disclosures about fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. We are currently evaluating the effect, if any, that the adoption of SFAS 157 will have on our financial position and results of operations.

In September 2006, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* (SAB 108). SAB 108 provides interpretive guidance on how the effects of prior-year uncorrected misstatements should be considered when quantifying misstatements in the current year financial statements. SAB 108 requires registrants to quantify misstatements using both an income statement (rollover) and balance sheet (iron curtain) approach and evaluate whether either approach results in a misstatement that, when all relevant quantitative and qualitative factors are considered, is material. If prior year errors that had been previously considered immaterial now are considered material based on either approach, no restatement is required so long as management properly applied its previous approach and all relevant facts and circumstances were considered. If prior years are not restated, the cumulative effect adjustment is recorded in opening accumulated earnings as of the beginning of the fiscal year of adoption. SAB 108 is effective for fiscal years ending on or after November 15, 2006, with earlier adoption encouraged. The adoption of SAB 108 did not have a material effect on our consolidated financial condition or results of operations.

In July 2006, the FASB issued FASB Interpretation No. 48 (FIN 48) *Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109*, to clarify certain aspects of accounting for uncertain tax positions, including issues related to the recognition and measurement of those tax positions. FIN 48 prescribes a recognition threshold and measurement attribute for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognizing, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. This interpretation is effective for fiscal years beginning after December 15, 2006. The cumulative effect of applying the provisions of FIN 48 will be reported as an adjustment to the opening balance of retained earnings or deficit at January 1, 2007. We are in the process

of evaluating the effect that the adoption of this interpretation will have on our results of operations and financial condition and we are not yet in a position to determine such effects.

Effective January 1, 2006, VIVUS adopted SFAS 123(revised 2004), *Share-Based Payment* (SFAS 123(R)), which requires the measurement and recognition of compensation expense for all stock-based payment awards made to employees and directors, including employee stock options, restricted stock, and stock appreciation rights (SARS) based on estimated fair values. See Note 1 to our consolidated financial statements for further discussion.

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

Dividend Policy

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

Cautionary Note on Forward-Looking Statements

Our business is subject to significant risks, including but not limited to, the risks inherent in our research and development activities, including the successful completion of clinical trials, the lengthy, expensive and uncertain process of seeking regulatory approvals, uncertainties associated both with the potential infringement of patents and other intellectual property rights of third parties, and with obtaining and enforcing our own patents and patent rights, uncertainties regarding government reforms and of product pricing and reimbursement levels, technological change, competition, manufacturing uncertainties and dependence on third parties. Even if our product candidates appear promising at an early stage of development, they may not reach the market for numerous reasons. Such reasons include the possibilities that the product will be ineffective or unsafe during clinical trials, will fail to receive necessary regulatory approvals, will be difficult to manufacture on a large scale, will be uneconomical to market or will be precluded from commercialization by proprietary rights of third parties. For more information about the risks we face, see Item 1.A. Risk Factors included in this report.

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

The Securities and Exchange Commission's rule related to market risk disclosure requires that we describe and quantify potential material losses from market risk sensitive instruments attributable to reasonably possible market changes. Market risk sensitive instruments include all financial or commodity instruments and other financial instruments that are sensitive to future changes in interest rates, currency exchange rates, commodity prices or other market factors.

Interest Rate Risk

We are exposed to interest rate risk on our short-term investments. The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest in highly liquid and high quality government and other debt securities. To minimize our exposure due to adverse shifts in interest rates, we invest in short-term

securities and ensure that the maximum weighted average of our maturity of our investments does not exceed 18 months. If a 10% change in interest rates were to have occurred on December 31, 2006, this change would not have had a material effect on the fair value of our investment portfolio as of that date. Due to the short holding period of our investments, we have concluded that we do not have a material financial market risk exposure.

We are also exposed to interest rate risk on the \$5.4 million loan from Crown Bank, N.A. obtained on January 4, 2006. 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%.

68

Item 8. *Financial Statements and Supplementary Data*

VIVUS, INC.

1. Index to Consolidated Financial Statements

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

<u>Reports of Independent Registered Public Accounting Firms</u>	70
<u>Consolidated Balance Sheets as of December 31, 2006 and 2005</u>	73
<u>Consolidated Statements of Operations and Other Comprehensive Income (Loss) for the years ended December 31, 2006, 2005 and 2004</u>	74
<u>Consolidated Statements of Stockholders' Equity for the years ended December 31, 2006, 2005 and 2004</u>	75
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2006, 2005 and 2004</u>	76
<u>Notes to Consolidated Financial Statements</u>	77
<u>Financial Statement Schedule II</u>	99

69

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of VIVUS, Inc.

We have audited the accompanying consolidated balance sheets of VIVUS, Inc. as of December 31, 2006 and 2005, and the related consolidated statements of operations and other comprehensive income (loss), stockholders' equity and cash flows for the years then ended. In connection with our audits, we also have audited the 2006 and 2005 data in financial statement schedule II. These financial statements and schedule are the responsibility of VIVUS, Inc.'s management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements audited by us present fairly, in all material respects, the consolidated financial position of VIVUS, Inc. at December 31, 2006 and 2005, and the consolidated results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

As discussed in Note 1 to the consolidated financial statements, on January 1, 2006, VIVUS adopted the provisions of Statement of Financial Accounting Standards No. 123 (revised), Share-Based Payment, and Statement of Financial Accounting Standards No. 151, Inventory Costs, an amendment of ARB No. 43, Chapter 4.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of VIVUS, Inc.'s internal control over financial reporting as of December 31, 2006, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 28, 2007 expressed an unqualified opinion thereon.

/s/ ODENBERG, ULLAKKO, MURANISHI &
CO. LLP
San Francisco, CA
February 28, 2007

The Board of Directors and Stockholders of VIVUS, Inc.

We have audited management's assessment, included in Management's Report on Internal Control Over Financial Reporting, included in Item 9A, that VIVUS, Inc. maintained effective internal control over financial reporting as of December 31, 2006, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). VIVUS, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of VIVUS, Inc.'s internal control over financial reporting based on our audit.

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

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

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

In our opinion, management's assessment that VIVUS, Inc. maintained effective internal control over financial reporting as of December 31, 2006, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, VIVUS, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of VIVUS, Inc. as of December 31, 2006 and 2005, and the related consolidated statements of operations and other comprehensive income (loss), stockholders' equity and cash flows for the years then ended and our report dated February 28, 2007 expressed an unqualified opinion thereon.

/s/ ODENBERG, ULLAKKO, MURANISHI &
CO. LLP
San Francisco, CA
February 28, 2007

The Board of Directors and Stockholders
VIVUS, Inc.:

We have audited the accompanying consolidated statements of operations and other comprehensive income (loss), stockholders' equity, and cash flows of VIVUS, Inc. and subsidiaries for the year ended December 31, 2004. In connection with our audit, we also have audited the 2004 data in financial statement schedule II. These consolidated financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and financial statement schedule based on our audits.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

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

/s/ KPMG LLP
KPMG LLP
San Francisco, California
March 15, 2005

VIVUS, INC.
CONSOLIDATED BALANCE SHEETS

(In thousands, except par value)

	December 31	
	2006	2005
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 44,628	\$ 22,236
Available-for-sale securities	14,243	4,770
Accounts receivable (net of allowance for doubtful accounts of \$67 and \$202 at December 31, 2006 and 2005, respectively)	4,359	7,604
Inventories, net	3,327	4,504
Prepaid expenses and other assets	2,408	1,024
Total current assets	68,965	40,138
Property, plant and equipment, net	8,549	9,144
Restricted cash	700	
Total assets	\$ 78,214	\$ 49,282
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 2,102	\$ 3,779
Accrued product returns	2,473	3,016
Accrued research and clinical expenses	460	1,886
Accrued licensing fees		1,972
Accrued chargeback reserve	1,531	1,832
Accrued employee compensation and benefits	1,490	1,280
Income taxes payable	1,245	1,215
Accrued and other liabilities	2,100	1,589
Total current liabilities	11,401	16,569
Notes payable	11,488	5,164
Deferred revenue	2,185	948
Total liabilities	25,074	22,681
Commitments and contingencies		
Stockholders' equity:		
Preferred stock; \$1.00 par value; 5,000 shares authorized; no shares issued and outstanding at December 31, 2006 and 2005		
Common stock; \$.001 par value; 200,000 shares authorized at December 31, 2006 and 2005; 58,144 shares issued and outstanding at December 31, 2006 and 44,642 at December 31, 2005		
	58	45
Additional paid-in capital	221,744	173,613
Accumulated other comprehensive income (loss)	(11)	(30)
Accumulated deficit	(168,651)	(147,027)
Total stockholders' equity	53,140	26,601
Total liabilities and stockholders' equity	\$ 78,214	\$ 49,282

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31		
	2006	2005	2004
Revenue			
United States product, net	\$ 14,280	\$ 11,697	\$ 16,419
International product	2,377	2,794	3,030
Other revenue	588	163	152
Total revenue	17,245	14,654	19,601
Operating expenses:			
Cost of goods sold and manufacturing expense	11,933	11,018	11,283
Research and development	13,316	17,005	18,676
Selling, general and administrative	14,579	11,916	11,730
Total operating expenses	39,828	39,939	41,689
Loss from operations	(22,583)	(25,285)	(22,088)
Interest and other income (expense):			
Interest income	1,573	1,094	622
Interest expense	(593)	(221)	(143)
Other (expense) income	(1)	(47)	32
Loss before income taxes	(21,604)	(24,459)	(21,577)
Provision for income taxes	(20)	(25)	(6)
Net loss	\$ (21,624)	\$ (24,484)	\$ (21,583)
Other comprehensive income (loss):			
Unrealized gain (loss) on securities, net of taxes	19	18	(112)
Comprehensive loss	\$ (21,605)	\$ (24,466)	\$ (21,695)
Net loss per share:			
Basic and diluted	\$ (0.45)	\$ (0.57)	\$ (0.57)
Shares used in per share computation:			
Basic and diluted	48,103	43,272	38,010

See accompanying notes to consolidated financial statements.

VIVUS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY
(In thousands)

	Common Stock		Additional	Accumulated	Accumulated	Total
	Shares	Amount	Paid-In Capital	Other Comprehensive Income (Loss)	Deficit	
Balances, December 31, 2003	37,788	\$ 38	\$ 152,093	\$ 64	\$ (100,960)	\$ 51,235
Sale of common stock through employee stock purchase plan	84		283			283
Exercise of common stock options for cash	255		859			859
Stock compensation costs			40			40
Net unrealized loss on securities				(112)		(112)
Net loss					(21,583)	(21,583)
Balances, December 31, 2004	38,127	38	153,275	(48)	(122,543)	30,722
Sale of common stock through employee stock purchase plan	120		277			277
Exercise of common stock options for cash	145		440			440
Stock compensation costs			44			44
Proceeds from private placement of common stock	6,250	7	21,243			21,250
Issue costs for private placement of common stock			(1,666)			(1,666)
Net unrealized gain on securities				18		18
Net loss					(24,484)	(24,484)
Balances, December 31, 2005	44,642	45	173,613	(30)	(147,027)	26,601
Sale of common stock through employee stock purchase plan	112		315			315
Exercise of common stock options for cash	120		360			360
Stock compensation costs			2,065			2,065
Proceeds from private placement of common stock	13,270	13	45,587			45,600
Issue costs for private placement of common stock			(196)			(196)
Net unrealized gain on securities				19		19
Net loss					(21,624)	(21,624)
Balances, December 31, 2006	58,144	\$ 58	\$ 221,744	\$ (11)	\$ (168,651)	\$ 53,140

See accompanying notes to consolidated financial statements.

VIVUS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31		
	2006	2005	2004
Cash flows from operating activities:			
Net loss	\$ (21,624)	\$ (24,484)	\$ (21,583)
Adjustments to reconcile net loss to net cash provided by (used for) operating activities:			
Provision for doubtful accounts	(135)	98	36
Provision for excess inventory	764		
Depreciation	1,074	1,341	1,936
Stock compensation expense	2,065	44	40
(Gain) loss on disposal of property and equipment	(14)	34	7
Changes in assets and liabilities:			
Accounts receivable	3,380	1,842	(6,957)
Inventories	413	(649)	(746)
Prepaid expenses and other assets	(1,384)	435	(351)
Accounts payable	(1,677)	659	203
Accrued product returns	(543)	(195)	189
Accrued research, clinical and licensing fees	(3,398)	(168)	3,568
Accrued chargeback reserve	(301)	206	682
Accrued employee compensation and benefits	210	(162)	193
Accrued and other liabilities	1,661	(111)	96
Net cash used for operating activities	(19,509)	(21,110)	(22,687)
Cash flows from investing activities:			
Land and buildings purchase		(7,142)	
Other property and equipment purchases	(501)	(123)	(118)
Release (grant) of restricted cash	(700)	3,324	
Proceeds from sale of property and equipment	36		1
Investment purchases	(26,513)	(42,371)	(20,451)
Proceeds from sale/maturity of securities	17,059	59,128	34,081
Net cash (used for) provided by investing activities	(10,619)	12,816	13,513
Cash flows from financing activities:			
Borrowing under note agreements	6,535	1,925	3,239
Principal payments under note agreement	(94)		
Exercise of common stock options	360	440	859
Sale of common stock through employee stock purchase plan	315	277	283
Net proceeds from issuance of common stock	45,404	19,584	
Net cash provided by financing activities	52,520	22,226	4,381
Net increase (decrease) in cash and cash equivalents	22,392	13,932	(4,793)
Cash and cash equivalents:			
Beginning of year	22,236	8,304	13,097
End of year	\$ 44,628	\$ 22,236	\$ 8,304
Supplemental cash flow disclosure:			
Interest paid	\$ 518	\$ 80	\$ 17
Income taxes paid	\$ 13	\$ 10	\$ 13
Non-cash investing and financing activities:			
Release of restoration liability	\$	\$ (3,021)	\$
Unrealized gain (loss) on securities	\$ 19	\$ 18	\$ (112)

See accompanying notes to consolidated financial statements.

VIVUS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Business and Significant Accounting Policies

Business

VIVUS, Inc. is a pharmaceutical company, incorporated in 1991, 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. Currently, the Company has development candidates addressing obesity, post-menopausal and sexual health, each of which targets an estimated existing or potential market in excess of \$1 billion annually. VIVUS' investigational product 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 an NDA was submitted to the FDA in the third quarter of 2006; Testosterone MDTs is being developed to treat hypoactive sexual desire disorder, for which a Phase 2 study has been completed; and avanafil is being developed for the treatment of erectile dysfunction; for which Phase 2 studies have been completed. In 1997, the Company launched MUSE (alprostadil), a transurethral applicator used for treating erectile dysfunction, in the United States and internationally through distribution partners.

At December 31, 2006, the Company's accumulated deficit was approximately \$168.7 million. Based on current plans, management expects to incur further losses for the foreseeable future. Management believes that the Company's cash, cash equivalents, and short-term investments at December 31, 2006, will be sufficient to meet the Company's obligations into 2008. Until the Company can generate sufficient levels of cash from its operations, the Company expects to continue to finance future cash needs primarily through proceeds from equity or debt financing, loans and collaborative agreements with corporate partners.

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

Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of VIVUS, Inc., VIVUS Real Estate LLC, a wholly owned subsidiary, VIVUS International Limited, a wholly owned subsidiary, and VIVUS Ireland Limited, VIVUS U.K. Limited and VIVUS B.V. Limited, wholly owned subsidiaries of VIVUS International Limited. All significant inter-company transactions and balances have been eliminated in consolidation. On February 20, 2004, VIVUS Ireland was officially dissolved. On December 31, 2005, VIVUS U.K. Limited became a dormant company.

Use of Estimates

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

Cash and Cash Equivalents

The Company considers highly liquid investments with maturities from the date of purchase of three months or less to be cash equivalents. All cash equivalents are in money market funds and commercial paper. The fair value of the funds approximated cost.

Available-for-Sale Securities

Available-for-sale securities represent investments in debt securities that are stated at fair value. The Company restricts its cash investments to:

- Direct obligations of the United States Treasury;
- Federal Agency securities which carry the direct or implied guarantee of the United States government; and
- Corporate securities, including commercial paper, rated A1/P1/F1 or better.

The difference between amortized cost (cost adjusted for amortization of premiums and accretion of discounts which are recognized as adjustments to interest income) and fair value, representing unrealized holding gains or losses, are recorded in Accumulated Other Comprehensive Income (Loss), a separate component of stockholders' equity until realized. The change in unrealized gains (losses) on investments included in accumulated other comprehensive income (loss) for 2006, 2005 and 2004, in thousands, are \$19, \$18, and \$(112), respectively.

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

Accounts Receivable, Allowances for Doubtful Accounts and Cash Discounts

The Company extends credit to its customers for product sales resulting in accounts receivable. For qualified customers, the Company grants payment terms of 2%, net 30 days. Customer accounts are monitored for past due amounts. Past due accounts receivable, determined to be uncollectible, are written off against the allowance for doubtful accounts. Allowances for doubtful accounts are estimated based upon past due amounts, historical losses and existing economic factors, and are adjusted periodically. Allowances for cash discounts are estimated based upon the amount of trade accounts receivable subject to the cash discounts. The Company routinely assesses its experience with cash discounts and adjusts the reserves accordingly. If actual cash discounts or uncollectible accounts are greater than the Company's estimates, additional reserves may be required. The accounts receivable are reported on the balance sheet, net of the allowance for doubtful accounts and allowance for payment terms.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents, short-term investments and accounts receivable. The Company has established guidelines to limit its exposure to credit risk by placing investments with high credit quality financial institutions, diversifying its investment portfolio and placing investments with maturities that maintain safety and liquidity.

Inventories

Inventories are stated at the lower of cost (first-in, first-out basis) or market and consist of raw materials and component parts, work in process and finished goods. Cost includes material and conversion costs. Inventory reserves are recorded for estimated obsolescence, unmarketable or excess inventory equal to the difference between the cost of inventory and the estimated market value based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required. In 2006, the Company recorded a \$764,000 inventory write-down related to the purchase of alprostadil, considered to be in excess of projected production needs.

During the quarter ended September 30, 1998, the Company established significant reserves against its inventory to align with new estimates of expected future demand for MUSE. As of December 31, 2006, the remaining inventory reserve balance is \$4.4 million. This remaining balance is related to the raw materials and component parts inventory that the Company previously estimated would not be used. Some portion of the fully reserved inventory has been used in production. When the Company records inventory reserves, it establishes a new, lower cost basis for the inventory for accounting purposes. Accordingly, to the extent that this fully reserved inventory was used in production in 2004, 2005 and 2006, it was charged to cost of goods sold at a zero basis, which had a favorable impact on cost of goods sold.

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs*, an amendment of ARB No. 43, Chapter 4. This Statement is meant to eliminate any differences existing between the FASB standards and the standards issued by the International Accounting Standards Board by clarifying that any abnormal idle facility expense, freight, handling costs and spoilage be recognized as current-period charges. The adoption of this Statement by VIVUS in the first quarter of 2006 did not have a material impact on results of operations, financial position or cash flows, as the Company had previously expensed a portion of its manufacturing overhead as period cost due to excess capacity.

Prepaid Expenses and Other Assets

Prepaid expenses and other assets generally consist of deposits, other receivables and prepayments for future services. Prepayments are expensed when the services are received.

Property, Plant and Equipment

Property, plant and equipment is stated at cost and includes land, buildings, building improvements, machinery and equipment, which includes tooling, computers and software, and furniture and fixtures. For financial reporting, depreciation is computed using the straight-line method over estimated useful lives of twenty years for buildings, and two to seven years for machinery and equipment, computers and software, and furniture and fixtures. Building improvements are amortized using the straight-line method over the estimated useful lives. Expenditures for repairs and maintenance, which do not extend the useful life of the property and equipment, are expensed as incurred. Upon retirement, the asset cost and related accumulated depreciation are relieved from the accompanying consolidated financial statements. Gains and losses associated with dispositions are reflected as a component of other income, net in the accompanying consolidated statements of operations and other comprehensive income (loss).

In accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, long-lived assets, such as property, plant and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to an estimate of undiscounted future cash flows expected to be generated by the asset. If the carrying amount of the asset exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset. Assets to be disposed

of would be separately presented in the balance sheet and reported at the lower of the carrying amount or fair value less costs to sell, and are no longer depreciated. The assets and liabilities of a disposed group classified as held for sale would be presented separately in the appropriate asset and liability sections of the balance sheet. The Company believes the future cash flows to be received from the long-lived assets will exceed the assets' carrying value, and accordingly the Company has not recognized any impairment losses through December 31, 2006.

Restricted Cash

In connection with a \$5.4 million loan from Crown Bank, N.A. (Crown) in the first quarter of 2006, the Company provided a \$700,000 Certificate of Deposit held by Crown as collateral on the loan, classified as restricted cash.

Fair Value of Financial Instruments

Financial instruments, including cash and cash equivalents, accounts receivable, accounts payable, and accrued liabilities, are carried at cost, which management believes approximates fair value because of the short-term maturity of these instruments.

Revenue Recognition

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

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

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

United States

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

International

The Company has supply agreements with Meda AB to market and distribute MUSE internationally in some Member States of the European Union. In Canada, the Company has entered into a license and supply agreement with Paladin Labs, Inc. for the marketing and distribution of MUSE. Sales to the Company's distribution partner, who supplies MUSE in the European marketplace, for 2006, 2005 and 2004 were 91.7%, 93.4%, and 96.7% of international sales, respectively. The balance of international sales was made to the Company's Canadian distribution partner.

The Company invoices its international distributors based on an agreed transfer price per unit, which is subject to revision based on contractual formulas upon quarterly reconciliations. Final pricing for

product shipments to international distributors is subject to contractual formulas based on the distributor's net realized price to its customers. The Company recognizes additional revenue, if any, upon finalization of pricing with its international distributors. International distributors generally do not have the right to return products unless the products are damaged or defective.

The Company initially recorded \$1.5 million of unearned revenue related to an upfront payment in accordance with the international supply agreement signed with Meda AB (Meda) in September 2002. In January 2006, the Company received a milestone payment from Meda of \$2.0 million. The milestone payment provides Meda with the right to continue to sell and distribute MUSE in its European territories. These amounts are being recognized as income ratably over the term of the supply agreement. Through December 31, 2006, \$950,000 has been recognized as revenue.

In November 2004, the Company recorded \$125,000 of unearned revenue related to an upfront licensing payment in accordance with an amendment to its international supply and distribution agreement with Paladin Labs, Inc. This amount is being recognized as income ratably over the term of the supply and distribution agreement. Through December 31, 2006, \$27,000 has been recognized as revenue.

Advertising and Sales Promotion expenses

Advertising and sales promotion expenses are charged to expense as incurred. The Company spent \$1.4 million in 2006, \$801,000 in 2005, and \$1.2 million in 2004 on advertising and sales promotion costs related to its marketed product, MUSE.

Shipping and Handling Costs

Shipping costs included in Selling, General and Administrative for 2006, 2005 and 2004, in thousands, are \$212, \$218, and \$200, respectively. Handling costs included in Cost of Goods Sold and Manufacturing Expense for 2006, 2005, and 2004, in thousands, are \$354, \$277, and \$332, respectively.

Research and Development Expenses and Accruals

Research and development (R&D) expenses include license fees, related compensation, contractor fees, facilities costs, administrative expenses and clinical trials at other companies and research institutions under agreements, which are generally cancelable, among other related research and development costs. The Company also records accruals for estimated clinical study costs. Clinical study costs represent costs incurred by clinical research organizations, or CROs, and clinical sites. These costs are recorded as a component of R&D expenses. The Company analyzes the progress of the clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the accrued liabilities. Significant judgments and estimates must be made and used in determining the accrued balance in any accounting period. Actual costs incurred may or may not match the estimated costs for a given accounting period. Actual results could differ from those estimates under different assumptions. Revisions are charged to expense in the period in which the facts that give rise to the revision become known.

Product Returns

The Company has estimated reserves for product returns from wholesalers, hospitals and pharmacies. The Company estimates its reserves by utilizing historical information and data obtained from external sources. The Company records reserves for anticipated returns of expired or damaged product in the United States. The Company follows this method since reasonably dependable estimates of product returns can be made based on historical experience. Revisions in returns estimates are charged to income in the period in which the facts that give rise to the revision become known. There is no right-of-return on expired product sold internationally subsequent to shipment; thus, no returns reserve is needed. The

Company routinely assesses its experience with product returns and adjusts the reserves accordingly. If actual product returns are greater than the Company's estimates, additional reserves may be required.

Government Chargebacks, Rebates and Sales Reserves

The Company has estimated reserves for government chargebacks for goods purchased by certain Federal government organizations including the Veterans Administration, Medicaid rebates to states for goods purchased by patients covered by Medicaid, Medicare and other rebate programs and cash discounts for prompt payment. The Company estimates its reserves by utilizing historical information, current contract and statutory requirements, estimated customer inventory levels and data obtained from external sources. In estimating government chargeback reserves, the Company analyzes actual chargeback amounts and applies historical chargeback rates to estimates of the quantity of units sold subject to chargebacks. In estimating Medicaid and other rebates, the historical rebate percentage is used to estimate future rebates. Effective January 1, 2006, MUSE no longer qualifies for Medicaid reimbursement, which has not had a significant impact to the Company's business. Effective January 1, 2007, MUSE will no longer qualify for Medicare Part D, which the Company does not believe will have a significant impact on its business. The Company routinely assesses its experience with Medicaid, Medicare and other rebates and government chargebacks and adjusts the reserves accordingly. If actual government chargebacks, Medicaid and Medicare rebates, and other rebates are greater than the Company's estimates, additional reserves may be required.

Share-based Compensation

On January 1, 2006, the Company adopted SFAS 123(revised 2004), *Share-Based Payment* (SFAS 123(R)), which requires the measurement and recognition of compensation expense for all stock-based payment awards made to employees and directors, including employee stock options, restricted stock, and stock appreciation rights (SARS) based on estimated fair values. The Company adopted SFAS 123(R) using the modified prospective transition method, which requires application of the accounting standard as of January 1, 2006, the first day of fiscal year 2006. The consolidated financial statements for the year ended December 31, 2006 reflect the impact of SFAS 123(R). In accordance with the modified prospective transition method, the consolidated financial statements for prior periods have not been restated to reflect the impact of SFAS 123(R). Therefore, the results for the fiscal 2006 are not directly comparable to the same period in the prior year.

On November 10, 2005, the FASB issued FASB Staff Position No. SFAS 123(R)-3, *Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards*. The Company has elected to adopt the alternative transition method provided in this FASB Staff Position for calculating the tax effects of share-based compensation pursuant to SFAS 123(R). The alternative transition method includes a simplified method to establish the beginning balance of the additional paid-in capital pool (APIC pool) related to the tax effects of employee share-based compensation, which is available to absorb tax deficiencies recognized subsequent to the adoption of SFAS 123(R).

Prior to the adoption of SFAS 123(R)

Prior to the adoption of SFAS 123(R), as permitted by SFAS No. 123, *Accounting for Stock-Based Compensation*, (SFAS 123) and SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*, the Company applied the existing accounting rules under APB Opinion No. 25, *Accounting for Stock Issued to Employees*, (APB 25) which provided that no compensation expense was charged for options granted at an exercise price equal to or greater than the market value of the underlying common stock on the date of grant.

The following table illustrates the effect on net loss and net loss per share as if the Company had applied the fair value recognition provisions of SFAS 123 to awards granted under the Company's stock-based compensation plans prior to the adoption. For purposes of this pro forma disclosure, the value of the options was estimated using a Black-Scholes option-pricing model (Black-Scholes Model) and amortized on an accelerated basis over the requisite service period of the individual grants, which generally equals the vesting period. In the pro forma information for the periods prior to 2006, the Company accounted for forfeitures as they occurred. The disclosures for the year ended December 31, 2006 were not presented because stock-based awards were accounted for under SFAS 123(R)'s fair-value method during this period.

	2005	2004
Net loss, as reported	\$ (24,484)	\$ (21,583)
Deduct total stock-based employee compensation expense determined under fair-value-based method for all awards, net of tax	(1,768)	(1,970)
Pro forma net loss	\$ (26,252)	\$ (23,553)
Net loss per share, as reported:		
Basic and diluted	\$ (0.57)	\$ (0.57)
Pro forma net loss per share:		
Basic and diluted	\$ (0.61)	\$ (0.62)

The weighted-average fair value of options granted in 2005 and 2004 was \$2.19 and \$3.17, respectively.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions used for grants in 2005 and 2004: no dividend yield, expected volatility of 53% and 66%, respectively, risk-free interest rates of 4% and between 2% to 4%, respectively and an expected term of 5 years for both years.

Effective February 28, 2005, the vesting of the 359,682 outstanding stock options granted on January 21, 2002, of which 82,479 were unvested options, was accelerated to that date. The options were originally scheduled to vest during the period from January 2002 to January 2012. On the accelerated vesting date, the per share market value of VIVUS stock of \$3.98 was less than the strike price of the options, which was \$8.08 per share. When considering this action, the Compensation Committee took into account that accelerating the vesting of these out-of-the money options prior to when the Company expected to adopt FAS 123R, would further reduce the amount of compensation expense that the Company would be required to record in 2006 and beyond as a result of the previously granted equity incentive awards. In addition, by accelerating these options before the implementation of FAS 123R, the expenses associated with the implementation of FAS 123R will be lower in future periods. The acceleration of these out-of-the money options did not cause any additional compensation expense in 2005. Under FAS 123R, the compensation expense associated with these out-of-the-money options would have been significant.

Income Taxes

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

License Agreements

The Company has obtained rights to patented technologies under several licensing agreements. Non-refundable licensing payments made on technologies that are yet to be proven are expensed to research and development. Royalties paid associated with existing products are expensed to cost of goods sold and manufacturing expense when the liability is generated upon sale of product.

Net (Loss) Income Per Share

Basic (loss) earnings per share, or EPS, is computed using the weighted average number of common shares outstanding during the periods. Diluted EPS is based on the weighted average number of common and common equivalent shares, which represent shares that may be issued in the future upon the exercise of outstanding stock options under the treasury stock method. The computation of basic and diluted EPS for the years ended December 31, 2006, 2005 and 2004 are as follows:

	2006	2005	2004
	(In thousands, except per share data)		
Net loss	\$ (21,624)	\$ (24,484)	\$ (21,583)
Net loss per share basic	\$ (.45)	\$ (.57)	\$ (.57)
Effect of dilutive securities (stock options)			
Net loss per share diluted	\$ (.45)	\$ (.57)	\$ (.57)
Shares used in the computation of net loss per share basic	48,103	43,272	38,010
Effect of dilutive securities (stock options)			
Diluted shares	48,103	43,272	38,010

Potentially dilutive options outstanding of 243,991, 161,212 and 696,815 at December 31, 2006, 2005 and 2004, respectively, are excluded from the computation of diluted EPS for 2006, 2005 and 2004 because the effect would have been antidilutive.

Future Accounting Requirements

In February 2007, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115*. SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value. This statement provides entities the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. This Statement is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. Management is currently evaluating the impact of adopting this Statement.

In September 2006, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) 157, *Fair Value Measurements*. SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles (GAAP) and expands disclosures about fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The Company is currently evaluating the effect, if any, that the adoption of SFAS 157 will have on its financial position and results of operations.

In September 2006, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* (SAB 108). SAB 108 provides interpretive guidance on how the effects of prior-year uncorrected misstatements should be considered when quantifying misstatements in the current year financial statements. SAB 108 requires registrants to quantify misstatements using both an income

statement (rollover) and balance sheet (iron curtain) approach and evaluate whether either approach results in a misstatement that, when all relevant quantitative and qualitative factors are considered, is material. If prior year errors that had been previously considered immaterial now are considered material based on either approach, no restatement is required so long as management properly applied its previous approach and all relevant facts and circumstances were considered. If prior years are not restated, the cumulative effect adjustment is recorded in opening accumulated earnings as of the beginning of the fiscal year of adoption. SAB 108 is effective for fiscal years ending on or after November 15, 2006, with earlier adoption encouraged. The adoption of SAB 108 did not have a material effect on the Company's consolidated financial condition or results of operations.

In July 2006, the FASB issued FASB Interpretation No. 48 (FIN 48) *Accounting for Uncertainty in Income Taxes* an interpretation of FASB *Statement No. 109* , to clarify certain aspects of accounting for uncertain tax positions, including issues related to the recognition and measurement of those tax positions. This interpretation is effective for fiscal years beginning after December 15, 2006. VIVUS is in the process of evaluating the impact of the adoption of this interpretation on its results of operations and financial condition.

Note 2. Cash, Cash Equivalents and Available-for-Sale Securities

The fair value and the amortized cost of cash, cash equivalents, and available-for-sale securities by major security type at December 31, 2006 and 2005 are presented in the tables that follow. Fair values are based on quoted market prices obtained from an independent broker. For each category of investment securities, the table presents gross unrealized holding gains and losses.

As of December 31, 2006 (in thousands):

	Amortized Cost	Fair Market Value	Unrealized Holding Gains	Unrealized Holding Losses
Cash and money market	\$ 24,710	\$ 24,710	\$	\$
Commercial paper	28,327	28,317		(10)
Corporate bonds	5,845	5,844		(1)
Total	58,882	58,871		(11)
Amount classified as cash and cash equivalents	(44,628)	(44,628)		
Amount classified as available-for-sale securities	\$ 14,254	\$ 14,243	\$	\$ (11)

As of December 31, 2005 (in thousands):

	Amortized Cost	Fair Market Value	Unrealized Holding Gains	Unrealized Holding Losses
Cash and money market	\$ 13,758	\$ 13,758	\$	\$
Commercial paper	8,478	8,476		(2)
Corporate bonds	400	400		
U.S. government securities	4,400	4,372		(28)
Total	27,036	27,006		(30)
Amount classified as cash and cash equivalents	(22,236)	(22,236)		
Amount classified as available-for-sale securities	\$ 4,800	\$ 4,770	\$	\$ (30)

Edgar Filing: VIVUS INC - Form 10-K

Available-for-sale securities with original maturities beyond one year from the balance sheet date are classified as non-current. All available-for-sale securities are classified as current assets at December 31, 2006 and December 31, 2005.

Note 3. Inventories

Inventory balances, net of reserves of \$4.4 million and \$3.8 million, as of December 31, 2006 and 2005, respectively, consist of (in thousands):

	2006	2005
Raw materials and component parts	\$ 2,793	\$ 3,666
Work in process	66	33
Finished goods	468	805
Inventory, net	\$ 3,327	\$ 4,504

As noted above, the Company has recorded significant reserves against the carrying value of its inventory of raw material and certain component parts. The reserves relate primarily to inventory that the Company previously estimated would not be used. In addition, in 2006 the Company recorded a \$764,000 inventory write-down related to the purchase of alprostadil, considered to be in excess of projected production needs. In the fourth quarter of 2004, the Company determined that it would likely not use the fully reserved raw materials inventory in future production and, consequently, none of the reserved raw materials was used in either 2005 or 2006. As of December 31, 2006, the Company does not intend to use any of the reserved raw materials in future production. In the first quarter of 2005, the Company determined that it likely would continue to use some portion of the fully reserved component parts in production. The Company used \$99,000, \$76,000 and \$844,000 of its fully reserved component parts inventory during 2006, 2005 and 2004, respectively. When the Company records inventory reserves, it establishes a new, lower cost basis for the inventory for accounting purposes. Accordingly, to the extent that this fully reserved inventory was used in production in 2004, 2005 and 2006, it was charged to cost of goods sold at a zero basis, which had a favorable impact on cost of goods sold. The original cost of the fully reserved inventory related to component parts is \$819,000 as of the end of 2006, and we intend to continue to use this reserved component parts inventory in production when appropriate.

Note 4. Property, Plant and Equipment

Property, plant and equipment as of December 31, 2006 and 2005, respectively, consist of (in thousands):

	2006	2005
Land	\$ 901	\$ 901
Buildings	3,102	3,102
Machinery and equipment	18,361	18,161
Computers and software	2,446	2,464
Furniture and fixtures	1,204	1,204
Building improvements	12,050	11,951
	38,064	37,783
Accumulated depreciation	(29,515)	(28,639)
Property and equipment, net	\$ 8,549	\$ 9,144

On December 22, 2005, the Company purchased from its landlord its principal manufacturing facility, which was previously leased, for \$7.1 million. The facilities include two buildings totaling 90,000 square feet, although one of the buildings is used for warehousing component parts. The purchase price was

funded in part by \$3.3 million, 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. As a result, the \$3.0 million restoration liability on this facility, which had been recorded in 1998, was eliminated and recorded as an adjustment against the purchase price of the building in December 2005.

For the years ended December 31, 2006, 2005 and 2004, depreciation expense, in thousands, was \$1,074, \$1,341 and \$1,936, respectively.

Note 5. Prepaid Expenses and Other Assets

Prepaid expenses and other assets includes a receivable of \$1.3 million for an FDA refund of the Company's application fee paid in September 2006 for the NDA for EvaMist and a refund of the fiscal year 2007 product and establishment fees for its marketed product, MUSE, which was paid to the FDA in October 2006. The Company is due a refund pursuant to Section 736(d)(1)(C) of the Federal Food, Drug and Cosmetic Act (FDC Act) on the basis that the fees paid by the Company exceed the anticipated present and future costs incurred by the FDA in conducting the process for the review of human drug applications for VIVUS, Inc.

Note 6. Notes Payable

Tanabe Line of Credit

In the first quarter of 2004, the Company signed an agreement for a secured line of credit with Tanabe Holding America, Inc., a subsidiary of Tanabe Seiyaku Co., Ltd., or Tanabe, allowing it to borrow up to \$8.5 million to be used for the development of avanafil, an erectile dysfunction compound that has completed Phase 2 clinical trials. The secured line of credit may be drawn upon quarterly and each quarterly borrowing has a 48-month term and bears interest at the annual rate of 2%. There are no financial covenants associated with this secured line of credit. Under certain conditions, at the Company's option, payments on this secured line of credit may be made, in whole or in part, in common stock. As of December 31, 2006, VIVUS had long-term notes payable to Tanabe of \$6.3 million, and \$2.2 million of available credit under this agreement. All the assets of the Company, except the land and buildings, serve as collateral for this line of credit.

Crown Bank N.A. Loan

On January 4, 2006, VIVUS, Inc. and Vivus Real Estate LLC, a wholly owned subsidiary of VIVUS, Inc. (jointly, the Company) entered into a Term Loan Agreement and a Commercial Mortgage Note (the Agreements) with Crown Bank N. A. (Crown) secured by the land and buildings, among other assets, located at 735 Airport Road and 745 Airport Road in Lakewood, New Jersey (the Facility). The Facility is the Company's principal manufacturing facility, which the Company purchased on December 22, 2005. Under the Agreements, the Company borrowed \$5,375,000 on January 4, 2006 from Crown payable over a 10-year term. 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%. Principal and interest of \$46,202 are payable monthly for the first 12 months based upon a 20 year amortization schedule and are adjusted annually at the time of the interest rate reset. All remaining principal is due on February 1, 2016. The Agreements contain prepayment penalties, and a requirement to maintain a depository account at Crown with a minimum collected balance of \$100,000 which, if not maintained, will result in an automatic increase in the interest rate on the note of one-half (0.5%) percent. The Facility, assignment of rents and leases on the Facility, and a \$700,000 Certificate of Deposit held by Crown, classified as restricted cash, serve as collateral for these Agreements.

Edgar Filing: VIVUS INC - Form 10-K

Total long-term notes payable consist of the following (in thousands):

	December 31,	
	2006	2005
Tanabe line of credit	\$ 6,324	\$ 5,164
Crown Bank N.A. loan	5,281	
Total notes payable	11,605	5,164
Less current portion	(117)	
Total long-term notes payable	\$ 11,488	\$ 5,164

Current portion of notes payable is included under the heading Accrued and other liabilities .

Future minimum principal payments of the long-term notes payable are as follows (in thousands):

Year ending December 31,	Tanabe Line of Credit	Crown Bank N.A. Loan	Total
2007	\$	\$ 117	\$ 117
2008	3,239	127	3,366
2009	1,925	138	2,063
2010	1,160	150	1,310
2011		164	164
Thereafter		4,585	4,585
Total	\$ 6,324	\$ 5,281	\$ 11,605

Note 7. Stockholders Equity

Common Stock

The Company is authorized to issue 200 million shares of common stock. As of December 31, 2006 and 2005, there were 58,144,264 and 44,641,591 shares, respectively, issued and outstanding.

On December 22, 2004, the Company filed a shelf Registration Statement (File Number 333-12159) on Form S-3 with the SEC, which allows it to offer and sell up to an aggregate of \$50 million of common stock from time to time in one or more offerings. The terms of any such future offering would be established at the time of such offering. On February 22, 2005, the Company filed a prospectus supplement with the SEC relating to an underwritten public offering of 7,500,000 shares of common stock under the existing shelf registration statement and supplement thereto. On March 15, 2005, VIVUS sold 6,250,000 shares of its common stock at a price of \$3.40 per share, providing the Company with net proceeds of \$19.6 million.

On May 10, 2006, the Company sold \$12.0 million of its common stock in a registered direct offering. Under the terms of the financing, the Company sold 3,669,725 shares of VIVUS common stock at a price of \$3.27 per share to two institutional investors. On May 11, 2006, the Company filed a prospectus supplement with the Securities and Exchange Commission relating to this registered direct offering under the existing shelf Registration Statement (File Number 333-12159) and supplement thereto.

On July 14, 2006, VIVUS, Inc. filed with the Securities and Exchange Commission (SEC) a shelf Registration Statement on Form S-3. The shelf Registration Statement (File Number 333-135793) was declared effective by the SEC on August 16, 2006, providing the Company with the ability to offer and sell up to an aggregate of \$80.0 million of common stock from time to time in one or more offerings. The terms of any such future offering would be established at the time of such offering. This shelf Registration Statement (File Number 333-135793) replaces shelf Registration Statement (File Number 333-12159).

On November 17, 2006, the Company raised \$33.6 million in a registered direct offering of VIVUS common stock pursuant to this shelf Registration Statement. Under the terms of this financing, the Company sold and issued a total of 6,750,000 shares of its common stock at a price of \$3.50 per share in an initial closing and an additional 2,850,000 shares at \$3.50 per share in a second closing on December 8, 2006. All of the shares of common stock were offered pursuant to the effective shelf Registration Statement on Form S-3 filed with the Securities and Exchange Commission on July 14, 2006.

Preferred Stock

The Company is authorized to issue 5 million shares of undesignated preferred stock with a par value of \$1.00 per share. As of December 31, 2006 and 2005, there are no preferred shares issued or outstanding. The Company may issue shares of preferred stock in the future, without stockholder approval, upon such terms as the Company's management and Board of Directors may determine.

Note 8. Stock Option and Purchase Plans

Stock Option Plan

Under the 2001 Stock Option Plan, or the 2001 Plan, which was approved by the stockholders at the annual meeting held on June 5, 2002, the Company may grant incentive or non-statutory stock options or stock purchase rights, or SPRs. On July 12, 2006, the Board of Directors adopted an amendment to the 2001 Plan to add the ability to issue Restricted Stock Units, or RSUs, under the 2001 Plan. In contrast to restricted stock awards, the newly permitted RSUs would represent an obligation of the Company to issue unrestricted shares of common stock or cash to the grantee only when and to the extent that the vesting criteria of the award are satisfied. As in the case of restricted stock awards, vesting criteria for RSUs can be based on time or other conditions specified by the Board or an authorized committee of the Board. However, until vesting occurs, the grantee is not entitled to any stockholder rights with respect to the unvested shares. Upon vesting of an RSU, the recipient receives one share of VIVUS stock for each vested restricted stock unit or a cash payment for the value thereof. The Company, in its sole discretion, may pay earned RSUs in cash, shares, or a combination thereof. Shares represented by RSUs that are fully paid in cash again will be available for grant under the Plan. The Company issues new shares for settlement of vested restricted stock units and exercises of stock options. The Company does not have a policy of purchasing its shares relating to its share-based programs.

The maximum aggregate number of shares that may be optioned and sold under the 2001 Plan is 1,000,000 shares plus (a) any shares that have been reserved but not issued under the Company's 1991 Incentive Stock Option Plan, or the 1991 Plan; (b) any shares returned to the 1991 Plan as a result of termination of options or repurchase of shares issued under the 1991 Plan; and (c) an annual increase to be added on the first day of the Company's fiscal year beginning 2003, equal to the lesser of (i) 1,000,000 shares, (ii) 2.5% of the outstanding shares on such date, or (iii) a lesser amount determined by the Board. The 2001 Plan allows the Company to grant incentive stock options to employees at not less than 100% of the fair market value of the stock (110% of fair market value for individuals who control more than 10% of the Company stock) at the date of grant, as determined by the Board of Directors.

The 2001 Plan allows the Company to grant non-statutory stock options to employees, directors and consultants at a price to be determined by the Board of Directors. The term of the option is determined by the Board of Directors on the date of grant but shall not be longer than ten years. The 2001 Plan allows the Company to grant SPRs to employees and consultants. Sales of stock under SPRs are made pursuant to restricted stock purchase agreements containing provisions established by the Board of Directors. The Company has a right, but not the obligation, to repurchase the shares at the original sale price, which expires at a rate to be determined by the Board of Directors. As of December 31, 2006, no SPRs have been granted under the 2001 Plan.

Edgar Filing: VIVUS INC - Form 10-K

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

Total estimated share-based compensation expense, related to all of the Company's share-based awards, recognized for the year ended December 31, 2006 was comprised as follows (in thousands, except per share data):

	Year Ended December 31, 2006
Cost of goods sold and manufacturing expense	\$ 348
Research and development	613
Selling, general and administrative	1,104
Share-based compensation expense before taxes	2,065
Related income tax benefits	
Share-based compensation expense, net of taxes	\$ 2,065
Net share-based compensation expense, per common share:	
Basic and diluted	\$ 0.04

At December 31, 2006, a total of 4,550,152 stock options were outstanding under our stock option plans. Stock-based compensation expense recognized for the year ended December 31, 2006 included compensation expense for stock options granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the pro forma provisions of SFAS 123. Included in stock-based compensation expense for the year ended December 31, 2006 was \$1.9 million related to stock options, \$142,000 related to the employee stock purchase plan, and \$16,000 related to restricted stock units, net of the estimated forfeitures.

As of December 31, 2006, unrecognized estimated compensation expense totaled \$1.6 million related to non-vested stock options, \$49,000 related to the employee stock purchase plan, and \$113,000 related to restricted stock units. The weighted average remaining requisite service period of the non-vested options was 1.3 years, of the employee stock purchase plan was 4.5 months, and of the restricted stock units was 4.7 years.

Valuation Assumptions

The fair value of stock options granted in the year ended December 31, 2006 was estimated using a Black-Scholes Model with the following weighted average assumptions:

	Twelve months ended December 31, 2006
Expected term (in years)	6.18
Volatility	75.41 %
Risk-free interest rate	4.88 %
Dividend yield	0.00 %

Expected Term: VIVUS's expected term represents the period that our stock-based awards are expected to be outstanding based on the simplified method provided in Staff Accounting Bulletin No. 107 (SAB 107) which averages an award's weighted average vesting period and expected term for plain vanilla share options. Under SAB 107, options are considered to be plain vanilla if they have the following basic characteristics: granted at-the-money; exercisability is conditioned upon service through the vesting date; termination of service prior to vesting results in forfeiture; limited exercise period following termination of service; and options are non-transferable and non-hedgeable. The range of expected terms used in the Black-Scholes Model in 2006 was 5.19 years to 6.25 years.

Expected Volatility: The Company estimated volatility using the historical share price performance over the expected term of the option. The Company also considered other factors such as its current clinical trials and other company activities that may affect the volatility of VIVUS stock in the future but determined that at this time, the historical volatility was more indicative of expected future stock performance. The range of expected volatility used in the Black-Scholes Model in 2006 was 68% to 77%.

Expected Dividend: The Black-Scholes Model requires a single expected dividend yield as an input. The Company does not anticipate paying any dividends in the near future.

Risk-Free Interest Rate: The Company bases the risk-free interest rate used in the Black-Scholes Model on the implied yield available on U.S. Treasury zero-coupon issues with an equivalent remaining term, in effect during the period of the grant. The range of risk-free interest rates used in the Black-Scholes Model in 2006 was 4.60% to 5.11%.

Estimated Pre-vesting Forfeitures: The Company develops pre-vesting forfeiture assumptions based on an analysis of historical data.

During 2006, options to purchase 15,000 shares of common stock were granted to a research consultant. The fair value of the options was estimated to be \$34,000 on the date of grant using the Black-Scholes option-pricing model with the following assumptions: no dividend yield, expected volatility of 75%, risk-free interest rate of 5.11% and an expected term of 6.25 years. In the year ended December 31, 2006, the Company recorded all of the compensation related to this grant to research and development expense.

During the third quarter of 2006, the Company granted 62,500 restricted stock units to an officer with a weighted average grant date fair value of \$2.04 per restricted stock unit. This grant contains a market condition and was valued using a binomial model. The following assumptions were used for valuing this grant: no dividend yield, expected volatility of 60.60%, risk-free interest rate of 4.70% and an expected term of 5 years.

Edgar Filing: VIVUS INC - Form 10-K

A summary of stock option award activity under these plans is as follows:

	Number of Shares	Weighted-Average Exercise Price
Outstanding, December 31, 2003	3,976,426	\$ 4.38
Granted	868,126	4.82
Exercised	(251,212)	3.41
Cancelled	(478,555)	4.14
Outstanding, December 31, 2004	4,114,785	4.56
Granted	1,132,178	3.76
Exercised	(144,523)	3.05
Cancelled	(697,776)	5.11
Outstanding, December 31, 2005	4,404,664	4.31
Granted	667,535	3.24
Exercised	(120,414)	2.99
Cancelled	(401,633)	4.09
Outstanding, December 31, 2006	4,550,152	\$ 4.21

A summary of restricted stock units award activity under the 2001 Plan as of December 31, 2006 and changes during the period then ended are presented below:

	Year Ended December 31, 2006			
	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Restricted stock units outstanding December 31, 2005		\$		
Granted	62,500	2.04		
Vested				
Forfeited				
Restricted stock units outstanding, December 31, 2006	62,500	\$ 2.04	4.7	\$ 255,000

All of the Company's restricted stock units were unvested as of December 31, 2006.

At December 31, 2006, stock options were outstanding and exercisable as follows:

Options Outstanding	Options Exercisable				
Range of Exercise Prices	Number Outstanding at December 31, 2006	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable December 31, 2006	Weighted-Average Exercise Price
\$2.00 - \$3.73	1,873,700	6.6 years	\$ 3.18	939,989	\$ 2.99
\$3.75 - \$4.58	1,772,499	5.6 years	\$ 4.16	1,489,291	\$ 4.14
\$4.59 - \$8.08	903,953	4.9 years	\$ 6.44	806,299	\$ 6.54
\$2.00 - \$8.08	4,550,152	5.9 years	\$ 4.21	3,235,579	\$ 4.40

The aggregate intrinsic value of outstanding options as of December 31, 2006 was \$875,000, of which \$614,000 related to exercisable options.

At December 31, 2006, 1,914,080 options remain available for grant. In the year ended December 31, 2006, in accordance with the terms of the 2001 Plan, the Company transferred a net total of 820,193 expired plan shares to the 2001 Plan. Options under these plans generally vest over four years, and all options expire after ten years.

Stock Purchase Plan

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

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

The fair value of employee stock purchases made under the ESPP in the year ended December 31, 2006 was also estimated using the Black-Scholes option pricing model. The following assumptions were used: expected term ranging from .49 years to .53 years, expected volatility ranging from 62.60% to 64.84%, no dividend yield and risk free rates ranging from 4.25% to 5.16%. The weighted average assumptions used in 2006 were: expected term of .51 years, expected volatility of 63.95%, no dividend yield and a risk free rate of 4.76%.

As of December 31, 2006, 1,033,288 shares have been issued to employees and there are 366,712 available for issuance under the Stock Purchase Plan. The weighted average fair market value of shares issued under the Stock Purchase Plan in 2006, 2005 and 2004 was \$2.80, \$2.30, and \$3.90 per share, respectively.

Note 9. Agreements

In 2001, VIVUS entered into a Development, Licensing and Supply Agreement with Tanabe for the development of avanafil, an oral PDE5 inhibitor product candidate for the treatment of erectile dysfunction. Under the terms of the 2001 Development, Licensing and Supply Agreement with Tanabe, the Company paid a \$2.0 million license fee obligation to Tanabe in the year ended December 31, 2006, which was previously accrued in the year ended December 31, 2004. The Company expects to make other substantial payments to Tanabe in accordance with its agreements with them. These payments are based on certain development, regulatory and sales milestones. In addition, VIVUS is required to make royalty payments on any future product sales.

In February 2004, the Company entered into exclusive licensing agreements with Acrux Limited (Acrux) and a subsidiary of Acrux under which it has agreed to develop and, if approved, commercialize Testosterone MDTS and EvaMist in the United States for various female health applications. Under the terms of the agreements, the Company agreed to pay to Acrux combined licensing fees of \$3.0 million, up to \$4.3 million for the achievement of certain clinical development milestones, up to \$6.0 million for achieving product approval milestones, and royalties on net sales in the United States following approval and commercialization of each product. The Company made a \$1.0 million milestone payment to Acrux in October 2006 related to the submission of a New Drug Application (NDA) to the FDA for EvaMist. The Company expensed \$1.0 million, \$375,000 and \$3.3 million of clinical development milestone and licensing

fees under the terms of the agreements in 2006, 2005 and 2004, respectively. Upon approval of the NDA for EvaMist, a \$3.0 million product approval milestone will be due to Acrux.

The Company has entered into several agreements to license patented technologies that are essential to the development and production of the Company's transurethral products for the treatment of ED. These agreements generally required milestone payments during the development period. In connection with these agreements, the Company is obligated to pay royalties on product sales covered by the license agreements (4% of United States and Canadian product sales and 3% of sales elsewhere in the world). In 2006, 2005 and 2004, the Company recorded royalty expenses, in thousands, of \$683, \$556 and \$949, respectively, as cost of goods sold and manufacturing expense.

International sales are transacted through distributors. The distribution agreements include certain milestone payments from the distributors to the Company upon achieving established sales thresholds.

Note 10. Commitments

Lease Commitments

The Company purchased its previously leased manufacturing facilities in Lakewood, New Jersey on December 22, 2005. In January 2000, the Company entered into a seven-year lease for its corporate headquarters in Mountain View, California, which expired in January 2007. In November 2006, the Company entered into a new 30-month lease for the existing Mountain View corporate headquarters location with its existing landlord. The new lease commenced on February 1, 2007. The base monthly rent is set at \$1.85 per square foot or \$26,000 per month. The lease expires on July 31, 2009 and allows the Company one option to extend the term of the lease for a period of one year from the expiration of the lease.

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

2007	\$ 586
2008	573
2009	334
	\$ 1,493

Rent expense, in thousands, under operating leases totaled \$751, \$1,466 and \$1,486 for the years ended December 31, 2006, 2005, and 2004, respectively.

Manufacturing Agreements

In November 2002, the Company entered into a manufacturing agreement to purchase raw materials from a supplier beginning in 2003 and ending in 2008. The Company's remaining commitment under this agreement is to purchase a minimum total of \$2.3 million of product from 2007 through 2008. In 2005, the Company purchased \$765,000 of product from this supplier. The Company did not purchase any product from this supplier in 2006.

In January 2004, the Company entered into a manufacturing agreement to purchase raw materials from an additional supplier beginning in 2004 and ending in 2006. In February 2006, the terms of this agreement were amended. In 2006, the Company purchased \$751,000 of product, and in 2005 it purchased \$240,000 of product. Per the terms of the amended agreement, the Company will be required to purchase a minimum total of \$765,000 of additional product from 2007 through 2008.

Other Agreements

We have entered into various agreements with clinical consultants and clinical research organizations to perform clinical studies on our behalf and, at December 31, 2006, our remaining commitment under these agreements totaled \$750,000. We have also entered into various agreements with research consultants and other contractors to perform drug research, testing and manufacturing including animal studies and, at December 31, 2006, our remaining commitment under these agreements totaled \$1.6 million. In addition, in December 2006, we entered into a marketing promotion agreement for our erectile dysfunction product, MUSE. At December 31, 2006, our remaining commitment under this agreement totaled \$1.1 million.

Royalties

The Company has certain royalty commitments associated with the shipment and licensing of certain products. Royalty expense is generally based on a dollar amount per unit shipped or a percentage of the underlying revenue. Royalty expense, which was recorded under cost of goods sold and manufacturing expense on the Company's consolidated statements of operations, in thousands, was approximately \$683, \$556, and \$949 in fiscal 2006, 2005, and 2004, respectively.

Indemnifications

In the normal course of business, the Company provides indemnifications of varying scope to customers against claims of intellectual property infringement made by third parties arising from the use of its products. Historically, costs related to these indemnification provisions have not been significant and the Company is unable to estimate the maximum potential impact of these indemnification provisions on our future results of operations.

To the extent permitted under Delaware law, the Company has agreements whereby it indemnifies its officers and directors for certain events or occurrences while the officer or director is, or was, serving at the Company's request in such capacity. The indemnification period covers all pertinent events and occurrences during the officer's or director's lifetime. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited; however, VIVUS has director and officer insurance coverage that reduces its exposure and enables the Company to recover a portion of any future amounts paid. The Company believes the estimated fair value of these indemnification agreements in excess of applicable insurance coverage is minimal.

Note 11. Income Taxes

Deferred income taxes result from differences in the recognition of expenses for tax and financial reporting purposes, as well as operating loss and tax credit carry forwards. Significant components of the Company's deferred income tax assets as of December 31, 2006 are as follows (in thousands):

	2006	2005
Deferred tax assets:		
Net operating loss carry forwards	\$ 46,419	\$ 37,279
Research and development credit carry forwards	7,449	6,284
Inventory reserve	1,707	1,469
Accruals and other	3,053	3,347
Depreciation	3,586	2,989
	62,214	51,368
Valuation allowance	(62,214)	(51,368)
Total	\$	\$

Edgar Filing: VIVUS INC - Form 10-K

For Federal and State income tax reporting purposes, respective net operating loss, or NOL, carry forwards of approximately \$125.7 million and \$60.9 million are available to reduce further taxable income, if any. SFAS 123R prohibits recognition of a deferred income tax asset for excess tax benefits due to stock option exercises that have not yet been realized through a reduction in income taxes payable. Excess tax benefits from employee stock option exercises are included in the deferred balances at December 31, 2005 as a component of the Company's net operating loss carryovers. The entire balance is offset by a full valuation allowance. As a result of adopting SFAS 123R, the unrecognized deferred tax benefits totaled \$45,000 and will be accounted for as a credit to additional paid-in capital, if and when realized through a reduction in income taxes payable. For Federal and State income tax reporting purposes, respective credit carry forwards of approximately \$5.4 million and \$3.2 million are available to reduce future taxable income, if any. The carry forwards, except for the California Research and Development Credit, expire on various dates through 2025. The California research and development credits do not expire. The Internal Revenue Code of 1986, as amended, contains provisions that may limit the net operating loss and credit carry forwards available for use in any given period upon the occurrence of certain events, including a significant change in ownership interest.

A valuation allowance has been recorded for the entire deferred tax asset as a result of uncertainties regarding the realization of the asset balance due to the history of losses and the variability of operating results. The net change in the valuation allowance for the years ended December 31, 2005 and December 31, 2006 was \$9.3 million and \$10.8 million, respectively. As of December 31, 2006 and 2005, the Company had no significant deferred tax liabilities.

The provision for income taxes attributable to continuing operations is based upon loss before provision for income taxes as follows, for the years ended December 31, 2006, 2005 and 2004 (in thousands):

	2006	2005	2004
Loss before income taxes:			
Domestic	\$ (21,590)	\$ (24,135)	\$ (20,388)
International	(14)	(324)	(1,189)
Total	\$ (21,604)	\$ (24,459)	\$ (21,577)

The provision for income taxes consists of the following components for the years ended December 31, 2006, 2005 and 2004 (in thousands):

	2006	2005	2004
Current			
Federal	\$	\$	\$
State	20	18	2
Foreign		7	4
Total provision/(benefit) for income taxes	\$ 20	\$ 25	\$ 6

The provisions for income taxes differs from the amount computed by applying the statutory federal income tax rates as follows, for the years ended December 31, 2006, 2005 and 2004:

	2006	2005	2004
(Benefit)/provision computed at federal statutory rates	(35)%	(35)%	(35)%
State income taxes, net of federal tax effect	(4)	(4)	(4)
Change in valuation allowance	39	39	38
Tax credits			1
(Benefit)/provision for income taxes	0 %	0 %	0 %

Note 12. Concentration of Customers and Suppliers

Sales to significant customers as a percentage of total revenues for the years ended December 31, 2006, 2005 and 2004 are as follows:

	2006	2005	2004
Customer A	51 %	42 %	46 %
Customer B	19 %	23 %	27 %
Customer C	10 %	15 %	12 %
Customer D	13 %	13 %	12 %

Accounts receivable at December 31, 2006 and 2005 by significant customer as a percentage of the total gross accounts receivable balance are as follows:

	2006	2005
Customer A	38 %	36 %
Customer B	31 %	48 %
Customer C	9 %	5 %
Customer D	18 %	8 %

The Company did not have any suppliers making up more than 10% of operating costs.

Note 13. 401(k) Plan

All of the Company's employees are eligible to participate in the VIVUS 401(k) Plan. Employer-matching contributions for the years ended December 31, 2006, 2005 and 2004, in thousands were \$270, \$270 and \$261, respectively. The employer-matching portion of the 401(k) plan began on July 1, 2000.

Note 14. Legal Matters

In the normal course of business, the Company receives claims and makes inquiries regarding patent infringement and other legal matters. The Company believes that it has meritorious claims and defenses and intends to pursue any such matters vigorously.

The Company has received notice from a former employee seeking payment due to their termination in 2005 and in the third quarter of 2006, the Company concluded this matter without a material impact on its financial position.

On November 14, 2006, the Company received a letter from Manatt, Phelps & Phillips LLP on behalf of Acrux DDS Pty Ltd., FemPharm PTY Ltd. and Acrux Limited (collectively "Acrux") notifying the Company of an alleged dispute under the Testosterone and Estradiol Development Agreements between VIVUS and Acrux. The Company believes it is in compliance with all material aspects of both of these agreements and have communicated this belief to Acrux. If the Company is unable to resolve the matter with Acrux, the Company intends to seek to enforce their rights under these agreements. The claims have not progressed further, but, to date, the claims have not been formally withdrawn. Development and commercialization of EvaMist and Testosterone MDTs continues as planned. The Company believes that they have a meritorious defense to claims made by Acrux in connection with the alleged dispute; however, in the event that Acrux should prevail in this matter, it could have a material adverse effect on VIVUS' business, financial condition and results of operations.

The Company is not aware of any other asserted or unasserted claims against it where an unfavorable resolution would have an adverse material impact on the operations or financial position of the Company.

Note 15. Related Party Transactions

Mario M. Rosati, one of the Company's directors, is also a member of Wilson Sonsini Goodrich and Rosati, Professional Corporation, which has served as the Company's outside corporate counsel since its formation and has received compensation at normal commercial rates for its services. In 2006, 2005 and 2004 the Company paid \$561,000, \$344,000 and \$305,000, respectively, to Wilson Sonsini Goodrich and Rosati for legal services.

Note 16. Selected Financial Data (Unaudited)**Selected Quarterly Financial Data (in thousands)**

	Quarter Ended,			
	March 31	June 30	September 30	December 31
2006				
Total revenue	\$ 1,267	\$ 3,640	\$ 4,031	\$ 8,307
Cost of goods sold	\$ 3,020	\$ 2,895	\$ 2,627	\$ 3,391
Net loss	\$ (8,826)	\$ (5,837)	\$ (6,160)	\$ (801)
Net loss per share:				
Basic and diluted	\$ (0.20)	\$ (0.12)	\$ (0.13)	\$ (0.02)
2005				
Total revenue	\$ 629	\$ 1,716	\$ 3,267	\$ 9,042
Cost of goods sold	\$ 2,090	\$ 2,049	\$ 2,477	\$ 4,402
Net loss	\$ (8,837)	\$ (8,650)	\$ (5,960)	\$ (1,037)
Net loss per share:				
Basic and diluted	\$ (0.22)	\$ (0.19)	\$ (0.13)	\$ (0.02)

FINANCIAL STATEMENT SCHEDULE

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

VIVUS, Inc.

SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS

(in thousands)

	Balance at Beginning of Period	Charged to Operations	Charges Utilized	Balance at End of Period
Allowance for Doubtful Accounts				
Fiscal year ended December 31, 2004	\$ 68	\$ 42	\$ (6)	\$ 104
Fiscal year ended December 31, 2005	104	133	(35)	202
Fiscal year ended December 31, 2006	202	(38)	(97)	67
Inventory Reserve				
Fiscal year ended December 31, 2004	5,553	158	(1,794)(1)	3,917
Fiscal year ended December 31, 2005	3,917	107	(258)(2)	3,766
Fiscal year ended December 31, 2006	3,766	877 (3)	(266)(4)	4,377
Accrued Product Returns				
Fiscal year ended December 31, 2004	3,023	1,154	(966)	3,211
Fiscal year ended December 31, 2005	3,211	571	(766)	3,016
Fiscal year ended December 31, 2006	3,016	1,076	(1,619)	2,473
Accrued Chargebacks Reserve				
Fiscal year ended December 31, 2004	904	3,299	(2,577)	1,626
Fiscal year ended December 31, 2005	1,626	3,129	(2,923)	1,832
Fiscal year ended December 31, 2006	\$ 1,832	\$ 2,791	\$ (3,092)	\$ 1,531

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

(2) The Company used \$76,000 of its fully reserved component parts inventory in production. The fully reserved inventory is charged to cost of goods sold at a zero basis when used, which has a favorable impact on gross profit. In the first quarter of 2005, the Company determined that it likely would continue to use some portion of the fully reserved component parts in production.

(3) In the first quarter of 2006, the Company recorded a \$764,000 inventory write-down related to the purchase of alprostadil considered to be in excess of projected production needs.

(4) The Company used \$99,000 of its fully reserved component parts inventory in production. The fully reserved inventory is charged to cost of goods sold at a zero basis when used, which has a favorable impact on gross profit.

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

None.

Item 9A. *Controls and Procedures*

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the timelines specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by SEC Rule 13a-15(b), the Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and the Company's Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of the end of the year covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

- (1) Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- (2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorization of our management and directors; and
- (3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisitions, use or disposition of our assets that could have a material effect on the financial statements.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk. Management is responsible for establishing and maintaining adequate internal control over financial reporting for the company.

Management has used the framework set forth in the report entitled *Internal Control-Integrated Framework* published by the Committee of Sponsoring Organizations of the Treadway Commission, known as COSO, to evaluate the effectiveness of the Company's internal control over financial reporting. Based on this assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2006. Odenberg Ullakko Muranishi & Co. LLP, the independent registered public accounting firm that audited the consolidated financial statements included in the Annual Report on Form 10-K, has issued an attestation report on management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2006. This report, which expresses an unqualified opinion on management's assessment of and the effectiveness of our internal controls over financial reporting as of December 31, 2006, is included herein.

There has been no change in our internal controls over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Item 9B. *Other Information*

None.

101

PART III

Item 10. *Directors, Executive Officers and Corporate Governance*

The information required by this item is hereby incorporated by reference from the information under the captions "Election of Directors" and "Executive Officers" contained in the Company's definitive Proxy Statement, to be filed with the Securities and Exchange Commission no later than 120 days from the end of the Company's last fiscal year in connection with the solicitation of proxies for its 2006 Annual Meeting of Stockholders. The information required by Section 16(a) is incorporated by reference from the information under the caption "Compliance with Section 16(a) of the Securities Exchange Act of 1934" in the Proxy Statement.

The Company has adopted a code of ethics that applies to its Chief Executive Officer, Chief Financial Officer, and to all of its other officers, directors, employees and agents. The code of ethics is available at the Corporate Governance section of the Investor Relations page on the Company's website at www.vivus.com. The Company intends to disclose future amendments to, or waivers from, certain provision of its code of ethics on the above website within five business days following the date of such amendment or waiver.

Item 11. *Executive Compensation*

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

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

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

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

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

Item 14. *Principal Accounting Fees and Services*

The information required by this item is incorporated by reference from the information under the caption "Ratification of Appointment of Independent Auditors" in the Company's Proxy Statement referred to in Item 10 above.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) Documents filed as part of this report.

1. Financial Statements

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

Index to Consolidated Financial Statements

Reports of Independent Registered Public Accounting Firms

Consolidated Balance Sheets as of December 31, 2006 and 2005

Consolidated Statements of Operations and Other Comprehensive Income (Loss) for the years ended December 31, 2006, 2005 and 2004

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2006, 2005 and 2004

Consolidated Statements of Cash Flows for the years ended December 31, 2006, 2005 and 2004

Notes to Consolidated Financial Statements

2. Financial Statement Schedules

The following financial statement schedule of VIVUS, Inc. as set forth on page 99 is filed as part of this Form 10-K and should be read in conjunction with the Financial Statements of VIVUS, Inc. incorporated by reference herein:

Schedule II - Valuation and Qualifying Accounts

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

3. Exhibits

The list of Exhibits required by Item 601 of Regulation S-K. See part (b) below.

(b). Exhibits

Exhibit

Number	Description
3.2(4)	Amended and Restated Certificate of Incorporation of the Registrant
3.3(3)	Bylaws of the Registrant, as amended
3.4(5)	Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock
4.1(4)	Specimen Common Stock Certificate of the Registrant
10.1(1)	Assignment Agreement by and between Alza Corporation and the Registrant dated December 31, 1993
10.2(1)	Memorandum of Understanding by and between Ortho Pharmaceutical Corporation and the Registrant dated February 25, 1992
10.3(1)	Assignment Agreement by and between Ortho Pharmaceutical Corporation and the Registrant dated June 9, 1992

103

Edgar Filing: VIVUS INC - Form 10-K

- 10.4(1) License Agreement by and between Gene A. Voss, MD, Allen C. Eichler, MD, and the Registrant dated December 28, 1992
- 10.5A(1) License Agreement by and between Ortho Pharmaceutical Corporation and Kjell Holmquist AB dated June 23, 1989
- 10.5B(1) Amendment by and between Kjell Holmquist AB and the Registrant dated July 3, 1992
- 10.5C(1) Amendment by and between Kjell Holmquist AB and the Registrant dated April 22, 1992
- 10.5D(1) Stock Purchase Agreement by and between Kjell Holmquist AB and the Registrant dated April 22, 1992
- 10.6A(1) License Agreement by and between Amsu, Ltd., and Ortho Pharmaceutical Corporation dated June 23, 1989
- 10.6B(1) Amendment by and between Amsu, Ltd., and the Registrant dated July 3, 1992
- 10.6C(1) Amendment by and between Amsu, Ltd., and the Registrant dated April 22, 1992
- 10.6D(1) Stock Purchase Agreement by and between Amsu, Ltd., and the Registrant dated July 10, 1992
- 10.11(3) Form of Indemnification Agreement by and among the Registrant and the Directors and Officers of the Registrant
- 10.12(2) 1991 Incentive Stock Plan and Form of Agreement, as amended
- 10.13(1) 1994 Director Option Plan and Form of Agreement
- 10.14(1) Form of 1994 Employee Stock Purchase Plan and Form of Subscription Agreement
- 10.17(1) Letter Agreement between the Registrant and Leland F. Wilson dated June 14, 1991 concerning severance pay
- 10.36(6) Form of Change of Control Agreements dated July 8, 1998 by and between the Registrant and certain Executive Officers of the Company
- 10.41(7) Distribution and Supply Agreement made as of November 20, 2000 between the Registrant and Paladin Labs, Inc.
- 10.42(7) Development, License and Supply Agreement made as of January 22, 2001 between the Registrant and Tanabe Seiyaku Co., Ltd.
- 10.42A(12) Amendment One to Agreement, dated January 9, 2004 between the Registrant and Tanabe Seiyaku Co., Ltd.
- 10.43(8) Settlement and Modification Agreement made as of July 12, 2001 between ASIVI, LLC, AndroSolutions, Inc., Gary W. Neal and the Registrant
- 10.44(9) 2001 Stock Option Plan and Form of Agreement
- 10.44A(18) 2001 Stock Option Plan (As Amended July 12, 2006)
- 10.44B(19) Form of Notice of Grant and Restricted Stock Unit Agreement for the VIVUS, Inc. 2001 Stock Option Plan (As Amended July 12, 2006)
- 10.45(10) Supply Agreement made as of September 3, 2002 between the Registrant and Meda AB

104

Edgar Filing: VIVUS INC - Form 10-K

- 10.46(11) Amendment Three, dated November 21, 2002 by and between the Registrant and CHINOIN Pharmaceutical and Chemical Works, Ltd.
- 10.48(11) Exclusive Distribution Agreement effective as of October 1, 2002 between the Registrant and Cord Logistics, Inc.
- 10.49(11) Distribution and Supply Agreement effective as of February 18, 2003 between the Registrant and Meda AB
- 10.50(12) Testosterone Development and Commercialization Agreement effective as of February 7, 2004 between the Registrant, Fempharm Pty Ltd. and Acrux DDS Pty Ltd.
- 10.51(12) Estradiol Development and Commercialization Agreement effective as of February 12, 2004 between the Registrant, Fempharm Pty Ltd. and Acrux DDS Pty Ltd.
- 10.52(12) Note Purchase Agreement dated January 8, 2004 between the Registrant and Tanabe Holding America, Inc.
- 10.53(12) Manufacture and Supply Agreement dated December 22, 2003 between the Registrant and NeraPharm spol., s.r.o.
- 10.53A(17) First Amendment and Waiver Manufacture and Supply Agreement, dated February 21, 2006 by and between the Company and NeraPharm spol, s.r.o.
- 10.54 (13) Amendment One dated October 11, 2004 to License and Supply Agreement made between the Registrant and Paladin Labs, Inc.
- 10.55(14) Agreement for Sale of Real Estate dated November 15, 2005 by and between the Registrant and 735 Airport Road, L.L.C.
- 10.56(14) Agreement for Sale of Real Estate dated November 15, 2005 by and between the Registrant and 745 Airport Road, L.L.C.
- 10.57(15) Term Loan Agreement dated January 4, 2006 by and between the Registrant and Vivus Real Estate LLC and Crown Bank, N.A.
- 10.58(15) Commercial Mortgage Note dated January 4, 2006 by and between the Registrant and Vivus Real Estate LLC and Crown Bank, N.A.
- 10.59(15) Mortgage and Security Agreement dated January 4, 2006 by and between Vivus Real Estate LLC and Crown Bank, N. A.
- 10.60(16) Lease Agreement effective November 1, 2006 by and between the Registrant and Castro Mountain View, LLC, Thomas A. Lynch, Trudy Molina Flores, Trustee of the Jolen Flores and Trudy Molina Flores Joint Living Trust dated April 3, 2001, E. William and Charlotte Duerkson, husband and wife, E. William and Charlotte Duerkson, Trustees of the Duerkson Family Trust dated February 16, 1999, Daniel F. Dutton, Jr. and Joyce F. Dutton, Trustees under the Dutton Family Trust dated September 16, 1993, Noel S. Schuurman, Trustee of the Noel S. Schuurman Trust, The Duarte Family Partners, L.P., Marie Straube, Trustee of the Marie Antoinette Clough Revocable Living Trust dated January 11, 1989, and Blue Oak Properties, Inc., CP6CC, LLC
- 21.2 Subsidiaries of the Registrant
- 23.1 Consent of ODENBERG, ULLAKKO, MURANISHI & Co. LLP, Independent Registered Public Accounting Firm

105

23.2	Consent of KPMG LLP, Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer, dated March 14, 2007, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended
31.2	Certification of Chief Financial Officer, dated March 14, 2007, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Confidential treatment granted.

Portions of the exhibit have been omitted pursuant to a request for confidential treatment. The confidential portions have been filed with the SEC.

- (1) Incorporated by reference to the same numbered exhibit filed with the Registrant's Registration Statement on Form S-1 No. 33-75698, as amended.
- (2) Incorporated by reference to the same numbered exhibit filed with the Registrant's Registration Statement on Form S-1 No. 33-90390, as amended.
- (3) Incorporated by reference to the same numbered exhibit filed with the Registrant's Form 8-B filed with the Commission on June 25, 1996.
- (4) Incorporated by reference to the same numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1996, as amended.
- (5) Incorporated by reference to exhibit 99.1 filed with Registrant's Amendment Number 2 to the Registration Statement of Form 8-A (File No. 0-23490) filed with the Commission on April 23, 1997.
- (6) Incorporated by reference to the same numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1998.
- (7) Incorporated by reference to the same numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 2000.
- (8) Incorporated by reference to the same numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.
- (9) Incorporated by reference to the same numbered exhibit filed with the Registrant's Registration Statement on Form S-8 filed with the Commission on November 15, 2001.
- (10) Incorporated by reference to the same numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.
- (11) Incorporated by reference to the same numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002.
- (12) Incorporated by reference to the same numbered exhibit filed with the Registrant's Annual Report on Form 10-Q for the quarter ended March 31, 2004.

(13) Incorporated by reference to the same numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 2004.

106

- (14) Incorporated by reference to the same numbered exhibit filed with the Registrant's Form 8-K filed with the Commission on December 23, 2005.
- (15) Incorporated by reference to the same numbered exhibit filed with the Registrant's Form 8-K filed with the Commission on January 6, 2006.
- (16) Incorporated by reference to the same numbered exhibit filed with the Registrant's Form 8-K filed with the Commission on November 7, 2006.
- (17) Incorporated by reference to the same numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006.
- (18) Incorporated by reference to exhibit 10.1 filed with the Registrant's Form 8-K filed with the Commission on July 13, 2006.
- (19) Incorporated by reference to exhibit 10.2 filed with the Registrant's Form 8-K filed with the Commission on July 13, 2006.

107

SIGNATURES

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

VIVUS, INC.,
a Delaware Corporation
By:

/s/ LELAND F. WILSON
Leland F. Wilson
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 14, 2007

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Leland F. Wilson and Timothy E. Morris as his attorney-in-fact for him, in any and all capacities, to sign each amendment to this Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact or his substitute or substitutes may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ LELAND F. WILSON Leland F. Wilson	President, Chief Executive Officer (Principal Executive Officer) and Director	March 14, 2007
/s/ VIRGIL A. PLACE Virgil A. Place	Chairman of the Board and Chief Scientific Officer and Director	March 14, 2007
/s/ TIMOTHY E. MORRIS Timothy E. Morris	Vice President of Finance and Chief Financial Officer (Principal Financial Officer)	March 14, 2007
/s/ LEE B. PERRY Lee B. Perry	Vice President and Chief Accounting Officer (Principal Accounting Officer)	March 14, 2007
/s/ GRAHAM STRACHAN Graham Strachan	Director	March 14, 2007
/s/ MARIO M. ROSATI Mario M. Rosati	Director	March 14, 2007
/s/ MARK B. LOGAN Mark B. Logan	Director	March 14, 2007
/s/ LINDA M. DAIRIKI SHORTLIFFE, M.D. Linda M. Dairiki Shortliffe, M.D.	Director	March 14, 2007

VIVUS, INC.

**REPORT ON FORM 10-K FOR
THE YEAR ENDED DECEMBER 31, 2006****INDEX TO EXHIBITS**

Exhibit Number	Description
3.2(4)	Amended and Restated Certificate of Incorporation of the Registrant
3.3(3)	Bylaws of the Registrant, as amended
3.4(5)	Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock
4.1(4)	Specimen Common Stock Certificate of the Registrant
10.1(1)	Assignment Agreement by and between Alza Corporation and the Registrant dated December 31, 1993
10.2(1)	Memorandum of Understanding by and between Ortho Pharmaceutical Corporation and the Registrant dated February 25, 1992
10.3(1)	Assignment Agreement by and between Ortho Pharmaceutical Corporation and the Registrant dated June 9, 1992
10.4(1)	License Agreement by and between Gene A. Voss, MD, Allen C. Eichler, MD, and the Registrant dated December 28, 1992
10.5A(1)	License Agreement by and between Ortho Pharmaceutical Corporation and Kjell Holmquist AB dated June 23, 1989
10.5B(1)	Amendment by and between Kjell Holmquist AB and the Registrant dated July 3, 1992
10.5C(1)	Amendment by and between Kjell Holmquist AB and the Registrant dated April 22, 1992
10.5D(1)	Stock Purchase Agreement by and between Kjell Holmquist AB and the Registrant dated April 22, 1992
10.6A(1)	License Agreement by and between Amsu, Ltd., and Ortho Pharmaceutical Corporation dated June 23, 1989
10.6B(1)	Amendment by and between Amsu, Ltd., and the Registrant dated July 3, 1992
10.6C(1)	Amendment by and between Amsu, Ltd., and the Registrant dated April 22, 1992
10.6D(1)	Stock Purchase Agreement by and between Amsu, Ltd., and the Registrant dated July 10, 1992
10.11(3)	Form of Indemnification Agreement by and among the Registrant and the Directors and Officers of the Registrant
10.12(2)	1991 Incentive Stock Plan and Form of Agreement, as amended
10.13(1)	1994 Director Option Plan and Form of Agreement
10.14(1)	Form of 1994 Employee Stock Purchase Plan and Form of Subscription Agreement
10.17(1)	Letter Agreement between the Registrant and Leland F. Wilson dated June 14, 1991 concerning severance pay
10.36(6)	Form of Change of Control Agreements dated July 8, 1998 by and between the Registrant and certain Executive Officers of the Company
10.41(7)	Distribution and Supply Agreement made as of November 20, 2000 between the Registrant and Paladin Labs, Inc.

109

10.42(7)	Development, License and Supply Agreement made as of January 22, 2001 between the Registrant and Tanabe Seiyaku Co., Ltd.
10.42A(12)	Amendment One to Agreement, dated January 9, 2004 between the Registrant and Tanabe Seiyaku Co., Ltd.
10.43(8)	Settlement and Modification Agreement made as of July 12, 2001 between ASIVI, LLC, AndroSolutions, Inc., Gary W. Neal and the Registrant
10.44(9)	2001 Stock Option Plan and Form of Agreement
10.44A(18)	2001 Stock Option Plan (As Amended July 12, 2006)
10.44B(18)	Form of Notice of Grant and Restricted Stock Unit Agreement for the VIVUS, Inc. 2001 Stock Option Plan (As Amended July 12, 2006)
10.45(10)	Supply Agreement made as of September 3, 2002 between the Registrant and Meda AB
10.46(11)	Amendment Three, dated November 21, 2002 by and between the Registrant and CHINOIN Pharmaceutical and Chemical Works, Ltd.
10.48(11)	Exclusive Distribution Agreement effective as of October 1, 2002 between the Registrant and Cord Logistics, Inc.
10.49(11)	Distribution and Supply Agreement effective as of February 18, 2003 between the Registrant and Meda AB
10.50(12)	Testosterone Development and Commercialization Agreement effective as of February 7, 2004 between the Registrant, Fempharm Pty Ltd. and Acrux DDS Pty Ltd.
10.51(12)	Estradiol Development and Commercialization Agreement effective as of February 12, 2004 between the Registrant, Fempharm Pty Ltd. and Acrux DDS Pty Ltd.
10.52(12)	Note Purchase Agreement dated January 8, 2004 between the Registrant and Tanabe Holding America, Inc.
10.53(12)	Manufacture and Supply Agreement dated December 22, 2003 between the Registrant and NeraPharm spol., s.r.o.
10.53A(17)	First Amendment and Waiver Manufacture and Supply Agreement, dated February 21, 2006 by and between the Company and NeraPharm spol, s.r.o.
10.54 (13)	Amendment One dated October 11, 2004 to License and Supply Agreement made between the Registrant and Paladin Labs, Inc.
10.55(14)	Agreement for Sale of Real Estate dated November 15, 2005 by and between the Registrant and 735 Airport Road, L.L.C.
10.56(14)	Agreement for Sale of Real Estate dated November 15, 2005 by and between the Registrant and 745 Airport Road, L.L.C.
10.57(15)	Term Loan Agreement dated January 4, 2006 by and between the Registrant and Vivus Real Estate LLC and Crown Bank, N.A.
10.58(15)	Commercial Mortgage Note dated January 4, 2006 by and between the Registrant and Vivus Real Estate LLC and Crown Bank, N.A.
10.59(15)	Mortgage and Security Agreement dated January 4, 2006 by and between Vivus Real Estate LLC and Crown Bank, N. A.

10.60(16)	Lease Agreement effective November 1, 2006 by and between the Registrant and Castro Mountain View, LLC, Thomas A. Lynch, Trudy Molina Flores, Trustee of the Jolen Flores and Trudy Molina Flores Joint Living Trust dated April 3, 2001, E. William and Charlotte Duerkson, husband and wife, E. William and Charlotte Duerkson, Trustees of the Duerkson Family Trust dated February 16, 1999, Daniel F. Dutton, Jr. and Joyce F. Dutton, Trustees under the Dutton Family Trust dated September 16, 1993, Noel S. Schuurman, Trustee of the Noel S. Schuurman Trust, The Duarte Family Partners, L.P., Marie Straube, Trustee of the Marie Antoinette Clough Revocable Living Trust dated January 11, 1989, and Blue Oak Properties, Inc., CP6CC, LLC
21.2	Subsidiaries of the Registrant
23.1	Consent of ODENBERG, ULLAKKO, MURANISHI & Co. LLP, Independent Registered Public Accounting Firm
23.2	Consent of KPMG LLP, Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer, dated March 14, 2007, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended
31.2	Certification of Chief Financial Officer, dated March 14, 2007, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Confidential treatment granted.

Portions of the exhibit have been omitted pursuant to a request for confidential treatment. The confidential portions have been filed with the SEC.

- (1) Incorporated by reference to the same numbered exhibit filed with the Registrant's Registration Statement on Form S-1 No. 33-75698, as amended.
- (2) Incorporated by reference to the same numbered exhibit filed with the Registrant's Registration Statement on Form S-1 No. 33-90390, as amended.
- (3) Incorporated by reference to the same numbered exhibit filed with the Registrant's Form 8-B filed with the Commission on June 25, 1996.
- (4) Incorporated by reference to the same numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1996, as amended.
- (5) Incorporated by reference to exhibit 99.1 filed with Registrant's Amendment Number 2 to the Registration Statement of Form 8-A (File No. 0-23490) filed with the Commission on April 23, 1997.
- (6) Incorporated by reference to the same numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1998.
- (7) Incorporated by reference to the same numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 2000.
- (8) Incorporated by reference to the same numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.

- (9) Incorporated by reference to the same numbered exhibit filed with the Registrant's Registration Statement on Form S-8 filed with the Commission on November 15, 2001.
- (10) Incorporated by reference to the same numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.
- (11) Incorporated by reference to the same numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002.
- (12) Incorporated by reference to the same numbered exhibit filed with the Registrant's Annual Report on Form 10-Q for the quarter ended March 31, 2004.
- (13) Incorporated by reference to the same numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 2004.
- (14) Incorporated by reference to the same numbered exhibit filed with the Registrant's Form 8-K filed with the Commission on December 23, 2005.
- (15) Incorporated by reference to the same numbered exhibit filed with the Registrant's Form 8-K filed with the Commission on January 6, 2006.
- (16) Incorporated by reference to the same numbered exhibit filed with the Registrant's Form 8-K filed with the Commission on November 7, 2006.
- (17) Incorporated by reference to the same numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006.
- (18) Incorporated by reference to exhibit 10.1 filed with the Registrant's Form 8-K filed with the Commission on July 13, 2006.
- (19) Incorporated by reference to exhibit 10.2 filed with the Registrant's Form 8-K filed with the Commission on July 13, 2006.