

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, 2007

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 001-33389

VIVUS, INC.

(Exact name of Registrant as specified in its charter)

Delaware  
(State or other jurisdiction  
of incorporation or organization)

94-3136179  
(IRS employer  
identification number)

1172 Castro Street  
Mountain View, California  
(Address of principal executive office)

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 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, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐ Smaller reporting company ☐  
(Do not check if a smaller reporting company)

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 29, 2007 totaled approximately \$299,905,130 based on the closing stock price as reported by the NASDAQ Global Market.

As of February 26, 2008, there were 58,878,157 shares of the Registrant's Common Stock, \$0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Document Description	10-K part
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, 2007 are incorporated by reference into Part III of this report.	III, ITEMS 10, 11, 12, 13, 14

## FISCAL 2007 FORM 10-K

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Certification of Chief Executive Officer  
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**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; (10) the volatility and liquidity of the financial markets; and (11) 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, incorporated in Delaware in 1991, dedicated to the development and commercialization of therapeutic products for large underserved markets. The investigational products currently under development could serve the obesity, diabetes and sexual health markets. Our current and future products in development will encompass patented proprietary formulations and novel delivery systems and future products may be developed by seeking new indications for previously approved pharmaceutical products. To date, through employment of this strategy we have one commercial product and several development-stage products that address these markets. In these sectors patients seek more effective treatment options with fewer negative side effects. With respect to obesity, analysts estimate that this potential market could exceed \$5 billion annually. Sales of approved drugs for diabetes exceed \$10 billion. The indications targeted by VIVUS' investigational sexual health products each represent a projected market greater than \$1 billion annually.

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

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

Our late-stage investigational product pipeline includes:

- **Qnexa™** for treating obesity, for which the pivotal Phase 3 studies have been initiated;

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

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

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

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

In 1997, we launched MUSE (alprostadil) in the United States and, together with our partners, internationally. We market MUSE as a prescription product for the treatment of erectile dysfunction.

#### *Our Future*

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

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

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

We have funded operations primarily through private and public offerings of our common stock and through product sales of MUSE. We expect to generate future net losses due to increases in operating expenses as investigational product candidates are advanced through the various stages of clinical development. In connection with the sale of Evamist, we received \$150 million. The sale of

Evamist was a unique transaction. As discussed in Note 12: "Sale of Evamist Product", an initial \$10 million was paid at closing and \$140 million was paid upon the FDA's approval of the Evamist NDA. These payments are non-refundable and have been recorded as deferred revenue and will be recognized as license and other revenue ratably over a 21.5-month period, from August 1, 2007 to May 15, 2009, which is the remaining term of a license to improvements to the MDTs applicator. As compared to revenues from product sales, license and other revenue will be significant on a quarterly basis until all of the revenue from the sale of Evamist is recognized, currently expected to be May 2009. Since the \$150 million has been received and we have no related contingencies, the future recognition of revenue and the corresponding reduction of deferred revenue related to the Evamist sale will have no impact on our cash flows from operations in future periods through May 2009. As of December 31, 2007, we have incurred a cumulative deficit of \$169.8 million and expect to incur operating losses in future years.

### ***Our Product Pipeline***

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

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

### **Obesity and Diabetes**

In 2004, the U.S. Centers for Disease Control and Prevention (the "CDC") ranked obesity as one of the top health threats 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%, of adults in the U.S. are overweight, and an estimated 60 million, or 30.5%, 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. are attributable to obesity. The total direct and indirect costs attributed to overweight and obesity amounted to approximately \$117 billion in 2000. Additionally, Americans spend more than \$30 billion annually on weight-loss products and services.

### **Diabetes**

Diabetes is a significant worldwide disease. Based on 2003 data, the International Diabetes Federation estimated that in 2005 there were 194 million adults with diabetes worldwide, an increase of over 40% since 1995. These figures included approximately 23 million in the United States and approximately 48 million in the European region. Approximately 90%, or 175 million, of diabetics worldwide suffer from type 2 diabetes, which is characterized by inadequate response to insulin and/or inadequate secretion of insulin as blood glucose levels rise. Therapies for type 2 diabetes are directed toward correcting the body's inadequate response with oral or injectable medications, or directly modifying insulin levels through injection of insulin or insulin analogs.

The currently approved oral medications for type 2 diabetes include insulin releasers such as glyburide, insulin sensitizers such as Actos and Avandia, inhibitors of glucose production by the liver

such as metformin, DPP-IV inhibitors like Januvia, as well as Precose and Glyset, which slow the uptake of glucose from the intestine. The worldwide market for diabetes medications exceeded \$10 billion in 2004, of which oral drugs exceeded \$6 billion. However, a significant portion of type 2 diabetics fail oral medications and require injected insulin therapy. Current oral medications for type 2 diabetes have a number of side effects, including hypoglycemia, weight gain and edema. Numerous pharmaceutical and biotechnology companies are seeking to develop insulin sensitizers, novel insulin formulations and other therapeutics to improve the treatment of diabetes. Previous clinical studies of topiramate in type 2 diabetics resulted in a reduction of hemoglobin A1c, a measure used to determine treatment efficacy of anti-diabetic agents. We are currently studying the impact of treating type 2 diabetics with Qnexa in an initial six-month Phase 2 study.

### ***Qnexa for Obesity***

Qnexa is our proprietary oral investigational product candidate for the treatment of obesity, incorporating low doses of active ingredients from two previously approved products, 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. Qnexa is a once-a-day capsule containing a proprietary formulation of controlled release topiramate and phentermine.

Previously, we reported results from a Phase 2 double blind, randomized, and placebo-controlled clinical trial in which patients on Qnexa lost, on average, 25.1 pounds as compared to patients in the placebo group, who 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 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, increased urinary frequency and headache. There were no dropouts in the Qnexa arm due to serious or severe adverse events.

The Phase 2 study also demonstrated significant improvements in patients' quality of life ("QoL"), such as self-esteem, public distress and physical function when treated with Qnexa. Treatment with topiramate alone showed no improvement in any aspects of quality of life despite significant weight loss. These results suggest that the component of phentermine increases the tolerability of topiramate, which was the scientific rationale for combining these two agents at low doses for the treatment of obesity and related co-morbidities.

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 secondary 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% of the adult American population. The

FDA does not consider the metabolic syndrome to represent a distinct disease entity or treatment indication. Nonetheless, in addition to lifestyle modification, a host of approved drug therapies now exist to address individual or multiple components of the syndrome (e.g., lipid altering agents, antihypertensives, insulin sensitizers). An initial Phase 2 clinical trial (OB-202) is currently underway in patients with type 2 diabetes. We may, in the future, conduct additional studies of Qnexa on these components of metabolic syndrome.

The primary efficacy endpoint for Phase 3 weight loss trials as recommended by the FDA is an assessment of the mean percent reduction in baseline body weight and the proportion of subjects who lose 5% or more of their baseline body weight compared to placebo over a one-year period. New FDA draft guidelines for obesity products set forth a primary efficacy benchmark 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 after 24 weeks, 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 after 24 weeks, 50% of the patients on Qnexa lost 10% of their baseline weight as compared to 8% of the patients 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, or with a once-a-day controlled release formulation of the product. We completed the development of our once-a-day controlled release formulation of Qnexa prior to the initiation of our Phase 3 clinical trials.

In June 2007, we announced the formation of our Qnexa Scientific Advisory Board (the "Qnexa SAB"), consisting of well-known experts in the areas of obesity, clinical trial design, psychology and diabetes. We appointed Dr. David Allison, Dr. Nancy Bohannon, Dr. Arthur Frank, Dr. Donna Ryan, Dr. Xavier Pi-Sunyer and Dr. Tom Wadden to the Qnexa SAB. These experts have provided guidance concerning Qnexa Phase 3 clinical trials and are available for continuing consultations.

We have successfully completed the Special Protocol Assessment ("SPA") process and have reached agreement with the FDA regarding key elements of the pivotal Phase 3 clinical trials of Qnexa for the treatment of obesity and weight-related co-morbidities. We have reached agreement with the FDA on study design features that will be employed throughout the entire Phase 3 program including the co-primary endpoints of the study, scope and size of the patient population, specific safety assessments, inclusion/exclusion criteria, duration of the trials and the statistical method for analyzing the co-primary study endpoints.

The Phase 3 Qnexa program will include two pivotal, double blind, placebo-controlled, multi-center studies comparing Qnexa to placebo over a 56-week treatment period. The studies are designed to prospectively demonstrate the safety and efficacy of Qnexa in obese and overweight patients with different baseline characteristics. The first study, known as EQUIP (OB-302), will enroll morbidly, or near-morbidly obese adult subjects with a body mass index ("BMI") of 35 or greater with or without controlled co-morbidities. The second trial, known as CONQUER (OB-303), will enroll overweight and obese adult subjects with BMI's from 27 to 45 and at least two co-morbid conditions, such as hypertension, dyslipidemia and type 2 diabetes. The co-primary endpoints for these studies will evaluate the differences between treatments in mean percent weight loss from baseline to the end of the treatment period, and the differences between treatments in the percentage of subjects achieving weight loss of 5% or more.



In November 2007, we initiated both of these two pivotal Phase 3 studies of Qnexa. All Phase 3 studies are utilizing our novel once-a-day formulation of Qnexa, which at full strength contains 15 mg phentermine immediate release and 92 mg topiramate controlled release. Pharmacokinetic-Pharmacodynamic (PK/PD) studies have confirmed that the once-a-day formulation is comparable to the twice-a-day formulation used in the Phase 2 study.

The Phase 3 program also includes a six-month confirmatory factorial-design study, known as EQUATE (OB-301), in obese subjects with BMI's from 30 to 45. This trial was initiated in December 2007 and completed enrollment in March 2008. The EQUATE study will evaluate two dose levels of Qnexa, compared to both placebo and the individual constituents of the combination. The primary endpoints will be similar to those evaluated in the pivotal studies.

Safety and tolerability of Qnexa will be determined by reporting adverse events, physical exam, clinical laboratory data, electrocardiogram, cognitive function tests, psychological assessments, and clinical assessment of clinical laboratory variables. The Phase 3 studies will enroll approximately 4,500 subjects.

### ***Qnexa for Diabetes***

In January 2008, we announced that we had initiated a six-month extension study for patients currently enrolled in the OB-202 diabetes study. The OB-202 study is a 28 week, randomized, double blind, placebo controlled, efficacy and safety study of Qnexa in the glycemic management of obese Type 2 diabetics. The newly initiated study, DM-230, will allow subjects to continue, in a blinded fashion as randomized, in the study for an additional 28 weeks.

The primary endpoint of the diabetes studies will be improvement of glycemic control as measured by a reduction of glycosylated hemoglobin (HbA1c) levels. The randomized, double-blind, parallel-designed study will also measure the effects of Qnexa on associated metabolic and cardiovascular risk factors as well as changes in total body weight, percent of baseline body weight lost, and a change in waist circumference. The OB-202 study will measure endpoints at the end of 28 weeks. The DM-230 study will measure endpoints after an additional 28 weeks, for a total time on treatment of one year.

Both diabetes studies are intended to assess both safety and efficacy of Qnexa in subjects with type 2 diabetes controlled with diet or oral medications. Subjects have a Body Mass Index (BMI) between 27 to 42 kg/m<sup>2</sup>. Patients on antidepressants such as SSRI's or SNRI's are allowed to participate in the study. The trials involve 10 centers nationwide. VIVUS has enrolled 210 subjects in the OB-202 study. As subjects complete the first 28 weeks of treatment they will roll over into the DM-230 study. Data from the OB-202 study is expected to be available in the second quarter of 2008.

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

### ***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, OB/GYNs have been prescribing Androgel®, an approved testosterone treatment for hypogonadism in males. In addition, Intrinsa™, a transdermal testosterone patch, is currently approved and available for sale in Europe.

Double-blind, multi-center, placebo-controlled clinical trials conducted by The Procter & Gamble Company to assess the effects of Intrinsa (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***

Luramist™ (Testosterone MDTs) is our patent protected, transdermal investigational product candidate being developed for the treatment of HSDD in women. The active ingredient in Luramist is the synthetic version of the testosterone that is present naturally in humans.

Luramist utilizes a proprietary, metered-dose transdermal spray, ("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. Acrux's independent studies have demonstrated that the Luramist system delivers sustained levels of testosterone in women over a 24-hour period and achieves an increasing number of satisfying sexual events.

We believe that our Luramist product candidate has significant advantages over patches and other transdermal gels that are being developed for this indication. The Luramist 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 Luramist, which showed a statistically significant improvement in the number of satisfying sexual events in pre-menopausal patients with HSDD. We met with the FDA to share results from our Phase 2 clinical study and to discuss the Phase 3 study requirements. We submitted a Phase 3 safety and efficacy protocol under the SPA process and met with the FDA in March 2007 to resolve the issues they raised regarding the details of

the protocol. Based on the outcome of this meeting and the FDA's feedback, we submitted a revised Phase 3 program to the FDA in the fourth quarter of 2007.

## **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 citrate (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 2007 of PDE5 inhibitor products for ED were in excess of \$3.5 billion, including approximately \$1.8 billion in sales of Viagra, approximately \$1.2 billion in sales of Cialis and approximately \$495 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., ("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.

We previously 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.

We previously 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.

We also previously announced 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). Results revealed that avanafil had less impact on blood pressure and heart rate than Viagra. The clinical significance of this data is unknown.

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 studies prior to the initiation of the Phase 3 trials. In December 2006, we filed an SPA for a Phase 3 clinical trial to the FDA. We have received a response to our SPA and we accepted the FDA's recommendations. The Phase 3 protocol and the SPA process for avanafil has been completed.

## **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 13 million units of MUSE have been sold since we introduced MUSE to the market.

In May 2005, results were reported from an independent 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 diseases and medical conditions. We also sponsor early stage clinical trials at various research institutions and intend to conduct early stage proof of concept studies on our own. 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.

### ***Sale of Evamist to K-V Pharmaceutical Company***

On March 30, 2007, we entered into a definitive agreement with K-V, to transfer our assets and grant a sublicense of our rights under the Acrux Agreement related to Evamist to K-V (the "Transaction"). The closing of the Transaction occurred on May 15, 2007. Under the terms of the Transaction, we received an upfront payment of \$10 million upon the closing. On July 27, 2007, we received FDA approval of the NDA for Evamist. On August 1, 2007, we transferred and assigned the Evamist FDA submissions, and all files related thereto to K-V and on August 8, 2007, K-V paid us the additional \$140 million milestone payment due upon FDA approval of the Evamist NDA. We may also receive certain one-time payments of up to \$30 million based on achieving certain annual net sales

thresholds for Evamist. In connection with the Transaction, in order to obtain Tanabe's blanket release of liens against our assets including the Evamist assets and intellectual property, we repaid the Tanabe line of credit.

In May 2006, we announced positive results from the 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 NDA for Evamist to the FDA in the third quarter of 2006 and made a \$1 million clinical development milestone payment to Acrux in October 2006 under the terms of our licensing agreement, related to this submission. Upon approval of the NDA for Evamist, a \$3 million product approval milestone became due and was paid to Acrux in August 2007. Per the terms of the Transaction, K-V paid \$1.5 million of this \$3 million milestone.

## **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. Additionally, the Food and Drug Amendment Act of 2007 requires all clinical trials we conduct for our drug candidates, both before and after approval, and the results of those trials, be included in a clinical trials registry database that is available and accessible to the public via the internet. Our failure to properly participate in the clinical trial database registry would subject us to significant civil penalties.

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 investigational 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 undergo periodic routine inspections 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, our PDE5 inhibitor investigational product candidate for the oral and local treatment of male and female sexual dysfunction. In September 2007, Tanabe merged with Mitsubishi Pharma Corporation, to form Mitsubishi Tanabe Pharma Corporation. The combined companies are one of Japan's leading pharmaceutical companies with estimated revenues of over \$2.3 billion in 2007.

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 have paid upfront licensing fees of \$5 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 million in connection with this milestone in 2006. We have further agreed to pay royalties on net sales of products containing avanafil. No payments were made in 2007 under this agreement with Tanabe. 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. On April 24, 2007, in connection with our sale of Evamist to K-V, we paid off the outstanding balance of \$6.7 million, including all accrued interest. On May 1, 2007, Tanabe signed a Termination and Release acknowledging payment in full of the principal and interest due under the line of credit and releasing the lien on our assets, and thereby terminating the line of credit.

As mentioned above, in September 2007, Tanabe merged with Mitsubishi. There can be no guarantee that this 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 Luramist and Evamist in the United States for various female health applications. Acrux's 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 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 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 \$4.8 million in clinical development milestones payments to date, including the \$1 million milestone payment we made to Acrux in October 2006 related to the submission of an NDA to the FDA for Evamist and the \$3 million product approval milestone payment for approval of this NDA, which was paid in August 2007. Per the terms of our Asset Purchase Agreement with K-V for the sale of our Evamist product, we granted a sublicense of our rights under the Acrux Agreement related to Evamist to K-V and K-V paid \$1.5 million of this \$3 million obligation. Although we have sublicensed our rights under the Acrux Agreement related to Evamist to K-V, we will continue to have certain obligations under this license in the event that K-V does not satisfy the requirements under the sublicense agreement.

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

On November 5, 2007, our legal counsel received a demand for arbitration under the Acrux Agreements relating to Luramist. Acrux's demand seeks a reversion of all rights assigned to VIVUS regarding Luramist, monetary damages, a portion of a milestone payment for Luramist under the Acrux Agreements and declaratory relief. We believe that we are in compliance with all material aspects of the Acrux Agreements including those related to Luramist and that we currently do not owe monetary damages or any milestone payment under the Acrux Agreements. If we are unable to resolve these Luramist related claims with Acrux, we intend to seek to enforce our rights under the Acrux



Agreements in arbitration. Development and commercialization of Luramist continues. We believe that we have a meritorious defense to the claims made by Acrux in connection with the alleged dispute concerning Luramist; however, in the event that Acrux should prevail in this matter, it could have a material adverse effect on our business, financial condition and results of operations.

## **Patents and Proprietary Technology**

We hold 31 patents and 7 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 our Lakewood, New Jersey manufacturing facility, which is 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 facility includes 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 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**

Generally, we intend to enter into an agreement with development and marketing partners that will provide commercial support for our products, as well as financial support for future late-stage development activities. We intend to retain co-promotional rights and may choose to create an organization to market our products.

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. In 2002, we signed an international distribution agreement with Meda AB ("Meda"). 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. We are aware of many pharmaceutical companies also actively engaged in the development of therapies for the treatment of obesity, diabetes and sexual dysfunction.

Current anti-obesity drugs include Xenical (orlistat), marketed by Roche, and Meridia (sibutramine), marketed by Abbott Labs. Orlistat works by inhibiting lipase, thus preventing digestion and absorption of dietary fat in the gastrointestinal tract. In 2007, Xenical accounted for approximately \$70 million in sales in the United States. Orlistat was launched over-the-counter in the United States by GlaxoSmithKline under the brand name Alli, in June 2007. Phentermine is the largest selling anti-obesity therapeutic and is available in several generic forms. Topamax, marketed by Johnson and Johnson, is not approved for the treatment of obesity but analysts estimate Topamax is used for this indication in an off-label manner. Sanofi-Aventis' Acomplia (rimonabant) was approved in the European Union in 2006 for the treatment of obesity (the drug is approved in a total of 51 countries worldwide). However, Sanofi withdrew the drug's NDA in the United States following an FDA advisory panel's recommendation against approval on the basis of safety concerns.

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

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

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

Other treatments for erectile dysfunction exist, such as needle injection therapies, vacuum constriction devices and penile implants, and the manufacturers of these products will most likely continue to develop or improve these therapies. In November 2007, NexMed, Inc. announced that the NDA filed for its ED product, a topically applied alprostadil cream, was accepted for review by the FDA.

Several companies are developing products that could compete with our investigational product candidates for the treatment of FSD including: The Procter & 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. In March 2007, Intrinsa became available through the National Health Service ("NHS") in the United Kingdom.

## **Research and Development**

We spent \$26.7 million in 2007, \$13.3 million in 2006, and \$17 million in 2005 on research, primarily to discover and develop our investigational product candidates in obesity and diabetes treatment, 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 29, 2008, we had 111 employees, 72 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 our relations with our employees are good and we have never experienced a work stoppage at any of our facilities.

## **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 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](http://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. Investigational product candidates that may appear to be promising at all stages of development may not reach the market for a number of reasons. Investigational product candidates may be found ineffective or may cause harmful side effects during clinical trials, may take longer to progress through clinical trials than had been anticipated, may not be able to achieve the pre-defined clinical endpoint due to statistical anomalies even though clinical benefit may have been achieved, may fail to receive necessary regulatory approvals, may prove impracticable to manufacture in commercial quantities at reasonable cost and with acceptable quality, or may fail to achieve market acceptance. Historically, our development efforts have been focused on products for sexual and postmenopausal health. While we have experience in managing Phase 1 through 3 clinical trials in support of various indications, we do not have any experience in managing Phase 3 clinical trials for obesity or clinical trials for diabetes. There can be no assurance that we will be successful with the limited experience and resources we have available at the present time relating to obesity or diabetes.

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

Pre-clinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of an investigational product candidate in the general population, but rather to test initial safety, to study pharmacokinetics and pharmacodynamics, to study limited efficacy in a selected disease population, and to identify and attempt to understand the investigational product candidate's side effects at various doses and schedules. Success in pre-clinical studies or completed clinical trials does

not ensure that later studies or trials, including continuing pre-clinical studies and large-scale clinical trials, will be successful nor does it necessarily predict future results. Favorable results in early studies or trials may not be repeated in later studies or trials, and investigational product candidates in later stage trials may fail to show acceptable safety and efficacy despite having progressed through initial-stage trials. In addition, the placebo rate in larger studies may be higher than expected.

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

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

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

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

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

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

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

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

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

refers to the combination of dexfenfluramine or Redux ("dexfen") and phentermine. Dexfenfluramine received FDA approval in 1996 for use as an appetite suppressant in the management of obesity.

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

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

Previous published studies suggest that the administration of topiramate alone, in conjunction with diet and a behavioral modification program, results in weight reduction in obese patients. The most prominent side effect seen in the published studies was paresthesia, (tingling of the extremities) experienced by 42% to 59% of patients. Drop outs due to paresthesia were 5% or less. In the Phase 2 Duke study, paresthesia was experienced in 38% of the patients on Qnexa. There were no drop outs in the Qnexa group due to paresthesia. The other common adverse events experienced in the topiramate monotherapy studies were also central nervous system ("CNS") related including fatigue, difficulty with attention, memory and concentration and depression. In the Phase 2 study, these CNS related side effects were also experienced but the difference was not significant when compared to placebo. The pharmaceutical company performing research of topiramate alone announced they had discontinued development of a time-release formulation due to side effects at high doses.

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 analysis of patients' suicidal tendencies be performed. While we do not expect a negative impact from the completion of this analysis on the ultimate approval of Qnexa, the labeled use of Qnexa may exclude patients with suicidal tendencies.

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

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

We anticipate that each of the approved drugs that are combined to produce our investigational product candidate, Qnexa, will be commercially available at prices lower than the price at which we would seek to market our investigational product candidate. We cannot be sure that physicians will view our products as sufficiently superior to a treatment regime of the individual active pharmaceutical ingredients as to justify the significantly higher cost we expect to seek for Qnexa, and they may prescribe the individual drugs already approved and marketed by other companies instead of our combination product. Even though our U.S. patent contains composition, product formulation and method-of-use claims that should protect Qnexa, that patent may be ineffective as a practical matter to protect against physicians prescribing the individual drugs marketed by other companies instead of our combination product. To the extent that the price of our product is significantly higher than the prices of the individual components as marketed by other companies, physicians may have a greater incentive to write prescriptions for the individual components instead of for our combination product, and this may limit how we price Qnexa. Similar concerns could also limit the reimbursement amounts private health insurers or government agencies in the United States are prepared to pay for Qnexa, which could also limit market and patient acceptance of our product, and could negatively impact our revenues and net income, if any. A physician could seek to prescribe off-label generics in place of Qnexa. Off-label use occurs when a drug that is approved by the FDA for one indication is legally prescribed by physicians for a different, unapproved indication. Topiramate, one of the ingredients in Qnexa, is not approved for obesity treatment. With regard to off-label substitution at the pharmacy level, we expect to rely on the novel dose ratios and novel pharmacokinetic properties of our investigational product candidate, to provide sufficient distinction such that generic preparations are not considered therapeutic equivalents by the FDA. State pharmacy laws in many instances preclude pharmacists from substituting with generic preparations if the products are not therapeutic equivalents. We believe there will be no commercially available doses of the active ingredients in Qnexa, when and if approved. Therefore, the lack of therapeutic equivalency restricts generic substitution by pharmacies and/or pharmacy benefit managers. However, we cannot be certain that pharmacists and/or pharmacy benefit managers will not substitute generics in place of Qnexa, which could significantly diminish its market potential. Physicians might also prescribe the individual components of an investigational product candidate prior to Qnexa's approval, which could adversely affect our development of the investigational product candidate due to our lack of control over the administration to patients of the combination of active pharmaceutical ingredients in our investigational product candidate, the occurrence of adverse effects, and other reasons. Such pre-approval use could also adversely affect our ability to market and commercialize Qnexa.

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

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

To obtain regulatory approval for Qnexa, we will be required to show that each active pharmaceutical ingredient in the investigational product candidate makes a contribution to the combined investigational product candidate's claimed effects and that the dosage of each component, including amount, frequency and duration, is such that the combination is safe and effective. As a



result, we will be required to include in our clinical trials an evaluation of each component drug as well as for the component drug in combination. This would likely require us to conduct more extensive and more expensive clinical trials than would be the case for many single agent pharmaceuticals. The need to conduct such trials could make it more difficult and costly to obtain regulatory approval of Qnexa than of a new drug containing only a single active pharmaceutical ingredient.

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

We have and will continue to in-license investigational product candidates from third parties. The United States rights to Evamist and Luramist were licensed from Acrux and its related affiliates. The rights to avanafil were licensed from Tanabe. The rights to Evamist, under the Acrux Agreement, were sublicensed to K-V upon closing of the sale of Evamist to K-V. Each of these agreements contains certain obligations. Failure to comply with the terms of the agreements could result in the early termination of these agreements. We believe we are in compliance with all the material terms of these agreements; however, there can be no assurance that this compliance will continue or that the licensors would not have a differing interpretation of the material terms of the agreements. If the license or sublicense agreements were terminated early or if the terms of the license or sublicense were contested for any reason, it would have a material adverse impact on our ability to commercialize products subject to these agreements, our ability to raise funds to finance the company, our stock price and our overall financial condition. In the event that the Acrux license was terminated, and at such time K-V was not in material breach of the sublicense, then we may be required to pay as liquidated damages an amount equal to the amounts paid by K-V for Evamist under our Asset Purchase Agreement with K-V.

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

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

We are, and in the future expect to be, dependent upon collaborative arrangements or strategic alliances to complete the development and commercialization of some of our investigational product

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

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

We may be unable to locate and enter into favorable agreements with third parties, which could delay or impair our ability to develop and commercialize our investigational product candidates and could increase our costs of development and commercialization. Dependence on collaborative arrangements or strategic alliances will subject us to a number of risks, including the risk that:

- we may not be able to control the amount and timing of resources that our collaborators may devote to the investigational product candidates;
- our collaborators may experience financial difficulties;
- we may be required to relinquish important rights such as marketing and distribution rights;
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- a collaborator could independently move forward with a competing investigational product candidate developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing our investigational product candidates.

**We face significant governmental regulation during our product development activities.**

The research, testing, manufacturing, selling and marketing of investigational product candidates are subject to extensive regulations by the FDA and other regulatory agencies in the United States and other countries. We cannot predict with certainty if or when we might submit for regulatory review those investigational product candidates currently under development. The FDA can suspend clinical studies at any time if the agency believes that the subjects participating in such studies are being exposed to unacceptable health risks.

Regulatory approval is never guaranteed, and the approval process typically takes several years and is extremely expensive. The FDA has substantial discretion in the drug approval process. Despite the time and expense involved, failure can occur at any stage.

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

In December 2004, an FDA advisory panel recommended against approval of a testosterone patch under development by another company to address female sexual dysfunction, specifically hypoactive

sexual desire disorder. The FDA indicated that more safety data would be required before it would be in a position to recommend approval. Subsequently, this company withdrew its New Drug Application. We are developing a investigational transdermal testosterone product candidate, Luramist, which is designed to address hypoactive sexual desire disorder. In light of the FDA panel's recommendation, we may be required to undertake additional or expanded clinical trials, which could be expensive and the cause of significant delays in our ability to submit our investigational product candidate to the FDA for consideration. In the end, we may be unsuccessful in obtaining FDA approval of our investigational 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 investigational product candidates would delay or prevent our ability to generate revenue from our investigational product candidates, which would adversely affect our financial results and our business.

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

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

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

If one of our investigational product candidates is approved by the FDA or by another regulatory authority for a territory outside of the United States, we will be held to extensive regulatory requirements over product manufacturing, labeling, packaging, adverse event reporting, storage, distribution, advertising, promotion and record keeping. Regulatory approvals may also be subject to significant limitations on the indicated uses or marketing of the investigational product candidates or who we may distribute to. Potentially costly post-marketing clinical studies may be required as a condition of approval to further substantiate safety or efficacy, or to investigate specific issues of interest to the regulatory authority. Previously unknown problems with the investigational product candidate, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the drug, and could lead to the withdrawal of the drug from the market.

In addition, the law or regulatory policies governing pharmaceuticals may change. New statutory requirements may be enacted or additional regulations may be enacted that could prevent or delay regulatory approval of our investigational product candidates. We cannot predict the likelihood, nature, extent or effects of government regulation that may arise from future legislation or administrative action, either in the United States or elsewhere. If we are not able to maintain regulatory compliance, we might not be permitted to market our products and our business could suffer.

**We rely on third parties to conduct pre-clinical and clinical trials and studies for our investigational product candidates in development and those third parties may not perform satisfactorily.**

Like many companies our size, we do not have the ability to conduct pre-clinical or clinical studies for our investigational product candidates without the assistance of third parties who conduct the studies on our behalf. These third parties are usually toxicology facilities and clinical research organizations, or CROs, that have significant resources and experience in the conduct of pre-clinical and clinical studies. The toxicology facilities conduct the pre-clinical safety studies as well as all associated tasks connected with these studies. The CROs typically perform patient recruitment, project management, data management, statistical analysis, and other reporting functions. We intend to use several different toxicology facilities and CROs for all of our pre-clinical and clinical studies. If these third party toxicology facilities or CROs do not successfully carry out their contractual duties or meet expected timelines, we may not be able to obtain regulatory approvals for our investigational product candidates on a timely basis, if at all, and we may not be able to successfully commercialize these investigational product candidates. If these third party toxicology facilities or CROs do not perform satisfactorily, we may not be able to locate acceptable replacements or enter into favorable agreements with them, if at all.

**We rely on third parties to manufacture sufficient quantities of compounds for use in our pre-clinical and clinical trials and future commercial operations and an interruption to this service may harm our business.**

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

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

**Risks Relating to our Operations**

**If we, or our suppliers, fail to comply with FDA and other government regulations relating to our manufacturing operations, we may be prevented from manufacturing our products or may be required to undertake significant expenditures to become compliant with regulations.**

After regulatory approval for a product is obtained, the product is subject to continual regulatory review. Manufacturing, labeling and promotional activities are continually regulated by the FDA and equivalent foreign regulatory agencies. For example, our third party manufacturers are required to maintain satisfactory compliance with current Good Manufacturing Practices, or cGMP. If these manufacturers fail to comply with applicable regulatory requirements, our ability to manufacture, market and distribute our products may be adversely affected. In addition, the FDA could issue

warning letters or could require the seizure or recall of products. The FDA could also impose civil penalties or require the closure of our manufacturing facility until cGMP compliance is achieved.

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 our international markets through the end of the third quarter of 2008. There can be no assurance that as this bulk supply is used through the end of the third quarter of 2008 for international product, that there will be a sufficient yield in the final quantity of foil with acceptable quality to support the international markets' MUSE demand. Although the foil supplier produced this bulk unprinted foil, the label printing will be done periodically. As a consequence, if there are unacceptable quality issues with the bulk foil, they may not be discovered as the bulk material is used through the end of the third quarter of 2008. If such foil quality issues do occur, we may be unable to meet international MUSE demand through the end of the third quarter of 2008.

We have a new vendor for the MUSE laminated foil. As this laminated foil is used to make the MUSE primary product container, there are significant qualifications and regulatory approvals that must be obtained prior to using the new vendor to produce foil to meet MUSE demand. These include, but are not limited to, vendor qualification, foil material qualification, MUSE product suitability studies, electron beam irradiation suitability, FDA approval, and MHRA approval. Although the FDA has granted approval for the use of foil from our new vendor for U.S. MUSE product, there can be no assurance that these qualifications and approvals will be successfully obtained from the MHRA or Canadian market regulatory agency, or that they will be obtained within the time needed to support MUSE demand before our current supply of foil is exhausted. Failure to receive adequate supplies of foil, failure to receive appropriate regulatory approvals for the change in materials and vendors, and any unforeseen quality or production issues due to the use of the new materials or vendors could have a material adverse effect on our business, financial condition and results of operations.

Failure to achieve satisfactory cGMP compliance as confirmed by routine and unannounced inspections could have a material adverse effect on our ability to continue to manufacture and distribute our products and, in the most serious case, result in the issuance of a regulatory warning letter or seizure or recall of products, injunction and/or civil penalties or closure of our manufacturing facility until cGMP compliance is achieved.

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

As a manufacturer of pharmaceuticals, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third party payors, certain federal and state healthcare laws and regulations pertaining to fraud, abuse and patients' rights are and will be

applicable to our business. We could be subject to healthcare fraud, abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The regulations that may affect our ability to operate include, but are not limited to:

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

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

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

After product approval by the FDA, our marketing activities will be subject to FDA and other regulatory review. If products are marketed in contradiction with FDA mandates, the FDA may issue warning letters that require specific remedial measures to be taken, as well as an immediate cessation of the impermissible conduct resulting in adverse publicity. The FDA may also order that all future promotional materials receive prior agency review and approval before use. For example, the FDA issued a warning letter to us in May 2004 in which the FDA objected to a specific television commercial as well as information contained on our website promoting MUSE, our FDA approved product for the treatment of erectile dysfunction. The letter indicated that we had failed to disclose or had minimized certain risks associated with MUSE. Through discussions with the FDA, we agreed to produce and have released a television commercial that we believe corrected the prior message and addressed the FDA's concerns. We incurred costs in providing this corrective information, which would have otherwise been utilized by us in a different manner. In March 2005, we received a letter from the FDA indicating that the matter had been closed.

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

Even if we receive regulatory approval of our products, such approval may involve limitations on the indicated uses or marketing claims we may make for our products. 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 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 investigational product candidates, either by developing our own capabilities or entering into agreements with others, we will not be able to successfully launch our investigational product candidates upon FDA approval. We

cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need. We may not be able to enter into any marketing or distribution agreements with third party providers on acceptable terms, if at all. In that event, we will not be able to generate significant revenues.

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

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

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

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

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

Competition in the pharmaceutical and medical products industries is intense and is characterized by extensive research efforts and rapid technological progress. We are aware of several pharmaceutical companies also actively engaged in the development of therapies for the treatment of obesity, diabetes and sexual health. These companies have substantially greater research and development capabilities as well as substantially greater marketing, financial and human resources than we do. In addition, many of these companies have significantly greater experience than us in undertaking pre-clinical testing, human clinical trials and other regulatory approval procedures. Our competitors may develop technologies and products that are more effective than those we are currently marketing or developing. Such developments could render our products less competitive or possibly obsolete. We are also competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have limited experience.

Current anti-obesity drugs include Xenical (orlistat), marketed by Roche, and Meridia (sibutramine), marketed by Abbott Labs. Orlistat works by inhibiting lipase, thus preventing digestion and absorption of dietary fat in the gastrointestinal tract. In 2007, Xenical accounted for approximately \$70 million in sales in the United States. Orlistat was launched over-the-counter in the United States by GlaxoSmithKline under the brand name Alli, in June 2007. Phentermine is the largest selling anti-obesity therapeutic and is available in several generic forms. Topamax, marketed by Johnson and Johnson, is not approved for the treatment of obesity but analysts estimate Topamax is used for this indication in an off-label manner. Sanofi-Aventis' Acomplia (rimonabant) was approved in the European Union in 2006 for the treatment of obesity (the drug is approved in a total of 51 countries worldwide). However, Sanofi withdrew the drug's NDA in the United States following an FDA advisory panel's recommendation against approval on the basis of safety concerns.



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

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

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

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

Other treatments for erectile dysfunction exist, such as needle injection therapies, vacuum constriction devices and penile implants, and the manufacturers of these products will most likely continue to develop or improve these therapies. In November 2007, NexMed, Inc. announced that the NDA filed for its ED product, a topically applied alprostadil cream, was accepted for review by the FDA.

Several companies are developing products that could compete with our investigational product candidates for the treatment of FSD including: The Proctor & Gamble Company is developing Intrinsa, a testosterone patch for the treatment of HSDD; BioSante Pharmaceuticals, Inc. is developing forms of testosterone gels for HSDD and Palatin Technologies, Inc. is developing a nasal spray to treat FSD. None of these investigational products has been approved by the FDA. In July 2006, the European Medicines Agency ("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. In March 2007, Intrinsa became available through the National Health Service ("NHS") in the United Kingdom.

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

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

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

**If our raw material suppliers fail to supply us with the Active Pharmaceutical Ingredients for our products and investigational product candidates, for which availability is limited, we may experience delays in our product development and commercialization.**

We are required to receive regulatory approval for suppliers. We obtained our current supply of alprostadil from two approved sources, NeraPharm, s.r.o., in the Czech Republic and Chinoin Pharmaceutical and Chemical Works Private 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 or phentermine. There can be no guarantees that we will be able to enter into such agreements under reasonable terms, if at all. We cannot guarantee that should we be successful in entering into such agreements we will be able to obtain the necessary regulatory approvals for these suppliers.

**We outsource several key parts of our operations, and any interruption in the services provided by third parties could harm our business.**

Under our outsourcing agreement with Cardinal Health, Inc. related to MUSE, Cardinal Health warehouses our finished goods for United States distribution; takes customer orders; picks, packs and ships our products; invoices customers; and collects related receivables. As a result of this distribution agreement, we are heavily dependent on Cardinal Health's efforts to fulfill orders and warehouse our products effectively in the United States. There can be no assurance that such efforts will continue to be successful.

Under our testing agreement, Gibraltar Laboratories performs sterility testing on finished product manufactured by us to ensure that it complies with product specifications. Gibraltar Laboratories also performs microbial testing on water and compressed gases used in the manufacturing process and microbial testing on environmental samples to ensure that the manufacturing environment meets appropriate cGMP regulations and cleanliness standards. As a result of this testing agreement, we are dependent on Gibraltar Laboratories to perform testing and issue reports on finished product and the manufacturing environment in a manner that meets cGMP regulations.

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

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

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

**We currently depend on a single source for the supply of plastic applicator components for MUSE and an interruption to this supply 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.

**All of our manufacturing operations are currently conducted at a single location, and a prolonged interruption to our manufacturing operations could harm our business.**

We purchased two buildings with a total combined 90,000 square feet in Lakewood, New Jersey, which we previously leased, on December 22, 2005. This facility is used for our manufacturing operation, which includes formulation, filling, packaging, analytical laboratories, storage, distribution and administrative offices, although one of the buildings is used for warehousing component parts. The FDA and the Medicines and Healthcare products Regulatory Agency, the regulatory authority in the United Kingdom, authorized us to begin commercial production and shipment of MUSE from this facility in June and March 1998, respectively. MUSE is manufactured in this facility and we have no plans to construct another manufacturing site. Since MUSE is produced with custom-made equipment under specific manufacturing conditions, the inability of our manufacturing facility to produce MUSE for whatever reason could have a material adverse effect on our business, financial condition and results of operations.

**We are dependent upon a single approved therapeutic approach to treat erectile dysfunction.**

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

**If we fail to retain our key personnel and hire, train and retain qualified employees, we may not be able to compete effectively, which could result in reduced revenues.**

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

**We are subject to additional risks associated with our international operations.**

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

**Any adverse changes in reimbursement procedures by government and other third party payors may limit our ability to market and sell our products or limit our product revenues and delay profitability.**

In the United States and elsewhere, sales of pharmaceutical products are dependent, in part, on the availability of reimbursement to the consumer from third party payors, such as government and private insurance plans. Third party payors are increasingly challenging the prices charged for medical products and services. Some third party payor benefit packages restrict reimbursement or do not provide coverage for specific drugs or drug classes. While a large percentage of prescriptions in the United States for MUSE have been reimbursed to some extent by third party payors since our commercial launch in January 1997, there can be no assurance that our products will be considered cost effective and that reimbursement to the consumer will continue to be available or sufficient to allow us to sell our products on a competitive basis.

In addition, certain healthcare providers are moving towards a managed care system in which such providers contract to provide comprehensive healthcare services, including prescription drugs, for a fixed cost per person. We are unable to predict the reimbursement policies employed by third party healthcare payors. Furthermore, reimbursement for MUSE could be adversely affected by changes in reimbursement policies of governmental or private healthcare payors.

The healthcare industry is undergoing fundamental changes that are the result of political, economic and regulatory influences. The levels of revenue and profitability of pharmaceutical companies may be affected by the continuing efforts of governmental and third party payors to contain or reduce healthcare costs through various means. Reforms that have been and may be considered include mandated basic healthcare benefits, controls on healthcare spending through limitations on the increase in private health insurance premiums and the types of drugs eligible for reimbursement and Medicare and Medicaid spending, the creation of large insurance purchasing groups and fundamental changes to the healthcare delivery system. Due to uncertainties regarding the outcome of healthcare reform initiatives and their enactment and implementation, we cannot predict which, if any, of the reform proposals will be adopted or the effect such adoption may have on us. There can be no assurance that future healthcare legislation or other changes in the administration or interpretation of government healthcare or third party reimbursement programs will not have a material adverse effect on us. Healthcare reform is also under consideration in some other countries.

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

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

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

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

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

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

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

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

We may face competition for our products from lower priced products from foreign countries that have placed price controls on pharmaceutical products. The Medicare Prescription Drug Improvement and Modernization Act of 2003 contains provisions that may change United States importation laws and expand consumers' ability to import lower priced versions of our investigational product candidates and competing products from Canada, where there are government price controls. These changes to United States importation laws will not take effect unless and until the Secretary of Health and Human Services certifies that the changes will lead to substantial savings for consumers and will not create a public health safety issue. The Secretary of Health and Human Services has not yet announced any plans to make this required certification. As directed by Congress, a task force on drug importation conducted a comprehensive study regarding the circumstances under which drug importation could be safely conducted and the consequences of importation on the health, medical costs and development of new medicines for United States consumers. The task force issued its report in December 2004, finding that there are significant safety and economic issues that must be addressed before importation of prescription drugs is permitted. In addition, a number of federal legislative proposals have been made to implement the changes to the United States importation laws without any certification, and to broaden permissible imports in other ways. Even if the changes do not take effect, and other changes are not enacted, imports from Canada and elsewhere may continue to increase due to market and political forces, and the limited enforcement resources of the FDA, the United States Customs Service and other government agencies. For example, Pub. L. No. 109-295, which was signed into law in October 2006 and provides appropriations for the Department of Homeland Security for the 2007 fiscal year, expressly prohibits the United States Customs Service from using funds to prevent individuals from importing from Canada less than a 90-day supply of a prescription drug for personal use, when the drug otherwise complies with the Federal Food, Drug, and Cosmetic Act. Further, several states and local governments have implemented importation schemes for their citizens, and, in the absence of federal action to curtail such activities, we expect other states and local governments to launch importation efforts. The importation of foreign products that compete with our own products could negatively impact our financial condition.

**Defending against claims relating to improper handling, storage or disposal of hazardous materials could be time consuming and expensive.**

Our research and development involves the controlled use of hazardous materials and our operations produce hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from those materials. Various laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. We may be sued for any injury or

contamination that results from our use or the use by third parties of these materials. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development and production efforts.

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

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

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

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

Furthermore, our on-going or planned clinical trials could be delayed or disrupted indefinitely upon the occurrence of a natural disaster. For example, in 2005, our clinical trials in the New Orleans area were interrupted by Hurricane Katrina. Future natural disasters could further delay our clinical trials process, thus adversely affecting our business and financial results.

**Risks Relating to our Intellectual Property**

**We may be sued for infringing the intellectual property rights of others or others may infringe on our intellectual property rights.**

There can be no assurance that our products do not or will not infringe on the patent or proprietary rights of others. Third parties may assert that we are employing their proprietary technology without authorization. For example, in October 2002, the United States Patent and Trademark Office (the "USPTO") issued to Pfizer a method of use patent, U.S. Patent No. 6,469,012. Pfizer immediately initiated litigation against competitors who 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.

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

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

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

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

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

Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Others may independently develop similar or alternative technologies or design around our patented technologies



or products. These companies would then be able to develop, manufacture and sell products that compete directly with our products. In that case, our revenues and operating results would decline.

In November 2007, NexMed submitted an NDA for a formulation of alprostadil for ED. It is unclear if the NexMed product would infringe on the patents we hold for MUSE. If the NexMed product is approved and is successfully commercialized, MUSE revenues could 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 investigational product candidates due to intellectual property rights held by third parties.**

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

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

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

## Risks Relating to our Financial Position and Need for Financing

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

Our capital resources are expected to continue to decline over the next several quarters as the result of spending on research and development projects, including clinical trials. On July 14, 2006, VIVUS, Inc. filed with the SEC a shelf Registration Statement on Form S-3. The shelf Registration Statement (File Number 333-135793) was declared effective by the SEC on August 16, 2006, providing us with the ability to offer and sell up to an aggregate of \$80 million of common stock from time to time in one or more offerings. The terms of any such future offering would be established at the time of such offering. On November 17, 2006, we raised \$33.6 million in a registered direct offering of our common stock pursuant to this shelf Registration Statement. Under the terms of this financing, we sold and issued a total of 6,750,000 shares of our common stock at a price of \$3.50 per share in an initial closing and an additional 2,850,000 shares in a second closing on December 8, 2006. On May 10, 2006, we raised \$12 million in a registered direct offering under an earlier shelf Registration Statement (File Number 333-121159) in which we sold and issued 3,669,725 shares of our common stock to two institutional investors at a price of \$3.27 per share.

On January 4, 2006, we obtained a \$5.4 million loan from Crown Bank, N.A. ("Crown"). The land and buildings, among other assets, located at our principal manufacturing facility and a \$700,000 Certificate of Deposit held by Crown serve as collateral for this loan. The loan is payable over a 10-year term. The interest rate is adjusted annually to a fixed rate for the year equal to the prime rate plus 1%, with a floor of 7.5%. On December 22, 2005, we purchased from our landlord our principal manufacturing facility, which was previously leased, for \$7.1 million. The purchase price was funded in part by \$3.3 million of restricted cash, which was being held by the landlord as cash collateral for renovations to the facility upon the termination of the lease and the remainder with cash.

We expect that our existing capital resources combined with future anticipated cash flows will be sufficient to support our operating activities at least through 2008. However, we anticipate that we will be required to obtain additional financing to fund the development of our research and development pipeline in future periods as well as to support the possible launch of any future products. Our future capital requirements will depend upon numerous factors, including:

- the progress and costs of our research and development programs;
- the scope, timing and results of pre-clinical testing and clinical trials;
- patient recruitment and enrollment in planned and future clinical trials;
- the costs involved in seeking regulatory approvals for our investigational product candidates;
- the costs involved in filing and pursuing patent applications, defending and enforcing patent claims;
- the establishment of collaborations and strategic alliances and the related costs;
- the cost of manufacturing and commercialization activities and arrangements;
- the results of operations;
- demand for MUSE;
- the cost, timing and outcome of regulatory reviews;
- the rate of technological advances;
- ongoing determinations of the potential commercial success of our products under development;

- the level of resources devoted to sales and marketing capabilities; and
- the activities of competitors.

To obtain additional capital when needed, we will evaluate alternative financing sources, including, but not limited to, the issuance of equity or debt securities, corporate alliances, joint ventures and licensing agreements. However, there can be no assurance that funding will be available on favorable terms, if at all. We are continually evaluating our existing portfolio and we may choose to divest, sell or spin-off one or more of our products or investigational product candidates at any time. We cannot assure you that we will successfully develop our products under development or that our products, if successfully developed, will generate revenues sufficient to enable us to earn a profit. If we are unable to obtain additional capital, management may be required to explore alternatives to reduce cash used by operating activities, including the termination of research and development efforts that may appear to be promising to us, the sale of certain assets and the reduction in overall operating activities.

**We have an accumulated deficit of \$169.8 million as of December 31, 2007 and we may continue to incur substantial operating losses for the future.**

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

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

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

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

We believe we are due a refund pursuant to Section 736(d)(1)(C) of the Federal Food, Drug and Cosmetic Act ("FDC Act") from the FDA for product and establishment fees paid in 2006 and 2007 and for the NDA application fee for Evamist paid in 2006 on the basis that the fees paid exceed the anticipated present and future costs incurred by the FDA in conducting the process for the review of human drug applications for VIVUS, Inc. To date, we have been unsuccessful in our attempts to collect these amounts from the FDA. We believe that we will collect these refund amounts from the FDA; however, should we be unable to collect on these claims, we will be required to reverse all or some part of these receivables.

**If we become subject to product liability claims, we may be required to pay damages that exceed our insurance coverage.**

The commercial sale of MUSE and our clinical trials expose us to a significant risk of product liability claims. In addition, pharmaceutical products are subject to heightened risk for product liability claims due to inherent side effects. We identify potential side effects in the patient package insert and

the physician package insert, both of which are distributed with MUSE. While we believe that we are reasonably insured against these risks, we may not be able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. A product liability claim in excess of, or excluded from, our insurance coverage would have to be paid out of cash reserves and could have a material adverse effect upon our business, financial condition and results of operations. Product liability insurance is expensive, difficult to maintain, and current or increased coverage may not be available on acceptable terms, if at all.

### **Risks Relating to an Investment in our Common Stock**

#### **Our stock price has been and may continue to be volatile.**

The market price of our common stock has been volatile and is likely to continue to be so. The market price of our common stock may fluctuate due to factors including, but not limited to:

- the Phase 3 program for Qnexa;
- the data from the current Phase 2 program for Qnexa in diabetes;
- announcements of technological innovations or new products by us or our competitors;
- announcements by licensors of our technology;
- our ability to increase demand for our products in the United States and internationally;
- our ability to successfully sell our products in the United States and internationally;
- actual or anticipated fluctuations in our financial results;
- our ability to obtain needed financing;
- economic conditions in the United States and abroad;
- the volatility and liquidity of the financial markets;
- comments by or changes in assessments of us or financial estimates by security analysts;
- adverse regulatory actions or decisions;
- any loss of key management;
- the results of our clinical trials or those of our competitors;
- developments or disputes concerning patents or other proprietary rights;
- product or patent litigation; and
- public concern as to the safety of products developed by us.

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

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

**Volatility in the stock prices of other companies may contribute to volatility in our stock price.**

The stock market in general, and the NASDAQ Global Market and the market for life sciences companies in particular, have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Further, there has been particular volatility in the market prices of securities of early stage and development stage life sciences companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance.

**Our share ownership is concentrated, and our officers, directors and principal stockholders acting collectively can exert significant control over matters requiring stockholder approval.**

Due to their combined stock holdings, our officers, directors and principal stockholders (stockholders holding greater than 5% of our common stock) acting collectively may have the ability to exercise significant influence over matters requiring stockholder approval including the election of directors and approval of significant corporate transactions. In addition, this concentration of ownership may delay or prevent a change in control of VIVUS and may make some transactions more difficult or impossible to complete without the support of these stockholders.

**Our operating results may fluctuate from quarter to quarter and this fluctuation may cause our stock price to decline.**

Our quarterly operating results have fluctuated in the past and are likely to fluctuate in the future. Factors contributing to these fluctuations include, among other items, the timing and enrollment rates of clinical trials for our drug candidates, the timing of significant purchases of MUSE by distributors, the timing of recognition of deferred revenue, and our need for clinical supplies. Thus, quarter-to-quarter comparisons of our operating results are not indicative of what we might expect in the future. As a result, in some future quarters our operating results may not meet the expectations of securities analysts and investors, which could result in a decline in the price of our stock.

**There may not be an active, liquid trading market for our common stock.**

There is no guarantee that an active trading market for our common stock will be maintained on the NASDAQ Global Market. Investors may not be able to sell their shares quickly or at the latest market price if trading in our stock is not active.

**Our charter documents and Delaware law could make an acquisition of our company difficult, even if an acquisition may benefit our stockholders.**

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

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

- authorize the issuance of preferred stock by the Board of Directors without prior stockholder approval, commonly referred to as "blank check" preferred stock, with rights senior to those of common stock;
- 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 123R"), *Share-Based Payment*, which requires that we record compensation expense in the statement of operations for share-based payments, such as employee stock options, using the fair value method. The adoption of this new standard is expected to continue to have a significant effect on our reported earnings, although it will not affect our cash flows, and could adversely impact our ability to provide accurate guidance on our future reported financial results due to the variability of the factors used to estimate the values of share-based payments. If factors change and we employ different assumptions or different valuation methods in the application of SFAS 123R in future periods, the compensation expense that we record under SFAS 123R may differ significantly from what we have recorded in the current period, which could negatively affect our stock price.

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

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

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

At December 31, 2007, we had \$37.8 million in cash and cash equivalents and \$141.7 million in available for sale securities. We invest our excess cash balances in money market and marketable securities, primarily high quality corporate debt securities and asset-backed securities, in accordance

with our investment policy approved by the Board of Directors. The investment policy has the primary investment objectives of preservation of principal while at the same time maximizing yields without significantly increasing risk; however, there may be times when certain of the securities in our portfolio will fall below the credit ratings required in the policy. If those securities are downgraded or impaired we would experience losses in the value of our portfolio which would have an adverse effect on our results of operations, liquidity and financial condition. Certain of these securities are subject to general credit, liquidity, market and interest rate risks, which may be exacerbated by U.S. sub-prime mortgage defaults that have affected various sectors of the financial markets and caused credit and liquidity issues.

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

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

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

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

**Item 1B. *Unresolved Staff Comments***

None.

## **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.

On November 14, 2006, the Company received a letter from Manatt, Phelps & Phillips LLP ("Manatt") on behalf of Acrux DDS Pty Ltd., FemPharm PTY Ltd., and Acrux Limited (collectively "Acrux") notifying the Company of an alleged dispute under the Testosterone ("Luramist") and Estradiol ("Evamist") Development Agreements (the "Acrux Agreements") between VIVUS and Acrux. The Company believes it is in compliance with all material aspects of the Acrux Agreements and has communicated this belief to Acrux. The claims relating to Evamist have not progressed further, but, to date, the claims have not been formally withdrawn. On November 5, 2007, Acrux made a demand for arbitration under the Acrux Agreements regarding its claims related to Luramist. Acrux's demand seeks a reversion of all rights assigned to the Company regarding Luramist, monetary damages, a portion of a milestone payment for Luramist under the Acrux Agreements and declaratory relief. The arbitration process is proceeding, with the parties selecting and qualifying potential arbitrators. The Company believes that it is in compliance with all material aspects of the Acrux Agreements including those related to Luramist and that it currently does not owe monetary damages or any milestone payment under the Acrux Agreements. Accordingly, the Company believes that it has 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. Notwithstanding the alleged dispute, the development and commercialization of Evamist and Luramist continue as planned.

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

## **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 Global Market under the symbol "VVUS." The following table sets forth for the periods indicated the quarterly high and low sales prices of our common stock as reported on the NASDAQ Global Market.

	Three Months Ended			
	March 31	June 30	September 30	December 31
2007				
High	\$ 5.33	\$ 5.92	\$ 6.19	\$ 5.82
Low	3.58	4.79	4.85	4.90
2006				
High	\$ 3.79	\$ 5.60	\$ 4.42	\$ 4.45
Low	2.82	2.90	2.95	3.18

#### Stockholders

As of February 26, 2008, there were 58,878,157 shares of outstanding common stock that were held by 4,127 shareholders of record and no outstanding shares of preferred stock. On February 26, 2008, the last reported sales price of our common stock on the NASDAQ Global Market was \$6.06 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, ("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, 2007, 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, ("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.

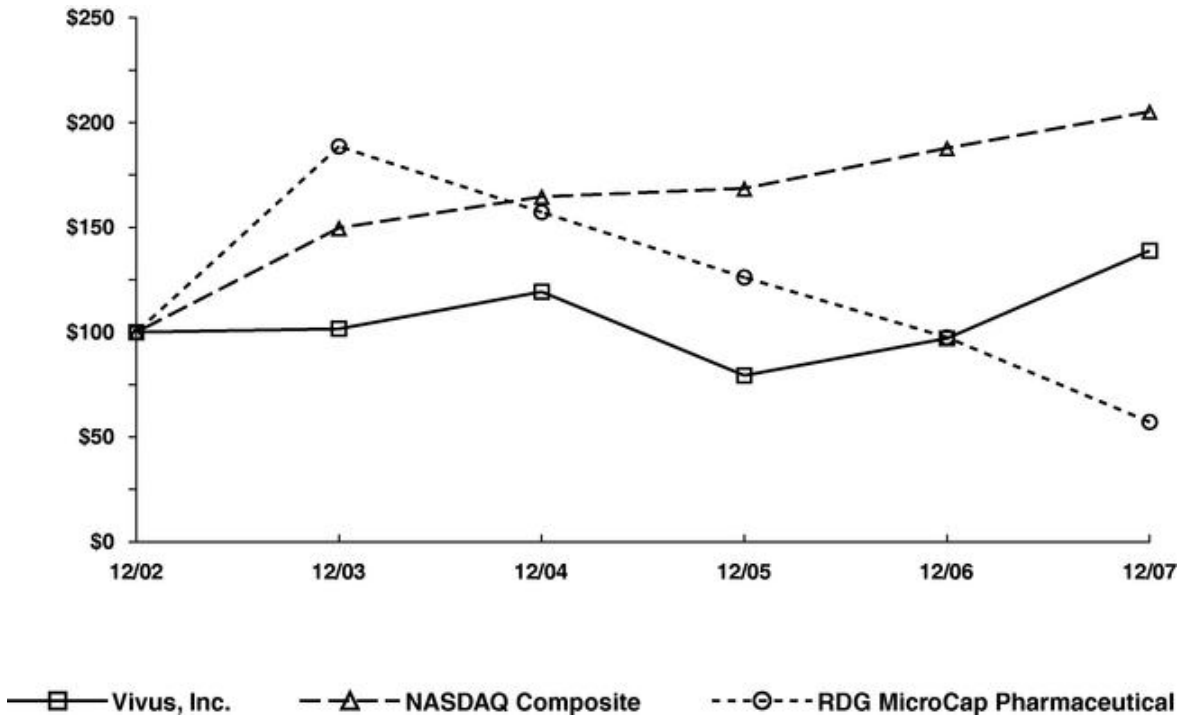
Additional information regarding our stock option plans and plan activity for fiscal 2007, 2006, and 2005 is provided in our consolidated financial statements. See Note 8: "Stock Option and Purchase Plans".

Information regarding equity compensation plans is incorporated by reference from Item 12 of this report.

Corporate Performance Graph

The following graph shows a comparison of total stockholder return for holders of our Common Stock from December 31, 2002, through December 31, 2007 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.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\*  
Among Vivus, Inc., The NASDAQ Composite Index  
And The RDG MicroCap Pharmaceutical Index



\* \$100 invested on 12/31/02 in stock or index-including reinvestment of dividends.  
Fiscal year ending December 31.

**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				
	2007	2006	2005	2004	2003
<i>Income Statement Data:</i>					
Product revenue—United States, net	\$ 15,020	\$ 14,280	\$ 11,697	\$ 16,419	\$ 18,953
Product revenue—International	4,332	2,377	2,794	3,030	3,302
License and other revenue	35,346	588	163	152	5,183
<b>Total revenue</b>	<b>54,698</b>	<b>17,245</b>	<b>14,654</b>	<b>19,601</b>	<b>27,438</b>
Operating expenses:					
Cost of goods sold and manufacturing expense	12,097	11,933	11,018	11,283	10,993
Research and development	26,681	13,316	17,005	18,676	7,724
Selling, general and administrative	17,374	14,579	11,916	11,730	9,839
<b>Total operating expenses</b>	<b>56,152</b>	<b>39,828</b>	<b>39,939</b>	<b>41,689</b>	<b>28,556</b>
Loss from operations	(1,454)	(22,583)	(25,285)	(22,088)	(1,118)
Interest and other income, net	4,165	979	826	511	773
Income (loss) before taxes	2,711	(21,604)	(24,459)	(21,577)	(345)
(Provision) benefit for income taxes	(5,095)	(20)	(25)	(6)	319
<b>Net loss</b>	<b>\$ (2,384)</b>	<b>\$ (21,624)</b>	<b>\$ (24,484)</b>	<b>\$ (21,583)</b>	<b>\$ (26)</b>
Net loss per basic and diluted share	\$ (0.04)	\$ (0.45)	\$ (0.57)	\$ (0.57)	\$ (0.00)
Shares used in per share computation	58,522	48,103	43,272	38,010	35,884
<i>Balance Sheet Data (at year end):</i>					
Working capital	\$ 90,230	\$ 57,564	\$ 23,569	\$ 25,466	\$ 30,099
Total assets	\$ 199,709	\$ 78,214	\$ 49,282	\$ 54,389	\$ 66,732
Long-term debt	\$ 5,062	\$ 11,488	\$ 5,164	\$ 3,239	\$ —
Accumulated deficit	\$ (169,829)	\$ (168,651)	\$ (147,027)	\$ (122,543)	\$ (100,960)
Stockholders' equity	\$ 60,167	\$ 53,140	\$ 26,601	\$ 30,722	\$ 51,235

**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; (10) the volatility and liquidity of the financial markets; and (11) 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, 2007, 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, incorporated in Delaware in 1991, dedicated to the development and commercialization of therapeutic products for large underserved markets. The investigational products currently under development could serve the obesity, diabetes and sexual health markets. Our current and future products in development will encompass patented proprietary formulations and novel delivery systems and future products may be developed by seeking new indications for previously approved pharmaceutical products. To date, through employment of this strategy we have one commercial product and several development-stage products that address these markets. In these sectors patients seek more effective treatment options with fewer negative side effects. With respect to obesity, analysts estimate that this potential market could exceed \$5 billion annually. Sales of approved drugs for diabetes exceed \$10 billion. The indications targeted by VIVUS' investigational sexual health products each represent a projected market greater than \$1 billion annually.

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

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

controlled release. Pharmacokinetic-Pharmacodynamic (PK/PD) studies indicated that the once-a-day formulation is comparable to the twice-a-day formulation used in the Phase 2 study.

Our late-stage investigational product pipeline includes:

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

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

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

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

In 1997, we launched MUSE (alprostadil) in the United States and, together with our partners, internationally. We market MUSE as a prescription product for the treatment of erectile dysfunction.

#### *Our Future*

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

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

It is our objective to become a leader in the development and commercialization of products for large underserved markets. We believe that we have strong intellectual property supporting several opportunities in obesity and diabetes treatment and sexual health. Our future growth will depend on

our ability to further develop and obtain regulatory approval of our investigational product candidates as well as in-licensing and product line extensions.

We have funded operations primarily through private and public offerings of our common stock and through product sales of MUSE. We expect to generate future net losses due to increases in operating expenses as investigational product candidates are advanced through the various stages of clinical development. In connection with the sale of Evamist, we received \$150 million. The sale of Evamist was a unique transaction. As discussed in Note 12: "Sale of Evamist Product", an initial \$10 million was paid at closing and \$140 million was paid upon the FDA's approval of the Evamist NDA. These payments are non-refundable and have been recorded as deferred revenue and will be recognized as license and other revenue ratably over a 21.5-month period, from August 1, 2007 to May 15, 2009, which is the remaining term of a license to improvements to the MDTS applicator. As compared to revenues from product sales, license and other revenue will be significant on a quarterly basis until all of the revenue from the sale of Evamist is recognized, currently expected to be May 2009. Since the \$150 million has been received and we have no related contingencies, the future recognition of revenue and the corresponding reduction of deferred revenue related to the Evamist sale will have no impact on our cash flows from operations in future periods through May 2009. As of December 31, 2007, we have incurred a cumulative deficit of \$169.8 million and expect to incur operating losses in future years.

### **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, 2007, the shipments of MUSE in the United States made in 2007, 2006 and a portion of the shipments in 2005 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 returns 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 is 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, 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 and effective January 1, 2007, MUSE no longer qualifies for Medicare Part D.
- **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, 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.



*License and Other Revenue:* We recognize license revenue in accordance with the Securities and Exchange Commission's Staff Accounting Bulletin No. 104, *Revenue Recognition*. When evaluating multiple element arrangements, we consider whether the components of the arrangement represent separate units of accounting as defined in Emerging Issues Task Force ("EITF") Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* ("EITF 00-21"). In accordance with EITF 00-21, we recognize revenue for delivered elements only when the delivered element has stand-alone value and we have objective and reliable evidence of fair value for each undelivered element. If the fair value of any undelivered element included in a multiple element arrangement cannot be objectively determined, revenue is deferred until all elements are delivered and services have been performed, or until fair value can objectively be determined for any remaining undelivered elements, or such elements are insignificant. Application of this standard requires subjective determinations and requires management to make judgments about the fair value of the individual elements and whether such elements are separable from the other aspects of the contractual relationship.

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.

On May 15, 2007, we closed our transaction with K-V Pharmaceutical Company ("K-V") for the sale of our product candidate, Evamist, a metered dose transdermal spray for the treatment of menopause symptoms. At the time of the sale, Evamist was an investigational product and was not yet approved by the FDA for marketing. The sale transaction contained multiple deliverables, including: the delivery at closing of the Evamist assets (mainly raw material inventory and certain fixed assets), a grant of a sublicense of our rights under a license related to Evamist, and a license to the MDTS applicator; the delivery upon receipt of regulatory approval of Evamist, along with all regulatory submissions; and, lastly, the delivery after FDA approval of certain transition services and a license to improvements to the MDTS applicator. We received approval from the FDA to market Evamist on July 27, 2007 ("FDA Approval"), and on August 1, 2007, we transferred and assigned the Evamist FDA submissions, and all files related thereto to K-V.

We received an upfront payment of \$10 million in May 2007 upon the closing and received an additional \$140 million milestone payment in August 2007 upon FDA Approval. These payments are non-refundable.

We evaluated this multiple deliverable arrangement under EITF 00-21 to determine whether the deliverables are divided into separate units of accounting.

Upon FDA Approval, the two remaining deliverables are the transition services to be performed under the Transition Services Agreement ("TSA") and a license to improvements to the MDTS applicator ("Improvement License") during the two-year period commencing with the closing, or May 15, 2007, and ending on May 15, 2009. We are able to establish fair value for the TSA.

As it relates to the Improvement License, no specific value was assigned in the agreement. We have no obligation to develop improvements to the MDTS applicator and have no plans to expend significant resources in this endeavor. However, as required under EITF 00-21, we do not have objective, reliable evidence of fair value or evidence of inconsequential value to the customer of the Improvement License. Accordingly, the delivered items, together with the undelivered items, are bundled together and are treated as one unit of accounting.

As a result, the initial \$10 million paid at closing and the \$140 million paid upon FDA Approval have been recorded as deferred revenue and will be recognized as license revenue, together with the future billings under the TSA, if any, ratably over the remaining 21.5-month term of the Improvement License, from August 1, 2007 to May 15, 2009. The revenue related to the transaction recognized in the

year ended December 31, 2007 is \$34.9 million and such revenue in future quarters is expected to be recognized as follows (in thousands):

Quarter ending	License revenue
March 31, 2008	\$ 20,930
June 30, 2008	\$ 20,930
September 30, 2008	\$ 20,930
December 31, 2008	\$ 20,930
March 31, 2009	\$ 20,930
June 30, 2009	\$ 10,465

We may also receive milestone payments of up to \$30 million based upon sales of Evamist through the term of the agreements. Revenues associated with these performance milestones will be recognized when they are earned and collectibility is reasonably assured.

#### *Research and Development Expenses*

Research and development ("R&D") expenses include license fees, related compensation, consultants fees, facilities costs, administrative expenses related to R&D activities and clinical trial costs at other companies and research institutions under agreements which are generally cancelable, among other related R&D costs. We also record accruals for estimated ongoing clinical trial costs. Clinical trial costs represent costs incurred by clinical research organizations, ("CROs"), and clinical sites. These costs are recorded as a component of R&D expenses. Under our agreements, progress payments are typically made to investigators, clinical sites and CROs. 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 make certain estimates and judgments in determining income tax expense for financial statement purposes. These estimates and judgments occur in the calculation of certain tax assets and liabilities, which arise from differences in the timing of recognition of revenue and expense for tax and financial statement purposes.

As part of the process of preparing our consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves us estimating our current tax exposure under the most recent tax laws and assessing temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities, which are included in our consolidated balance sheets.

We assess the likelihood that we will be able to recover our deferred tax assets. We consider all available evidence, both positive and negative, including historical levels of income, expectations and

risks associated with estimates of future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for a valuation allowance. If it is not more likely than not that we will recover our deferred tax assets, we will increase our provision for taxes by recording a valuation allowance against the deferred tax assets that we estimate will not ultimately be recoverable. As a result of our analysis of all available evidence, both positive and negative, as of December 31, 2007, it was not considered more likely than not that our deferred tax assets would be realized.

The provision for income taxes in the amount of \$5.1 million for the year ended December 31, 2007, relates to the U.S. alternative minimum tax ("AMT"), tax expense as a result of excess tax benefits related to share-based compensation plans (the benefit of which is recorded on the consolidated balance sheet as additional paid-in capital) and state income taxes. The utilization of tax loss carryforwards is limited in the calculation of AMT and as a result, a federal tax charge was recorded in the year ended December 31, 2007. The current AMT liability is available as a credit against future tax obligations upon the full utilization or expiration of the Company's net operating loss carryforward. The provision reflects tax recognition of the entire \$150 million in non-refundable payments we received from K-V in the year ended December 31, 2007 for the sale of Evamist (see Note 12: "Sale of Evamist Product" to the notes to consolidated financial statements included in this Form 10-K).

As of December 31, 2007, we believed that the amount of the deferred tax assets recorded on our consolidated balance sheet would not ultimately be recovered. However, should there be a change in our ability to recover our deferred tax assets; we would recognize a benefit to our tax provision in the period in which we determine that it is more likely than not that we will recover our deferred tax assets.

In July 2006, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 48 ("FIN No. 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 No. 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 No. 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 adopting FIN No. 48 on January 1, 2007 was recognized as a change in accounting principle, recorded as an adjustment to the opening balance of accumulated deficit on the adoption date. As a result of the implementation of FIN No. 48, we recognized a decrease of approximately \$1.2 million in our income tax liability, which resulted in a decrease of \$1.2 million in accumulated deficit. See Note 11: "Income Taxes" to the notes to consolidated financial statements included in this Form 10-K for a discussion of the impact of adopting FIN No. 48 on January 1, 2007.

#### *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. In 2007, we disposed of \$2.8 million of fully reserved alprostadil which had no impact on cost of goods sold. As of December 31, 2007, the remaining inventory reserve balance is \$1.7 million relating to raw materials and components. In the first quarter of 2005, we determined that we likely would continue to use some portion of the fully reserved component parts inventory 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 2007, 2006 and 2005, 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*

We focus on liquidity and capital preservation in our investments in available-for-sale securities. Through February 28, 2008, we restricted our 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 and asset-backed securities, including commercial paper, rated A1/P1/F1 or better.

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

On February 29, 2008, the Audit Committee of the Board of Directors approved a change to the investment policy to be more restrictive in the focus on liquidity and capital preservation in our investments in available-for-sale securities. Future cash investments are restricted 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 debt obligations rated AA3/AA- or A-1+/P-1 or better or asset-backed commercial paper rated A-1+/P-1 or better.

The weighted average maturity of our portfolio for new investments is not to exceed 9 months.

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

We determine the appropriate classification of marketable securities at the time of purchase and reevaluate such designation at each balance sheet date. Our marketable securities have been classified and accounted for as available-for-sale. These securities are carried at fair value, as provided by our investment advisor, Columbia Management LLC ("Columbia"), an affiliate of Bank of America. We may or may not hold securities with stated maturities greater than 12 months until maturity. In response to changes in the availability of and the yield on alternative investments as well as liquidity requirements, we will occasionally sell these securities prior to their stated maturities. As these securities are viewed by us as available to support current operations, based on the provisions of Accounting Research Bulletin No. 43, Chapter 3A, *Working Capital—Current Assets and Liabilities*, securities with maturities beyond 12 months are classified as current assets under the caption available-for-sale securities in our consolidated balance sheets. Our marketable securities are maintained at one financial institution and are governed by our investment policy as approved by our Board of Directors.

Our policy is to record investments in marketable 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 marketable 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).

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 2007, 2006 and 2005, in thousands, are \$(57), \$19 and \$18, respectively. We recognize all realized gains and losses on our available-for-sale securities in income before provision for income taxes.

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

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

The securities distributed to us from Strategic Cash included corporate bonds, commercial paper, asset-backed securities and other securities. Certain of the securities transferred to us from Strategic Cash, totaling \$3.9 million in fair value at transfer, did not comply with our investment policy due to either credit ratings, length of maturities or sectors not allowed under the policy. These securities were approved by the Audit Committee of the Board of Directors for acceptance into our portfolio. The securities received on redemption will be subject to changes in value depending on market conditions.

We monitor our investment portfolio for impairment on a periodic basis. In the event that the carrying value of an investment exceeds its fair value and the decline in value is determined to be other-than-temporary, an impairment charge is recorded and a new cost basis for the investment is established. In order to determine whether a decline in value is other-than-temporary, we evaluate, among other factors: the duration and extent to which the fair value has been less than the carrying value; our financial condition and business outlook, including key operational and cash flow metrics, current market conditions and future trends in our industry; our relative competitive position within the industry; and our intent and ability to retain the investment for a period of time sufficient to allow for any anticipated recovery in fair value.

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 follow the fair value method of accounting for share-based compensation arrangements in accordance with the Financial Accounting Standards Board ("FASB") Statement of Financial Accounting Standards ("SFAS") 123R, *Share-Based Payment* ("SFAS 123R"). We adopted SFAS 123R effective January 1, 2006 using the modified prospective method of transition. Under SFAS 123R, the estimated fair value of share-based-compensation, including stock options and restricted stock units granted under our Stock Option Plan and purchases of common stock by employees at a discount to market price under the Employee Stock Purchase Plan ("the ESPP"), is recognized as compensation expense. Compensation expense for purchases under the ESPP is recognized based on the estimated fair value of the common stock purchase rights during each offering period and the percentage of the purchase discount.

We recorded \$3.9 million of share-based compensation expense for the year ended December 31, 2007, and \$2.1 million of share-based compensation expense for the year ended December 31, 2006. Share-based compensation expense is allocated among cost of goods sold and manufacturing, research and development and selling, general and administrative expenses based on the function of the related employee. This charge had no impact on our cash flows for the periods presented.

We use the Black-Scholes option pricing model to estimate the fair value of the share-based awards as of the grant date. The Black-Scholes model, by its design, is highly complex, and dependent upon key data inputs estimated by management. The primary data inputs with the greatest degree of judgment are the estimated lives of the share-based awards and the estimated volatility of our stock price. The Black-Scholes model is highly sensitive to changes in these two data inputs. We calculated the estimated life of stock options granted using a "simplified" method, which is based on the average of the vesting term and the term of the option, as a result of guidance from the SEC, as contained in Staff Accounting Bulletin No. 107 permitting the initial use of this method. We determine expected volatility using the historical method, which is based on the daily historical trading data of our common stock over the expected term of the option. Management selected the historical method primarily because we have not identified a more reliable or appropriate method to predict future volatility. For more information about SFAS 123R, see Note 8: "Stock Option and Purchase Plans" to the notes to consolidated financial statements included in this Form 10-K.

## RESULTS OF OPERATIONS

### Executive Overview

For the year ended December 31, 2007, we reported a net loss of \$2.4 million, or \$0.04 net loss per share, as compared to a net loss of \$21.6 million, or \$0.45 net loss per share, during the same period in 2006. The decreased net loss in the year ended December 31, 2007, as compared to the year ended December 31, 2006, was primarily due to the amortization of the deferred license revenue earned due to the sale of Evamist to K-V in May 2007. The increase in revenue was partially offset by an increase in operating expenses, primarily for research and development, in the year ended December 31, 2007 as compared to the year ended December 31, 2006.

In connection with the sale of Evamist, we received \$150 million. The sale of Evamist was a unique transaction. As discussed in Note 1: "Business and Significant Accounting Policies—Sale of Evamist Product" and Note 12: "Sale of Evamist Product", an initial \$10 million was paid at closing and \$140 million was paid upon FDA approval of Evamist. These payments are non-refundable and have been recorded as deferred revenue and will be recognized as license and other revenue ratably over a 21.5-month period, from August 1, 2007 to May 15, 2009, which is the remaining term of a license to improvements to the MDTS applicator. As compared to revenues from product sales, license and other revenue will be significant on a quarterly basis until all of the revenue from the sale of Evamist is recognized, currently expected to be May 2009. Since the \$150 million has been received and we have no related contingencies, the future recognition of revenue and the corresponding reduction of deferred revenue related to the Evamist sale will have no impact on our cash flows from operations in future periods through May 2009.

The revenue related to the transaction recognized in the year ended December 31, 2007 is \$34.9 million and the revenue in future quarters is expected to be recognized as follows (in thousands):

Quarter ending	License revenue
March 31, 2008	\$ 20,930
June 30, 2008	\$ 20,930
September 30, 2008	\$ 20,930
December 31, 2008	\$ 20,930
March 31, 2009	\$ 20,930
June 30, 2009	\$ 10,465

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' clinical development programs for sexual health, partially offset by increased spending related to the Qnexa program.

With the exception of income generated from the revenue recognition of the \$150 million received from K-V, we may have continued losses in future years, depending on the timing of our research and development expenditures, because we expect MUSE sales to remain steady and we plan to continue to invest in clinical development of our current research and development investigational product candidates to bring those potential products to market.

	Years Ended December 31,			% Change Increase/(Decrease)	
	2007	2006	2005	2007 vs 2006	2006 vs 2005
(In thousands, except percentages)					
United States product, net	\$ 15,020	\$ 14,280	\$ 11,697	5%	22%
International product	4,332	2,377	2,794	82%	(15)%
License and other revenue	35,346	588	163	5,911%	261%
Total revenues	\$ 54,698	\$ 17,245	\$ 14,654	217%	18%

Worldwide product revenues from the sales of MUSE were \$19.4 million in 2007, an increase of \$2.7 million, or 16%, from the worldwide sales of MUSE in 2006. Product revenue in the United States for the year ended December 31, 2007 was \$15 million, as compared to \$14.3 million in 2006. The increase in domestic revenues in 2007 is mainly due to increases in both domestic prices and shipment volume. 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 2007 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 2007 represent approximately 3 to 4 months of excess demand. The increase in international revenues in 2007 is mainly due to the timing of orders from our international distributors as well as adjustments to our sales allowance. The increase in license and other revenue is primarily due to the amortization of the deferred license revenue earned due to the sale of Evamist.

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 was mainly due to increases in both domestic prices and shipment volume, partially offset by the timing of orders from our international distributors. The increase in other revenue is primarily due to the amortization of a \$2 million milestone payment from our European distributor, Meda AB that we received in the first quarter of 2006.

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

On March 30, 2007, we announced that we had entered into a definitive agreement with K-V, to transfer our assets and grant a sublicense of our rights under the Acrux Agreement related to Evamist to K-V (the "Transaction"). The closing of the Transaction occurred on May 15, 2007 and on July 27, 2007, we received FDA approval of the Evamist NDA. An initial \$10 million was paid at closing and \$140 million was paid upon FDA Approval. These payments have been recorded as deferred revenue and will be recognized as revenue ratably over the remaining 21.5-month term of the Improvement License, from August 1, 2007 to May 15, 2009.



	Years Ended December 31,			% Change Increase	
	2007	2006	2005	2007 vs 2006	2006 vs 2005
(In thousands, except percentages)					
Cost of goods sold and manufacturing	\$ 12,097	\$ 11,933	\$ 11,018	1%	8%

Cost of goods sold and manufacturing ("cost of goods sold") in the year ended December 31, 2007 increased \$164,000, or 1%, to \$12.1 million, as compared to \$11.9 million for the year ended December 31, 2006. The increase in cost of goods sold and manufacturing expense is the result of increased stock-based compensation expense of \$178,000, partially offset by other cost of goods sold and manufacturing expense net decreases of \$14,000 in the year ended December 31, 2007. As a result of excess manufacturing capacity at our New Jersey facility, we expensed approximately \$5.9 million in manufacturing overhead costs as period costs in the year ended December 31, 2007, as compared to \$6.2 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 in the year ended December 31, 2006 increased \$915,000, or 8%, to \$11.9 million, as compared to \$11 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 alprostadi in excess of projected production needs, \$348,000 of additional stock-based compensation expense, 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 as period costs in the year ended December 31, 2006, as compared to \$6.8 million the prior year.

We anticipate that cost of goods sold in 2008 will be similar to costs incurred in 2007.

#### Research and development

	Years Ended December 31,			% Change Increase/(Decrease)	
	2007	2006	2005	2007 vs 2006	2006 vs 2005
(In thousands, except percentages)					
Research and development	\$ 26,681	\$ 13,316	\$ 17,005	100%	(22)%

Research and development expenses in the year ended December 31, 2007 increased \$13.4 million, or 100%, to \$26.7 million, as compared to \$13.3 million for the year ended December 31, 2006. This increase was primarily the result of a \$12.4 million net increase in project related spending (including increased spending of \$15.8 million for Qnexa partially offset by decreased spending of \$1.8 million for Evamist and \$1.4 million for ALISTA) and a net increase of \$1 million in non-project related spending (primarily due to increases of \$260,000 in stock-based compensation expense and \$489,000 in increased compensation and related expense due to an increase in headcount) in the year ended December 31, 2007 as compared to the year ended December 31, 2006. Evamist and ALISTA clinical trial activities ended in 2006 and consequently, aside from the \$1.5 million milestone payment made to Acrux in August 2007 for the approval of Evamist, there was little spending on these projects in 2007.

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 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 million, \$613,000 of stock-based compensation expense and an incremental increase in other research and development related spending in 2006 as compared to the prior year.

We anticipate that our research and development expenses will continue to increase significantly in 2008, as we continue to advance the clinical program for Qnexa for the treatment of obesity and our other programs. The current remaining contractual obligation with our primary contract research organization for the Phase 3 Qnexa trials totals \$46.5 million which will be recorded as research and development expense in the next two years. There are likely to be additional research and development expenses related to Qnexa and our other programs under development. 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. If we are successful in obtaining FDA regulatory approval for any new investigational product candidates being developed through our research and development efforts, we do not expect to recognize revenue from sales of such new products, if any, for several years.

We filed an NDA for Evamist with the FDA in the third quarter of 2006 and in October 2006 made a \$1 million clinical development milestone payment to Acrux under the terms of our licensing agreement related to this filing, which was expensed in the third quarter of 2006. On July 27, 2007, the FDA approved the NDA for Evamist. K-V paid \$1.5 million of the \$3 million product approval milestone payment made to Acrux in August 2007 for the approval of the NDA for Evamist.

#### *Selling, general and administrative*

	Years Ended December 31,			% Change Increase	
	2007	2006	2005	2007 vs 2006	2006 vs 2005
(In thousands, except percentages)					
Selling, general and administrative	\$ 17,374	\$ 14,579	\$ 11,916	19%	22%

Selling, general and administrative expenses in the year ended December 31, 2007 of \$17.4 million increased \$2.8 million, or 19% as compared to the year ended December 31, 2006. In the year ended December 31, 2007, the increase is primarily due to incremental increases in non-cash stock-based compensation expense of \$1.4 million, MUSE related sales and marketing expenses of \$439,000, accrued compensation of \$422,000, accounting, tax and audit fees of \$172,000 (due in part to the sale of Evamist and other tax consultation), investor relations expenses of \$158,000, board of director fees of \$144,000 and corporate legal fees of \$115,000, as compared to the year ended December 31, 2006.

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 \$1.1 million in non-cash stock-based compensation expense, and incremental net increases in MUSE related sales and marketing expenses of \$1 million and legal fees of \$514,000, as compared to the year ended December 31, 2005.

We anticipate that our selling, general and administrative expenses in 2008 will be similar to 2007.

#### *Interest income and expense*

Interest income for the year ended December 31, 2007 was \$4.7 million, as compared to \$1.6 million for the year ended December 31, 2006. The increase in interest income is primarily due to the increase in our average investment cash balance (due to the receipt of \$150 million from K-V for the sale of Evamist in 2007) for the year ended December 31, 2007 as compared to the same period in 2006, partially offset by the \$1 million realized loss on investments due to the redemption-in-kind of our investment in the Columbia Strategic Cash Portfolio (see Note 2: "Cash, Cash Equivalents and

Available-for-Sale Securities"). Interest expense for the year ended December 31, 2007 was \$538,000 as compared to \$593,000 during the same period in 2006. On April 24, 2007, in connection with the sale of Evamist to K-V, we paid off the \$6.7 million outstanding balance on the Tanabe line of credit, including all accrued interest and terminated the line of credit.

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.

#### *Provision for income taxes*

Provision for income taxes for the year ended December 31, 2007 was \$5.1 million, as compared to \$20,000 for the year ended December 31, 2006. The provision for income taxes in the amount of \$5.1 million for the year ended December 31, 2007 relates to the U.S. AMT, tax expense as a result of the excess tax benefits related to share-based compensation plans (the benefit of which is recorded on the consolidated balance sheet as additional paid-in capital) and state income taxes, while the provision for the year ended December 31, 2006 relates to state income taxes. The utilization of tax loss carryforwards is limited in the calculation of AMT and as a result, a federal tax charge was recorded in the year ended December 31, 2007. This provision reflects tax recognition of the entire \$150 million in non-refundable payments we received from K-V in the year ended December 31, 2007 for the sale of Evamist.

Provision for income taxes for the year ended December 31, 2006 was \$20,000, as compared to \$25,000 for the year ended December 31, 2005. The provision for income taxes for the year ended December 31, 2006 relates to state income taxes, while the provision for the year ended December 31, 2005 relates to both state and foreign income taxes.

#### **Liquidity and Capital Resources**

*Cash.* Unrestricted cash, cash equivalents and available-for-sale securities totaled \$179.5 million at December 31, 2007, as compared to \$58.9 million at December 31, 2006. The increase in cash, cash equivalents and available-for-sale securities of \$120.6 million is the net result of cash provided by operating activities offset by cash used for investing and financing activities for the year ended December 31, 2007. Included in these amounts are the \$150 million received from the K-V transaction and \$2.4 million from exercises of stock options, partially offset by the \$6.7 million payoff of the Tanabe loan.

Since inception, we have financed operations primarily from the issuance of equity securities. Through December 31, 2007, we raised \$230.1 million from financing activities, received \$150 million from the sale of Evamist and had an accumulated deficit of \$169.8 million at December 31, 2007.

*Available-for-sale securities.* We focus on liquidity and capital preservation in our investments in available-for-sale securities. Through February 28, 2008, we restricted our 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 and asset-backed securities, including commercial paper, rated A1/P1/F1 or better.

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

On February 29, 2008 the Audit Committee of the Board of Directors approved a change to the investment policy to be more restrictive in the focus on liquidity and capital preservation in our investments in available-for-sale securities. Future investments are restricted 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 debt obligations rated AA3/AA- or A-1+/P-1 or better or asset-backed commercial paper rated A-1+/P-1 or better.

The weighted average maturity of our portfolio for new investments is not to exceed 9 months.

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

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

*Accounts Receivable.* Accounts receivable (net of allowance for doubtful accounts) at December 31, 2007 was \$4.2 million, as compared to \$4.4 million at December 31, 2006. Currently, we do not have any significant concerns related to accounts receivable or collections. As of February 15, 2008, we had collected 96% of the December 31, 2007 accounts receivable.

*Liabilities.* Total liabilities were \$139.5 million at December 31, 2007, \$114.4 million higher than at December 31, 2006. The change in total liabilities includes a \$114.5 million net increase in deferred revenue, primarily due to \$150 million in deferred license revenue received from K-V on the sale of Evamist, a \$5.7 million increase in accounts payable due to the timing of payments for goods and services supporting the development effort for Qnexa, and a reduction in notes payable, primarily due to the \$6.7 million payoff of the Tanabe loan in the second quarter of 2007. As mentioned above, the deferred revenue balance primarily results from the K-V transaction and the related amortization over time of the revenue. Deferred revenue is a non-cash liability and does not represent any future obligations on our part.

We have entered into manufacturing agreements with suppliers to purchase raw materials. As of December 31, 2007, our remaining commitment under these agreements is to purchase a minimum of \$3.1 million of product from 2008 through 2011. 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 commercialize Luramist 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 million, up to \$4.3 million for the achievement of certain clinical development milestones, up to \$6 million for achieving product approval milestones, and royalties on net sales in the United States upon commercialization of each product. We made a \$1 million clinical development milestone payment to Acrux in October 2006 related to the submission of an NDA to the FDA for Evamist and we made an additional \$3 million product approval milestone payment for the approval of this NDA in August 2007. Per the terms of our Asset Purchase Agreement with K-V for the sale of our Evamist product, K-V paid \$1.5 million of this milestone obligation.

*Operating Activities.* Our operating activities provided \$124.1 million and used \$19.5 and \$21.1 million of cash during the years ended December 31, 2007, 2006 and 2005, respectively. During the year ended December 31, 2007, our net operating loss of \$2.4 million was offset by the deferral of \$114.5 million of license revenue, primarily due to the receipt of \$150 million from K-V for the sale of Evamist, an increase in accounts payable of \$5.7 million due to the timing of payments, and \$3.9 million in non-cash stock-based compensation expense. These operating cash flow sources were offset by an increase in prepaid expenses and other assets of \$2.9 million (including \$1.9 million in receivables from the FDA for product and establishment fees for MUSE and NDA application fees for Evamist and a receivable of \$919,000 for previous federal estimated tax paid).

During the year ended December 31, 2006, our net operating loss of \$21.6 million was partially offset by a \$3.3 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 million in 2006.

During the year ended December 31, 2005, our net operating loss of \$24.5 million was partially offset by a \$1.9 million reduction in our accounts receivable, due to the collection of monies owed to us, and non-cash depreciation expense of \$1.3 million.

*Investing Activities.* Our investing activities used \$128.8 and \$10.6 million and provided \$12.8 million in cash during the years ended December 31, 2007, 2006 and 2005, respectively. The fluctuations from period to period are due primarily to the investment of the \$150 million received from the K-V transaction and the timing of purchases, sales and maturity of investment securities. In addition, in 2006, we provided Crown Bank with a \$700,000 Certificate of Deposit as security for the loan agreement we entered into with them on January 4, 2006 and in 2005, we purchased from our landlord our principal manufacturing facility for \$7.1 million offset by the release of restricted cash of \$3.3 million.

*Financing Activities.* Financing activities used cash of \$2.1 million and provided cash of \$52.5 and \$22.2 million during the years ended December 31, 2007, 2006 and 2005, respectively. In 2007, the cash used by financing activities was primarily due to the \$6.7 million payoff of the Tanabe loan in the second quarter of 2007, partially offset by \$2.4 million in proceeds from the exercise of stock options and \$1.6 million in excess tax benefits related to share-based compensation plans, which is correspondingly shown as a use of cash for operating activities. 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 2005, these amounts include the proceeds from the March 15, 2005 sale of 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. In 2007, 2006 and 2005, these amounts also include borrowings under note agreements, 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 Holding America, Inc., a subsidiary of Tanabe Seiyaku Co., Ltd., or Tanabe, allowing us to borrow up to \$8.5 million to be used for the development of avanafil. The secured line of credit could be drawn upon quarterly and each quarterly borrowing had a 48-month term and bore interest at the annual rate of 2%. On April 24, 2007, in connection with the sale of Evamist to K-V, we paid off the \$6.7 million outstanding balance on the Tanabe line of credit, including all accrued interest and terminated the line of credit. All of the assets of the Company, except the land and buildings, served as collateral for this line of credit. On May 1, 2007, Tanabe signed a Termination and Release acknowledging payment in full of the principal and interest due under the line of credit and releasing the lien on the Company's assets.

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. The interest rate is adjusted annually to a fixed rate for the year equal to the prime rate plus 1%, with a floor of 7.5%. Principal and interest are payable monthly 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 interest rate was 9.25% and 8.25% for the years ended December 31, 2007 and 2006, respectively.

On December 22, 2004, we filed a shelf registration statement (File Number 333-12159) on Form S-3 with the SEC, which allows 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 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 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 an investigational 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 investigational 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 investigational product candidate. The duration and the cost of clinical trials may vary significantly over the life of a project as a result of matters arising during the clinical studies, including, among others, the following:

- we or the FDA may suspend trials;
- we may discover that an investigational 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 investigational 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 substantial evidence of 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 early 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 investigational product candidates;
- the costs involved in filing and pursuing patent applications and enforcing patent claims;
- the establishment of collaborations, sublicenses 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.

We anticipate that our existing capital resources combined with anticipated future cash flows will be sufficient to support our operating needs at least through 2008. However, we anticipate that we may require additional funding to continue our research and product development programs, to conduct preclinical studies and trials, for operating expenses, to pursue regulatory approvals for our investigational 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. Similar to the transaction with Evamist we may consider divesting any of our products in development or our commercial product in order to raise additional funding. 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 investigational product candidates. To the extent that we are unable to obtain third party funding for such expenses, we expect that increased expenses may result in future 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 investigational product candidates at any time. We cannot assure you that we will successfully develop our products under development or that our products, if successfully developed, will generate revenues sufficient to enable us to earn a profit.

### ***Contractual Obligations***

The following table summarizes our contractual obligations at December 31, 2007 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				
	Total	2008	2009-2011	2012-2013	Thereafter
	(in thousands)				
Operating leases	\$ 879	\$ 555	\$ 324	—	—
Manufacturing and other agreements	5,332	2,600	2,732	—	—
Clinical trials	60,159	46,672	13,487	—	—
Notes payable	5,175	113	413	\$ 346	\$ 4,303
<b>Total contractual obligations</b>	<b>\$ 71,545</b>	<b>\$ 49,940</b>	<b>\$ 16,956</b>	<b>\$ 346</b>	<b>\$ 4,303</b>

### Operating Leases

We purchased our previously leased manufacturing facilities in Lakewood, New Jersey on December 22, 2005. 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.

### Manufacturing and Other Agreements

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, research and development, general and administrative services, 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. In May 2007, we amended the terms of this agreement and our remaining commitment is to purchase a minimum total of \$2.3 million of product from 2008 through 2011.

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. Our remaining commitment under this agreement is \$765,000 at December 31, 2007.

#### *Other Agreements*

We have remaining commitments under various general and administrative services agreements totaling \$1.9 million at December 31, 2007, including \$1.2 million related to Mr. Wilson's Employment Agreement (see below). We have also entered into various agreements with research consultants and other contractors to perform regulatory services, drug research, testing and manufacturing including animal studies and, at December 31, 2007, our remaining commitment under these agreements totaled \$210,000. In addition, we have entered into marketing promotion and other agreements for MUSE with a remaining commitment totaling \$169,000 as of December 31, 2007.

On December 19, 2007, the Compensation Committee of the Board of Directors of the Company approved an employment agreement (the "Employment Agreement") with Leland F. Wilson, the Company's President and Chief Executive Officer. The Employment Agreement includes salary, incentive compensation, retirement benefits and length of employment, among other items, as agreed to with Mr. Wilson. The Employment Agreement has an initial term of two years commencing on the effective date, June 1, 2007 (the "Effective Date"). On the second anniversary of the Effective Date, the Employment Agreement will automatically renew for an additional one-year term unless either party provides the other party with a notice of non-renewal.

### Clinical Trials

We have entered into various agreements with clinical consultants, investigators, clinical suppliers and clinical research organizations to perform clinical trial management and clinical studies on our behalf and, at December 31, 2007, our remaining commitment under these agreements totaled \$60.2 million. We make payments to these providers based upon the number of patients enrolled and the length of their participation in the trials. These obligations, however, are contingent on future events, e.g. the rate of patient accrual in our clinical trials. This amount represents the remaining contractual amounts due under various contracts, although all of these contracts could be cancelled by us, in which case we would only be liable to the vendors for work performed to the date of cancellation.

### Notes Payable

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. The interest rate is adjusted annually to a fixed rate for the year equal to the prime rate plus 1%, with a floor of 7.5%. Principal and interest are payable monthly 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 interest rate was 9.25% and 8.25% for the years ended December 31, 2007 and 2006, respectively. As of December 31, 2007, we have a principal balance of \$5.2 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 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 million in connection with this milestone in 2006. We have further agreed to pay royalties on net sales of products containing avanafil. No payments were made under this agreement with Tanabe in the year ended December 31, 2007.

#### 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 Luramist 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 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 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 \$4.8 million in clinical development milestones payments to date, including the \$1 million milestone payment we made to Acrux in October 2006 related to the submission of an NDA to the FDA for Evamist and the \$3 million product approval milestone payment for approval of this NDA, which was paid in August 2007. Per the terms of our Asset Purchase Agreement with K-V for the sale of our Evamist product, we granted a sublicense of our rights under the Acrux Agreement related to Evamist to K-V and K-V paid \$1.5 million of this \$3 million obligation. Although we have sublicensed our rights under the Acrux Agreement related to Evamist to K-V, we will continue to have certain obligations under this license in the event that K-V does not satisfy the requirements under the sublicense agreement. See Note 12: "Sale of Evamist Product" to the consolidated financial statements included in this Form 10-K for additional information concerning the terms of this agreement and Note 15: "Legal Matters" for further information regarding Acrux.

#### ***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 and to certain of our clinical research organizations and investigators sites. 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.

Pursuant to the terms of the K-V transaction for the sale of Evamist, we made certain representations and warranties concerning our rights and assets related to Evamist and our authority to

enter into and consummate the transaction. We also made certain covenants which survive the closing date of the transaction, including a covenant not to operate a business that competes, in the United States, and its territories and protectorates, with the Evamist product.

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 December 2007, the FASB issued SFAS No. 141(R) "*Business Combinations*" ("SFAS 141(R)"). SFAS 141(R) changes several underlying principles in applying the purchase method of accounting. Among the significant changes, SFAS 141(R) requires a redefining of the measurement date of a business combination, expensing direct transaction costs as incurred, capitalizing in-process research and development costs as an intangible asset and recording a liability for contingent consideration at the measurement date with subsequent re-measurements recorded in the results of operations. SFAS 141(R) also requires that costs for business restructuring and exit activities related to the acquired company will be included in the post-combination financial results of operations and also provides new guidance for the recognition and measurement of contingent assets and liabilities in a business combination. In addition, SFAS 141(R) requires several new disclosures, including the reasons for the business combination, the factors that contribute to the recognition of goodwill, the amount of acquisition related third-party expenses incurred, the nature and amount of contingent consideration, and a discussion of pre-existing relationships between the parties. SFAS 141(R) is effective for the Company as of January 1, 2009. Management is currently evaluating the impact of adopting this Statement, but we do not expect it to have a material impact on our consolidated financial position or results of operations.

In December 2007, the FASB issued SFAS No. 160 "*Noncontrolling Interests in Consolidated Financial Statements, an Amendment of ARB No. 51*", ("SFAS 160"). SFAS 160 establishes accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. SFAS 160 requires noncontrolling interests in subsidiaries initially to be measured at fair value and classified as a separate component of equity. SFAS 160 also requires a new presentation on the face of the consolidated financial statements to separately report the amounts attributable to controlling and non-controlling interests. SFAS 160 is effective for the Company as of January 1, 2009. Management is currently evaluating the impact of adopting this Statement, but we do not expect it to have a material impact on our consolidated financial position or results of operations.

In September 2007, the FASB ratified Emerging Issues Task Force Issue No. 07-1 "*Accounting for Collaborative Agreements*", ("EITF 07-1"). EITF 07-1 defines collaborative agreements as contractual arrangements that involve a joint operating activity. These arrangements involve two (or more) parties who are both active participants in the activity and that are exposed to significant risks and rewards dependent on the commercial success of the activity. EITF 07-1 provides that a company should report the effects of adoption as a change in accounting principle through retrospective application to all periods and requires additional disclosures about a company's collaborative arrangements. EITF 07-1 is effective for the Company as of January 1, 2009. The adoption of EITF 07-1 is not expected to have a material impact on our consolidated financial position or results of operations.

In June 2007, the FASB ratified EITF 07-03, "*Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*", which requires nonrefundable advance payments for future R&D activities to be capitalized and recognized as an expense as the goods are delivered or services are performed. Earlier application is not permitted. EITF 07-03 is effective for fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. The adoption of EITF 07-1 is not expected to have a material impact on our consolidated financial position or results of operations.

In February 2007, the FASB issued SFAS 159, "*The Fair Value Option for Financial Assets and Financial Liabilities—Including an amendment of FASB Statement No. 115*". SFAS 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, but we do not expect it to have a material impact on our consolidated financial position or results of operations.

In September 2006, the FASB issued 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 the Company as of January 1, 2008 for financial assets and financial liabilities within its scope. In February 2008, the FASB issued FASB Staff Position No. FAS 157-2 "*Effective Date of FASB Statement No. 157*" ("FSP FAS 157-2"), which defers the effective date of SFAS 157 for all non-financial assets and non-financial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), for fiscal years beginning after November 15, 2008 and interim periods within those fiscal years for items within the scope of FSP FAS 157-2. Management is currently evaluating the impacts and disclosures of this standard, but would not expect SFAS No. 157 to have a material impact on VIVUS' consolidated results of operations or financial condition.

### **Dividend Policy**

We have not paid any dividends since our 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 investigational 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.

**Market Risk**

Market risk represents the risk of loss that may impact our financial position, results of operations or cash flows due to adverse changes in financial and commodity market prices and rates. We are exposed to market risk in the area of changes in United States interest rates. We do not have any material foreign currency or other derivative financial instruments. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We attempt to increase the safety and preservation of our invested principal funds by limiting default risk, market risk and reinvestment risk. We mitigate default risk by investing in investment grade securities.

**Interest Rate Risk**

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 widely diversified investments consisting of investment grade securities. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the interest rate later rises, the principal amount of our investment will probably decline. Based on information provided by our investment advisor, Columbia Management LLC, a hypothetical 100 basis point increase in interest rates reduces the fair value of our available-for-sale securities at December 31, 2007 by approximately \$300,000. To minimize this risk in the future, we intend to maintain our portfolio of cash equivalents and marketable securities in a variety of securities.

We hold investments in both fixed rate and floating rate interest earning instruments, and both carry a degree of interest rate risk. Fixed rate securities may have their fair market value adversely impacted due to a rise in interest rates, while floating rate securities may produce less income than expected if interest rates fall. Due in part to these factors, our future investment income may fall short of expectations due to changes in market conditions and in interest rates or we may suffer losses in principal if forced to sell securities which may have declined in market value due to changes in interest rates.

We have investments in commercial paper, corporate bonds, asset-backed securities, and other securities. While the Company now earns a premium interest rate on these investments, some of these investments are not liquid. The Company presently does not need to access these funds for operating purposes. We have the ability to generally hold our investments until maturity and therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our securities portfolio. In the event the Company needs to access these funds, it may not be able to do so without a loss of principal.

We are also exposed to interest rate risk on the \$5.2 million loan payable to Crown Bank, N.A. as of December 31, 2007. The loan is payable over a 10-year term. The interest rate is adjusted annually to a fixed rate for the year equal to the prime rate plus 1%, with a floor of 7.5%. The interest rate was 9.25% and 8.25% for the years ended December 31, 2007 and 2006, respectively.

VIVUS, INC.

1. **Index to Consolidated Financial Statements**

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

<a href="#"><u>Reports of Independent Registered Public Accounting Firm</u></a>	79
<a href="#"><u>Consolidated Balance Sheets as of December 31, 2007 and 2006</u></a>	81
<a href="#"><u>Consolidated Statements of Operations and Other Comprehensive Income (Loss) for the years ended December 31, 2007, 2006 and 2005</u></a>	82
<a href="#"><u>Consolidated Statements of Stockholders' Equity for the years ended December 31, 2007, 2006 and 2005</u></a>	83
<a href="#"><u>Consolidated Statements of Cash Flows for the years ended December 31, 2007, 2006 and 2005</u></a>	84
<a href="#"><u>Notes to Consolidated Financial Statements</u></a>	85
<a href="#"><u>Financial Statement Schedule II</u></a>	119

## 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, 2007 and 2006, and the related consolidated statements of operations and other comprehensive income (loss), stockholders' equity and cash flows for each of the three years in the period ended December 31, 2007. Our audits also included the financial statement schedule listed in Item 15(a)(2). These financial statements and schedule are the responsibility of the Company'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, 2007 and 2006, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, 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, 2007, the Company adopted Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an Interpretation of FAS 109*. Also as discussed in Note 1 to the consolidated financial statements, on January 1, 2006, the Company 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), VIVUS, Inc.'s internal control over financial reporting as of December 31, 2007, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 4, 2008 expressed an unqualified opinion thereon.

/s/ ODENBERG, ULLAKKO, MURANISHI & CO. LLP

San Francisco, CA

March 4, 2008



## Report of Independent Registered Public Accounting Firm

*The Board of Directors and Stockholders of VIVUS, Inc.*

We have audited VIVUS, Inc.'s internal control over financial reporting as of December 31, 2007, 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 included in Management's Report on Internal Control Over Financial Reporting included in Item 9A. Our responsibility is to express an opinion on the company'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, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, 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, VIVUS, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, 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, 2007 and 2006, and the related consolidated statements of operations and other comprehensive income (loss), stockholders' equity and cash flows for each of the three years in the period ended December 31, 2007 and our report dated March 4, 2008 expressed an unqualified opinion thereon.

/s/ ODENBERG, ULLAKKO, MURANISHI & CO. LLP

San Francisco, CA

March 4, 2008

VIVUS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except par value)

	December 31	
	2007	2006
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 37,838	\$ 44,628
Available-for-sale securities	141,672	14,243
Accounts receivable (net of allowance for doubtful accounts of \$29 and \$67 at December 31, 2007 and 2006, respectively)	4,202	4,359
Inventories, net	2,567	3,327
Prepaid expenses and other assets	5,313	2,408
Total current assets	191,592	68,965
Property, plant and equipment, net	7,417	8,549
Restricted cash	700	700
Total assets	\$ 199,709	\$ 78,214
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 7,768	\$ 2,102
Accrued product returns	2,498	2,473
Accrued research and clinical expenses	1,902	460
Accrued chargeback reserve	1,314	1,531
Accrued employee compensation and benefits	1,999	1,490
Income taxes payable	—	1,245
Deferred revenue—short term	84,183	594
Accrued and other liabilities	1,698	1,506
Total current liabilities	101,362	11,401
Notes payable—long term	5,062	11,488
Deferred revenue—long term	33,118	2,185
Total liabilities	139,542	25,074
Commitments and contingencies		
Stockholders' equity:		
Preferred stock; \$1.00 par value; 5,000 shares authorized; no shares issued and outstanding at December 31, 2007 and 2006	—	—
Common stock; \$.001 par value; 200,000 shares authorized at December 31, 2007 and 2006; 58,873 and 58,144 shares issued and outstanding at December 31, 2007 and December 31, 2006, respectively	59	58
Additional paid-in capital	230,005	221,744
Accumulated other comprehensive loss	(68)	(11)
Accumulated deficit	(169,829)	(168,651)
Total stockholders' equity	60,167	53,140
Total liabilities and stockholders' equity	\$ 199,709	\$ 78,214

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		
	2007	2006	2005
Revenue:			
United States product, net	\$ 15,020	\$ 14,280	\$ 11,697
International product	4,332	2,377	2,794
License and other revenue	35,346	588	163
Total revenue	54,698	17,245	14,654
Operating expenses:			
Cost of goods sold and manufacturing expense	12,097	11,933	11,018
Research and development	26,681	13,316	17,005
Selling, general and administrative	17,374	14,579	11,916
Total operating expenses	56,152	39,828	39,939
Loss from operations	(1,454)	(22,583)	(25,285)
Interest and other income (expense):			
Interest income	4,703	1,573	1,094
Interest expense	(538)	(593)	(221)
Other expense	—	(1)	(47)
Income (loss) before income taxes	2,711	(21,604)	(24,459)
Provision for income taxes	(5,095)	(20)	(25)
Net loss	\$ (2,384)	\$ (21,624)	\$ (24,484)
Other comprehensive income (loss):			
Unrealized (loss) gain on securities, net of taxes	(57)	19	18
Comprehensive loss	\$ (2,441)	\$ (21,605)	\$ (24,466)
Net loss per share:			
Basic and diluted	\$ (0.04)	\$ (0.45)	\$ (0.57)
Shares used in per share computation:			
Basic and diluted	58,522	48,103	43,272

See accompanying notes to consolidated financial statements.

VIVUS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amount				
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
Share-based compensation expense	—	—	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
Share-based compensation expense	—	—	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
Sale of common stock through employee stock purchase plan	83	—	295	—	—	295
Exercise of common stock options for cash	646	1	2,414	—	—	2,415
Share-based compensation expense	—	—	3,903	—	—	3,903
Excess tax benefit of share-based compensation plans	—	—	1,649	—	—	1,649
Reclassification of income taxes payable to accumulated deficit	—	—	—	—	1,206	1,206
Net unrealized loss on securities	—	—	—	(57)	—	(57)
Net loss	—	—	—	—	(2,384)	(2,384)
Balances, December 31, 2007	58,873	\$ 59	\$ 230,005	\$ (68)	\$ (169,829)	\$ 60,167

See accompanying notes to consolidated financial statements.

VIVUS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31		
	2007	2006	2005
<b>Cash flows from operating activities:</b>			
Net loss	\$ (2,384)	\$ (21,624)	\$ (24,484)
Adjustments to reconcile net loss to net cash provided by (used for) operating activities:			
Provision for doubtful accounts	4	(38)	87
Provision for excess inventory	98	835	83
Depreciation	1,080	1,074	1,341
Net recognized loss on investments	1,033	—	—
Share-based compensation expense	3,903	2,065	44
Excess tax benefits related to share-based compensation plans	(1,649)	—	—
(Gain) loss on disposal of property and equipment	(15)	(14)	34
Sale of Evamist assets	559	—	—
Changes in assets and liabilities:			
Accounts receivable	152	3,283	1,853
Inventories	452	342	(732)
Prepaid expenses and other assets	(2,905)	(1,384)	435
Accounts payable	5,666	(1,677)	659
Accrued product returns	25	(543)	(195)
Accrued research, clinical and licensing fees	1,442	(3,398)	(168)
Accrued chargeback reserve	(217)	(301)	206
Accrued employee compensation and benefits	509	210	(162)
Deferred revenue	114,522	1,538	(163)
Income taxes payable	1,610	(460)	(104)
Accrued and other liabilities	197	583	156
Net cash provided by (used for) operating activities	124,082	(19,509)	(21,110)
<b>Cash flows from investing activities:</b>			
Land and buildings purchase	—	—	(7,142)
Other property and equipment purchases	(301)	(501)	(123)
Release (grant) of restricted cash	—	(700)	3,324
Proceeds from sale of property and equipment	19	36	—
Short-term investments transferred from cash and cash equivalents	(68,283)	—	—
Investment purchases	(97,041)	(26,513)	(42,371)
Proceeds from sale/maturity of securities	36,805	17,059	59,128
Net cash (used for) provided by investing activities	(128,801)	(10,619)	12,816
<b>Cash flows from financing activities:</b>			
Borrowing under note agreements	379	6,535	1,925
Principal payments under note agreements	(6,809)	(94)	—
Exercise of common stock options	2,415	360	440
Excess tax benefits related to share-based compensation plans	1,649	—	—
Sale of common stock through employee stock purchase plan	295	315	277
Net proceeds from issuance of common stock	—	45,404	19,584
Net cash (used for) provided by financing activities	(2,071)	52,520	22,226
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>(6,790)</b>	<b>22,392</b>	<b>13,932</b>
<b>Cash and cash equivalents:</b>			
Beginning of year	44,628	22,236	8,304
End of year	\$ 37,838	\$ 44,628	\$ 22,236
<b>Supplemental cash flow disclosure:</b>			
Interest paid	\$ 518	\$ 518	\$ 80
Income taxes paid	\$ 4,414	\$ 13	\$ 10
<b>Non-cash investing and financing activities:</b>			
Reclassification of income taxes payable to accumulated deficit	\$ 1,206	\$ —	\$ —
Release of restoration liability	\$ —	\$ —	\$ (3,021)
Unrealized (loss) gain on securities	\$ (57)	\$ 19	\$ 18

See accompanying notes to consolidated financial statements.

## 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, diabetes 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 Phase 3 studies have been initiated; Qnexa for treating diabetes, for which a Phase 2 study is underway; Luramist (Testosterone MDTs) is being developed to treat hypoactive sexual desire disorder in women, for which a Phase 2 study has been completed; and avanafil is being developed for the treatment of erectile dysfunction; for which Phase 2 studies have been completed. Another of our investigational products, Evamist, a metered dose transdermal estradiol spray approved for the treatment of vasomotor symptoms associated with menopause, was sold to K-V Pharmaceutical Company ("K-V") on May 15, 2007. The Evamist New Drug Application ("NDA") was approved by the U.S. Food and Drug Administration ("FDA") on July 27, 2007. 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, 2007, the Company's accumulated deficit was approximately \$169.8 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, 2007, will be sufficient to meet the Company's obligations at least through 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., and its wholly owned subsidiaries: VIVUS Real Estate LLC, VIVUS International Limited, VIVUS Ireland Limited, VIVUS U.K. Limited and VIVUS B.V. 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. In December 2007, the Company commenced the dissolution of VIVUS International Limited.

*Reclassifications*

Certain prior year amounts in the consolidated financial statements have been reclassified to conform to the current year presentation.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 1. Business and Significant Accounting Policies (Continued)***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, certificate of deposit and commercial paper. These amounts are recorded at cost, which approximates fair value.

Cash with restrictions for a period of greater than twelve months is classified as restricted cash, a non-current asset.

*Available-for-Sale Securities*

The Company focuses on liquidity and capital preservation in its investments in available-for-sale securities. At December 31, 2007, investments were restricted 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 and asset-backed securities, including commercial paper, rated A1/P1/F1 or better.

The weighted average maturity of the Company's portfolio was not to exceed 18 months.

The Company determines the appropriate classification of its investments in marketable securities at the time of purchase and reevaluates such designation at each balance sheet date. The Company's marketable securities have been classified and accounted for as available-for-sale. These securities are carried at fair value. The Company may or may not hold securities with stated maturities greater than 12 months until maturity. In response to changes in the availability of and the yield on alternative investments as well as liquidity requirements, the Company will occasionally sell these securities prior to their stated maturities. As these securities are viewed by the Company as available to support current operations, based on the provisions of Accounting Research Bulletin No. 43, Chapter 3A, *Working Capital—Current Assets and Liabilities*, securities with maturities beyond 12 months are classified as current assets under the caption available-for-sale securities in the accompanying consolidated balance sheets. Marketable securities are maintained at one financial institution and are governed by the Company's investment policy as approved by the Board of Directors.

The Company invests excess cash balances in money market and marketable securities, primarily corporate debt securities and asset-backed securities, with the primary investment objective of preservation of principal while at the same time maximizing yields without significantly increasing risk.

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

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 1. Business and Significant Accounting Policies (Continued)**

income in the accompanying consolidated statements of operations and other comprehensive income (loss).

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 2007, 2006 and 2005, in thousands, are \$(57), \$19 and \$18, respectively. The Company recognizes all realized gains and losses on available-for-sale securities in income before provision for income taxes.

The Company monitors its investment portfolio for impairment on a periodic basis. In the event that the carrying value of an investment exceeds its fair value and the decline in value is determined to be other-than-temporary, an impairment charge is recorded and a new cost basis for the investment is established. In order to determine whether a decline in value is other-than-temporary, the Company evaluates, among other factors: the duration and extent to which the fair value has been less than the carrying value; the Company's financial condition and business outlook, including key operational and cash flow metrics, current market conditions and future trends in its industry; its relative competitive position within the industry; and its intent and ability to retain the investment for a period of time sufficient to allow for any anticipated recovery in fair value.

*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 cash discounts.

*Concentration of Credit Risk*

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents, available-for-sale-securities and accounts receivable. The Company has established guidelines to limit its exposure to credit risk by placing investments with a high credit quality financial institution, diversifying its investment portfolio and placing investments with maturities that maintain safety and liquidity within the Company's liquidity needs.

*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



## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 1. Business and Significant Accounting Policies (Continued)**

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. In 2007, we disposed of \$2.8 million of fully reserved alprostadil, which had no impact on cost of goods sold. As of December 31, 2007, the remaining inventory reserve balance is \$1.7 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 2005, 2006 and 2007, 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

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 1. Business and Significant Accounting Policies (Continued)**

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, 2007.

*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, restricted cash, accounts receivable, accounts payable, and accrued liabilities, are carried at cost, which management believes approximates fair value based on the short-term maturity of these financial instruments or their market rates.

*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.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 1. Business and Significant Accounting Policies (Continued)***International*

The Company has supply agreements with Meda AB ("Meda") 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. ("Paladin") for the marketing and distribution of MUSE. Sales to Meda, who supplies MUSE in the European marketplace, for 2007, 2006 and 2005 were 95.8%, 91.7% and 93.4% of international sales, respectively. The balance of international sales was made to Paladin.

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 in September 2002. In January 2006, the Company received a milestone payment from Meda of \$2 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, 2007, \$1.4 million has been recognized as revenue.

*License and Other Revenue*

The Company recognizes license revenue in accordance with the Securities and Exchange Commission's Staff Accounting Bulletin No. 104, *Revenue Recognition*, and Emerging Issues Task Force ("EITF") Issue 00-21, *Revenue Arrangements with Multiple Deliverables*. Revenue arrangements with multiple deliverables are divided into separate units of accounting if certain criteria are met, including whether the delivered item has standalone value to the customer, and whether there is objective, reliable evidence of the fair value of the undelivered items. Consideration received is allocated among the separate units of accounting based on their relative fair values, and the applicable revenue recognition criteria are identified and applied to each of the units.

Revenue from non-refundable, upfront license fees where the Company has 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.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 1. Business and Significant Accounting Policies (Continued)***Sale of Evamist Product*

On May 15, 2007, the Company closed its transaction with K-V Pharmaceutical Company for the sale of its product candidate, Evamist. At the time of the sale, Evamist was an investigational product and was not yet approved by the FDA for marketing. The sale transaction contained multiple deliverables, including: the delivery at closing of the Evamist assets, a grant of a sublicense of our rights under a license related to Evamist, and a license to the metered-dose transdermal spray, or MDTs, applicator; the delivery upon receipt of regulatory approval of the approved drug along with all regulatory submissions; and, lastly, the delivery after FDA approval of certain transition services and a license to improvements to the MDTs applicator. The Company received approval from the FDA to market Evamist on July 27, 2007 ("FDA Approval"), and on August 1, 2007, the Company transferred and assigned the Evamist FDA submissions, and all files related thereto to K-V. The Company received an upfront payment of \$10 million upon the closing and received an additional \$140 million milestone payment in August 2007 upon FDA Approval. These payments are non-refundable.

Upon FDA Approval, the two remaining deliverables are the transition services to be performed under the Transition Services Agreement ("TSA") and a license to improvements to the MDTs applicator during the two-year period commencing with the closing, or May 15, 2007, and ending on May 15, 2009. The Company has been able to establish fair value for the TSA. Given the unique nature of the license to improvements, the Company is unable to obtain objective, reliable evidence of its fair value.

Accordingly, the delivered items, together with the undelivered items, are treated as one unit of accounting. Since the deliverables are treated as a single unit of accounting, the total cash received, \$150 million, will be recognized as revenue on a pro-rata basis over the term of the last deliverable, which in this case is the license to improvements which expires on May 15, 2009. As a result, the initial \$10 million paid at closing and the \$140 million paid upon FDA Approval have been recorded as deferred revenue and will be recognized as revenue together with the future billings, if any, under the TSA, ratably over the remaining 21.5-month term of the license to improvements, from August 1, 2007 to May 15, 2009. Through December 31, 2007, \$34.9 million has been recognized as revenue.

The Company may also receive milestone payments of up to \$30 million based upon sales of Evamist through the term of the agreements. Revenue associated with performance milestones will be recognized based upon the achievement of the milestones, as defined in the respective agreements.

*Advertising and Sales Promotion expenses*

Advertising and sales promotion expenses are charged to expense as incurred. The Company spent \$1.6 million in 2007, \$1.4 million in 2006 and \$801,000 in 2005 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 2007, 2006 and 2005, in thousands, are \$216, \$212 and \$218, respectively. Handling costs included in "Cost of Goods Sold and Manufacturing Expense" for 2007, 2006 and 2005, in thousands, are \$330, \$354 and \$277, respectively.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 1. Business and Significant Accounting Policies (Continued)***Research and Development Expenses and Accruals*

Research and development (R&D) expenses include license fees, related compensation, contractor fees, facilities costs, allocated 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 ongoing clinical trial costs. Clinical trial costs represent costs incurred by clinical research organizations, ("CROs"), and clinical sites. These costs are recorded as a component of R&D expenses. Progress payments are typically made to investigators, clinical sites and CROs under these agreements by the Company. 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 and effective January 1, 2007, MUSE no longer qualifies for Medicare Part D. The Company routinely assesses its experience with Medicare and other rebates and government chargebacks and adjusts the reserves accordingly. If actual government chargebacks and other rebates are greater than the Company's estimates, additional reserves may be required. Revisions to estimates are charged to income in the period in which the facts that give rise to the revision become known.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 1. Business and Significant Accounting Policies (Continued)***Share-based Compensation—Adoption of SFAS 123R*

On January 1, 2006, the Company adopted SFAS 123 (revised 2004), *Share-Based Payment* ("SFAS 123R"), 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 123R 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 years ended December 31, 2006 and 2007, reflect the impact of SFAS 123R. 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 123R. Therefore, the results for the fiscal 2007 and 2006 are not directly comparable to the same period in 2005.

On November 10, 2005, the FASB issued FASB Staff Position No. SFAS 123R-3, *Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards*. The Company 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 123R. 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 123R.

Prior to January 1, 2006, the Company had not realized the tax benefit in its tax returns of any compensation related to the share-based awards. Accordingly, the Company has no tax benefits available to credit towards its historical APIC pool calculation. As of January 1, 2006, the APIC pool of the Company was \$0. During the years ended December 31, 2007 and 2006, tax benefits of \$1.6 million and \$0, respectively, were recognized as an increase to the additional paid-in capital balance. In accordance with SFAS 123R, the tax effect of the excess tax benefits related to share-based compensation plans of \$1.6 million and \$0 is reported as a financing cash flow in the accompanying consolidated statement of cash flows for the years ended December 31, 2007 and 2006, respectively.

*Prior to the adoption of SFAS 123R*

Prior to the adoption of SFAS 123R, 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 year ended December 31, 2005, the Company accounted for forfeitures as they occurred. The disclosures for the years ended

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## Note 1. Business and Significant Accounting Policies (Continued)

December 31, 2007 and 2006 were not presented because stock-based awards were accounted for under SFAS 123R's fair-value method during this period.

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

The weighted-average fair value of options granted in 2005 was \$2.19.

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: no dividend yield, expected volatility of 53%, risk-free interest rate of 4% and an expected term of 5 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. However, should there be a change in the Company's ability to recover its deferred tax assets, the Company would recognize a benefit to its tax provision in the period in which it was determined that it is more likely than not that the Company will recover its deferred tax assets.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## Note 1. Business and Significant Accounting Policies (Continued)

In July 2006, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 48 ("FIN No. 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 No. 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 No. 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 adopting FIN No. 48 on January 1, 2007 was recognized as a change in accounting principle, recorded as an adjustment to the opening balance of accumulated deficit on the adoption date. As a result of the implementation of FIN No. 48, the Company recognized a decrease of approximately \$1.2 million in its income tax liability, which resulted in a decrease of \$1.2 million in accumulated deficit.

## 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, 2007, 2006 and 2005 are as follows:

	2007	2006	2005
	(In thousands, except per share data)		
Net loss	\$ (2,384)	\$ (21,624)	\$ (24,484)
Net loss per share—basic	\$ (.04)	\$ (.45)	\$ (.57)
Effect of dilutive securities (stock options)	—	—	—
Net loss per share—diluted	\$ (.04)	\$ (.45)	\$ (.57)
Shares used in the computation of net loss per share—basic	58,522	48,103	43,272
Effect of dilutive securities (stock options)	—	—	—
Diluted shares	58,522	48,103	43,272

Potentially dilutive options outstanding of 2,828,510, 4,115,653 and 3,523,309 at December 31, 2007, 2006 and 2005, respectively, are excluded from the computation of diluted EPS for 2007, 2006 and 2005 because the effect would have been antidilutive.



## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 1. Business and Significant Accounting Policies (Continued)***Future Accounting Requirements*

In December 2007, the FASB issued SFAS No. 141(R) "*Business Combinations*" ("SFAS 141(R)"). SFAS 141(R) changes several underlying principles in applying the purchase method of accounting. Among the significant changes, SFAS 141(R) requires a redefining of the measurement date of a business combination, expensing direct transaction costs as incurred, capitalizing in-process research and development costs as an intangible asset and recording a liability for contingent consideration at the measurement date with subsequent re-measurements recorded in the results of operations. SFAS 141(R) also requires that costs for business restructuring and exit activities related to the acquired company will be included in the post-combination financial results of operations and also provides new guidance for the recognition and measurement of contingent assets and liabilities in a business combination. In addition, SFAS 141(R) requires several new disclosures, including the reasons for the business combination, the factors that contribute to the recognition of goodwill, the amount of acquisition related third-party expenses incurred, the nature and amount of contingent consideration, and a discussion of pre-existing relationships between the parties. SFAS 141(R) is effective for the Company as of January 1, 2009. The Company is currently evaluating the impact of adopting this Statement, but does not expect it to have a material impact on the Company's consolidated financial position or results of operations.

In December 2007, the FASB issued SFAS No. 160 "*Noncontrolling Interests in Consolidated Financial Statements, an Amendment of ARB No. 51*", ("SFAS 160"). SFAS 160 establishes accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. SFAS 160 requires noncontrolling interests in subsidiaries initially to be measured at fair value and classified as a separate component of equity. SFAS 160 also requires a new presentation on the face of the consolidated financial statements to separately report the amounts attributable to controlling and non-controlling interests. SFAS 160 is effective for the Company as of January 1, 2009. The Company is currently evaluating the impact of adopting this Statement, but does not expect it to have a material impact on the Company's consolidated financial position or results of operations.

In September 2007, the FASB ratified Emerging Issues Task Force Issue No. 07-1 "*Accounting for Collaborative Agreements*", ("EITF 07-1"). EITF 07-1 defines collaborative agreements as contractual arrangements that involve a joint operating activity. These arrangements involve two (or more) parties who are both active participants in the activity and that are exposed to significant risks and rewards dependent on the commercial success of the activity. EITF 07-1 provides that a company should report the effects of adoption as a change in accounting principle through retrospective application to all periods and requires additional disclosures about a company's collaborative arrangements. EITF 07-1 is effective for the Company as of January 1, 2009. The adoption of EITF 07-1 is not expected to have a material impact on the Company's consolidated financial position or results of operations.

In June 2007, the FASB ratified EITF 07-03, "*Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*", which requires nonrefundable advance payments for future R&D activities to be capitalized and recognized as an expense as the goods are delivered or services are performed. Earlier application is not permitted. EITF 07-03 is effective for fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. The adoption of EITF 07-1 is not expected to have a material impact on the Company's consolidated financial position or results of operations.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 1. Business and Significant Accounting Policies (Continued)**

In February 2007, the FASB issued SFAS 159, "*The Fair Value Option for Financial Assets and Financial Liabilities—Including an amendment of FASB Statement No. 115*". SFAS 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. The Company is currently evaluating the impact of adopting this Statement, but does not expect the adoption to have a material impact on the Company's consolidated financial position or results of operations.

In September 2006, the FASB issued 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 the Company as of January 1, 2008 for financial assets and financial liabilities within its scope. In February 2008, the FASB issued FASB Staff Position No. FAS 157-2 "*Effective Date of FASB Statement No. 157*" ("FSP FAS 157-2"), which defers the effective date of SFAS 157 for all non-financial assets and non-financial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), for fiscal years beginning after November 15, 2008 and interim periods within those fiscal years for items within the scope of FSP FAS 157-2. The Company is currently evaluating the impacts and disclosures of this standard, but would not expect SFAS No. 157 to have a material impact on VIVUS' consolidated results of operations or 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, 2007 and 2006 are presented in the tables that follow. Fair values are based on market prices obtained from our investment advisor, Columbia Management Advisors, LLC, an affiliate of Bank of America. For each category of investment securities, the table presents gross unrealized holding gains and losses.

As of December 31, 2007 (in thousands):

	Amortized Cost	Estimated Fair Value	Unrealized Holding Gains	Unrealized Holding Losses
Cash and money market	\$ 19,358	\$ 19,358	\$ —	\$ —
Commercial paper	17,199	17,200	1	—
Asset backed and other securities	82,031	82,059	28	—
Corporate bonds	60,990	60,893	—	(97)
<b>Total cash, cash equivalents and available-for-sale securities</b>	<b>\$ 179,578</b>	<b>\$ 179,510</b>	<b>\$ 29</b>	<b>\$ (97)</b>

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## Note 2. Cash, Cash Equivalents and Available-for-Sale Securities (Continued)

As of December 31, 2006 (in thousands):

	Amortized Cost	Estimated Fair 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 cash, cash equivalents and available-for-sale securities	\$ 58,882	\$ 58,871	\$ —	\$ (11)

The Company does not have any securities that have been in a continuous unrealized loss position for 12 months or longer.

The following table summarizes our available-for-sale securities by the contractual maturity date as of December 31, 2007 (in thousands):

	Amortized Cost	Estimated Fair Value
Due within one year	\$ 53,383	\$ 53,417
Due within one year to two years	38,306	38,233
*No single maturity date	68,531	68,502
	\$ 160,220	\$ 160,152

\* Securities with no single maturity date include mortgage and asset backed securities.

Actual maturities may differ from the contractual maturities because borrowers may have the right to call or prepay certain obligations.

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

In early December 2007, VIVUS was notified by Columbia that the Strategic Cash fund was closed and that the fund was to be liquidated. The fund no longer supported the \$1 per share net asset value and switched to a market value fund in which all investments were marked to market. VIVUS was given the option of staying in the fund and receiving cash proceeds from the fund as its holdings were liquidated or receiving a pro-rata share of the investments held by the fund. Upon advice from the investment advisor, the Company took a redemption-in-kind consisting of cash, interest receivable and a pro-rata distribution of the underlying securities, consisting principally of high quality corporate debt and asset-backed securities. Prior to the redemption the Company's investment in Strategic Cash was \$84.4 million. On December 20, 2007 and December 21, 2007, the Company received its redemption-in-kind consisting of securities with a market value of \$68.7 million, interest receivable of \$300,000 and cash of \$14.4 million. The difference between the Company's investment in Strategic Cash of \$84.4 million and the fair value of the securities, cash and interest receivable totaling \$83.4 million

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 2. Cash, Cash Equivalents and Available-for-Sale Securities (Continued)**

received in-kind resulted in a loss of \$1 million. This loss of \$1 million is reflected in interest income in the consolidated statement of operations and other comprehensive income (loss).

The gross realized losses on the sale of available-for-sale securities during the years ended December 31, 2007, 2006 and 2005 were \$1 million, \$7,000 and \$0, respectively.

**Note 3. Inventories**

Inventory balances, net of reserves of \$1.7 million and \$4.4 million, as of December 31, 2007 and 2006, respectively, consist of (in thousands):

	2007	2006
Raw materials and component parts	\$ 2,224	\$ 2,793
Work in process	38	66
Finished goods	305	468
Inventory, net	\$ 2,567	\$ 3,327

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 2007, we disposed of \$2.8 million of fully reserved alprostadil, which had no impact on cost of goods sold. 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, 2007, 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 \$86,000, \$99,000 and \$76,000 of its fully reserved component parts inventory during 2007, 2006 and 2005, 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 2007, 2006 and 2005, 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 \$732,000 as of the end of 2007, and we intend to continue to use this reserved component parts inventory in production when appropriate.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 4. Property, Plant and Equipment**

Property, plant and equipment as of December 31, 2007 and 2006, respectively, consist of (in thousands):

	2007	2006
Land	\$ 901	\$ 901
Buildings	3,317	3,102
Machinery and equipment	17,701	18,361
Computers and software	2,521	2,446
Furniture and fixtures	1,327	1,204
Building improvements	11,894	12,050
	37,661	38,064
Accumulated depreciation	(30,244)	(29,515)
Property and equipment, net	\$ 7,417	\$ 8,549

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 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, 2007, 2006 and 2005, depreciation expense, in thousands, was \$1,080, \$1,074 and \$1,341, respectively.

**Note 5. Prepaid Expenses and Other Assets**

Prepaid expenses and other assets as of December 31, 2007 and 2006, respectively, consist of (in thousands):

	2007	2006
Receivable from Food and Drug Administration	\$ 1,932	\$ 1,279
Refundable federal income taxes	919	—
Prepaid clinical studies	1,277	211
Interest receivable	825	219
Other prepaid expenses and assets	360	699
Total	\$ 5,313	\$ 2,408

The Company paid an application fee to the FDA in September 2006 for the NDA for Evamist of \$767,000. In addition, the Company has paid product and establishment fees for its marketed product, MUSE, for the fiscal year 2007 of \$512,000 (which was paid to the FDA in October 2006) and for the fiscal year 2008 of \$653,000 (which was paid to the FDA in October 2007). The Company is due a refund pursuant to Section 736(d)(1)(C) of the Federal Food, Drug and Cosmetic Act ("FDCA") 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. In

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 5. Prepaid Expenses and Other Assets (Continued)**

addition, prepaid expenses and other assets includes a receivable of \$919,000 for a refund of the Company's estimated federal income tax for the year ended December 31, 2007, which was paid in December 2007.

**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. On April 24, 2007, in connection with the Company's sale of Evamist to K-V (see Note 12: "Sale of Evamist Product"), the Company paid off the outstanding balance of \$6.7 million, including all accrued interest. All the assets of the Company, except the land and buildings, served as collateral for this line of credit. On May 1, 2007, Tanabe signed a Termination and Release acknowledging payment in full of the principal and interest due under the line of credit and releasing the lien on the Company's assets, and thereby terminating the line of credit. In September 2007, Tanabe Seiyaku Co., Ltd., following its merger with Mitsubishi Pharma Corporation, announced its name change to Mitsubishi Tanabe Pharma Corporation.

*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 is 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 are payable monthly 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 interest rate was 9.25% and 8.25% for the years ended December 31, 2007 and 2006, respectively. 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.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 6. Notes Payable (Continued)**

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

	December 31,	
	2007	2006
Tanabe line of credit	\$ —	\$ 6,324
Crown Bank N.A. loan	5,175	5,281
<b>Total notes payable</b>	<b>5,175</b>	<b>11,605</b>
Less current portion	(113)	(117)
<b>Total long-term notes payable</b>	<b>\$ 5,062</b>	<b>\$ 11,488</b>

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

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

Year ending December 31,	Crown Bank N.A. Loan
2008	\$ 113
2009	125
2010	137
2011	151
2012	164
Thereafter	4,485
<b>Total</b>	<b>\$ 5,175</b>

**Note 7. Stockholders' Equity***Common Stock*

The Company is authorized to issue 200 million shares of common stock. As of December 31, 2007 and 2006, there were 58,872,905 and 58,144,264 shares, respectively, issued and outstanding.

On May 10, 2006, the Company sold \$12 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 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).

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 7. Stockholders' Equity (Continued)**

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.

On December 22, 2004, we filed a shelf registration statement (File Number 333-12159) on Form S-3 with the SEC, which allows 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.

*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, 2007 and 2006, 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.

*Stockholder Rights Plan*

On March 26, 2007, the Board of Directors of the Company adopted a Stockholder Rights Plan (the "Rights Plan") and amended its bylaws. Under the Rights Plan, the Company will issue a dividend of one right for each share of its common stock held by stockholders of record as of the close of business on April 13, 2007.

The Rights Plan is designed to guard against partial tender offers and other coercive tactics to gain control of the company without offering a fair and adequate price and terms to all of the Company's stockholders. The Rights Plan is intended to provide the Board of Directors with sufficient time to consider any and all alternatives to such an action and is similar to plans adopted by many other publicly traded companies. The Rights Plan was not adopted in response to any efforts to acquire the Company, and the Company is not aware of any such efforts.

Each right will initially entitle stockholders to purchase a fractional share of the Company's preferred stock for \$26.00. However, the rights are not immediately exercisable and will become exercisable only upon the occurrence of certain events. If a person or group acquires, or announces a tender or exchange offer that would result in the acquisition of 15% or more of the Company's common stock while the Stockholder Rights Plan remains in place, then, unless the rights are redeemed by the Company for \$.001 per right, the rights will become exercisable by all rights holders except the acquiring person or group for the Company's shares or shares of the third party acquirer having a value of twice the right's then-current exercise price.



## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 7. Stockholders' Equity (Continued)**

The Board of Directors also amended provisions of the Company's bylaws concerning procedures for the calling of special stockholder meetings and establishing the agenda and board nominees at annual stockholders meetings. The Company filed these bylaw amendments with the SEC on Form 8-K on March 28, 2007.

**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. 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, 2007, no SPRs have been granted under the 2001 Plan.

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.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## Note 8. Stock Option and Purchase Plans (Continued)

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

	Year ended December 31,					
	2007		2006		2005	
	Number of Shares	Weighted- Average Exercise Price	Number of Shares	Weighted- Average Exercise Price	Number of Shares	Weighted- Average Exercise Price
Balance at beginning of year	4,550,152	\$ 4.21	4,404,664	\$ 4.31	4,114,785	\$ 4.56
Options:						
Granted	1,688,278	\$ 4.28	667,535	\$ 3.24	1,132,178	\$ 3.76
Exercised	(645,605)	\$ 3.74	(120,414)	\$ 2.99	(144,523)	\$ 3.05
Cancelled	(244,324)	\$ 5.20	(401,633)	\$ 4.09	(697,776)	\$ 5.11
Balance at end of year	5,348,501	\$ 4.25	4,550,152	\$ 4.21	4,404,664	\$ 4.31
Exercisable at end of year	3,226,260	\$ 4.35	3,235,579	\$ 4.40	2,985,081	\$ 4.40
Weighted average grant-date fair value of options granted during the year		\$ 2.78		\$ 2.26		\$ 2.19

*Restricted Stock Units*

On July 12, 2006, the Board of Directors adopted an amendment to the 2001 Plan to add the ability to issue Restricted Stock Units, ("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.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 8. Stock Option and Purchase Plans (Continued)**

A summary of restricted stock units award activity under the 2001 Plan as of December 31, 2007 and changes during the period then ended are presented below:

	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
Granted	—	—		
Vested	—	—		
Forfeited	—	—		
Restricted stock units outstanding, December 31, 2007	62,500	\$ 2.04	3.7	\$ 255,000

All of the Company's restricted stock units were unvested as of December 31, 2007.

*Summary of Stock Options*

At December 31, 2007, stock options were outstanding and exercisable as follows:

Options Outstanding		Options Exercisable			
Range of Exercise Prices	Number Outstanding at December 31, 2007	Weighted- Average Remaining Contractual Life	Weighted- Average Exercise Price	Number Exercisable December 31, 2007	Weighted- Average Exercise Price
\$2.00-\$3.88	1,856,038	5.8 years	\$ 3.30	1,324,253	\$ 3.26
\$3.90-\$4.25	2,233,884	8.0 years	\$ 4.18	770,627	\$ 4.08
\$4.50-\$8.08	1,258,579	5.0 years	\$ 5.76	1,131,380	\$ 5.82
\$2.00-\$8.08	5,348,501	6.5 years	\$ 4.25	3,226,260	\$ 4.35

The aggregate intrinsic value of outstanding options as of December 31, 2007 was \$6 million, of which \$3.7 million related to exercisable options.

At December 31, 2007, 1,470,126 options remain available for grant. 1,000,000 of these shares were registered on a Form S-8 filed with the SEC on April 25, 2007. In the year ended December 31, 2007, in accordance with the terms of the 2001 Plan, the Company transferred a net total of 42,388 expired plan shares to the 2001 Plan. Options under these plans generally vest over four years, and all options expire after ten years.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 8. Stock Option and Purchase Plans (Continued)***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).

As of December 31, 2007, 1,116,255 shares have been issued to employees and there are 283,745 available for issuance under the Stock Purchase Plan. The weighted average fair value of shares issued under the Stock Purchase Plan in 2007, 2006 and 2005 was \$1.42, \$1.40 and \$0.93 per share, respectively.

*Share-based Compensation Expense*

Total estimated share-based compensation expense, related to all of the Company's share-based awards, recognized for the years ended December 31, 2007 and 2006 was comprised as follows (in thousands, except per share data):

	Year Ended December 31, 2007	Year Ended December 31, 2006
Cost of goods sold and manufacturing expense	\$ 526	\$ 348
Research and development	873	613
Selling, general and administrative	2,504	1,104
Share-based compensation expense before taxes	3,903	2,065
Related income tax benefits	—	—
Share-based compensation expense, net of taxes	\$ 3,903	\$ 2,065
Net share-based compensation expense, per common share:		
Basic and diluted	\$ 0.07	\$ 0.04

At December 31, 2007, a total of 5,348,501 stock options were outstanding under our stock option plans. Stock-based compensation expense recognized for the years ended December 31, 2007 and 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, 2007 was \$3.7 million related to stock options, \$105,000 related to the employee stock purchase plan, and \$51,000 related to restricted stock units, net of the estimated forfeitures. Included in stock-based

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 8. Stock Option and Purchase Plans (Continued)**

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.

On December 19, 2007, the Compensation Committee of the Board of Directors approved an Employment Agreement with Leland F. Wilson, the Company's President and Chief Executive Officer. Among other things, the Employment Agreement provides for full acceleration with respect to Mr. Wilson's outstanding unvested equity awards with an exercise period equal to the later of 12 months from termination of employment or 12 months from termination of service from the Board of Directors upon his retirement, subject to certain conditions. The additional time during which Mr. Wilson is allowed to exercise his options is considered a modification under SFAS 123R and resulted in additional net compensation expense of approximately \$844,000, to be amortized over the new requisite service period. The fair value of each modified option grant was estimated on the date of modification using the Black-Scholes option-pricing model with the following weighted-average assumptions: no dividend yield, expected volatility of between 43.6% and 67.6%, risk-free interest rate of between 3.3% and 3.7% and an expected term of between 1.2 and 7 years.

Also on December 19, 2007, the Compensation Committee approved a resolution pursuant to which non-employee members of the Board of Directors shall be entitled, upon termination of service from the Board of Directors, to an exercise period equal to 12 months from termination of service from the Board of Directors for such directors' then-outstanding equity awards. The additional time during which the Board of Directors is allowed to exercise their options is considered a modification under SFAS 123R and resulted in additional compensation expense of approximately \$116,000, to be recognized over the remaining requisite service period. The fair value of each modified option grant was estimated on the date of modification using the Black-Scholes option-pricing model with the following weighted-average assumptions: no dividend yield, expected volatility of between 42.3% and 60.3%, risk-free interest rate of between 3.3% and 3.5% and an expected term of between 0.5 years and 5.9 years.

As of December 31, 2007, unrecognized estimated compensation expense totaled \$2.7 million related to non-vested stock options, \$44,000 related to the employee stock purchase plan, and \$60,000 related to restricted stock units. The weighted average remaining requisite service period of the non-vested options was 1.2 years, of the employee stock purchase plan was 4.5 months, and of the restricted stock units was 3.7 years.

*Valuation Assumptions*

The fair value of stock options granted in the years ended December 31, 2007 and 2006 was estimated using Black-Scholes Model with the following weighted average assumptions (not including

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## Note 8. Stock Option and Purchase Plans (Continued)

the option modifications for Mr. Wilson and the Board of Directors approved on December 19, 2007, as noted above):

	Non-Director Stock Options		Director Stock Options		ESPP	
	Year Ended		Year Ended		Year Ended	
	2007	2006	2007	2006	2007	2006
Expected life (in years)	6.25	6.25	5.19	5.19	0.50	0.49
Volatility	67.97%	76.03%	63.24%	68.55%	44.12%	64.83%
Risk-free interest rate	4.58%	4.87%	4.62%	4.98%	4.32%	5.10%
Dividend yield	—	—	—	—	—	—

*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"; exerciseability 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. Options granted to our Board of Directors generally become fully vested after eight months, while those granted to our employees become fully vested after four years. As a result of this and other differences identified between these two groups, we have valued their options using separate assumptions.

*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 planned 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 price volatility.

*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.

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

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 8. Stock Option and Purchase Plans (Continued)**

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.

**Note 9. Agreements**

In 2001, VIVUS entered into a Development, Licensing and Supply Agreement with Tanabe for the development of avanafil. Under the terms of the 2001 Development, Licensing and Supply Agreement with Tanabe, the Company paid a \$2 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 agreed to develop and, if approved, commercialize Testosterone MDTs ("Luramist") and Evamist in the United States for various female health applications. Under the terms of the agreements, the Company agreed to pay to Acrux for Luramist licensing fees of \$2 million, up to \$3.3 million for the achievement of certain clinical development milestones, up to \$3 million for achieving product approval milestones, and royalties on net sales in the United States following approval and commercialization. For Evamist, the Company agreed to pay to Acrux licensing fees of \$1 million, up to \$1 million for the achievement of certain clinical development milestones, up to \$3 million for achieving product approval milestones, and royalties on net sales in the United States following approval and commercialization. The Company made a \$1 million milestone payment to Acrux in October 2006 related to the submission of an NDA to the FDA for Evamist. Upon approval of the NDA for Evamist, a \$3 million product approval milestone became due and was paid to Acrux in August 2007. Per the terms of the Asset Purchase Agreement with K-V for the sale of Evamist, K-V paid \$1.5 million of this \$3 million obligation. Although the Company has sublicensed its rights under the Acrux Agreement related to Evamist to K-V, the Company will continue to have certain obligations under this license in the event that K-V does not satisfy the requirements under the sublicense agreement. See Note 12: "Sale of Evamist Product" below for additional information concerning the terms of this agreement and Note 15: "Legal Matters" for further information regarding 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 product for the treatment of erectile dysfunction. In connection with these agreements, the Company is obligated to pay royalties on product sales of MUSE (4% of United States and Canadian product sales and 3% of sales

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 9. Agreements (Continued)**

elsewhere in the world). In 2007, 2006 and 2005, the Company recorded royalty expenses, in thousands, of \$890, \$683, and \$556, 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 including upon achieving established sales thresholds. To date, we have collected \$3.6 million in milestone payments from our current international distributors.

**Note 10. Commitments***Lease Commitments*

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):

2008	\$	555
2009		324
		<hr/>
	\$	879
		<hr/>

Rent expense, in thousands, under operating leases totaled \$528, \$751 and \$1,466 for the years ended December 31, 2007, 2006 and 2005, 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. In May 2007, the terms of the agreement were amended and the Company's remaining commitment is to purchase a minimum total of \$2.3 million of product from 2008 through 2011.

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 to require the purchase of a minimum total of \$1.5 million of product from 2006 through 2008. The Company's remaining commitment under this agreement is \$765,000 at December 31, 2007.

*Other Agreements*

The Company has entered into various agreements with clinical consultants, investigators, clinical suppliers and clinical research organizations to perform clinical studies on its behalf and, at December 31, 2007, its remaining commitment under these agreements totaled \$60.2 million. The Company has remaining commitments under various general and administrative services agreements totaling \$1.9 million at December 31, 2007, including \$1.2 million related to Mr. Wilson's Employment Agreement (see below). The Company has also entered into various agreements with research



## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 10. Commitments (Continued)**

consultants and other contractors to perform regulatory services, drug research, testing and manufacturing including animal studies and, at December 31, 2007, its remaining commitment under these agreements totaled \$210,000. In addition, the Company has entered into marketing promotion and other agreements for its erectile dysfunction product, MUSE, with a remaining commitment totaling \$169,000 as of December 31, 2007.

On December 19, 2007, the Compensation Committee of the Board of Directors of the Company approved an employment agreement (the "Employment Agreement") with Leland F. Wilson, the Company's President and Chief Executive Officer. The Employment Agreement includes salary, incentive compensation, retirement benefits and length of employment, among other items, as agreed to with Mr. Wilson. The Employment Agreement has an initial term of two years commencing on the effective date, June 1, 2007 (the "Effective Date"). On the second anniversary of the Effective Date, the Employment Agreement will automatically renew for an additional one-year term unless either party provides the other party with a notice of non-renewal.

*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 and to certain of our clinical research organizations and investigator sites. 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.

Pursuant to the terms of the Asset Purchase Agreement for the sale of the Evamist product to K-V, the Company made certain representations and warranties concerning its rights and assets related to Evamist and the Company's authority to enter into and consummate the transaction. The Company also made certain covenants which survive the closing date of the transaction, including a covenant not to operate a business that competes, in the United States, and its territories and protectorates, with the Evamist product. See Note 15: "Legal Matters" for further information regarding Acrux.

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.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**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 carryforwards. Significant components of the Company's deferred income tax assets as of December 31, 2007 and 2006 are as follows (in thousands):

	2007	2006
Deferred tax assets:		
Net operating loss carry forwards	\$ 1,937	\$ 46,419
Research and development credit carry forwards	9,014	7,449
Inventory reserve	635	1,707
Accruals and other	2,627	3,053
Depreciation	4,175	3,586
Deferred revenue	44,774	—
	63,162	62,214
Valuation allowance	(63,162)	(62,214)
Total	\$ —	\$ —

The Company makes certain estimates and judgments in determining income tax expense for financial statement purposes. These estimates and judgments occur in the calculation of certain tax assets and liabilities, which arise from differences in the timing of recognition of revenue and expense for tax and financial statement purposes.

As part of the process of preparing its consolidated financial statements, the Company is required to estimate its income taxes in each of the jurisdictions in which it operates. This process involves the Company estimating its current tax exposure under the most recent tax laws and assessing temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities, which are included in the Company's consolidated balance sheets.

The Company assesses the likelihood that it will be able to recover its deferred tax assets. The Company considers all available evidence, both positive and negative, including historical levels of income, expectations and risks associated with estimates of future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for a valuation allowance. If it is not more likely than not that the Company will recover its deferred tax assets, the Company will increase its provision for taxes by recording a valuation allowance against the deferred tax assets that the Company estimates will not ultimately be recoverable. As a result of the Company's analysis of all available evidence, both positive and negative, as of December 31, 2007, it was not considered more likely than not that the Company's deferred tax assets would be realized.

The net change in the valuation allowance for the years ended December 31, 2007 and December 31, 2006 was \$948,000 and \$10.8 million, respectively. As of December 31, 2007 and 2006, the Company had no significant deferred tax liabilities.

For federal and state income tax reporting purposes, respective net operating loss, ("NOL"), carryforwards of approximately \$6 million and \$1 million are available to reduce future 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.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## Note 11. Income Taxes (Continued)

Post adoption of SFAS 123R, the unrecognized deferred tax benefits totaled \$81,000 and have been accounted for as a credit to additional paid-in capital, as they have been realized through a reduction in income taxes payable. For federal and state income tax reporting purposes, respective credit carryforwards of approximately \$5.6 million and \$1.5 million are available to reduce future taxable income, if any. These carryforwards, except for the California research and development credit, expire on various dates through 2026. 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 carryforwards available for use in any given period upon the occurrence of certain events, including a significant change in ownership interest.

The Company recently concluded a study of its NOL carryforwards to determine whether such amounts are limited under IRC Sec. 382. The Company does not believe the limitations will significantly impact its ability to offset income with available NOLs.

The provision for income taxes is based upon income (loss) before provision for income taxes as follows, for the years ended December 31, 2007, 2006 and 2005 (in thousands):

	2007	2006	2005
Income (loss) before income taxes:			
Domestic	\$ 3,138	\$ (21,590)	\$ (24,135)
International	(427)	(14)	(324)
Total income (loss) before taxes	\$ 2,711	\$ (21,604)	\$ (24,459)

The provision for income taxes consists of the following components for the years ended December 31, 2007, 2006 and 2005 (in thousands):

	2007	2006	2005
Current			
Federal	\$ 4,026	\$ —	\$ —
State	1,069	20	18
Foreign	—	—	7
Total provision for income taxes	\$ 5,095	\$ 20	\$ 25

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## Note 11. Income Taxes (Continued)

The provisions for income taxes differ from the amount computed by applying the statutory federal income tax rates as follows, for the years ended December 31, 2007, 2006 and 2005:

	2007	2006	2005
Provision/(benefit) computed at federal statutory rates	35%	(35)%	(35)%
State income taxes, net of federal tax effect	26	(4)	(4)
Change in valuation allowance	107	39	39
Foreign losses not benefited	6	—	—
Permanent items	30	—	—
Tax credits	(16)	—	—
True up of State NOLs	—	—	—
	<u>188%</u>	<u>0%</u>	<u>0%</u>

The provision for income taxes in the amount of \$5.1 million for the year ended December 31, 2007 relates to the U.S. alternative minimum tax ("AMT"), tax expense as a result of excess tax benefits related to share-based compensation plans (the benefit of which is recorded on the balance sheet as additional paid-in capital) and certain state income taxes. The utilization of tax loss carryforwards is limited in the calculation of AMT and as a result, a federal tax charge was recorded in the year ended December 31, 2007. The current AMT liability is available as a credit against future tax obligations upon the full utilization or expiration of the Company's net operating loss carryforward.

Effective January 1, 2007, the Company adopted Financial Accounting Standards Interpretation, ("FIN No. 48"), *Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109*. FIN No. 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of uncertain tax positions taken or expected to be taken in a company's income tax return, and also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FIN No. 48 utilizes a two-step approach for evaluating uncertain tax positions accounted for in accordance with SFAS No. 109, *Accounting for Income Taxes* ("SFAS No. 109"). Step one, Recognition, requires a company to determine if the weight of available evidence indicates that a tax position is more likely than not to be sustained upon audit, including resolution of related appeals or litigation processes, if any. Step two, Measurement, is based on the largest amount of benefit, which is more likely than not to be realized upon ultimate settlement.

Upon adoption of FIN No. 48, the Company recognized a cumulative effect adjustment of \$1.2 million, decreasing its income tax liability for unrecognized tax benefits, and decreasing the January 1, 2007 accumulated deficit balance. At January 1, 2007, after the foregoing decrease in the tax liability, the Company did not have any unrecognized tax benefits.

The Company recognizes interest and penalties accrued on any unrecognized tax benefits as a component of its provision for income taxes. As of January 1, 2007, the Company had no accrual for payment of interest and penalties related to unrecognized tax benefits, nor were any amounts for interest or penalties recognized during the year ended December 31, 2007.

Although the Company files U.S. federal, various state, and foreign tax returns, the Company's only major tax jurisdictions are the United States, California and New Jersey. Tax years 1991 to 2006

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 11. Income Taxes (Continued)**

remain subject to examination by the appropriate governmental agencies due to tax loss carryovers from those years.

**Note 12. Sale of Evamist Product**

On March 30, 2007, the Company entered into a definitive agreement with K-V to transfer the assets and grant a sublicense of its rights under the Company's agreement with Acrux related to Evamist, a metered dose transdermal spray for the treatment of menopause symptoms, to K-V (the "Transaction"). At the time of the sale, Evamist was an investigational product not yet approved by the FDA for marketing. Under the Transaction, the Company received an upfront payment of \$10 million at the closing and, upon approval of the NDA for Evamist on July 27, 2007 and the transfer and assignment of the NDA submissions to K-V on August 1, 2007 received an additional \$140 million (see Note 1: "Business and Significant Accounting Policies—Sale of Evamist Product").

The Company may also receive certain one-time payments of up to \$30 million based on K-V achieving certain annual net sales thresholds for Evamist. In addition, per the terms of the Transaction, K-V reimbursed VIVUS for \$1.5 million of the \$3 million milestone payment paid by VIVUS to Acrux upon FDA Approval of the NDA. In connection with the Transaction, in order to obtain Tanabe's release of liens against all assets including the Evamist assets and intellectual property, the Company repaid the Tanabe line of credit (see Note 6: "Notes Payable").

**Note 13. Concentration of Customers and Suppliers**

Sales to significant customers as a percentage of total revenues for the years ended December 31, 2007, 2006 and 2005 are as follows:

	2007	2006	2005
Customer A	53%	51%	42%
Customer B	15%	19%	23%
Customer C	14%	10%	15%
Customer D	11%	13%	13%

Accounts receivable at December 31, 2007 and 2006 by significant customer as a percentage of the total gross accounts receivable balance are as follows:

	2007	2006
Customer A	53%	38%
Customer B	23%	31%
Customer C	4%	9%
Customer D	15%	18%

The Company relies on third party sole-source manufacturers to produce its clinical trial materials, components and raw materials. Third party manufacturers may not be able to meet the Company's needs with respect to timing, quantity or quality. Several of the Company's manufacturers are sole-source manufacturers where no alternative suppliers exist. In the year ended December 31, 2007, the Company's sole-source manufacturer of Qnexa Phase 3 clinical supplies and sole-source CRO

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 13. Concentration of Customers and Suppliers (Continued)**

responsible for conducting Qnexa Phase 3 clinical trials represented 21% and 29%, respectively, of the Company's total research and development expenses in the year ended December 31, 2007.

**Note 14. 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, 2007, 2006 and 2005, in thousands were \$267, \$270 and \$270, respectively. The employer-matching portion of the 401(k) plan began on July 1, 2000.

**Note 15. 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.

On November 14, 2006, the Company received a letter from Manatt, Phelps & Phillips LLP ("Manatt") on behalf of Acrux DDS Pty Ltd., FemPharm PTY Ltd., and Acrux Limited (collectively "Acrux") notifying the Company of an alleged dispute under the Testosterone ("Luramist") and Estradiol ("Evamist") Development Agreements (the "Acrux Agreements") between VIVUS and Acrux. The Company believes it is in compliance with all material aspects of the Acrux Agreements and has communicated this belief to Acrux. The claims relating to Evamist have not progressed further, but, to date, the claims have not been formally withdrawn. On November 5, 2007, Acrux made a demand for arbitration under the Acrux Agreements regarding its claims related to Luramist. Acrux's demand seeks a reversion of all rights assigned to the Company related to Luramist, monetary damages, a portion of a milestone payment for Luramist under the Acrux Agreements and declaratory relief. The arbitration process is proceeding, with the parties selecting and qualifying potential arbitrators. The Company believes that it is in compliance with all material aspects of the Acrux Agreements, including those relating to Luramist and that it currently does not owe monetary damages or any milestone payment under the Acrux Agreements. Accordingly, the Company believes that it has 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 conditions and results of operations. Notwithstanding the dispute, the development and commercialization of Evamist and Luramist continue as planned.

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 16. 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 2007, 2006 and 2005 the Company paid \$788,000, \$561,000 and \$344,000, respectively, to Wilson Sonsini Goodrich and Rosati for legal services.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## Note 17. Selected Financial Data (Unaudited)

## Selected Quarterly Financial Data (in thousands)

	Quarter Ended,			
	March 31	June 30	September 30	December 31
2007				
Total revenue	\$ 1,689	\$ 4,098	\$ 19,088	\$ 29,823
Cost of goods sold	\$ 2,571	\$ 3,191	\$ 2,736	\$ 3,599
Net (loss) income	\$ (7,391)	\$ (6,678)	\$ 1,321	\$ 10,364
Net (loss) income per share:				
Basic	\$ (0.13)	\$ (0.11)	\$ 0.02	\$ 0.18
Diluted	\$ (0.13)	\$ (0.11)	\$ 0.02	\$ 0.17
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)

# 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
<b>Allowance for Doubtful Accounts</b>				
Fiscal year ended December 31, 2005	\$ 104	\$ 87	\$ 11	\$ 202
Fiscal year ended December 31, 2006	202	(38)	(97)	67
Fiscal year ended December 31, 2007	67	4	(42)	29
<b>Inventory Reserve</b>				
Fiscal year ended December 31, 2005	3,917	83	(234)(1)	3,766
Fiscal year ended December 31, 2006	3,766	835(2)	(224)(3)	4,377
Fiscal year ended December 31, 2007	4,377	98	(2,811)(4)	1,664
<b>Accrued Product Returns</b>				
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
Fiscal year ended December 31, 2007	2,473	1,372	(1,347)	2,498
<b>Accrued Chargebacks Reserve</b>				
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
Fiscal year ended December 31, 2007	\$ 1,531	\$ 3,249	\$ (3,466)	\$ 1,314

- (1) 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.
- (2) 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.
- (3) 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.
- (4) The Company used \$86,000 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 2007, the Company disposed of \$2.8 million of fully reserved alprostadil which had no impact on cost of goods sold.



**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, 2007. 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 the effectiveness of our internal control over financial reporting as of December 31, 2007. This report, which expresses an unqualified opinion on the effectiveness of our internal controls over financial reporting as of December 31, 2007, 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.

## 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 2007 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](http://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

#### Equity Compensation Plans Approved by Stockholders

Information about our equity compensation plans at December 31, 2007 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)	5,411,001	\$ 4.25	1,470,126
Equity compensation plans not approved by stockholders(b)	—	\$ —	—
Total	5,411,001	\$ 4.25	1,470,126

(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.

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 Firm 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 Firm  
Consolidated Balance Sheets as of December 31, 2007 and 2006  
Consolidated Statements of Operations and Other Comprehensive Income (Loss) for the years ended December 31, 2007, 2006 and 2005  
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2007, 2006 and 2005  
Consolidated Statements of Cash Flows for the years ended December 31, 2007, 2006 and 2005  
Notes to Consolidated Financial Statements

##### 2. Financial Statement Schedules

The following financial statement schedule of VIVUS, Inc. as set forth on page 119 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
2.1(20)††	Asset Purchase Agreement, by and among the Registrant and K-V Pharmaceutical Company, dated as of March 30, 2007
3.1(4)	Amended and Restated Certificate of Incorporation of the Registrant
3.2(21)	Amended and Restated Bylaws of the Registrant
3.3(5)	Amended and Restated Certificate of Designation of the Registrant
4.1(4)	Specimen Common Stock Certificate of the Registrant
4.2(22)	Preferred Stock Rights Agreement dated as of March 27, 2007 between the Registrant and Computershare Investor Services, LLC

- 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
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- 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.
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- 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)
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- 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
- 10.61(23)†† Termination and Release executed by Tanabe Holding America, Inc. dated May 1, 2007
- 10.62(24)†† Master Services Agreement dated as of September 12, 2007 between the Registrant and Medpace, Inc.
- 10.63(25)†† Amendment Four to the Manufacturing Agreement by and between the Registrant and CHINOIN Pharmaceutical and Chemical Works Private Co. Ltd., effective as of December 31, 2006
- 10.64(26) VIVUS, Inc. Performance Incentive Plan Fiscal 2007
- 10.65(27) Employment Agreement dated December 20, 2007 between the Company and Leland F. Wilson
- 10.66(28) Form of Change in Control and Severance Agreement dated December 19, 2007 by and between the Registrant and Certain of its Executive Officers
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- 23.1 Consent of ODENBERG, ULLAKKO, MURANISHI & Co. LLP, Independent Registered Public Accounting Firm
- 24 Power of Attorney (See signature page)
- 31.1 Certification of Chief Executive Officer, dated March 6, 2008, 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 6, 2008, 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

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† Confidential treatment granted.

†† Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

(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.
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- (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.
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- (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.
- (20) Incorporated by reference to the same numbered exhibit filed with the Registrant's Form 8-K (File No. 001-33389) filed with the Commission on May 21, 2007.
- (21) Incorporated by reference to Exhibit 3.1 filed with the Registrant's Form 8-K (File No. 001-33389) filed with the Commission on March 28, 2007.
- (22) Incorporated by reference to Exhibit 4.1 filed with the Registrant's Registration Statement on Form 8-A (File No. 001-33389) filed with the Commission on March 28, 2007.

- (23) Incorporated by reference to the same numbered exhibit filed with the Registrant's Form 8-K (File No. 001-33389) filed with the Commission on May 4, 2007.
- (24) Incorporated by reference to the same numbered exhibit filed with the Registrant's Form 8-K (File No. 001-33389) filed with the Commission on September 18, 2007.
- (25) Incorporated by reference to Exhibit 10.60 filed with the Registrant's Form 8-K (File No. 001-33389) filed with the Commission on May 8, 2007.
- (26) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Form 8-K (File No. 001-33389) filed with the Commission on April 26, 2007.
- (27) Incorporated by reference to Exhibit 10.63 filed with the Registrant's Form 8-K (File No. 001-33389) filed with the Commission on December 21, 2007.
- (28) Incorporated by reference to Exhibit 10.64 filed with the Registrant's Form 8-K (File No. 001-33389) filed with the Commission on December 21, 2007.

## 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 6, 2008

## 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
<u>/s/ LELAND F. WILSON</u> Leland F. Wilson	President, Chief Executive Officer (Principal Executive Officer) and Director	March 6, 2008
<u>/s/ MARK B. LOGAN</u> Mark B. Logan	Chairman of the Board and Director	March 6, 2008
<u>/s/ TIMOTHY E. MORRIS</u> Timothy E. Morris	Vice President of Finance and Chief Financial Officer (Principal Financial Officer)	March 6, 2008
<u>/s/ LEE B. PERRY</u> Lee B. Perry	Vice President and Chief Accounting Officer (Principal Accounting Officer)	March 6, 2008
<u>/s/ VIRGIL A. PLACE</u> Virgil A. Place	Chief Scientific Officer and Director	March 6, 2008

/s/ GRAHAM STRACHAN

Director

March 6, 2008

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Graham Strachan

/s/ MARIO M. ROSATI

Director

March 6, 2008

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Mario M. Rosati

/s/ LINDA M. DAIRIKI SHORTLIFFE, M.D.

Director

March 6, 2008

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Linda M. Dairiki Shortliffe, M.D.

**REPORT ON FORM 10-K FOR  
THE YEAR ENDED DECEMBER 31, 2007**

**INDEX TO EXHIBITS**

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- (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.
- (20) Incorporated by reference to the same numbered exhibit filed with the Registrant's Form 8-K (File No. 001-33389) filed with the Commission on May 21, 2007.
- (21) Incorporated by reference to Exhibit 3.1 filed with the Registrant's Form 8-K (File No. 001-33389) filed with the Commission on March 28, 2007.
- (22) Incorporated by reference to Exhibit 4.1 filed with the Registrant's Registration Statement on Form 8-A (File No. 001-33389) filed with the Commission on March 28, 2007.
- (23) Incorporated by reference to the same numbered exhibit filed with the Registrant's Form 8-K (File No. 001-33389) filed with the Commission on May 4, 2007.
- (24) Incorporated by reference to the same numbered exhibit filed with the Registrant's Form 8-K (File No. 001-33389) filed with the Commission on September 18, 2007.
- (25) Incorporated by reference to Exhibit 10.60 filed with the Registrant's Form 8-K (File No. 001-33389) filed with the Commission on May 8, 2007.
- (26) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Form 8-K (File No. 001-33389) filed with the Commission on April 26, 2007.
- (27) Incorporated by reference to Exhibit 10.63 filed with the Registrant's Form 8-K (File No. 001-33389) filed with the Commission on December 21, 2007.
- (28) Incorporated by reference to Exhibit 10.64 filed with the Registrant's Form 8-K (File No. 001-33389) filed with the Commission on December 21, 2007.



## LIST OF SUBSIDIARIES

The following is a list of subsidiaries of VIVUS, Inc.

1. VIVUS Real Estate LLC, a wholly owned subsidiary of VIVUS, Inc.
  2. VIVUS International Limited, a wholly owned subsidiary of VIVUS, Inc.
  3. VIVUS UK Limited, a wholly owned subsidiary of VIVUS, Inc.
  4. VIVUS BV Limited, a wholly owned subsidiary of VIVUS, Inc.
  5. VIVUS Ireland Limited, a wholly owned subsidiary of VIVUS, Inc.
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QuickLinks

[Exhibit 21.2](#)

[LIST OF SUBSIDIARIES](#)

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the Registration Statements on Forms S-8 (No. 033-75698, No. 333-06486, No. 333-29939, No. 333-57374, No. 333-73394, No. 333-104287, No. 333-107006 and No. 333-142354) and Forms S-3 (No. 333-105985, No. 333-121519 and No. 333-135793) of VIVUS, Inc. of our reports dated March 4, 2008, relating to the consolidated financial statements and schedule of VIVUS, Inc. and the effectiveness of internal control over financial reporting of VIVUS, Inc., included in this Annual Report on Form 10-K for the year ended December 31, 2007.

/s/ ODENBERG, ULLAKKO, MURANISHI & CO. LLP  
San Francisco, California  
March 4, 2008

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QuickLinks

[Exhibit 23.1](#)

[CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM](#)

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT  
TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Leland F. Wilson, President and Chief Executive Officer, certify that:

1. I have reviewed this annual report on Form 10-K of VIVUS, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 6, 2008

By: /s/ LELAND F. WILSON

Name: Leland F. Wilson  
Title: President and Chief Executive Officer

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QuickLinks

[Exhibit 31.1](#)

[CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002](#)



**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT  
TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Timothy E. Morris, Vice President, Finance and Chief Financial Officer, certify that:

1. I have reviewed this annual report on Form 10-K of VIVUS, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 6, 2008

By: /s/ TIMOTHY E. MORRIS

Name: Timothy E. Morris  
Title: Vice President, Finance and Chief Financial Officer

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QuickLinks

[Exhibit 31.2](#)

[CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002](#)

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER  
PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Leland F. Wilson, President and Chief Executive Officer of VIVUS, Inc., certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of VIVUS, Inc. on Form 10-K for the period ending December 31, 2007 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report on Form 10-K fairly presents in all material respects the financial condition and results of operations of VIVUS, Inc. This written statement is being furnished to the Securities and Exchange Commission as an exhibit to such Annual Report on Form 10-K. A signed original of this statement has been provided to VIVUS, Inc. and will be retained by VIVUS, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Date: March 6, 2008

By: /s/ LELAND F. WILSON

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Leland F. Wilson  
*President and Chief Executive Officer*

I, Timothy E. Morris, Vice President, Finance and Chief Financial Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of VIVUS, Inc. on Form 10-K for the period ending December 31, 2007 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report on Form 10-K fairly presents in all material respects the financial condition and results of operations of VIVUS, Inc. This written statement is being furnished to the Securities and Exchange Commission as an exhibit to such Annual Report on Form 10-K. A signed original of this statement has been provided to VIVUS, Inc. and will be retained by VIVUS, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Date: March 6, 2008

By: /s/ TIMOTHY E. MORRIS

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Timothy E. Morris  
*Vice President, Finance and Chief Financial Officer*

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## QuickLinks

[Exhibit 32](#)

[CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002](#)