VIVUS INC
Form 10-K
March 10, 2010

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2009

OR

o **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	**94-3136179**
(State or other jurisdiction of incorporation or organization)	(IRS employer identification number)
1172 Castro Street Mountain View, California	**94040**
(Address of principal executive office)	(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 o No ý

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 o No ý

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 ý No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

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. o

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 o	Accelerated filer ý	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

The aggregate market value of the common equity held by non-affiliates of the Registrant as of June 30, 2009 totaled approximately $418,853,140 based on the closing stock price as reported by the NASDAQ Global Market.

As of February 26, 2010, there were 80,738,994 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, 2009 are incorporated by reference into Part III of this report.	III, ITEMS 10, 11, 12, 13, 14

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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 "may," "will," "believe," "expect," "intend," "anticipate," "predict," "should," "planned," "continue," "likely," "opportunity," "estimated," and "potential," the negative use of these words or other similar words. 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 investigational product candidates and products; (7) risks related to noncompliance with United States Food and Drug Administration, or the FDA, regulations; (8) our ability to demonstrate through clinical testing the safety and effectiveness of our clinical investigational product candidates; (9) the timing of initiation and completion of clinical trials and submissions to the FDA;(10) uncertainties around the acceptance and ultimate approval of our new drug application for Qnexa® and any actions taken on behalf of regulatory authorities during the review process; (11) the volatility and liquidity of the financial markets; (12) our liquidity and capital resources; (13) our expected future revenues, operations and expenditures; and (14) other factors that are described from time to time in our periodic filings with the Securities and Exchange Commission, or the SEC, including those set forth in this filing as "Item 1A. Risk Factors."

Item 1. *Business*

Overview

VIVUS, Inc. is a biopharmaceutical company, incorporated in 1991, dedicated to the development and commercialization of therapeutic products for large underserved markets. Currently, we have one drug that has been approved by the FDA, and several investigational product candidates in late stages of clinical development, that are focused on market opportunities in obesity and related morbidities, including sleep apnea and diabetes, and sexual health. With respect to obesity, it is estimated that the potential worldwide pharmaceutical market for obesity could approach $5 billion annually. Annual worldwide sales of approved drugs for diabetes currently exceed $10 billion. There are currently no approved pharmaceutical therapies for sleep apnea; however, the sales of devices and related consumables used to treat sleep apnea exceed $2 billion annually. The indications targeted by our investigational sexual health product candidates each represent a projected worldwide market greater than $1 billion annually. We market MUSE®, a legacy product, as a prescription treatment for erectile dysfunction in the United States and, together with our partners, internationally.

Recent Developments

On March 1, 2010, we announced that the FDA had accepted for filing the New Drug Application, or NDA, for Qnexa for the treatment of obesity. Further, the FDA has set October 28, 2010 as the Prescription Drug User Fee Act, or PDUFA, date whereby we may expect a response to the review of the NDA.

On January 11, 2010, we announced new data from an analysis of the recently completed Phase 3 study, REVIVE TA-301, of avanafil, an investigational product candidate for the treatment of erectile

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dysfunction, or ED. Patients who attempted intercourse within 15 minutes of dosing were successful 67%, 69% and 72% of the time on 50, 100 and 200 mg of avanafil, respectively, as compared to 29% of the patients on placebo ($p<0.05$). The previously-disclosed top-line results of the REVIVE study evaluating the safety and efficacy of avanafil in 646 patients showed that all three doses of avanafil met the primary study endpoints by demonstrating a statistically significant improvement in erectile function as measured by the Sexual Encounter Profile, or SEP and improvements in the International Index of Erectile Function, or IIEF score.

On January 7, 2010, we announced positive results from a Phase 2 study evaluating the safety and efficacy of Qnexa, our investigational product candidate, for the treatment of obstructive sleep apnea, or OSA. This study demonstrated statistically significant improvement in the apnea/hypopnea index, or AHI, which is a measure of the severity of sleep apnea, in patients with OSA treated with Qnexa for 28 weeks. Qnexa-treated patients on average had a 69% reduction in sleep apnea and hypopnea events as compared to patients on placebo. Qnexa-treated patients also experienced significant weight loss, improvements in blood pressure, and increased blood oxygen saturation during overnight polysomnography (sleep lab study). OSA is a sleep-related breathing disorder that involves a decrease or complete cessation in airflow despite an ongoing effort to breathe. OSA is associated with an increased risk of hypertension, diabetes, stroke, myocardial infarction, sudden cardiac death and all-cause mortality. It has been estimated that approximately 18 million Americans have sleep apnea, and currently, there is no medication approved by the FDA for the treatment of OSA.

On December 29, 2009, we announced that an NDA had been submitted to the FDA seeking approval of Qnexa for the treatment of obesity, including weight loss and maintenance of weight loss, in patients who are obese or overweight with co-morbidities such as hypertension, type 2 diabetes, dyslipidemia or central adiposity. Qnexa is our proprietary oral investigational product candidate which incorporates low doses of active ingredients from two previously approved products, phentermine and topiramate. We have previously completed the Special Protocol Assessment, or SPA, process and have agreement with the FDA regarding key elements of the pivotal Phase 3 protocols (OB-301 and OB-303) of Qnexa for the treatment of obesity and weight-related co-morbidities.

On November 18, 2009, we announced positive results from REVIVE (TA-301), a Phase 3 pivotal study evaluating the safety and efficacy of avanafil, our oral investigational product candidate for the treatment of erectile dysfunction, or ED, in 646 patients. The REVIVE study met all primary endpoints across the three doses studied by demonstrating statistically significant improvement in erectile function as measured by the SEP and improvements in the IIEF score. The pivotal study, conducted under an SPA with the FDA, also demonstrated successful intercourse in 30 minutes or less after dosing, and a favorable side-effect and safety profile.

On September 23, 2009, we closed an underwritten public offering of our common stock that provided us with gross proceeds of $108.7 million before deducting underwriting discounts and commissions and other offering expenses. Under this offering, we sold 9,000,000 shares of our common stock at a price per share of $10.50 and the underwriters purchased 1,350,000 additional shares of common stock at the same price to cover over-allotments.

On September 9, 2009, we announced the results of our pivotal Phase 3 trials for Qnexa, EQUIP (OB-302) and CONQUER (OB-303).

EQUIP (OB-302)

The EQUIP study included 1,267 morbidly obese patients (1,050 females and 217 males) across 93 centers in the United States. The average baseline body mass index, or BMI, of the study population was 42.1 kg/m2 and baseline weight was 256 pounds (a BMI of >30 kg/m2 is classified as obese per guidelines from the U.S. Department of Health and Human Services). Patients had a 4-week dose titration period followed by 52 weeks of treatment. The study was a randomized, double-blind, placebo-

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controlled, 3-arm, prospective trial with patients randomized to receive once-a-day treatment with placebo, low-dose Qnexa or full-dose Qnexa. Patients were asked to follow a hypocaloric diet representing a 500-calorie/day deficit and advised to implement a simple lifestyle modification program. Weight loss results from the study are summarized as follows:

	ITT-LOCF			Completers		
EQUIP (OB-302) 56 weeks	**Placebo (n=498)**	**Qnexa low-dose (n=234)**	**Qnexa full-dose (n=498)**	**Placebo (n=241)**	**Qnexa low-dose (n=138)**	**Qnexa full-dose (n=301)**
Mean weight loss (%)	1.6%	5.1%*	11.0%	2.5%	7.0%*	14.7%*
Greater than or equal to 5% weight loss rate	17%	45%*	67%*	26%	59%*	84%*

ITT-LOCF: Intent-to-treat with last observation carried forward

* p<0.0001 vs. placebo

CONQUER (OB-303)

The CONQUER study included 2,487 overweight and obese patients (1,737 females and 750 males) with high blood pressure, high cholesterol or type 2 diabetes across 93 centers in the United States. The average baseline BMI of the study population was 36.6 kg/m2 and baseline weight was 227 pounds. Patients had a 4-week dose titration period followed by 52 weeks of treatment. The study was a randomized, double-blind, placebo-controlled, 3-arm, prospective trial with patients randomized to receive once-a-day treatment with placebo, mid-dose Qnexa or full-dose Qnexa. Patients were asked to follow a hypocaloric diet representing a 500-calorie/day deficit and advised to implement a simple lifestyle modification program. Weight loss results from the study are summarized as follows:

	ITT-LOCF			Completers		
CONQUER (OB 303) 56 weeks	**Placebo (n=979)**	**Qnexa mid-dose (n=488)**	**Qnexa full-dose (n=981)**	**Placebo (n=564)**	**Qnexa mid-dose (n=344)**	**Qnexa full-dose (n=634)**
Mean weight loss (%)	1.8%	8.4%*	10.4%*	2.4%*	10.5%*	13.2%*
Greater than or equal to 5% weight loss rate	21%	62%*	70%*	26%	75%*	85%*

* p<0.0001 vs. placebo

The primary efficacy endpoint for Phase 3 weight loss trials, as recommended by the FDA, is at least a 5% mean reduction in baseline body weight compared to placebo or at least 35% of patients losing 5% or more of their baseline body weight. In Europe, the Committee for Medicinal Products for Human Use of the European Medicines Agency 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. The FDA and foreign authorities require pivotal obesity studies to be conducted for at least one year. Although the results for both of our Phase 2 studies and all of our Phase 3 obesity trials met these current guidelines for efficacy, there can be no assurance that these results will be acceptable to the FDA.

Our Future

Our goal is to build a successful biopharmaceutical 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;

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establishing internal capabilities or strategic relationships with marketing partners to maximize sales potential for our products that require significant commercial support; and

licensing complementary clinical stage investigational product candidates or technologies with competitive advantages from third parties for new and established markets.

It is our objective to become a leader in the development and commercialization of products for large underserved markets. We believe we have strong intellectual property supporting several opportunities in obesity and related disorders, such as sleep apnea and diabetes, and sexual health. Our future growth depends on our ability to further develop and obtain regulatory approval of our investigational product candidates for indications that we are studying, or plan to study, as well as in-licensing and product line extensions.

We have funded operations primarily through private and public offerings of our common stock, through the sale of the rights to Evamist and through product sales of MUSE (alprostadil). We expect to generate future net losses due to increases in operating expenses as our various investigational product candidates are advanced through the various stages of clinical development and for pre-commercialization activities. In connection with the sale of Evamist, we received to date an aggregate of $150 million. The sale of Evamist was a unique transaction. An initial $10 million was paid at closing and $140 million was paid upon the FDA's approval of the Evamist NDA. These payments were non-refundable and were originally recorded as deferred revenue and were recognized as license and other revenue ratably over a 21.5-month period, from August 1, 2007 to May 15, 2009. All of the revenue deferred from the Evamist sale has been recognized. As of December 31, 2009, we have incurred a cumulative deficit of $234.1 million and expect to incur operating losses in future years.

Our Investigational Product Candidates

Our investigational product pipeline includes two late-stage clinical product candidates. One of these investigational products, Qnexa, has recently completed Phase 3 clinical trials for obesity and Phase 2 clinical trials for diabetes and obstructive sleep apnea. We submitted an NDA to the FDA for Qnexa in December 2009. Avanafil is currently in Phase 3 trials for erectile dysfunction and we announced data from one of these trials, REVIVE (TA-301), in November 2009. Luramist is our investigational product candidate for the treatment of hypoactive sexual desire disorder, or HSDD.

Product	Indication	Status	Commercial rights
Qnexa (phentermine and topiramate CR)	Obesity	Phase 3 studies completed; NDA submitted	Worldwide
Qnexa (phentermine and topiramate CR)	Diabetes	Phase 2 study completed	Worldwide
Qnexa (phentermine and topiramate CR)	Obstructive Sleep Apnea	Phase 2 study completed	Worldwide
Avanafil (PDE5 inhibitor)	Erectile dysfunction	Phase 3 ongoing; One Phase 3 study completed	Worldwide license from Mitsubishi Tanabe Pharma Corporation (ex. certain Asian markets)
Luramist (Testosterone MDTS)	Hypoactive sexual desire disorder	Phase 2 completed	United States (licensed from Acrux)

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Qnexa for Obesity

Obesity is a chronic disease condition that affects millions of people and often requires long-term or invasive treatment to promote and sustain weight loss. In the National Health and Nutrition Examination Survey, or NHANES, conducted for 2007-2008, 68% of adults in the United States (72.3% of men and 64.1% of women) were classified as overweight, defined as a body mass index, or BMI ≥25, and 33.8% were obese (BMI≥30). Data from NHANES also found that almost 17% of school children were obese and almost 32% were overweight for the 2007-2008 time period. Obesity in children is defined as having a BMI at or above the 95th percentile and being overweight is defined as having a BMI at or above 85th percentile. The percentage of American men and women classified as overweight and obese has more than doubled since 1962. Researchers fear that the percentage of American adults that are obese could climb as high as 43% in the next ten years. Obesity is the second leading cause of preventable death in the United States. According to a study performed by the Centers for Disease Control and Prevention, or CDC, as reported in the Journal of the American Medical Association, an estimated 112,000 excess deaths a year in the United States are attributable to obesity. Additionally, Americans spend more than $30 billion annually on weight-loss products and services.

Qnexa is our proprietary oral investigational product candidate for the treatment of obesity, incorporating low doses of active ingredients from two previously approved products, phentermine and topiramate. We believe that by combining these compounds, Qnexa targets 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 phentermine and topiramate. Our first U.S patent on Qnexa (US 7,056,890 B2) and our EU patent on Qnexa (EU EP 1187603) both expire in 2020.

EQUATE (OB-301) Phase 3 study

The obesity development program included a six-month Phase 3 pivotal factorial-design study, known as EQUATE. The EQUATE study included 756 obese patients (599 females and 157 males) across 32 centers in the United States. The average baseline BMI of the study population was 36 kg/m2, baseline weight was 223 pounds and average height was 5 feet 6 inches. Patients in the EQUATE study had a 4-week dose titration period followed by 24 weeks of treatment. The study was a randomized, double-blind, placebo-controlled, 7-arm, prospective trial with patients randomized to receive once-a-day treatment with full-dose Qnexa (15 mg phentermine/92 mg topiramate CR), mid-dose Qnexa (7.5 mg phentermine/46 mg topiramate CR), the respective phentermine and topiramate constituents, or placebo. Patients were asked to follow a hypocaloric diet representing a 500-calorie/day deficit and were advised to implement a simple lifestyle modification program.

The EQUATE study met the co-primary endpoints by demonstrating weight loss with both the full-dose and mid-dose of Qnexa were significantly greater than the individual drug components and placebo. Patients treated with full-dose and mid-dose Qnexa had an average weight loss of 9.2% and 8.5% respectively, as compared to weight loss of 1.7% reported in the placebo group (ITT-LOCF p<.00001). Average weight loss was 19.8 pounds and 18.2 pounds in the treatment arms as compared to 3.3 pounds in the placebo group. Qnexa was well-tolerated, with no reported drug-related serious adverse events in the study. The proportion of patients losing 5% or more of their initial body weight was 66% for full-dose, 62% for mid-dose and 15% for placebo (ITT-LOCF p<0.0001).

The most common drug-related adverse events reported for the full-dose, mid-dose and placebo group were paresthesia, or tingling of the extremities, dry mouth, altered taste, headache and constipation. Reported drug-related adverse events for depression and altered mood were minimal (1.9%, 0.9% and 1.8%, respectively). Patients on antidepressants such as selective serotonin reuptake inhibitors, or SSRI's, or serotonin-norepinephrine reuptake inhibitors, or SNRI's, were allowed to

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participate in the studies. Patients were monitored for depression and suicidality using the PHQ-9 questionnaire, a validated mental health assessment tool agreed to by the FDA for use in our studies. Individual depression assessments for each subject, as measured by PHQ-9, demonstrated statistically significant improvements ($p<0.05$) from baseline for both Qnexa treatment groups. Overall average completion rate in this study for the Qnexa treatment group was 70%.

The EQUATE study was designed as a weight loss trial; however, additional analysis of the results showed a control of blood sugar in these non-diabetic patients treated with Qnexa as compared to the placebo group. Patients treated with Qnexa had improvement in glycemic control as measured by a reduction in hemoglobin A1c (HbA1c) compared to placebo. The overall placebo-subtracted reduction in HbA1c was 0.11% and 0.10% for Qnexa full and mid-dose, respectively, over the 28-week treatment period ($p < 0.0001$). Baseline HbA1c levels were 5.48% and 5.42% for the full-dose and mid-dose groups.

EQUIP (OB-302) AND CONQUER (0B-303) Phase 3 studies

The Qnexa development program also included two large Phase 3 randomized, double-blind, placebo-controlled, 3-arm, prospective, multi-center studies comparing Qnexa to placebo over a 56-week treatment period. All Phase 3 studies utilized our once-a-day formulation of Qnexa, which at full-dose contains 15 mg phentermine and 92 mg of a proprietary controlled release formulation of topiramate. The Phase 3 studies were designed to prospectively demonstrate the safety and efficacy of Qnexa in obese and overweight patients with different baseline characteristics. The co-primary endpoints for these studies evaluated 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 patients achieving weight loss of 5% or more. Patients were asked to follow a hypocaloric diet representing a 500-calorie/day deficit and were advised to implement a simple lifestyle modification program.

The first year-long Phase 3 study, known as EQUIP, enrolled 1,267 morbidly obese patients (1,050 females and 217 males) with a BMI that equaled or exceeded 35 kg/m2 with or without controlled co-morbidities. The average baseline BMI of the study population was 42.1 kg/m2 and baseline weight was 256 pounds. Patients had a 4-week dose titration period followed by 52 weeks of treatment with patients randomized to receive once-a-day treatment with low-dose Qnexa, full-dose Qnexa or placebo.

The EQUIP study met the co-primary endpoints by demonstrating that patients treated with full-dose and low-dose Qnexa had an average weight loss of 11.0% and 5.1% respectively, as compared to weight loss of 1.6% in the placebo group (ITT-LOCF $p<0.0001$). Average weight loss was 37 pounds and 18 pounds with full-dose Qnexa and low-dose Qnexa, respectively, as compared to 6 pounds in the placebo group. The proportion of patients losing 5% or more of their initial body weight was 67% for full-dose, 45% for low-dose and 17% for placebo (ITT-LOCF $p<0.0001$).

The most common drug-related adverse events reported in the EQUIP study for the full-dose, low-dose and placebo group were tingling of the extremities, dry mouth, altered taste, headache and constipation. A significantly greater proportion of patients completed the study on Qnexa as compared to placebo patients. Overall average completion rates were 59%, 57% and 47% for patients taking full-dose Qnexa, low-dose Qnexa and placebo, respectively.

The second year-long Phase 3 trial, known as CONQUER, enrolled 2,487 overweight and obese adult patients (1,737 females and 750 males) with BMI's from 27 kg/m2 to 45 kg/m2 and at least two co-morbid conditions, such as hypertension, dyslipidemia and type 2 diabetes. The average baseline BMI of the study population was 36.6 kg/m2 and baseline weight was 227 pounds. Patients had a 4-week dose titration period followed by 52 weeks of treatment with patients randomized to receive once-a-day treatment with full-dose Qnexa, mid-dose Qnexa or placebo.

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The CONQUER study also met the co-primary endpoints by demonstrating that patients treated with full-dose and mid-dose Qnexa had an average weight loss of 10.4% and 8.4%, respectively, as compared to weight loss of 1.8% in the placebo group (ITT-LOCF p<0.0001). Average weight loss was 30 pounds and 24 pounds with full-dose Qnexa and mid-dose Qnexa, respectively, as compared to 6 pounds in the placebo group. The proportion of patients losing 5% or more of their initial body weight was 70% for full-dose, 62% for mid-dose and 21% for placebo (ITT-LOCF p<0.0001).

The most common drug-related adverse events reported in the CONQUER study for the full-dose, mid-dose, and placebo group were tingling of the extremities, dry mouth, altered taste, headache and constipation. A significantly greater proportion of patients completed the study on Qnexa as compared to placebo patients. Overall average completion rates were 64%, 69%, and 57% for patients taking full- dose Qnexa, mid-dose Qnexa and placebo, respectively.

In the EQUIP and CONQUER studies, there was no difference between Qnexa and placebo for reported incidence of moderate or severe depression/depressed mood (1.9%, 1.2%, 1.7% and 1.7% for Qnexa full-, mid- and low-dose and placebo, respectively). Patients were monitored for depression and suicidality using the PHQ-9 questionnaire, a validated mental health assessment tool, and the C-SSRS, or Columbia Suicidality Severity Rating Scale, agreed to by the FDA for use in our studies. Overall, depression scores, quality of life, including self-esteem and general health, significantly improved for patients on Qnexa. In addition, Qnexa was well-tolerated and there was no difference between Qnexa (0.4%) and placebo (0.4%) for serious adverse events that were considered to be drug-related by investigators in these studies.

We completed a "Thorough QT", or TQT, prolongation study evaluating patients taking Qnexa. The QT interval represents the time for both ventricular depolarization and repolarization to occur in the heart, and therefore roughly estimates the duration of an average ventricular action potential. If abnormally prolonged or shortened, there is a risk of developing ventricular arrhythmias. The study was completed with no drug-related signal for QT prolongation. Patients taking Qnexa also underwent complex and extensive cognitive and psychomotor testing using validated, FDA recognized testing methodologies. There was no clinically relevant change in overall cognitive function or effect on psychomotor skills seen in patients taking Qnexa.

We have initiated a one-year extension study for patients who complete the CONQUER study. The extension study is known as SEQUEL (OB-305). Patients continue in a blinded fashion in their respective treatment groups. This extension study is not required by the FDA nor did it need to be completed prior to submission of the NDA for Qnexa for the treatment of obesity. We have enrolled over 650 patients in this study. The purpose of this study is to provide long-term safety and efficacy data for commercial purposes and to support the Marketing Authorization Application, or MAA, filing in Europe.

In 2007, 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 patients, 159 women and 41 men, with an average age of 40 and a mean BMI of 38.6 kg/m2. 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 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. The most common adverse events included tingling, 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 improvements in patients' quality of life, such as self-esteem, public distress and physical function, when treated with Qnexa.

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We have entered into a Master Services Agreement and related Task Orders with Medpace, Inc., or Medpace, pursuant to which Medpace will perform certain clinical research services in connection with the clinical trials for Qnexa. Our aggregate payment obligations under the agreement for services entered into during 2007 through 2009, out of pocket expenses and pass through costs totals approximately $75 million of which we have paid approximately $65.9 million through December 31, 2009. We have agreed to defend and indemnify Medpace against third party claims arising from the services other than claims resulting from Medpace's negligence, willful misconduct, violation of law or material breach of the Master Service Agreement or a Task Order. We can terminate the agreement at any time without cause. Medpace may terminate the agreement following our material breach of the agreement that remains uncured.

Separately, we have entered into a Master Services Agreement and related Task Orders with Quintiles, Inc., or Quintiles, pursuant to which Quintiles will perform certain clinical research services in connection with the clinical trials for avanafil. Our aggregate payment obligations entered into during 2008 and 2009 under the agreement for services, out of pocket expenses and pass through costs totals approximately $27.3 million of which we have paid approximately $18.7 million through December 31, 2009. We have agreed to defend and indemnify Quintiles against third party claims arising from the services other than claims resulting from Quintiles's negligence, willful misconduct, violation of law or material breach of the Master Service Agreement or a Task Order. We can terminate the agreement at any time without cause. Quintiles may terminate the agreement following our material breach of the agreement that remains uncured.

Qnexa for Obstructive Sleep Apnea

Obstructive sleep apnea, or OSA, is a condition in which patients momentarily pause or stop breathing altogether while sleeping. The pauses in breathing can occur frequently throughout the course of sleep. Sleep apnea is often undiagnosed and can lead to severe health problems and even death if left untreated. It is estimated that about 18 million people in the United States have obstructive sleep apnea. Currently, there are no approved pharmacologic treatments for OSA. Modafanil is approved for the treatment of residual daytime sleepiness associated with OSA, but does not specifically treat the sleep apnea condition.

In January 2010, we announced positive results from a Phase 2 study evaluating the safety and efficacy of Qnexa for the treatment of OSA. This Phase 2 study (OB-204) was a single-center, randomized, double-blind, placebo-controlled parallel group trial including 45 obese men and women (BMI 30 to 40 kg/m2 inclusive), 30 to 65 years of age with OSA (apnea/hypopnea index, or AHI, greater than or equal to 15 at baseline), who had not been treated with, or who were not compliant with continuous positive airway pressure, or CPAP, within three months of screening. Patients were randomized to placebo or full-dose Qnexa. CPAP is the current standard of care treatment for the majority of patients with moderate or severe OSA, defined as an apnea-hypopnea index, or AHI, of 15 or more events per hour. Although CPAP is effective in treating OSA when properly and consistently used, compliance (as defined by use for at least 4 hours per night, on at least 70% of nights) may be as low as 50-60%.

In the OB-204 study, patients underwent a four-week dose titration followed by 24 weeks of additional treatment. All patients were also provided with a lifestyle modification program focusing on diet and exercise. Overnight polysomnography in a sleep laboratory was performed at baseline, Week 8 and Week 28. The primary endpoint was the change in AHI between baseline and Week 28; secondary endpoints included weight loss, improvement in overnight oxygen saturation and reduction in blood pressure.

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The study demonstrated statistically significant improvement in AHI in patients with OSA treated with Qnexa for 28 weeks. Qnexa-treated patients also experienced significant weight loss, improvements in blood pressure, and overnight blood oxygen saturation.

Highlights of the study include:

- Patients treated with Qnexa for 28 weeks had a 69% reduction in the AHI
- Qnexa treatment reduced the number of apnea/hypopnea events from a mean of 46 events per hour of sleep to 14 compared to placebo patients with a reduction from a mean 44 events per hour of sleep to 27 (ITT-LOCF p<0.001 active vs. placebo)
- Qnexa treated patients lost 10.2% body weight, or 23.8 lbs in 28 weeks compared to 4.3% for placebo patients, or 10.4 lbs, (ITT-LOCF p<0.001 active vs. placebo)
- Systolic blood pressure was reduced by 15 mm Hg in the Qnexa group from a mean of 138 mm Hg at baseline (ITT-LOCF p<0.04 active vs. placebo)
- Mean overnight blood oxygen saturation was significantly improved in Qnexa patients (p<0.014 active vs. placebo)

Sleep apnea is one of the leading co-morbidities associated with obesity and research has shown that weight loss can improve OSA. Qnexa treatment was well-tolerated with no serious adverse events reported in the Qnexa arm; the most common side-effects were dry mouth, altered taste and sinus infection.

Qnexa for Diabetes

Diabetes is a significant worldwide disease. Based on the fourth edition of the *Diabetes Atlas* published in 2009, the International Diabetes Federation estimated that in 2008 there were 285 million people with diabetes worldwide, with 27 million of those people living in the United States. Diabetes, mostly type 2 diabetes, is projected to reach 6.6% of the world's adult population in 2010, with almost 70% of the total in developing countries. The CDC estimates, based on 2007 data, that nearly 24 million people in the United States have diabetes, mostly type 2 diabetes, and that 57 million people have pre-diabetes, a condition that puts people at increased risk of diabetes. Type 2 diabetes is characterized by inadequate response to insulin and/or inadequate secretion of insulin as blood glucose levels rise. Currently approved 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 was estimated at $24 billion in 2007, according to IMS Health. However, it is estimated that 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 common drug-related 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, a component of Qnexa, in type 2 diabetics resulted in a clinically meaningful reduction of hemoglobin A1c, a measure used to determine treatment efficacy of anti-diabetic agents.

In December 2008, we announced the results of our DM-230 diabetes study, a 56-week, Phase 2 clinical trial in 130 type 2 diabetics conducted at 10 sites in the United States. Patients treated with Qnexa had a reduction in hemoglobin A1c of 1.6%, from 8.8% to 7.2%, as compared to 1.1% from

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8.5% to 7.4% in the placebo group (ITT LOCF p=0.0381) at 56 weeks. Patients in the study were actively managed according to American Diabetes Association, or ADA, standards of care with respect to diabetes medications and lifestyle modification. For patients treated with placebo, increases in the number and doses of concurrent anti-diabetic medications were required to bring about the observed reduction in HbA1c. By contrast, concurrent anti-diabetic medications were reduced over the course of the trial in patients treated with Qnexa ($p<0.05$).

Fasting plasma glucose levels were reduced in patients treated with Qnexa from 176 mg/dL to 133 mg/dL, as compared to a decrease from 171 mg/dL to 145 mg/dL for the placebo group (p=0.02). Over 56 weeks, patients treated with Qnexa also lost 9.4% of their baseline body weight, or 20.5 pounds, as compared to 2.7%, or 6.1 pounds, for the placebo group ($p<0.0001$). Sixty-five percent of the Qnexa patients lost at least 5% of their body weight as compared to 24% in the placebo group ($p<0.001$), and 37% of the Qnexa patients lost at least 10% of their body weight as compared to 9% of patients in the placebo group ($p<0.001$). Patients treated with Qnexa had reductions in blood pressure, triglycerides and waist circumference. Both treatment groups had a study completion rate greater than 90%.

The most common drug-related side effects reported were tingling, constipation and nausea. Patients on antidepressants such as SSRI's or SNRI's were allowed to participate in the studies. Patients were monitored for depression and suicidality using the PHQ-9 questionnaire, a validated mental health assessment tool agreed to by the FDA for use in our studies. Patients treated with Qnexa demonstrated greater improvements in PHQ-9 scores from baseline to the end of the study than the placebo group.

Despite a mean baseline HbA1c level of 8.8%, 53% of the patients treated with Qnexa were able to achieve the ADA recommended goal of 7% or lower, versus 40% of the patients in the placebo arm ($p<0.05$). The incidence of hypoglycemia in the treatment and placebo arms were similar (12% and 9%, respectively). Patients in the Qnexa arm experienced no treatment-related serious adverse events.

The DM-230 Phase 2 study enrolled 130 patients, who completed OB-202, our Phase 2 study for the treatment of obesity, at 10 study sites to continue in a blinded fashion as previously randomized for an additional 28 weeks. The results of the DM-230 study included assessments from the start of the OB-202 study through the end of the DM-230 study in this population, for a total treatment period of 56 weeks.

Qnexa for Other Indications

We believe Qnexa may be helpful in treating other obesity-related diseases including nonalcoholic steatohepatitis or its precursor, nonalcoholic fatty liver disease, also known as fatty liver disease. Qnexa may also be helpful in treating hyperlipidemia or an elevation of lipids (fats) in the bloodstream. These lipids include cholesterol, cholesterol esters (compounds), phospholipids and triglycerides.

Avanafil for Erectile Dysfunction

Erectile dysfunction, or ED, is defined as the inability to attain or maintain an erection sufficient for intercourse. ED was reported by 52% of men between the ages of 40 to 70, in the Massachusetts Male Aging Study, with the incidence increasing with age. Erectile dysfunction, frequently associated with vascular problems, is particularly common in men with diabetes and in those who have had a radical prostatectomy for prostate cancer. PDE5 inhibitors such as sildenafil (Viagra®), vardenafil (Levitra®) and tadalafil (Cialis®), which inhibit the breakdown of cyclic guanosine monophosphate, have been shown to be effective oral treatments for ED.

The worldwide sales in 2009 of PDE5 inhibitor products for the treatment of ED were in excess of $3.8 billion, including approximately $1.9 billion in sales of Viagra, approximately $1.6 billion in sales of Cialis and approximately $350 million in estimated sales of Levitra. Based on the aging population and

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the desire to maintain an active sexual lifestyle, we believe the market for PDE5 inhibitors will continue to grow.

Avanafil is an oral PDE5 inhibitor investigational product candidate, which we licensed from Tanabe Seiyaku Co., Ltd., or Tanabe, in 2001. In October 2007, Tanabe and Mitsubishi Pharma Corporation completed their merger and announced their name change to Mitsubishi Tanabe Pharma Corporation, or MTPC. Our US patent on avanafil (US 6,656,935) expires in 2020.

We have exclusive worldwide development and commercialization rights for avanafil with the exception of certain Asian markets.

Pre-clinical and clinical data suggest that avanafil:

- is highly selective to PDE5, which we believe may result in a favorable side effect profile; and
- is fast-acting as compared to the current commercially available PDE5 inhibitors

We previously announced results from a Phase 2, multi-center, 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 avanafil-treated patients met all the primary endpoints 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 patients 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 in patients 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.

In November 2009, we announced results of the first of several pivotal Phase 3 studies of avanafil. The first study, REVIVE (TA-301) was a randomized, double-blind, placebo-controlled Phase 3 study of avanafil in 646 men. Participants in the study had ED for at least six months; 72% of study participants had tried at least one other ED treatment. Patients underwent a four-week, non-treatment run-in period followed by 12 weeks of treatment with one of three doses of avanafil: 50 mg, 100 mg and 200 mg or placebo. Patients were instructed to attempt sexual intercourse 30 minutes after taking avanafil, with no restrictions on food or alcohol consumption. The primary endpoints of the study were improvement in erectile function as measured by the Sexual Encounter Profile, or SEP, and improvements in the International Index of Erectile Function, or IIEF, score; secondary endpoints included patient satisfaction with erections and with sexual experience. This Phase 3 study was conducted under a Special Protocol Assessment, or SPA, with the FDA.

The REVIVE study met all primary endpoints across the three doses studied by demonstrating statistically significant improvement in erectile function as measured by the SEP and improvements in the IIEF score. Highlights of the study include:

- Nearly 80% of sexual attempts among patients on the 200 mg dose of avanafil had erections sufficient for intercourse (SEP2);
- Full efficacy, as measured by successful intercourse (SEP3), was reported by avanafil patients on all 3 dose levels in 15 minutes or less;

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Full efficacy was maintained for all doses across multiple time points from 15 minutes to beyond six hours;

All FDA-defined primary endpoints were met across all three doses of avanafil;

Avanafil was well tolerated as demonstrated by a high retention rate (85%);

There were no reported drug-related serious adverse events in the study; and

Avanafil patients reported low rates of common PDE5i side effects (headache, flushing and upset stomach)

Patients on all 3 dose levels achieved an overall improvement in erectile function, as measured by improvement in the IIEF. IIEF scores range from 0-30 and measure the severity of erectile dysfunction as follows: severe dysfunction is less than or equal to 10; moderate is 11-16; and mild/minimal is 17-25. IIEF results of the study were:

	Baseline	End of Treatment
Placebo	12.4	15.3
Avanafil 50 mg	12.7	18.1
Avanafil 100 mg	12.6	20.9
Avanafil 200 mg	12.7	22.2

(p</=0.001 vs. placebo)

Patients on avanafil had erections sufficient for vaginal penetration as measured by the Sexual Encounter Profile question number 2 (SEP2):

	Baseline	End of Treatment
Placebo	47%	54%
Avanafil 50 mg	45%	64%
Avanafil 100 mg	46%	74%
Avanafil 200 mg	48%	77%

(p<0.001 vs. placebo)

Patients taking avanafil experienced successful intercourse as measured by the Sexual Encounter Profile question 3 (SEP3):

	Baseline	End of Treatment
Placebo	13%	27%
Avanafil 50 mg	13%	41%
Avanafil 100 mg	14%	57%
Avanafil 200 mg	12%	57%

(p<0.001 vs. placebo)

The most commonly reported side effects in patients taking avanafil (all doses combined) included headache (7.0% vs. 1.2% placebo), flushing (4.6% vs. 0% placebo) and nasal congestion (2.3% vs. 1.2%); there were no reports of visual disturbances such as "blue vision."

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In January 2010, we announced new data from an analysis of REVIVE TA-301. Patients who attempted intercourse within 15 minutes of dosing were successful 67%, 69% and 72% of the time on 50, 100 and 200 mg of avanafil, respectively, as compared to 29% of the patients on placebo ($p<0.05$).

We previously completed a Phase 1 "Thorough QT", or TQT, study evaluating 100 mg and 800 mg of avanafil compared to placebo and a known positive control. The study was successfully completed with no concern associated with QT prolongation.

The Phase 3 program will include three additional studies. REVIVE Diabetes (TA-302) has completed enrollment and has randomized 390 patients with ED associated with diabetes; REVIVE-RP (TA-303) has commenced enrollment and will randomize up to 375 patients with ED following a radical prostatectomy. Patients undergo a four-week run-in period followed by 12 weeks of treatment. Patients are randomized to placebo or one of two dose levels of active drug. The primary endpoints of the study will be the same as those used in TA-301, namely, improvement in erectile function as measured by the Sexual Encounter Profile and the IIEF score. Patients are instructed to attempt sexual intercourse 30 minutes after taking avanafil, with minimal restrictions on food or alcohol consumption. REVIVE-Diabetes and REVIVE-RP will study two doses of avanafil: 100 mg and 200 mg.

In March of 2009, we initiated an open-label safety study (TA-314) evaluating the long-term safety and tolerability of avanafil as part of our development toward NDA submission. TA-314 is being conducted over one year in approximately 600 patients across 40 U.S. centers; patients completing either the 12-week REVIVE or REVIVE-Diabetes studies are eligible to participate in TA-314. Results of the study are expected to be available by late 2010.

In total, it is estimated that the Phase 3 avanafil clinical program will enroll approximately 1,300 patients. We anticipate submitting an NDA with the FDA for avanafil in the first half of 2011.

Luramist for Hypoactive Sexual Desire Disorder

We believe that the market for the treatment of sexual disorders in women is large and underserved. A paper published in 1999 in the *Journal of the American Medical Association* noted that 43% of U.S. 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, or FSD. However, some believe this figure is overstated. Currently, there are no pharmaceutical treatments on the market that have been approved by the FDA for the treatment of this sexual disorder in women.

Hypoactive Sexual Desire Disorder, or 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. A study published in the July 2009 issue of *The Journal of Sexual Medicine*, reported that, according to an

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independent survey, 80% of physicians believe there is a need or great need for an FDA-approved treatment for women with HSDD. In addition, 90% of these doctors would prescribe an approved product rather than currently available therapies used off-label.

Double-blind, multi-center, placebo-controlled clinical trials conducted by The Procter & Gamble Company, or P&G, 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 2009, the P&G pharmaceutical products including Intrinsa were sold to Warner-Chilcott plc. In addition, a 2005 independent clinical study, conducted by Acrux in 261 patients, demonstrated that testosterone applied transdermally with a spray has the ability to increase the number of sexually satisfying events in pre-menopausal women with HSDD.

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, or MDTS, applicator that delivers a precise amount of testosterone to the skin. We licensed the U.S. rights for this product from Acrux in 2004. The metered spray enables patients to apply a precise dose of testosterone for transdermal delivery. The applied dose dries in approximately 60 seconds and becomes invisible. 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 investigational 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.

Previously, we announced Phase 2 results for Luramist, which showed an 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. In 2008, we reached agreement with the FDA regarding the SPA for the Phase 3 efficacy trial for Luramist. We plan to conduct two identically designed efficacy trials. In addition, we reached agreement with the FDA on the safety requirements necessary for NDA submission.

Under the SPA, we have agreed with the FDA to design features for the pivotal Phase 3 efficacy studies including the primary endpoints, the scope and size of the patient population to be studied, inclusion/exclusion criteria, duration of the trials and elements of the statistical analysis plan. The pivotal Phase 3 program will include two double-blind, placebo-controlled trials that will enroll menopausal women for six months of treatment. The primary endpoints in the clinical trials are an increase in sexual desire and the number of satisfying sexual events, with a secondary endpoint of a decrease in sexual distress.

In addition to the two pivotal Phase 3 efficacy trials, we have reached agreement with the FDA on a design for a cardiovascular safety study. The safety study will be a randomized, double-blind, placebo-controlled, multi-center, cardiovascular event-based outcomes study. Patients will be required to have an average exposure of 12 months. The study will enroll approximately 5,200 postmenopausal women, aged 50 years or older, who have at least one cardiovascular risk factor. As an event-driven study, analysis of outcomes may occur when there is an average exposure of 12 months and a sufficient number of cardiovascular events have occurred. Patients enrolled in the safety study will remain in the

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study for up to five years to allow longer term assessments of cardiovascular and breast cancer risks. These longer term assessments out to five years are not required for NDA submission.

In November 2006, we were notified of certain claims by Acrux regarding the Luramist agreements. On November 5, 2007, Acrux made a demand for arbitration under the Testosterone Agreement regarding certain claims related to Luramist. Acrux's demand sought a reversion of all rights assigned to us related to Luramist, monetary damages and the payment of a milestone payment for Luramist under the Testosterone Agreement and declaratory relief. We asserted counterclaims against Acrux in the arbitration and sought the enforcement of our rights under the Testosterone Agreement. The arbitration hearing concluded on January 23, 2009, and on April 6, 2009 the panel of arbitrators, or the Panel, issued its Interim Arbitration Award finding in our favor that we were in compliance with the Testosterone Agreement and denying all of the relief sought by Acrux in its demand. The Panel found that we were not in breach of the Luramist license agreement and that we had used diligent, commercially reasonable efforts to develop Luramist. The Panel further ruled in our favor on our counter claim that Acrux had breached the Luramist license agreement by failing to provide certain know-how and certain improvements in the formulation and delivery device for Luramist. The Panel denied the Acrux claim for additional milestone payments. The Panel has ordered Acrux to turn over certain information to us that was previously withheld in violation of the agreement by Acrux. After the parties failed to agree on a new Outside Date by which we are to commence our first Phase 3 trial for Luramist, the Panel reset the Outside Date of April 30, 2006 to April 1, 2010 to reflect the regulatory environment. Under the licensing agreement with Acrux, a milestone payment of $1 million is due to Acrux upon the earlier of commencing a Phase 3 study for Luramist or the Outside Date, April 1, 2010. The milestone is due in monthly installments of $166,667 for each month of delay in commencing Phase 3 after the Outside Date until the milestone is paid in full. There can be no assurance that Acrux would not continue to pursue legal action against us if we do not commence the first Phase 3 trial by the Outside Date.

MUSE for Erectile Dysfunction

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.

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 40% were able to achieve natural erections sufficient for intercourse.

We have obtained the exclusive rights to patents, patent applications and other intellectual property related to MUSE through a series of license and assignment agreements with Alza Corporation, Ortho Pharmaceutical Corporation, Gene A. Voss, M.D. and Allen C. Eichler, M.D., Kjell Holmquist AB and Amsu, Ltd. These licenses and assignments are royalty bearing, requiring the Company to pay an aggregate of 4% of net sales of MUSE in royalties. Our obligations to pay royalties under the license and assignment agreements terminate upon a fixed date or the last to expire of the licensed or assigned patents under the agreements. Absent an extension by the issuance of any

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additional patents covered by the licenses, our royalty obligations are set to terminate in (1) January 2012 (2%), (2) July 2010 (1%), and (3) August 2016 (1%). Either party to the agreements may terminate under certain limited circumstances, including material breach. In addition to our royalty obligations, we have agreed to defend and indemnify the licensors and assignors against third party claims arising from our use of the licensed or assigned patents, patent applications and other intellectual property. The aggregate royalties incurred were $783,000, $829,000 and $730,000 for the years ended December 31, 2009, 2008 and 2007, respectively. Other than the royalty payments, we have no other material payment obligations under these license and assignment agreements.

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 Evamist Agreement to K-V, or the Transaction. The closing of the Transaction occurred on May 15, 2007. Under the terms of the Transaction, upon the closing, we received an upfront payment of $10 million. 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. In August 2008, we assigned all of our rights and obligations under the Evamist license agreement to K-V. In connection with the Transaction, in order to obtain MTPC's blanket release of liens against our assets including the Evamist assets and intellectual property, we repaid the MTPC 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. Under the terms of the Transaction, K-V paid $1.5 million of this $3 million milestone.

Deerfield Financing

On April 3, 2008, we entered into several agreements with Deerfield Management Company, L.P., or Deerfield, a healthcare investment fund, and its affiliates, Deerfield Private Design Fund L.P. and Deerfield Private Design International, L.P. (collectively, the Deerfield Affiliates). Certain of the agreements were amended and restated on March 16, 2009. Under the agreements, Deerfield and its affiliates agreed to provide us with $30 million in funding. The $30 million in funding consists of $20 million from the Funding and Royalty Agreement, or FARA, entered into with a newly incorporated subsidiary of Deerfield, or the Deerfield Sub, and $10 million from the sale of our common stock. Under the FARA, the Deerfield Sub made $3.3 million payments to us in April, September and December 2008 and February, June and September 2009. The Company has received all of the required payments under the FARA. Such payments are referred to as the Funding Payments. We will pay royalties on the current net sales of MUSE and, if approved, on future sales of avanafil, an

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investigational product candidate to the Deerfield Sub. The term of the FARA is 10 years. The FARA includes covenants requiring us to use commercially reasonable efforts to preserve our intellectual property, to manufacture, promote and sell MUSE, and to develop avanafil. At the closing on April 15, 2008, under the securities purchase agreement, the Deerfield Affiliates purchased 1,626,017 shares of our common stock for an aggregate purchase price of $10 million, and we paid to the Deerfield Affiliates a $500,000 fee and reimbursed approximately $200,000 in certain expenses incurred in this transaction. The number of shares was determined based on the volume weighted average price on the NASDAQ Global Market of the Company's common stock on the three days prior to the execution of the securities purchase agreement dated as of April 3, 2008. The agreements also provided us with an option to purchase, and the Deerfield Affiliates with an option to compel us to purchase, the Deerfield Sub holding the royalty rights, each as described in greater detail below. If either party exercises its option, any further royalty payments would be effectively terminated. Collectively, these transactions are referred to as the Deerfield Transactions.

Also in connection with the Deerfield Transactions, the Company, the Deerfield Affiliates and the Deerfield Sub entered into the Option and Put Agreement, dated April 3, 2008, and an Amended and Restated Option and Put Agreement dated March 16, 2009, or the OPA. Pursuant to the OPA, the Deerfield Affiliates have granted us an option to purchase all of the outstanding shares of common stock of the Deerfield Sub from the Deerfield Affiliates, referred to as the Option, and we have agreed to grant the Deerfield Affiliates an option to require us to purchase all of the outstanding shares of common stock of the Deerfield Sub from the Deerfield Affiliates, referred to as the Put Right.

If we exercise the Option, base consideration for the Option exercise, or Base Option Price, will be:

$25 million, less $2 million we paid upon closing, if the Option is exercised on or prior to the third anniversary of the execution of the OPA; or

$28 million, less $2 million we paid upon closing, if the Option is exercised subsequent to the third anniversary but prior to the fourth anniversary of the execution of the OPA.

The aggregate consideration payable by VIVUS upon exercise of the Option, or the Option Purchase Price, would be equal to the sum of the Base Option Price, *plus*: (i) the cash and cash equivalents held by the Deerfield Sub at the date of the closing of the resulting sale of the common stock of the Deerfield Sub; (ii) accrued and unpaid royalties; and *minus* (i) the option premium of $2 million that was paid at the closing of the transaction (referred to as the Option Premium); (ii) accrued but unpaid taxes; (iii) unpaid Funding Payments; (iv) loans payable by the Deerfield Sub; and (v) any other outstanding liabilities of the Deerfield Sub. The Option terminates on the fourth anniversary of the execution of the OPA.

In consideration of the grant of the Option, at closing we paid $2 million to the Deerfield Affiliates. As indicated in the calculation of the Option Purchase Price, if the Option is exercised by us, the Option Premium will be applied to reduce the Option Purchase Price.

The Put Right terminates on the tenth anniversary of the execution of the OPA and will become exercisable on the earliest of:

the third anniversary of the execution of the OPA;

any date on which:

(1) the market capitalization of the Company falls below $50 million; or

(2) the amount of cash and cash equivalents, as defined, held by the Company falls below $15 million; or

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(3) the fifteenth day following the delivery of written notice to the Company that we have failed to make Royalty Payments in accordance with the provisions of the FARA unless we make such Royalty Payments prior to such fifteenth day; or

(4) a Major Transaction, as defined below, closes.

If the Deerfield Affiliates exercise the Put Right, base consideration for the put exercise, or the Base Put Price, will be:

$23 million, if the Put Right is exercised on or prior to the third anniversary of the execution of the OPA, or April 3, 2011, and we have notified the Deerfield Affiliates of our intent to enter into a Major Transaction (such notice is referred to as a Major Transaction Notice); or

$26 million, if the Put Right is exercised subsequent to the third anniversary of the execution of the OPA, or April 3, 2011, and we have provided the Deerfield Affiliates a Major Transaction Notice; or

$17 million, in all other cases.

The aggregate consideration payable by the Company upon exercise of the Put Right, or the Put Purchase Price, would be equal to the sum of the Base Put Price, *plus*: (i) the cash and cash equivalents held by the Deerfield Sub at the date of the closing of the resulting sale of the common stock of the Deerfield Sub; (ii) accrued and unpaid royalties; and *minus* (i) accrued but unpaid taxes; (ii) unpaid Funding Payments; (iii) loans payable by the Deerfield Sub, and (iv) any other outstanding liabilities of the Deerfield Sub.

Pursuant to the OPA, the following events would qualify as Major Transactions:

a consolidation, merger, exchange of shares, recapitalization, reorganization, business combination or similar event:

(1) following which the holders of the Company's common stock immediately preceding such event either:

(a) no longer hold a majority of the shares of the Company's common stock; or

(b) no longer have the ability to elect a majority of the Company's Board of Directors;

(2) as a result of which shares of the Company's common stock are changed into (or the shares of common stock become entitled to receive) the same or a different number of shares of the same or another class or classes of stock or securities of the Company or another entity, collectively referred to as Change in Control Transactions;

a sale or transfer of the Company's assets in one transaction or a series of related transactions for a purchase price of more than $350 million where the consideration to be payable at or within 30 days of closing of such transaction or transactions has a value of more than $350 million, or a sale, transfer or license of all or substantially all the Company's assets or proprietary rights that relate specifically to MUSE or avanafil; or

a purchase, tender or exchange offer made to the holders of outstanding shares of the Company's common stock, such that following such purchase, tender or exchange offer a Change in Control Transaction shall have occurred; or

an issuance or series of issuances in a series of related transactions by the Company of an aggregate number of shares of common stock in excess of 20% of the Company's outstanding common stock on April 3, 2008 if, immediately prior to such issuance, the market capitalization of the Company is less than $300 million.

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In connection with the FARA, the Deerfield Sub and the Company have entered into a Royalty Security Agreement, whereby we have granted the Deerfield Sub a security interest in certain collateral related to MUSE and avanafil including: all of our drug applications; all existing and future licenses relating to the development, manufacture, warehousing, distribution, promotion, sale, importing or pricing of MUSE and avanafil; our intellectual property and all of the accounts, inventory and equipment arising out of or relating to MUSE and avanafil. In connection with the OPA, the Deerfield Affiliates and the Company have entered into a security agreement whereby we have granted the Deerfield Affiliates a security interest in the same Collateral as defined by the Royalty Security Agreement. The security interest granted to the Deerfield Affiliates has priority over that granted to the Deerfield Sub by the Royalty Security Agreement.

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 Investigational New Drug, or 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 must be 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 patients.

Typically, human clinical trials are conducted in three phases that may overlap. In Phase 1, clinical trials are conducted with a small number of patients 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 substantial evidence 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 a New Drug Application, or 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, may request additional information or further research or studies, or may 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

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products for a considerable period of time and may 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 product candidates, both before and after approval, and the results of those trials when available, to 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 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. 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, adverse publicity, 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 noted 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.

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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, or 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, or 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

Mitsubishi Tanabe Pharma Corporation

In January 2001, we entered into an exclusive development, license and supply agreement with Tanabe Seiyaku Co., Ltd., or Tanabe, now Mitsubishi Tanabe Pharma Corporation, or MTPC, and hereinafter referred to as MTPC, 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, MTPC 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 MTPC an exclusive, royalty-free license within those countries for oral products that we develop containing avanafil. In addition, we agreed to grant MTPC an exclusive option to obtain an exclusive, royalty-bearing license within those countries for non-oral products that we develop containing avanafil. MTPC 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 MTPC 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 triggered one of the clinical development milestone criteria noted above. We paid MTPC $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 MTPC in the years ended December 31, 2007 and 2008; however, we paid MTPC $4 million in January 2009 following the enrollment in December 2008 of the first patient in the first Phase 3 clinical studies. We expect to make other substantial payments to MTPC in accordance with our agreements with MTPC as we continue to develop and, if approved for sale, commercialize avanafil for the oral treatment of male sexual dysfunction. Such potential future milestone payments total $15 million and include payments upon: the first submission of an NDA; obtainment of the first regulatory approval in the United States and any major European country, and achievement of $250 million or more in calendar year sales.

The term of the MTPC agreement is based on a country-by-country and on a product-by-product basis. The term shall continue until the later of (i) ten years after the date of the first sale for a particular product, or (ii) the expiration of the last-to-expire patents within the MTPC patents covering such product in such country. In the event that our product is deemed to be (i) insufficiently effective or insufficiently safe relative to other PDE5 inhibitor compounds based on published information, or (ii) not economically feasible to develop due to unforeseen regulatory hurdles or costs as measured by

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standards common in the pharmaceutical industry for this type of product, we have the right to terminate the agreement with MTPC with respect to such product.

Acrux

In February 2004, we entered into exclusive licensing agreements with Acrux Limited, or 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. Future potential milestone payments to Acrux for Luramist total $5.5 million and are payable upon (1) the dosage of the first patient in the Phase 3 clinical studies, (2) the first submission of an NDA, and (3) obtainment of the first regulatory approval in the United States. We have paid $4.8 million in clinical development milestone 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. Under 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 Evamist Agreement to K-V and K-V paid $1.5 million of this $3 million obligation. In August 2008, the Company assigned all of its rights and obligations under the Evamist license agreement to K-V.

In November 2006, we were notified of certain claims by Acrux regarding the Luramist agreements. On November 5, 2007, Acrux made a demand for arbitration under the Testosterone Agreement regarding certain claims related to Luramist. Acrux's demand sought a reversion of all rights assigned to us related to Luramist, monetary damages and the payment of a milestone payment for Luramist under the Testosterone Agreement and declaratory relief. We asserted counterclaims against Acrux in the arbitration and sought the enforcement of our rights under the Testosterone Agreement. The arbitration hearing concluded on January 23, 2009, and on April 6, 2009 the panel of arbitrators, or the Panel, issued its Interim Arbitration Award finding in our favor that we were in compliance with the Testosterone Agreement and denying all of the relief sought by Acrux in its demand. The Panel found that we were not in breach of the Luramist license agreement and that we had used diligent, commercially reasonable efforts to develop Luramist. The Panel further ruled in our favor on our counter claim that Acrux had breached the Luramist license agreement by failing to provide certain know-how and certain improvements in the formulation and delivery device for Luramist. The Panel denied the Acrux claim for additional milestone payments. The Panel has ordered Acrux to turn over certain information to us that was previously withheld in violation of the agreement by Acrux. After the parties failed to agree on a new Outside Date by which we are to commence our first Phase 3 trial for Luramist, the Panel reset the Outside Date of April 30, 2006 to April 1, 2010 to reflect the regulatory environment. Acrux will be eligible to receive the previously agreed upon Phase 3 milestone payment of $1 million to be paid out at the earlier of the start of the Phase 3 trials or the Outside Date. The milestone is due in six monthly installments of $166,667 for each month of delay in commencing the Phase 3 trials after the Outside Date until the milestone is paid in full. There can be no assurance that Acrux would not continue to pursue legal action against us if we do not commence the first Phase 3 trial by the Outside Date. Please refer to Note 16: "Legal Matters" for additional information concerning the Acrux matter.

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Other

On October 16, 2001, we entered into an assignment agreement, or the Assignment Agreement, with Thomas Najarian, M.D. for a combination of pharmaceutical agents for the treatment of obesity and other disorders, or the Combination Therapy, that has since been the focus of our investigational product development program for Qnexa for the treatment of obesity, obstructive sleep apnea and diabetes. The Combination Therapy and all related patent applications, or the Patents, were transferred to us with worldwide rights to develop and commercialize the Combination Therapy and exploit the Patents. Pursuant to the Assignment Agreement, we have paid a total of $220,000 to Dr. Najarian through December 31, 2009 and have issued him options to purchase 40,000 shares of our common stock. We are obligated under the terms of the Assignment Agreement to make a milestone payment of $1 million and issue an option to purchase 20,000 shares of our common stock to Dr. Najarian upon marketing approval by the United States Food and Drug Administration of a product for the treatment of obesity that is based upon the Combination Therapy and Patents. This assignment will require us to pay royalties on worldwide net sales of a product for the treatment of obesity that is based upon the Combination Therapy and Patents until the last-to-expire of the assigned Patents. To the extent that we decide not to commercially exploit the Patents, the Assignment Agreement will terminate and the Combination Therapy and Patents will be assigned back to Dr. Najarian. In 2006, Dr. Najarian joined VIVUS as a part-time employee and currently serves as our Principal Scientist.

Patents and Proprietary Technology

We hold 31 patents and 11 patent applications in the United States and Canada. 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. Our portfolio of patents as it relates to our investigational drugs and marketed product is summarized as follows:

QNEXA	
U.S. Patent No. 7,056,890	Expiring 06/14/2020
U.S. Patent No. 7,553,818	Expiring 06/14/2020
U.S. Patent No. 7,659,256	Expiring 06/14/2020
U.S. Patent No. 7,674,776	Expiring 06/14/2020
U.S. Patent Publication No. 2008/0255093	Pending
U.S. Patent Publication No. 2008/0255093	Pending
U.S. Patent Publication No. 2008/0312163	Pending
U.S. Patent Publication No. 2009/0304789	Pending
U.S. Patent Publication No. 2009/0304785	Pending
U.S. Patent Publication No. 2008/0312163	Pending
AVANAFIL	
U.S. Patent No. 6,656,935	Expiring 09/13/2020
U.S. Patent No. 6,797,709	Expiring 09/13/2020
MUSE	
U.S. Patent No. 5,242,391	Expiring 09/07/2010
U.S. Patent No. 5,474,535	Expiring 12/12/2012
U.S. Patent No. 5,482,039	Expiring 03/25/2014
U.S. Patent No. 5,769,088	Expiring 03/25/2014
U.S. Patent No. 5,773,020	Expiring 04/25/2010
U.S. Patent No. 5,820,587	Expiring 03/14/2015
U.S. Patent No. 5,886,039	Expiring 03/23/2016
U.S. Patent No. 6,093,181	Expiring 07/25/2017
U.S. Patent No. 6,113,939	Expiring 09/05/2017
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U.S. Patent No. 5,843,961	Expiring 12/01/2015
U.S. Patent No. 5,849,803	Expiring 12/15/2015
U.S. Patent No. 5,855,548	Expiring 06/14/2016
U.S. Patent No. 5,922,341	Expiring 10/28/2017
U.S. Patent No. 5,925,629	Expiring 10/28/2017
U.S. Patent No. 5,942,512	Expiring 08/24/2016
U.S. Patent No. 6,037,346	Expiring 10/28/2017
U.S. Patent No. 6,127,363	Expiring 10/28/2017
U.S. Patent No. 6,156,753	Expiring 10/28/2017
U.S. Patent No. 6,403,597	Expiring 10/28/2017
U.S. Patent No. 6,495,154	Expiring 11/21/2020
U.S. Patent No. 6,548,490	Expiring 10/28/2017
U.S. Patent No. 6,946,141	Expiring 11/21/2020
Canadian Patent No. 1320442	Expiring 07/20/2010
LURAMIST	
U.S. Patent No. 6,299,900	Expiring 12/18/2018
U.S. Patent No. 6,818,226	Expiring 09/01/2019
U.S. Patent No. 6,923,983	Expiring 02/19/2019
U.S. Patent No. 7,438,203	Expiring 12/18/2018
U.S. Patent Publication No. 2006/0280783	Pending
U.S. Patent Publication No. 2007/0071803	Pending
U.S. Patent Publication No. 2008/0152597	Pending
U.S. Patent Publication No. 2005/0002868	Pending

Qnexa contains two active substances, phentermine and topiramate, which have already been approved individually for use in medicinal products in the European Union. There is no approved product containing a fixed dose combination of phentermine and topiramate. We have been advised that Qnexa is considered a reference product under the EU rules governing medicinal products for the purpose of granting a fresh and independent period of regulatory data protection.

Since a new fixed combination product is considered a reference product within the meaning of Article 10(2)(a) of Directive 2001/83, it is entitled to a fresh period of regulatory data protection. According to Article 10(1) coupled with Article 10(2)(b) of Directive 2001/83/EC for nationally authorized products, this period of data protection is set at 10 years. Within 8 years of those 10 years, a generic applicant is not permitted to cross refer to the preclinical and clinical trial data relating to the reference product. Even if the generic product is authorized, it cannot be placed on the market until the full 10-year regulatory data protection has expired. This 10-year data protection may be extended cumulatively to a maximum period of 11 years if during the first 8 years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. This essentially is the formula of 8+2+1 for regulatory data protection applied in the EU. An identical formula for regulatory data protection is set out in Article 14(11) of Regulation (EC) 726/2004 for all centrally authorized products. If we are successful in obtaining a new indication, which is considered by the regulatory authorities to bring about a significant clinical benefit like diabetes or sleep apnea with Qnexa in the EU, we could, under the current EU rules, enjoy a total period of 11 years of data exclusivity.

We also hold foreign counterparts, patents and patent applications in major foreign jurisdictions related to our U.S. patents. 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.

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Manufacturing

We own our manufacturing facility located in Lakewood, New Jersey, 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. One of the buildings is used for warehousing component parts. The FDA and the Medicines and Healthcare products Regulatory Agency, or 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 may 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. 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 costly and 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 and device companies for the treatment of sleep apnea. 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 we have 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, researching and developing.

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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. Mergers, acquisitions, joint ventures and similar events may also significantly change the competitive environment.

Current approved 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 January 2010, the EMEA suspended the marketing authorization of sibutramine in Europe. The FDA added additional warnings to the label for sibutramine. The impact of these changes for sibutramine on Qnexa is unknown at this time. There are several drugs in development for obesity including product candidates in Phase 3 clinical trials being developed by Novo Nordisk A/S and Orexigen Therapeutics, Inc., and approximately 20 product candidates in Phase 2 clinical trials by companies including Neurosearch A/S and GlaxoSmithKline, among others. Partners Takeda Pharmaceutical Company Limited and Amylin Pharmaceuticals, Inc. announced in February 2010 that they are planning late-stage testing of an anti-obesity agent. Arena Pharmaceuticals, Inc. has completed Phase 3 studies and in December 2009 submitted an NDA with the FDA for its product candidate.

All of these drugs are or will be 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 Qnexa, if approved.

There are also surgical approaches to treat severe obesity that are becoming increasingly accepted and could become competitors against our product candidate, Qnexa. Two of the most well established surgical procedures are gastric bypass surgery and adjustable gastric banding. In addition, other potential approaches that utilize various implantable devices or surgical tools are in development. Some of these approaches are in late stage development and may be approved for marketing. Companies such as Allergan, Inc., Boston Scientific Corporation, Covidien Ltd, EnteroMedics, Inc., GI Dynamics, Inc., Johnson & Johnson, Leptos Biomedical, Inc., Medtronic Inc., and Satiety, Inc. are all active in this space and may have substantially greater resources than we have.

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 Corporation in the United States.

There are currently three PDE5 inhibitors approved for the treatment of erectile dysfunction in the U.S.: sildenafil, vardenafil, and tadalafil. Worldwide sales of these products were approximately $3.8 billion in 2009. Additional PDE5 inhibitors are in various stages of development by other companies. Warner-Chilcott plc has licensed the U.S. rights to udenafil, a PDE5i from Dong-A. Warner-Chilcott continues the Phase 3 development of this compound for ED. Other treatments for erectile dysfunction, or ED, 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., or NexMed, announced that the NDA submitted for its ED product, Vitaros®, a topically applied alprostadil cream, was accepted for review by the FDA. In February 2009, NexMed announced that they had sold the U.S. rights to Vitaros to Warner Chilcott Company, Inc. (a subsidiary of Warner Chilcott, Ltd., NASDAQ:WCRX), or Warner. Under the reported terms of the agreement, NexMed received an initial, up-front payment of $2.5 million and is eligible to receive an additional payment of $2.5 million upon Warner's receipt of

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FDA approval of the NDA. If the NDA for Vitaros is approved and Warner is successful in commercializing this product, the sales of MUSE will decline, which will have an adverse effect on the results of our operations and cash flows from sales of MUSE. We have also become aware of compounding pharmacies that are selling various products that include alprostadil. The sale of these products may violate certain of our intellectual property rights. The impact of the sales of products sold by compounding pharmacies that include alprostadil is unknown.

Two companies are developing products that could compete with our investigational product candidates for the treatment of FSD. The Proctor & Gamble Company has been developing Intrinsa, a testosterone patch for the treatment of HSDD, but announced in December 2008 that they will halt research and consider divestiture of their four key pharmaceutical brands, including Intrinsa. On August 24, 2009, Proctor & Gamble Company and Warner Chilcott plc announced an agreement for the sale of Proctor & Gamble's pharmaceuticals business to Warner Chilcott plc for an up-front cash payment of $3.1 billion. BioSante Pharmaceuticals, Inc. is developing forms of testosterone gels for HSDD. None of these investigational products have been approved by the FDA. In July 2006, the European Medicines Agency 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 in the United Kingdom.

Boehringer Ingelheim, or BI, has reported Phase 3 results of flibanserin, an oral agent, for the treatment of HSDD. BI reported data from pooled, pivotal Phase 3 clinical trials that demonstrate flibanserin 100 mg taken once daily at bedtime significantly increased the number of Satisfying Sexual Events, or SSEs, and sexual desire while significantly decreasing the distress associated with HSDD. Pooled North American Phase 3 trial results (DAISY and VIOLET) of 1,378 pre-menopausal women with HSDD showed a statistically significant increase in the frequency of SSEs per month in women taking flibanserin 100 mg (from 2.8 at baseline to 4.5), versus placebo (2.7 at baseline increasing to 3.7) over the 24-week study period. Flibanserin also demonstrated statistically significant improvements in sexual desire versus placebo as measured by an electronic diary (the eDiary For HSDD Trials). This finding was further supported by data from the desire domain of the Female Sexual Function Index, or FSFI, as an independent secondary measure.

Other key secondary endpoints showed flibanserin significantly improved sexual functioning (as measured by the FSFI total score), distress related to sexual dysfunction (as measured by the Female Sexual Distress Scale-Revised, or FSDS-R, score) and distress related to low sexual desire (FSDS-R Item 13 score) versus placebo.

European Phase 3 trial results for ORCHID of 634 pre-menopausal women with HSDD showed women taking flibanserin 100 mg had statistically significant improvements in their level of sexual desire, as measured by the eDiary. These findings were supported by a trend towards an increase in the FSFI desire domain. In addition, there was a statistically significant improvement in the level of distress associated with sexual dysfunction (as measured by the FSDS-R total score) as well as distress related to low sexual desire (FSDS-R Item 13) which is the second key parameter for the diagnosis of HSDD. A numerical increase in the number of SSEs compared to placebo supports the efficacy of flibanserin in pre-menopausal women suffering with HSDD.

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;

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experience and expertise in exploitation and protection 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. Our competitors may also develop drugs or surgical approaches that are more effective, more useful and less costly than ours and may also be more successful in manufacturing and marketing their products. In addition, our competitors may be more effective in commercializing their products. We currently outsource our manufacturing and therefore rely on third parties for that competitive expertise. There can be no assurance that we will be able to develop or contract for these capabilities on acceptable economic terms, or at all.

Research and Development

We incurred $71.1 million in 2009, $77 million in 2008, and $26.7 million in 2007 in research and development expenses, primarily to discover and develop our investigational product candidates in obesity, sleep apnea 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 26, 2010, we had 126 employees, 77 of which are located at our manufacturing facility in Lakewood, New Jersey and 49 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*, when such reports

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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, or 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 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 endpoints 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.

We are largely dependent on the success of our two investigational product candidates: Qnexa, for treatment of obesity, and avanafil, for treatment of erectile dysfunction, and cannot be certain that either product candidate will receive timely regulatory approval, if at all, or be successfully commercialized.

We currently have only a limited number of product candidates in clinical development, and our business currently depends on their successful development and commercialization. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are subject to extensive regulation by the U.S. Food and Drug Administration, or FDA, and other regulatory authorities in the United States and other countries, which regulations differ from country to country. We are not permitted to market our product candidates in the United States until we receive approval of a new drug application, or NDA, from the FDA, or in any foreign countries until we receive the requisite approval from the regulatory authorities of such countries.

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Regulatory approval of an NDA or NDA supplement is not guaranteed. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional pre-clinical studies and clinical trials. The number of pre-clinical studies and clinical trials that will be required for FDA approval varies depending on the product candidate, the disease or condition that the product candidate is designed to target and the regulations applicable to any particular product candidate. The FDA can delay, limit or deny approval of a product candidate for many reasons, including:

- the FDA may not deem a product candidate safe and effective;
- the FDA may not find the data from pre-clinical studies and clinical trials sufficient to support approval;
- the FDA may require additional pre-clinical or clinical studies;
- the FDA may not accept our stability data for commercial product;
- the FDA may not approve of our third-party manufacturers' processes and facilities;
- Although the FDA accepted our electronic NDA submission for Qnexa, it may not accept future NDA submissions from us due to, among other reasons, the formatting of the submission; or
- the FDA may change its approval policies, adopt new regulations or provide new guidance with significant requirements not currently included or considered by us when seeking NDA approval.

We recently submitted our NDA for Qnexa for the treatment of obesity to the FDA for approval. Our next most advanced investigation product candidate, avanafil, has not completed all of the large, pivotal Phase 3 clinical trials for efficacy and safety that are required for FDA approval. Notwithstanding our belief that the data collected from our three Phase 3 trials of Qnexa is promising, and even if we believe that data collected from our pre-clinical studies and clinical trials of our other product candidates are promising and that our information and procedures regarding chemistry, manufacturing and controls are sufficient, our data may not be sufficient to support approval by the FDA or any other foreign regulatory authority.

In addition, we believe that the regulatory review of NDAs for drug candidates intended for widespread use by a large proportion of the general population is becoming increasingly focused on safety. In this regard, it is likely that some of our investigational product candidates, including Qnexa and avanafil, will be subject to increased scrutiny to show adequate safety than would investigational product candidates for more acute or life-threatening diseases, such as cancer or HIV. Recently, the FDA notified healthcare professionals that the review of additional data from a post-approval study indicates an increased risk of heart attack and stroke in patients with a history of cardiovascular disease using sibutramine. Based on the serious nature of the review findings, the FDA requested, and the manufacturer agreed, to add a new contraindication to the sibutramine drug label stating that sibutramine is not to be used in patients with a history of cardiovascular disease, including history of coronary artery disease (e.g., heart attack, angina), stroke or transient ischemic attack, or TIA, heart arrhythmias, congestive heart failure, peripheral arterial disease, or uncontrolled hypertension (e.g., > 145/90 mmHg).

The European Medicines Agency has completed a review of the safety and effectiveness of sibutramine. The Agency's Committee for Medicinal Products for Human Use, or CHMP, has concluded that the benefits of sibutramine do not outweigh its risks, and that all marketing authorizations for medicines containing sibutramine should be suspended throughout Europe. We are unable to determine the impact on Qnexa, if any, of the recent actions in the U.S. and Europe with regards to sibutramine. If any regulatory agency were to require additional studies, including studies to address cardiovascular events, the impact on the timing of approval and if approved, commercialization of Qnexa, avanafil or any of our investigational product candidates, could be delayed. Even if approved,

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drug candidates may not be approved for all indications requested and such approval may be subject to limitations on the indicated uses for which the drug may be marketed and may have restricted access programs. Our business and reputation may be harmed by any failure or significant delay in receiving regulatory approval for the sale of any drugs resulting from our investigational product candidates. As a result, we cannot predict when or whether regulatory approval will be obtained for any of our investigational product candidates currently under development.

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 small number of study subjects in a selected disease population, and to identify and attempt to understand the investigational product candidate's side effects at various doses and dosing 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.

Although we recently announced results from two pivotal Phase 3 clinical trials for safety and efficacy of our most advanced investigational product candidate, Qnexa, we continue to analyze the data collected in these trials. Consequently, it is possible that further analysis of this and other data on Qnexa may yield information or suggest conclusions not yet known that may negatively impact our ability to obtain regulatory approval for Qnexa as a treatment for obesity, market acceptance or safety profile.

Our other investigational product candidates, avanafil and Luramist, have not successfully completed all of 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 product candidates may not predict results from studies in larger numbers of patients in multiple sites drawn from more diverse populations treated for longer periods of time. The smaller and shorter 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, dosage, delivery system or choose to study different populations than had been 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 (1996) and migraine prevention (2004). Published studies on topiramate reported that topiramate treatment produced weight loss. By combining 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 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. Earlier studies with Qnexa were completed using a twice-a-day dose. 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 used a once-a-day formulation in our completed Phase 3 studies of Qnexa. We have completed various

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pharmacokinetic studies of the once-a-day formulations to characterize the pharmacokinetic profile of the once-a-day formulation of Qnexa. The FDA has also asked us to study the effects of a lower dose of Qnexa, which we did in the Phase 3 obesity trials.

We may be required to demonstrate through large, long-term outcome trials that our investigational product candidates are safe and effective for use in a broad population prior to obtaining regulatory approval. There is typically a high rate of attrition from the failure of investigational product candidates proceeding through clinical trials. If any of our investigational product candidates fail to demonstrate sufficient safety and efficacy in any clinical trial, we will experience potentially significant delays in, or may 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 investigational product candidates 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 mid to late-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 with substantial evidence through pre-clinical testing and/or clinical trials that our investigational product candidates are safe and effective in humans for the indication being studied. Conducting clinical trials is a complex, lengthy, expensive and uncertain process. Completion of clinical trials and approval by the FDA may take several years or more. Our ability to complete clinical trials may be delayed, suspended or terminated by many factors, including, but not limited to:

- inability to obtain or manufacture sufficient quantities of drugs for use in clinical trials;
- inability of the manufactured product to meet stability requirements;
- failure to receive approval by the FDA of our clinical trial protocols;
- changes in clinical trial protocols or analysis plans made by us or imposed by the FDA;
- poor safety or effectiveness of our investigational product candidates;
- slower than expected rate of and higher than expected cost of patient recruitment;
- retaining patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up;
- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or investigators;

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delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;

unfavorable results from ongoing clinical trials and pre-clinical studies;

uncertainty regarding proper dosing;

difficulty or inability to achieve bioequivalence between commercial formulations and clinical trial formulations;

failure of our clinical research organizations to comply with all regulatory and contractual requirements or otherwise perform their services in a timely or acceptable manner;

scheduling conflicts with participating clinicians and clinical institutions;

termination of clinical trials by one or more clinical trial sites;

inability or unwillingness of medical investigators to follow our clinical protocols;

inability to adequately follow patients after treatment;

insufficient data to support regulatory approval;

collecting, reviewing and analyzing our clinical trial data;

unforeseen safety issues;

unforeseen issues with formulation or stability of investigational product candidates;

obtaining institutional review board, or IRB, approval to conduct a clinical trial at a prospective site;

government or regulatory delays; or

inability 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 our investigational product candidates. 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 on favorable terms, if at all, or generate product revenues from that investigational candidate or revenues would be delayed, our reputation in the industry and in the investment community would likely be significantly damaged, and our stock price would likely decrease significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate.

Our bioequivalence studies may fail to demonstrate acceptable comparability between formulations of investigational product candidates used in our Phase 3 clinical trials and new formulations, if any, of investigational product candidates we might choose to launch commercially, or choose to commercialize later, after launch.

We may choose to develop a new formulation of any or all of our investigational product candidates that may be different from the formulation used in our Phase 3 clinical trials. If changes are made, or if a new formulation is used, we will need to demonstrate comparable bioequivalence between the formulation used in our Phase 3 clinical trials and the new formulation, should we choose to launch or later commercialize this new formulation. If we are unable to demonstrate that the formulation used in our Phase 3 clinical trials is bioequivalent to the new formulation we intend to launch or later commercialize, then we may be required to conduct additional clinical trials or repeat some or all of our Phase 3 clinical trials for our investigational product candidate, or we may need to develop an

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alternative commercial formulation for the investigational product candidate that is bioequivalent. As a result, our ability to obtain approval of the investigational product candidate, if any, may be delayed. We have performed a bioequivalence study on a new formulation of Qnexa that we intend to launch, if approved, which was determined to be equivalent to the formulation used in the Phase 3 trials.

Association with fen-phen could lead to increased scrutiny of our investigational product candidate, Qnexa.

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 and the EQUATE Phase 3 study that contained two phentermine arms. The combination of fenfluramine or PONDIMIN, or fen, and phentermine, or 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.

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 correlation 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 valve 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, or 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 not demonstrated that phentermine causes PPH and valvular heart disease, when used in larger populations, there can be no assurance that Qnexa will not demonstrate rare, but significant cardiovascular or other detrimental side effects when used by the general population. 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 commercial sale.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval or limit the commercial profile of an approved label.

Side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restricted label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. The most common side effects reported in the first Phase 3 study of avanafil were headache, flushing and nasal congestion. The most common side effects reported in our Phase 3 trials of Qnexa were paresthesia (tingling of the extremities), dry mouth, altered taste, headache and constipation. In addition, the constituent drugs of Qnexa each has its own side effect profile that is included in its current product label. If Qnexa is approved by the FDA, we would anticipate that the label would include the side effect profiles of each

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of the constituent drugs. While the constituent drugs that make up Qnexa have post-marketing safety records and while we have tested these constituent drugs in combination in our clinical trials of Qnexa, to date, the combination of these constituent drugs has not received regulatory approval. While we believe our Phase 3 Qnexa clinical trials have generated safety and efficacy data, the approvability and eventual labeling of Qnexa will be determined by the FDA. For example, in 2007, the Endocrinologic and Metabolic Drugs Advisory Committee convened by the FDA reviewed another company's obesity product candidate, rimonabant, and determined not to recommend approval of the product candidate to the FDA, based on concerns regarding the safety profile of the product candidate in particular, depression, suicidality and seizures.

Phentermine and topiramate are each separately approved for sale by the FDA and have been on the market for many years. In general, significant adverse events and side effects observed in pre-clinical, clinical and post-marketing studies are included in the full prescribing information or label for each drug. The label for TOPAMAX contains reports of side effects, warnings and precautions including metabolic acidosis, acute myopia and secondary angle closure glaucoma, decreased sweating and hyperthermia, cognitive-related dysfunction, psychiatric and behavioral disturbances including one completed suicide in a patient during a bipolar trial, somnolence and fatigue, sudden unexplained death in epileptics, kidney stones, paresthesia and various drug interactions. The label for ADIPEX, a popular branded form of phentermine, contains warnings and precautions including recommendation against coadministration of phentermine with other drugs for weight loss. Adverse side effects include, among other things, pulmonary hypertension, valvular heart disease, drug abuse and dependence, overstimulation, restlessness, dizziness, insomnia, euphoria, dysphoria, tremor, headache, dryness of the mouth, diarrhea, constipation, impotence and changes in libido. The warnings and precautions for both of these products are updated often.

Previously 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 EQUATE, EQUIP and CONQUER Phase 3 obesity studies, tingling was experienced in 23%, 19% and 21%, respectively, of the patients on the full-dose of Qnexa. In the Phase 2 diabetes study, paresthesia was experienced by 17% of the patients. The other common adverse events reported in the published topiramate monotherapy studies were also central nervous system, or CNS, related including fatigue, difficulty with attention, memory and concentration, and depression. In our obesity and diabetes studies, these CNS-related side effects were low, but they were higher than placebo. The pharmaceutical company performing research of topiramate alone for the treatment of obesity announced they had discontinued their development program including their controlled-release formulation.

The FDA has also issued an alert on the use of antiepileptic drugs and a potential risk of increased suicidal ideation. As part of our Phase 3 obesity trials for Qnexa, we prospectively assessed the potential risk of suicidal tendencies. The results of the extensive assessments performed in our Phase 3 trials for Qnexa indicated no signal for suicidal behavior or ideation. On July 10, 2008, the FDA held a Joint Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee and the Psychopharmacologic Drugs Advisory Committee. The advisory committee and representatives from the Pediatric Advisory Committee, and the Drug Safety and Risk Management Advisory Committee considered the results of FDA's analysis of suicidality (both suicidal ideation and behavior) from placebo-controlled clinical studies of 11 antiepileptic drugs. One of the drugs included in the discussion was topiramate (marketed as TOPAMAX, Ortho-McNeil-Janssen Pharmaceuticals Inc.). The FDA discussed with the committee, in light of the results, whether any additional actions are necessary. The committee recognized that there is an increased risk of suicidality and recommended to the FDA that additional information should be provided to patients regarding the risks and benefits of

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antiepileptic drugs; however, the committee strongly recommended against a Black Box warning to be applied to antiepileptic drugs. In December 2008, the FDA asked the manufacturers of the antiepileptic drugs included in the analysis to add warnings about suicidality to the labels and to issue a medication guide covering the results of the meta-analysis. In April 2009, the FDA approved these new labels. We anticipate that the label for Qnexa, if approved, will contain the similar suicidality warnings to those contained in the topiramate label.

The preliminary experience from an observational registration study conducted in the United Kingdom on women with epilepsy who became pregnant, published in the July 22, 2008 edition of *Neurology*, stated that the major congenital malformations, or MCM, rate observed in the study among infants born to women who were taking topiramate and other antiepileptics during their pregnancy raised some concerns. The UK Epilepsy and Pregnancy Register is a voluntary registry in the United Kingdom that collects information in order to gather and publish information on the relative safety of antiepileptic drugs in this population. In the study, 203 pregnancies were followed, of which 13 (9%) had an MCM on polytherapy and three (4.8%) had an MCM on topiramate monotherapy. The MCMs included oral clefts and hypospadias. It has been reported that prenatal exposure to certain antiepileptic drugs increases the risk of MCM from a background risk of between 1% and 2% to between 4% and 9%.

Pregnant women or women who planned on becoming pregnant were not eligible to participate in the Qnexa clinical trials. Women of child-bearing potential were advised to use and agreed to use two forms of birth control during the study. Patients who became pregnant during the study period were required to immediately discontinue study medication. We are aware that patients in the studies did become pregnant. They were taken off the study medication and followed through to delivery. While we did not observe any changes in teratogenic activity in those pregnancies, we anticipate the labeling for Qnexa, if approved, will contain a warning against use by women who are or are considering becoming pregnant.

There were no dropouts in the Qnexa arm of our Phase 2 study due to serious or severe adverse events. In the Phase 3 EQUIP and CONQUER studies, there was no difference between Qnexa (0.4%) and placebo (0.4%) drug-related serious adverse events. In the Phase 3 EQUATE study, there were no reported drug-related serious adverse events. To date, the clinical results we have obtained for our other investigational product candidates, avanafil and Luramist, 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, physicians, analysts, investors, the media or the public in general our business, financial condition and results of operations will be materially harmed.

If any of our product candidates receives marketing approval and we or others identify unknown side effects caused by the product, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- regulatory authorities may require the addition of labeling statements, such as a "black box" warning with Qnexa or a contraindication;
- we may be required to create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;

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we could be asked to formulate a risk evaluation mitigation strategy, or REMS, that could include a program of post-marketing surveillance or restricted distribution for physicians who prescribe our products and patients being treated with our products;

we could be sued and held liable for injury to individuals exposed to or taking our products; and

our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of Qnexa and could substantially increase the costs of commercializing our product candidate.

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 with individual drugs contained in the Qnexa formulation and immediate competition.

Each of the approved drugs that are combined to produce our investigational product candidate, Qnexa, is 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 Qnexa as sufficiently superior to a treatment regime of Qnexa's individual active pharmaceutical ingredients as to justify the significantly higher cost we expect to seek for Qnexa, and they may prescribe the individual generic drugs already approved and marketed by other companies instead of our combination product. Even though our U.S. and European patents contain composition, product formulation and method-of-use claims that we believe protect Qnexa, those patents may be ineffective as a practical matter to protect against physicians prescribing the individual drugs marketed by other companies instead of our combination product. Our patents and pending patent applications do not prevent physicians from prescribing the generic constituents of our product candidates. Phentermine and topiramate are currently available in generic form, although the doses used in Qnexa are currently not available and no controlled or sustained release formulation of topiramate exists. We believe that a practitioner seeking safe and effective therapy is not likely to prescribe such off-label generics in place of Qnexa because the dosage strengths, pharmacokinetic profiles and titration regimens recommended for Qnexa are not available using existing generic preparations of immediate release, or IR, phentermine or topiramate. However, to the extent that the price of Qnexa 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 or market Qnexa. Similar concerns could also limit the reimbursement amounts private health insurers or government agencies in the U.S. are prepared to pay for Qnexa, which could also limit market and patient acceptance of our product, and could negatively impact our revenues. 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 indication not approved by the FDA. Topiramate, one of the ingredients in Qnexa, is not approved for obesity treatment.

With regard to off-label substitution at the pharmacy level, we cannot be certain that pharmacists and/or pharmacy benefit managers will not seek prescriber authorization to substitute generics in place of Qnexa, which could significantly diminish its market potential. Wide scale generic substitution by physicians and at the pharmacy level could have substantial negative consequences to our business.

In many countries where we may plan to market Qnexa, including Europe and Canada, the pricing of prescription drugs is controlled by the government or regulatory agencies. The government or 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.

We may choose or be required by regulatory authorities to restrict distribution of Qnexa to specialty pharmacies after physicians and patients register to ensure a safe and secure launch. Our

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success in distributing our product candidate in this manner could be limited, which could have an adverse effect on our business, financial condition and results of operations and cash flow.

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 are required to show that each active pharmaceutical ingredient in our 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 more effective than each of the components. As a result, we were required to include in our clinical trial protocols an evaluation of each component drug as well as for the component drug in combination. This required us to conduct more extensive and more expensive clinical trials than would be the case for many single agent pharmaceuticals. The need to conduct such trials could make it more difficult and costly to obtain regulatory approval of Qnexa than of a new drug containing only a single active pharmaceutical ingredient. The OB-301, or EQUATE, Phase 3 trial was designed to meet the combination guidelines set by the FDA. The EQUATE study contained separate component arms as well as the combination. We believe the results of the EQUATE study meet FDA guidelines for combination therapy studies; however, there can be no assurance that we have satisfied the combination requirements to the FDA's satisfaction or that further testing of the combination will not be required. The EQUATE study also contained a mid-dose of Qnexa containing 7.5 mg of phentermine and 46 mg of topiramate CR. The mid-dose was also included in the CONQUER, or OB-303, study. We did not complete a component study for the low-dose. We have filed for approval of all three doses. The number of patients on the low-dose in OB-302 or the mid-dose in the OB-303 study may not be sufficient for approval. We have no assurance that any of the doses of Qnexa will be approved or that additional pre-clinical and clinical testing may not be needed prior to approval. In addition, if the FDA does not approve the full-dose of Qnexa, there is no assurance that they would approve the mid-dose or any other dose of Qnexa.

We have in-licensed all or a portion of the rights to our product candidates from third parties. If we default on any of our material obligations under those licenses, we could lose rights to our product candidates.

We have in-licensed and otherwise contracted for rights to our product candidates, and we may enter into similar licenses in the future to supplement our product candidate pipeline. Under the relevant agreements, we are subject to commercialization, development, sublicensing, royalty, insurance and other obligations. If we fail to comply with any of these requirements, or otherwise breach these license agreements, the licensor may have the right to terminate the license in whole or to terminate the exclusive nature of the license. Loss of any of these licenses or the exclusive rights provided therein could harm our financial condition and operating results.

In particular, the United States rights to Evamist and Luramist were licensed from Acrux and its related affiliates. The rights to avanafil were licensed from Tanabe Seiyaku Co., Ltd., or Tanabe, in 2001. In October 2007, Tanabe and Mitsubishi Pharma Corporation completed their merger and announced their name change to Mitsubishi Tanabe Pharma Corporation, or MTPC. The rights to Evamist were sublicensed to K-V. In August 2008, we assigned all of our rights and obligations under the Evamist license agreement to K-V. The rights to Qnexa were licensed from Dr. Najarian in 2001. We believe we are in compliance with all the material terms of our current 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 agreements were terminated early or if the terms of the license were contested for any reason, it would have a material adverse impact on our ability to commercialize products subject to these agreements, our ability to raise funds to finance the company, our stock price and our overall financial condition. The monetary and disruption costs of any disputes involving our collaborative agreements could be significant despite rulings in our favor.

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For example, VIVUS and Acrux Limited through its wholly owned subsidiary FemPharm Pty Ltd., or Acrux, are parties to the Testosterone Development and Commercialization Agreement dated February 12, 2004, or the Testosterone Agreement. The Testosterone Agreement covers our investigational product candidate, Luramist, which is licensed from Acrux under the Testosterone Agreement. On November 5, 2007, Acrux made a demand for arbitration under the Testosterone Agreement regarding certain claims related to Luramist. Acrux's demand sought a reversion of all rights assigned to us related to Luramist, monetary damages and the payment of a milestone payment for Luramist under the Testosterone Agreement and declaratory relief. We asserted counterclaims against Acrux in the arbitration and sought the enforcement of our rights under the Testosterone Agreement. The arbitration hearing concluded on January 23, 2009, and on April 6, 2009 the panel of arbitrators, or the Panel, issued its Interim Arbitration Award finding in favor of the Company that we were in compliance with the Testosterone Agreement and denying all of the relief sought by Acrux in its demand. The Panel found that we have used diligent, commercially reasonable efforts to develop Luramist. The Panel further ruled in our favor on our counter claim that Acrux had breached the Luramist license agreement by failing to provide certain know-how and certain improvements in the formulation and delivery device for Luramist. The Panel denied the Acrux claim for additional milestone payments. The Panel has ordered Acrux to turn over certain information to us that was previously withheld in violation of the agreement by Acrux. After the parties failed to agree on a new Outside Date by which we are to commence our first Phase 3 trial for Luramist, the Panel reset the Outside Date of April 30, 2006 to April 1, 2010 to reflect the regulatory environment. Acrux will be eligible to receive the previously agreed upon Phase 3 milestone payment of $1 million to be paid out at the earlier of the start of the Phase 3 trials or the Outside Date. Currently we are planning an additional pharmacokinetic/pharmacodynamic study to review a new formulation of Luramist. Under the agreement with Acrux, a milestone payment of $1 million is due to Acrux upon the earlier of commencing a Phase 3 study for Luramist or the Outside Date, April 1, 2010. The milestone is due in monthly installments of $166,667 for each month of delay in commencing Phase 3 after the Outside Date until the milestone is paid in full. There can be no assurance that Acrux would not continue to pursue legal action against us if we do not commence the first Phase 3 trial by the Outside Date. To the extent we are unable to comply with these obligations, the Luramist license may be terminated. The monetary and disruption costs of this arbitration were significant despite the favorable rulings by the Panel.

While we may be entitled to future milestone payments under existing contractual arrangements, we may not receive these payments.

Certain of our contractual arrangements include future milestone payments to us based upon the other party achieving defined sales targets. Meeting those milestone targets is dependent on the performance of the other party to the contractual arrangement and we have little, or no, control over those outcomes. We have no assurance any of those milestone targets will be achieved and that the milestones will be paid to us.

For example, on March 30, 2007, we entered into a definitive agreement with K-V to transfer the assets and grant a sublicense of our rights under our licensing agreement with Acrux related to Evamist, a metered-dose transdermal spray for the treatment of menopause symptoms, to K-V. Under the terms of this agreement, we are also eligible to receive certain one-time payments of up to $30 million based on K-V achieving certain annual net sales thresholds for Evamist. In January 2009, K-V and certain of its subsidiaries announced a voluntary recall of most of its prescription products. In addition, K-V voluntarily suspended the manufacturing and shipping of all of its products. Subsequent to the recall, K-V announced plans to reduce its workforce by 700 employees. Evamist is not manufactured by K-V and was not subject to the recall. In July 2009, K-V announced that it had hired a firm that specializes in restructurings and bankruptcies. Given the uncertainties with K-V, it is difficult to determine the extent of the adverse impact on Evamist. Although we are entitled to additional

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milestone payments from future sales of Evamist by K-V, at the present time we do not anticipate receiving any additional milestone payments from sales of Evamist.

We are dependent upon collaborative arrangements and strategic alliances.

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 certain rights or pay royalties, 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, or MTPC. The rights and obligation of our license agreement with Tanabe have been transferred to MTPC. It is unclear at this time what effect, if any, the merger will have on our agreement with MTPC. While we currently have no indication of any adverse material effects with regards to the collaboration, there can be no guarantee that the merger of Tanabe and Mitsubishi will not have an adverse material effect on the performance by MTPC under our agreement, which in turn could lead to a material adverse effect on our business, financial condition and results of operations.

We may be unable to 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;
- our collaborators may be required to disclose our confidential information or may fail to protect our confidential information;
- 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 adversely affect a collaborator's willingness or ability to satisfactorily complete its obligations to meet our requirements under any arrangement;
- legal disputes or disagreements may occur with our collaborative partners;
- 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 and approved pharmaceuticals is 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 our investigational product candidates currently under development, except for Qnexa for which the NDA was submitted to the FDA on December 29, 2009. Even if submitted, the FDA can suspend or modify clinical studies at any time if the agency believes that the patients 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.

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In July 2008, an FDA advisory panel discussed the role of cardiovascular outcomes assessment in the pre-approval and post-approval settings for drugs and biologics developed for the treatment of type 2 diabetes mellitus. The panel recommended that sponsors conduct a long-term cardiovascular trial or to provide other equivalent evidence to rule out an unacceptable cardiovascular risk. The FDA has since published a guidance document in December 2008 for the evaluation of cardiovascular risk in new antidiabetic therapies specifically for the treatment of type 2 diabetes. In general, the FDA recommends that sponsors should compare the incidence of important cardiovascular events occurring with the antidiabetic investigational agent to the incidence of the same type of events with the control group to estimate the relative risk of the investigational antidiabetic agent. This may be accomplished by either conducting an integrated analysis (meta-analysis) of the Phase 2 and Phase 3 studies, if the investigational drug was in late-stage development at the time the December 2008 guidance was published, or conduct a single, large, prospective long-term cardiovascular safety outcomes study prior to NDA submission. A long-term cardiovascular study would take several years to complete and would require resources that may be beyond our current capabilities. Qnexa, in development for diabetes is subject to this recommendation. The FDA, however, has neither required a meta-analysis of the Qnexa Phase 2 and 3 data, nor a prospective long-term cardiovascular safety outcomes study to be performed for Qnexa as a treatment for obesity. There can be no assurance, however, that the FDA would not in the future require us to perform a cardiovascular safety outcomes study, pre- or post-approval, for Qnexa as a treatment for obesity. The FDA has notified healthcare professionals that the review of data from a post-approval outcomes trial of an anti-obesity agent, subutramine, indicates an increased risk of heart attack and stroke in patients with a history of cardiovascular disease. Based on the serious nature of the review findings, the FDA requested, and the manufacturer agreed, to add a new contraindication to the sibutramine drug label stating that sibutramine is not to be used in patients with a history of cardiovascular disease. We have no reason to believe Qnexa would be subject to the same requirements. If we are required to complete a long-term cardiovascular safety outcomes study for Qnexa, the ultimate approval may be delayed for several years and the overall cost of the program will significantly increase.

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 company. Rimonabant was 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 company withdrew its NDA for rimonabant shortly after the advisory panel meeting. Although the active ingredients in Qnexa have been previously approved by FDA at higher doses for other indications, it is a centrally acting drug that may increase the risk of psychiatric side effects such as depression and/or suicidal ideation.

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 NDA. We are developing an investigational transdermal testosterone product candidate, Luramist, which is designed to address hypoactive sexual desire disorder. We recently reached agreement with the FDA regarding a long-term cardiovascular event study that we must complete prior to submitting Luramist for approval. We estimate we will have to enroll a minimum of 5,200 patients, over the age of 50, with one cardiovascular risk factor. The average minimum exposure to Luramist in the safety study is 12 months. The safety study is an events-driven study and patients will be followed until the minimum number of pre-defined cardiovascular events has occurred. Despite the agreement with the FDA on the size and scope of the safety study, 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

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product candidate to the FDA for consideration. In the end, we may be unsuccessful in obtaining FDA approval of Luramist or any of our investigational product candidates.

We are not permitted to market any of our investigational product candidates in the United States until we receive approval from the FDA. As a consequence, any failure to obtain or delay in obtaining FDA approval for our investigational product candidates would delay or prevent our ability to generate revenue from our investigational product candidates, which would adversely affect our financial results and our business.

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

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

Following regulatory approval of any investigational product candidates, we will 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 required to comply with extensive regulations for 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 and how we may distribute our products. Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. For example, the label ultimately approved for Qnexa, if any, may include restrictions on use, including restrictions based on child-bearing potential or pregnancy status, level of obesity and duration of treatment or a boxed warning related to concerns regarding antidepressants, antiepileptics or otherwise. The FDA may also require the distribution of a Medication Guide to patients outlining the increased risk of suicidal thinking or behavior in children and adolescents or other populations. The FDA could also require a registry to track the patients utilizing the product or implement a risk evaluation mitigation strategy, or REMS that could restrict access to the drug.

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. For example, the safety study for Luramist will require us to follow patients for five years in order to assess potential cardiovascular risks and breast cancer. While we may submit an NDA for Luramist after patients have had an average exposure of 12 months and a minimum number of pre-defined cardiovascular incidences have occurred, there can be no assurance that Luramist will be approved or, if approved, that safety issues would not arise subsequent to such approval. Previously unknown problems with the investigational product candidate, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the drug, and could lead to the withdrawal of the drug from the market.

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Manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or cGMP, regulations, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory agencies must approve these manufacturing facilities before they can be used to manufacture our products, and these facilities are subject to ongoing regulatory inspections. In addition, regulatory agencies subject a drug, its manufacturer and the manufacturer's facilities to continual review and inspections. The subsequent discovery of previously unknown problems with a drug, including adverse events of unanticipated severity or frequency, or problems with the facility where the drug is manufactured, may result in restrictions on the marketing of that drug, up to and including withdrawal of the drug from the market. If our manufacturing facilities or those of our suppliers fail to comply with applicable regulatory requirements, it could result in regulatory action and additional costs to us. Failure to comply with applicable FDA and other regulatory requirements may, either before or after product approval, if any, subject our company to administrative or judicially imposed sanctions, including:

- issuance of Form 483 notices, Warning Letters and adverse publicity by the FDA or other regulatory agencies;
- imposition of fines and other civil penalties due to product liability or other issues;
- criminal prosecutions;
- injunctions, suspensions or revocations of regulatory approvals;
- suspension of any ongoing clinical trials;
- total or partial suspension of manufacturing;
- delays in commercialization;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our collaborators;
- refusals to permit drugs to be imported into or exported from the United States;
- restrictions on operations, including costly new manufacturing requirements; and
- product recalls or seizures.

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. Contract Manufacturing Organizations, or CMOs, and their vendors or suppliers may also face changes in regulatory requirements from governmental agencies in the U.S. and other countries. We cannot predict the likelihood, nature, extent or effects of government regulation that may arise from future legislation or administrative action, either in the U.S. 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.

Even if we receive regulatory approval to commercialize our product candidates, our ability to generate revenues from any resulting products will be subject to a variety of risks, many of which are out of our control.

Even if our investigational product candidates obtain regulatory approval, those products may not gain market acceptance among physicians, patients, healthcare payers or the medical community. Coverage and reimbursement of our product candidates by third-party payors, including government payors, generally is also necessary for optimal commercial success. We believe that the degree of market acceptance and our ability to generate revenues from such products will depend on a number of factors, including:

timing of market introduction of competitive drugs;

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efficacy and safety of our product candidates;

prevalence and severity of any side effects;

potential or perceived advantages or disadvantages over alternative treatments including generics;

the relative convenience and ease of administration and dosing schedule;

strength of sales, marketing and distribution support;

price of our future products, both in absolute terms and relative to alternative treatments;

the effectiveness of our or any future collaborators' sales and marketing strategies;

the effect of current and future healthcare laws on our product candidates;

availability of coverage and reimbursement from government and other third-party payers;

the willingness of patients to pay out of pocket in the absence of third-party coverage; and

product labeling or product insert requirements of the FDA or other regulatory authorities.

If our approved investigational product candidates, if any, fail to achieve market acceptance, we may not be able to generate significant revenue to achieve or sustain profitability. In addition, our efforts to educate the medical community and third-party payors on the benefits of our investigational product candidates may require significant resources and may never be successful.

We have limited sales and marketing experience and resources and we may not be able to effectively market and sell our investigational product candidates, if approved, in the United States and/or internationally without a global pharmaceutical partner.

We are developing Qnexa, our obesity investigational product candidate, for large markets traditionally served by general and family practitioners and internists. Generalist physicians number in the several hundred thousand in the United States. Traditional pharmaceutical companies employ groups of sales representatives numbering in the thousands to call on this large generalist physician population. In order to adequately address these physician groups, we must establish sales and marketing collaborations or co-promotion arrangements or expend significant resources to develop our own sales and marketing presence. We currently possess limited resources and may not be successful in developing our own sales and marketing presence or establishing sales and marketing collaborations or co-promotion arrangements on acceptable terms, if at all. We may also decide to forego any form of collaboration and develop sales and marketing capabilities on our own. We also face competition in our search for collaborators, co-promoters and sales force personnel. We may rely on third parties to develop or commercialize our investigational product candidates. These third parties may fail to develop or effectively commercialize our investigational product candidates because they cannot obtain the necessary regulatory approvals, decide to pursue a competitive potential product that may be developed outside of the collaboration or fail to devote the resources necessary to realize the full commercial potential of our investigational product candidates.

Even if our investigational product candidates receive regulatory approval in the United States, we may never receive approval for or commercialize our products outside of the United States.

To market any of our investigational product candidates outside of the United States, we and our collaborators must comply with numerous and varying regulatory requirements of other countries. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks associated with FDA approval as well as additional, presently unanticipated, risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining

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such approval could have the same adverse effects detailed above regarding FDA approval in the United States. As described above, such effects include the risks that our investigational product candidates may not be approved for all indications requested, which could limit the uses of our product candidates and have an adverse effect on their commercial potential or require costly, post-marketing follow-up studies.

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.

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, safety monitoring companies, clinical investigators and clinical sites and clinical research organizations, or CROs, which 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. Safety monitoring companies collect reported adverse events that are reported from patients and healthcare providers during clinical trials. Clinical investigators and clinical sites enroll patients and conduct clinical testing according to clinical protocols. The CROs typically review data generated by clinical investigators, perform project management, data management, statistical analysis, and other reporting functions. We intend to use several different facilities and CROs for all of our pre-clinical and clinical studies. We have contracted with a safety monitoring company that we intend to use for all of our clinical trials. If these third party toxicology facilities, the safety monitoring company, clinical investigators, clinical sites 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, the safety monitoring company, clinical investigators, clinical sites or CROs do not perform satisfactorily, we may not be able to locate acceptable replacement third parties or enter into favorable agreements with these third parties, if at all. These third parties may also fail economically, which would impact our ability to obtain and utilize the results of the studies performed by these third parties.

We rely on third parties to manufacture sufficient quantities of compounds within product specifications as required by regulatory agencies 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 and there may be long lead times to obtain 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 or our third-party manufacturers may encounter delays and problems in manufacturing our investigational product candidates or approved drugs for a variety of reasons, including accidents during operation, failure of equipment, delays in receiving materials, natural or other disasters, political or governmental changes, or other factors inherent in operating complex manufacturing facilities. Supply chain management is difficult. Commercially available starting materials, reagents and excipients may become scarce or more expensive to procure, and we may not be able to obtain favorable terms in agreements with subcontractors. We or our third-party manufacturers may not be able to operate our respective manufacturing facilities in a cost-effective manner or in a time frame that is consistent with our expected future manufacturing needs. If we or our third-party manufacturers cease or interrupt production or if our third-party manufacturers and other service providers fail to supply materials, products or services to us for any reason, such interruption could delay progress on our programs, or interrupt the commercial supply, with the potential for additional costs and lost revenues. If this were to occur, we may also need to seek alternative means to fulfill our manufacturing needs.

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We have completed the development of a once-a-day formulation of Qnexa. The contract manufacturer we selected to develop a once-a-day formulation supplied the entire product for the Phase 3 program. In addition, this contract manufacturer is our sole source of clinical and commercial supplies for Qnexa. Stability data of the once-a-day capsule and the container closure system is limited. We have only recently manufactured commercial registration batches of Qnexa. These batches may not pass certain release specifications. In addition, the stability data from these batches may not be adequate on their own to support customary acceptable expiration dating. While this contract manufacturer has significant experience in commercial scale up manufacturing, there is no assurance that they will be successful with the commercial scale up of Qnexa which could have a material adverse impact on our development plan, market price of our common stock and financial condition.

We rely on third parties to maintain appropriate levels of confidentiality of the data compiled during clinical trials.

We seek to maintain the confidential nature of our confidential information through contractual provisions in our agreements with third parties, including our agreements with clinical research organizations, or CROs, that manage our clinical studies for our investigational product candidates. These CROs may fail to comply with their obligations of confidentiality or may be required as a matter of law to disclose our confidential information. As the success of our clinical studies depends in large part on our confidential information remaining confidential prior to, during and after a clinical study, any disclosure could have a material adverse effect on the outcome of a clinical study, our business, financial condition and results of operations.

Risks Relating to our Operations

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

One example of non-conformance came to light during the first quarter of 2009, when we, as part of our routine testing, identified that certain lots of the 125 mcg and 250 mcg strength MUSE product had exceeded the specified limit of allowable impurities. The identified product was out of compliance with the impurity specification in the 18th-24th month of its shelf life. In 2008, sales of the 125 mcg and 250 mcg strength MUSE represented 11% of our worldwide sales. Upon identifying this

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non-conformance, we promptly notified the FDA. The occurrence of known impurities to some level is typical within most pharmaceutical products. Our investigation concerning this MUSE impurity issue identified that the elevation in impurities was caused during the routine sterilization process. We continue to perform monitoring for impurities and additional lots of commercialized product may also be identified as containing levels of impurity that exceed the product's specifications. Although we believe that this impurity poses no safety risk to the patients, as part of our commitment to maintaining cGMP and compliance to FDA regulations, on May 20, 2009, VIVUS sent a notice to our wholesale distributors to recall specific lots of 125 mcg and 250 mcg product that remain in the wholesaler's inventory. The quantities of recalled product received-to-date by VIVUS from the recall effort have not been significant. There can be no assurance that a further product recall will not occur in the future from similar or other variations of the manufacturing process. Also, there can be no assurance that inherent and future variations in the sterilization process will not produce product that will exceed the product's impurity specification or that would have some other adverse effect that would still render the product to not be within its full range of specification over the full course of its shelf life. Should a further recall be necessary, there may be periods when the 125 mcg and 250 mcg strength MUSE product are not fully available to the commercial market and these strengths may go into a back order status. All MUSE products had a 24-month shelf life; however, in September 2009, we received approval from the FDA to reduce the shelf life of our 125 mcg and 250 mcg MUSE product from 24 months to 18 months. We are currently manufacturing the 125 mcg and 250 mcg MUSE product with an 18-month shelf life. During the fourth quarter of 2009, we began to manufacture and ship125 mcg and 250 mcg MUSE product with an 18-month shelf life. In addition, in the fourth quarter of 2009, we used the newly manufactured 125 mcg and 250 mcg product with the 18-month shelf life dating to replace and exchange any then existing 125 mcg and 250 mcg product in the wholesalers' inventories that had the prior 24-month shelf life dating. We completed the product exchange during the fourth quarter of 2009. The FDA and/or international regulatory agencies may require us to perform extensive investigations and/or process revalidations in relationship to the resolution of this issue. Should such extensive investigations or process revalidations be necessary, a further product recall be made, or a product shortage and back order occur, there could be a material adverse impact on our business, financial condition and results of operations.

Non-conformance issues may occur in our manufacturing operations or in the operations of our vendors and suppliers, which could have an adverse impact on our ability to manufacture our products and investigational product candidates. For example, in late March 2008, we identified a non-conformance issue in one container of a raw material for MUSE, as supplied by the raw material vendor. All MUSE units manufactured from this container were within the VIVUS held inventory, were separated from our other inventory and were subsequently destroyed. As required, we appropriately notified the FDA of this raw material incident. In a timely manner, we completed an investigation of this non-conformance, which concluded that the impact of this raw material non-conformance was limited to those units of MUSE produced from the one subject container. All of these units had already been identified and separated out of our normal inventory. We also shared our findings and actions directly with the FDA. We have negotiated a partial financial settlement with the supplier of this non-conforming material. Although we believe this incident to be complete from a product impact point of view, there can be no assurance that any future raw material non-conformance would not have a much greater negative impact to production, inventory supply, market demand supply, or even require a recall of previously distributed MUSE units. In addition, the costs associated with a future interruption in supply could be significant and our future financial results could be adversely affected.

Failure to achieve satisfactory cGMP compliance as confirmed by routine and unannounced inspections could have a material adverse effect on our ability to continue to manufacture and distribute our commercial products and, in the most serious case, result in the issuance of a regulatory

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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 are 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 that 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 that 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, exclusion of our products from medical healthcare programs like Medicare and Medicaid, 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.

Any pre-marketing and marketing activities for our investigational product candidates and approved products are subject to continued governmental regulation.

Prior to and after product approval by the FDA, any pre-marketing and marketing activities will be subject to FDA and other regulatory review. Certain activities undertaken prior to approval may be considered pre-approval promotion. Pre-approval promotion of investigational product candidates is

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prohibited by FDA regulations. Failure to comply with these regulations may result in delays in the ultimate approval of our investigational product candidates. After approval, 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. Certain states have also adopted regulations and reporting requirements surrounding the promotion of pharmaceuticals. MUSE, and Qnexa, if approved, would be subject to these regulations. Failure to comply with state requirements may affect our ability to promote or sell pharmaceuticals products in certain states. This in turn could have a material adverse impact on our financial results and financial condition.

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 investigational product candidates, such approval may involve limitations on the indicated uses or marketing claims we may make for our products and distribution channels. For example, the safety study for Luramist requires that we follow patients for five years in total to detect cardiovascular events and breast cancer. Further, later discovery of previously unknown problems for Luramist or any of our investigational product candidates 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, financial condition and stock price. 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, results of operations and stock price.

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 MUSE.

Sales of our current and any future products are subject to continued governmental regulation, as well as 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

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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 product labeling or after actual use of the product. There can be no assurance that our MUSE 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, our ability to generate revenues will be adversely affected.

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 products 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, we are not able to anticipate if our largest wholesaler customer, McKesson Corporation, will continue its historical pattern of making purchases in the fourth quarter that exceed expected quarterly demands. If McKesson Corporation does not repeat this pattern of purchasing quantities of MUSE that exceed quarterly demands, revenues from the sale of MUSE in 2010 may be lower as compared to 2009.

Sales to significant customers as a percentage of total revenues for the years ended December 31, 2009, 2008 and 2007 are as follows:

	2009	2008	2007
McKesson Corporation	54%	51%	53%
Cardinal Health	21%	21%	15%
Meda AB	9%	12%	14%
AmerisourceBergen	11%	12%	11%

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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 costly and 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 and device companies for the treatment of sleep apnea. 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 researching and developing. Such developments could render our products or our investigational product candidates less competitive or possibly obsolete. We are also competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have limited experience. Mergers, acquisitions, joint ventures and similar events may also significantly change the competition.

Current approved 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 January 2010, the EMEA suspended the marketing authorization of sibutramine in Europe. The FDA added additional warnings to the label for sibutramine. The impact of these changes for sibutramine on Qnexa is unknown at this time. There are several drugs in development for obesity including product candidates in Phase 3 clinical trials being developed by Novo Nordisk A/S and Orexigen Therapeutics, Inc., and approximately 20 product candidates in Phase 2 clinical trials by companies including Neurosearch A/S and GlaxoSmithKline, among others. Partners Takeda Pharmaceutical Company Limited and Amylin Pharmaceuticals, Inc. announced in February 2010 that they are planning late-stage testing of an anti-obesity agent. Arena Pharmaceuticals, Inc. has completed Phase 3 studies and in December 2009 submitted an NDA with the FDA for its product candidate.

All of these drugs are or will be 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 obesity investigational product candidate.

In October 2008, Sanofi-Aventis announced that it halted sales of its weight loss drug, Acomplia, in the wake of a recommendation by a European regulatory panel that the product be pulled off the market over safety concerns. The company has also halted all human trials of the Acomplia obesity medicine after health authorities in a few countries requested local tests be stopped. In January 2010, Abbott Labs suspended the sales of sibutramine in Europe.

There are also surgical approaches to treat severe obesity that are becoming increasingly accepted and could become competitors against our product candidate, Qnexa. Two of the most well established surgical procedures are gastric bypass surgery and adjustable gastric banding. In addition, other potential approaches that utilize various implantable devices or surgical tools are in development. Some of these approaches are in late stage development and may be approved for marketing. Companies such as Allergan, Inc., Boston Scientific Corporation, Covidien Ltd, EnteroMedics, Inc., GI Dynamics, Inc., Johnson & Johnson, Leptos Biomedical, Inc., Medtronic Inc., and Satiety, Inc. are all active in this space and may have substantially greater resources than we have.

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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 Corporation in the United States.

There are currently three PDE5 inhibitors approved for the treatment of erectile dysfunction in the U.S.: sildenafil, vardenafil, and tadalafil. Worldwide sales of these products were approximately $3.8 billion in 2009. Additional PDE5 inhibitors are in various stages of development by other companies. Warner-Chilcott plc has licensed the U.S. rights to udenafil, a PDE5i from Dong-A. Warner-Chilcott continues the Phase 3 development of this compound for ED. Other treatments for erectile dysfunction, or ED, 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., or NexMed, announced that the NDA submitted for its ED product, Vitaros®, a topically applied alprostadil cream, was accepted for review by the FDA. In February 2009, NexMed announced that they had sold the U.S. rights to Vitaros to Warner Chilcott Company, Inc. (a subsidiary of Warner Chilcott, Ltd., NASDAQ:WCRX), or Warner. Under the reported terms of the agreement, NexMed received an initial, up-front payment of $2.5 million and is eligible to receive an additional payment of $2.5 million upon Warner's receipt of FDA approval of the NDA. If the NDA for Vitaros is approved and Warner is successful in commercializing this product, the sales of MUSE will decline, which will have an adverse effect on the results of our operations and cash flows from sales of MUSE. We have also become aware of compounding pharmacies that are selling various products that include alprostadil. The sale of these products may violate certain intellectual property rights we own. The impact of the sales of products sold by compounding pharmacies that include alprostadil is unknown.

Two companies are developing products that could compete with our investigational product candidates for the treatment of FSD. The Proctor & Gamble Company has been developing Intrinsa, a testosterone patch for the treatment of HSDD, but announced in December 2008 that they will halt research and consider divestiture of their four key pharmaceutical brands, including Intrinsa. On August 24, 2009, Proctor & Gamble Company and Warner Chilcott plc announced an agreement for the sale of Proctor & Gamble's pharmaceuticals business to Warner Chilcott plc for an up-front cash payment of $3.1 billion. BioSante Pharmaceuticals, Inc. is developing forms of testosterone gels for HSDD. None of these investigational products have been approved by the FDA. In July 2006, the European Medicines Agency 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 in the United Kingdom.

Boehringer Ingelheim, or BI, has reported Phase 3 results of flibanserin, an oral agent, for the treatment of HSDD. BI reported data from pooled, pivotal Phase 3 clinical trials that demonstrate flibanserin 100 mg taken once daily at bedtime significantly increased the number of Satisfying Sexual Events, or SSEs, and sexual desire while significantly decreasing the distress associated with HSDD. Pooled North American Phase 3 trial results (DAISY and VIOLET) of 1,378 pre-menopausal women with HSDD showed a statistically significant increase in the frequency of SSEs per month in women taking flibanserin 100 mg (from 2.8 at baseline to 4.5), versus placebo (2.7 at baseline increasing to 3.7) over the 24-week study period. Flibanserin also demonstrated statistically significant improvements in sexual desire versus placebo as measured by an electronic diary (the eDiary For HSDD Trials). This finding was further supported by data from the desire domain of the Female Sexual Function Index, or FSFI, as an independent secondary measure.

Other key secondary endpoints showed flibanserin significantly improved sexual functioning (as measured by the FSFI total score), distress related to sexual dysfunction (as measured by the Female

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Sexual Distress Scale-Revised, or FSDS-R, score) and distress related to low sexual desire (FSDS-R Item 13 score) versus placebo.

European Phase 3 trial results for ORCHID of 634 pre-menopausal women with HSDD showed women taking flibanserin 100 mg had statistically significant improvements in their level of sexual desire, as measured by the eDiary. These findings were supported by a trend towards an increase in the FSFI desire domain. In addition, there was a statistically significant improvement in the level of distress associated with sexual dysfunction (as measured by the FSDS-R total score) as well as distress related to low sexual desire (FSDS-R Item 13) which is the second key parameter for the diagnosis of HSDD. A numerical increase in the number of SSEs compared to placebo supports the efficacy of flibanserin in pre-menopausal women suffering with HSDD.

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. Our competitors may also develop drugs or surgical approaches that are more effective, more useful and less costly than ours and may also be more successful in manufacturing and marketing their products. In addition, our competitors may be more effective in commercializing their products. We currently outsource our manufacturing and therefore rely on third parties for that competitive expertise. There can be no assurance that we will be able to develop or contract for these capabilities on acceptable economic terms, or at all.

If our raw material supplier fails to supply us with the active pharmaceutical ingredients, or APIs, 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 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. Currently, we only have a manufacturing agreement with Chinoin 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. During the second quarter of 2009 a portion of our existing inventory of alprostadil exceeded its shelf life and is no longer usable in the manufacturing of MUSE. We do not expect the loss of this material to impede our ability to meet the demand for MUSE.

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.

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In addition, we currently do not have supply agreements in place for phentermine or topiramate, the APIs used in our investigational product candidate, Qnexa. Nor do we have a supply agreement for the commercial manufacture of Qnexa, if approved. 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 prior 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., or E-Beam, and Beam One, LLC, or Beam One, for the sterilization of MUSE. Although both companies are approved for the sterilization of MUSE, E- Beam is not currently an operational facility. If E-Beam is unable to become operational or interruptions in MUSE sterilization services occur for any reason, including a decision by E-Beam or Beam One to discontinue providing these 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 alprostadil and an interruption to this supply could harm our business.

We rely on a single manufacturing company, Chinoin Pharmaceutical and Chemical Works Private Co., Ltd., in Hungary, or Chinoin, for our supply of alprostadil. We currently have a written manufacturing agreement with Chinoin to supply alprostadil through 2011. There is no assurance that we will be able to re-establish a manufacturing agreement with NeraPharm, s.r.o., in the Czech Republic, or NeraPharm, an alternative supplier from whom we previously purchased alprostadil, or

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that we will be able to identify and qualify additional sources of alprostadil. We are required to receive FDA approval for new suppliers before using a new supply source. Until we secure a new manufacturing agreement with NeraPharm or qualify additional sources of alprostadil, we are entirely dependent upon Chinoin. If interruptions in this supply occur for any reason, including a decision by Chinoin to discontinue manufacturing, labor disputes or a failure of Chinoin 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 alprostadil could have a material adverse effect on our business, financial condition or results of operations.

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

We rely on a single injection molding company, Medegen Medical Products, LLC, or 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, Flint Hills Resources. Orders to Medegen are made on a periodic basis with purchase orders. We do not have a written agreement with Medegen for the supply of the plastic applicator components. There can be no assurance that we will be able to obtain components from Medegen or to identify and qualify additional sources of 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 prior to using supplies from a new vendor. 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, a failure of Medegen to follow regulations or the inability of Medegen to secure a new source of resin, 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.

We were notified by Medegen that the Flint Hills Resources facility in Texas discontinued manufacturing the resin required for MUSE plastic components in early 2009. The Flint Hills Resources facility in Texas has been the single source used by Medegen for the MUSE plastic components. Medegen has some inventory of resin from the Flint Hills Texas facility. We currently have in inventory plastic components from Medegen to support the projected MUSE production requirements through the second quarter of 2011. Medegen has identified a new source of resin and re-qualified all of our molds. There is no assurance the manufacturing molds will continue to pass inspection and be available for future use. The inability to utilize these molds and the inability of Medegen to secure an alternative resin supplier 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 laminated foil components for MUSE and an interruption to this supply source could harm our business.

We rely on a single lamination company, Glenroy, Inc., or Glenroy, for our supply of laminated foil. In turn, Glenroy obtains its supply of resin, a key ingredient of the laminated foil, from a single source, Flint Hills Resources in Texas. Orders to Glenroy are made on a periodic basis with purchase orders. We do not have a written agreement with Glenroy for the supply of the laminated foil. If we are unable to obtain foil from Glenroy for any reason, or if we are unable to identify and qualify additional sources of foil, or additional foil produced using a new resin, we could experience interruptions in supply, which would harm our business. We are required to receive FDA approval for new suppliers prior to using supplies from a new vendor. Until we secure and qualify additional sources of laminated foil, we are entirely dependent upon Glenroy. If interruptions in this supply occur for any reason, including a decision by Glenroy to discontinue manufacturing, labor disputes, a failure of Glenroy to follow regulations or the inability of Glenroy to secure an alternative resin supplier, the

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manufacture and marketing of MUSE and other potential products could be delayed or prevented. An extended interruption in the supply of laminated foil could have a material adverse effect on our business, financial condition or results of operations.

We were notified by Glenroy that the Flint Hills Resources facility located in Texas discontinued manufacturing the resin required for laminated foil in early 2009. The Flint Hills Resources Texas facility has been the single source used by Glenroy for the MUSE laminated foil. We currently have in inventory laminated foil from Glenroy to support the projected MUSE production requirements through the second quarter of 2011. Glenroy has identified a new source of resin and is in the process of qualifying the vendor. Our inability to secure a qualified source for additional laminated foil and/or Glenroy's inability to secure the necessary resin would have a material adverse effect on our business, financial condition and results of operations.

Previously, there was a global shortage of Acetonitrile, a solvent that is required in the testing and verification of MUSE, and an interruption to this supply could harm our business.

In early 2009, we were notified by several of our laboratory supply vendors of a global shortage of Acetonitrile, a solvent that is required in the testing and verification of MUSE. Currently, there is no issue with securing Acetonitrile and we believe the global shortage has ended. However, our inability to secure Acetonitrile in the future would have a material adverse effect on our business, financial condition and results of operations.

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

We own two buildings with a total combined 90,000 square feet in Lakewood, New Jersey. This facility is used for our MUSE 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, competitive products, 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.

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We depend upon consultants and outside contractors extensively in important roles within our company.

We outsource many key functions of our business and therefore rely on a substantial number of consultants, and we will need to be able to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. However, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials or other development activities may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for our investigational product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

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 or delays in the development of our product candidates .

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 design, execution and analysis, 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.

Allegations of discrimination, wrongful termination or other employment matters, regardless of merit, could negatively affect our operations by causing us to allocate additional monetary and personnel resources to these issues.

In the ordinary course of business we may become involved in lawsuits and subject to various claims from current and former employees including wrongful termination, sexual discrimination, retaliation, hostile work environment and other employment matters. We are currently a party to a lawsuit involving a former employee. We have also been named as a potential defendant in a complaint filed by a former employee. We have investigated each of the claims and believe the allegations have no merit and that we have meritorious defenses to any such allegations. Due to the current economic downturn, employees may be more likely to file employment-related claims. Employment-related claims also appear more likely following a poor performance review. Although there may be no merit to such claims or legal matters, we may be required to allocate additional monetary and personnel resources to defend against these type of allegations.

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.

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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. These proposals include measures that would limit or prohibit payments for some medical treatments or subject the pricing of drugs to government control and regulations changing the rebates we are required to provide. These changes could impact our ability to maximize revenues in the Federal marketplace. In addition, Congress currently is considering health care reform legislation that could affect the prices of MUSE or our investigational product candidates under certain health care programs. These proposals include expanding the 340B drug pricing program to allow additional types of health care providers to purchase drugs at significant discounts and to require those discounts on inpatient drugs as well, increasing the minimum Medicaid drug rebate percentage, expanding Medicaid rebate liability to drugs purchased under Medicaid managed care contracts, increasing the Medicaid rebate on new formulations of existing drugs, and requiring Medicaid rebates to be paid on drugs provided to certain enrollees in the Medicare Part D prescription drug benefit. 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 other countries where we currently or intend to market our product.

We expect to experience pricing pressures in connection with the sale of MUSE and our investigational product candidates, if approved, due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals. If we fail to successfully secure and maintain reimbursement coverage for MUSE or our investigational product candidates or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed. Congress has recently been discussing and may be in the process of enacting healthcare reform, which, if enacted, could adversely affect the pharmaceutical industry as a whole, and therefore could have a material adverse effect on our business.

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Both of the active ingredients in Qnexa, phentermine and topiramate are available as generics. 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 or any other indication, if approved, from third party payors or the United States government. Furthermore, there can be no assurance that healthcare providers would not actively seek to provide patients with 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 candidate, 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.

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

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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, safety monitoring company and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, accidents, 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 product development efforts and adversely affect results.

Our MUSE 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 ongoing 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. In addition, our offices are located in the San Francisco Bay

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Area, near known earthquake fault zones and are therefore vulnerable to damage from earthquakes. In October 1989, a major earthquake in our area caused significant property damage and a number of fatalities. We are also vulnerable to damage from other disasters such as power loss, fire, floods and similar events. If a significant disaster occurs, our ability to continue our operations could be seriously impaired and we may not have adequate insurance to cover any resulting losses. Any significant unrecoverable losses could seriously impair our operations and financial conditions.

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

We believe the Supreme Court ruling in *KSR International Co. vs. Teleflex, Inc.* raised 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 ruling will have on our current or future patents and patent applications. If we are unable to defend the patents currently issued on our commercial product and investigational product 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 and morbidities related to obesity including sleep apena and diabetes and male and female sexual health among other products. Qnexa is our investigational product candidate involving low doses of phentermine and topiramate. On June 6, 2006, the initial United States patent 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 2020. In January 2009, the European Patent Office granted European patent No. 1,187,603, which broadly covers Qnexa and its use as a weight loss treatment. The patent extends the intellectual property protection of Qnexa beyond the already issued patents in the United States and abroad. 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 U.S. Patent No. 7,056,890 B2. On March 9, 2010, U.S. Patent No. 7,674,776 issued with method, composition, and dosage form claims, including claims drawn to a method for treating Syndrome X, a common multisymptomatic disorder often found in obese patients, and to a method for treating side effects of obesity such as sleep apnea. On February 9, 2010, U.S. Patent No. 7,659,256 issued significantly broadenening both the method and composition-of-matter protection afforded Qnexa by

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our initial U.S. Patent No. 7,056,890 B2. On June 30, 2009, U.S. Patent No. 7,553,818 was issued drawn to a method for effecting weight loss by co-administration of varying doses of phentermine and topiramate. This patent also expands on the initial coverage provided by our U.S. Patent No. 7,056,890 B2. Each of these U.S. patents for Qnexa expires in 2020. The primary focus of the patent applications is on combination therapy using a sympathomimetic agent (such as phentermine) and an anticonvulsant (such as topiramate) for the treatment of obesity and other related disorders. We are aware of issued patents for the use of topiramate alone or in combination for obesity. We have worked closely with our patent counsel to put together a cogent patent strategy and are building a strong patent portfolio in an attempt to obtain exclusivity over the life of the patents.

The procedures for obtaining a patent in the United States and in most foreign countries are complex. These procedures require an analysis of the scientific technology related to the invention and many sophisticated legal issues. Obtaining patent rights outside the United States often requires the translation of highly technical documents and an improper translation could lead to the loss of, or otherwise jeopardize, the patent protection of our inventions. Ensuring adequate quality of translators and foreign patent attorneys is often very challenging. Consequently, the process for having our pending patent applications issue as patents will be difficult, complex and time consuming. We do not know when, or if, we will obtain additional patents for our technologies, or if the scope of the patents obtained will be sufficient to protect our product candidates, or be considered sufficient by parties reviewing our patent positions pursuant to a potential licensing or financing transaction.

In addition, other entities may challenge the validity or enforceability of our patents and patent applications in litigation or administrative proceedings. Even the issuance of a patent is not conclusive as to its validity or enforceability. We cannot make assurances as to how much protection, if any, will be given to our patents if we attempt to enforce them or they are challenged. It is possible that a competitor or a generic pharmaceutical provider may successfully challenge our patents and those challenges may result in reduction or elimination of our patents' coverage.

The USPTO has over the last few years tried to enact and/or has proposed changes in the rules governing (i) the duties of patent applicants to disclose information that relates to their applications, (ii) the ability of patent applicants to file unlimited numbers of patent applications and patent claims that concern closely related inventions and/or different aspects of the same invention, and (iii) the manner in which the USPTO will decide whether to require patent applicants to separate closely related inventions into separate patent applications. Some of these rule changes are being challenged in the courts. It is unclear which of these rule changes, if any, will be allowed by the courts and which of them will continue to be pursued. In addition, the United States Congress is considering changes to federal patent laws on several issues including, but not limited to: (i) the information can be used to determine whether an invention is not new and, therefore, not patentable, (ii) the limits on the independent administrative rulemaking authority of the USPTO, (iii) the duties of patent applicants to disclose information that relates to their applications, (iv) whether, under what circumstances, and how many times a third party can challenge an issued United States patent before the USPTO, (v) whether and under what circumstances patent applicants can lose their ability to enforce their patents in the United States based on their failure to disclose certain information relating to their inventions, and (vi) how damages for patent infringement may be reduced based by a number of factors, including the similarity of a patented invention to preexisting technologies.

We believe that the United States is by far the largest single market for pharmaceuticals in the world. Because of the critical nature of patent rights to the pharmaceutical industry, changes in United States patent rules and laws could have a profound effect on our future profits. Several of the patent rule and law changes that are being considered could significantly weaken patent protections in the United States in general. They may also have a disproportionately large negative impact on the biotechnology and pharmaceutical industries in particular, as well as tilt the balance of market control and distribution of profits between the manufacturers of patented pharmaceutical products and the

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manufacturers of generic pharmaceutical products towards the generics manufacturers. At present there is considerable uncertainty as to which patent rules and laws will be changed and whether changes to the patent rules will ultimately be enforced or struck down by the courts.

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

We seek to protect our confidential information by entering into confidentiality agreements with employees, collaborators, CROs, consultants and potential investors. Nevertheless, employees, collaborators, consultants or potential investors 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.

A dispute regarding the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be costly and result in delays or termination of our future research, development, manufacturing and sales activities.

Our commercial success also depends upon our ability to develop and manufacture our product candidates and market and sell our drugs and conduct our research and development activities without infringing or misappropriating the proprietary rights of others. There are many patents and patent applications filed, and that may be filed, by others relating to drug discovery and development programs that could be determined to be similar, identical or superior to ours or our licensors or collaborators. We may be exposed to future litigation by others based on claims that our product candidates, technologies or activities infringe the intellectual property rights of others. Numerous United States and foreign issued patents and pending patent applications owned by others also exist in the therapeutic areas in, and for the therapeutic targets for, which we are developing drugs. There are also numerous issued patents and patent applications to chemical compounds or synthetic processes that may be necessary or useful to use in our research, development, manufacturing or commercialization activities. These could materially affect our ability to develop our product candidates or manufacture, import or sell drugs, and our activities, or those of our licensors or collaborators, could be determined to infringe these patents. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our investigational product candidates or technologies may infringe. There also may be existing patents, of which we are not aware, that our investigational product candidates or technologies may infringe. Further, there may be issued patents or pending patent applications in fields relevant to our business, of which we are or may become aware, that we believe (i) are invalid or we do not infringe; (ii) relate to immaterial portions of our overall drug discovery, development, manufacturing and commercialization efforts; or (iii) in the case of pending patent applications, the resulting patent would not be granted or, if granted, would not likely be enforced in a manner that would materially impact such efforts. We cannot assure you that others holding any of these patents or patent applications will not assert infringement claims against us for damages or seek to enjoin our activities. We also cannot assure you that, in the event of litigation, we will be able to successfully assert any belief we may have as to non-infringement, invalidity or immateriality, or that any infringement claims will be resolved in our favor.

In addition, others may infringe or misappropriate our proprietary rights, and we may have to institute costly legal action to protect our intellectual property rights. We may not be able to afford the costs of enforcing or defending our intellectual property rights against others.

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There could also be significant litigation and other administrative proceedings in our industry that affect us regarding patent and other intellectual property rights. Any legal action or administrative action against us, or our collaborators, claiming damages or seeking to enjoin commercial activities relating to our drug discovery, development, manufacturing and commercialization activities could:

require us, or our collaborators, to obtain a license to continue to use, manufacture or market the affected drugs, methods or processes, which may not be available on commercially reasonable terms, if at all;

prevent us from importing, making, using, selling or offering to sell the subject matter claimed in patents held by others and subject us to potential liability for damages;

consume a substantial portion of our managerial, scientific and financial resources; or

be costly, regardless of the outcome.

Furthermore, because of the substantial amount of pre-trial document and witness discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the trading price of our common stock.

We cannot protect our intellectual property rights throughout the world.

Filing, prosecuting, defending and enforcing patents on all of our drug discovery technologies and all of our potential investigational product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies to develop their own drugs in jurisdictions where we have not obtained patent protection. These drugs may compete with our investigational product candidates and may not be covered by any of our patent claims or other intellectual property rights. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, the patent owner has failed to "work" the invention in that country or the third party has patented improvements). In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. Compulsory licensing of life-saving drugs is also becoming increasingly popular in developing countries either through direct legislation or international initiatives. Such compulsory licenses could be extended to include some of our product candidates, which could limit our potential revenue opportunities. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patents and other intellectual property protection, particularly those relating to biotechnology and/or pharmaceuticals, which makes it difficult for us to stop the infringement of our patents. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

We may face additional competition outside of the United States as a result of a lack of patent enforcement in foreign countries and off-label use of other dosage forms of the generic components in our investigational product candidates.

While we have filed patent applications in many countries outside the United States, and have obtained some patent coverage for certain of our product candidates in certain foreign countries, we do not currently have widespread patent protection for Qnexa outside the United States and have no

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protection in many foreign jurisdictions. Even if international patent applications ultimately issue or receive approval, it is likely that the scope of protection provided by such patents will be different from, and possibly less than, the scope provided by our corresponding U.S. patents. The success of our international market opportunity is dependent upon the enforcement of patent rights in various other countries. A number of countries in which we have filed or intend to file patent applications have a history of weak enforcement and/or compulsory licensing of intellectual property rights. Even if we have patents issued in these jurisdictions, there can be no assurance that our patent rights will be sufficient to prevent generic competition or unauthorized use.

We may face competition from the off-label use of other dosage forms of the generic components in our product candidates. In addition, others may attempt to commercialize our product candidate combinations in countries or other markets where we do not have patent protection for all of our product candidates. In particular, it is possible that patients will seek to acquire the generic IR components of our product candidate Qnexa (phentermine and topiramate). The off-label use of the generic IR components in the United States or the importation of the generic IR components from foreign markets could adversely affect the commercial potential for our product candidates and adversely affect our overall business and financial results.

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 or overtly threatened 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 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.

Our failure to successfully acquire, develop and market additional investigational product candidates or approved products would impair our ability to grow.

As part of our growth strategy, we may acquire, in-license, develop and/or market additional products and investigational product candidates. Because our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select and acquire promising pharmaceutical product candidates and products.

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The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any products that we develop or approved products that we may acquire will be commercialized profitably or achieve market acceptance.

We may participate in new partnerships and other strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time we consider strategic transactions, such as out-licensing or in-licensing of compounds or technologies, acquisitions of companies and asset purchases. Additional potential transactions we may consider include a variety of different business arrangements, including strategic partnerships, joint ventures, spin-offs, restructurings, divestitures, business combinations and investments. In addition, another entity may pursue us as an acquisition target. Any such transactions may require us to incur non-recurring or other charges, may increase our near and long-term expenditures and may pose significant integration challenges, require additional expertise or disrupt our management or business, which could harm our operations and financial results.

As part of an effort to enter into significant transactions, we conduct business, legal and financial due diligence with the goal of identifying and evaluating material risks involved in the transaction. Despite our efforts, we ultimately may be unsuccessful in ascertaining or evaluating all such risks and, as a result, might not realize the intended advantages of the transaction. If we fail to realize the expected benefits from any transaction we may consummate, whether as a result of unidentified risks, integration difficulties, regulatory setbacks or other events, our business, results of operations and financial condition could be adversely affected.

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Setbacks and consolidation in the pharmaceutical and biotechnology industries, and our or our collaborators' inability to obtain third-party coverage and adequate reimbursement, could make partnering more difficult and diminish our revenues.

Setbacks in the pharmaceutical and biotechnology industries, such as those caused by safety concerns relating to high-profile drugs like Avandia, Vioxx and Celebrex, or drug candidates, as well as competition from generic drugs, litigation, and industry consolidation, may have an adverse effect on us. For example, pharmaceutical companies may be less willing to enter into new collaborations or continue existing collaborations if they are integrating a new operation as a result of a merger or acquisition or if their therapeutic areas of focus change following a merger. Moreover, our and our collaborators' ability to commercialize any of our drugs that may be approved will depend in part on government regulation and the availability of coverage and adequate reimbursement from third-party payers, including private health insurers and government payers, such as the Medicaid and Medicare programs, increases in government-run, single-payer health insurance plans and compulsory licenses of drugs. Government and third-party payers are increasingly attempting to contain healthcare costs by limiting coverage and reimbursement levels for new drugs. Given the continuing discussion regarding the cost of healthcare, managed care, universal healthcare coverage and other healthcare issues, we cannot predict with certainty what additional healthcare initiatives, if any, will be implemented or the effect any future legislation or regulation will have on our business. These efforts may limit our commercial opportunities by reducing the amount a potential collaborator is willing to pay to license our programs or drug candidates in the future due to a reduction in the potential revenues from drug sales. Moreover, legislation and regulations affecting the pricing of pharmaceuticals may change before regulatory agencies approve our product candidates for marketing. Adoption of such legislation and regulations could further limit pricing approvals for, and reimbursement of, drugs. A government or third-party payer decision not to approve pricing for, or provide adequate coverage and reimbursements of, our product candidates could limit market acceptance of such drugs.

We will need to obtain FDA approval of our proposed product names and any failure or delay associated with such approval may adversely impact our business.

Any name we intend to use for our investigational product candidates will require approval from the FDA, regardless of whether we have secured a formal trademark registration from the USPTO. The FDA typically conducts a rigorous review of proposed product names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims. If the FDA objects to one of our proposed product names, we will be required to adopt an alternative name for that investigational product candidate. If we adopt an alternative name, we would lose the benefit of our existing trademark applications and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA, which could cause delays that would adversely impact our business. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize 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, which would force us to delay, reduce or eliminate product development programs or commercialization efforts.

We expect that our existing capital resources combined with future anticipated cash flows will be sufficient to support our operating activities at least into 2011. However, we anticipate that we will be required to obtain additional financing to fund the development of our research and development

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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 studies 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, sublicenses and strategic alliances and the related costs including milestone payments;
- the costs involved in establishing a commercial operation and in launching a product without a partner;
- the cost of manufacturing and commercialization activities and arrangements;
- the results of operations;
- demand for MUSE;
- the potential forced purchase of the royalty streams we previously sold to Deerfield;
- the cost, timing and outcome of regulatory reviews;
- the rate of technological advances;
- ongoing determinations of the potential commercial success of our investigational product candidates under development;
- the state of the economy and financing environment;
- the level of resources devoted to sales and marketing capabilities;

the regulatory approval environment and regulatory hurdles for safety assessment for new product candidates;

the health care reimbursement system or the impact of healthcare reform, if any, imposed by the new administration; and

the activities of competitors.

Future capital requirements will also depend on the extent to which we acquire or invest in additional complementary businesses, products and technologies. We currently have no commitments or agreements relating to any of these types of transactions.

We have substantially less money than we need to develop our compounds into commercially available drugs. It takes many years and potentially hundreds of millions of dollars to successfully develop a pre-clinical or early clinical compound into an approved and commercially marketed drug, and our efforts may not result in any additional marketed drugs, aside from MUSE. We may need additional funds or a partner to bring our most advanced investigational product candidate, Qnexa, to market, if ever.

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 investigational product candidates under development or, if successfully developed or approved, that our products will generate revenues sufficient to enable us to earn a profit. If we are unable to obtain additional capital, management may be required to

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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. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our development programs or our commercialization efforts.

Raising additional funds by issuing securities will cause dilution to existing stockholders and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership will be diluted. We have financed our operations, and we expect to continue to finance our operations, primarily by issuing and selling our common stock. In light of our need for additional financing, we may issue additional shares of common stock that could dilute your ownership in our company and may include terms that give new investors rights that are superior to yours. For example, on September 23, 2009, we sold 10,350,000 shares of our common stock through an underwriting agreement at a price of $10.50 per share resulting in gross proceeds to us of $108.7 million. Moreover, any issuances by us of equity securities may be at or below the prevailing market price of our common stock and in any event may have a dilutive impact on your ownership interest, which could cause the market price of our common stock to decline.

We may also raise additional funds through the incurrence of debt, and the holders of any debt we may issue would have rights superior to your rights in the event we are not successful and are forced to seek the protection of bankruptcy laws. In addition, debt financing typically contains covenants that restrict operating activities. Our loan with Crown Bank, N.A., is secured by the land and buildings, among other assets, located at our principal manufacturing facility and a $700,000 Certificate of Deposit held by Crown. Additionally, our intellectual property and all of the accounts receivable, inventory and equipment arising out of or relating to MUSE and avanafil are collateral for the Deerfield transaction, which also contains a variety of covenants, including requiring us to use commercially reasonable efforts to preserve our intellectual property, manufacture, promote and sell MUSE, and develop avanafil. Any future debt financing we enter into may involve similar or more onerous covenants that restrict our operations.

If we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our current product candidates, potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. If adequate funds are not available, our ability to achieve profitability or to respond to competitive pressures would be significantly limited and we may be required to delay, significantly curtail or eliminate the development of one or more of our product candidates.

The current global economic environment poses severe challenges to our business strategy, which relies on access to capital from the markets and our collaborators.

The global economy, including credit markets and the financial services industry, has been experiencing a period of substantial turmoil and uncertainty. These conditions have generally made equity and debt financing more difficult to obtain, and may negatively impact our ability to complete financing transactions. The duration and severity of these conditions is uncertain, as is the extent to which they may adversely affect our business and the business of current and prospective collaborators and vendors. If the global economy does not improve or worsens, we may be unable to secure additional funding to sustain our operations or to find suitable partners to advance our internal programs, even if we receive positive results from our research and development or business development efforts.

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Our investment in the clinical development and manufacture of a commercial supply of Qnexa may not result in any benefit to us if Qnexa is not approved for commercial sale.

We have invested significant resources in the clinical development of Qnexa. We are planning for and investing significant resources now in preparation for application for marketing approval and planning for manufacture of commercial supply and sales and marketing. Our engagement in these resource-intensive activities puts significant investment at risk if we do not obtain regulatory approval and successfully commercialize Qnexa in the United States. There is no assurance that our development of Qnexa will lead successfully to regulatory approval, or that obtaining regulatory approval will lead to commercial success. If Qnexa is not approved for commercial sale or if its development is delayed for any reason, our full investment in Qnexa may be at risk, we may face significant costs to dispose of unusable inventory, and our business and financial condition would be materially adversely affected.

The investment of our cash balance and our available-for-sale securities are subject to risks which may cause losses and affect the liquidity of these investments.

At December 31, 2009, we had $40.8 million in cash and cash equivalents and $166.2 million in available-for-sale securities. While at December 31, 2009 our excess cash balances were invested in money market and U.S. Treasury securities, our investment policy as approved by the Board of Directors, also provides for investments in debt securities of U.S. government agencies, corporate debt securities and asset-backed securities. The investment policy has the primary investment objectives of preservation of principal; 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. An investment in money market mutual funds is not insured or guaranteed by the Federal Deposit Insurance Corporation or any other government agency. Although money market mutual funds seek to preserve the value of the investment at $1 per share, it is possible to lose money by investing in money market mutual funds.

The holders of our stock and other securities may take actions that are contrary to your interests, including selling their stock.

A small number of our stockholders hold a significant amount of our outstanding stock. These stockholders may support competing transactions and have interests that are different from yours. Sales of a large number of shares of our stock by these large stockholders or other stockholders within a short period of time could adversely affect our stock price.

Capital appreciation, if any, of our common stock will be your sole source of gain on an investment in our stock for the foreseeable future.

We have paid no cash dividends on any of our classes of capital stock to date and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We may become involved in securities class action litigation that could divert management's attention and harm our business.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of pharmaceutical companies. These broad market fluctuations may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical

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companies have experienced significant stock price volatility in recent years. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business.

We have an accumulated deficit of $234.1 million as of December 31, 2009 and we may continue to incur substantial operating losses for the future.

We have generated a cumulative net loss of $234.1 million for the period from our inception through December 31, 2009, and we anticipate losses in future years due to continued 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, 2009, we had approximately $170.5 million of net operating loss, or NOL, carryforwards with which to offset our future taxable income for federal and state income tax reporting purposes. We used $121.2 million federal and $32.2 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 of approximately $2.1 million pursuant to Section 736(d)(1)(C) of the Federal Food, Drug and Cosmetic Act, or FDC Act from the FDA for product and establishment fees paid in 2007, 2008 and 2009 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 collected $1.3 million from the FDA. We believe that we will collect these remaining 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 remaining 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.

In addition, we develop, test and manufacture drugs that are used by humans. We face an inherent risk of product liability exposure related to the testing of our product candidates in clinical trials. An individual may bring a liability claim against us if one of our product candidates or drugs causes, or merely appears to have caused, an injury. If we cannot successfully defend ourselves against a product

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liability claim, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our drug;
- injury to our reputation;
- withdrawal of clinical trial patients;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- loss of revenues; and
- the inability to commercialize our product candidates.

Damages awarded in a product liability action could be substantial and could have a negative impact on our financial condition. Whether or not we were ultimately successful in product liability litigation, such litigation would consume substantial amounts of our financial and managerial resources, and might result in adverse publicity, all of which would impair our business.

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 FDA review of our NDA for Qnexa for obesity;
- results within the clinical trial programs for Qnexa and avanafil or other results or decisions affecting the development of our investigational product candidates;
- announcements of technological innovations or new products by us or our competitors;
- announcements of Phase 3 data of other anti-obesity compounds in development;
- announcements by licensors of our technology;
- the outcome of the Financial Industry Regulatory Authority, or FINRA, routine review of trading surrounding the September 9, 2009 announcement of positive results from the EQUIP (OB-302) and CONQUER (OB-303) studies

evaluating the safety and efficacy of Qnexa;

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;

sales by insiders;

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 relative to those of our competitors;

deviations in our operating results from the estimates of securities analysts or other analyst comments;

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discussions of us or our stock price by the financial and scientific press and in online investor communities;

developments or disputes concerning patents or other proprietary rights;

licensing, 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 other 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 or recruit key employees, all of whom have been or will be granted stock options as an important part of their compensation packages.

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. 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 stock price could decline significantly based on the results and timing of clinical trials and pre-clinical studies of, and decisions affecting, our most advanced product candidates.

The results and timing of clinical trials and pre-clinical studies can affect our stock price. Pre-clinical studies include experiments performed in test tubes, in animals, or in cells or tissues from humans or animals. These studies include all drug studies except those conducted in human patients, and may occur before or after initiation of clinical trials for a particular compound. Results of clinical trials and pre-clinical studies of Qnexa, avanafil or our other product candidates may not be viewed favorably by us or third parties, including investors, analysts, potential collaborators, the academic and medical community, and regulators. The same may be true of how we design the development programs of our most advanced product candidates and regulatory decisions (including by us or regulatory authorities) affecting those development programs. Biotechnology and biopharmaceutical company stock prices have declined significantly when such results and decisions were unfavorable or perceived negatively or when a drug candidate did not otherwise meet expectations.

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 our company and may make some transactions more difficult or impossible to complete without the support of these stockholders.

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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 product candidates, timing of milestone payments, 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.

Future sales of our common stock may depress our stock price.

Sales of our stock by our executive officers and directors, or the perception that such sales may occur, could adversely affect the market price of our stock. We have also registered all common stock that we may issue under our employee benefits plans. As a result, these shares can be freely sold in the public market upon issuance, subject to restrictions under the securities laws. Some of our executive officers have adopted trading plans under SEC Rule 10b5-1 to dispose of a portion of their stock. Any of our executive officers or directors may adopt such trading plans in the future. If any of these events cause a large number of our shares to be sold in the public market, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

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

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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, *Share-Based Payment*, as codified in FASB ASC topic 718, *Compensation Stock Compensation,* or ASC 718, 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 significant obligations and uncertainty of compliance 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' review and 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.

Risks Relating to our Transaction with Deerfield Management Company, L.P. and Affiliates

Simultaneously with the sale of securities to funds affiliated with Deerfield or the Deerfield Affiliates, on April 15, 2008, we entered into the Funding and Royalty Agreement, or FARA, an Option and Put Agreement, or the OPA, and a Security Agreement with the Deerfield Sub, a newly incorporated subsidiary of Deerfield. The FARA and OPA were amended on March 16, 2009. We also entered into a Security Agreement with the shareholders of the Deerfield Sub. Under the terms of the FARA, the Deerfield Sub made $3.3 million payments to us in April, September and December 2008 and February, June and September 2009, constituting all of the required payments under the FARA. As part of the funding arrangement, we have agreed to continue our development of avanafil, our oral PDE5i for the Deerfield Sub. The FARA also provides that we will pay royalties on the net MUSE sales on a quarterly basis. Under the FARA, the royalty payments continue for 10 years. There are no

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minimum royalties due; however, we have agreed to maintain the promotion of MUSE consistent with our prior efforts. The OPA provides that we may purchase all the outstanding shares of the Deerfield Sub, thus ending any further royalty payments. The OPA allows for the purchase of the shares of the Deerfield Sub by us for $23 million on a net basis through the first three years and $26 million net from the third to fourth year. The purchase amounts are net of the $2 million premium paid to Deerfield Affiliates for the call option. We have no ability to repurchase the shares after the fourth year. The OPA provides that Deerfield Affiliates can force a sale of all the shares of the Deerfield Sub to us beginning after the third year through the tenth year. The timing on the sale of the shares could be accelerated under certain conditions including a change-in-control, sale of MUSE or avanafil, sale of major assets and the sale of securities in a transaction or a series of related transactions by us that exceed 20% of our outstanding common stock at the date the OPA was signed if at the time of the sale our market capitalization is below $300 million, (each, a Major Transaction). Under these conditions, the cost of the shares of the Deerfield Sub would be $23 million before the third anniversary and $26 million from the third to tenth anniversary. The sale of the shares of the Deerfield Sub could also accelerate if our cash, cash equivalents and available for sale securities falls below $15 million or our market capitalization falls below $50 million. As security for the payment of royalties we have pledged certain unencumbered MUSE and avanafil assets to the Deerfield Sub. As security for the payment under the forced purchase of shares of the Deerfield Sub to us, we have pledged certain unencumbered MUSE and avanafil assets to Deerfield Affiliates.

Under the FARA, the payment of the royalties may result in the MUSE operations being unprofitable. If we fail to exercise the option to repurchase the shares of the Deerfield Sub or if Deerfield Affiliates does not force us to purchase the shares of the Deerfield Sub, we will continue to pay royalties into 2018. We agreed to continue to promote MUSE at levels consistent with our current efforts. This requirement may force us to allocate resources that could be better utilized for other activities. If we decide to sell the MUSE business line or related assets, we will be forced to purchase the shares of the Deerfield Sub. The royalty payments and required commitment under the FARA may have an adverse effect on our cash flows, the market price of our common stock, our ability to raise money, financial position and results of operations. Under the OPA, the shareholders of the Deerfield Sub have agreed to indemnify us for certain liabilities related to the operations of the Deerfield Sub, if any. Should we incur any such liabilities and the shareholders of the Deerfield Sub fail to pay for such liabilities as part of the indemnity, we would have to reallocate our resources to paying such liabilities and incur further expenses to enforce our right to indemnification under the OPA.

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

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

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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 30-month lease for our corporate headquarters located in Mountain View, California. The 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 expired on July 31, 2009. On December 16, 2008, we entered into a first amendment to this lease. Under the terms of the amended lease, we will continue to lease the office space for our corporate headquarters for a two-year period commencing on August 1, 2009 and expiring on July 31, 2011. The base monthly rent is set at $1.64 per square foot or $23,000 per month. The amended lease allows us one option to extend the term of the lease for one year from the expiration of the lease. On November 12, 2009, we entered into a second amendment to this lease. The second amendment commenced on January 1, 2010, expires on July 31, 2011 and expands the leased space. The base rent for the expansion space is set at $2.25 per square foot or $8,500 per month. The option to extend the term of the amended lease for one year from the expiration of the lease applies to this expansion space as well.

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

The Company and Acrux Limited through its wholly owned subsidiary FemPharm Pty Ltd., or Acrux, are parties to the Testosterone Development and Commercialization Agreement dated February 12, 2004, or the Testosterone Agreement. The Testosterone Agreement covers the Company's investigational product candidate, Luramist, which is licensed from Acrux under the Testosterone Agreement. On November 5, 2007, Acrux made a demand for arbitration under the Testosterone Agreement regarding certain claims related to Luramist. Acrux's demand sought a reversion of all rights assigned to the Company related to Luramist, monetary damages and the payment of a milestone payment for Luramist under the Testosterone Agreement and declaratory relief. The Company asserted counterclaims against Acrux in the arbitration and sought the enforcement of the Company's rights under the Testosterone Agreement. The arbitration hearing concluded on January 23, 2009, and on April 6, 2009 the panel of arbitrators, or the Panel, issued its Interim Arbitration Award finding in favor of the Company that it was in compliance with the Testosterone Agreement and denying all of the relief sought by Acrux in its demand. The Panel found that the Company was not in breach of the Luramist license agreement and that the Company has used diligent, commercially reasonable efforts to develop Luramist. The Panel further ruled in favor of the Company on its counter claim that Acrux had breached the Luramist license agreement by failing to provide certain know-how and certain

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improvements in the formulation and delivery device for Luramist. The Panel denied the Acrux claim for additional milestone payments. The Panel has ordered Acrux to turn over certain information to the Company that was previously withheld in violation of the agreement by Acrux. After the parties failed to agree on a new Outside Date by which the Company is to commence its first Phase 3 trial for Luramist, the Panel reset the Outside Date of April 30, 2006 to April 1, 2010 to reflect the regulatory environment. Under the licensing agreement with Acrux a milestone payment of $1 million is due to Acrux upon the earlier of commencing a Phase 3 study for Luramist or the Outside Date, April 1, 2010. The milestone is due in six monthly installments of $166,667 for each month of delay in commencing Phase 3 after the Outside Date until the milestone is paid in full. There can be no assurance that Acrux would not continue to pursue legal action against us if we do not commence the first Phase 3 trial by the Outside Date.

In the ordinary course of business the Company may become involved in lawsuits and subject to various claims from current and former employees including wrongful termination, sexual discrimination, retaliation, hostile work environment and other employment matters. The Company is currently a party to a lawsuit involving a former employee. The Company has also been named as a potential defendant in a complaint filed by a former employee. The Company has investigated each of the claims and believes the allegations have no merit and that the Company has meritorious defenses to such charges. Due to the current economic downturn, employees may be more likely to file employment-related claims. Employment-related claims also may be more likely following a poor performance review. Although there may be no merit to such claims or legal matters, the Company may be required to allocate additional monetary and personnel resources to defend against these type of allegations. The Company believes the disposition of the current lawsuit and claims is not likely to have a material effect on our financial condition or liquidity.

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.

Item 4. ***Reserved.***

None.

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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
2009				
High	$ 5.55	$ 6.20	$ 12.88	$ 10.85
Low	2.72	3.61	5.55	7.07
2008				
High	$ 6.55	$ 7.84	$ 9.27	$ 8.16
Low	5.01	4.87	6.73	4.28

Stockholders

As of February 26, 2010, there were 80,738,994 shares of outstanding common stock that were held by 3,690 shareholders of record and no outstanding shares of preferred stock. On February 26, 2010, the last reported sales price of our common stock on the NASDAQ Global Market was $8.40 per share.

Dividends

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

Stock Options

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

Pursuant to our 2001 Stock Option Plan, or the 2001 Plan, which was approved by the stockholders at the annual meeting held on June 5, 2002, we may grant incentive or non-statutory stock options or stock purchase rights, or SPRs. The 2001 Plan allows us to grant incentive stock options to employees at not less than 100% of the fair market value of the stock (110% of fair market value for individuals who control more than 10% of our stock) at the date of grant, as determined by the Board of Directors. The 2001 Plan allows us to grant non-statutory stock options to employees, directors and consultants at a price to be determined by the Board of Directors. The term of the option is determined by the Board of Directors on the date of grant but shall not be longer than ten years. The 2001 Plan allows us to grant SPRs to employees and consultants. Sales of stock under SPRs are made pursuant to restricted stock purchase agreements containing provisions established by the Board of Directors. We have a right, but not the obligation, to repurchase the shares at the original sale price, which expires at a rate to be determined by the Board of Directors. As of December 31, 2009, no SPRs have been granted under the 2001 Plan.

On July 12, 2006, the Board of Directors adopted an amendment to the 2001 Plan to add the ability to issue Restricted Stock Units, or RSUs, under the 2001 Plan. In contrast to restricted stock awards, the RSUs represent an obligation of VIVUS to issue unrestricted shares of common stock or

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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 2009, 2008 and 2007 is provided in our consolidated financial statements. See Note 9: "Stock Option and Purchase Plans".

As of March 1, 2010, we had 25,619 stock options available for grant. Our ability to retain and recruit employees is dependent in significant part on our ability to issue performance-based and new hire stock option grants. Rather than seeking to amend our 2001 Plan that is set to expire in 2011, we will seek stockholder approval of a new stock option plan at the next annual meeting of stockholders. There can be no assurance that our stockholders will approve a new stock option plan and the lack of a new plan may have a significant negative impact on our ability to retain and recruit employees

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

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Stock Performance Graph

The following graph shows a comparison of total stockholder return for holders of our common stock from December 31, 2004, through December 31, 2009 compared with the NASDAQ Stock Market (U.S.) Index, RDG MicroCap Pharmaceutical Index and the RDG SmallCap 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, the stock represented by the RDG MicroCap Pharmaceutical Index, the stock represented by the RDG SmallCap 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 smallcap 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.

We are now including the RDG SmallCap Pharmaceutical index to the previously filed NASDAQ Stock Market (U.S.) and RDG SmallCap Pharmaceutical Index. We feel that the RDG SmallCap Pharmaceutical index provides a more appropriate comparison to peer companies in our sector with similar market capitalization. The RDG SmallCap Pharmaceutical index will be used in our performance graph going forward.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*

Among Vivus, Inc., The NASDAQ Composite Index,
The RDG MicroCap Pharmaceutical Index
And The RDG SmallCap Pharmaceutical Index

*

$100 invested on 12/31/04 in stock or index-including reinvestment of dividends. Fiscal year ending December 31.

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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				
	2009	**2008**	**2007**	**2006**	**2005**
Income Statement Data:					
Product revenue United States, net	$ 15,836	$ 14,974	$ 15,020	$ 14,280	$ 11,697
Product revenue International	2,347	3,076	4,332	2,377	2,794
License and other revenue	31,858	84,183	35,346	588	163
Total revenue	50,041	102,233	54,698	17,245	14,654
Operating expenses:					
Cost of goods sold and manufacturing expense	11,950	11,956	12,097	11,933	11,018
Research and development	71,075	76,996	26,681	13,316	17,005
Selling, general and administrative	21,033	18,904	17,374	14,579	11,916
Total operating expenses	104,058	107,856	56,152	39,828	39,939
Loss from operations	(54,017)	(5,623)	(1,454)	(22,583)	(25,285)
Interest income (expense)					
Interest income	2,019	4,439	4,703	1,573	1,094
Interest expense	(4,079)	(1,064)	(538)	(594)	(268)
Other-than-temporary loss on impaired securities	(654)	(7,689)			
Total interest income (expense)	(2,714)	(4,314)	4,165	979	826
Income (loss) before taxes	(56,731)	(9,937)	2,711	(21,604)	(24,459)
Benefit (provision) for income taxes	2,440	(3)	(5,095)	(20)	(25)
Net loss	$ (54,291)	$ (9,940)	$ (2,384)	$ (21,624)	$ (24,484)
Net loss per basic and diluted share	$ (0.75)	$ (0.16)	$ (0.04)	$ (0.45)	$ (0.57)
Shares used in per share computation	72,779	63,724	58,522	48,103	43,272
Balance Sheet Data (at year end):					
Working capital	$ 200,852	$ 134,880	$ 90,230	$ 57,564	$ 23,569
Total assets	$ 230,032	$ 207,622	$ 199,289	$ 78,214	$ 49,282
Long-term debt	$ 19,998	$ 11,177	$ 5,062	$ 11,488	$ 5,164

Accumulated deficit	$ (234,060)	$ (179,769)	$ (169,829)	$ (168,651)	$ (147,027)
Stockholders' equity	$ 186,726	$ 131,213	$ 60,167	$ 53,140	$ 26,601

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

Forward Looking Statement

This Management's Discussion and Analysis of Financial Conditions and Results of Operations and other parts of this Form 10-K contain "forward-looking" statements that involve risks and uncertainties. These statements typically may be identified by the use of forward-looking words or phrases such as "may," "will," "believe," "expect," "intend," "anticipate," "predict," "should," "planned," "continue," "likely," "opportunity," "estimated," and "potential," the negative use of these words or other similar words. 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 investigational product candidates and products; (7) risks related to noncompliance with United States Food and Drug Administration, or the FDA, regulations; (8) our ability to demonstrate through clinical testing the safety and effectiveness of our clinical investigational product candidates; (9) the timing of initiation and completion of clinical trials and submissions to the FDA; (10) uncertainties around the acceptance and ultimate approval of our New Drug Application for Qnexa® and any actions taken on behalf of regulatory authorities during the review process; (11) the volatility and liquidity of the financial markets; (12) our liquidity and capital resources; (13) our expected future revenues, operations and expenditures; and (14) other factors that are described from time to time in our periodic filings with the Securities and Exchange Commission, or the SEC, 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, 2009, 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 biopharmaceutical company, incorporated in 1991, dedicated to the development and commercialization of therapeutic products for large underserved markets. Currently, we have one drug that has been approved by the FDA, and several investigational product candidates in late stages of clinical development, and we are focused on market opportunities in obesity and related morbidities including sleep apnea and diabetes and sexual health. With respect to obesity, it is estimated that the potential worldwide pharmaceutical market for obesity could approach $5 billion annually. Annual sales of approved drugs for diabetes currently exceed $10 billion. There are currently no approved pharmaceutical therapies for sleep apnea; however, the sales of devices and related consumables used to treat sleep apnea exceed $2 billion annually. The indications targeted by our investigational sexual health product candidates each represent a projected market greater than $1 billion annually. We market MUSE®, a legacy product, as a prescription product for the treatment of erectile dysfunction in the United States and, together with our partners, internationally.

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Recent Developments

On March 1, 2010, we announced that the FDA had accepted for filing the New Drug Application, or NDA, for Qnexa for the treatment of obesity. Further, the FDA has set October 28, 2010 as the date whereby we may expect a response to the review of the NDA.

On January 11, 2010, we announced new data from an analysis of the recently completed Phase 3 study, REVIVE TA-301, of avanafil, an investigational product candidate for the treatment of erectile dysfunction, or ED. Patients who attempted intercourse within 15 minutes of dosing were successful 67%, 69% and 72% of the time on 50, 100 and 200 mg of avanafil, respectively, as compared to 29% of the patients on placebo ($p<0.05$). The previously-disclosed top-line results of the REVIVE study evaluating the safety and efficacy of avanafil in 646 patients showed that all three doses of avanafil met the FDA-defined primary study endpoints by demonstrating a statistically significant improvement in erectile function as measured by the Sexual Encounter Profile, or SEP and improvements in the International Index of Erectile Function, or IIEF score.

On January 7, 2010, we announced positive results from a Phase 2 study evaluating the safety and efficacy of Qnexa®, our investigational product, for the treatment of obstructive sleep apnea, or OSA. This study demonstrated statistically significant improvement in the apnea/hypopnea index, or AHI, which is a measure of the severity of sleep apnea, in patients with OSA treated with Qnexa for 28 weeks. Qnexa-treated patients on average had a 69% reduction in sleep apnea and hypopnea events as compared to patients on placebo. Qnexa-treated patients also experienced significant weight loss, improvements in blood pressure, and increased blood oxygen saturation during overnight polysomnography (sleep lab study). OSA is a sleep-related breathing disorder that involves a decrease or complete cessation in airflow despite an ongoing effort to breathe. OSA is associated with an increased risk of hypertension, diabetes, stroke, myocardial infarction, sudden cardiac death and all-cause mortality. It has been estimated that approximately 18 million Americans have sleep apnea, and currently there in no medication approved by the FDA for the treatment of OSA.

On December 29, 2009, we announced that an NDA had been submitted to the FDA seeking approval of Qnexa for the treatment of obesity, including weight loss and maintenance of weight loss, in patients who are obese or overweight with co-morbidities such as hypertension, type 2 diabetes, dyslipidemia or central adiposity. Qnexa is our proprietary oral investigational product candidate which incorporates low doses of active ingredients from two previously approved products, phentermine and topiramate. We have previously completed the Special Protocol Assessment, or SPA, process and have agreement with the FDA regarding key elements of the pivotal Phase 3 protocols (OB-301 and OB-303) of Qnexa for the treatment of obesity and weight-related co-morbidities.

On November 18, 2009, we announced positive results from REVIVE (TA-301), a Phase 3 pivotal study evaluating the safety and efficacy of avanafil, our investigational product candidate for the treatment of erectile dysfunction, or ED, in 646 patients. The REVIVE study met all primary endpoints across the three doses studied by demonstrating statistically significant improvement in erectile function as measured by the SEP and improvements in the IIEF score. The pivotal study, conducted under an SPA with the FDA, also demonstrated successful intercourse in 30 minutes or less after dosing, and a favorable side-effect and safety profile.

On September 23, 2009, we closed an underwritten public offering of our common stock that provided us with gross proceeds of $108.7 million before deducting underwriting discounts and commissions and other offering expenses. Under this offering, we sold 9,000,000 shares of our common stock at a price per share of $10.50 and the underwriters purchased 1,350,000 additional shares of common stock at the same price to cover over-allotments.

On September 9, 2009, we announced the results of our pivotal Phase 3 trials for Qnexa, EQUIP (OB-302) and CONQUER (OB-303).

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EQUIP (OB-302)

The EQUIP study included 1,267 morbidly obese patients (1,050 females and 217 males) across 93 centers in the United States. The average baseline body mass index, or BMI, of the study population was 42.1 kg/m2 and baseline weight was 256 pounds (a BMI of >30 kg/m2 is classified as obese per guidelines from the U.S. Department of Health and Human Services). Patients had a 4-week dose titration period followed by 52 weeks of treatment. The study was a randomized, double-blind, placebo-controlled, 3-arm, prospective trial with patients randomized to receive once-a-day treatment with placebo, low-dose Qnexa or full-dose Qnexa. Patients were asked to follow a hypocaloric diet representing a 500-calorie/day deficit and advised to implement a simple lifestyle modification program. Weight loss results from the study are summarized as follows:

	ITT-LOCF			Completers		
EQUIP (OB-302) 56 weeks	**Placebo (n=498)**	**Qnexa low-dose (n=234)**	**Qnexa full-dose (n=498)**	**Placebo (n=241)**	**Qnexa low-dose (n=138)**	**Qnexa full-dose (n=301)**
Mean weight loss (%)	1.6%	5.1%*	11.0%	2.5%	7.0%*	14.7%*
Greater than or equal to 5% weight loss rate	17%	45%*	67%*	26%	59%*	84%*

ITT-LOCF: Intent-to-treat with last observation carried forward

* p<0.0001 vs. placebo

CONQUER (OB-303)

The CONQUER study included 2,487 overweight and obese patients (1,737 females and 750 males) with high blood pressure, high cholesterol or type 2 diabetes across 93 centers in the United States. The average baseline BMI of the study population was 36.6 kg/m2 and baseline weight was 227 pounds. Patients had a 4-week dose titration period followed by 52 weeks of treatment. The study was a randomized, double-blind, placebo-controlled, 3-arm, prospective trial with patients randomized to receive once-a-day treatment with placebo, mid-dose Qnexa or full-dose Qnexa. Patients were asked to follow a hypocaloric diet representing a 500-calorie/day deficit and advised to implement a simple lifestyle modification program. Weight loss results from the study are summarized as follows:

	ITT-LOCF			Completers		
CONQUER (OB 303) 56 weeks	**Placebo (n=979)**	**Qnexa mid-dose (n=488)**	**Qnexa full-dose (n=981)**	**Placebo (n=564)**	**Qnexa mid-dose (n=344)**	**Qnexa full-dose (n=634)**
Mean weight loss (%)	1.8%	8.4%*	10.4%*	2.4%*	10.5%*	13.2%*
Greater than or equal to 5% weight loss rate	21%	62%*	70%*	26%	75%*	85%*

* p<0.0001 vs. placebo

The primary efficacy endpoint for Phase 3 weight loss trials, as recommended by the FDA, is at least a 5% mean reduction in baseline body weight compared to placebo or at least 35% of patients losing 5% or more of their baseline body weight. In Europe, the Committee for Medicinal Products for Human Use of the European Medicines Agency 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. The FDA and foreign authorities require pivotal obesity studies to be conducted for at least one year. Although the results for both of our Phase 2 studies and all of our Phase 3 obesity trials met these current guidelines for efficacy, there can be no assurance that these results will be acceptable to the FDA.

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Our Future

Our goal is to build a successful biopharmaceutical 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 internal capabilities or strategic relationships with marketing partners to maximize sales potential for our products that require significant commercial support; and
- licensing complementary clinical stage investigational product candidates or technologies with competitive advantages from third parties for new and established markets.

It is our objective to become a leader in the development and commercialization of products for large underserved markets. We believe we have strong intellectual property supporting several opportunities in obesity and related disorders such as sleep apnea and diabetes, and sexual health. Our future growth depends on our ability to further develop and obtain regulatory approval of our investigational product candidates for indications that we are studying, or plan to study, as well as in-licensing and product line extensions.

We have funded operations primarily through private and public offerings of our common stock, through the sale of the rights to Evamist and through product sales of MUSE (alprostadil). We expect to generate future net losses due to increases in operating expenses as our various investigational product candidates are advanced through the various stages of clinical development and for pre-commercialization activities. In connection with the sale of Evamist, we received to date an aggregate of $150 million. The sale of Evamist was a unique transaction. An initial $10 million was paid at closing and $140 million was paid upon the FDA's approval of the Evamist NDA. These payments were non-refundable and were originally recorded as deferred revenue and were recognized as license and other revenue ratably over a 21.5-month period, from August 1, 2007 to May 15, 2009. All of the revenue deferred from the Evamist sale has been recognized. As of December 31, 2009, we have incurred a cumulative deficit of $234.1 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 available-for-sale securities, 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.

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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 and other rebate programs, 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. We sell one pharmaceutical product, MUSE, which is sold in four dosages. The 1,000 mcg and 500 mcg product has a 24-month shelf-life and, beginning in the fourth quarter of 2009, the 250 mcg and 125 mcg product has an 18-month shelf-life. As of December 31, 2009, the shipments of MUSE in the United States made in 2009, 2008 and a portion of the shipments in 2007 remain subject to future returns.

The following table summarizes our product subject to return as of December 31, 2009:

	Estimated Gross Sales Value	Period of Expiration	
		From	To
	(In thousands)		
2009	$ 22,146	Sep-10	Nov-11
2008	$ 17,840	Sep-09	Oct-10
2007	5,824	Jan-09	Nov-09
Estimated gross sales value of product subject to return as of December 31, 2009	$ 45,810		

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 returns data obtained from external sources, along with the shelf life of the product. We believe that the information obtained from external sources is reliable, but we are unable to independently verify the accuracy of such data. 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

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period in which the information that gives rise to the revision becomes known. We consider a one-percentage point variance in our returns rate to be a reasonably likely change in the percentage of our product returns to related gross sales. A one-percentage point change in the estimated product returns rate recognized on gross sales in 2009 would lead to an approximate $221,000 effect on our net sales and operating losses.

The following table summarizes the activity in the accounts related to accrued product returns:

	2009	2008	2007
	(In thousands)		
Balance at January 1	$ (2,865)	$ (2,498)	$ (2,473)
Current provision related to sales made in current period	(1,441)	(1,345)	(1,299)
Current provision related to sales made in prior periods	16	31	(73)
Actual product returns	1,264	947	1,347
Balance at December 31	$ (3,026)	$ (2,865)	$ (2,498)

At December 31, 2007, our returns rate was increased from 6% to 6.5%, based upon an increasing trend of product returns. The returns rate of 6.5% has been used since December 31, 2007. The product returns reserve at December 31, 2009, covering the estimated returns exposure for product shipped in 2009, 2008 and a portion of 2007, was estimated at $3 million. This product returns reserve calculation is based upon the most recent information available, and we believe is reasonable and adequate to cover the estimated future credit memos to be issued for the return of prior sales of MUSE. Quarterly, we will continue to monitor the product returns experience and make adjustments to the product returns reserve, as appropriate.

Chargebacks: Chargebacks include government chargebacks which are contractual commitments by us to provide MUSE to federal government organizations including the Veterans Administration at specified prices and other rebate programs including those with managed care organizations, for the reimbursement of portions of the prescriptions filled that are covered by these programs. Allowances for chargebacks are recorded at the time of sale to the wholesaler distributors and accrued as a reserve. In estimating the chargeback reserve, we analyze actual government chargeback and rebate amounts paid and apply chargeback rates to estimates of the quantity of units subject to chargeback. We estimate this reserve by utilizing historical information, contractual and statutory requirements, end-customer prescription demand data, estimated quantities sold to these organizations and estimated wholesaler inventory levels based upon data obtained from our larger wholesaler customers which we began receiving in 2007. At that time, we determined the inventory data we had received from the larger wholesaler customers was more reliable than our previous estimates. This change in estimated wholesaler inventory levels in 2007 resulted in a decrease in the chargeback provision of $447,000 related to prior period sales. We believe that the information received from the wholesaler customers regarding inventory levels and information received from external sources regarding end-customer prescription demand are reliable, but we are unable to independently verify the accuracy of such data. Effective January 1, 2007, MUSE no longer qualifies for Medicare Part D. We routinely reassess the chargeback estimates and adjust the reserves accordingly. We consider a two-percentage point variance to be a reasonably likely change in the percentage of chargebacks to related gross sales. A two-percentage point change in the estimated chargebacks rate would lead to an approximate $445,000 effect on our net sales and operating losses in 2009.

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The following table summarizes the activity in the accounts related to accrued chargebacks:

	2009	2008	2007
	(In thousands)		
Balance at January 1	$ (1,379)	$ (1,314)	$ (1,531)
Current provision related to sales made in current period	(4,505)	(4,062)	(3,598)
Current provision related to sales made in prior periods	(33)	(19)	349
Actual chargebacks	4,300	4,016	3,466
Balance at December 31	$ (1,617)	$ (1,379)	$ (1,314)

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.

The following table summarizes the activity in the accounts related to cash discounts:

	2009	2008	2007
	(In thousands)		
Balance at January 1	$ (74)	$ (76)	$ (54)
Current provision related to sales made in current period	(443)	(421)	(419)
Actual cash discounts	375	423	397
Balance at December 31	$ (142)	$ (74)	$ (76)

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 SEC's Staff Accounting Bulletin No. 104, *Revenue Recognition*, as codified in the Financial Accounting Standards Board's, or FASB, Accounting Standards Codification, or ASC, topic 605, *Revenue Recognition*, or ASC 605. 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 Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*, or EITF 00-21, as codified in FASB ASC topic 605, subtopic 25 *Multiple Element Arrangements,* or ASC 605-25. 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

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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 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, or FDA Approval, and on August 1, 2007, we transferred and assigned the Evamist FDA submissions, and all files related thereto to K-V. In August 2008, we assigned all of our rights and obligations under the Evamist license agreement 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 to determine whether the deliverables were divided into separate units of accounting.

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

As it relates to the Improvement License, no specific value was assigned in the agreement. We had no obligation to develop improvements to the MDTS applicator and had no plans to expend significant resources in this endeavor. However, we did 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, were bundled together and were treated as one unit of accounting.

As a result, the initial $10 million paid at closing and the $140 million paid upon FDA Approval were recorded as deferred revenue and have been recognized as license revenue ratably over the 21.5-month term of the Improvement License, from August 1, 2007 to May 15, 2009. The revenue related to the transaction recognized for years ended December 31, 2009, 2008 and 2007 was $31.4 million, $83.7 million and $34.9 million, respectively.

In September 2009, the FASB issued Accounting Standards Update, or ASU, No. 2009-13, *Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements*. ASU No. 2009-13 amends the guidance for measurement and separation of deliverables in multiple element arrangements under EITF Issue 00-21, as codified in FASB ASC 605-25, and significantly increases the related disclosure requirements. Under this new guidance, which will be effective for us beginning January 1, 2011, our accounting for the revenue from the sale of the Evamist transaction may have been different.

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Research and Development Expenses

Research and development, or 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 that 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, or CROs, and clinical sites and include advertising for clinical trials and patient recruitment costs. These costs are recorded as a component of R&D expenses and are expensed as incurred. 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. 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 consolidated balance sheet, net of the allowance for doubtful accounts. See Schedule II Valuation and Qualifying Accounts table. This summarizes the activity in the accounts related to 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, 2009, it was considered more likely than not that the Company's deferred tax assets would not be realized. 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, or FASB, issued FASB Interpretation No. 48, or FIN No. 48, *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109,* as codified in FASB ASC 740-10*Income Taxes*, to clarify certain aspects of accounting for

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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 on January 1, 2007.

Inventories

Inventories are valued at the lower of cost or market. 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. During the quarter ended September 30, 1998, we established significant reserves against our inventory to align with the then new estimates of expected future demand for MUSE. As of December 31, 2009, the remaining inventory reserve balance is $1.6 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. In the third quarter of 2009, we determined that we would also likely use some portion of the fully reserved raw materials inventory. 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 the years ended December 31, 2009, 2008 and 2007 it was charged to cost of goods sold at a zero basis, which had a favorable impact on cost of goods sold. During the second quarter of 2009, a portion of our existing inventory of alprostadil exceeded its shelf life and is no longer usable in the manufacturing of MUSE. We increased our inventory reserves by $487,000 for this raw material. We do not expect the loss of this material to impede our ability to meet the demand for MUSE.

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. At December 31, 2009, all cash equivalents are invested in money market funds and U.S. Treasury securities. These accounts are recorded at cost, which approximates fair value.

Cash with restrictions for a period of greater than 12 months is classified as restricted cash, a non-current asset.

Available-for-Sale Securities

We focus on liquidity and capital preservation in our investments in available-for-sale securities. Our investment policy, as approved by the Audit Committee of the Board of Directors, allows us to invest our excess cash balances in money market and marketable securities, primarily U.S. Treasury securities and debt securities of U.S. government agencies, corporate debt securities and asset-backed securities. The investment policy has the primary investment objectives of preservation of principal; 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.

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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. 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 may sell these securities prior to their stated maturities. As these securities are viewed by us as available to support current operations securities with maturities beyond 12 months are classified as current assets.

Securities are carried at fair value, with the unrealized gains and losses, net of taxes, reported as a component of stockholders' equity, unless the decline in value is deemed to be other-than-temporary and we intend to sell such securities before recovering their costs, in which case such securities are written down to fair value and the loss is charged to other-than-temporary loss on impaired securities. We evaluate our investment securities for other-than-temporary declines based on quantitative and qualitative factors. Any realized gains or losses on the sale of marketable securities are determined on a specific identification method, and such gains and losses are reflected as a component of interest income.

SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, FSP SFAS 115-2 and SFAS 124-4, *Recognition and Presentation of Other-than-Temporary Impairments ("FSP 115-2/SFAS 124-2")* and SAB Topic 5M, *Accounting for Non-current Marketable Equity Securities*, as codified in FASB ASC topic 320, *Investments Debt and Equity Securities*, or ASC 320, provide guidance on determining when an investment is other-than-temporarily impaired. FSP 115-2/124-2 is effective for all periods ending after June 15, 2009 and provides additional guidance designed to create a greater clarity and consistency in accounting for and presenting impairment losses on securities. In reviewing our non-U.S. Government available-for-sale securities, we concluded that we intend to sell the debt securities before recovering their costs and consequently these securities are included in our assessment of other-than-temporarily impaired securities. For securities that are deemed to be other-than-temporarily impaired, the security is adjusted to fair value and the resulting losses are recognized in other-than-temporary loss on impaired securities in the consolidated statements of operations.

During our quarterly impairment assessments, we determined that a decline in value of certain securities was other-than-temporary. Accordingly, we recorded other-than-temporary impairment adjustments of $654,000 in the year ended December 31, 2009. We included this non-cash impairment charge in other-than-temporary loss on impaired securities in the consolidated statements of operations and other comprehensive income (loss). These securities covered a number of industries.

During our quarterly impairment assessments in 2008, we also determined that a decline in value of certain securities was other-than-temporary. Accordingly, we recorded other-than-temporary impairment adjustments of $7.7 million in the year ended December 31, 2008. We included this non-cash impairment charge in other-than-temporary loss on impaired securities in the consolidated statements of operations and other comprehensive income (loss). Included in the charge taken in 2008 was $2.4 million related to corporate bonds issued by Lehman Brothers Holdings Inc., or Lehman (or their respective subsidiaries, as appropriate). On September 15, 2008, Lehman filed for bankruptcy protection under Chapter 11 of the United States Bankruptcy Code. Accordingly, recovery of the full value of our Lehman bonds, if any, was deemed remote and we recognized an other-than-temporary impairment in the year ended December 31, 2008. In addition, other-than-temporary impairments recognized in 2008 included impairments on investments for which we determined the impairment was other-than-temporary due to credit downgrades and/or our intent and ability to hold the investment to maturity. These securities covered a number of industries. In addition, due to the lack of a readily available market for certain of our available-for-sale securities totaling $1.3 million and the continued uncertainty in the capital markets in 2008, we expected to recover the carrying values of these securities

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beyond the next 12 months. Consequently, we classified those available-for-sale securities as non-current in the consolidated balance sheets at December 31, 2008.

Contingencies and Litigation

We are periodically involved in disputes and litigation related to a variety of matters. When it is probable that we will experience a loss, and that loss is quantifiable, we record appropriate reserves. We record legal fees and costs as an expense when incurred.

Share-Based Payments

We follow the fair value method of accounting for share-based compensation arrangements in accordance with SFAS 123R, *Share-Based Payment*, as codified in FASB ASC topic 718, *Compensation Stock Compensation,* or ASC 718. 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, or 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 $4.8 million, $4.7 million and $3.9 million of share-based compensation expense for the years ended December 31, 2009, 2008, and 2007, respectively. 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. The expected term of the options represents the period of time that options granted are expected to be outstanding and is derived by analyzing the historical experience of similar awards, giving consideration to the contractual terms of the stock-based awards, vesting schedules and expectations of future employee behavior. 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 9: "Stock Option and Purchase Plans" to the notes to the consolidated financial statements included in this Form 10-K.

Fair Value

On January 1, 2008, we adopted SFAS No. 157 *Fair Value Measurements,* as codified in FASB ASC 820, *Fair Value Measurements and Disclosures,* or ASC 820, and effective October 10, 2008, we adopted FSP No. SFAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active,* except as it applies to the nonfinancial assets and nonfinancial liabilities subject to FSP 157-2. On January 1, 2009, we adopted SFAS No 157 with respect to non-financial assets and non-financial liabilities. On June 15, 2009 we adopted FSP 157-4, *Determining Fair Value When the Volume and Level of Activity for the Assets or Liabilities Have Significantly Decreased and Identifying Transactions That Are Not Orderly.* Adoption of the provisions of these standards did not have a material effect on our financial position.

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Financial Instruments Measured at Fair Value. Our cash and cash equivalents and available-for-sale financial instruments are carried at fair value and we make estimates regarding valuation of these assets measured at fair value in preparing the consolidated financial statements.

Fair Value Measurement Definition and Hierarchy. SFAS No. 157 defines fair value as the price that would be received to sell an asset or paid to transfer a liability (i.e., the "exit price") in an orderly transaction between market participants at the measurement date.

Valuation Technique. SFAS No. 157 establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of VIVUS. Unobservable inputs are inputs that reflect our assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances. SFAS No. 157 prescribes three valuation techniques that shall be used to measure fair value as follows:

1. Market Approach uses prices or other relevant information generated by market transactions involving identical or comparable assets or liabilities.

2. Income Approach uses valuation techniques to convert future cash flow amounts to a single present value amount (discounted).

3. Cost Approach the amount that currently would be required to replace the service capacity of an asset (i.e., current replacement cost).

One or a combination of the approaches above can be used to calculate fair value, whichever results in the most representative fair value.

In addition to the three valuation techniques, SFAS No. 157 prescribes a fair value hierarchy in order to increase consistency and comparability in fair value measurements and related disclosures. The hierarchy is broken down into three levels based on the reliability of inputs as follows:

Level 1 Valuations based on quoted prices in active markets for identical assets. Since valuations are based on quoted prices that are readily and regularly available in an active market, valuation of these products does not entail a significant degree of judgment.

These types of instruments primarily consist of financial instruments whose value is based on quoted market prices such as cash, money market funds and U.S. Treasury securities that are actively traded. Management judgment was required to determine our policy that defines the levels at which sufficient volume and frequency of transactions is met for a market to be considered active.

Level 2 Valuations based on quoted prices in markets that are not active or for which all significant inputs are observable, directly or indirectly. Quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

The types of instruments valued based on other observable inputs include debt securities of U.S. government agencies, corporate bonds, mortgage-backed and asset-backed products. Substantially all of these assumptions are observable in the marketplace, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace.

Level 3 Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

These types of instruments have included certain corporate bonds, mortgage-backed securities and asset-backed securities. We have no Level 3 securities as of December 31, 2009. Level 3 is comprised of

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unobservable inputs that are supported by little or no market activity. These instruments are considered Level 3 when their fair values are determined using pricing models, discounted cash flows or similar techniques and at least one significant model assumption or input is unobservable. Level 3 may still include some observable inputs such as yield spreads derived from markets with limited activity. Level 3 financial assets include securities for which there is limited market activity such that the determination of fair value requires significant judgment or estimation. The availability of observable inputs can vary from product to product and is affected by a wide variety of factors, including, for example, the type of product, whether the product is new and not yet established in the marketplace, and other characteristics particular to the transaction. To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by us in determining fair value is greatest for instruments categorized in Level 3. In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, for disclosure purposes the level in the fair value hierarchy within which the fair value measurement in its entirety falls is determined based on the lowest level input that is significant to the fair value measurement in its entirety.

Fair Value Measurements

As of December 31, 2009, our cash and cash equivalents and available-for-sale securities measured at fair value on a recurring basis totaled $207 million.

All of our cash and cash equivalents and available-for-sale securities are in cash, money market instruments and U.S. Treasury securities at December 31, 2009, and these are classified as Level 1. The valuation techniques used to measure the fair values of these financial instruments were derived from quoted market prices, as substantially all of these instruments have maturity dates, if any, within one year from the date of purchase and active markets for these instruments exists.

Deerfield Financing

On April 3, 2008, we entered into several agreements with Deerfield Management Company, L.P., or Deerfield, a healthcare investment fund, and its affiliates, Deerfield Private Design Fund L.P. and Deerfield Private Design International, L.P. (collectively, the Deerfield Affiliates). Certain of these agreements were amended and restated on March 16, 2009. Please refer to Note 6: "Deerfield Financing" and Note 7: "Notes Payable" to the notes to consolidated financial statements included in this Form 10-K for additional information on these agreements. Under the agreements, Deerfield and its affiliates agreed to provide $30 million in funding to the Company. The $30 million in funding consists of $20 million from the Funding and Royalty Agreement, or FARA, and $10 million from the sale of the Company's common stock. Under the FARA, the Deerfield Affiliates made $3.3 million payments to us in April, September, and December 2008 and February, June and September 2009, constituting all of the required payments under the FARA. We have agreed to pay royalties on the current net sales of MUSE and if approved, on future sales of avanafil, an investigational product candidate, to the Deerfield Sub, a newly incorporated subsidiary of Deerfield. The agreements also provide us with an option to purchase, and the Deerfield Affiliates with an option to compel us to purchase, the Deerfield Sub holding the royalty rights. If either party exercises its option, any further royalty payments would be effectively terminated. In exchange for the option right, we paid $2 million to the Deerfield Affiliates.

We have evaluated the Deerfield financing in accordance with FASB Financial Interpretation No., or FIN, 46(R), *Consolidation of Variable Interest Entities*, or FIN 46R, as codified in FASB ASC topic 810, *Consolidation,* or ASC 810, and determined that the Deerfield Sub may constitute a Variable Interest Entity, or VIE; however, we have also determined that the Company is not the primary beneficiary of this VIE at this time and we therefore have concluded that we are not required to consolidate the Deerfield Sub.

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In accordance with Emerging Issues Task Force Issue 88-18, *Sale of Future Revenues*, as codified in FASB ASC 605, the transaction is in substance a financing arrangement, or loan that will be repaid by us. The minimum repayment amount would be $17 million, the amount of the unconditional put option held by Deerfield Affiliates, plus royalties paid on MUSE sales, and avanafil sales if approved, during the term of the agreement. Accordingly, we have recorded the advances from the Deerfield Affiliates, net of the $2 million option right payment and related fees and expenses, as a loan. Using the interest method under APB Opinion No. 21, *Interest on Receivables and Payables*, as codified in FASB ASC topic 835, *Interest,* subtopic 30, *Imputation of Interest* or ASC 835-30, interest on the loan will be recognized over three years, which is the estimated term of the loan based on the earliest date that the Deerfield Affiliates could require us to repay the amounts advanced.

RESULTS OF OPERATIONS

Executive Overview

For the year ended December 31, 2009, we reported a net loss of $54.3 million or $0.75 net loss per share, as compared to a net loss of $9.9 million, or $0.16 net loss per share during the same period in 2008. The increased net loss in the year ended December 31, 2009, as compared to the year ended December 31, 2008, was primarily due to a decrease in license and other revenue recognized on the portion of K-V deferred license revenue from the sale of Evamist amortized in 2009 as compared to 2008, where we recognized a full year of deferred revenue, partially offset by decreased operating expenses. The decrease in operating expenses in 2009 as compared to 2008 was primarily attributable to reduced spending on Qnexa for obesity, partially offset by increased spending related to our Phase 3 clinical trials of avanafil for the treatment of erectile dysfunction and increased selling, general and administrative expense primarily due to Qnexa pre-commercialization expenses and an increase in non-cash share-based compensation expense. In addition, we had a reduction in other-than-temporary impairment losses in 2009 as compared to 2008. In 2009, we also had a $2.4 million benefit for income taxes primarily due to a carryback claim of losses generated in 2008 which allows us to obtain a refund for Federal income taxes which we paid in 2007.

On April 3, 2008, we entered into several agreements with Deerfield, a healthcare investment fund, and its affiliates. Certain of these agreements were amended and restated on March 16, 2009. Under the agreements Deerfield and its affiliates provided $30 million in funding to us. The $30 million in funding included $20 million from the FARA, and $10 million from the sale of the Company's common stock at the closing on April 15, 2008 in connection with the registered direct offering mentioned above under a securities purchase agreement. Under the FARA, the Deerfield Affiliates made $3.3 million payments to us in April, September and December 2008 and February, June and September 2009, constituting all of the required payments under the FARA. The amounts of funding provided under the FARA, net of certain amounts, represent a financial obligation, a loan payable by the Company in which the principal and interest will be repaid through royalty payments and the exercise of the option or put rights.

In connection with the sale of Evamist, we received $150 million. The sale of Evamist was a unique transaction. An initial $10 million was paid at closing and $140 million was paid upon FDA approval of Evamist. These payments were non-refundable and were recorded as deferred revenue and have been recognized as license and other revenue ratably over a 21.5-month period, from August 1, 2007 to May 15, 2009, which was the remaining term of a license to improvements to the MDTS applicator. No improvements to the MDTS applicator were made during this period. As compared to revenues from product sales, license and other revenue was significant on a quarterly basis during this 21.5-month period. Since the $150 million was received and we had no related contingencies, the recognition of revenue and the corresponding reduction of deferred revenue related to the Evamist sale had no impact on our cash flows from operations during this period. The revenue related to the Evamist transaction recognized in 2009 was $31.4 million.

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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 consistent with prior years and we plan to continue to invest in clinical development of our current research and investigational product candidates to bring those potential products to market.

Revenue

	Years Ended December 31,			% Change Increase/(Decrease)	
	2009	2008	2007	2009 vs 2008	2008 vs 2007
	(In thousands, except percentages)				
United States product, net	$ 15,836	$ 14,974	$ 15,020	6%	0%
International product	2,347	3,076	4,332	(24)%	(29)%
License and other revenue	31,858	84,183	35,346	(62)%	138%
Total revenues	$ 50,041	$ 102,233	$ 54,698	(51)%	87%

Worldwide product revenues from the sales of MUSE were $18.2 million in 2009, an increase of $133,000, or 1%, from the worldwide sales of MUSE in 2008. U.S. product revenues increased in 2009 as compared to the prior year period primarily due to higher prices for MUSE and a modest increase in units shipped. The increase in U.S. product revenues for 2009 was partially offset by both an increase in the sales allowance for pricing discounts for certain government customers of $208,000 and an allowance of $72,000 for out-of-specification production identified in the first quarter of 2009. Domestic demand for MUSE at the retail and government level remains consistent with the prior period, averaging just less than 200,000 units per quarter. Similar to prior years, in the fourth quarter 2009, our largest wholesaler customer made purchases that were greater than current demand. Based upon fourth quarter demand for MUSE, we estimate purchases made by wholesaler customers in the fourth quarter 2009 represent approximately 3 months of excess demand. In the fourth quarter 2008 and prior years, at least one other major wholesaler customer had also purchased quantities in excess of demand. The increase in MUSE domestic shipments is a result of fluctuations in inventory levels at the wholesale level and is not indicative of any trend.

The decrease in international revenue in 2009 as compared to 2008 was principally due to decreases in units shipped based upon the timing of orders from our international partners and to a reduction in transfer prices resulting from the difference in currency exchange rates. If these exchange rate differences and lower transfer prices were to occur again, our future international product revenue would be negatively impacted. Also contributing to the reduction in international revenues in 2009 was the allowance of $116,000 for certain out-of-specification production identified in the first quarter of 2009.

In the first quarter of 2009, through our routine testing, we identified that certain production lots of the lower strength MUSE shipped did not meet certain specifications applied toward the end of the 24-month shelf life. This out-of-specification condition appears to arise in the last six months of the 24-month shelf life. This condition does not pose any safety risk to patients. In May 2009, we issued a voluntary recall of specific lots of 125 mcg and 250 mcg MUSE product remaining in the U.S. wholesaler's inventory. Units of 125 mcg and 250 mcg represented 13% of total domestic units shipped in 2008.

In September 2009, we received approval from the FDA to reduce the shelf life of our 125 mcg and 250 mcg MUSE product from 24 months to 18 months and we are currently manufacturing the 125 mcg and 250 mcg MUSE product with an 18-month shelf life. During the fourth quarter of 2009, we began shipping 125 mcg and 250 mcg MUSE product with an 18-month shelf life. We offered an exchange of product with the 18-month shelf life for any product with the 24-month shelf life remaining in the wholesalers' inventories and, in the fourth quarter of 2009, we completed the product exchange.

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We believe all affected product has now been returned by the wholesalers and the final cost of the recall and exchange was $72,000.

Although the demand for MUSE has stabilized, we are not able to anticipate if our largest wholesaler customer will continue its historical pattern of making purchases in the fourth quarter that exceed expected quarterly demand. If our largest wholesaler customer does not repeat this pattern of purchasing quantities of MUSE that exceed quarterly demands, revenues from the sale of MUSE in 2010 may be lower as compared to 2009.

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 Evamist Agreement to K-V, or the Transaction. In August 2008, we assigned all of our rights and obligations under the Evamist license agreement to K-V. 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 were recorded as deferred revenue and have been recognized as revenue ratably over the 21.5-month term of the Improvement License, from August 1, 2007 to May 15, 2009.

Worldwide product revenues from the sales of MUSE were $18.1 million in 2008, a decrease of $1.3 million, or 7%, from the worldwide sales of MUSE in 2007. U.S. product revenues decreased in 2008 as compared to the prior year period primarily due to a decrease in shipments of MUSE partially offset by a price increase for 2008. In 2007, product revenue was higher due to an adjustment to our sales allowances for chargebacks of $447,000. The sales adjustment in 2007 was the result of updated information received from certain wholesaler customers of the inventory in the distribution channel. The decrease in international revenues in 2008 is mainly due to the timing of orders from our international distributors as well as adjustments to our sales allowance in 2007. The increase in license and other revenue is primarily due to the amortization of the K-V deferred license revenue.

Cost of goods sold and manufacturing

				% Change Increase/(Decrease)	
	Years Ended December 31,				
	2009	2008	2007	2009 vs 2008	2008 vs 2007
	(In thousands, except percentages)				
Cost of goods sold and manufacturing	$ 11,950	$ 11,956	$ 12,097	0%	(1)%

Cost of goods sold and manufacturing, or cost of goods sold, was $12 million in the years ended December 31, 2009 and 2008. While cost of goods sold remained constant in 2009, there was a nominal reduction in units shipped as compared to 2008. Costs of goods sold and manufacturing for 2009 included an increase in quality control related expenses of $413,000 and an increase in inventory reserves of $487,000 for raw material which exceeded its shelf life, which were partially offset by recoveries from the supplier and insurance proceeds totaling $409,000 for the loss on non-conformance of raw materials which occurred in 2009. In 2008, we incurred inventory disposal costs of $444,000 due to the non-conformance of certain raw materials. We expensed approximately $6.1 million of manufacturing overhead costs in the year ended December 31, 2009, as compared to $6 million during the same period in 2008 as period costs because of excess manufacturing capacity at our New Jersey facility. This accounting treatment is due to the fact that the manufacturing capacity of the New Jersey plant far exceeds the level of production.

Cost of goods sold and manufacturing, or cost of goods sold, in the year ended December 31, 2008 decreased $141,000, or 1%, to $12 million, as compared to $12.1 million for the year ended December 31, 2007. The decrease in cost of goods sold is primarily due to a one-time charge of $559,000 for the sale of Evamist assets in May 2007 partially offset by the disposal of inventory due to the non-conformance of certain raw materials in 2008. We expensed approximately $6 million of

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manufacturing overhead costs in the year ended December 31, 2008, as compared to $5.9 million during the same period in 2007 as period costs because of excess manufacturing capacity at our New Jersey facility.

We anticipate that cost of goods sold and manufacturing in 2010 will be similar to costs incurred in 2009.

Research and development

	Years Ended December 31,			% Change Increase/(Decrease)	
	2009	2008	2007	2009 vs 2008	2008 vs 2007
	(In thousands, except percentages)				
Research and development	$ 71,075	$ 76,996	$ 26,681	(8)%	189%

Research and development expenses in the year ended December 31, 2009 decreased $5.9 million, or 8%, to $71.1 million, as compared to $77 million in the same period last year. This decrease was the net result of decreased spending for Qnexa for obesity of $12.2 million, Qnexa for diabetes of $3.3 million, decreased non-cash share-based compensation expense of $554,000, and a net decrease in other research and development spending of $564,000, partially offset by increased avanafil program spending of $10.7 million in the year ended December 31, 2009, as compared to the same period last year. In the year ended December 31, 2009, we incurred $19.1 million for services provided by one clinical research organization on the Qnexa Phase 3 studies, which represented 27% of our research and development expenses for the period. Separately, we incurred another $17 million for services provided by another clinical research organization on the avanafil Phase 3 studies, which represented 24% of our research and development expenses for the year ended December 31, 2009.

We anticipate that our research and development expenses in 2010 will decline from costs incurred in 2009, as we continue the obesity extension study, we continue to advance the clinical program for avanafil for erectile dysfunction and further studies for our other investigational products. The current remaining contractual obligation for payments to our primary contract research organization, or CRO, for the Phase 3 avanafil trials totals $8.6 million, which includes amounts in accrued research and clinical expenses as of December 31, 2009. There are likely to be additional research and development expenses related to avanafil and our other investigational products 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 pre-clinical studies. Regardless, 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 at least a year or more due to the length of time required to develop investigational product candidates into commercially viable products.

Research and development expenses in the year ended December 31, 2008 increased $50.3 million, or 189%, to $77 million, as compared to $26.7 million for the year ended December 31, 2007. This increase was primarily due to increased spending for our investigational product candidates currently in Phase 3 clinical trials. In the year ended December 31, 2008, Qnexa for obesity spending increased by $38.5 million, avanafil spending increased by $8.9 million and other project expenses increased on a net basis by $102,000 as compared to the prior year. In addition, non-project related expenses increased by $2.8 million (primarily attributable to $1 million in increased compensation and related expense due to an increase in headcount, increased consulting expense of $644,000, increased non-cash stock based compensation expense of $602,000 and a net increase in other non-project related spending of $579,000). In the years ended December 31, 2008 and 2007, we incurred $44.7 million and $7.8 million, respectively, for services provided by one CRO on the Qnexa Phase 3 studies, which represented 58% and 29%, respectively, of our total research and development expenses. In the years ended

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December 31, 2008 and 2007, we incurred $6.2 million and $5.6 million, respectively, for clinical supplies and formulation work performed by our sole-source manufacturer, which represented 8% and 21%, respectively, of our total research and development expenses.

Selling, general and administrative

	Years Ended December 31,			% Change Increase	
	2009	2008	2007	2009 vs 2008	2008 vs 2007
	(In thousands, except percentages)				
Selling, general and administrative	$ 21,033	$ 18,904	$ 17,374	11%	9%

Selling, general and administrative expenses in the year ended December 31, 2009 increased $2.1 million, or 11% to $21 million as compared to the same period in 2008. In the year ended December 31, 2009, the increase is primarily due to Qnexa pre-commercialization expenses of $1.2 million, incremental increases of $542,000 in non-cash share-based compensation expense, $588,000 in sales expenses (including $299,000 in MUSE related wholesaler distribution fees), partially offset by a $201,000 decrease in marketing expenses as compared to the year ended December 31, 2008.

Selling, general and administrative expenses in the year ended December 31, 2008, increased $1.5 million, or 9%, to $18.9 million as compared to the year ended December 31, 2007. The increase is primarily due to incremental increases in corporate legal fees of $1 million, primarily due to the Acrux arbitration, sales distribution fees of $409,000, compensation expense of $383,000, investor relations expense of $379,000, a net decrease of $1.2 million in MUSE advertising and sales promotion costs and other net selling, general and administrative expenses increases of $510,000, as compared to the year ended December 31, 2007.

We anticipate that our selling, general and administrative expenses in 2010 will increase substantially compared to those in 2009 due to Qnexa pre-approval and pre-commercialization related expenses.

Interest income and expense

Interest income, net for the year ended December 31, 2009 was $2 million as compared to $4.4 million for the year ended December 31, 2008. The decrease in interest income in the year ended December 31, 2009 as compared to the same period last year was largely due to lower interest rates, year-over-year, on our cash, cash equivalents and available-for-sale securities balances resulting from a change in policy to invest primarily in U.S. government securities, which earn lower rates of interest. In 2009, we recognized a net realized gain of $1.1 million related to the sale of securities.

Interest income, net for the year ended December 31, 2008 was $4.4 million as compared to $4.7 million for the year ended December 31, 2007. The decrease in interest income in the year ended December 31, 2008 as compared to the same period last year is primarily due to a decrease in our investment yields. In 2008, we recognized a net realized loss of $979,000 related to the sale of securities.

Interest expense for the year ended December 31, 2009 was $4.1 million as compared to $1.1 million during the same period last year. The net increase in interest expense in the year ended December 31, 2009 as compared to the same period in 2008 is primarily due to increased interest expense on the Deerfield financing.

Interest expense for the year ended December 31, 2008 was $1.1 million as compared to $538,000 during the same period last year. The net increase in interest expense in the year ended December 31, 2008 as compared to the same period in 2007 is also primarily due to interest expense on the Deerfield financing.

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We recognized an other-than-temporary loss on impaired securities of $654,000 for the year ended December 31, 2009, as compared to $7.7 million for the year ended December 31, 2008. The majority of the other-than-temporary losses on impaired securities were recorded on securities obtained in late 2007 through the redemption-in-kind distribution from the Bank of America Columbia Strategic Cash Portfolio Fund. We no longer hold these securities in our portfolio at December 31, 2009.

The other-than-temporary loss on impaired available-for-sale securities was $7.7 million in the year ended December 31, 2008, which included a $2.4 million loss related to our investment in corporate bonds issued by Lehman Brothers Holdings Inc., or Lehman (or their respective subsidiaries, as appropriate). On September 15, 2008, Lehman filed for bankruptcy protection under Chapter 11 of the United States Bankruptcy Code. Accordingly, recovery of the full value of our Lehman bonds, if any, was deemed remote and we recognized an other-than-temporary impairment loss in the third quarter of 2008. The $7.7 million other-than-temporary loss primarily represented unrealized impairment losses recorded on securities that were classified as available-for-sale securities on our consolidated balance sheet as of December 31, 2008. The majority of the other-than-temporary losses on impaired securities were recorded on securities obtained in late 2007 through the redemption-in-kind distribution from the Bank of America Columbia Strategic Cash Portfolio.

There was no other-than-temporary impairment losses in the year ended December 31, 2007.

From 2005 and until December 2007, we had an investment in the Bank of America Columbia Strategic Cash Portfolio, or Strategic Cash, offered by our investment advisor, Columbia Management LLC, or Columbia. Strategic Cash was an enhanced money market fund in which the fund sought to maintain a $1 per share net asset value.

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, Columbia, we took redemption-in-kind distribution consisting of cash, interest receivable and a pro-rata distribution of the underlying securities, consisting principally of 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 distribution 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 was reflected in interest income in the consolidated statement of operations and other comprehensive income (loss) for the year ended December 31, 2007.

Benefit (provision) for income taxes

We recorded a benefit for income taxes for the year ended December 31, 2009 of $2.4 million primarily due to our filing a carryback claim of losses generated in 2008, pursuant to the IRS Revenue Procedure 2009-52. The Revenue Procedure was issued in the fourth quarter of 2009 and allows losses generated in 2008 or 2009 to be carried back up to five years.

Provision for income taxes for the year ended December 31, 2008 was $3,000, as compared to $5.1 million for the year ended December 31, 2007. The provision for income taxes for the year ended December 31, 2008 relates to state income taxes. 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. The utilization of

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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 reflected 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. As mentioned above, during the year ended December 31, 2009, we recorded an anticipated benefit from filing a carryback claim of losses generated in 2008 which allows us to obtain a refund for Federal income taxes which we recorded in 2007.

Liquidity and Capital Resources

Cash. Unrestricted cash, cash equivalents and available-for-sale securities totaled $207 million at December 31, 2009, as compared to $189.2 million at December 31, 2008. The increase in unrestricted cash, cash equivalents and available-for-sale securities of $17.8 million is the net result of cash provided by financing and investing activities, including $102.7 million in net proceeds from the underwritten public offering of our common stock, $10 million in cash from the Deerfield financing and $2.7 million from stock option exercises and ESPP purchases received in the year ended December 31, 2009, partially offset by cash used for operating activities.

Since inception, we have financed operations primarily from the issuance of equity securities. Through December 31, 2009, we raised $403.7 million from financing activities, received $150 million from the sale of Evamist and had an accumulated deficit of $234.1 million at December 31, 2009.

At December 31, 2009, we had $40.8 million in cash and cash equivalents and $166.2 million in available-for-sale securities. We invest our excess cash balances in money market and marketable securities, primarily U.S. Treasury securities and debt securities of U.S. government agencies, corporate debt securities and asset-backed securities, in accordance with our investment policy. At December 31, 2009, all of our cash equivalents and available-for-sale securities were invested in either U.S. government securities or money market funds that invest only in U.S. Treasury securities. The investment policy has the primary investment objectives of preservation of principal; 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 realized or unrealized losses in the value of our portfolio, which would have an adverse effect on our results of operations, liquidity and financial condition.

Investment securities are exposed to various risks, such as interest rate, market and credit. Due to the level of risk associated with certain investment securities and the level of uncertainty related to changes in the value of investment securities, it is possible that changes in these risk factors in the near term could have an adverse material impact on our results of operations or shareholders' equity.

Accounts Receivable. Accounts receivable (net of allowance for doubtful accounts) at December 31, 2009 was $7.3 million, as compared to $4.2 million at December 31, 2008. Currently, we do not have any significant concerns related to accounts receivable or collections. As of February 16, 2010, we had collected 99% of the accounts receivable outstanding at December 31, 2009.

Liabilities. Total liabilities were $43.3 million at December 31, 2009; $33.1 million lower than at December 31, 2008. The change in total liabilities includes a $31.9 million net decrease in deferred revenue primarily due to the amortization of the remainder of the $150 million in deferred license revenue received from K-V on the sale of Evamist.

We have entered into a manufacturing agreement with a supplier to purchase alprostadil. As of December 31, 2009, our remaining commitment under this agreement is to purchase a minimum of $765,000 of product in 2011. Should our inventory of alprostadil 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, or Acrux, and a subsidiary of Acrux under which we have agreed to develop and, if approved, commercialize

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Luramist and Evamist in the United States for various female health applications. Under the terms of the agreements, we 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, we 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. 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. Under 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 used $96.1 million, used $63.6 million and provided $124.1 million during the years ended December 31, 2009, 2008 and 2007, respectively. During the year ended December 31, 2009, our net operating loss of $54.3 million was offset by $4.8 million in non-cash share-based compensation expense, a $654,000 other-than-temporary loss on impaired securities, a $487,000 provision for obsolete inventory due to alprostadil that has exceeded its shelf life, a $1.6 million increase in accrued and other liabilities, primarily due to an increase in accrued interest payable on the Deerfield loan, and $1.2 million in depreciation expense. These positive cash flows to our net operating loss were in turn offset by the recognition of $31.9 million in revenue, primarily due to the amortization of deferred license revenue from the receipt of $150 million from K-V for the sale of Evamist, an $8.7 million decrease in accounts payable due to the timing of payments, a $3.1 million increase in accounts receivable due to timing of the December 2009 buy-in as compared to the prior year, a $2.7 million increase in prepaid expenses (primarily due to a $2.4 million receivable from the IRS related to carryback claims on our amended 2007 federal income tax return), and a $4 million decrease in accrued research and clinical expenses, primarily due to the winding down of the Qnexa for obesity development efforts.

During the year ended December 31, 2008, our net operating loss of $9.9 million includes a $7.7 million other-than-temporary loss on impaired securities, $4.7 million in non-cash stock based compensation expense, a $5 million increase in accrued research and clinical expenses primarily due to the Qnexa for obesity development effort, a $9.4 million increase in accounts payable due to the timing of payments, and a $1.1 million decrease in prepaid and other assets. These positive cash flows to our net operating loss were in turn offset by the recognition of $84.2 million in revenue primarily due to the amortization of deferred license revenue from the receipt of $150 million from K-V for the sale of Evamist.

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 $2.5 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).

Investing Activities. Our investing activities used $43.4 million, provided $9.8 million, and used $128.8 million in cash during the years ended December 31, 2009, 2008 and 2007, respectively. The fluctuations from period to period are due primarily to investment of the $150 million received from the K-V transaction and to the timing of purchases, sales and maturity of investment securities.

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Financing Activities. Financing activities provided cash of $114.2 million, $82 million, and used cash of $2.1 million during the years ended December 31, 2009, 2008 and 2007, respectively. In 2009, the cash provided by financing activities included $102.7 million in net proceeds from the underwritten public offering of our common stock, $10 million in cash from the Deerfield financing and $2.7 million from stock option exercises and ESPP purchases, partially offset by $1.2 million in principal payments under our notes payable. In 2008, the cash provided by financing activities included cash receipts from the Deerfield financing including $9.7 million in net proceeds from the issuance of common stock and $7.6 million from the FARA, net proceeds of $63.7 million from the registered direct offering of our common stock, $2.2 million in proceeds from the exercise of stock options and $275,000 from the sale of common stock through our ESPP partially offset by $1.4 million in principal payments under our notes payable. In 2007, the cash used by financing activities was primarily due to the $6.7 million payoff of the MTPC 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.

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., or 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 the Crown 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%. 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 7.5%, 7.5%, and 9.25% for the years ended December 31, 2009, 2008 and 2007, respectively.

On April 15, 2008, we closed the Deerfield Transaction in which Deerfield and its affiliates agreed to provide us with $30 million in funding. Certain of the agreements with Deerfield were amended and restated on March 16, 2009. The $30 million in funding consists of $20 million from the FARA entered into with the Deerfield Sub, and $10 million from the sale of our common stock under a securities purchase agreement. Under the FARA, the Deerfield Sub made $3.3 million payments to us in April, September and December 2008 and February, June and September 2009, constituting all of the required payments under the FARA. We will pay royalties on the current net sales of MUSE and if approved, future sales of avanafil, an investigational product candidate, to the Deerfield Sub. The term of the FARA is 10 years. The FARA includes covenants requiring us to use commercially reasonable efforts to preserve our intellectual property, manufacture, promote and sell MUSE, and develop avanafil. At the closing on April 15, 2008, in connection with the registered direct offering under the securities purchase agreement, the Deerfield Affiliates purchased 1,626,017 shares of our common stock for an aggregate purchase price of $10 million and we paid to the Deerfield Affiliates a $500,000 fee and reimbursed certain expenses incurred in this transaction of approximately $200,000, registered under the shelf Registration Statement (File Number 333-135793), filed with the SEC on July 14, 2006. The number of shares was determined based on the volume weighted average price on the NASDAQ Global Market of the Company's common stock on the three days prior to the execution of the securities purchase agreement dated as of April 3, 2008.

The agreements also provided us with an option to purchase, and the Deerfield Affiliates with an option to compel us to purchase, or put right, the Deerfield Sub holding the royalty rights through a purchase and sale of all the shares of the Deerfield Sub. If we exercise our right to purchase the Deerfield Sub, the net price will be $23 million if exercised before April 3, 2011 or $26 million if exercised after April 3, 2011 but before April 3, 2012 (the purchase price is subject to other adjustments, as defined in the agreement). After April 3, 2011, the Deerfield Affiliates may exercise the

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right to compel us to purchase the Deerfield Sub at a price of $17 million. This price could increase up to $26 million, and the timing of the sale of the shares could be accelerated under certain conditions including a change-in-control, sale of MUSE or avanafil, sale of major assets and the sale of securities in a transaction or a series of related transactions by the Company that exceed 20% of our outstanding common stock at the date the Option and Put Agreement was signed if at the time of the sale the Company's market capitalization is below $300 million (each, a Major Transaction). Under these conditions, the cost of the shares of the Deerfield Sub would be $23 million on or before April 3, 2011 and $26 million from April 3, 2011 through April 3, 2018. The sale of the shares of the Deerfield Sub could also accelerate if the Company's cash, cash equivalents and available for sale securities falls below $15 million or the Company's market capitalization falls below $50 million. The purchase prices under the put right are subject to other adjustments as defined in the agreements. If either party exercises its option, any further royalty payments would be effectively terminated. In exchange for the option right, we paid $2 million to the Deerfield Affiliates. Our intellectual property and all of the accounts receivable, inventory and equipment arising out of or relating to MUSE and avanafil are collateral for this transaction.

On May 5, 2008, we filed with the SEC a shelf Registration Statement on Form S-3 (File Number 333-150649), which was declared effective by the SEC on May 29, 2008, providing us with the ability to offer and sell up to an aggregate of $150 million of our common stock from time to time in one or more offerings. The terms of any such future offering would be established at the time of such offering.

On May 6, 2008, we filed with the SEC a Post-Effective Amendment No. 1 to Form S-3 (File No. 333-135793), which was filed with the SEC on July 14, 2006, to deregister any securities registered and not otherwise sold thereunder.

On August 6, 2008, we sold $65 million of our common stock in a registered direct offering. Under the terms of the financing, we sold 8,365,508 shares of our common stock at a price of $7.77 per share. On August 5, 2008, the Company filed a prospectus supplement with the SEC relating to this registered direct offering under the existing shelf Registration Statement (File Number 333-150649).

On September 17, 2009, we entered into an underwriting agreement, or the Underwriting Agreement, with J.P. Morgan Securities Inc., as representative of the several underwriters named therein, or the Underwriters, relating to the public offering and sale of 9,000,000 shares of our common stock. Pursuant to the Underwriting Agreement, the Underwriters agreed to purchase, subject to customary closing conditions, 9,000,000 shares of our common stock. We also granted the Underwriters a 30-day option to purchase up to 1,350,000 additional shares of common stock on the same terms and conditions as set forth above to cover over-allotments, which the Underwriters exercised in full. The 10,350,000 shares were sold at a price to the public of $10.50 per share which resulted in approximately $108.7 million in gross proceeds before deducting underwriting discounts and commissions and other offering expenses. The transaction closed on September 23, 2009. The offering was made pursuant to the effective shelf registration statement on Form S-3 (Registration No. 333-161948), including the prospectus dated September 16, 2009 contained therein, as supplemented.

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 and approval by the FDA 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 an investigational product 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.

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The nature and efforts required to develop our investigational product candidates into commercially viable products include research to identify a clinical candidate, pre-clinical 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 investigational product 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 pre-clinical 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 investigational product programs are difficult to estimate and are subject to considerable variation. Our inability to complete our research and investigational product programs 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 or be impacted by 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 costs involved in establishing a commercial operation and in launching a product without a partner;

the cost of manufacturing and commercialization activities and arrangements;

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the ultimate results of the stability of the batches of Qnexa produced for commercialization:

the results of operations;

demand for MUSE;

the potential forced purchase of the royalty streams we previously sold to Deerfield;

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 state of the economy and financing environment;

the regulatory approval environment and regulatory hurdles for safety assessment for new products;

the health care reimbursement system or the impact of healthcare reform, if any, imposed by the U.S. federal government;

the level of resources devoted to sales and marketing capabilities;

adverse perceptions and interpretations of Qnexa or the data by outside analysts or others; 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 into 2011. However, we anticipate that we may require additional funding to continue our research and investigational product development programs, to conduct pre-clinical studies and trials, to fund operating expenses, to pursue regulatory approvals for our investigational product candidates, to finance 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 or new manufacturing and marketing capabilities in the future, to manufacture quantities of our investigational product candidates for approval and commercialization, or to launch a product. In particular, we expect to make other substantial payments to the inventor of Qnexa pending approval by the FDA, Acrux and MTPC, 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 selling or licensing 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 at any time. The sale of additional equity securities would result in additional dilution to our stockholders. We may also seek additional funding through strategic alliances, acquisitions of companies with cash balances 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 investigational product 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 and to pay royalties on future product sales. 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 sell 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 approved for sale, will generate revenues sufficient to enable us to earn a profit.

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Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2009, excluding amounts already recorded on our consolidated balance sheet as accounts payable, and the effect such obligations are expected to have on our liquidity and cash flow in future fiscal years. This table includes our enforceable and legally binding obligations and future commitments, as well as obligations related to all contracts that we are likely to continue, regardless of the fact that they were cancelable as of December 31, 2009. These do not include milestones, with the exception of the $1 million Phase 3 milestone payment due to Acrux for Luramist on or before April 1, 2010 and assumes non-termination of agreements. These obligations, commitments and supporting arrangements represent payments based on current operating plans, which are subject to change:

		Payments Due by Period			
Contractual obligations	**Total**	**2010**	**2011-2013**	**2014-2015**	**Thereafter**
			(in thousands)		
Operating leases	$ 1,017	$ 678	$ 339	$	$
Manufacturing and other agreements	8,282	7,449	815	15	3
Clinical trials	18,664	18,664			
Milestone payments	1,000	1,000			
Notes payable	20,155	157	15,801	441	3,756
Interest payable	9,737	5,049	2,390	607	1,691
Total contractual obligations	$ 58,855	$ 32,997	$ 19,345	$ 1,063	$ 5,450

Operating Leases

We purchased our previously leased manufacturing facilities in Lakewood, New Jersey on December 22, 2005. In November 2006, we entered into a 30-month lease for our corporate headquarters located in Mountain View, California. The 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 expired on July 31, 2009. On December 16, 2008, we entered into a first amendment to this lease. Under the terms of the amended lease, we will continue to lease the office space for our corporate headquarters for a two-year period commencing on August 1, 2009 and expiring on July 31, 2011. The base monthly rent is set at $1.64 per square foot or $23,000 per month. The amended lease allows us one option to extend the term of the lease for one year from the expiration of the lease. On November 12, 2009, we entered into a second amendment to this lease. The second amendment commenced on January 1, 2010, expires on July 31, 2011 and expands the leased space. The base rent for the expansion space is set at $2.25 per square foot or $8,500 per month. The option to extend the term of the amended lease for one year from the expiration of the lease applies to this expansion space as well.

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 alprostadil 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 $765,000 of product in 2011.

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Other Agreements

We have remaining commitments under various general and administrative services agreements totaling $2.4 million at December 31, 2009, including $1.3 million related to Leland F. Wilson's Employment Agreement (see paragraph 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, 2009, our remaining commitment under these agreements totaled $1.9 million. We have entered into marketing promotion and related agreements for our erectile dysfunction product, MUSE. At December 31, 2009, our remaining commitment under the MUSE agreements totaled $1.6 million. In addition, we have entered into agreements related to the pre-commercialization of Qnexa for obesity. The remaining commitments under these agreements totaled $1.6 million at December 31, 2009.

On December 19, 2007, the Compensation Committee of the Board of Directors of the Company approved an employment agreement, or 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 had an initial term of two years commencing on the effective date, June 1, 2007, or 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. On January 23, 2009, the Compensation Committee approved an amendment to the Employment Agreement, or the Amendment, which amends the Employment Agreement. Pursuant to the Amendment, the initial term of the Employment Agreement was increased from two to three years commencing on June 1, 2007 and other relevant dates were also extended to reflect the three-year initial term.

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, 2009, our remaining commitment under these agreements totaled $18.7 million, which includes nearly all of the accrued research and clinical expenses of $2.4 million in the consolidated balance sheet as of December 31, 2009. 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 and Interest Payable

Crown Loan

On January 4, 2006, we obtained a $5.4 million mortgage loan from Crown. The land and buildings, among other assets, located at our principal MUSE 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 7.5%, 7.5% and 9.25% for the years ended December 31, 2009, 2008 and 2007, respectively. As of December 31, 2009, we have a principal balance of $4.9 million remaining on the Crown loan.

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We have included in the above table the estimated interest payments based upon current interest rates that we expect to make in accordance with the terms of the loan agreement. However, should we decide to prepay the loan, there would be a prepayment premium, in lieu of the interest payable in the above table, which would have been 2% at December 31, 2009 (the fourth year of the loan term). If prepayment occurs in the fifth year or thereafter, the premium would be 1%.

Deerfield Financing

On April 3, 2008, we entered into several agreements with Deerfield Management Company, L.P., or Deerfield, a healthcare investment fund, and its affiliates, Deerfield Private Design Fund L.P. and Deerfield Private Design International, L.P. (collectively, the Deerfield Affiliates). Certain of the agreements were amended and restated on March 16, 2009. Under the agreements, Deerfield and its affiliates agreed to provide us with $30 million in funding. The $30 million in funding consists of $20 million from the Funding and Royalty Agreement, or FARA, entered into with a newly incorporated subsidiary of Deerfield, or the Deerfield Sub, and $10 million from the sale of our common stock. Under the FARA, the Deerfield Sub made $3.3 million payments to us in April, September and December 2008 and February, June and September 2009, constituting all of the required payments under the FARA. Such payments are referred to as the Funding Payments. We will pay royalties on the current net sales of MUSE and, if approved, on future sales of avanafil, an investigational product candidate to the Deerfield Sub. The term of the FARA is 10 years. The FARA includes covenants requiring us to use commercially reasonable efforts to preserve our intellectual property, to manufacture, promote and sell MUSE, and to develop avanafil. At the closing on April 15, 2008, under the securities purchase agreement, the Deerfield Affiliates purchased 1,626,017 shares of our common stock for an aggregate purchase price of $10 million, and we paid to the Deerfield Affiliates a $500,000 fee and reimbursed approximately $200,000 in certain expenses incurred in this transaction. The number of shares was determined based on the volume weighted average price on the NASDAQ Global Market of the Company's common stock on the three days prior to the execution of the securities purchase agreement dated as of April 3, 2008. The agreements also provided us with an option to purchase, and the Deerfield Affiliates with an option to compel us to purchase, the Deerfield Sub holding the royalty rights, each as described in greater detail below. If either party exercises its option, any further royalty payments would be effectively terminated. Collectively, these transactions are referred to as the Deerfield Transactions.

Also in connection with the Deerfield Transactions, the Company, the Deerfield Affiliates and the Deerfield Sub entered into the Option and Put Agreement, dated April 3, 2008, and an Amended and Restated Option and Put Agreement dated March 16, 2009, or the OPA. Pursuant to the OPA, the Deerfield Affiliates have granted us an option to purchase all of the outstanding shares of common stock of the Deerfield Sub from the Deerfield Affiliates, referred to as the Option, and we have agreed to grant the Deerfield Affiliates an option to require us to purchase all of the outstanding shares of common stock of the Deerfield Sub from the Deerfield Affiliates, referred to as the Put Right.

If we exercise the Option, base consideration for the Option exercise, or Base Option Price, will be:

$25 million, less $2 million we paid upon closing, if the Option is exercised on or prior to the third anniversary of the execution of the OPA; or

$28 million, less $2 million we paid upon closing, if the Option is exercised subsequent to the third anniversary but prior to the fourth anniversary of the execution of the OPA.

The aggregate consideration payable by VIVUS upon exercise of the Option, or the Option Purchase Price, would be equal to the sum of the Base Option Price, *plus*: (i) the cash and cash equivalents held by the Deerfield Sub at the date of the closing of the resulting sale of the common stock of the Deerfield Sub; (ii) accrued and unpaid royalties; and *minus* (i) the option premium of

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$2 million that was paid at the closing of the transaction (referred to as the Option Premium); (ii) accrued but unpaid taxes; (iii) unpaid Funding Payments; (iv) loans payable by the Deerfield Sub, and (v) any other outstanding liabilities of the Deerfield Sub. The Option terminates on the fourth anniversary of the execution of the OPA.

In consideration of the grant of the Option, at closing we paid $2 million to the Deerfield Affiliates. As indicated in the calculation of the Option Purchase Price, if the Option is exercised by us, the Option Premium will be applied to reduce the Option Purchase Price.

The Put Right terminates on the tenth anniversary of the execution of the OPA and will become exercisable on the earliest of:

the third anniversary of the execution of the OPA;

any date on which:

(1) the market capitalization of the Company falls below $50 million; or

(2) the amount of cash and cash equivalents, as defined, held by the Company falls below $15 million; or

(3) the fifteenth day following the delivery of written notice to the Company that we have failed to make Royalty Payments in accordance with the provisions of the FARA unless we make such Royalty Payments prior to such fifteenth day; or

(4) a Major Transaction, as defined below, closes.

If the Deerfield Affiliates exercise the Put Right, base consideration for the put exercise, or the Base Put Price, will be:

$23 million, if the Put Right is exercised on or prior to the third anniversary of the execution of the OPA, or April 3, 2011, and we have notified the Deerfield Affiliates of our intent to enter into a Major Transaction (such notice is referred to as a Major Transaction Notice); or

$26 million, if the Put Right is exercised subsequent to the third anniversary of the execution of the OPA, or April 3, 2011, and we have provided the Deerfield Affiliates a Major Transaction Notice; or

$17 million, in all other cases.

The aggregate consideration payable by the Company upon exercise of the Put Right, or the Put Purchase Price, would be equal to the sum of the Base Put Price, *plus*: (i) the cash and cash equivalents held by the Deerfield Sub at the date of the closing of the resulting sale of the common stock of the Deerfield Sub; (ii) accrued and unpaid royalties; and *minus* (i) accrued but unpaid taxes; (ii) unpaid Funding Payments; (iii) loans payable by the Deerfield Sub, and (iv) any other outstanding liabilities of the Deerfield Sub.

Pursuant to the OPA, the following events would qualify as Major Transactions:

a consolidation, merger, exchange of shares, recapitalization, reorganization, business combination or similar event:

(1)

following which the holders of the Company's common stock immediately preceding such event either:

(a) no longer hold a majority of the shares of the Company's common stock; or

(b) no longer have the ability to elect a majority of the Company's Board of Directors;

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(2)

as a result of which shares of the Company's common stock are changed into (or the shares of common stock become entitled to receive) the same or a different number of shares of the same or another class or classes of stock or securities of the Company or another entity, collectively referred to as Change in Control Transactions;

a sale or transfer of the Company's assets in one transaction or a series of related transactions for a purchase price of more than $350 million where the consideration to be payable at or within 30 days of closing of such transaction or transactions has a value of more than $350 million, or a sale, transfer or license of all or substantially all the Company's assets or proprietary rights that relate specifically to MUSE or avanafil; or

a purchase, tender or exchange offer made to the holders of outstanding shares of the Company's common stock, such that following such purchase, tender or exchange offer a Change in Control Transaction shall have occurred; or

an issuance or series of issuances in a series of related transactions by the Company of an aggregate number of shares of common stock in excess of 20% of the Company's outstanding common stock on April 3, 2008 if, immediately prior to such issuance, the market capitalization of the Company is less than $300 million.

In connection with the FARA, the Deerfield Sub and the Company have entered into a Royalty Security Agreement, whereby we have granted the Deerfield Sub a security interest in certain collateral related to MUSE and avanafil including: all of our drug applications; all existing and future licenses relating to the development, manufacture, warehousing, distribution, promotion, sale, importing or pricing of MUSE and avanafil; our intellectual property and all of the accounts, inventory and equipment arising out of or relating to MUSE and avanafil. In connection with the OPA, the Deerfield Affiliates and the Company have entered into a security agreement whereby we have granted the Deerfield Affiliates a security interest in the same Collateral as defined by the Royalty Security Agreement. The security interest granted to the Deerfield Affiliates has priority over that granted to the Deerfield Sub by the Royalty Security Agreement.

In accordance with Emerging Issues Task Force Issue 88-18, *Sale of Future Revenues*, as codified in FASB ASC 605, the FARA transaction is in substance a financing arrangement, or loan that will be repaid by us. The minimum repayment amount would be $17 million, the amount of the unconditional put option held by Deerfield Affiliates, plus royalties paid on MUSE sales, and avanafil sales if approved, during the term of the agreement. Accordingly, we have recorded the advances from the Deerfield Affiliates, net of the $2 million option right payment and related fees and expenses, as a loan. We have received all of the required advances under the financing arrangement and recorded a loan of $17 million, the minimum amount owed under the FARA. The $17 million loan is lower than the contractual amounts owed if we exercise our call option of $23 million to $26 million, or if the Deerfield Affiliates require us to purchase the shares as a result of a Major Transaction (see Note 6: "Deerfield Financing"). Using the interest method under APB Opinion No. 21, *Interest on Receivables and Payables*, as codified in FASB ASC topic 835, *Interest,* subtopic 30, *Imputation of Interest* or ASC 835-30, interest on the loan will be calculated and recognized over three years, which is the estimated term of the loan based on the earliest date that the Deerfield Affiliates could require us to repay the amounts advanced. The Deerfield Affiliates will receive a quarterly payment based on net sales of MUSE. The above Contractual Obligations table includes estimated interest payable on the principal owing at December 31, 2009 from the Deerfield Financing based upon a 31% imputed effective interest rate whereas actual quarterly royalty payments are based upon a percentage of net MUSE sales at a rate substantially lower than the imputed effective interest rate used to calculate interest expense.

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Additional Payments

We have entered into development, license and supply agreements that 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 or other payments are due, we have not included these potential future obligations in the above table.

Mitsubishi Tanabe Pharma Corporation

In January 2001, we entered into an exclusive development, license and supply agreement with Tanabe Seiyaku Co., Ltd., or Tanabe, now Mitsubishi Tanabe Pharma Corporation, or MTPC, and hereinafter referred to as MTPC, 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, MTPC 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 MTPC an exclusive, royalty-free license within those countries for oral products that we develop containing avanafil. In addition, we agreed to grant MTPC an exclusive option to obtain an exclusive, royalty-bearing license within those countries for non-oral products that we develop containing avanafil. MTPC 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 MTPC 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 triggered one of the clinical development milestone criteria noted above. We paid MTPC $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 MTPC in the years ended December 31, 2007 and 2008; however, we paid MTPC $4 million in January 2009 following the enrollment in December 2008 of the first patient in the first Phase 3 clinical studies. We expect to make other substantial payments to MTPC in accordance with our agreements with MTPC as we continue to develop and, if approved for sale, commercialize avanafil for the oral treatment of male sexual dysfunction. Such potential future milestone payments total $15 million in the aggregate and include payments upon: the first submission of an NDA; obtainment of the first regulatory approval in the United States and any major European country; and achievement of $250 million or more in calendar year sales.

The term of the MTPC agreement is based on a country-by-country and on a product-by-product basis. The term shall continue until the later of (i) ten years after the date of the first sale for a particular product, or (ii) the expiration of the last-to-expire patents within the MTPC patents covering such product in such country. In the event that our product is deemed to be (i) insufficiently effective or insufficiently safe relative to other PDE5 inhibitor compounds based on published information, or (ii) not economically feasible to develop due to unforeseen regulatory hurdles or costs as measured by standards common in the pharmaceutical industry for this type of product, we have the right to terminate the agreement with MTPC with respect to such product.

Acrux

In February 2004, we entered into exclusive licensing agreements with Acrux Limited, or 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

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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.

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. Future potential milestone payments to Acrux for Luramist total $5.5 million and are payable upon (1) the dosage of the first patient in the Phase 3 clinical studies, (2) the first submission of an NDA, and (3) obtainment of the first regulatory approval in the United States.

For Evamist, we 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. We 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. Under 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. In August 2008, we assigned all of our rights and obligations under the Evamist license agreement to K-V.

In November 2006, we were notified of certain claims by Acrux regarding the Luramist agreements. On November 5, 2007, Acrux made a demand for arbitration under the Testosterone Agreement regarding certain claims related to Luramist. Acrux's demand sought a reversion of all rights assigned to us related to Luramist, monetary damages and the payment of a milestone payment for Luramist under the Testosterone Agreement and declaratory relief. We asserted counterclaims against Acrux in the arbitration and sought the enforcement of our rights under the Testosterone Agreement. The arbitration hearing concluded on January 23, 2009, and on April 6, 2009 the panel of arbitrators, or the Panel, issued its Interim Arbitration Award finding in favor of VIVUS that we were in compliance with the Testosterone Agreement and denying all of the relief sought by Acrux in its demand. The Panel found that we were not in breach of the Luramist license agreement and that we had used diligent, commercially reasonable efforts to develop Luramist. The Panel further ruled in our favor on our counter claim that Acrux had breached the Luramist license agreement by failing to provide certain know-how and certain improvements in the formulation and delivery device for Luramist. The Panel denied the Acrux claim for additional milestone payments. The Panel has ordered Acrux to turn over certain information to us that was previously withheld in violation of the agreement by Acrux. After the parties failed to agree on a new Outside Date by which we are to commence our first Phase 3 trial for Luramist, the Panel reset the Outside Date of April 30, 2006 to April 1, 2010 to reflect the regulatory environment. Acrux will be eligible to receive the previously agreed upon Phase 3 milestone payment of $1 million to be paid out at the earlier of the start of Phase 3 trials or the Outside Date. The milestone is due in six monthly installments of $166,667 for each month of delay in commencing Phase 3 after the Outside Date until the milestone is paid in full. There can be no assurance that Acrux would not continue to pursue legal action against us if we do not commence the first Phase 3 trial by the Outside Date. This milestone payment has been included in the table of contractual obligations above.

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Other

On October 16, 2001, we entered into an assignment agreement, or the Assignment Agreement, with Thomas Najarian, M.D. for a combination of pharmaceutical agents for the treatment of obesity and other disorders, or the Combination Therapy, that has since been the focus of our investigational product development program for Qnexa for the treatment of obesity, obstructive sleep apnea and diabetes. The Combination Therapy and all related patent applications, or the Patents, were transferred to us with worldwide rights to develop and commercialize the Combination Therapy and exploit the Patents. Pursuant to the Assignment Agreement, we have paid a total of $220,000 to Dr. Najarian through December 31, 2009 and have issued him options to purchase 40,000 shares of our common stock. We are obligated under the terms of the Assignment Agreement to make a milestone payment of $1 million and issue an option to purchase 20,000 shares of our common stock to Dr. Najarian upon marketing approval by the United States Food and Drug Administration of a product for the treatment of obesity that is based upon the Combination Therapy and Patents. This assignment will require us to pay royalties on worldwide net sales of a product for the treatment of obesity that is based upon the Combination Therapy and Patents until the last-to-expire of the assigned Patents. To the extent that we decide not to commercially exploit the Patents, the Assignment Agreement will terminate and the Combination Therapy and Patents will be assigned back to Dr. Najarian. In 2006, Dr. Najarian joined VIVUS as a part-time employee and currently serves as our Principal Scientist.

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, 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 its clinical research organizations and investigators sites against liabilities incurred in connection with any third-party claim arising from the work performed on behalf of the Company, among others. 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 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 that 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.

Pursuant to the terms of the Funding and Royalty Agreement with Deerfield, we made certain representations, warranties and covenants related to MUSE and avanafil. Covenants include that we will maintain all registrations and regulatory rights to sell and promote MUSE in the United States, we will continue to manufacture and promote MUSE and will continue the development of avanafil. We also entered into a covenant that we will not manufacture, promote or sell any product that competes with avanafil in the United States other than MUSE.

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

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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 January 2010, the FASB issued ASU 2010-06, *Fair Value Measurements Disclosures*, which amends Subtopic 820-10 of the FASB Accounting Standards Codification to require new disclosures for fair value measurements and provides clarification for existing disclosures requirements. More specifically, this update will require (a) an entity to disclose separately the amounts of significant transfers in and out of Levels 1 and 2 fair value measurements and to describe the reasons for the transfers; and (b) information about purchases, sales, issuances and settlements to be presented separately (i.e. present the activity on a gross basis rather than net) in the reconciliation for fair value measurements using significant unobservable inputs (Level 3 inputs). This update clarifies existing disclosure requirements for the level of disaggregation used for classes of assets and liabilities measured at fair value and requires disclosures about the valuation techniques and inputs used to measure fair value for both recurring and nonrecurring fair value measurements using Level 2 and Level 3 inputs. The Company does not anticipate that the adoption of this statement effective January 1, 2010 will materially expand its consolidated financial statement footnote disclosures.

In October 2009, the FASB issued ASU 2009-13, *Multiple-Deliverable Revenue Arrangements,* (amendments to FASB ASC Topic 605, *Revenue Recognition*), or ASU 2009-13, and ASU 2009-14, *Certain Arrangements That Include Software Elements*, (amendments to FASB ASC Topic 985, *Software*), or ASU 2009-14. ASU 2009-13 requires entities to allocate revenue in an arrangement using estimated selling prices of the delivered goods and services based on a selling price hierarchy. The amendments eliminate the residual method of revenue allocation and require revenue to be allocated using the relative selling price method. ASU 2009-14 removes tangible products from the scope of software revenue guidance and provides guidance on determining whether software deliverables in an arrangement that includes a tangible product are covered by the scope of the software revenue guidance. ASU 2009-13 and ASU 2009-14 should be applied on a prospective basis for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, with early adoption permitted. We are currently evaluating the effect of the adoption of ASU 2009-13 and ASU 2009-14 on our consolidated financial statements.

In June 2009, the FASB issued SFAS No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles, a replacement of FASB Statement No. 162*, as codified in FASB ASC topic 105, *Generally Accepted Accounting Principles,* or ASC 105. This statement establishes the FASB Accounting Standards Codification as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in conformity with GAAP. The adoption of this statement effective September 30, 2009 did not have a material effect on our consolidated financial statements.

In June 2009, the FASB issued SFAS No. 167, *Amendments to FASB Interpretation No. 46(R)*, as codified in ASC 810. This statement amends the consolidation guidance applicable to variable interest entities and the definition of a variable interest entity, and requires enhanced disclosures to provide more information about an enterprise's involvement in a variable interest entity. This statement also requires ongoing assessments of whether an enterprise is the primary beneficiary of a variable interest entity. This statement is effective for our fiscal year beginning January 1, 2010. We do not believe that the adoption of this statement will have a material effect on our consolidated financial statements.

In May 2009, the FASB issued SFAS No. 165, *Subsequent Events*, as codified in FASB ASC topic 855, *Subsequent Events*. This statement establishes general standards of accounting for and disclosures

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of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. The standard is based on the same principles that currently exist in the auditing standards. U.S. GAAP requires disclosure for certain non-recognized subsequent events, the nature of the event and an estimate of its financial effect or a statement that such an estimate cannot be made. The adoption of this statement effective June 30, 2009 did not have a material effect on our consolidated financial statements.

In April 2009, the FASB issued FSP FAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments*, as codified in FASB ASC topic 825-10, *Financial Instruments*. This statement requires disclosures about fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. This statement also requires those disclosures in summarized financial information at interim reporting periods. This statement is effective for interim reporting periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. It does not require disclosures for earlier periods presented for comparative purposes at initial adoption. In periods after initial adoption, this statement requires comparative disclosures only for periods ending after initial adoption. On June 30, 2009, we adopted this statement, which did not have a material effect on the determination or reporting of our financial results.

In April 2009, the FASB issued FSP FAS 115-2 and FAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments,* as codified in FASB ASC topic 320-10*, Investments Debt and Equity Securities,* or ASC 320. This statement amends the other-than-temporary impairment guidance for debt securities to make the guidance more operational and to improve the presentation and disclosure of other-than-temporary impairments on debt and equity securities in the financial statements. It does not amend existing recognition and measurement guidance related to other-than-temporary impairments of equity securities. This statement modifies the requirements for recognizing other-than-temporarily impaired debt securities and revises the existing impairment model for such securities, by modifying the current *intent and ability* indicator in determining whether a debt security is other-than-temporarily impaired. This statement is effective for interim and annual reporting periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. The statement does not require disclosures for earlier periods presented for comparative purposes at initial adoption. In periods after initial adoption, this statement requires comparative disclosures only for periods ending after initial adoption. On June 30, 2009, we adopted this statement, which did not have a material effect on the determination or reporting of our financial results.

In April 2009, the FASB issued FSP FAS 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly*, as codified in ASC 820-10. This statement provides additional guidance for estimating fair value when the volume and level of activity for the asset or liability have significantly decreased. This statement includes guidance on identifying circumstances that indicate a transaction is not orderly. The statement also provides guidance on how to determine the fair value of assets and liabilities in the current economic environment and reemphasizes that the objective of a fair value measurement remains an exit price. If we were to conclude that there has been a significant decrease in the volume and level of activity of the asset or liability in relation to *normal* market activities, quoted market values may not be representative of fair value and we may conclude that a change in valuation technique or the use of multiple valuation techniques may be appropriate. This statement is effective for interim and annual reporting periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. It does not require disclosures for earlier periods presented for comparative purposes at initial adoption. In periods after initial adoption, this statement requires comparative disclosures only for periods ending after initial adoption. On June 30, 2009, we adopted this statement, which did not have a material effect on the determination or reporting of our financial results.

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In October 2008, the FASB issued FASB Staff Position, or FSP, SFAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active*, as codified in ASC 820. This statement clarifies the application of fair value in a market that is not active and addresses application issues such as the use of internal assumptions when relevant observable data does not exist, the use of observable market information when the market is not active and the use of market quotes when assessing the relevance of observable and unobservable data. This statement is effective for all periods presented in accordance with SFAS No. 157. The guidance in this statement was effective immediately and did not have a significant impact on our consolidated financial position or results of operations upon adoption. See Note 2: "Cash, Cash Equivalents and Available-for-Sale Securities" to the notes to consolidated financial statements in this Form 10-K for information and related disclosures regarding our fair value measurements.

In February 2008, the FASB issued FSP SFAS 157-2, as codified in ASC 820, which delays the effective date of SFAS 157 for non-financial assets and non-financial liabilities, except for items that are recognized or disclosed at fair value on a recurring basis (items that are remeasured at least annually). This statement deferred the effective date of SFAS 157 for non-financial assets and non-financial liabilities until our fiscal year beginning on January 1, 2009. On January 1, 2009, we adopted this statement, which did not have a material impact on our consolidated financial position or results of operations.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations,* as codified in FASB ASC topic 805, *Business Combinations*, or ASC 805. This statement changes several underlying principles in applying the purchase method of accounting. Among the significant changes, it 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. This statement 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, it 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. On January 1, 2009, we adopted this statement, which did not 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. 07-01, *Accounting for Collaborative Agreements,* or EITF 07-01, as codified in ASC 605. This statement 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. The statement 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. On January 1, 2009, we adopted this statement, which did not have a material impact on our consolidated financial position or results of operations.

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.

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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 our potential 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 and Interest Rate Risk

Our cash, cash equivalents and available-for-sale securities as of December 31, 2009 consisted primarily of money market funds and U.S. Treasury securities. Our cash is invested in accordance with an investment policy approved by our board of directors that specifies the categories (money market funds, U.S. Treasury securities and debt securities of U.S. government agencies, corporate bonds, asset-backed securities, and other securities), allocations, and ratings of securities we may consider for investment. Currently, we have focused on investing in U.S. Treasuries until market conditions improve.

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are in short-term marketable debt securities. The primary objective of our investment activities is to preserve principal. Some of the securities that we invest in may be subject to market risk. This means that a change in prevailing interest rates may cause the value of the investment to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of our investment may decline. A hypothetical 100 basis point increase in interest rates reduces the fair value of our available-for-sale securities at December 31, 2009 by approximately $585,000. In general, money market funds are not subject to market risk because the interest paid on such funds fluctuates with the prevailing interest rate.

Recently, there has been concern in the credit markets regarding the value of a variety of mortgage-backed and auction rate securities and the resultant effect on various securities markets. In addition, continuing concerns over inflation, energy costs, geopolitical issues, the availability and cost of credit, the U.S. mortgage market and a declining residential real estate market in the U.S. have contributed to increased volatility and diminished expectations for the economy and the markets going forward. These factors combined with volatile oil prices, declining business and consumer confidence and increased unemployment, have precipitated an economic recession and fears of a possible depression. Domestic and international equity markets continue to experience heightened volatility and turmoil. These events and the continuing market upheavals may have an adverse effect on us. In the

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event of a continuing market downturn, our results of operations could be adversely affected by those factors in many ways including making it more difficult for us to raise funds if necessary and may cause stock price volatility. Our investment policy, as approved by our board of directors, allows us to invest in cash, cash equivalents and available-for-sale securities that are not federally insured. Given the current economic instability, we cannot provide assurance that we will not experience losses on these investments.

We are also exposed to interest rate risk on the $4.9 million loan payable to Crown Bank, N.A. as of December 31, 2009. 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 7.5%, 7.5% and 9.25% for the years ended December 31, 2009, 2008 and 2007, respectively.

Foreign Currency Exchange and Foreign Economic Conditions Risk

We receive international revenue from distributors selling products outside the United States. We charge these distributors in U.S. dollars and they sell in their local denomination. In addition, we guarantee a minimum margin percentage, which is affected by current foreign exchange rates. As a result, our financial results could be significantly affected by factors such as changes in foreign currency exchange rates or weak economic conditions in the foreign markets in which our licensed products are sold. Our exposure to foreign exchange rates is most significant relative to the Euro and United Kingdom Pound Sterling.

When the dollar strengthens against foreign currencies, the dollar value of foreign-currency-denominated revenue decreases; when the dollar weakens, the dollar value of the foreign-currency-denominated revenue increases. The Company invoices its international distributors based on an agreed transfer price per unit in United States dollars, which is subject to revision upon quarterly reconciliations based on contractual formulas. Final pricing for product shipments to international distributors is subject to contractual formulas based on the distributor's net realized price in the local currency to its customers. The Company recognizes additional revenue, if any, or reductions to the transfer price, upon finalization of pricing with its international distributors. Accordingly, changes in exchange rates, and in particular a strengthening of the dollar, may adversely affect our international revenue as expressed in dollars.

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Item 8. ***Financial Statements and Supplementary Data***

VIVUS, INC.

1.

Index to Consolidated Financial Statements

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

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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, 2009 and 2008, 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, 2009. 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, 2009 and 2008, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2009, 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, 2008, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 157, *Fair Value Measurement* (included in Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 820, *Fair Value Measurements and Disclosures*).

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, 2009, 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 8, 2010 expressed an unqualified opinion thereon.

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

San Francisco, CA

March 8, 2010

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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, 2009, 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 Annual 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, 2009, 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, 2009 and 2008, 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, 2009 and our report dated March 8, 2010 expressed an unqualified opinion thereon.

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

San Francisco, CA

March 8, 2010

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VIVUS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except par value)

	December 31	
	2009	**2008**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 40,750	$ 66,121
Available-for-sale securities	166,241	121,789
Accounts receivable (net of allowance for doubtful accounts of $27 and $23 at December 31, 2009 and 2008, respectively)	7,259	4,157
Inventories, net	2,702	3,041
Prepaid expenses and other assets	6,410	3,744
Total current assets	223,362	198,852
Property, plant and equipment, net	5,970	6,726
Restricted cash	700	700
Available-for-sale securities		1,344
Total assets	$ 230,032	$ 207,622
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 8,485	$ 17,205
Accrued product returns	3,026	2,865
Accrued research and clinical expenses	2,426	6,435
Accrued chargeback reserve	1,617	1,379
Accrued employee compensation and benefits	3,072	2,394
Accrued and other liabilities	3,421	1,836
Deferred revenue	463	31,858
Total current liabilities	22,510	63,972
Notes payable net of current portion	19,998	11,177
Deferred revenue	798	1,260
Total liabilities	43,306	76,409
Commitments and contingencies		
Stockholders' equity:		
Preferred stock; $1.00 par value; 5,000 shares authorized; no shares issued and outstanding at December 31, 2009 and 2008		
Common stock; $.001 par value; 200,000 shares authorized at December 31, 2009 and 2008; 80,607 and 69,667 shares issued and outstanding at December 31, 2009 and December 31, 2008, respectively	81	70
Additional paid-in capital	420,708	310,558
Accumulated other comprehensive income (loss)	(3)	354
Accumulated deficit	(234,060)	(179,769)
Total stockholders' equity	186,726	131,213

Total liabilities and stockholders' equity	$ 230,032	$ 207,622

See accompanying notes to consolidated financial statements.

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VIVUS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

AND OTHER COMPREHENSIVE INCOME (LOSS)

(In thousands, except per share data)

	Years Ended December 31		
	2009	**2008**	**2007**
Revenue:			
United States product, net	$ 15,836	$ 14,974	$ 15,020
International product	2,347	3,076	4,332
License and other revenue	31,858	84,183	35,346
Total revenue	50,041	102,233	54,698
Operating expenses:			
Cost of goods sold and manufacturing expense	11,950	11,956	12,097
Research and development	71,075	76,996	26,681
Selling, general and administrative	21,033	18,904	17,374
Total operating expenses	104,058	107,856	56,152
Loss from operations	(54,017)	(5,623)	(1,454)
Interest (expense) income:			
Interest income, net	2,019	4,439	4,703
Interest expense	(4,079)	(1,064)	(538)
Other-than-temporary loss on impaired securities	(654)	(7,689)	
Total interest (expense) income	(2,714)	(4,314)	4,165
Income (loss) before benefit (provision) for income taxes	(56,731)	(9,937)	2,711
Benefit (provision) for income taxes	2,440	(3)	(5,095)
Net loss	$ (54,291)	$ (9,940)	$ (2,384)
Other comprehensive income (loss):			
Unrealized gain (loss) on securities, net of taxes	(357)	422	(57)
Comprehensive loss	$ (54,648)	$ (9,518)	$ (2,441)
Net loss per share:			
Basic and diluted	$ (0.75)	$ (0.16)	$ (0.04)
Shares used in per share computation:			
Basic and diluted	72,779	63,724	58,522

See accompanying notes to consolidated financial statements.

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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, 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
Sale of common stock through employee stock purchase plan	64		275			275
Exercise of common stock options for cash	738	1	2,182			2,183
Share-based compensation expense			4,718			4,718
Proceeds from private placement of common stock	9,992	10	74,990			75,000
Issue costs for private placement of common stock			(1,612)			(1,612)
Net unrealized gain on securities				422		422
Net loss					(9,940)	(9,940)
Balances, December 31, 2008	69,667	70	310,558	354	(179,769)	131,213
Sale of common stock through employee stock purchase plan	99		361			361
Exercise of common stock options for cash	491	1	2,349			2,350
Share-based compensation expense			4,791			4,791
Proceeds from underwritten public offering of common stock	10,350	10	108,665			108,675
Issue costs for underwritten public offering of common stock			(6,016)			(6,016)
Net unrealized loss on securities				(357)		(357)
Net loss					(54,291)	(54,291)
Balances, December 31, 2009	80,607	$ 81	$ 420,708	$ (3)	$ (234,060)	$ 186,726

See accompanying notes to consolidated financial statements.

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VIVUS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Years Ended December 31		
	2009	**2008**	**2007**
Cash flows from operating activities:			
Net loss	$ (54,291)	$ (9,940)	$ (2,384)
Adjustments to reconcile net loss to net cash provided by (used for) operating activities:			
Provision for doubtful accounts	4	(6)	4
Provision for excess inventory	487	213	98
Depreciation	1,164	1,141	1,080
Net realized (gain)/loss on investments	(1,085)	979	1,033
Other-than-temporary loss on impaired securities	654	7,689	
Share-based compensation expense	4,791	4,718	3,903
Excess tax benefits related to share-based compensation expense			(1,649)
Gain on disposal of property and equipment			(15)
Sale of Evamist assets			559
Changes in assets and liabilities:			
Accounts receivable	(3,106)	51	152
Inventories	(148)	(687)	452
Prepaid expenses and other assets	(2,666)	1,149	(2,485)
Accounts payable	(8,720)	9,437	5,666
Accrued product returns	161	367	25
Accrued research and clinical expenses	(4,009)	4,953	1,022
Accrued chargeback reserve	238	65	(217)
Accrued employee compensation and benefits	678	395	509
Deferred revenue	(31,857)	(84,183)	114,522
Income taxes payable			1,610
Accrued and other liabilities	1,573	105	197
Net cash provided by (used for) operating activities	(96,132)	(63,554)	124,082
Cash flows from investing activities:			
Property and equipment purchases	(408)	(450)	(301)
Proceeds from sale of property and equipment			19
Short-term investments transferred from cash and cash equivalents			(68,283)
Investment purchases	(220,606)	(123,381)	(97,041)
Proceeds from sale/maturity of securities	177,572	133,674	36,805
Net cash provided by (used for) investing activities	(43,442)	9,843	(128,801)
Cash flows from financing activities:			
Proceeds from notes payable	10,000	7,556	379
Payments of notes payable	(1,167)	(1,408)	(6,809)
Exercise of common stock options	2,350	2,183	2,415
Excess tax benefits related to share-based compensation expense			1,649
Sale of common stock through employee stock purchase plan	361	275	295
Net proceeds from issuance of common stock	102,659	73,388	
Net cash provided by (used for) financing activities	114,203	81,994	(2,071)
Net increase (decrease) in cash and cash equivalents	(25,371)	28,283	(6,790)
Cash and cash equivalents:			
Beginning of year	66,121	37,838	44,628

End of year	$ 40,750	$ 66,121	$ 37,838
Supplemental cash flow disclosure:			
Interest paid	$ 2,861	$ 831	$ 518
Income taxes paid	$ 16	$ 64	$ 4,414
Non-cash investing and financing activities:			
Reclassification of income taxes payable to accumulated deficit	$	$	$ 1,206
Unrealized gain (loss) on securities	$ (357)	$ 422	$ (57)

See accompanying notes to consolidated financial statements.

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Business and Significant Accounting Policies

Business

VIVUS is a biopharmaceutical company, incorporated in 1991, developing innovative, next-generation therapies to address unmet needs in obesity and related morbidities including sleep apnea and diabetes and sexual health. The Company's lead product in clinical development, Qnexa®, has completed Phase 3 clinical trials for the treatment of obesity and an NDA was submitted to the FDA in December 2009. Qnexa is also in Phase 2 clinical development for the treatment of sleep apnea and type 2 diabetes. In the area of sexual health, VIVUS is in Phase 3 development with avanafil, a PDE5 inhibitor for the treatment of erectile dysfunction, and in Phase 2 development of Luramist for the treatment of hypoactive sexual desire disorder, or HSDD, in women. MUSE® (alprostadil), a first generation therapy for the treatment of ED, is already on the market and generating revenue for VIVUS. Current and investigational product candidates in development will encompass patented proprietary formulations and novel delivery systems. Investigational products may be developed by seeking new indications for previously approved pharmaceutical products.

At December 31, 2009, the Company's accumulated deficit was approximately $234.1 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 available-for-sale securities at December 31, 2009 will be sufficient to meet the Company's obligations into 2011. Until the Company can generate sufficient levels of cash from its operations, the Company expects to continue to finance its 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. The Company operates in a single segment, the development and commercialization of novel therapeutic products.

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 U.K. Limited and VIVUS B.V. Limited. All significant inter-company transactions and balances have been eliminated in consolidation. On December 31, 2005, VIVUS U.K. Limited became a dormant company. On March 20, 2008, VIVUS International Limited was dissolved.

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.

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1. Business and Significant Accounting Policies (Continued)

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. At December 31, 2009, all cash equivalents are invested in money market funds and U.S. Treasury securities. These accounts are recorded at cost, which approximates fair value.

Cash with restrictions for a period of greater than 12 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. The Company's investment policy, as approved by the Audit Committee of the Board of Directors, allows it to invest its excess cash balances in money market and marketable securities, primarily U.S. Treasury securities and debt securities of U.S. government agencies, corporate debt securities and asset-backed securities in accordance with its investment policy. The investment policy has the primary investment objectives of preservation of principal; however, there may be times when certain of the securities in the Company's portfolio will fall below the credit ratings required in the policy. If those securities are downgraded or impaired the Company would experience losses in the value of its portfolio which would have an adverse effect on its results of operations, liquidity and financial condition.

The Company determines the appropriate classification of marketable securities at the time of purchase and reevaluates such designation at each balance sheet date. Marketable securities have been classified and accounted for as available-for-sale. 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 may sell these securities prior to their stated maturities. As these securities are viewed by the Company as available to support current operations, securities with maturities beyond 12 months are classified as current assets.

Securities are carried at fair value, with the unrealized gains and losses, net of taxes, reported as a component of stockholders' equity, unless the decline in value is deemed to be other-than-temporary and the Company intends to sell such securities before recovering their costs, in which case such securities are written down to fair value and the loss is charged to other-than-temporary loss on impaired securities. The Company evaluates its investment securities for other-than-temporary declines based on quantitative and qualitative factors. Any realized gains or losses on the sale of marketable securities are determined on a specific identification method, and such gains and losses are reflected as a component of interest income.

Accounts Receivable, Allowances for Doubtful Accounts and Cash Discounts

The Company extends credit to its customers for product sales resulting in accounts receivable. 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 in the consolidated balance sheets, net of the allowance for doubtful accounts.

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1. Business and Significant Accounting Policies (Continued)

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 number of high credit quality institutions, diversifying its investment portfolio and placing investments with maturities that maintain safety and liquidity within the Company's liquidity needs.

Inventories

Inventories are valued at the lower of cost or market. The Company records 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 the Company, additional inventory write-downs may be required. 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 is used in production in the company, it was charged to cost of goods sold at a zero basis.

The Company expenses 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 balance sheets. 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).

Long-lived assets, such as property, plant and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to an estimate of undiscounted future cash flows expected to be generated by the asset. If the carrying amount of the asset exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset. Assets to be disposed of would be separately presented in the consolidated balance sheet and

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1. Business and Significant Accounting Policies (Continued)

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 consolidated 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, 2009.

Restricted Cash

In connection with a $5.4 million mortgage loan from Crown Bank, N.A., or 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 in the accompanying consolidated balance sheets.

Fair Value

On January 1, 2008, the Company adopted SFAS No. 157 *Fair Value Measurements,* as codified in FASB ASC 820, *Fair Value Measurements and Disclosures,* or ASC 820, and effective October 10, 2008, the Company adopted FSP No. SFAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active,* except as it applies to the nonfinancial assets and nonfinancial liabilities subject to FSP 157-2. On January 1, 2009, the Company adopted SFAS No 157 with respect to non-financial assets and non-financial liabilities. On June 15, 2009, the Company adopted FSP 157-4, *Determining Fair Value When the Volume and Level of Activity for the Assets or Liabilities Have Significantly Decreased and Identifying Transactions That Are Not Orderly.* Adoption of the provisions of these standards did not have a material effect on the Company's financial position.

Financial Instruments Measured at Fair Value. Cash and cash equivalents and available-for-sale financial instruments are carried at fair value and the Company makes estimates regarding valuation of these assets measured at fair value in preparing the consolidated financial statements.

Fair Value Measurement Definition and Hierarchy. SFAS No. 157 defines fair value as the price that would be received to sell an asset or paid to transfer a liability (i.e., the "exit price") in an orderly transaction between market participants at the measurement date.

Valuation Technique. SFAS No. 157 establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances. SFAS No. 157 prescribes three valuation techniques that shall be used to measure fair value as follows:

1. Market Approach uses prices or other relevant information generated by market transactions involving identical or comparable assets or liabilities.

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1. Business and Significant Accounting Policies (Continued)

2. Income Approach uses valuation techniques to convert future cash flow amounts to a single present value amount (discounted).

3. Cost Approach the amount that currently would be required to replace the service capacity of an asset (i.e., current replacement cost).

One or a combination of the approaches above can be used to calculate fair value, whichever results in the most representative fair value.

In addition to the three valuation techniques, SFAS No. 157 prescribes a fair value hierarchy in order to increase consistency and comparability in fair value measurements and related disclosures. The hierarchy is broken down into three levels based on the reliability of inputs as follows:

Level 1 Valuations based on quoted prices in active markets for identical assets. Since valuations are based on quoted prices that are readily and regularly available in an active market, valuation of these products does not entail a significant degree of judgment.

These types of instruments primarily consist of financial instruments whose value is based on quoted market prices such as cash, money market funds and U.S. Treasury securities that are actively traded. Management judgment was required to determine the Company's policy that defines the levels at which sufficient volume and frequency of transactions is met for a market to be considered active.

Level 2 Valuations based on quoted prices in markets that are not active or for which all significant inputs are observable, directly or indirectly. Quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

The types of instruments valued based on other observable inputs include debt securities of U.S. government agencies, corporate bonds, mortgage-backed and asset-backed products. Substantially all of these assumptions are observable in the marketplace, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace.

Level 3 Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

These types of instruments have included certain corporate bonds, mortgage-backed securities and asset-backed securities. The Company has no Level 3 securities at December 31, 2009. Level 3 is comprised of unobservable inputs that are supported by little or no market activity. These instruments are considered Level 3 when their fair values are determined using pricing models, discounted cash flows or similar techniques and at least one significant model assumption or input is unobservable. Level 3 may still include some observable inputs such as yield spreads derived from markets with limited activity. Level 3 financial assets include securities for which there is limited market activity such that the determination of fair value requires significant judgment or estimation.

The availability of observable inputs can vary from product to product and is affected by a wide variety of factors, including, for example, the type of product, whether the product is new and not yet established in the marketplace, and other characteristics particular to the transaction. To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1. Business and Significant Accounting Policies (Continued)

the Company in determining fair value is greatest for instruments categorized in Level 3. In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, for disclosure purposes, the level in the fair value hierarchy within which the fair value measurement in its entirety falls is determined based on the lowest level input that is significant to the fair value measurement in its entirety.

Fair Value Measurements

As of December 31, 2009, the Company's cash and cash equivalents and available-for-sale securities measured at fair value on a recurring basis totaled $207 million. All of the Company's cash and cash equivalents and available-for-sale securities are cash, money market instruments and U.S. Treasury securities and these are classified as Level 1. The valuation techniques used to measure the fair values of these financial instruments were derived from quoted market prices, as substantially all of these instruments have maturity dates, if any, within one year from the date of purchase and active markets for these instruments exists.

Revenue Recognition

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

persuasive evidence of an arrangement exists;

shipment has occurred;

the sales price is fixed or determinable; and

collectibility is reasonably assured.

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

United States

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

International

The Company has supply agreements with Meda AB, or Meda, to market and distribute MUSE internationally in some Member States of the European Union. In Canada, the Company entered into a license and supply agreement with Paladin Labs, Inc., or Paladin, for the marketing and distribution of MUSE. Sales to Meda for 2009, 2008, and 2007 were 94%, 93%, and 95.8% of international sales, respectively. The balance of international sales was made to Paladin.

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1. Business and Significant Accounting Policies (Continued)

The Company invoices its international distributors based on an agreed transfer price per unit, in United States dollars, which is subject to revision upon quarterly reconciliations based on contractual formulas. Final pricing for product shipments to international distributors is subject to contractual formulas based on the distributor's net realized price in the local currency to its customers. The Company recognizes additional revenue, if any, or reductions to revenue, 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 received a $1.5 million upfront payment in connection with the international supply agreement signed with Meda in September 2002. In January 2006, the Company also 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 Union territories. These amounts were recorded as deferred revenue and are being recognized ratably over the term of the supply agreement. Through December 31, 2009, $2.3 million has been recognized as revenue.

License and Other Revenue

The Company recognizes license revenue in accordance with the Securities and Exchange Commission's, or SEC's, Staff Accounting Bulletin No. 104, *Revenue Recognition*, and Emerging Issues Task Force, or EITF, Issue 00-21, *Revenue Arrangements with Multiple Deliverables,* as codified in FASB ASC topic 605, *Revenue Recognition*, or ASC 605. 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.

Sale of Evamist product

On May 15, 2007, the Company closed its transaction with K-V Pharmaceutical Company, or K-V, 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 Food and Drug Administration, or FDA, for marketing. The sale transaction contained multiple deliverables, including: the delivery at closing of the Evamist assets, a grant of a sublicense of the Company's rights under a license agreement 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, or 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

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1. Business and Significant Accounting Policies (Continued)

upon FDA Approval. These payments are non-refundable. In August 2008, the Company assigned all of its rights and obligations under the Evamist license agreement to K-V.

Upon FDA Approval, the two remaining deliverables were the transition services to be performed under the Transition Services Agreement, or 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 was able to establish fair value for the TSA. Given the unique nature of the license to improvements, the Company was unable to obtain objective, reliable evidence of its fair value.

Accordingly, the delivered items, together with the undelivered items, were treated as one unit of accounting. Since the deliverables were treated as a single unit of accounting, the total cash received, $150 million, was recognized as revenue on a pro-rata basis over the term of the last deliverable, which in this case was the license to improvements that expired on May 15, 2009. As a result, the initial $10 million paid at closing and the $140 million paid upon FDA Approval were recorded as deferred revenue and have been recognized as revenue ratably over the remaining 21.5-month term of the license to improvements, from August 1, 2007 to May 15, 2009. All of the revenue deferred from the Evamist sale has now been recognized.

The Company is also eligible to 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.

Under the terms of the transaction, K-V reimbursed the Company for $1.5 million of the $3 million milestone payment paid by the Company to Acrux upon FDA Approval of the NDA.

Advertising and Sales Promotion Expenses

Advertising and sales promotion expenses are charged to expense as incurred. The Company incurred $34,000 in 2009, $6,000 in 2008 and $1.2 million in 2007 in advertising and sales promotion costs related to its marketed product, MUSE.

Shipping and Handling Costs

Shipping costs included in "Selling, General and Administrative" for the years ended December 31, 2009, 2008 and 2007 are $192,000, $228,000 and $216,000, respectively. Handling costs included in "Cost of Goods Sold and Manufacturing Expense" for the years ended December 31, 2009, 2008 and 2007 are $312,000, $362,000 and $330,000, respectively.

Research and Development Expenses and Accruals

Research and development, or 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. The Company also records accruals for estimated ongoing clinical trial costs. Clinical trial costs represent costs incurred by clinical research organizations, or CROs, and clinical sites and include advertising for clinical trials and patient recruitment costs. These costs are recorded as a component of R&D expenses and are expensed as incurred. Under the Company's agreements, progress payments are typically made to investigators, clinical sites and CROs. The

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1. Business and Significant Accounting Policies (Continued)

Company analyzes 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.

Product Returns

The Company has estimated reserves for product returns from wholesalers, hospitals and pharmacies in the United States. 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, and other rebate programs, including those with managed care organizations, 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 government chargeback and rebate amounts paid and applies chargeback rates to estimate of the quantity of units subject to chargeback. The Company routinely assesses its experience with government chargebacks and other rebates 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.

Share-Based Payments

The Company follows the fair value method of accounting for share-based compensation arrangements in accordance with SFAS 123R, *Share-Based Payment*, as codified in FASB ASC topic 718, *Compensation Stock Compensation,* or ASC 718. Compensation expense is recognized, using a fair-value based method, for all costs related to share-based payments including stock options and restricted stock units and stock issued under the employee stock purchase plan. The Company estimates the fair value of share-based payment awards on the date of the grant using an option-pricing model. The Company adopted SFAS 123R effective January 1, 2006 using the modified prospective method of transition. The Company adopted the simplified method to calculate the beginning balance of the additional paid-in capital, or APIC, pool of excess tax benefits, and to determine the subsequent effect on the APIC pool and consolidated statements of cash flows of the tax effects of employee stock-based compensation awards. See Note 9: "Stock Option and Purchase Plans" for further discussion of the Company's stock-based compensation plans.

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1. Business and Significant Accounting Policies (Continued)

Income Taxes

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 the Company's consolidated financial statements, the Company is required to estimate its income taxes in each of the jurisdictions in which the Company 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, 2009, it was considered more likely than not that the Company's deferred tax assets would not 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 the Company determines that it is more likely than not that it will recover its deferred tax assets.

In July 2006, the Financial Accounting Standards Board, or FASB, issued FASB Interpretation No. 48, or FIN No. 48, *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109,* as codified in FASB ASC 740-10, *Income Taxes*, 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 was 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 on January 1, 2007.

Contingencies and Litigation

The Company is periodically involved in disputes and litigation related to a variety of matters. When it is probable that the Company will experience a loss, and that loss is quantifiable, the Company records appropriate reserves. The Company records legal fees and costs as an expense when incurred.

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1. Business and Significant Accounting Policies (Continued)

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 Income (Loss) Per Share

The Company computes basic net income (loss) per share applicable to common shareholders based on the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share 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. Common share equivalents are excluded from the computation in periods in which they have an anti-dilutive effect. Stock options for which the price exceeds the average market price over the period have an anti-dilutive effect on net income per share and, accordingly, are excluded from the calculation. When there is a net loss, other potentially dilutive common equivalent shares are not included in the calculation of net loss per share since their inclusion would be anti-dilutive.

The computation of basic and diluted EPS for the years ended December 31, 2009, 2008 and 2007 are as follows:

	2009	2008	2007
	(In thousands, except per share data)		
Net loss	$ (54,291)	$ (9,940)	$ (2,384)
Net loss per share basic	$ (.75)	$ (.16)	$ (.04)
Effect of dilutive securities			
Net loss per share diluted	$ (.75)	$ (.16)	$ (.04)
Shares used in the computation of net loss per share basic	72,779	63,724	58,522
Effect of dilutive securities			
Diluted shares	72,779	63,724	58,522

As the Company recognized a net loss for the years ended December 31, 2009, 2008 and 2007, all potential common equivalent shares were excluded for these periods as they were anti-dilutive. Potentially dilutive options outstanding of 3,333,108, 3,282,348 and 2,828,510 at December 31, 2009, 2008 and 2007, respectively, were not included in the computation of diluted net loss per share for the Company because the effect would be anti-dilutive.

Recent Accounting Requirements

In October 2009, the FASB issued ASU 2009-13, *Multiple-Deliverable Revenue Arrangements,* (amendments to FASB ASC Topic 605, *Revenue Recognition*), or ASU 2009-13, and ASU 2009-14, *Certain Arrangements That Include Software Elements*, (amendments to FASB ASC Topic 985, *Software*), or ASU 2009-14. ASU 2009-13 requires entities to allocate revenue in an arrangement using estimated

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1. Business and Significant Accounting Policies (Continued)

selling prices of the delivered goods and services based on a selling price hierarchy. The amendments eliminate the residual method of revenue allocation and require revenue to be allocated using the relative selling price method. ASU 2009-14 removes tangible products from the scope of software revenue guidance and provides guidance on determining whether software deliverables in an arrangement that includes a tangible product are covered by the scope of the software revenue guidance. ASU 2009-13 and ASU 2009-14 should be applied on a prospective basis for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, with early adoption permitted. The Company is currently evaluating the effect of the adoption of ASU 2009-13 and ASU 2009-14 on its consolidated financial statements.

In June 2009, the FASB issued SFAS No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles, a replacement of FASB Statement No. 162*, as codified in FASB ASC topic 105, *Generally Accepted Accounting Principles,* or ASC 105. This statement establishes the FASB Accounting Standards Codification as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in conformity with GAAP. The adoption of this statement effective September 30, 2009 did not have a material effect on the Company's consolidated financial statements

In June 2009, the FASB issued SFAS No. 167, *Amendments to FASB Interpretation No. 46(R)*, as codified in ASC 810. This statement amends the consolidation guidance applicable to variable interest entities and the definition of a variable interest entity, and requires enhanced disclosures to provide more information about an enterprise's involvement in a variable interest entity. This statement also requires ongoing assessments of whether an enterprise is the primary beneficiary of a variable interest entity. This statement is effective for the Company's fiscal year beginning January 1, 2010. The Company does not believe that the adoption of this statement will have a material effect on its consolidated financial statements.

In May 2009, the FASB issued SFAS No. 165, *Subsequent Events*, as codified in FASB ASC topic 855, *Subsequent Events*. This statement establishes general standards of accounting for and disclosures of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. The standard is based on the same principles that currently exist in the auditing standards. U.S. GAAP requires disclosure for certain non-recognized subsequent events, the nature of the event and an estimate of its financial effect or a statement that such an estimate cannot be made. The Company has evaluated subsequent events for the period from December 31, 2009, the date of these financial statements, to the date these financial statements are being filed with the Securities Exchange Commission ("SEC"). There were no events or transactions occurring during this subsequent event reporting period which require recognition in the financial statements.

In April 2009, the FASB issued FSP FAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments*, as codified in FASB ASC topic 825-10, *Financial Instruments*. This statement requires disclosures about fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. This statement also requires those disclosures in summarized financial information at interim reporting periods. This statement is effective for interim reporting periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. It does not require disclosures for earlier periods presented for comparative purposes at initial adoption. In periods after initial adoption, this statement requires comparative disclosures only for periods ending after initial adoption. On June 30, 2009, the Company

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1. Business and Significant Accounting Policies (Continued)

adopted this statement, which did not have a material effect on the determination or reporting of its financial results.

In April 2009, the FASB issued FSP FAS 115-2 and FAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments,* as codified in FASB ASC topic 320-10*, Investments Debt and Equity Securities,* or ASC 320-10. This statement amends the other-than-temporary impairment guidance for debt securities to make the guidance more operational and to improve the presentation and disclosure of other-than-temporary impairments on debt and equity securities in the financial statements. It does not amend existing recognition and measurement guidance related to other-than-temporary impairments of equity securities. This statement modifies the requirements for recognizing other-than-temporarily impaired debt securities and revises the existing impairment model for such securities, by modifying the current *intent and ability* indicator in determining whether a debt security is other-than-temporarily impaired. This statement is effective for interim and annual reporting periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. The statement does not require disclosures for earlier periods presented for comparative purposes at initial adoption. In periods after initial adoption, this statement requires comparative disclosures only for periods ending after initial adoption. On June 30, 2009, the Company adopted this statement, which did not have a material effect on the determination or reporting of its financial results.

In April 2009, the FASB issued FSP FAS 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly*, as codified in ASC 820-10, *Fair Value Measurements and Disclosures*. This statement provides additional guidance for estimating fair value in accordance with SFAS No. 157, *Fair Value Measurements*, when the volume and level of activity for the asset or liability have significantly decreased. This statement also includes guidance on identifying circumstances that indicate a transaction is not orderly. The statement also provides guidance on how to determine the fair value of assets and liabilities in the current economic environment and reemphasizes that the objective of a fair value measurement remains an exit price. If the Company were to conclude that there has been a significant decrease in the volume and level of activity of the asset or liability in relation to *normal* market activities, quoted market values may not be representative of fair value and the Company may conclude that a change in valuation technique or the use of multiple valuation techniques may be appropriate. This statement is effective for interim and annual reporting periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. The statement does not require disclosures for earlier periods presented for comparative purposes at initial adoption. In periods after initial adoption, this statement requires comparative disclosures only for periods ending after initial adoption. On June 30, 2009, the Company adopted this statement, which did not have a material effect on the determination or reporting of its financial results.

In October 2008, the FASB issued FASB Staff Position, or FSP, SFAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active*, as codified in ASC 820. This statement clarifies the application of SFAS No. 157 in a market that is not active and addresses application issues such as the use of internal assumptions when relevant observable data does not exist, the use of observable market information when the market is not active and the use of market quotes when assessing the relevance of observable and unobservable data. This statement is effective for all periods presented in accordance with SFAS No. 157. The guidance in this statement was effective immediately and did not have a significant impact on the Company's consolidated financial position or

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1. Business and Significant Accounting Policies (Continued)

results of operations upon adoption. See Note 2: "Cash, Cash Equivalents and Available-for-Sale Securities" to the notes to consolidated financial statements in this Form 10-K for information and related disclosures regarding the Company's fair value measurements.

In February 2008, the FASB issued FSP SFAS 157-2, as codified in ASC 820, which delays the effective date of SFAS 157 for non-financial assets and non-financial liabilities, except for items that are recognized or disclosed at fair value on a recurring basis (items that are remeasured at least annually). This statement deferred the effective date of SFAS 157 for non-financial assets and non-financial liabilities until the Company's fiscal year beginning on January 1, 2009. On January 1, 2009, the Company adopted this statement, which did not have a material impact on its consolidated financial position or results of operations.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations,* as codified in FASB ASC topic 805, *Business Combinations*, or ASC 805. This statement changes several underlying principles in applying the purchase method of accounting. Among the significant changes, it 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. This statement 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, this statement 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. On January 1, 2009, the Company adopted this statement, which did not have a material impact on its consolidated financial position or results of operations.

In September 2007, the FASB ratified Emerging Issues Task Force Issue No. 07-01, *Accounting for Collaborative Agreements,* or EITF 07-01, as codified in ASC 605. This statement 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. This statement 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. On January 1, 2009, the Company adopted this statement, which did not have a material impact on its consolidated financial position or results of operations.

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, 2009 and 2008 are presented in the tables that follow.

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

As of December 31, 2009 (in thousands):

Cash and cash equivalents	Amortized Cost	Estimated Fair Value	Gross Unrealized Gains	Gross Unrealized Losses
Cash and money market funds	$ 38,742	$ 38,742	$	$
U.S. Treasury securities	2,009	2,008		(1)
Total cash and cash equivalents	$ 40,751	$ 40,750	$	$ (1)

Available-for-sale securities	Amortized Cost	Estimated Fair Value	Gross Unrealized Gains	Gross Unrealized Losses
U.S. Treasury securities	$ 166,243	$ 166,241	$ 34	$ (36)
Total available-for-sale securities	$ 166,243	$ 166,241	$ 34	$ (36)

As of December 31, 2008 (in thousands):

Cash and cash equivalents	Amortized Cost	Estimated Fair Value	Gross Unrealized Gains	Gross Unrealized Losses
Cash and money market funds	$ 66,121	$ 66,121	$	$
Total cash and cash equivalents	$ 66,121	$ 66,121	$	$

Available-for-sale securities	Amortized Cost	Estimated Fair Value	Gross Unrealized Gains	Gross Unrealized Losses
U.S. Treasury securities and debt securities of U.S. government agencies	$ 100,061	$ 100,412	$ 351	$
Corporate bonds	8,393	8,387		(6)
Asset backed and other securities	12,981	12,990	10	(1)
Total available-for-sale securities	$ 121,435	$ 121,789	$ 361	$ (7)

Available-for-sale securities, non-current	Amortized Cost	Estimated Fair Value	Gross Unrealized Gains	Gross Unrealized Losses
Corporate bonds	$ 1,067	$ 1,067	$	$
Asset backed and other securities	277	277		
Total available-for-sale securities, non current	$ 1,344	$ 1,344	$	$

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

The following table summarizes the Company's available-for-sale securities by the contractual maturity date as of December 31, 2009 (in thousands):

	Amortized Cost	Estimated Fair Value
Due within one year	$ 166,243	$ 166,241
	$ 166,243	$ 166,241

The following table summarizes the net realized gains (losses) on available-for-sale securities for the periods presented (in thousands):

	Years Ended December 31,		
	2009	2008	2007
Realized gains	$ 1,637	$ 394	$ 2
Realized losses	(552)	(1,373)	(1,035)
Net realized gains (losses)	$ 1,085	$ (979)	$ (1,033)

During the year ended December 31, 2009, the Company sold and received paydowns totaling $24 million of fixed income securities, which resulted in net realized gains of $1.1 million. During the year ended December 31, 2008, the Company sold and received paydowns totaling $85.2 million of fixed income securities which resulted in net realized losses of $979,000. In the ordinary course of business, the Company may sell securities at a loss for a number of reasons, including, but not limited to: (i) changes in the investment environment; (ii) expectation that the fair value could deteriorate further; (iii) desire to reduce exposure to an issuer or an industry; (iv) changes in credit quality; or (v) changes in expected cash flow.

At December 31, 2009, the Company had the following cash equivalent and available-for-sale securities that were in an unrealized loss position (in thousands):

	Less Than 12 Months	
December 31, 2009	Gross Unrealized Losses	Estimated Fair Value
U.S. Treasury securities	$ (37)	$ 79,709
Total	$ (37)	$ 79,709

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

At December 31, 2008, the Company had the following available-for-sale securities that were in an unrealized loss position but were not deemed to be other-than-temporarily impaired (in thousands):

	Less Than 12 Months		12 Months or Greater	
December 31, 2008	**Gross Unrealized Losses**	**Estimated Fair Value**	**Gross Unrealized Losses**	**Estimated Fair Value**
Corporate bonds	$ (6)	$ 231	$	$
Asset backed and other securities	(1)	1,144		
Total	$ (7)	$ 1,375	$	$

The gross unrealized losses reported above for December 31, 2009 and 2008 were primarily caused by general fluctuations in market interest rates from the respective purchase date of these securities through the end of those periods. The gross unrealized loss of $37,000 at December 31, 2009 is attributable to the Company's holding in 32 individual securities from one issuer, the U.S. Treasury.

As the Company presently does not intend to sell its debt securities and believes it will not likely be required to sell the securities that are in an unrealized loss position before recovery of their amortized cost, the Company does not consider these securities to be other-than-temporarily impaired.

As of December 31, 2009 and 2008, the temporary unrealized gains (losses) on cash, cash equivalents and available-for-sale securities, net of tax, of $(3,000) and $354,000, respectively, were included in accumulated other comprehensive income (loss) in the accompanying consolidated balance sheets. As of December 31, 2009, a significant portion of the available-for-sale securities that the Company held were investment grade with an average rating of AAA/Aaa.

SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, FSP SFAS 115-2 and SFAS 124-4, *Recognition and Presentation of Other-than-Temporary Impairments ("FSP 115-2/SFAS 124-2")* and SAB Topic 5M, *Accounting for Non-current Marketable Equity Securities*, as codified in FASB ASC topic 320-10, *Investments Debt and Equity Securities*, or ASC 320-10, provides guidance on determining when an investment is other-than-temporarily impaired. Investments are reviewed quarterly for indicators of other-than-temporary impairment. Effective for all periods ending after June 15, 2009, it provides additional guidance designed to create a greater clarity and consistency in accounting for and presenting impairment losses on securities. In reviewing its non-U.S. Government available-for-sale securities, the Company concluded that it intends to sell the debt securities before recovering their costs. Therefore, in accordance with the above recent guidance, the Company recognized an "other-than-temporary" impairment of $654,000 on these securities during the year ended December 31, 2009. The Company included this non-cash impairment charge in other-than-temporary loss on impaired securities in the consolidated statements of operations and other comprehensive loss. These securities covered a number of industries. At December 31, 2009, all available-for-sale securities were invested in U.S. Treasuries.

During the Company's quarterly impairment assessments in 2008, the Company determined that a decline in value of certain securities was other-than-temporary. Accordingly, the Company recorded other-than-temporary impairment adjustments of $7.7 million in the year ended December 31, 2008. The Company included this non-cash impairment charge in other-than-temporary loss on impaired securities in the consolidated statements of operations and other comprehensive income (loss).

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

Included in the charge taken in 2008 was $2.4 million related to corporate bonds issued by Lehman Brothers Holdings Inc., or Lehman (or their respective subsidiaries, as appropriate). In addition, other-than-temporary impairments recognized in 2008 included impairments on investments for which the Company determined that the impairment was other-than-temporary due to credit downgrades and/or the Company's intent and ability to hold the investment to maturity. These securities covered a number of industries.

Fair Value Measurements

Effective January 1, 2008, the Company adopted SFAS No. 157, *Fair Value Measurements*, as codified in FASB ASC 820, *Fair Value Measurements and Disclosures,* or ASC 820, which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. Broadly, the framework clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability.

As a basis for considering such assumptions, this statement establishes a three-tier value hierarchy, which prioritizes the inputs used in measuring fair value as follows: (Level 1) observable inputs such as quoted prices in active markets; (Level 2) inputs other than the quoted prices in active markets that are observable either directly or indirectly; and (Level 3) unobservable inputs in which there is little or no market data, which require the Company to develop its own assumptions. This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value. On a recurring basis, the Company measures its marketable securities at fair value.

The following fair value hierarchy tables present information about the Company's assets (cash and cash equivalents and available-for-sale securities) measured at fair value on a recurring basis as of December 31, 2009 (in thousands):

		Basis of Fair Value Measurements		
	Balance at December 31, 2009	Level 1	Level 2	Level 3
Cash and cash equivalents:				
Cash and money market funds	$ 38,742	$ 38,742	$	$
U.S. Treasury securities	2,008	2,008		
Total cash and cash equivalents	$ 40,750	$ 40,750	$	$

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

		Basis of Fair Value Measurements		
	Balance at December 31, 2009	Level 1	Level 2	Level 3
Available-for-sale securities:				
U.S. Treasury securities	$ 166,241	$ 166,241	$	$
Total available-for-sale securities	$ 166,241	$ 166,241	$	$
Reported as:				
Cash and cash equivalents	$ 40,750			
Available-for-sale securities	166,241			
Total	$ 206,991			

The following fair value hierarchy tables present information about the Company's assets (cash and cash equivalents and available-for-sale securities) measured at fair value on a recurring basis as of December 31, 2008 (in thousands):

		Basis of Fair Value Measurements		
	Balance at December 31, 2008	Level 1	Level 2	Level 3
Cash and cash equivalents and available-for-sale securities:				
Cash and cash equivalents	$ 66,121	$ 66,121	$	$
U.S. Treasury securities	92,479	92,479		
Debt securities of U.S. government agencies	7,933		7,933	
Corporate bonds	9,455		9,006	449
Asset backed and other securities	13,266		11,401	1,865
Total	$ 189,254	$ 158,600	$ 28,340	$ 2,314
Reported as:				
Cash and cash equivalents	$ 66,121			
Available-for-sale securities	121,789			
Available-for-sale securities, non-current	1,344			
Total	$ 189,254			

Fair values are based on quoted market prices, where available. These fair values are obtained primarily from third party pricing services, which generally use Level 1 or Level 2 inputs for the determination of fair value in accordance with ASC 820. Third party pricing services normally derive the security prices through recently reported trades for identical or similar securities making adjustments through the reporting date based upon available market observable information. For securities not actively traded, the third party pricing services may use quoted market prices of comparable instruments or discounted cash flow analyses, incorporating inputs that are currently observable in the markets for similar securities. Inputs that are often used in the valuation methodologies include, but are not limited to, benchmark yields, broker quotes, credit spreads, default

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

rates and prepayment speeds. The Company performs a review of the prices received from third parties to determine whether the prices are reasonable estimates of fair value.

The Company generally obtains one price for each investment security. The Company performs a review to assess if the evaluated prices represent a reasonable estimate of their fair value. This process involves quantitative and qualitative analysis by the Company. Examples of procedures performed include, but are not limited to, initial and ongoing review of pricing service methodologies, review of the prices received from the pricing service, and comparison of prices for certain securities with different appropriate price sources for reasonableness. As a result of this analysis, if the Company determines there is a more appropriate fair value based upon available market data, which happens infrequently, the price of a security is adjusted accordingly. The pricing service provides information to indicate which securities were priced using market observable inputs so that the Company can properly categorize its financial assets in the fair value hierarchy.

The following tables present additional information about Level 3 assets measured at fair value on a recurring basis. Unobservable inputs are used to determine the fair value of positions that the Company has classified within the Level 3 category. The types of instruments valued based on Level 3 inputs included structured investment vehicles (SIVs) and residential and commercial mortgage asset backed securities issued in the United States.

These Level 3 securities were valued using an independent pricing source that used their proprietary models. The Company reviewed the inputs and assumptions used in these fair value models for reasonableness.

The changes in Level 3 assets measured at fair value on a recurring basis for the year ended December 31, 2009 were (in thousands):

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3)		
Activity for the Year Ended December 31, 2009	**Corporate bonds**	**Asset backed and other securities**	**Total**
Balance at December 31, 2008	$ 449	$ 1,865	$ 2,314
Transfers into Level 3(a)		459	459
Transfers out of Level 3(a)			
Total realized/unrealized gains/(losses) included in net income/(loss)	248	(47)	201
Total unrealized gains/(losses) included in other comprehensive income/(loss)			
Purchases, sales, issuances, and settlements, net			
Purchases			
Issuances			
Sales	(697)	(2,277)	(2,974)
Settlements			
Balance at December 31, 2009	$	$	$

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

The changes in Level 3 assets measured at fair value on a recurring basis for the year ended December 31, 2008 were (in thousands):

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3)		
Activity for the Year Ended December 31, 2008	**Corporate bonds**	**Asset backed and other securities**	**Total**
Balance at December 31, 2007	$ 1,050	$ 282	$ 1,332
Transfers into Level 3(a)	9,783	5,993	15,776
Transfers out of Level 3(a)	(5,535)	(3,307)	(8,842)
Total realized/unrealized gains/(losses) included in net income/(loss)	(1,662)	(372)	(2,034)
Total unrealized gains/(losses) included in other comprehensive income/(loss)	(12)	20	8
Purchases, sales, issuances, and settlements, net			
Purchases			
Issuances			
Sales	(3,175)	(751)	(3,926)
Settlements			
Balance at December 31, 2008	$ 449	$ 1,865	$ 2,314

(a) Transfers out of Level 3 are considered to occur at the beginning of the period. Transfers into Level 3 are considered to occur at the end of the period. Transfers into Level 3 were a result of increased use of input data that could not be validated with other market data, resulting from continued deterioration in the credit markets.

As of December 31, 2009, the Company does not have any liabilities that are measured at fair value on a recurring basis.

Certain assets and liabilities are measured at fair value on a nonrecurring basis; that is, the instruments are not measured at fair value on an ongoing basis but are subject to fair value adjustments only in certain circumstances (for example, when there is evidence of impairment). There were no assets or liabilities measured at fair value on a nonrecurring basis during the year ended December 31, 2009.

Note 3. Inventories

Inventory balances, net of reserves of $1.6 million and $1.4 million, as of December 31, 2009 and 2008, respectively, consist of (in thousands):

	2009	**2008**
Raw materials and component parts	$ 2,381	$ 2,719
Work in process	52	40
Finished goods	269	282
Inventory, net	$ 2,702	$ 3,041

Inventory balances serve as collateral for the Company's loans (see Note 6: "Deerfield Financing"). As noted above, the Company has recorded significant reserves against the carrying value

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 3. Inventories (Continued)

of its inventory of raw material and certain component parts. The reserves relate primarily to inventories that the Company estimated would have no future use. In the second quarter of 2009, the Company increased the reserve for raw materials by $487,000 for a portion of its existing inventory of alprostadil that has exceeded its shelf life and is no longer usable in the manufacturing of MUSE. The Company determined that it would likely continue to use some portion of the fully reserved raw materials and component parts in production. The Company used $97,000 and $67,000 of its fully reserved component parts inventory during the years ended December 31, 2009 and 2008, respectively. In the years ended December 31, 2009 and 2008, the Company used $104,000 and $0, respectively, of its fully reserved raw materials inventory. As of December 31, 2009, the original cost of the fully reserved inventory is $438,000 related to component parts and $1.1 million related to raw materials. The Company intends to continue to use some portion of these reserved component parts and raw materials in production when appropriate.

Note 4. Property, Plant and Equipment

Property, plant and equipment as of December 31, 2009 and 2008, respectively, consist of (in thousands):

	2009	2008
Land	$ 901	$ 901
Buildings	3,420	3,317
Machinery and equipment	17,980	17,868
Computers and software	2,789	2,703
Furniture and fixtures	1,396	1,366
Building improvements	11,984	11,954
	38,470	38,109
Accumulated depreciation	(32,500)	(31,383)
Property and equipment, net	$ 5,970	$ 6,726

For the years ended December 31, 2009, 2008 and 2007, depreciation expense was $1.2 million, $1.1 million, and $1.1 million, respectively. Substantial balances of property, plant and equipment serve as collateral for the Company's loans (see Note 6: "Deerfield Financing" and Note 7: "Notes Payable").

Note 5. Prepaid Expenses and Other Assets

Prepaid expenses and other assets as of December 31, 2009 and 2008, respectively, consist of (in thousands):

	2009	2008
Receivable from Food and Drug Administration	$ 2,140	$ 1,877
Refundable federal income taxes	2,447	156
Prepaid clinical studies	520	200
Interest receivable	474	368
Prepaid insurance	429	448
Other prepaid expenses and assets	400	695
Prepaid expenses and other assets	$ 6,410	$ 3,744

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 5. Prepaid Expenses and Other Assets (Continued)

The Company has paid product and establishment fees for its marketed product, MUSE, for the fiscal year 2008 of $653,000 (which was paid to the FDA in October 2007), for the fiscal year 2009 of $712,000 (which was paid to the FDA in September 2008) and for the fiscal year 2010 of $776,000 (which was paid in September 2009). The Company believes it is due a refund pursuant to Section 736(d)(1)(C) of the Federal Food, Drug and Cosmetic Act, or FDC Act, on the basis that the fees paid by the Company exceed the anticipated present and future costs incurred by the FDA in conducting the process for the review of the Company's human drug applications for VIVUS, Inc. The Company also paid product and establishment fees for MUSE for fiscal year 2007 in October 2006, for which it received a refund of $525,000 in May 2009, on this same basis. In addition, the Company paid an application fee to the FDA in September 2006 for the NDA for Evamist of $767,000, for which it received a refund in April 2008, again, on this same basis. In January 2010, the Company collected $2.4 million in refundable federal income taxes.

Note 6. Deerfield Financing

On April 3, 2008, the Company entered into several agreements with Deerfield Management Company, L.P., or Deerfield, a healthcare investment fund, and its affiliates, Deerfield Private Design Fund L.P. and Deerfield Private Design International, L.P. (collectively, the Deerfield Affiliates). Certain of the agreements were amended and restated on March 16, 2009. Under the agreements, Deerfield and its affiliates agreed to provide $30 million in funding to the Company. The $30 million in funding consists of $20 million from a Funding and Royalty Agreement, or FARA, entered into with a newly incorporated subsidiary of Deerfield, or the Deerfield Sub, and $10 million from the sale of the Company's common stock under a securities purchase agreement. Under the FARA, the Deerfield Sub made $3.3 million payments to the Company in April, September and December 2008 and February, June and September 2009, constituting all of the required payments under the FARA. The Company will pay royalties on the current net sales of MUSE and if approved, on future sales of avanafil, an investigational product candidate, to the Deerfield Sub. The term of the FARA is 10 years. The FARA includes covenants requiring the Company to use commercially reasonable efforts to preserve its intellectual property, manufacture, promote and sell MUSE, and develop avanafil.

The agreements also provide the Company with an option to purchase, and the Deerfield Affiliates with an option to compel the Company to purchase, or put right, the Deerfield Sub holding the royalty rights. If the Company exercises its right to purchase the Deerfield Sub, the net price will be $23 million if exercised before April 3, 2011, or $26 million if exercised after April 3, 2011 but before April 3, 2012 (the purchase prices are subject to other adjustments as defined in the agreement). After April 3, 2011, the Deerfield Affiliates may exercise the right to compel the Company to purchase the Deerfield Sub at a price of $17 million. This price could increase up to $26 million, and the timing of the sale of the shares could be accelerated under certain conditions including a change-in-control, sale of MUSE or avanafil, sale of major assets and the sale of securities in a transaction or a series of related transactions by the Company that exceed 20% of the Company's outstanding common stock at the date the Option and Put Agreement was signed if at the time of the sale the Company's market capitalization is below $300 million (each, a Major Transaction). Under these conditions, the cost of the shares of the Deerfield Sub would be $23 million on or before April 3, 2011 and $26 million from April 3, 2011 through April 3, 2018. The sale of the shares of the Deerfield Sub could also accelerate if the Company's cash, cash equivalents and available for sale securities falls below $15 million or the Company's market capitalization falls below $50 million. The purchase prices under the put right are subject to other adjustments as defined in the agreements. If either party exercises its option, any

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 6. Deerfield Financing (Continued)

further royalty payments would be effectively terminated. In exchange for the option right, the Company paid $2 million to the Deerfield Affiliates. The Company's intellectual property and all of the accounts receivable, inventory and machinery and equipment arising out of or relating to MUSE and avanafil are collateral for this transaction. At December 31, 2009, substantially all of the accounts receivable, inventory and machinery and equipment on the Company's consolidated balance sheet relates to MUSE and serves as collateral for this transaction.

The Company has evaluated the Deerfield financing in accordance with FASB Financial Interpretation No., or FIN, 46(R), *Consolidation of Variable Interest Entities*, or FIN 46R, as codified in FASB ASC topic 810, *Consolidation,* or ASC 810, and determined that the Deerfield Sub may constitute a Variable Interest Entity, or VIE; however, the Company has also determined that it is not the primary beneficiary of this VIE at this time and has therefore concluded that the Company is not required to consolidate the Deerfield Sub (see Note 7: "Notes Payable").

Note 7. Notes Payable

Deerfield Financing

In accordance with Emerging Issues Task Force (EITF) Issue 88-18, *Sale of Future Revenues*, as codified in FASB ASC 605, the FARA transaction is in substance a financing arrangement, or loan, that will be repaid by the Company. The minimum repayment amount would be $17 million, the amount of the unconditional put option held by the Deerfield Affiliates, plus royalties paid during the term of the agreement on sales of MUSE and, if approved, avanafil. Accordingly, the Company has recorded the advances from the Deerfield Affiliates, net of the $2 million option right payment and related fees and expenses, as a loan. The Company has received all of the required advances under the financing arrangement and has recorded this as a loan. The loan amount is lower than the contractual amounts owed if the Company exercises its call option of $23 million to $26 million, or if the Deerfield Affiliates require the Company to purchase the shares as a result of a "Major Transaction" (see Note 6: "Deerfield Financing"). Using the interest method under APB Opinion No. 21, *Interest on Receivables and Payables*, as codified in FASB ASC topic 835, *Interest,* subtopic 30, *Imputation of Interest* or ASC 835-30, interest expense on the loan will be calculated and recognized over three years, which is the estimated term of the loan based on the earliest date that the Deerfield Affiliates could require the Company to repay the amounts advanced. The Deerfield Affiliates will receive a quarterly payment based on net sales of MUSE. The initial imputed effective annual interest rate on the financing was approximately 32% as calculated based upon quarterly advances under the FARA, up to a loan balance of $17 million, offset by the estimated quarterly royalty payments to the Deerfield Affiliates. The imputed interest rate was revised to 31% at December 31, 2009 and 33% at December 31, 2008 based on the actual royalty payments made and the timing of payments and advances in 2009 and 2008, respectively. The imputed effective interest rate is utilized for purposes of calculating the interest expense only and does not reflect the amount of royalty paid to the Deerfield Affiliates on a quarterly basis. Quarterly royalty payments are based on a percentage of net MUSE sales at a rate substantially lower than the imputed effective interest rate used to calculate interest expense.

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, or the Agreements, with Crown Bank N. A., or Crown, secured by the land and buildings, among

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 7. Notes Payable (Continued)

other assets, located at 735 Airport Road and 745 Airport Road in Lakewood, New Jersey, or 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 7.5% and 7.5% for the years ended December 31, 2009 and 2008, respectively. Because the interest rate is variable, and based on a market rate, the carrying value of the debt approximates fair value. 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 percent (0.5%). 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.

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

	December 31, 2009	December 31, 2008
Deerfield loan	$ 15,255	$ 6,277
Crown Bank N.A. loan	4,900	5,045
Total notes payable	20,155	11,322
Less current portion	(157)	(145)
Total long-term notes payable	$ 19,998	$ 11,177

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

Future minimum principal payments of the long-term notes payable as of December 31, 2009 are as follows (in thousands):

As of December 31, 2009	Deerfield Loan	Crown Bank N.A. Loan	Total
2010	$	$ 157	$ 157
2011	15,255	169	15,424
2012		181	181
2013		197	197
2014		212	212
Thereafter		3,984	3,984
Total	$ 15,255	$ 4,900	$ 20,155

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 8. Stockholders' Equity

Common Stock

The Company is authorized to issue 200 million shares of common stock. As of December 31, 2009 and 2008, there were 80,607,481 and 69,667,163 shares, respectively, issued and outstanding.

On April 3, 2008, the Company entered into several agreements with the Deerfield Affiliates (see Note 6: Deerfield Financing). Under the agreements, Deerfield and its affiliates agreed to provide $30 million in funding to the Company. The $30 million in funding consists of $20 million from a FARA and $10 million from the sale of the Company's common stock under a securities purchase agreement. At the closing on April 15, 2008, under the securities purchase agreement, the Deerfield Affiliates purchased 1,626,017 shares of the Company's common stock for an aggregate purchase price of $10 million and the Company paid to the Deerfield Affiliates a $500,000 fee and reimbursed approximately $200,000 in certain expenses incurred in this transaction, registered under the shelf Registration Statement (File Number 333-135793) filed with the SEC on July 14, 2006. The number of shares was determined based on the volume weighted average price on the NASDAQ Global Market of the Company's common stock on the three days prior to the execution of the securities purchase agreement dated as of April 3, 2008.

On May 5, 2008, the Company filed with the SEC a shelf Registration Statement on Form S-3 (File Number 333-150649), which was declared effective by the SEC on May 29, 2008, providing the Company with the ability to offer and sell up to an aggregate of $150 million of common stock from time to time in one or more offerings. The terms of any such future offering would be established at the time of such offering.

On May 5, 2008, the Company filed a Form S-8 with the SEC registering 1,000,000 shares of common stock, par value $0.001 per share, under the 2001 Stock Option Plan, as amended.

On May 6, 2008, the Company filed with the SEC a Post-Effective Amendment No. 1 to Form S-3 (File No. 333-135793), or the Registration Statement, which was filed with the SEC on July 14, 2006, to amend the Registration Statement to deregister any securities registered pursuant to the Registration Statement and not otherwise sold thereunder.

On August 6, 2008, the Company sold $65 million of its common stock in a registered direct offering. Under the terms of the financing, the Company sold 8,365,508 shares of its common stock at a price of $7.77 per share. On August 5, 2008, the Company filed a prospectus supplement with the SEC relating to this registered direct offering under the existing shelf Registration Statement (File Number 333-150649).

On March 9, 2009, the Company filed a Form S-8 (File Number 333-157787) with the SEC registering 1,000,000 shares of common stock, par value $0.001 per share, under the 2001 Stock Option Plan, as amended.

On September 17, 2009, the Company entered into an underwriting agreement, or the Underwriting Agreement, with J.P. Morgan Securities Inc., as representative of the several underwriters named therein, or the Underwriters, relating to the public offering and sale of 9,000,000 shares of the Company's common stock. Pursuant to the Underwriting Agreement, the Underwriters agreed to purchase, subject to customary closing conditions, 9,000,000 shares of the Company's common stock. The Company also granted the Underwriters a 30-day option to purchase up to 1,350,000 additional shares of common stock on the same terms and conditions as set forth above to cover over-allotments,

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 8. Stockholders' Equity (Continued)

which the Underwriters exercised in full. The 10,350,000 shares were sold at a price to the public of $10.50 per share which resulted in approximately $108.7 million in gross proceeds to the Company before deducting underwriting discounts and commissions and other offering expenses. The transaction closed on September 23, 2009. The offering was made pursuant to the Company's effective shelf registration statement on Form S-3 (Registration No. 333-161948), including the prospectus dated September 16, 2009 contained therein, as supplemented.

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, 2009 and 2008, 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, or 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. The Rights will expire on the earliest of (i) April 13, 2017 (the final expiration date), or (ii) redemption or exchange of the Rights.

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 of Director nominees at annual stockholders meetings. The Company filed these bylaw amendments with the SEC on Form 8-K on March 28, 2007.

Note 9. 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

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 9. Stock Option and Purchase Plans (Continued)

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, 2009, 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.

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

	Years Ended December 31,					
	2009		2008		2007	
	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	6,107,304	$ 4.80	5,348,501	$ 4.25	4,550,152	$ 4.21
Options:						
Granted	2,132,382	$ 4.62	1,557,058	$ 6.05	1,688,278	$ 4.28
Exercised	(491,134)	$ 4.79	(698,262)	$ 3.40	(645,605)	$ 3.74
Cancelled	(194,776)	$ 5.01	(99,993)	$ 4.52	(244,324)	$ 5.20
Balance at end of year	7,553,776	$ 4.74	6,107,304	$ 4.80	5,348,501	$ 4.25
Exercisable at end of year	4,493,391	$ 4.63	3,739,766	$ 4.52	3,226,260	$ 4.35
Weighted average grant-date fair value of options granted during the year		$ 2.72		$ 3.33		$ 2.78

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 9. Stock Option and Purchase Plans (Continued)

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, or RSUs, under the 2001 Plan. In contrast to restricted stock awards, the RSUs 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.

A summary of restricted stock units award activity under the 2001 Plan as of December 31, 2009 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, 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
Granted				
Vested	(62,500)	(2.04)		
Forfeited				
Restricted stock units outstanding December 31, 2008				
Granted				
Vested				
Forfeited				
Restricted stock units outstanding, December 31, 2009		$		$

There were no restricted stock units outstanding as of December 31, 2009.

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 9. Stock Option and Purchase Plans (Continued)

Summary of Stock Options

At December 31, 2009, stock options were outstanding and exercisable as follows:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding at December 31, 2009	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable December 31, 2009	Weighted-Average Exercise Price
$2.95 - $4.23	3,599,716	6.9 years	$ 3.94	1,889,043	$ 3.69
$4.25 - $6.05	3,402,629	6.8 years	$ 5.12	2,290,115	$ 4.99
$6.10 - $8.08	551,431	6.1 years	$ 7.68	314,233	$ 7.68
$2.95 - $8.08	7,553,776	6.8 years	$ 4.74	4,493,391	$ 4.63

The aggregate intrinsic value of outstanding options as of December 31, 2009 was $33.7 million, of which $20.5 million related to exercisable options.

At December 31, 2009, 1,059,455 options remain available for grant. 1,000,000 of these shares were registered on a Form S-8 filed with the SEC on February 16, 2010. On January 22, 2010, the Company granted 1,054,385 of these options. During the year ended December 31, 2009, in accordance with the terms of the 2001 Plan, the Company transferred a net total of 15,500 expired plan shares to the 2001 Plan. Options under these plans generally vest over four years, and all options expire after 10 years

Stock Purchase Plan

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

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

As of December 31, 2009, 1,279,754 shares have been issued to employees and there are 120,246 shares available for issuance under the Employee Stock Purchase Plan. The weighted average fair value of shares issued under the Stock Purchase Plan in 2009, 2008 and 2007 was $2.34, $1.76 and $1.42 per share, respectively.

Share-based Compensation Expense

The Company accounts for share-based compensation in accordance with SFAS No. 123R, *Share-Based Payment*, as codified in FASB ASC topic 718, *Compensation Stock Compensation*, or ASC 718, which was adopted January 1, 2006, utilizing the modified prospective transition method.

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 9. Stock Option and Purchase Plans (Continued)

Total estimated share-based compensation expense, related to all of the Company's share-based awards, recognized for the years ended December 31, 2009, 2008 and 2007 was comprised as follows (in thousands, except per share data):

	December 31, 2009	December 31, 2008	December 31, 2007
Cost of goods sold and manufacturing expense	$ 688	$ 602	$ 526
Research and development	921	1,476	873
Selling, general and administrative	3,182	2,640	2,504
Share-based compensation expense before taxes	4,791	4,718	3,903
Related income tax benefits			
Share-based compensation expense, net of taxes	$ 4,791	$ 4,718	$ 3,903
Net share-based compensation expense, per common share:			
Basic and diluted	$ 0.07	$ 0.07	$ 0.07

At December 31, 2009, a total of 7,553,776 stock options were outstanding under the Company's stock option plans. Stock-based compensation expense recognized for the years ended December 31, 2009 and 2008 included compensation expense for stock options granted prior to, but not yet vested as of January 1, 2006. Included in stock-based compensation expense for the year ended December 31, 2009 was $4.6 million related to stock options and $181,000 related to the employee stock purchase plan, net of the estimated forfeitures. Included in stock-based compensation expense for the year ended December 31, 2008 was $4.6 million related to stock options, $92,000 related to the employee stock purchase plan, and $60,000 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 Wilson, the Company's President and Chief Executive Officer. Among other things, the Employment Agreement modified the outstanding equity awards to Mr. Wilson providing for full acceleration with respect to all outstanding unvested equity awards upon his termination or retirement. The modification also extended the exercise period equal to the later of 12 months from termination or retirement of employment or 12 months from termination of service from the Board of Directors, 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, of which $299,000 was recognized immediately and for which the balance is being amortized and recognized 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

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 9. Stock Option and Purchase Plans (Continued)

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, 2009, unrecognized estimated compensation expense totaled $3.8 million related to non-vested stock options and $68,000 related to the employee stock purchase plan. The weighted average remaining requisite service period of the non-vested options was 1.2 years and of the employee stock purchase plan was 4.5 months.

Valuation Assumptions

The fair value of each option award is estimated on the grant date using a Black-Scholes option-pricing model that uses the weighted average assumptions noted in the following table. Prior to January 1, 2008, the Company 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. Effective January 1, 2008, the expected term, which represents the period of time that options granted are expected to be outstanding, is derived by analyzing the historical experience of similar awards, giving consideration to the contractual terms of the stock-based awards, vesting schedules and expectations of future employee behavior. Expected volatilities are estimated using the historical share price performance over the expected term of the option. The Company also considers 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. The risk-free interest rate for the period matching the expected term of the option is based on the U.S. Treasury yield curve in effect at the time of the grant. The Black-Scholes Model also requires a single expected dividend yield as an input. The Company does not anticipate paying any dividends in the near future. The Company develops pre-vesting forfeiture assumptions based on an analysis of historical data.

The following table sets forth information about the weighted-average assumptions used for options granted in the years ended December 31, 2009, 2008 and 2007:

	December 31,		
	2009	2008	2007
Expected life (in years)	5.67	5.58	6.16
Volatility	65.49%	59.92%	67.54%
Risk-free interest rate	2.14%	2.73%	4.58%
Dividend yield			

Note 10. Agreements

In 2001, VIVUS entered into a Development, Licensing and Supply Agreement with Tanabe for the development of avanafil, an oral PDE5 inhibitor product candidate for the treatment of erectile dysfunction. In October 2007, Tanabe and Mitsubishi Pharma Corporation completed their merger and announced their name change to Mitsubishi Tanabe Pharma Corporation, or MTPC. 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. No payments were

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 10. Agreements (Continued)

made under this agreement with MTPC in the year ended December 31, 2008; however, the Company paid MTPC $4 million in January 2009 following the enrollment in December 2008 of the first patient in the first Phase 3 clinical study. The Company expects to make other substantial payments to MTPC in accordance with its agreements with MTPC as the Company continues to develop and, if approved for sale, commercialize avanafil for the oral treatment of male sexual dysfunction. Such potential future milestone payments total $15 million in the aggregate and include payments upon: the first submission of an NDA; obtainment of the first regulatory approval in the United States and any major European country; and achievement of $250 million or more in calendar year sales.

The term of the MTPC agreement is based on a country-by-country and on a product-by-product basis. The term shall continue until the later of (i) ten years after the date of the first sale for a particular product, or (ii) the expiration of the last-to-expire patents within the MTPC patents covering such product in such country. In the event that the Company's product is deemed to be (i) insufficiently effective or insufficiently safe relative to other PDE5 inhibitor compounds based on published information, or (ii) not economically feasible to develop due to unforeseen regulatory hurdles or costs as measured by standards common in the pharmaceutical industry for this type of product, the Company has the right to terminate the agreement with MTPC with respect to such product.

In February 2004, the Company entered into exclusive licensing agreements with Acrux Limited, or Acrux, and a subsidiary of Acrux under which it agreed to develop and, if approved, commercialize Testosterone MDTS, or 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. Under 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. In August 2008, the Company assigned all of its rights and obligations under the Evamist license agreement to K-V.

On October 16, 2001, the Company entered into an assignment agreement, or the Assignment Agreement, with Thomas Najarian, M.D. for a combination of pharmaceutical agents for the treatment of obesity and other disorders, or the Combination Therapy, that has since been the focus of our investigational product development program for Qnexa for the treatment of obesity, obstructive sleep apnea and diabetes. The Combination Therapy and all related patent applications, or the Patents, were transferred to the Company with worldwide rights to develop and commercialize the Combination Therapy and exploit the Patents. Pursuant to the Assignment Agreement, the Company has paid a total of $220,000 to Dr. Najarian through December 31, 2009 and has issued him options to purchase 40,000 shares of our common stock. The Company is obligated under the terms of the Assignment Agreement to make a milestone payment of $1 million and issue an option to purchase 20,000 shares of VIVUS' common stock to Dr. Najarian upon marketing approval by the United States Food and Drug

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 10. Agreements (Continued)

Administration of a product for the treatment of obesity that is based upon the Combination Therapy and Patents. This assignment will require the Company to pay royalties on worldwide net sales of a product for the treatment of obesity that is based upon the Combination Therapy and Patents until the last-to-expire of the assigned Patents. To the extent that the Company decides not to commercially exploit the Patents, the Assignment Agreement will terminate and the Combination Therapy and Patents will be assigned back to Dr. Najarian. In 2006, Dr. Najarian joined the Company as a part-time employee and currently serves as the Company's Principal Scientist.

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 elsewhere in the world). In the years ended 2009, 2008 and 2007, the Company recorded royalty expenses of $783,000, $829,000 and $890,000, 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, the Company has collected $3.6 million in milestone payments from its current international distributors.

Note 11. Interest Income, net

The components of interest income, net were as follows (in thousands):

	Years Ended December 31,		
	2009	2008	2007
Interest income	$ 934	$ 5,418	$ 5,736
Realized gains (losses) on marketable securities, net	1,085	(979)	(1,033)
Interest income, net	$ 2,019	$ 4,439	$ 4,703

Note 12. Commitments

Lease Commitments

In November 2006, the Company entered into a 30-month lease for its corporate headquarters located in Mountain View, California. The 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 expired on July 31, 2009. On December 16, 2008, the Company entered into a first amendment to this lease. Under the terms of the amended lease, it will continue to lease the office space for its corporate headquarters for a two-year period commencing on August 1, 2009 and expiring on July 31, 2011. The base monthly rent is set at $1.64 per square foot or $23,000 per month. The amended lease allows the Company one option to extend the term of the lease for one year from the expiration of the lease. On November 12, 2009, the Company entered into a second amendment to this lease. The second amendment commenced on January 1, 2010, expires on July 31, 2011 and expands the leased space. The base rent for the expansion space is set at $2.25 per square foot or $8,500 per month. The option to extend the term of the amended lease for one year from the expiration of the lease applies to this expansion space as well.

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 12. Commitments (Continued)

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

2010	$	678
2011		339
Total	$	1,017

Rent expense under operating leases totaled $531,000, $549,000 and $528,000 for the years ended December 31, 2009, 2008 and 2007, respectively.

Manufacturing Agreements

In November 2002, the Company entered into a manufacturing agreement to purchase alprostadil from a supplier beginning in 2003 and ending in 2008. In May 2007, the terms of the agreement were amended to require the purchase of a minimum total of $2.3 million of product from 2007 through 2011. The Company's remaining commitment under this agreement is $765,000.

Other Agreements

The Company has entered into various agreements with clinical consultants and clinical research organizations to perform clinical studies on its behalf and at December 31, 2009, its remaining commitment under these agreements totaled $18.7 million. The Company has remaining commitments under various general and administrative services agreements totaling $2.4 million at December 31, 2009, including $1.3 million related to Leland F. Wilson's Employment Agreement (see paragraph below). The Company has 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, 2009, its remaining commitment under these agreements totaled $1.9 million. The Company has entered into marketing promotion and related agreements for its erectile dysfunction product, MUSE. At December 31, 2009, its remaining commitment under these marketing agreements totaled $1.6 million. In addition, the Company has entered into agreements related to the pre-commercialization of Qnexa for obesity. The remaining commitments under these agreements totaled $1.6 million at December 31, 2009.

On December 19, 2007, the Compensation Committee of the Board of Directors of the Company approved an employment agreement, or 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 had an initial term of two years commencing on the effective date, June 1, 2007, or 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. On January 23, 2009, the Compensation Committee approved an amendment to the Employment Agreement, or the Amendment, which amends the Employment Agreement. Pursuant to the Amendment, the initial term of the Employment Agreement was increased from two to three years commencing on June 1, 2007 and other relevant dates were also extended to reflect the three-year initial term.

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 12. Commitments (Continued)

Indemnifications

In the normal course of business, the Company provides indemnifications of varying scope to certain customers against claims of intellectual property infringement made by third parties arising from the use of its products and to its clinical research organizations and investigator sites against liabilities incurred in connection with any third-party claim arising from the work performed on behalf of the Company, among others. 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 its 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 that 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 16: "Legal Matters" for further information regarding Acrux.

Pursuant to the terms of the Funding and Royalty Agreement with Deerfield, the Company made certain representations, warranties and covenants related to MUSE and avanafil. Covenants include that it will maintain all registrations and regulatory rights to sell and promote MUSE in the United States, it will continue to manufacture and promote MUSE and will continue the development of avanafil. The Company also entered into a covenant that it will not manufacture, promote or sell any product that competes with avanafil in the United States other than MUSE.

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, the Company maintains director and officer insurance coverage that reduces its exposure and enables the Company to recover a portion of any future amounts paid. The Company believes the estimated fair value of these indemnification agreements in excess of applicable insurance coverage is minimal.

Note 13. 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

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 13. Income Taxes (Continued)

Company's deferred income tax assets as of December 31, 2009, 2008 and 2007 are as follows (in thousands):

	2009	2008
Deferred tax assets:		
Net operating loss carry forwards	$ 63,836	$ 31,537
Research and development credit carry forwards	12,251	10,237
Inventory reserve	603	556
Accruals and other	8,021	7,359
Depreciation	5,816	4,851
Deferred revenue	483	12,747
	91,010	67,287
Valuation allowance	(91,010)	(67,287)
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 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. The 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, 2009, it was considered more likely than not that the Company's deferred tax assets would not be realized, and as a result, the Company recorded a valuation allowance for its deferred tax assets.

The net increase in the valuation allowance for the years ended December 31, 2009, 2008 and 2007 was $23.7 million, $4.1 million, and $948,000, respectively. As of December 31, 2009, the Company had no significant deferred tax liabilities.

For federal and state income tax reporting purposes, respective net operating loss, or NOL, carryforwards of approximately $170.5 million and $95.4 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. Post adoption of SFAS 123R, the unrecognized deferred tax benefits totaled $1 million, of

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 13. Income Taxes (Continued)

which $81,000 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 $11 million and $1.9 million are available to reduce future taxable income, if any. These net operating loss and tax credit carryforwards, except for the California research and development credit, expire on various dates through 2029. 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 (benefit)/provision for income taxes is based upon (loss)/income before (benefit)/provision for income taxes as follows, for the years ended December 31, 2009, 2008 and 2007 (in thousands):

	2009	2008	2007
Income (loss) before income taxes:			
Domestic	$ (56,731)	$ (9, 956)	$ 3,138
International		19	(427)
Total income (loss) before taxes	$ (56,731)	$ (9,937)	$ 2,711

The (benefit)/provision for income taxes consists of the following components for the years ended December 31, 2009, 2008 and 2007 (in thousands):

	2009	2008	2007
Current			
Federal	$ (2,421)	$ (8)	$ 4,026
State	10	24	1,069
Foreign			
Total current (benefit)/provision for income taxes	$ (2,411)	$ 16	$ 5,095
Deferred			
Federal	$ (29)	$ (13)	$
State			
Foreign			
Total deferred benefit for income taxes	$ (29)	$ (13)	$
Total (benefit)/provision for income taxes	$ (2,440)	$ 3	$ 5,095

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 13. Income Taxes (Continued)

A reconciliation between the U.S. federal statutory tax rate and the Company's effective tax rate is as follows, for the years ended December 31, 2009, 2008 and 2007:

	2009	2008	2007
Tax at U.S. federal statutory rate	(35)%	(35)%	35%
State income taxes, net of federal tax effect			26
Change in valuation allowance	39	35	107
Foreign losses not benefited			6
Permanent items	1	10	30
Tax credits	(5)	(10)	(16)
Refund of prior taxes	(4)		
Effective tax rate	(4)%	0%	188%

During the year ended December 31, 2009, the Company recorded an anticipated benefit from filing a carryback claim of losses generated in 2008, pursuant to the IRS Revenue Procedure 2009-52. The Revenue Procedure was issued in the fourth quarter of 2009 and allows losses generated in 2008 or 2009 to be carried back up to five years. The Company also recorded an anticipated benefit of $30,000 related to refundable research and development tax credits due to enactment of the American Recovery and Reinvestment Act of 2009, signed into law on February 17, 2009.

The provision for income taxes in the amount of $5.1 million for the year ended December 31, 2007 related to the U.S. alternative minimum tax, or 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. As mentioned above, during the year ended December 31, 2009, the Company recorded an anticipated benefit from filing a carryback claim of losses generated in 2008 which allows the Company to obtain a refund for income taxes which were recorded in 2007.

Effective January 1, 2007, the Company adopted Financial Accounting Standards Interpretation, or FIN No. 48, *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109*, as codified in FASB ASC 740-10*Income Taxes*. 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, and through December 31, 2009, 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 years ended December 31, 2007, 2008 and 2009.

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 2008 remain subject to examination by the appropriate governmental agencies due to tax loss carryovers from those years.

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 14. Concentration of Customers and Suppliers

Sales to significant customers as a percentage of total revenues for the years ended December 31, 2009, 2008 and 2007 are as follows:

	2009	2008	2007
McKesson Corporation	54%	51%	53%
Cardinal Health	21%	21%	15%
Meda AB	9%	12%	14%
Amerisource Bergen	11%	12%	11%

Accounts receivable at December 31, 2009 and 2008 by significant customer as a percentage of the total gross accounts receivable balance are as follows:

	2009	2008
McKesson Corporation	76%	54%
Cardinal Health	8%	13%
Meda AB	4%	9%
Amerisource Bergen	11%	15%

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. For the years ended December 31, 2009, 2008 and 2007, the Company incurred $19.1 million , $44.7 million and $7.8 million, respectively, for services provided by one clinical research organization on the Qnexa Phase 3 studies, which represented 27%, 58% and 29%, respectively, of the Company's total research and development expenses. Separately, the Company incurred another $17 million for services provided by another clinical research organization on the avanafil Phase 3 studies, which represented 24% of the Company's total research and development expenses for the year ended December 31, 2009. For the years ended December 31, 2009, 2008 and 2007, the Company incurred $7.8 million, $6.2 million and $5.6 million, respectively, for clinical supplies and formulation work performed by the Company's sole-source manufacturer, which represented 11%, 8% and 21%, respectively, of the Company's total research and development expenses.

Note 15. 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, 2009, 2008 and 2007 were $317,000, $246,000 and $267,000, respectively. The employer-matching portion of the 401(k) plan began on July 1, 2000.

Note 16. Legal Matters

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

The Company and Acrux Limited through its wholly owned subsidiary FemPharm Pty Ltd., or Acrux, are parties to the Testosterone Development and Commercialization Agreement dated

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 16. Legal Matters (Continued)

February 12, 2004, or the Testosterone Agreement. The Testosterone Agreement covers the Company's investigational product candidate, Luramist, which is licensed from Acrux under the Testosterone Agreement. On November 5, 2007, Acrux made a demand for arbitration under the Testosterone Agreement regarding certain claims related to Luramist. Acrux's demand sought a reversion of all rights assigned to the Company related to Luramist, monetary damages and the payment of a milestone payment for Luramist under the Testosterone Agreement and declaratory relief. The Company asserted counterclaims against Acrux in the arbitration and sought the enforcement of the Company's rights under the Testosterone Agreement. The arbitration hearing concluded on January 23, 2009, and on April 6, 2009 the panel of arbitrators, or the Panel, issued its Interim Arbitration Award finding in favor of the Company that it was in compliance with the Testosterone Agreement and denying all of the relief sought by Acrux in its demand. The Panel found that the Company was not in breach of the Luramist license agreement and that the Company has used diligent, commercially reasonable efforts to develop Luramist. The Panel further ruled in favor of the Company on its counter claim that Acrux had breached the Luramist license agreement by failing to provide certain know-how and certain improvements in the formulation and delivery device for Luramist. The Panel denied the Acrux claim for additional milestone payments. The Panel has ordered Acrux to turn over certain information to the Company that was previously withheld in violation of the agreement by Acrux. After the parties failed to agree on a new Outside Date by which the Company is to commence its first Phase 3 trial for Luramist, the Panel reset the Outside Date of April 30, 2006 to April 1, 2010 to reflect the regulatory environment. Acrux will be eligible to receive the previously agreed upon Phase 3 milestone payment of $1 million to be paid out at the earlier of the start of Phase 3 trials or the Outside Date. The milestone is due in six monthly installments of $166,667 for each month of delay in commencing Phase 3 after the Outside Date until the milestone is paid in full. There can be no assurance that Acrux would not continue to pursue legal action against us if we do not commence the first Phase 3 trial by the Outside Date.

In the ordinary course of business the Company may become involved in lawsuits and subject to various claims from current and former employees including wrongful termination, sexual discrimination and employment matters. The Company is currently a party to a lawsuit involving a former employee. The Company has also been named as a potential defendant in a complaint filed by a former employee. The Company has investigated each of the claims and believes the allegations have no merit and that the Company has meritorious defenses to such charges. Due to the current economic downturn, employees may be more likely to file employment-related claims. Employment-related claims also may be more likely following a poor performance review. Although there may be no merit to such claims or legal matters, the Company may be required to allocate additional monetary and personnel resources to defend against these type of allegations. The Company believes the disposition of the current lawsuit and claims is not likely to have a material effect on its financial condition or liquidity.

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 17. Related Party Transactions

Mario M. Rosati, one of the Company's directors until June 13, 2008, is also a member of Wilson Sonsini Goodrich & 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

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 17. Related Party Transactions (Continued)

these services. During the years ended December 31, 2008 and 2007, the Company paid $758,000, and $788,000, respectively, to Wilson Sonsini Goodrich and Rosati for legal services. On April 17, 2008, Mr. Rosati notified the Company of his decision not to stand for re-election at the Company's 2008 annual meeting held on June 13, 2008 and is no longer a member of the Company's Board of Directors as of that date.

Note 18. Subsequent Events (Unaudited)

On February 16, 2010, the Company filed a Form S-8 with the SEC registering 1,000,000 shares of common stock, par value $0.001 per share, under the 2001 Stock Option Plan, as amended.

Note 19. Selected Financial Data (Unaudited)

Selected Quarterly Financial Data (in thousands)

	Quarter Ended,			
	March 31	June 30	September 30	December 31
2009				
Total revenue	$ 22,232	$ 14,725	$ 4,435	$ 8,649
Cost of goods sold	$ 2,603	$ 2,877	$ 2,609	$ 3,861
Net loss	$ (6,809)	$ (13,204)	$ (21,066)	$ (13,212)
Net loss per share:				
Basic and diluted	$ (0.10)	$ (0.19)	($ 0.30)	$ (0.16)
2008				
Total revenue	$ 22,688	$ 25,269	$ 25,477	$ 28,799
Cost of goods sold	$ 2,787	$ 2,929	$ 2,547	$ 3,693
Net (loss) income	$ (7,092)	$ 3,579	$ 266	$ (6,693)
Net (loss) income per share:				
Basic and diluted	$ (0.12)	$ 0.06	$ 0.00	$ (0.10)

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FINANCIAL STATEMENT SCHEDULE

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

VIVUS, Inc.
SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS
(in thousands)

	Balance at Beginning of Period	Charged to Operations	Charges Utilized	Balance at End of Period
Allowance for Doubtful Accounts				
Fiscal year ended December 31, 2007	$ 67	$ 4	$ (42)	$ 29
Fiscal year ended December 31, 2008	29	(6)		23
Fiscal year ended December 31, 2009	23	45	(41)	27
Inventory Reserve				
Fiscal year ended December 31, 2007	4,377	98	(2,811)(1)	1,664
Fiscal year ended December 31, 2008	1,664	213	(432)(2)	1,445
Fiscal year ended December 31, 2009	1,445	224	(95)(3)	1,574
Accrued Product Returns				
Fiscal year ended December 31, 2007	2,473	1,372	(1,347)	2,498
Fiscal year ended December 31, 2008	2,498	1,314	(947)	2,865
Fiscal year ended December 31, 2009	2,865	1,425	(1,264)	3,026
Accrued Chargebacks Reserve				
Fiscal year ended December 31, 2007	1,531	3,249	(3,466)	1,314
Fiscal year ended December 31, 2008	1,314	4,081	(4,016)	1,379
Fiscal year ended December 31, 2009	$ 1,379	$ 4,538	$ (4,300)	$ 1,617

(1) 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.

(2) The Company used $67,000 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.

(3) The Company used $97,000 of its fully reserved component parts inventory and $104,000 of its fully reserved raw materials 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.

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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 Annual 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.

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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, 2009. 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, 2009. This report, which expresses an unqualified opinion on the effectiveness of our internal controls over financial reporting as of December 31, 2009, 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.

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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 2009 Annual Meeting of Stockholders. The information required by Section 16(a) is incorporated by reference from the information under the caption "Compliance with Section 16(a) of the Securities Exchange Act of 1934" in the Proxy Statement.

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

Item 11. ***Executive Compensation***

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

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

Equity Compensation Plans Approved by Stockholders

Information about our equity compensation plans at December 31, 2009 that were approved by our stockholders was as follows:

Plan Category	Number of Shares to be issued Upon Exercise of Outstanding Options and Rights(a)	Weighted Average Exercise Price of Outstanding Options	Number of Shares Remaining Available for Future Issuance(c)
Equity compensation plans approved by stockholders	7,553,776	$ 4.74	1,179,701
Equity compensation plans not approved by stockholders(b)			
Total	7,553,776	$ 4.74	1,179,701

(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.

(c) Includes 1,059,455 shares for the 2001 Stock Option Plan and 120,246 shares for the 1994 Employee Stock Purchase Plan.

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.

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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.

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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

2. Financial Statement Schedules

The following financial statement schedule of VIVUS, Inc. as set forth on page 145 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(1)	Asset Purchase Agreement, by and among the Registrant and K-V Pharmaceutical Company, dated as of March 30, 2007
3.1(2)	Amended and Restated Certificate of Incorporation of the Registrant
3.2(3)	Amended and Restated Bylaws of the Registrant
3.3(4)	Amended and Restated Certificate of Designation of the Registrant
4.1(5)	Specimen Common Stock Certificate of the Registrant
4.2(6)	Preferred Stock Rights Agreement dated as of March 27, 2007 between the Registrant and Computershare Investor Services, LLC

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Exhibit Number	Description
10.1(7)	Assignment Agreement by and between Alza Corporation and the Registrant dated December 31, 1993
10.2(7)	Memorandum of Understanding by and between Ortho Pharmaceutical Corporation and the Registrant dated February 25, 1992
10.3(7)	Assignment Agreement by and between Ortho Pharmaceutical Corporation and the Registrant dated June 9, 1992
10.4(7)	License Agreement by and between Gene A. Voss, M.D., Allen C. Eichler, M.D., and the Registrant dated December 28, 1992
10.5A(7)	License Agreement by and between Ortho Pharmaceutical Corporation and Kjell Holmquist AB dated June 23, 1989
10.5B(7)	Amendment by and between Kjell Holmquist AB and the Registrant dated July 3, 1992
10.5C(7)	Amendment by and between Kjell Holmquist AB and the Registrant dated April 22, 1992
10.5D(7)	Stock Purchase Agreement by and between Kjell Holmquist AB and the Registrant dated April 22, 1992
10.6A(7)	License Agreement by and between Amsu, Ltd., and Ortho Pharmaceutical Corporation dated June 23, 1989
10.6B(7)	Amendment by and between Amsu, Ltd., and the Registrant dated July 3, 1992
10.6C(7)	Amendment by and between Amsu, Ltd., and the Registrant dated April 22, 1992
10.6D(7)	Stock Purchase Agreement by and between Amsu, Ltd., and the Registrant dated July 10, 1992
10.11(8)	Form of Indemnification Agreement by and among the Registrant and the Directors and Officers of the Registrant
10.12(9)	1991 Incentive Stock Plan and Form of Agreement, as amended
10.13(7)	1994 Director Option Plan and Form of Agreement
10.14(7)	Form of 1994 Employee Stock Purchase Plan and Form of Subscription Agreement
10.17(7)	Letter Agreement between the Registrant and Leland F. Wilson dated June 14, 1991 concerning severance pay
10.41(10)	Distribution and Supply Agreement made as of November 20, 2000 between the Registrant and Paladin Labs, Inc.
10.42(10)	Development, License and Supply Agreement effective as of December 28, 2000 between the Registrant and Tanabe Seiyaku Co., Ltd.
10.42A(11)	Amendment One to Agreement, dated January 9, 2004 between the Registrant and Tanabe Seiyaku Co., Ltd.
10.43(12)	Settlement and Modification Agreement made as of July 12, 2001 between ASIVI, LLC, AndroSolutions, Inc., Gary W. Neal and the Registrant
10.44(13)	2001 Stock Option Plan and Form of Agreement
10.44A(14)	2001 Stock Option Plan (as amended July 12, 2006)

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Exhibit Number	Description
10.44B(15)	Form of Notice of Grant and Restricted Stock Unit Agreement for the VIVUS, Inc. 2001 Stock Option Plan
10.45(16)	Supply Agreement made as of September 3, 2002 between the Registrant and Meda AB
10.46(17)	Amendment Three, dated November 21, 2002 by and between the Registrant and Chinoin Pharmaceutical and Chemical Works, Ltd.
10.48(17)	Exclusive Distribution Agreement effective as of October 1, 2002 between the Registrant and Cord Logistics, Inc.
10.49(17)	Distribution and Supply Agreement effective as of February 18, 2003 between the Registrant and Meda AB
10.50(11)	Testosterone Development and Commercialization Agreement effective as of February 7, 2004 between the Registrant, Fempharm Pty Ltd. and Acrux DDS Pty Ltd.
10.51(11)	Estradiol Development and Commercialization Agreement effective as of February 12, 2004 between the Registrant, Fempharm Pty Ltd. and Acrux DDS Pty Ltd.
10.52(11)	Note Purchase Agreement dated January 8, 2004 between the Registrant and Tanabe Holding America, Inc.
10.54(18)	Amendment One dated October 11, 2004 to License and Supply Agreement made between the Registrant and Paladin Labs, Inc.
10.55(19)	Agreement for Sale of Real Estate dated November 15, 2005 by and between the Registrant and 735 Airport Road, L.L.C.
10.56(19)	Agreement for Sale of Real Estate dated November 15, 2005 by and between the Registrant and 745 Airport Road, L.L.C.
10.57(20)	Term Loan Agreement dated January 4, 2006 by and between the Registrant and Vivus Real Estate LLC and Crown Bank, N.A.
10.58(20)	Commercial Mortgage Note dated January 4, 2006 by and between the Registrant and Vivus Real Estate LLC and Crown Bank, N.A.
10.59(20)	Mortgage and Security Agreement dated January 4, 2006 by and between Vivus Real Estate LLC and Crown Bank, N. A.
10.60(21)	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(22)	Termination and Release executed by Tanabe Holding America, Inc. dated May 1, 2007
10.62(23)	Master Services Agreement dated as of September 12, 2007 between the Registrant and Medpace, Inc.

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Exhibit Number	Description
10.63(24)	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(25)	VIVUS, Inc. Performance Incentive Plan Fiscal 2007
10.65(26)	Employment Agreement dated December 20, 2007 between the Registrant and Leland F. Wilson
10.66(27)	Form of Change in Control and Severance Agreement dated December 19, 2007 by and between the Registrant and Certain of its Executive Officers
10.67(28)	Securities Purchase Agreement dated April 3, 2008 by and among the Registrant, Deerfield Private Design Fund L.P., Deerfield Private Design International, L.P. and Deerfield Management Company, L.P.
10.68(29)	Funding and Royalty Agreement dated April 3, 2008 by and between Deerfield ED Corporation and the Registrant
10.69(30)	Subscription Agreement dated April 3, 2008 by and between Deerfield ED Corporation and Deerfield Private Design Fund L.P.
10.70(31)	Subscription Agreement dated April 3, 2008 by and between Deerfield ED Corporation and Deerfield Private Design International, L.P.
10.71(32)	Option and Put Agreement dated April 3, 2008 by and among the Registrant and Deerfield ED Corporation, Deerfield Private Design International, L.P. and Deerfield Private Design Fund L.P.
10.72(33)	Security Agreement dated April 3, 2008 by and between Deerfield ED Corporation and the Registrant
10.73(34)	Security Agreement, Exhibit 4 to the Option and Put Agreement, dated April 3, 2008 by and between the Registrant and Deerfield Private Design Fund L.P. and Deerfield Private Design International, L.P.
10.74(35)	First Amendment to Lease between Castro Mountain View, LLC and CP6CC, LLC as tenants in common and successor in interest to 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., a California limited partnership, Marie Straube, Trustee of the Marie Antoinette Clough Revocable Living Trust dated January 11, 1989 and Blue Oak Properties, Inc., a California corporation (collectively, the "Landlord") and the Registrant
10.75(36)	Exhibit A: Medpace Task Order Number: 06 dated as of December 15, 2008 pursuant to that certain Master Services Agreement, between the Registrant and Medpace, Inc., dated as of September 12, 2007.
10.76(37)	First Amendment to the Employment Agreement dated December 20, 2007 by and between the Registrant and Leland F. Wilson.

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Exhibit Number	Description
10.77(38)	Underwriting Agreement, dated as of September 17, 2009, by and between the Registrant and J.P. Morgan Securities Inc., as representative of several underwriters named therein.
10.78	Second Amendment to Lease between Castro Mountain View, LLC and CP6CC, LLC, as tenants in common and successor in interest to 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., a California limited partnership, Marie Straube, Trustee of the Marie Antoinette Clough Revocable Living Trust dated January 11, 1989 and Blue Oak Properties, Inc., a California corporation (collectively, the "Landlord") and the Registrant
10.79	Assignment Agreement by and between Thomas Najarian, M.D. and the Registrant dated October 16, 2001.
21.2	Subsidiaries of the Registrant
23.1	Consent of Odenberg, Ullakko, Muranishi & Co. LLP, Independent Registered Public Accounting Firm
24	Power of Attorney (See page 186)
31.1	Certification of Chief Executive Officer, dated March 10, 2010, 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 10, 2010, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Confidential treatment granted.

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 Current Report on Form 8-K filed with the Commission on May 21, 2007.

(2) Incorporated by reference to Exhibit 3.2 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1996.

(3) Incorporated by reference to the same numbered exhibit filed with the Registrant's Current Report on Form 8-K filed with the Commission on November 3, 2009.

(4) Incorporated by reference to the same numbered exhibit filed with the Registrant's Registration Statement on Form 8-A filed with the Commission on March 28, 2007.

(5) Incorporated by reference to the same numbered exhibit filed with the Registrant's Annual Report on Form 10-K/A for the fiscal year ended December 31, 1996.

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(6)

Incorporated by reference to Exhibit 4.1 filed with the Registrant's Registration Statement on Form 8-A filed with the Commission on March 28, 2007.

(7)

Incorporated by reference to the same numbered exhibit filed with the Registrant's Registration Statement on Form S-1 No. 33-75698, as amended.

(8)

Incorporated by reference to the same numbered exhibit filed with the Registrant's Form 8-B filed with the Commission on June 25, 1996.

(9)

Incorporated by reference to the same numbered exhibit filed with the Registrant's Registration Statement on Form S-1 No. 33-90390, as amended.

(10)

Incorporated by reference to the same numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000.

(11)

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, 2004.

(12)

Incorporated by reference to the same numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.

(13)

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.

(14)

Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on July 13, 2006.

(15)

Incorporated by reference to Exhibit 10.2 filed with the Registrant's Current Report on Form 8-K filed with the Commission on July 13, 2006.

(16)

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.

(17)

Incorporated by reference to the same numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2002.

(18)

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

(19)

Incorporated by reference to the same numbered exhibit filed with the Registrant's Current Report on Form 8-K filed with the Commission on December 23, 2005.

(20)

Incorporated by reference to the same numbered exhibit filed with the Registrant's Current Report on Form 8-K filed with the Commission on January 6, 2006.

(21)

Incorporated by reference to the same numbered exhibit filed with the Registrant's Current Report on Form 8-K filed with the Commission on November 7, 2006.

(22)

Incorporated by reference to the same numbered exhibit filed with the Registrant's Current Report on Form 8-K filed with the Commission on May 4, 2007.

(23)

Incorporated by reference to the same numbered exhibit filed with the Registrant's Current Report on Form 8-K filed with the Commission on September 18, 2007.

(24)

Incorporated by reference to Exhibit 10.60 filed with the Registrant's Current Report on Form 8-K filed with the Commission on May 8, 2007.

(25)

Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on April 26, 2007.

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(26) Incorporated by reference to Exhibit 10.63 filed with the Registrant's Current Report on Form 8-K filed with the Commission on December 24, 2007.

(27) Incorporated by reference to Exhibit 10.64 filed with the Registrant's Current Report on Form 8-K filed with the Commission on December 24, 2007.

(28) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on April 4, 2008.

(29) Incorporated by reference to Exhibit 10.2 filed with the Registrant's Current Report on Form 8-K filed with the Commission on April 4, 2008.

(30) Incorporated by reference to Exhibit 10.3 filed with the Registrant's Current Report on Form 8-K filed with the Commission on April 4, 2008.

(31) Incorporated by reference to Exhibit 10.4 filed with the Registrant's Current Report on Form 8-K filed with the Commission on April 4, 2008.

(32) Incorporated by reference to Exhibit 10.5 filed with the Registrant's Current Report on Form 8-K filed with the Commission on April 4, 2008.

(33) Incorporated by reference to Exhibit 10.6 filed with the Registrant's Current Report on Form 8-K filed with the Commission on April 4, 2008.

(34) Incorporated by reference to Exhibit 10.7 filed with the Registrant's Current Report on Form 8-K filed with the Commission on April 4, 2008.

(35) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on December 18, 2008.

(36) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on December 24, 2008.

(37) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on January 29, 2009.

(38) Incorporated by reference to Exhibit 1.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on September 17, 2009.

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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
Chief Executive Officer
(Principal Executive Officer)

Date: March 10, 2010

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POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ LELAND F. WILSON Leland F. Wilson	Chief Executive Officer (Principal Executive Officer) and Director	March 10, 2010
/s/ MARK B. LOGAN Mark B. Logan	Chairman of the Board and Director	March 10, 2010
/s/ PETER Y. TAM Peter Y. Tam	President and Director	March 10, 2010
/s/ TIMOTHY E. MORRIS Timothy E. Morris	Vice President of Finance and Chief Financial Officer (Principal Financial Officer)	March 10, 2010
/s/ LEE B. PERRY Lee B. Perry	Vice President and Chief Accounting Officer (Principal Accounting Officer)	March 10, 2010
/s/ VIRGIL A. PLACE Virgil A. Place	Chief Scientific Officer and Director	March 10, 2010
/s/ GRAHAM STRACHAN Graham Strachan	Director	March 10, 2010
/s/ CHARLES J. CASAMENTO Charles J. Casamento	Director	March 10, 2010
/s/ LINDA M. DAIRIKI SHORTLIFFE, M.D. Linda M. Dairiki Shortliffe, M.D.	Director	March 10, 2010

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VIVUS, INC.
REPORT ON FORM 10-K FOR
THE YEAR ENDED DECEMBER 31, 2009

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10.13(7)	1994 Director Option Plan and Form of Agreement

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10.58(20)	Commercial Mortgage Note dated January 4, 2006 by and between the Registrant and Vivus Real Estate LLC and Crown Bank, N.A.

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10.59(20)	Mortgage and Security Agreement dated January 4, 2006 by and between Vivus Real Estate LLC and Crown Bank, N. A.
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Exhibit Number	Description
10.74(35)	First Amendment to Lease between Castro Mountain View, LLC and CP6CC, LLC, as tenants in common and successor in interest to 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., a California limited partnership, Marie Straube, Trustee of the Marie Antoinette Clough Revocable Living Trust dated January 11, 1989 and Blue Oak Properties, Inc., a California corporation (collectively, the "Landlord") and the Registrant
10.75(36)	Exhibit A: Medpace Task Order Number: 06 dated as of December 15, 2008 pursuant to that certain Master Services Agreement, between the Registrant and Medpace, Inc., dated as of September 12, 2007.
10.76(37)	First Amendment to the Employment Agreement dated December 20, 2007 by and between the Registrant and Leland F. Wilson.
10.77(38)	Underwriting Agreement, dated as of September 17, 2009, by and between the Registrant and J.P. Morgan Securities Inc., as representative of several underwriters named therein.
10.78	Second Amendment to Lease between Castro Mountain View, LLC and CP6CC, LLC, as tenants in common and successor in interest to 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., a California limited partnership, Marie Straube, Trustee of the Marie Antoinette Clough Revocable Living Trust dated January 11, 1989 and Blue Oak Properties, Inc., a California corporation (collectively, the "Landlord") and the Registrant
10.79	Assignment Agreement by and between Thomas Najarian, M.D. and the Registrant dated October 16, 2001.
21.2	Subsidiaries of the Registrant
23.1	Consent of Odenberg, Ullakko, Muranishi & Co. LLP, Independent Registered Public Accounting Firm
24	Power of Attorney (See page 186)
31.1	Certification of Chief Executive Officer, dated March 10, 2010, 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 10, 2010, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended

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Exhibit Number	Description
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Confidential treatment granted.

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 Current Report on Form 8-K filed with the Commission on May 21, 2007.

(2) Incorporated by reference to Exhibit 3.2 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1996.

(3) Incorporated by reference to the same numbered exhibit filed with the Registrant's Current Report on Form 8-K filed with the Commission on November 3, 2009.

(4) Incorporated by reference to the same numbered exhibit filed with the Registrant's Registration Statement on Form 8-A filed with the Commission on March 28, 2007.

(5) Incorporated by reference to the same numbered exhibit filed with the Registrant's Annual Report on Form 10-K/A for the fiscal year ended December 31, 1996.

(6) Incorporated by reference to Exhibit 4.1 filed with the Registrant's Registration Statement on Form 8-A filed with the Commission on March 28, 2007.

(7) Incorporated by reference to the same numbered exhibit filed with the Registrant's Registration Statement on Form S-1 No. 33-75698, as amended.

(8) Incorporated by reference to the same numbered exhibit filed with the Registrant's Form 8-B filed with the Commission on June 25, 1996.

(9) Incorporated by reference to the same numbered exhibit filed with the Registrant's Registration Statement on Form S-1 No. 33-90390, as amended.

(10) Incorporated by reference to the same numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000.

(11) 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, 2004.

(12) Incorporated by reference to the same numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.

(13)

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.

(14)

Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on July 13, 2006.

(15)

Incorporated by reference to Exhibit 10.2 filed with the Registrant's Current Report on Form 8-K filed with the Commission on July 13, 2006.

(16)

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.

(17)

Incorporated by reference to the same numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2002.

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(18)

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

(19)

Incorporated by reference to the same numbered exhibit filed with the Registrant's Current Report on Form 8-K filed with the Commission on December 23, 2005.

(20)

Incorporated by reference to the same numbered exhibit filed with the Registrant's Current Report on Form 8-K filed with the Commission on January 6, 2006.

(21)

Incorporated by reference to the same numbered exhibit filed with the Registrant's Current Report on Form 8-K filed with the Commission on November 7, 2006.

(22)

Incorporated by reference to the same numbered exhibit filed with the Registrant's Current Report on Form 8-K filed with the Commission on May 4, 2007.

(23)

Incorporated by reference to the same numbered exhibit filed with the Registrant's Current Report on Form 8-K filed with the Commission on September 18, 2007.

(24)

Incorporated by reference to Exhibit 10.60 filed with the Registrant's Current Report on Form 8-K filed with the Commission on May 8, 2007.

(25)

Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on April 26, 2007.

(26)

Incorporated by reference to Exhibit 10.63 filed with the Registrant's Current Report on Form 8-K filed with the Commission on December 24, 2007.

(27)

Incorporated by reference to Exhibit 10.64 filed with the Registrant's Current Report on Form 8-K filed with the Commission on December 24, 2007.

(28)

Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on April 4, 2008.

(29)

Incorporated by reference to Exhibit 10.2 filed with the Registrant's Current Report on Form 8-K filed with the Commission on April 4, 2008.

(30)

Incorporated by reference to Exhibit 10.3 filed with the Registrant's Current Report on Form 8-K filed with the Commission on April 4, 2008.

(31)

Incorporated by reference to Exhibit 10.4 filed with the Registrant's Current Report on Form 8-K filed with the Commission on April 4, 2008.

(32)

Incorporated by reference to Exhibit 10.5 filed with the Registrant's Current Report on Form 8-K filed with the Commission on April 4, 2008.

(33)

Incorporated by reference to Exhibit 10.6 filed with the Registrant's Current Report on Form 8-K filed with the Commission on April 4, 2008.

(34)

Incorporated by reference to Exhibit 10.7 filed with the Registrant's Current Report on Form 8-K filed with the Commission on April 4, 2008.

(35)

Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on December 18, 2008.

(36)

Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on December 24, 2008.

(37)

Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on January 29, 2009.

(38)

Incorporated by reference to Exhibit 1.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on September 17, 2009.