VIVUS INC
Form 10-K
February 26, 2013

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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, 2012

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**
	The NASDAQ Global Select Market

Common Stock, $.001 Par Value
(Title of class)
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 ý No o

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 ý No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) 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 ý	Accelerated filer o	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, 2012 totaled approximately $2,847,137,500 based on the closing stock price as reported by the NASDAQ Global Market.

As of February 19, 2013, there were 100,660,029 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, 2012 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 may typically be identified by the use of forward-looking words or phrases such as "anticipate," "believe," "forecast," "estimate," "expect," "intend," "likely," "may," "plan," "potential," "predict," "opportunity" and "should," 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 limited commercial experience with Qsymia in the United States, or U.S.; (2) the timing of initiation and completion of the clinical studies required as part of the approval of Qsymia by the U.S. Food and Drug Administration, or FDA; (3) the response from the FDA to the data that VIVUS will submit relating to post-approval clinical studies; (4) the impact of the indicated uses and contraindications contained in the Qsymia label and the Risk Evaluation and Mitigation Strategy, or REMS, requirements; (5) the impact of distribution of Qsymia through a certified home delivery pharmacy network; (6) whether or not the FDA approves our amendment to the REMS for Qsymia, which, if approved, would allow dispensing through select certified retail pharmacies to increase access while meeting all requirements of the REMS; (7) that we may be required to provide further analysis of previously submitted clinical trial data; (8) the negative opinion of the European Medicines Agency's, or EMA, Committee for Medicinal Products for Human Use, or CHMP, for the Marketing Authorization Application, or MAA, for Qsymia; (9) our ability to successfully commercialize or establish a marketing partnership for avanafil, which will be marketed in the U.S. under the name STENDRA ; (10) the ability of our partners to maintain regulatory approvals to manufacture and adequately supply our products to meet demand; (11) our history of losses and variable quarterly results; (12) substantial competition; (13) risks related to the failure to protect our intellectual property and litigation in which we may become involved; (14) uncertainties of government or third-party payor reimbursement; (15) our reliance on sole source suppliers; (16) our limited sales and marketing and manufacturing experience; (17) our reliance on third parties and our collaborative partners; (18) our failure to continue to develop innovative investigational drug candidates and drugs; (19) risks related to the failure to obtain FDA or foreign authority clearances or approvals and noncompliance with FDA or foreign authority regulations; (20) our ability to demonstrate through clinical testing the safety and effectiveness of our investigational drug candidates; (21) the timing of initiation and completion of clinical trials and submissions to foreign authorities; (22) the results of post-marketing studies are not favorable; (23) compliance with post-marketing regulatory standards is not maintained; (24) the volatility and liquidity of the financial markets; (25) our liquidity and capital resources; (26) our expected future revenues, operations and expenditures and (27) 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 is a biopharmaceutical company dedicated to commercializing and developing innovative therapies to address unmet needs in obesity, sleep apnea, diabetes and sexual health. Our drug, Qsymia (phentermine and topiramate extended-release) (formerly known as Qnexa®) was approved by the FDA for the treatment of obesity as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index, or BMI, of 30 or greater (obese), or 27 or greater (overweight) in the presence of at least one weight-related comorbidity, such as hypertension, type 2 diabetes mellitus or high cholesterol (dyslipidemia). Qsymia incorporates low

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doses of active ingredients from two previously approved drugs, phentermine and topiramate. Although the exact mechanism of action is not known, Qsymia is believed to target appetite and satiety, or the feeling of being full, the two main mechanisms that impact eating behavior. We announced the U.S. market availability of Qsymia for obesity in September 2012. On February 21, 2013, the CHMP confirmed its October 18, 2012 decision to deny the MAA for Qsiva (phentermine/topiramate ER) for the treatment of obesity in the European Union, or EU. We have completed Phase 2 clinical studies for Qsymia for the treatment of sleep apnea and Qsymia for the treatment of type 2 diabetes.

Our drug, STENDRA, or avanafil, was approved by the FDA for the treatment of erectile dysfunction, or ED, in the U.S. We, through collaboration arrangements with third parties, intend to market and sell STENDRA in the U.S. and, if approved, under the trade name SPEDRA in the EU and other territories outside the U.S.

We were incorporated in California in 1991 and reincorporated in Delaware in 1996. Our corporate headquarters is located at 1172 Castro Street, Mountain View, California and our phone number is (650) 934-5200.

Our Strategy

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

- successfully commercializing Qsymia in the U.S.;
- entering into and supporting a collaboration agreement for the commercialization of STENDRA for the treatment of ED in the U.S.;
- obtaining regulatory approval for SPEDRA for the treatment of ED in the EU and other territories worldwide; and
- if approved, entering into and supporting collaboration agreements for the commercialization of SPEDRA for the treatment of ED in the EU and other territories worldwide.

It is our objective to become a leader in the development and commercialization of drugs 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 drug candidates for indications that we have studied, or plan to study, as well as in-licensing and product line extensions.

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Products and Development Programs

Our approved drugs and investigational drug candidates are summarized as follows:

Drug	Indication	Status	Commercial rights
Qsymia (phentermine and topiramate extended-release)	Obesity	NDA approved July 2012; First commercial sale September 2012	Worldwide
Qsymia (phentermine and topiramate extended-release)	Obstructive Sleep Apnea	MAA denied Phase 2 study completed	Worldwide
Qsymia (phentermine and topiramate extended-release)	Diabetes	Phase 2 study completed	Worldwide
STENDRA (avanafil)	Erectile dysfunction	NDA approved April 2012; Seeking collaboration agreement MAA submitted March 2012; Preparing response to Day 180 List of Outstanding Issues, or LoOIs	Worldwide license from Mitsubishi Tanabe Pharma Corporation, or MTPC (excluding certain Asian markets)

Qsymia for the treatment of Obesity

Many factors contribute to excess weight gain. These include environmental factors, genetics, health conditions, certain medications, emotional factors and other behaviors. All this contributes to more than 110 million Americans being obese or overweight with at least one weight-related comorbidity. Excess weight increases the risk of conditions including type 2 diabetes, high cholesterol, high blood pressure, heart disease, sleep apnea, stroke and osteoarthritis. According to the National Institutes of Health, or NIH, losing just 10% of body weight may help obese patients reduce the risk of developing other weight-related medical conditions, while making a meaningful difference in health and well-being.

Qsymia for the treatment of obesity was approved as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial BMI of 30 or greater (obese), or 27 or greater (overweight) in the presence of at least one weight-related comorbidity, such as hypertension, type 2 diabetes mellitus or high cholesterol (dyslipidemia). Qsymia incorporates low doses of active ingredients from two previously approved drugs, phentermine and topiramate. Although the exact mechanism of action is unknown, Qsymia is believed to target appetite and satiety, or the feeling of being full, the two main mechanisms that impact eating behavior.

We initially launched Qsymia for distribution to eligible patients through the home delivery networks of two certified pharmacies, CVS Pharmacy and Walgreens. Since then, we have expanded the

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distribution of Qsymia to include the home delivery networks of Express Scripts, Wal-Mart Pharmacy and, for its members only, Kaiser Permanente.

Qsymia was approved with a REMS with a goal of informing prescribers and patients of reproductive potential about an increased risk of orofacial clefts in infants exposed to Qsymia during the first trimester of pregnancy, the importance of pregnancy prevention for females of reproductive potential receiving Qsymia and the need to discontinue Qsymia immediately if pregnancy occurs. The Qsymia REMS program includes a medication guide, healthcare provider training, distribution through certified home delivery pharmacies, an implementation system and a time table for assessments. On October 17, 2012, we submitted an amendment to our New Drug Application, or NDA, that requests a modification of the REMS for Qsymia, which, if approved, would allow dispensing through select certified retail pharmacies, to increase access while meeting all requirements of the REMS. This amendment to our NDA was made at the mutual request of VIVUS and the FDA, as documented in the FDA approval letter.

As part of the approval of Qsymia, we have committed to conduct post-marketing studies. We will conduct a study to assess the long-term treatment effect of Qsymia on the incidence of major adverse cardiovascular events in overweight and obese subjects with confirmed cardiovascular disease, studies to assess the safety and efficacy of Qsymia for weight management in obese pediatric and adolescent subjects, studies to assess drug utilization and pregnancy exposure, a study to assess renal function, as well as animal and in vitro studies. We are finalizing the designs and protocols for these studies at the current time and expect to begin the studies in late 2013.

On December 17, 2010, we filed an MAA with the EMA to market Qsiva in the EU for the treatment of obesity. On October 18, 2012, we received the formal opinion from the EMA's CHMP recommending against approval of the MAA for Qsiva in the EU due to concerns over the potential cardiovascular and central nervous system effects associated with long-term use, teratogenic potential and use by patients for whom Qsiva would not have been indicated. We appealed this opinion and the CHMP again denied the MAA on February 21, 2013. We intend to seek approval for Qsymia in other territories outside the United States and intend to commercialize Qsymia in such territories where we obtain approval through collaboration agreements with third parties.

Qsymia in development for Obstructive Sleep Apnea

Obstructive sleep apnea, or OSA, is a chronic and potentially serious sleep disorder in which breathing is abnormally shallow, or hypopnea, or stops altogether, or apnea, for at least ten seconds. These repetitive events are associated with collapse of the upper airway during sleep, and may occur five to thirty or more times per hour. Although many cases are unrecognized, symptoms may include snoring, fatigue or sleepiness during the day.

OSA afflicts approximately 3% to 7% of the U.S. population. Data from the Wisconsin Cohort Study indicate that the prevalence of OSA in people 30-60 years of age is 9-24% for men and 4-9% for women. OSA is associated with an increased risk of hypertension, cardiovascular disease, myocardial infarction, stroke and increased mortality.

The current standard of care treatment for OSA is continuous positive airway pressure, or CPAP, in which the upper airway is kept open by increased air pressure, but CPAP provides benefits only when used consistently. Many patients find CPAP to be inconvenient or uncomfortable, and compliance with CPAP treatment limits its effectiveness.

We believe a safe and effective pharmacologic treatment for OSA could be useful and more acceptable to some patients than CPAP, but no drug is currently approved to treat OSA.

In January 2010, we announced positive results from a Phase 2 study evaluating the safety and efficacy of Qsymia for the treatment of moderate to severe OSA. This Phase 2 study (OB-204) was a single-center, randomized, double-blind, placebo-controlled parallel group trial including 45 obese men

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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 CPAP within three months of screening. Patients were randomized to placebo or top dose Qsymia. We are currently contemplating when to undertake a Phase 3 study.

Qsymia in development for Diabetes

Diabetes is a disease in which the body does not produce or properly use insulin. Insulin is a hormone that is needed to convert sugar and starches into energy needed for daily life. 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 cause of diabetes continues to be a mystery, although both genetics and environmental factors such as obesity and lack of exercise appear to play roles.

There are 23.6 million children and adults in the U.S., or 7.8% of the population, who have diabetes. While an estimated 17.9 million Americans have been diagnosed with diabetes, unfortunately, another 5.7 million Americans (or nearly one quarter) are unaware that they have the disease. It is estimated that there are nearly 350 million diabetics worldwide.

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. Approved injectable medications for type 2 diabetes treatment include glucagon-like peptide-1, or GLP-1, analogs such as Liraglutide, marketed under the brand name Victoza, developed by Novo Nordisk and Exenatide, marketed under the brand name Byetta, and a long-acting version of Exenatide marketed under the brand name Bydureon, developed by Amylin Pharmaceuticals and Eli Lilly and Company. Studies to date suggest GLP-1s improve control of blood glucose by increasing insulin secretion, delaying gastric emptying, and suppressing prandial glucagon secretion. Clinical studies have reported that patients treated with GLP-1s have reported weight loss of approximately six to eight pounds.

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 Qsymia, in type 2 diabetics resulted in a clinically meaningful reduction of hemoglobin A1c, or HbA1c, a measure used to determine treatment efficacy of anti-diabetic agents.

In December 2008, we announced the results of our DM-230 diabetes study. The DM-230 Phase 2 study enrolled 130 patients, who had completed our Phase 2 study for the treatment of obesity (OB-202), at ten study sites in the U.S., 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.

Patients treated with Qsymia had a reduction in HbA1c of 1.6%, from 8.8% to 7.2%, as compared to 1.1% from 8.5% to 7.4% in the placebo-treated standard of care group (Intent to Treat population Using the Last Observation Carried Forward Method, or ITT LOCF, p=0.0381) at 56 weeks. All 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 Qsymia ($p<0.05$).

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Over 56 weeks, patients treated with Qsymia 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 Qsymia patients lost at least 5% of their body weight, as compared to 24% in the placebo group ($p<0.001$), and 37% of the Qsymia 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 Qsymia had reductions in blood pressure, triglycerides and waist circumference. Both treatment groups had a study completion rate of greater than 90%.

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

Despite a mean baseline HbA1c level of 8.8%, 53% of the patients treated with Qsymia 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 was similar (12% and 9%, respectively). Patients in the Qsymia arm experienced no treatment-related serious adverse events.

We also studied the effect of Qsymia on well-controlled diabetics as part of our Phase 3 obesity study, CONQUER, (OB-303). The results were consistent and supportive of the Phase 2 results.

Data from the Phase 3 EQUATE trial (OB-301) demonstrated that weight loss with Qsymia stops the progression of type 2 diabetes in obese, non-diabetic patients. The results of DM-230 demonstrated that weight loss with Qsymia can significantly lower blood sugar in type 2 diabetics. Results from both of these studies were presented at the ADA's annual scientific session in June 2009. We are currently contemplating when to undertake a Phase 3 study.

Qsymia in development for Other Indications

We believe Qsymia may be helpful in treating other obesity-related diseases including nonalcoholic steatohepatitis, or NASH, or its precursor, nonalcoholic fatty liver disease, or NAFLD, also known as fatty liver disease. We believe Qsymia 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. In addition, we believe Qsymia may be helpful in patients with hypertension that do not respond well to antihypertensive medication. We are currently contemplating whether to pursue these other indications.

STENDRA for the treatment of Erectile Dysfunction

Erectile dysfunction, or ED, affects an estimated 52% of men between the ages of 40 and 70. Prevalence increases with age and can be caused by a variety of factors, including medications (anti-hypertensives, histamine receptor antagonists); lifestyle (tobacco, alcohol use); diseases (diabetes, cardiovascular conditions, prostate cancer); and spinal cord injuries. Left untreated, ED can negatively impact relationships and self-esteem, causing feelings of embarrassment and guilt. About half of men being treated with currently available phosphodiesterase 5, or PDE5, inhibitors are dissatisfied with treatment. The market opportunity for ED medical treatments continues to grow, with worldwide sales of PDE5 inhibitors exceeding $5 billion in 2012.

Our drug, STENDRA (avanafil), is an oral PDE5 inhibitor we have licensed from MTPC. STENDRA was approved by the FDA on April 27, 2012 for the treatment of ED. As part of the approval of STENDRA, we are committed to conduct two post-approval clinical studies. The first is a

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randomized, double-blind, placebo-controlled, parallel group multicenter clinical trial on the effect of STENDRA on spermatogenesis in healthy adult males and males with mild erectile dysfunction, or ED. The other study is a double-blind, randomized, placebo-controlled, single-dose clinical trial to assess the effects of STENDRA on multiple parameters of vision, including, but not limited to, visual acuity, intraocular pressure, pupillometry, and color vision discrimination in healthy male subjects. We are currently in the planning stages and expect to begin these studies in 2013.

In March 2012, we filed an MAA with the EMA to market avanafil in the EU for the treatment of ED. The approved trade name for STENDRA in the EU is SPEDRA. In January 2013, we received the Day 180 LoOIs from the EMA. We are currently reviewing the LoOIs which covers a broad range of topics including, without limitation, questions relating to clinical relevance in certain populations as well as questions regarding drug-drug interaction and pharmacokinetics. We are in the process of preparing our response to the CHMP. In order to respond to certain of the items contained in the LoOIs we have requested and have been granted a 30 day extension to respond.

Through collaboration arrangements with third parties, we intend to market and sell STENDRA in the U.S. and, if approved, SPEDRA in the EU and other territories outside the United States. We are currently in discussions with potential collaboration partners for all stated territories.

Other Programs

We have licensed and intend to continue to license from third parties the rights to other investigational drug candidates 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 and conducting clinical trials, formulation and investigational drug candidate development to commercialize pharmaceuticals for unmet medical needs or for disease states that are underserved by currently approved drugs. We intend to develop products with a proprietary position or that complement our other products currently under development, although there can be no assurance that any of these investigational product candidates will be successfully developed and approved by regulatory authorities.

Government Regulations

FDA Regulation

Prescription pharmaceutical products are subject to extensive pre- and post-marketing regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, and its implementing regulations govern, among other things, requirements for the testing, development, manufacturing, quality control, safety, efficacy, approval, labeling, storage, recordkeeping, reporting, distribution, import, export, advertising and promotion of drug products.

The activities required before a pharmaceutical agent may be marketed in the U.S. begin with pre-clinical testing. Pre-clinical tests generally 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 in human volunteers 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, or GCP, which establish standards for conducting, recording data from, and reporting results of, clinical trials, and are intended to assure that the data and reported results are credible, accurate, and that the rights, safety and well-being of study participants are protected. Clinical trials must be 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.

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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, regulations and guidelines for obtaining informed consent from study subjects, as well as other ethical factors and the safety of human patients. The sponsoring company, the FDA, or the Institutional Review Board, or IRB, may suspend or terminate a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

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. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has twelve months in which to complete its initial review of a standard NDA and respond to the applicant, and eight months for a priority NDA. The FDA does not always meet its PDUFA goal dates and in certain circumstances, the review process and the PDUFA goal date may be extended. In addition, even if FDA approval is granted, it 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. In addition, the FDA may require the establishment of REMS that may, for instance, restrict distribution and impose burdensome implementation requirements. Our approved product Qsymia is subject to a REMS program.

Satisfaction of FDA premarket approval requirements for new drugs typically takes several years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or targeted disease. Government regulation may delay or prevent marketing of potential products for a considerable period of time and 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, products are subject to continuing regulation by the FDA. 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 PMR 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 required us to perform PMR studies for both of our approved products, Qsymia and STENDRA. 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 investigational drug 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.

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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 current Good Manufacturing Practice, or cGMP regulations. Compliance with cGMP includes adhering to requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, and records and reports. 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.

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. A product cannot be commercially promoted before it is approved. After approval, product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling approved by the FDA. The FDA has very broad enforcement authority. Failure to abide by these regulations can result in adverse publicity, and/or enforcement actions, including the issuance of a warning letter directing the entity to correct deviations from FDA standards, and state and federal civil and criminal investigations and prosecutions. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products.

Companies that manufacture or distribute drug products or that hold approved NDAs must comply with other regulatory requirements, including submitting annual reports, reporting information about adverse drug experiences, and maintaining certain records. In addition, we are subject to various laws and regulations regarding 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.

In addition to regulations in the U.S., we are subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our investigational drug 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.

United States Healthcare Reform

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, which is referred to in this report as the Affordable Care Act or the PPACA, was adopted in the United States. This law substantially changes

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the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Affordable Care Act contains a number of provisions that are expected to impact our business and operations, in some cases in ways we cannot currently predict. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, fraud and abuse and enforcement. These changes will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

Additional provisions of the Affordable Care Act, some of which became effective in 2011, may negatively affect our revenues in the future. For example, as part of the Affordable Care Act's provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program, or the donut hole, manufacturers are required to provide a 50% discount on branded prescription drugs dispensed to beneficiaries within this donut hole. The Affordable Care Act also makes changes to the Medicaid Drug Rebate Program, discussed further herein, including increasing the minimum rebate from 15.1% to 23.1% of the average manufacturer price for most innovator products and from 11% to 13% for non-innovator products.

Many of the Affordable Care Act's most significant reforms do not take effect until 2014 and thereafter, and their details will be shaped significantly by implementing regulations that have yet to be proposed. In 2012, the Supreme Court of the United States heard challenges to the constitutionality of the individual mandate and the viability of certain provisions of the Affordable Care Act. The Supreme Court's decision upheld most of the Affordable Care Act and determined that requiring individuals to maintain "minimum essential" health insurance coverage or pay a penalty to the Internal Revenue Service was within Congress's constitutional taxing authority. However, the Supreme Court struck down a provision in the Affordable Care Act that penalized states that choose not to expand their Medicaid programs through an increase in the Medicaid eligibility income limit from a state's current eligibility levels to 133% of the federal poverty limit. As a result of the Supreme Court's ruling, it is unclear whether states will expand their Medicaid programs by raising the income limit to 133% of the federal poverty level and whether there will be more uninsured patients in 2014 than anticipated when Congress passed the Affordable Care Act. For each state that does not choose to expand its Medicaid program, there will be fewer insured patients overall, which could impact our sales, business and financial condition.

Pharmaceutical Pricing and Reimbursement

In both U.S. and foreign markets, our ability to commercialize our products successfully, and to attract commercialization partners for our products, depends in significant part on the availability of adequate financial coverage and reimbursement from third-party payors, including, in the United States, governmental payors such as the Medicare and Medicaid programs, managed care organizations, and private health insurers. Third-party payors are increasingly challenging the prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost effectiveness of our products. Even with studies, our products may be considered less safe, less effective or less cost-effective than existing products, and third-party payors may not provide coverage and reimbursement for our product candidates, in whole or in part.

Political, economic and regulatory influences are subjecting the healthcare industry in the United States to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our products profitably. We anticipate that the United States Congress, state legislatures and the private sector will continue to consider and may adopt healthcare policies intended to curb rising healthcare costs. These cost containment measures include: controls on government funded

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reimbursement for drugs; new or increased requirements to pay prescription drug rebates to government health care programs; controls on healthcare providers; challenges to the pricing of drugs or limits or prohibitions on reimbursement for specific products through other means; requirements to try less expensive products or generics before a more expensive branded product; changes in drug importation laws; expansion of use of managed care systems in which healthcare providers contract to provide comprehensive healthcare for a fixed cost per person; and public funding for cost effectiveness research, which may be used by government and private third-party payors to make coverage and payment decisions.

Payors also are increasingly considering new metrics as the basis for reimbursement rates, such as average sales price, average manufacturer price and Actual Acquisition Cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates, and Centers for Medicare and Medicaid Services, or CMS, has begun making pharmacy National Average Drug Acquisition Cost and National Average Retail Price data publicly available on at least a monthly basis. Therefore, it may be difficult to project the impact of these evolving reimbursement mechanics on the willingness of payors to cover our products.

We participate in the Medicaid Drug Rebate program, established by the Omnibus Budget Reconciliation Act of 1990 and amended by the Veterans Health Care Act of 1992 as well as subsequent legislation. Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to the CMS, the federal agency that administers the Medicaid Drug Rebate program. This includes the average manufacturer price and, in the case of innovator products, the best price for each drug.

Federal law requires that any company that participates in the Medicaid rebate program also participate in the Public Health Service's 340B drug pricing discount program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid rebate program. Changes to the definition of average manufacturer price and the Medicaid rebate amount under PPACA and CMS's issuance of final regulations implementing those changes also could affect our 340B ceiling price calculations and negatively impact our results of operations.

In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by PHS 340B eligible entities and certain federal agencies, we participate in the Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program, established by Section 603 of the Veterans Health Care Act of 1992. Under this program, we are obligated to make our product available for procurement on an FSS contract and charge a price to four federal agencies VA, Department of Defense, Public Health Service, and Coast Guard that is no higher than the statutory Federal Ceiling Price, or FCP. The FCP is based on the non-federal average manufacturer price, or Non-FAMP, which we calculate and report to the VA on a quarterly and annual basis. As a new manufacturer, we are currently operating under an Interim Agreement, which is a truncated version of the FSS contract that allows the manufacturer to sell to FSS purchasers while it goes through the lengthy process of negotiating an FSS contract. We also participate in the Tricare Retail Pharmacy program, established by Section 703 of the National Defense Authorization Act for FY 2008 and related regulations, under which we pay quarterly rebates on utilization of

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innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between Annual Non-FAMP and FCP.

We expect to experience pricing pressures in the United States in connection with the sale of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. In various European countries we expect to be subject to continuous cost-cutting measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative.

We are unable to predict what additional legislation, regulations or policies, if any, relating to the healthcare industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation, regulations or policies would have on our business. Any cost containment measures, including those listed above, or other healthcare system reforms that are adopted, could have a material adverse effect on our ability to operate profitably.

Corporate Collaborations and Licenses from Third Parties

Mitsubishi Tanabe Pharma Corporation

In January 2001, we entered into an exclusive development, license and clinical trial and commercial supply agreement with Tanabe Seiyaku Co., Ltd., or Tanabe, now Mitsubishi Tanabe Pharma Corporation, or MTPC, and hereinafter collectively 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 was our primary responsibility. The MTPC agreement contains a number of milestone payments to be made by VIVUS based on various triggering events. Through December 31, 2012, under the terms of the MTPC agreement, we have paid a total of $13.0 million to MTPC, including a $3.0 million milestone payment made in June 2012, upon FDA approval of STENDRA, or avanafil. In addition, during 2012, we purchased from MTPC $7.4 million of inventory under the supply portion of the Agreement in preparation for the commercial launch in the U.S. and certain other territories that use the U.S. approval.

We expect to make other substantial payments to MTPC in accordance with the MTPC agreement as we continue to develop avanafil in our territories outside of the United States and, if approved for sale, commercialize avanafil for the oral treatment of male sexual dysfunction in those territories. Potential future milestone payments include $2.0 million upon the obtainment of the first regulatory approval in any major European country and $6.0 million upon the achievement of $250.0 million or more in worldwide net sales during any calendar year.

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) 10 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.

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In August 2012, we entered into an amendment to the MTPC agreement which, among other matters, allows us to manufacture the active pharmaceutical ingredients, or API, and tablets for avanafil and expands our rights to develop and commercialize avanafil for all indications. The amendment permits us to manufacture the API and tablets for avanafil ourselves or through a third-party supplier at any time; however, the transition away from MTPC supply will need to occur on or before June 2015. On February 21, 2013, we entered into the third amendment to our agreement with MTPC which, among other things, expands our rights, or those of our sublicensees, to enforce the patents licensed under the MTPC agreement against alleged infringement, and clarifies the rights and duties of the parties and our sublicensees upon termination of the MTPC agreement. In addition, we are obligated to use our best commercial efforts to market STENDRA in the U.S. by December 31, 2013.

Other

In October 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 drug candidate development program for Qsymia for the treatment of obesity, obstructive sleep apnea and diabetes. The Combination Therapy and all related patent applications, or the Patents, were transferred to VIVUS with worldwide rights to develop and commercialize the Combination Therapy and exploit the Patents. Pursuant to the Assignment Agreement, through December 31, 2012, we have paid a total of $1.2 million and have issued fully vested and exercisable options to purchase 60,000 shares of VIVUS' common stock to Dr. Najarian. In addition, the Assignment Agreement 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 the Company as a part-time employee and currently serves as a Principal Scientist.

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Patents, Proprietary Technology and Data Exclusivity

We own or are the exclusive licensee of 33 patents and 14 published patent applications in the U.S. 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 primarily relates to Qsymia, our FDA approved drug for the treatment of obesity, and STENDRA, our FDA approved drug for the treatment of erectile dysfunction, is summarized as follows:

QSYMIA	
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. 2009/0304785 A1	Pending
U.S. Patent Publication No. 2010/0105765 A1	Pending
U.S. Patent Publication No. 2010/0215739 A1	Pending
U.S. Patent Publication No. 2012/0196881 A1	Pending
Canadian Patent No. 2,377,330	Expiring 06/14/2020
Canadian Patent Publication No. 2,691,991 A1	Pending
Canadian Patent Publication No. 2,727,313 A1	Pending
Canadian Patent Publication No. 2,727,319 A1	Pending
STENDRA	
U.S. Patent No. 6,656,935	Expiring 09/13/2020
U.S. Patent No. 7,501,409	Expiring 05/05/2023
Canadian Patent No. 2,383,466	Expiring 09/13/2020
ERECTILE DYSFUNCTION	
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. 5,820,587	Expiring 03/14/2015
U.S. Patent No. 5,849,803	Expiring 12/15/2015
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. 6,037,346	Expiring 10/28/2017
U.S. Patent No. 6,093,181	Expiring 07/25/2017
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. 2,305,394	Expiring 10/28/2018

The EU has adopted a harmonized approach to data and marketing exclusivity under Regulation (EC) No. 726/2004 and Directive 2001/83/EC. The exclusivity scheme applies to products that have been authorized in the EU by either the EMA, through the centralized procedure, or the competent authorities of the Member States of the European Economic Area, or EEA, under the Decentralized or Mutual Recognition procedures. The approach (known as the 8+2+1 formula) permits eight years of data exclusivity and 10 years of marketing exclusivity. Within the first eight years of the 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

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cumulatively to a maximum period of 11 years if during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for a new (second) therapeutic indication which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

In addition to the Canadian patents and applications identified in the table, 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 approved drugs and investigational drug candidates, and we rely on trade secrets and proprietary technologies in developing potential drugs. 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 investigational drug candidates in development.

Manufacturing

Our commercial products, Qsymia and STENDRA, together with their respective active pharmaceutical ingredients, or APIs, and finished products, as well as our clinical supplies, are manufactured on a contract basis. In addition, packaging for the commercial distribution of the Qsymia product capsules and the STENDRA product tablets is performed by contract packaging companies. We expect to continue to contract with other third-party providers for manufacturing services, including APIs, finished products, and packaging operations as needed. Although we believe that our current agreements and purchase orders with third-party manufacturers provide for sufficient operating capacity to support the anticipated commercial demand for Qsymia and STENDRA and our clinical supplies, we have only one approved contract manufacturer for each aspect of the manufacturing and packaging processes. If we are unable to obtain a sufficient supply of Qsymia or STENDRA for our commercial sales, or the clinical supplies to support our clinical trials, or if we should encounter delays or difficulties in our relationships with our manufacturers or packagers, we may lose potential sales, have difficulty entering into a collaboration agreement for the commercialization of STENDRA or our clinical trials may be delayed.

The API and the tablets for STENDRA (avanafil) are currently manufactured by MTPC. MTPC has arrangements for the three main starting materials necessary for the manufacturing of avanafil API. In August 2012, we entered into an amendment to our agreement with MTPC that permits us to manufacture the API and tablets for avanafil ourselves or through third-party suppliers at any time. The transition away from MTPC supply will need to occur on or before June 2015.

We currently do not have any manufacturing facilities and intend to continue to rely on third parties for the supply of the starting materials, API and finished dosage forms (tablets and capsules). However, we cannot be certain that we will be successful in entering into such agreements with other suppliers or that we will be able to obtain the necessary regulatory approvals for these suppliers in a timely manner or at all.

Catalent manufactured the supply for our Phase 3 program for Qsymia, and Catalent currently manufactures our clinical and commercial supplies for Qsymia. Catalent has been successful in validating the commercial manufacturing process for Qsymia at a scale which has been able to support the launch of Qsymia in the U.S. market. While Catalent has significant experience in commercial scale manufacturing, there is no assurance that they will be successful with the commercial scale manufacturing of Qsymia.

We attempt to prevent disruption of supplies through supply agreements, purchase orders, appropriate forecasting, maintaining stock levels and other strategies. In the event we are unable to manufacture our products, either directly or indirectly through others or on commercially acceptable terms, if at all, we may not be able to commercialize our products as planned. Although we are taking these actions to avoid a disruption in supply, we cannot provide assurance that we may not experience a disruption in the future.

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Sales and Marketing

We rely on PDI, Inc., or PDI, a third-party contract sales organization, to assist with the hiring of sales representatives and the promotion of Qsymia to physicians. Our internal sales and marketing personnel manage and supervise the activities of this sales force.

We depend on the success of PDI in performing its services, and we cannot be certain PDI will cooperate with us to perform its obligations under the agreement. Although they are contractually obligated, we cannot control the amount of resources that will be devoted by PDI to the promotion of Qsymia. Any failure of PDI to perform its obligations or delay in allocating resources to the promotion of Qsymia could adversely affect the commercialization of Qsymia and materially harm our business, financial condition and results of operations.

Qsymia Distribution and REMS

We have contracted with Cardinal Health PTS, LLC, or Cardinal Health, a third-party distribution and supply-chain management company, to warehouse Qsymia and distribute it to the certified home delivery pharmacies that then distribute Qsymia directly to patients. Cardinal Health provides billing, collection and returns services. We also have entered into agreements with select certified pharmacies, including CVS Pharmacy, Express Scripts, Walgreens, Wal-Mart Pharmacy and Kaiser Permanente to distribute Qsymia to eligible patients through their home delivery networks. We rely on these certified pharmacies to implement a number of safety procedures and to report certain information to the third-party data warehouse.

Our distribution channel for Qsymia was only recently deployed, and some patients and physicians have experienced delays processing and filling prescriptions. Additionally, some Qsymia prescriptions were brought to retail pharmacies that do not dispense the drug. We believe that some prescriptions may never be filled as a result of these factors.

Failure to maintain our contracts with Cardinal Health, with the select certified home delivery pharmacies, or the third-party data warehouse, or the inability or failure of any of them to adequately perform under the contracts, could negatively impact the distribution of Qsymia, or adversely affect our ability to comply with the REMS applicable to Qsymia. Failure to coordinate financial systems could also negatively impact our ability to accurately report and forecast product revenue. If we are unable to effectively manage the distribution and data collection process, sales of Qsymia could be severely compromised and our business, financial condition and results of operations would be harmed.

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 medical device companies for the treatment of sleep apnea. Many of these companies have substantially greater research and development capabilities as well as substantially greater marketing, financial and human resources than we do. Our competitors may develop technologies and products that are more effective than those we are currently marketing or researching and developing. Some of the drugs which may compete with Qsymia may not have a REMS requirement and the accompanying complexities such a requirement presents. Such developments could render Qsymia and STENDRA less competitive or possibly obsolete. We are also competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have limited experience.

Qsymia for the treatment of chronic weight management competes with several approved anti-obesity drugs including, Belviq (lorcaserin), Arena Pharmaceutical's approved anti-obesity compound to be marketed by Eisai Inc., Eisai Co., Ltd.'s U.S. subsidiary; Xenical (orlistat), marketed by Roche; alli, the over-the-counter version of orlistat, marketed by GlaxoSmithKline; and Suprenza

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(phentermine hydrochloride), marketed by Akrimax Pharmaceuticals, LCL. In addition, Orexigen Therapeutics, Inc., or Orexigen, has an investigational drug in late stage testing, Contrave, which, according to Orexigen, could be approved and on the market in 2014. Contrave would be marketed by Takeda Pharmaceutical Company Limited.

There are also several drugs in development for obesity including an investigational drug candidate, liraglutide, in Phase 3 clinical trials being developed by Novo Nordisk A/S. Victoza (liraglutide) is approved by the FDA for the treatment of type 2 diabetes. The approved doses are 1.2mg and 1.8mg in the U.S. and EU while Victoza 3.0mg is being developed for the treatment of obesity. In addition, there are several other investigational drug candidates in Phase 2 clinical trials. In January 2013, Rhythm Pharmaceuticals announced the initiation of a Phase 2 clinical trial with RM-493, a small-peptide melanocortin 4 receptor (MC4R) agonist, for the treatment of obesity. There are a number of generic pharmaceutical drugs that are prescribed for obesity, predominantly phentermine. Phentermine is sold at much lower prices than we charge for Qsymia and is available in retail pharmacies. The availability of branded prescription drugs, generic drugs and over-the-counter drugs could limit the demand for, and the price we are able to charge for, Qsymia.

We also may face competition from the off-label use of the generic components in our drugs. In particular, it is possible that patients will seek to acquire phentermine and topiramate, the generic components of Qsymia. Neither of these generic components has a REMS program and both are available at retail pharmacies. Although the dose strength of these generic components has not been approved by the FDA for use in the treatment of obesity, the off-label use of the generic components in the U.S. or the importation of the generic components from foreign markets could adversely affect the commercial potential for our drugs and adversely affect our overall business, financial conditions and results of operations.

Qsymia and STENDRA may also face challenges and competition from newly developed generic products. Under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, newly approved drugs and indications may benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act stimulates competition by providing incentives to generic pharmaceutical manufacturers to introduce non-infringing forms of patented pharmaceutical products and to challenge patents on branded pharmaceutical products. If we are unsuccessful at challenging an Abbreviated New Drug Application, or ANDA, filed pursuant to the Hatch-Waxman Act, a generic version of Qsymia or STENDRA may be launched, which would harm our business.

There are also surgical approaches to treat severe obesity that are becoming increasingly accepted. Two of the most well established surgical procedures are gastric bypass surgery and adjustable gastric banding, or lap bands. In February 2011, the FDA approved the use of a lap band in patients with a BMI of 30 (reduced from 35) with comorbidities. The lowering of the BMI requirement will make more obese patients eligible for lap band surgery. 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.

We anticipate that STENDRA (avanafil) for the treatment of ED will compete with PDE5 inhibitors in the form of oral medications including Viagra® (sildenafil citrate), marketed by Pfizer, Inc.; Cialis® (tadalafil), marketed by Eli Lilly and Company; Levitra® (vardenafil), co-marketed by GlaxoSmithKline plc and Schering-Plough Corporation in the U.S.; and STAXYN (vardenafil in an oral disintegrating tablet, or ODT), co-marketed by GlaxoSmithKline plc and Merck & Co., Inc.

As patents for the three major PDE5 inhibitors, sildenafil citrate, tadalafil and vardenafil, expire beginning in 2017, we anticipate that generic PDE5 inhibitors will enter the market. Generic PDE5 inhibitors would likely be sold at lower prices and may reduce the demand for STENDRA especially at the prices we would be required to charge for STENDRA to cover our manufacturing and other costs. In addition, PDE5 inhibitors are in various stages of development by other companies. Warner-

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Chilcott plc has licensed the U.S. rights to udenafil, a PDE5 inhibitor from Dong-A Pharmaceutical. Warner-Chilcott continues Phase 3 development of this compound. Other treatments for 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.

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 drugs and future investigational drug 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;
- investigational drug candidate 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 drug 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 $32.1 million in 2012, $24.6 million in 2011 and $40.0 million in 2010 in research and development expenses, primarily to support the approval efforts for Qsymia and STENDRA.

Employees

As of February 19, 2013, we had 121 employees located at our corporate headquarters in Mountain View, California and in the field. 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 clinical trials and commercial sales and general liability and directors' and officers' liability insurance for our operations. 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. Although we have obtained product liability insurance coverage for Qsymia, we may be unable to maintain this product liability coverage for Qsymia or any other of our approved drugs in amounts or scope sufficient to provide us with adequate coverage against all potential risks.

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 SEC 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 the 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 Business

Our success will depend on our ability to effectively and profitably commercialize Qsymia™.

We began commercial sales of Qsymia in September 2012, and initial sales of Qsymia have been slow. Our success will depend on our ability to effectively and profitably commercialize Qsymia, formerly known as Qnexa®, which will include our ability to:

- create market demand for Qsymia through education, marketing and sales activities;
- achieve market acceptance and generate product sales;
- receive adequate levels of reimbursement from third-party payors, such as private insurance programs;
- comply with the post-marketing requirements established by the U.S. Food and Drug Administration, or FDA, including the Risk Evaluation and Mitigation Strategy, or REMS, and any other requirements established by the FDA in the future;
- conduct the post-marketing studies required by the FDA;
- comply with other healthcare regulatory requirements;
- ensure that the active pharmaceutical ingredients, or APIs, for Qsymia and the finished product are manufactured in sufficient quantities and in compliance with requirements of the FDA and similar foreign regulatory agencies and with an acceptable quality and pricing level in order to meet commercial demand; and
- ensure that the entire supply chain for Qsymia, from API to finished product, efficiently and consistently delivers Qsymia to our customers.

Prior to the commercialization of Qsymia, we have not had any commercial products since the divestiture of MUSE in November 2010. While our management and key personnel have significant experience launching and commercializing drugs at VIVUS and at other companies, we have only recently begun to work together to commercialize Qsymia and we cannot be certain that we will be successful. If we are unable to

successfully commercialize Qsymia, our ability to generate product sales

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will be severely limited, which will have a material adverse impact on our business, financial condition, and results of operations.

We intend to market and sell STENDRA™ (avanafil) in the U.S. under a collaboration arrangement with a third party. We also intend to market and sell SPEDRA™ (avanafil) outside the U.S., if approved, under collaboration arrangements with third parties. These arrangements might subject us to a number of risks.

We intend to enter into collaborative arrangements or strategic alliances with pharmaceutical partners or others to commercialize STENDRA in the U.S. and, if approved, to commercialize SPEDRA outside the U.S.

We may be unable to enter into agreements with third parties for these arrangements on favorable terms or at all, which could delay or impair our ability to commercialize STENDRA and SPEDRA in the relevant territories. Additionally, dependence on collaborative arrangements or strategic alliances will subject us to a number of risks, including the following:

- we may not be able to control the commercialization of our drug products in the relevant territories, including amount, timing and quality of resources that our collaborators may devote to our drug products;
- our collaborators may experience financial, regulatory or operational difficulties, which may impair their ability to commercialize our drug products;
- our collaborators may be required under the laws of the relevant territory to disclose our confidential information or may fail to protect our confidential information;
- as a requirement of the collaborative arrangement, we may be required to relinquish important rights with respect to our drug products, 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 commercialization or other obligations under any collaborative arrangement;
- legal disputes or disagreements may occur with one or more of our collaborators;
- a collaborator could independently move forward with a competing investigational drug candidate developed either independently or in collaboration with others, including with one of our competitors; and
- a collaborator could terminate the collaborative arrangement, which could negatively impact the continued commercialization of our drug products.

Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing our products abroad.

We intend to market and sell SPEDRA, if approved, in the European Union, or EU, and in other territories outside the U.S. through collaboration arrangements with third parties. In order to market products in the EU and many other foreign jurisdictions, we must obtain separate regulatory approvals. In March 2012, we filed a Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMA, to market SPEDRA in the EU for the treatment of ED. In January 2013, we received the Day 180 List of Outstanding Issues, or LoOIs, for SPEDRA from the EMA's Committee for Medicinal Products for Human Use, or CHMP. We are currently reviewing the LoOIs which covers a broad range of topics including, without limitation, questions relating to clinical relevance in certain populations as well as questions regarding drug-drug interaction and pharmacokinetics. We are in the process of preparing our response to the CHMP. In order to respond to certain of the items contained in the LoOIs we have requested and have been granted a 30 day extension to respond. We have had limited interactions with foreign regulatory authorities, and the approval procedures vary among countries and can involve additional testing. Approval by the FDA

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does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries. For example, Qsymia was approved in the U.S. by the FDA; however, we were denied an MAA for the same product in the EU. Foreign regulatory approvals may not be obtained on a timely basis, or at all, for any of our products and the failure to receive regulatory approvals in a foreign country would prevent us from marketing our products in that country, which could have a material adverse effect on our business, financial condition and results of operations.

We intend to market SPEDRA outside the U.S., if approved, which will subject us to risks related to conducting business internationally.

We, together with our affiliates and partners, intend to manufacture, market, and distribute SPEDRA, if approved, outside the U.S. We expect that we will be subject to additional risks related to conducting business internationally, including:

different regulatory requirements for drug approvals in foreign countries;

differing U.S. and foreign drug import and export rules;

reduced protection for intellectual property rights in some foreign countries;

unexpected changes in tariffs, trade barriers and regulatory requirements;

different reimbursement systems;

economic weakness, including inflation, or political instability in particular foreign economies and markets;

compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

foreign taxes, including withholding of payroll taxes;

foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;

workforce uncertainty in countries where labor unrest is more common than in the U.S.;

production shortages resulting from events affecting raw material supply or manufacturing capabilities abroad;

potential liability resulting from development work conducted by these distributors; and

business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters.

We rely in part on a third-party contract sales organization for certain sales and marketing support services for Qsymia.

We rely on PDI, Inc., or PDI, a third-party contract sales organization, to assist with the hiring of sales representatives and the promotion of Qsymia to physicians. Our internal sales and marketing personnel manage and supervise the activities of this sales force. Nevertheless, we face risks in our partial reliance on the third-party contract sales organization including the following:

PDI may not apply the expected financial resources or required expertise to successfully promote Qsymia;

PDI may not invest in the continued development of a sales force and the related infrastructure at levels that ensure that sales of Qsymia reach their full potential;

PDI, or its sales representatives, may not comply with applicable legal or regulatory requirements, including the requirement to promote drugs only for uses for which they have been approved;

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disputes may arise between us and PDI that may delay the commercialization of Qsymia or adversely affect its sales or profitability; and

PDI may enter into agreements with other parties that have products that could compete with Qsymia.

We depend on the success of PDI in performing its services, and we cannot be certain PDI will cooperate with us to perform its obligations under the agreement. Although they are contractually obligated, we cannot control the amount of resources that will be devoted by PDI to the promotion of Qsymia. Any failure of PDI to perform its obligations or to continue to allocate resources to the promotion of Qsymia could adversely affect the commercialization of Qsymia and materially harm our business, financial condition and results of operations.

Our failure to manage and maintain our distribution network for Qsymia could compromise the commercialization of this product.

We rely on Cardinal Health PTS, LLC, or Cardinal Health, a third-party distribution and supply-chain management company, to warehouse Qsymia and distribute it to the certified home delivery pharmacies that then distribute Qsymia directly to patients. Cardinal Health provides billing, collection and returns services. We also have entered into agreements with select certified pharmacies, including CVS Pharmacy, Express Scripts, Walgreens, Wal-Mart Pharmacy and Kaiser Permanente, to distribute Qsymia to eligible patients through their home delivery networks. As this distribution channel is new, patients and physicians have experienced delays in processing prescriptions and some prescriptions were sent to retail pharmacies and will not be dispensed. In addition to providing services to support the distribution and use of Qsymia, each of the pharmacies has agreed to comply with the REMS program certified pharmacy requirements and will provide us with the necessary patient and prescribing physician data. We have contracted with a third-party data warehouse to collect this patient and prescribing physician data from the certified pharmacy home delivery network and report it to us. We rely on this third-party data in order to recognize revenue and comply with the REMS requirements for Qsymia, such as data analysis. This distribution and data collection network requires significant coordination with our sales and marketing, finance, regulatory and medical affairs teams, in light of the REMS requirements applicable to Qsymia.

Cardinal Health is our exclusive supplier of distribution logistics services, and accordingly we depend on Cardinal Health to satisfactorily perform its obligations under our agreement with them. Pursuant to the REMS program applicable to Qsymia, our distribution network is through a small number of certified home delivery pharmacies, and we rely on these pharmacies to implement a number of safety procedures and report certain information to the third-party data warehouse. Failure to maintain our contracts with Cardinal Health, with the select certified home delivery pharmacies, or with the third-party data warehouse, or the inability or failure of any of them to adequately perform under the contracts, could negatively impact the distribution of Qsymia, or adversely affect our ability to comply with the REMS applicable to Qsymia. Failure to comply with a requirement of an approved REMS can result in, among other things, civil penalties, operating restrictions and criminal prosecution. Failure to coordinate financial systems could also negatively impact our ability to accurately report and forecast product revenue. If we are unable to effectively manage the distribution and data collection process, sales of Qsymia could be severely compromised and our business, financial condition and results of operations would be harmed.

If we are unable to enter into agreements with suppliers or our suppliers fail to supply us with the APIs for our drugs or if we rely on sole source suppliers, we may experience delays in commercializing our drugs.

We currently do not have supply agreements for extended-release topiramate or phentermine, which are the APIs used in Qsymia. We cannot guarantee that we will be successful in entering into supply agreements on reasonable terms or at all or that we will be able to obtain or maintain the necessary regulatory approvals for these suppliers in a timely manner or at all.

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We anticipate that we will continue to rely on single source suppliers for phentermine and extended-release topiramate for the foreseeable future. Any production shortfall on the part of our suppliers that impairs the supply of phentermine or extended-release topiramate could have a material adverse effect on our business, financial condition and results of operations. If we are unable to obtain a sufficient quantity of these compounds, there could be a substantial delay in successfully developing a second source supplier. An inability to continue to source product from any of these suppliers, which could be due to regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands or quality issues, could adversely affect our ability to satisfy demand for Qsymia, which could adversely affect our product sales and operating results materially, which could significantly harm our business.

The API and the tablets for STENDRA are currently manufactured by Mitsubishi Tanabe Pharma Corporation, or MTPC. MTPC has arrangements for the three main starting materials necessary for the manufacturing of avanafil API. The MTPC manufacturing sites for the API (avanafil) and STENDRA tablets have been inspected by the U.S. authorities. We do not believe the results of those inspections will have an impact on MTPC's ability to supply STENDRA, or the approval, or the timing of approval, of SPEDRA in the EU. However, if MTPC is unable to receive approval from foreign regulators and maintain ongoing FDA or foreign regulatory compliance, or manufacture STENDRA's API or tablets in sufficient quantities to meet projected demand, the EU approval, the U.S. commercial launch, and future sales of STENDRA and SPEDRA will be adversely effected, which in turn could have a detrimental impact on our financial results and could impact our ability to enter into a collaboration for the commercialization of STENDRA and SPEDRA, if approved.

In August 2012, we entered into an amendment to our agreement with MTPC that permits us to manufacture the API and tablets for STENDRA ourselves or through third-party suppliers at any time, and we are required under the amendment to transition away from MTPC supply on or before June 2015.

We currently do not have any manufacturing facilities and intend to continue to rely on third parties for the supply of the starting materials, API and tablets. However, we cannot be certain that we will be successful in entering into such agreements with other suppliers or that we will be able to obtain the necessary regulatory approvals for these suppliers in a timely manner or at all.

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

We have in-licensed and otherwise contracted for rights to Qsymia and STENDRA, and we may enter into similar licenses in the future. Under the relevant agreements, we are subject to commercialization, development, supply, 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, we license the rights to avanafil from MTPC, and we have certain obligations to MTPC in connection with that license. For example, we are obligated to use our best commercial efforts to market STENDRA in the U.S. by December 31, 2013. Failure to launch STENDRA in the U.S. before this date may result in us losing our license to STENDRA in the U.S. and could adversely impact the commercial future of STENDRA outside of the U.S. In addition, we license the rights to Qsymia from Dr. Najarian. We believe we are in compliance with the material terms of our license agreements with MPTC and Dr. Najarian. However, there can be no assurance that this compliance will continue or that the licensors will 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 licenses 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 our operations, our stock

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price and our overall financial condition. The monetary and disruption costs of any disputes involving our agreements could be significant despite rulings in our favor.

Our ability to gain market acceptance and generate revenues will be subject to a variety of risks, many of which are out of our control.

Qsymia and STENDRA may not gain market acceptance among physicians, patients, healthcare payors or the medical community. We believe that the degree of market acceptance and our ability to generate revenues from such drugs will depend on a number of factors, including:

- our distribution system for Qsymia, which will be limited to a certified home delivery pharmacy network in accordance with the REMS requirement;
- contraindications for Qsymia and STENDRA;
- competition and timing of market introduction of competitive drugs;
- efficacy and safety in the approved setting;
- prevalence and severity of any side effects, including those of the generic components of our drugs;
- emergence of previously unknown side effects, including those of the generic components of our drugs;
- results of any post-approval studies;
- potential or perceived advantages or disadvantages over alternative treatments including generics;
- the relative convenience and ease of administration and dosing schedule;
- the convenience and ease of purchasing the drug, as perceived by potential patients;
- strength of sales, marketing and distribution support;
- price 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;
- availability of coverage and reimbursement from government and other third-party payors;

the level of mandatory discounts required under federal and state healthcare programs and the volume of sales subject to those discounts;

recommendations for prescribing physicians to complete certain educational programs for prescribing drugs;

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

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

Our drugs may fail to achieve market acceptance or generate significant revenue to achieve or sustain profitability. In addition, our efforts to educate the medical community and third-party payors on the safety and benefits of our drugs may require significant resources and may not be successful.

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We are required to complete post-approval studies mandated by the FDA for both Qsymia and STENDRA, and such studies are expected to be costly and time consuming. If the results of these studies reveal unacceptable safety risks, Qsymia or STENDRA may be required to be withdrawn from the market.

As part of the approval for STENDRA, the FDA is requiring us to perform two post-approval clinical studies. The first is a randomized, double-blind, placebo-controlled, parallel group multicenter clinical trial on the effect of STENDRA on spermatogenesis in healthy adult males and males with mild erectile dysfunction, or ED. The other study is a double-blind, randomized, placebo-controlled, single-dose clinical trial to assess the effects of STENDRA on multiple parameters of vision, including, but not limited to, visual acuity, intraocular pressure, pupillometry, and color vision discrimination in healthy male subjects. If we are unable to complete these studies or the results of these studies reveal unacceptable safety risks, we could be required to perform additional tests and regulatory approval could even be withdrawn.

As part of the approval of Qsymia, we are required to conduct several post-marketing studies, including a study to assess the long-term treatment effect of Qsymia on the incidence of major adverse cardiovascular events in overweight and obese subjects with confirmed cardiovascular disease, studies to assess the safety and efficacy of Qsymia for weight management in obese pediatric and adolescent subjects, studies to assess drug utilization and pregnancy exposure and a study to assess renal function. The details of the cardiovascular outcomes study, known as ACQLAIM, have not yet been agreed upon with the FDA. This study could cost between $150.0 and $250.0 million and take as long as five years to complete. Enrollment is expected to begin in the fourth quarter of 2013. There can be no assurance that the FDA will not request or require us to provide additional information or undertake additional prospective studies or retrospective observational studies or that we will be able to agree with the FDA on the details of ACQLAIM.

In addition, at the FDA's request, we initiated a retrospective observational study utilizing existing electronic medical claims healthcare databases to review fetal outcomes, including the incidence of congenital malformations and oral cleft, in the offspring of women who received treatment with topiramate, for any condition or at any dose, or FORTRESS. We announced preliminary results from FORTRESS in December 2011. The results of the study are considered to be preliminary until the results are validated, which we expect to complete in the second half of 2013. If the results of this study reveal unacceptable safety risks for topiramate, we could be required to perform additional studies and regulatory approval could even be withdrawn.

In addition to these studies, the FDA may also require us to commit to perform other 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, 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 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 complete our post-approval clinical trials for Qsymia and STENDRA, obtain regulatory approval for our current and

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future investigational drug candidates, successfully commercialize our approved drugs 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 commercially reasonable terms, or at all.

Qsymia is a combination of two active ingredient drug products approved individually by the FDA that are commercially available and marketed by other companies, although the specific dose strengths and formulation (extended-release vs. immediate-release) would differ. As a result, Qsymia may be subject to substitution by prescribing physicians with individual drugs contained in the Qsymia formulation, which would adversely affect our business.

Although Qsymia is a once-a-day, proprietary extended-release formulation, each of the approved APIs (phentermine and topiramate extended-release) that is combined to produce Qsymia is commercially available as drug products at prices that together are lower than the price at which we sell Qsymia. In addition, the distribution and sale of these drug products is not limited under a REMS program, as is the case with Qsymia. Further, the individual drugs contained in the Qsymia formulation are available in retail pharmacies and neither has a Pregnancy Category X, which is used to indicate that the risks involved in the use of the drug in pregnant women clearly outweigh potential benefits, as is the case with Qsymia. We cannot be sure that physicians will view Qsymia as sufficiently superior to a treatment regimen of Qsymia's individual APIs to justify the significantly higher cost for Qsymia, and they may prescribe the individual generic drugs already approved and marketed by other companies instead of our combination drug. Although our U.S. and European patents contain composition, product formulation and method-of-use claims that we believe protect Qsymia, these patents do not prevent physicians from prescribing the individual generic constituents marketed by other companies instead of our combination drug. Phentermine and topiramate are currently available in generic form, although the doses used in Qsymia are currently not available and no extended-release formulation of topiramate is currently available. In addition, topiramate is not approved for obesity treatment, and phentermine is only approved for short-term treatment of obesity. However, because the price of Qsymia 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 outside of their approved indication, instead of for our combination drug, and this may limit how we price or market Qsymia. Similar concerns could also limit the reimbursement amounts private health insurers or government agencies in the U.S. are prepared to pay for Qsymia, which could also limit market and patient acceptance of our drug and could negatively impact our revenues.

In many regions and countries where we may plan to market Qsymia, the pricing of reimbursed prescription drugs is controlled by the government or regulatory agencies. The government or regulatory agencies in these countries could determine that the pricing for Qsymia should be based on prices for its APIs when sold separately, rather than allowing us to market Qsymia at a premium as a new drug.

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

Qsymia and STENDRA, like all pharmaceutical products, are subject to heightened risk for product liability claims due to inherent potential side effects. For example, because topiramate, a component of Qsymia, may increase the risk of congenital malformation in infants exposed to topiramate during the first trimester of pregnancy and also may increase the risk of suicidal thoughts and behavior, such risks may be associated with Qsymia as well. Other potential risks involving Qsymia may include, but are not limited to, an increase in resting heart rate, acute angle closure glaucoma, cognitive and psychiatric adverse events, metabolic acidosis, an increase in serum creatinine,

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hypoglycemia in patients with type 2 diabetes, kidney stone formation, decreased sweating and hypokalemia, or lower-than-normal amount of potassium in the blood.

Although we have obtained product liability insurance coverage for Qsymia, we may be unable to maintain this product liability coverage for Qsymia or any other of our approved drugs in amounts or scope sufficient to provide us with adequate coverage against all potential risks. 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 through third parties, approved drugs and future investigational drug candidates that are used by humans. We face an inherent risk of product liability exposure related to the testing of our approved drugs and investigational drug candidates in clinical trials. An individual may bring a liability claim against us if one of our approved drugs or future investigational drug candidates causes, or merely appears to have caused, an injury.

If we cannot successfully defend ourselves against a product liability claim, whether involving Qsymia, STENDRA or a future investigational drug candidate, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

injury to our reputation;

withdrawal of clinical trial patients;

costs of defending the claim and/or related litigation;

cost of any potential adverse verdict;

substantial monetary awards to patients or other claimants; and

the inability to commercialize our drugs.

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. In addition, product liability claims could result in an FDA investigation of the safety or efficacy of our product, our third-party manufacturing processes and facilities, or our marketing programs. An FDA investigation could also potentially lead to a recall of our products or more serious enforcement actions, limitations on the indications for which they may be used, or suspension or withdrawal of approval.

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 medical device companies for the treatment of sleep apnea. Many of these companies have substantially greater research and development capabilities as well as substantially greater marketing, financial and human resources than we do. Some of the drugs which may compete with Qsymia may not have a REMS requirement and the accompanying complexities such a requirement presents. 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 Qsymia and STENDRA less competitive or possibly obsolete. We are also competing with

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respect to marketing capabilities and manufacturing efficiency, areas in which we have limited experience.

Qsymia for the treatment of chronic weight management competes with several approved anti-obesity drugs including, Belviq® (lorcaserin), Arena Pharmaceutical's approved anti-obesity compound to be marketed by Eisai Inc., Eisai Co., Ltd.'s U.S. subsidiary; Xenical (orlistat), marketed by Roche; alli®, the over-the-counter version of orlistat, marketed by GlaxoSmithKline; and Suprenza (phentermine hydrochloride), marketed by Akrimax Pharmaceuticals, LCL. In addition, Orexigen Therapeutics, Inc., or Orexigen, has an investigational drug in late stage testing, Contrave®, which, according to Orexigen, could be approved and on the market in 2014. Contrave would be marketed by Takeda Pharmaceutical Company Limited.

There are also several drugs in development for obesity including an investigational drug candidate, liraglutide, in Phase 3 clinical trials being developed by Novo Nordisk A/S. Victoza® (liraglutide) is approved by the FDA for the treatment of type 2 diabetes and also is being developed for the treatment of obesity. In addition, there are several other investigational drug candidates in Phase 2 clinical trials. There are also a number of generic pharmaceutical drugs that are prescribed for obesity, predominantly phentermine. Phentermine is sold at much lower prices than we charge for Qsymia and is available in retail pharmacies. The availability of a branded prescription drugs, generic drugs and over-the-counter drugs could limit the demand for, and the price we are able to charge for, Qsymia.

We also may face competition from the off-label use of the generic components in our drugs. In particular, it is possible that patients will seek to acquire phentermine and topiramate, the generic components of Qsymia. Neither of these generic components has a REMS program and both are available at retail pharmacies. Although the dose strength of these generic components has not been approved by the FDA for use in the treatment of obesity, the off-label use of the generic components in the U.S. or the importation of the generic components from foreign markets could adversely affect the commercial potential for our drugs and adversely affect our overall business, financial conditions and results of operations.

There are also surgical approaches to treat severe obesity that are becoming increasingly accepted. Two of the most well established surgical procedures are gastric bypass surgery and adjustable gastric banding, or lap bands. In February 2011, the FDA approved the use of a lap band in patients with a BMI of 30 (reduced from 35) with comorbidities. The lowering of the BMI requirement will make more obese patients eligible for lap band surgery. 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.

We anticipate that STENDRA (avanafil) for the treatment of erectile dysfunction will compete with PDE5 inhibitors in the form of oral medications including Viagra® (sildenafil citrate), marketed by Pfizer, Inc.; Cialis® (tadalafil), marketed by Eli Lilly and Company; Levitra® (vardenafil), co-marketed by GlaxoSmithKline plc and Schering-Plough Corporation in the U.S.; and STAXYN (vardenafil in an oral disintegrating tablet, or ODT), co-marketed by GlaxoSmithKline plc and Merck & Co., Inc.

As patents for the three major PDE5 inhibitors, sildenafil citrate, tadalafil and vardenafil, expire beginning in 2017, we anticipate that generic PDE5 inhibitors will enter the market. Generic PDE5 inhibitors would likely be sold at lower prices and may reduce the demand for STENDRA especially at the prices we would be required to charge for STENDRA to cover our manufacturing and other costs. In addition, PDE5 inhibitors are in various stages of development by other companies. Warner-Chilcott plc has licensed the U.S. rights to udenafil, a PDE5 inhibitor from Dong-A Pharmaceutical. Warner-Chilcott continues Phase 3 development of this compound. Other treatments for 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.

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Qsymia and STENDRA may also face challenges and competition from newly developed generic products. Under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, newly approved drugs and indications may benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act stimulates competition by providing incentives to generic pharmaceutical manufacturers to introduce non-infringing forms of patented pharmaceutical products and to challenge patents on branded pharmaceutical products. If we are unsuccessful at challenging an Abbreviated New Drug Application, or ANDA, filed pursuant to the Hatch-Waxman Act, a generic version of Qsymia or STENDRA may be launched, which would harm our business.

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 drugs and future investigational drug 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;

investigational drug candidate 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 drug 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.

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, any of 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 expected benefits 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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Our failure to successfully acquire, develop and market additional investigational drug candidates or approved drugs 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 drug candidates. We have not in-licensed any new product candidates in several years. 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 investigational drug candidates and products.

The process of proposing, negotiating and implementing a license or acquisition of an investigational drug 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 investigational drug 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 investigational drug 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, integration and maintenance 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 investigational drug candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and obtaining approval by the FDA and applicable foreign regulatory authorities. All investigational drug candidates are prone to certain failures that are relatively common in the field of drug development, including the possibility that an investigational drug candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot be certain that any drugs that we develop or approved products that we may acquire will be commercialized profitably or achieve market acceptance.

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 investigational drug candidates or commercialization of our approved drugs.

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, commercial operations, research and development, regulatory and legal affairs, business development, clinical trial design, execution and analysis, and pre-clinical testing. There can be no

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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 programs, investigational drug candidate development, approved drug commercialization efforts and business operations.

We rely on third parties and collaborative partners to manufacture sufficient quantities of compounds within product specifications as required by regulatory agencies for use in our pre-clinical and clinical trials and 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 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, natural or other disasters, or a failure of the third parties to follow regulations, we may not be able to obtain regulatory approvals for our investigational drug candidates and may not be able to successfully commercialize these investigational drug candidates or our approved drugs.

Our third-party manufacturers and collaborative partners, may encounter delays and problems in manufacturing our investigational drug 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, excipients, and other materials may become scarce, more expensive to procure, or not meet quality standards, and we may not be able to obtain favorable terms in agreements with subcontractors. Our third-party manufacturers, may not be able to operate manufacturing facilities in a cost-effective manner or in a time frame that is consistent with our expected future manufacturing needs. If 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.

For example, Catalent supplied the product for the Phase 3 program for Qsymia and is our sole source of clinical and commercial supplies for Qsymia. Catalent has been successful in validating the commercial manufacturing process for Qsymia at a scale which has been able to support the launch of Qsymia in the U.S. market. While Catalent has significant experience in commercial scale manufacturing, there is no assurance that they will be successful with the commercial scale manufacturing of Qsymia, which may be required to support future increases in market demand of Qsymia. Such a failure by Catalent to further scale up the commercial manufacturing process for Qsymia could have a material adverse impact on our ability to realize commercial success with Qsymia in the U.S. market, and have a material adverse impact on our plan, market price of our common stock and financial condition.

In the case of STENDRA, we currently rely on MTPC to supply the API (avanafil) and the tablets for STENDRA. MTPC is responsible for all aspects of manufacture, including obtaining the starting materials for the production of API. If MTPC is unable to manufacture the API for STENDRA or tablets in sufficient quantities to meet projected demand future sales of STENDRA could be adversely effected, which in turn could have a detrimental impact on our financial results and could impact our ability to enter into a collaboration for the commercialization of STENDRA.

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In August 2012, we entered into an amendment to our agreement with MTPC that permits us to manufacture the API and tablets for avanafil ourselves or through third parties. According to the amendment, the transition of manufacturing from MTPC must occur on or before June 2015. The transfer of technology to, and qualification of, a new supplier is expensive, time consuming and logistically complicated. The technology transfer needed for this transition is highly dependent on the cooperation of MTPC and its current suppliers. If MTPC, or its current suppliers, is unable to effectively transfer the technology or supply on commercially reasonable terms, the approvability, partnerability and commercial success of STENDRA could be adversely impacted. Any future manufacturing sites would need to be inspected by the U.S. and EU authorities, and any failure of such manufacturing sites to receive approval from FDA or foreign authorities, obtain and maintain ongoing FDA or foreign regulatory compliance, or manufacture avanafil API or STENDRA tablets in expected quantities, could adversely affect future sales of STENDRA, which in turn could have a detrimental impact on our financial results and could impact our ability to enter into a collaboration for the commercialization of STENDRA.

We rely on third parties to maintain appropriate levels of confidentiality of the data compiled during clinical, pre-clinical and retrospective observational studies and 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 drug 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.

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

Even though we do not bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse are and will be applicable to our business. The regulations that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Law, which prohibits, among other things, knowingly or willingly offering, paying, soliciting or receiving remuneration, directly or indirectly, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care items or service reimbursable under federal healthcare programs such as Medicare and Medicaid. Further, the Affordable Care Act, among other things, amends the intent requirement of the federal anti-kickback statute. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. This statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common manufacturer business arrangements and activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations of our products may be subject to scrutiny if they do not qualify for an exemption or safe harbor. We seek to comply with the

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exemptions and safe harbors whenever possible, but our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability;

the federal False Claims Laws, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. Many pharmaceutical and other healthcare companies have been investigated and have reached substantial financial settlements with the federal government under the False Claims Act for a variety of alleged improper marketing activities, including providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees, grants, free travel, and other benefits to physicians to induce them to prescribe the company's products; and inflating prices reported to private price publication services, which are used to set drug payment rates under government healthcare programs. In addition, in recent years the government has pursued False Claims Act cases against a number of pharmaceutical companies for causing false claims to be submitted as a result of the marketing of their products for unapproved, and thus non-reimbursable, uses. Pharmaceutical and other healthcare companies also are subject to other federal false claim laws, including federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs;

numerous federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use and disclosure of personal information. Other countries also have, or are developing, laws governing the collection, use and transmission of personal information. In addition, most healthcare providers who prescribe our product and from whom we obtain patient health information are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, or HIPAA. We are not a HIPAA covered entity and we do not operate as a business associate to any covered entities. Therefore, these privacy and security requirements do not apply to us. However, we could be subject to criminal penalties if we knowingly obtain individually identifiable health information from a covered entity in a manner that is not authorized or permitted by HIPAA or for aiding and abetting the violation of HIPAA. We are unable to predict whether our actions could be subject to prosecution in the event of an impermissible disclosure of health information to us. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect our business, including recently enacted laws in a majority of states requiring security breach notification. These laws could create liability for us or increase our cost of doing business;

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 under Medicaid and other state programs or, in several states, apply regardless of the payor. Some state laws also require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in the states. Other states prohibit providing meals to prescribers or other marketing related activities. Still other states require the posting of information relating to clinical studies and their outcomes. In addition, California, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs or marketing codes of conduct. Additional states are considering or recently have considered similar proposals. Foreign governments often have similar regulations which we also will be subject to in those countries where we market and sell products; and

the federal Physician Payment Sunshine Act will require extensive tracking of physician and teaching hospital payments, maintenance of a payments database, and public reporting of the payment data. Centers for Medicare and Medicaid Services, or CMS, recently issued a final rule

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implementing the Physician Payment Sunshine Act provisions and clarified the scope of the reporting obligations, as well as that manufacturers must begin tracking on August 1, 2013 and must report payment data to CMS by March 31, 2014.

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 from government 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.

Marketing activities for our approved drugs are subject to continued governmental regulation.

The FDA has the authority to impose significant restrictions, including REMS requirements, on approved products through regulations on advertising, promotional and distribution activities. After approval, if products are marketed in contradiction with FDA laws and regulations, 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 require 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. Qsymia and STENDRA are subject to these regulations. Failure to comply with state requirements may affect our ability to promote or sell pharmaceuticals drugs in certain states. This in turn could have a material adverse impact on our financial results and financial condition and could subject us to significant liability, including civil and administrative remedies as well as criminal sanctions.

We are subject to ongoing regulatory obligations and restrictions, which may result in significant expense and limit our ability to commercialize our drugs.

We are required to comply with extensive regulations for drug manufacturing, labeling, packaging, adverse event reporting, storage, distribution, advertising, promotion and record keeping in connection with the marketing of Qsymia and STENDRA. Regulatory approvals may also be subject to significant limitations on the indicated uses or marketing of the investigational drug candidates or to whom and how we may distribute our products. Even after FDA approval is obtained, the FDA may still impose significant restrictions on a drug's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. For example, the labeling approved for Qsymia includes restrictions on use, including recommendations for pregnancy testing, level of obesity and duration of treatment. We are subject to ongoing regulatory obligations and restrictions which may result in significant expense and limit our ability to commercialize Qsymia. The FDA has also required the distribution of a Medication Guide to patients outlining the increased risk of teratogenicity with fetal exposure and the possibility of suicidal thinking or behavior. In addition, the FDA has required a REMS that may act to limit access to the drug, reduce our revenues and/or increase our costs. The FDA may modify the Qsymia REMS in the future to be more or less restrictive.

Even if we receive FDA and other regulatory approvals, if we or others identify adverse side effects after any of our products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn and reformulation of our products, additional clinical trials, changes in labeling and additional marketing applications may be required, any of which could harm our business and cause our stock price to decline.

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We and our contract manufacturers are subject to significant regulation with respect to manufacturing of our products.

All of those involved in the preparation of a therapeutic drug for clinical trials or commercial sale, including our existing supply contract manufacturers, and clinical trial investigators, are subject to extensive regulation. Components of a finished drug product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with current Good Manufacturing Practices, or cGMP. These regulations govern quality control of the manufacturing processes and documentation policies and procedures, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Our facilities and quality systems and the facilities and quality systems of our third-party contractors must be inspected routinely for compliance. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulation occurs independent of such an inspection or audit, we or the FDA may require remedial measures that may be costly and/or time consuming for us or a third party to implement and that may include the issuance of a warning letter, temporary or permanent suspension of a clinical trial or commercial sales, recalls, market withdrawals, seizures, or the temporary or permanent closure of a facility. Any such remedial measures would be imposed upon us or third parties with whom we contract until satisfactory cGMP compliance is achieved. The FDA could also impose civil penalties. We must also comply with similar regulatory requirements of foreign regulatory agencies.

We obtain the necessary raw materials and components for the manufacture of Qsymia and STENDRA as well as certain services, such as analytical testing packaging and labeling, from third parties. In particular, we rely on Catalent Pharma Solutions, LLC to supply Qsymia capsules and Packaging Coordinators, Inc., or PCI, for Qsymia packaging services. 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. Because manufacturing processes are highly complex and are subject to a lengthy regulatory approval process, alternative qualified supply may not be available on a timely basis or at all. Difficulties, problems or delays in our suppliers and service providers' manufacturing and supply of raw materials, components and services could delay our clinical trials, increase our costs, damage our reputation and cause us to lose revenue or market share if we are unable to timely meet market demands.

In addition, we have an agreement with MTPC to supply the API and the tablets for STENDRA. The MTPC manufacturing sites have been inspected by the U.S. authorities. We do not believe the results of those inspections will have an impact on MTPC's ability to supply STENDRA, or the approval, or the timing of approval, of SPEDRA in the EU. However, if MTPC is unable to receive approval from foreign authorities, and maintain ongoing FDA or foreign regulatory compliance, or manufacture avanafil API or STENDRA tablets in sufficient quantities to meet projected demand, the EU approval, the U.S. commercial launch, and future sales of STENDRA will be adversely effected, which in turn could have a detrimental impact on our financial results and could impact our ability to enter into a collaboration for the commercialization of STENDRA. In August 2012, we entered into an amendment to our agreement with MTPC that permits us to manufacture the API and STENDRA tablets for avanafil ourselves or through third parties. According to the amendment, the transition of manufacturing from MTPC must occur on or before June 2015. The technology transfer needed for this transition is highly dependent on the cooperation of MTPC and its current suppliers. If MTPC, or its current suppliers, is unable to effectively transfer the technology or supply on commercially reasonable terms, the approvability, partnerability and commercial success of STENDRA could be adversely impacted. Any future manufacturing sites would need to be inspected by the U.S. and EU authorities,

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and any failure of such manufacturing sites to receive approval from FDA or foreign authorities, obtain and maintain ongoing FDA or foreign regulatory compliance, or manufacture avanafil API or tablets in expected quantities, could adversely affect future sales of STENDRA, which in turn could have a detrimental impact on our financial results and could impact our ability to enter into a collaboration for the commercialization of STENDRA.

Any adverse changes in reimbursement procedures by government and other third-party payors may limit our ability to market and sell our approved drugs, or any future drugs, if approved or limit our product revenues and delay profitability.

In the U.S. and abroad, sales of pharmaceutical drugs 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, charge co-pays to patients, or do not provide coverage for specific drugs or drug classes.

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.

The healthcare industry in the U.S. and abroad 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.

The Affordable Care Act substantially changed the way healthcare is financed by both governmental and private insurers, and could have a material adverse effect on our future business, cash flows, financial condition and results of operations, including by operation of the following provisions:

Effective March 23, 2010, drug rebates are due on the utilization of Medicaid managed care organizations. This expanded eligibility affects rebate liability for that utilization.

Effective January 1, 2011, pharmaceutical companies must provide a 50% discount on branded prescription drugs dispensed to beneficiaries within the Medicare Part D coverage gap or "donut hole," which is a funding gap that currently exists in the Medicare Part D prescription drug program. We currently do not anticipate coverage under Medicare Part D, but this could change in the future.

Effective January 1, 2011, the U.S. Federal government must allocate an annual branded prescription drug fee among pharmaceutical manufacturers of branded prescription drugs based on the dollar value of their branded prescription drug sales to certain federal health care programs identified in the law. The Affordable Care Act determines an individual manufacturer's market share as the ratio of its aggregate sales of branded prescription drugs during the preceding calendar year as a percentage of the aggregate branded prescription drug sales for all covered manufacturers. Each individual pharmaceutical manufacturer will pay a

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prorated share of the branded prescription drug fee of $2.8 billion in 2013 (and set to increase in ensuing years) based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law.

Changes made by the Affordable Care Act are expected to result in the coverage of 32 million uninsured individuals through an expansion of the Medicaid program, and private sector coverage either through their employer or the new state-based Health Insurance Exchanges effective in 2014. In 2012, the Supreme Court of the United States heard challenges to the constitutionality of the individual mandate and the viability of certain provisions of the Affordable Care Act. The Supreme Court's decision upheld most of the Affordable Care Act and determined that requiring individuals to maintain "minimum essential" health insurance coverage or pay a penalty to the Internal Revenue Service was within Congress's constitutional taxing authority. However, the Supreme Court struck down a provision in the Affordable Act that penalized states that choose not to expand their Medicaid programs through an increase in the Medicaid eligibility income limit from a state's current eligibility levels to 133% of the federal poverty limit. As a result of the Supreme Court's ruling, it is unclear whether states will expand their Medicaid programs by raising the income limit to 133% of the federal poverty level and whether there will be more uninsured patients in 2014 than anticipated when Congress passed the Affordable Care Act. For each state that does not choose to expand its Medicaid program, there will be fewer insured patients overall, which could impact our sales, business and financial condition. We expect any Medicaid expansion to impact the number of adults in Medicaid more than children because many states have already set their eligibility criteria for children at or above the level designated in the Affordable Care Act. An increase in the proportion of patients who receive our drugs and who are covered by Medicaid could adversely affect our net sales.

Presently, uncertainty exists as many of the specific determinations necessary to implement the Affordable Care Act have yet to be decided and communicated to industry participants. At this time, we cannot predict the full impact of the Affordable Care Act, or the timing and impact of any future rules or regulations promulgated to implement the Affordable Care Act.

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 intend to market Qsymia.

We expect to experience pricing and reimbursement pressures in connection with the sale of Qsymia, STENDRA and our investigational drug candidates, if approved, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. In addition, we may confront limitations in insurance coverage for Qsymia, STENDRA and our investigational drug candidates. For example, the Medicare program generally does not provide coverage for drugs used to treat erectile dysfunction or drugs used to treat obesity. Similarly, other insurers may determine that such products are not covered under their programs. If we fail to successfully secure and maintain reimbursement coverage for our investigational drug candidates or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our investigational drug candidates and our business will be harmed. Congress has enacted healthcare reform and may enact further reform, which could adversely affect the pharmaceutical industry as a whole, and therefore could have a material adverse effect on our business.

Both of the active pharmaceutical ingredients in Qsymia, phentermine and topiramate, are available as generics and do not have a REMS requirement. The exact doses of the active ingredients in Qsymia are different than those currently available for the generic components. State pharmacy laws prohibit pharmacists from substituting drugs with differing doses and formulations. The safety and

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efficacy of Qsymia is 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 Qsymia as a treatment for obesity or any other indication, if approved, from third-party payors or the U.S. government. Furthermore, there can be no assurance that healthcare providers would not actively seek to provide patients with generic versions of the active ingredients in Qsymia in order to treat obesity at a potential lower cost and outside of the REMS requirements.

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 investigational 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 approved drugs or future investigational drug candidates will depend in part on government regulation and the availability of coverage and adequate reimbursement from third-party payors, including private health insurers and government payors, such as the Medicaid and Medicare programs, increases in government-run, single-payor health insurance plans and compulsory licenses of drugs. Government and third-party payors 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 investigational drug candidates in the future due to a reduction in the potential revenues from drug sales. Adoption of legislation and regulations could limit pricing approvals for, and reimbursement of, drugs. A government or third-party payor decision not to approve pricing for, or provide adequate coverage and reimbursements of, our drugs could limit market acceptance of these drugs.

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 contract sales organization, or CSO, 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 investigational drug candidate development programs and drug manufacturing operations. For example, the loss of clinical trial data from completed or ongoing clinical trials for our investigational drug 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 was 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 drug candidates, or commercialization of our approved drugs, could be delayed. If we are unable to restore our information systems in the event of a systems failure, our communications, daily operations and the ability to develop our investigational drug candidates and approved drug commercialization efforts would be severely affected.

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Natural disasters or resource shortages could disrupt our investigational drug candidate development and approved drug commercialization efforts and adversely affect results.

Our ongoing or planned clinical trials and approved drug commercialization efforts could be delayed or disrupted indefinitely upon the occurrence of a natural disaster. For example, Hurricane Sandy in October 2012 has hindered our Qsymia sales efforts, the nature and extent of which is not yet known. 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 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. Our supplier of STENDRA is located in Japan near known earthquake fault zones and is vulnerable to damage from earthquakes and tsunamis. 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

Obtaining intellectual property rights is a complex process, and we may be unable to adequately protect our proprietary technologies.

We hold various patents and patent applications in the U.S. and abroad targeting obesity and morbidities related to obesity, including sleep apnea and diabetes, and sexual health, among other indications. The procedures for obtaining a patent in the U.S. 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. 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 investigational drug candidates or products, or be considered sufficient by parties reviewing our patent positions pursuant to a potential licensing or financing transaction.

In addition, even if our patent applications issue as patents, we cannot make assurances as to how much protection, if any, will be provided by these patents. 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 could decline.

Other entities may also challenge the validity or enforceability of our patents and patent applications in litigation or administrative proceedings. The sponsor of a generic application seeking to rely on one of our approved drug products as the reference listed drug must make one of several certifications regarding each listed patent. A "Paragraph III" certification is the sponsor's statement that it will wait for the patent to expire before obtaining approval for its product. A "Paragraph IV" certification is a challenge to the patent; it is an assertion that the patent does not block approval of the later product, either because the patent is invalid or unenforceable or because the patent, even if valid, is not infringed by the new product. Once the FDA accepts for filing a generic application containing a Paragraph IV certification, the applicant must within 20 days provide notice to the reference listed drug, or RLD, NDA holder and patent owner that the application with patent challenge has been submitted, and provide the factual and legal basis for the applicant's assertion that the patent is invalid or not infringed. If the NDA holder or patent owner file suit against the generic applicant for patent infringement within 45 days of receiving the Paragraph IV notice, the FDA is prohibited from approving the generic application for a period of 30 months from the date of receipt

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of the notice. If the RLD has new chemical entity exclusivity and the notice is given and suit filed during the fifth year of exclusivity, the 30-month stay does not begin until five years after the RLD approval. The FDA may approve the proposed product before the expiration of the 30-month stay if a court finds the patent invalid or not infringed or if the court shortens the period because the parties have failed to cooperate in expediting the litigation. If a competitor or a generic pharmaceutical provider successfully challenges our patents, the protection provided by these patents could be reduced or eliminated and our ability to commercialize any approved drugs would be at risk. In addition, if a competitor or generic manufacturer were to receive approval to sell a generic or follow-on version of one of our products, our approved product would become subject to increased competition and our revenues for that product would be adversely affected.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The U.S. Patent Office is currently developing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act have only recently become effective, while others will not become effective until 18 months after its enactment. Accordingly, it is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

We also may rely on trade secrets and other unpatented confidential information to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We seek to protect our trade secrets and other confidential information by entering into confidentiality agreements with employees, collaborators, vendors (including CROs and our CSO), consultants and, at times, with potential investors. Nevertheless, employees, collaborators, vendors, consultants or potential investors may still disclose or misuse our trade secrets and other 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.

If we believe that others have infringed or misappropriated our proprietary rights, we may need to institute legal action to protect our intellectual property rights. Such legal action may be expensive, and we may not be able to afford the costs of enforcing or defending our intellectual property rights against others.

We may be sued for infringing the intellectual property rights of others, which could be costly and result in delays or termination of our future research, development, manufacturing and sales activities.

Our commercial success also depends, in part, upon our ability to develop future investigational drug candidates, market and sell approved drugs and conduct our other research, development and commercialization activities without infringing or misappropriating the patents and other proprietary rights of others. There are many patents and patent applications owned by others that could be relevant to our business. For example, there are numerous U.S. and foreign issued patents and pending patent applications owned by others that are related to the therapeutic areas in which we have approved drugs or future investigational drug candidates as well as the therapeutic targets to which these drugs and candidates are directed. There are also numerous issued patents and patent applications covering chemical compounds or synthetic processes that may be necessary or useful to use in our research, development, manufacturing or commercialization activities. Because patent

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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 approved drugs, future investigational drug candidates or technologies may infringe. There also may be existing patents, of which we are not aware, that our approved drugs, investigational drug candidates or technologies may infringe. Further, it is not always clear to industry participants, including us, which patents cover various types of products or methods. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. 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. If we are sued for patent infringement, we would need to demonstrate that our products or methods do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid or unenforceable, and we may not be able to do this.

There can be no assurance that approved drugs or future investigational drug candidates do not or will not infringe on the patents 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.

If a person or entity files a legal action or administrative action against us, or our collaborators, claiming that our drug discovery, development, manufacturing or commercialization activities infringes a patent owned by the person or entity, 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 any current or future approved drugs, 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 investigational drug candidates or be required to cease commercializing any affected current or future approved drugs and our operating results would be harmed.

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 may face additional competition outside of the U.S. as a result of a lack of patent coverage in some territories and differences in patent prosecution and enforcement laws in foreign counties.

Filing, prosecuting, defending and enforcing patents on all of our drug discovery technologies and all of our approved drugs and potential investigational drug candidates throughout the world would be prohibitively expensive. While we have filed patent applications in many countries outside the U.S., and have obtained some patent coverage for SPEDRA in certain foreign countries, we do not currently have widespread patent protection for these drugs outside the U.S. and have no protection in many foreign jurisdictions. 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 approved drugs or future investigational drug candidates and may not be covered by any of our patent claims or other intellectual property rights.

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

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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. 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. 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.

Attempting 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.

Our failure to successfully acquire, develop and market additional investigational drug candidates or approved drugs 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 drug 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 investigational drug candidates and products.

The process of proposing, negotiating and implementing a license or acquisition of an investigational drug 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 investigational drug 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 investigational drug 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, integration and maintenance 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 investigational drug 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 investigational drug candidates are prone to risks of failure typical of pharmaceutical investigational drug candidate development, including the possibility that an

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investigational drug candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any drugs that we develop or approved products that we may acquire will be commercialized profitably or achieve market acceptance.

Risks Relating to our Financial Position and Need for Financing

We may 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 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 through 2013. Should product sales and planned partnering activities be significantly less than internal expectations, we would need to raise additional capital to support operating activities through 2013 and beyond. However, we anticipate that we will be required to obtain additional financing to fund our commercialization efforts, additional clinical studies for approved products and the development of our research and development pipeline in future periods. Our future capital requirements will depend upon numerous factors, including:

- the cost required to maintain the certified home delivery pharmacy network and REMS program for Qsymia, including a substantial cost to expand into retail locations, if the amendment to our NDA requesting a modification of the REMS program for Qsymia is approved;
- our ability to successfully commercialize Qsymia in the U.S. on a timely basis;
- our ability to successfully commercialize through marketing partnerships for STENDRA in the U.S. and SPEDRA, if approved, in our territories outside the U.S.;
- the cost, timing and outcome of the post-approval clinical studies the FDA has required us to perform as part of the approval for STENDRA and Qsymia;
- the progress and costs of our research and development programs;
- the scope, timing, costs and results of pre-clinical, clinical and retrospective observational studies and trials;
- the cost of access to electronic records and databases that allow for retrospective observational studies;
- patient recruitment and enrollment in future clinical trials;
- the costs involved in seeking regulatory approvals for future drug 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 level of resources devoted to our future sales and marketing capabilities;

the cost, timing and outcome of litigation, if any;

the impact of healthcare reform, if any, imposed by the federal government; and

the activities of competitors.

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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.

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 drugs and/or investigational drug candidates at any time. We cannot assure you that our drugs will generate revenues sufficient to enable us to earn a profit. If we are unable to obtain additional capital, management may be required to explore alternatives to reduce cash used by operating activities, including the termination of research and development efforts that may appear to be promising to us, the sale of certain assets and the reduction in overall operating activities. 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. For example, in March 2012, we sold 9,000,000 shares of our common stock resulting in net proceeds to us of approximately $192.0 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. To raise additional capital, we may choose to issue additional securities at any time and at any price.

We may also raise additional capital through the incurrence of debt, and the holders of any debt we may issue would have rights superior to our stockholders' 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. Any future debt financing we enter into may involve similar or more onerous covenants that restrict our operations.

If we raise additional capital through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our drugs or future investigational drug 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 commercialization of one or more of our approved drugs or the development of one or more of our future investigational drug candidates.

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, 2012, we had $58.6 million in cash and cash equivalents and $156.0 million in available-for-sale securities. While at December 31, 2012, our excess cash balances were invested in money market and U.S. Treasury securities, our investment policy as approved by our Board of Directors, also provides for investments in debt securities of U.S. government agencies, corporate debt securities and asset-backed securities. Our 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. Although the U.S. Congress was able to resolve

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the debt ceiling issue in time to avoid default, the major credit rating agencies have expressed their ongoing concern about the high levels of debt that the U.S. government has taken on. Standard & Poor's announced that it had revised its outlook on the long-term credit rating of the U.S. to negative, which could affect the trading market for U.S. government securities. These factors could impact the liquidity or valuation of our available-for-sale securities, all of which were invested in U.S. treasury securities as of December 31, 2012. 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.

Our involvement in securities related class action litigation could divert our resources and 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 related 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 companies often experience significant stock price volatility in connection with their investigational drug candidate development programs, the review of marketing applications by regulatory authorities and the commercial launch of newly approved drugs. We are a defendant in federal and consolidated state shareholder derivative lawsuits. These securities related class action lawsuits generally allege that we and our officers misled the investing public regarding the safety and efficacy of Qsymia and the prospects for the FDA's approval of the Qsymia NDA as a treatment for obesity. Securities related class action litigation often is expensive and diverts management's attention and our financial resources, which could adversely affect our business. For example, following the Court's granting of our prior motion to dismiss with leave to amend, on September 27, 2012, the Honorable Phyllis J. Hamilton of the U.S. District Court for the Northern District of California granted, with prejudice, our motion to dismiss the putative class action lawsuit captioned *Kovtun v. Vivus, Inc., et al.*, Case No. 4:10-CV-04957-PJH. Despite the granting of the prior two motions to dismiss, on October 26, 2012, plaintiff filed a Notice of Appeal to the U.S. Court of Appeals for the Ninth Circuit, and on February 19, 2013 plaintiff filed his opening appellate brief. Briefing is expected to continue into April 2013.

We have an accumulated deficit of $486.1 million as of December 31, 2012, and we may continue to incur substantial operating losses for the future.

We have generated a cumulative net loss of $486.1 million for the period from our inception through December 31, 2012, 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 and other tax attributes to offset future taxable income may be limited.

As of December 31, 2012, we had approximately $424.7 million and $118.1 million of net operating loss, or NOL, carryforwards with which to offset our future taxable income for federal and state income tax reporting purposes, respectively. We used $121.2 million federal and $32.2 million state NOLs to offset our year ended December 31, 2007 federal and state taxable income, which included the $150.0 million in gain recognized from our sale of Evamist. Utilization of our net operating loss and tax

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credit carryforwards, or Tax Attributes, may be subject to substantial annual limitations provided by the Internal Revenue Code and similar state provisions to the extent certain ownership changes are deemed to occur. Such an annual limitation could result in the expiration of the Tax Attributes before utilization. The Tax Attributes reflected above have not been reduced by any limitations. To the extent it is determined upon completion of the analysis that such limitations do apply, we will adjust the Tax Attributes accordingly. We face the risk that our ability to use our Tax Attributes will be substantially restricted if we undergo an "ownership change" as defined in Section 382 of the U.S. Internal Revenue Code, or Section 382. An ownership change under Section 382 would occur if "5-percent shareholders," within the meaning of Section 382, collectively increased their ownership in the Company by more than fifty percentage points over a rolling three-year period. There can be no assurance that a Section 382 ownership change has not occurred or will not occur in the future.

We may have exposure to additional tax liabilities that could negatively impact our income tax provision, net income, and cash flow.

We are subject to income taxes and other taxes in both the U.S. and the foreign jurisdictions in which we currently operate or have historically operated. The determination of our worldwide provision for income taxes and current and deferred tax assets and liabilities requires judgment and estimation. In the ordinary course of our business, there are many transactions and calculations where the ultimate tax determination is uncertain. We are subject to regular review and audit by U.S. tax authorities as well as subject to the prospective and retrospective effects of changing tax regulations and legislation. Although we believe our tax estimates are reasonable, the ultimate tax outcome may materially differ from the tax amounts recorded in our consolidated financial statements and may materially affect our income tax provision, net income, or cash flows in the period or periods for which such determination and settlement is made.

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:

- our ability to meet the expectations of investors related to the commercialization of Qsymia and STENDRA;
- the costs, timing and outcome of post-approval clinical studies which the FDA has required us to perform as part of the approval for STENDRA and Qsymia;
- the cost required to maintain the certified home delivery pharmacy network and REMS program for Qsymia, including a substantial cost to expand into retail locations, if the amendment to our NDA requesting a modification of the REMS program is approved;
- results within the clinical trial programs for Qsymia and STENDRA or other results or decisions affecting the development of our investigational drug candidates;
- announcements of technological innovations or new products by us or our competitors;
- approval of or announcements of other anti-obesity compounds in development;
- publication of generic drug combination weight loss data by outside individuals or companies;
- actual or anticipated fluctuations in our financial results;
- our ability to obtain needed financing;

sales by insiders or major stockholders;

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economic conditions in the U.S. and abroad;

the volatility and liquidity of the financial markets;

comments by or changes in assessments of us or financial estimates by security analysts;

negative reports by the media or industry analysts on various aspects of our products, our performance and our future operations;

adverse regulatory actions or decisions;

any loss of key management;

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

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

investment activities employed by short sellers of our common stock;

developments or disputes concerning patents or other proprietary rights;

reports of prescription data by us or from independent third parties for our products;

licensing, product, patent or securities litigation; and

public concern as to the safety and efficacy of our drugs or future investigational drug candidates 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 related class action litigation is often brought against a company and senior officers following periods of volatility in the market price of its securities. We have been a defendant in shareholder lawsuits a securities class action against the Company and several senior officers has been dismissed with prejudice but plaintiff has filed an appeal and we could be the target of similar litigation in the future, particularly if we release news about the Company and its performance that proves to be disappointing to investors. Securities related litigation, whether with or without merit, could result in substantial costs and divert management's attention and financial 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.

Our operating results are unpredictable and may fluctuate. If our operating results are below the expectations of securities analysts or investors, the trading price of our stock could decline.

Our operating results will likely fluctuate from fiscal quarter to fiscal quarter, and from year to year, and are difficult to predict. Although we have commenced sales of Qsymia, we may never increase these sales or become profitable. In addition, we have not entered into a

marketing, sales or promotional arrangement with a pharmaceutical partner to commercialize STENDRA. Our operating expenses are largely independent of sales in any particular period. We believe that our quarterly and annual results of operations may be negatively affected by a variety of factors. These factors include, but are not limited to, the level of patient demand for Qsymia and STENDRA, the ability of our distribution partners to process and ship product on a timely basis, the success of our third-party's manufacturing efforts to meet customer demand, fluctuations in foreign exchange rates, investments in

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sales and marketing efforts to support the sales of Qsymia and STENDRA, investments in the research and development efforts, and expenditures we may incur to acquire additional products.

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.

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

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

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

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

In addition, we are governed by the provisions of Section 203 of Delaware General Corporate Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us. These and other provisions in our charter documents could reduce the price that investors might be willing to pay for shares of our common stock in the future and result in the market price being lower than it would be without these provisions.

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

None.

Item 2. ***Properties***

In November 2006, we entered into a 30-month lease for our corporate headquarters located in Mountain View, California, or Castro Lease. On February 14, 2012, we extended the lease term for the current premises for a period of twelve months commencing August 1, 2012 and terminating July 31, 2013. In addition, we have a lease on an additional 4,914 square feet of office space located at 1174 Castro Street, Mountain View, California, or the Expansion Space, which is adjacent to our current corporate headquarters. The lease for the Expansion Space has a term of 60 months

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commencing March 15, 2012, with an option to extend the term for one year from the expiration of the new lease.

We entered into a lease effective as of December 11, 2012 for new principal executive offices, consisting of an approximately 45,240 square foot building, located at 351 East Evelyn Avenue, Mountain View, California, or the Evelyn Lease. The Evelyn Lease has an initial term of approximately 84 months, commencing on the later of (i) May 1, 2013 and (ii) four months following delivery of the premises to us. We have one option to renew the Evelyn Lease for a term of three years at the prevailing market rate. We expect to occupy our new principal executive offices in the spring of 2013.

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

Item 3. ***Legal Proceedings***

Securities Related Class Action Lawsuits

The Company and two of its officers were defendants in a putative class action lawsuit captioned *Kovtun v. Vivus, Inc., et al.*, Case No. 4:10-CV-04957-PJH, in the U.S. District Court, Northern District of California. The action, filed in November 2010, alleged violations of Section 10(b) and 20(a) of the federal Securities Exchange Act of 1934 based on allegedly false or misleading statements made by the defendants in connection with the Company's clinical trials and NDA for Qsymia as a treatment for obesity. In the Amended Class Action Complaint filed on April 4, 2011, the plaintiff alleged generally that the defendants misled investors regarding the prospects for Qsymia's NDA approval, and the drug's efficacy and safety. On June 3, 2011, the defendants filed a motion to dismiss, which, after briefing and argument was granted but extending plaintiff leave to amend. On November 9, 2011, plaintiff filed his Second Amended Class Action Complaint, again generally alleging that the defendants misled investors regarding the prospects for Qsymia's NDA approval, and Qsymia's efficacy and safety. On December 30, 2011, defendants filed a motion to dismiss the Second Amended Complaint. Briefing concluded in late March 2012, and the motion was argued to the Court on April 18, 2012. On September 27, 2012, Judge Phyllis J. Hamilton granted defendants' motion to dismiss the Second Amended Complaint and dismissed the action with prejudice. She entered final judgment for defendants the same day. On October 26, 2012, plaintiff filed a Notice of Appeal to the U.S. Court of Appeals for the Ninth Circuit. Plaintiff filed his opening appellate brief on February 19, 2013. Briefing is expected to continue into April 2013.

Additionally, certain of the Company's officers and directors are defendants in a shareholder derivative lawsuit captioned *Turberg v. Logan, et al.*, Case No. CV-10-05271-PJH, pending in the same federal court. In the plaintiff's Verified Amended Shareholder Derivative Complaint filed June 3, 2011, the plaintiff largely restated the allegations of the *Kovtun* action and alleged that the directors breached fiduciary duties to the Company by purportedly permitting the Company to violate the federal securities laws as alleged in the *Kovtun* action. The parties had agreed to stay the litigation pending resolution of the defendants' second motion to dismiss in the *Kovtun* action, but have now extended that stay through resolution of the appeal. The same individuals are also named defendants in consolidated shareholder derivative suits pending in the California Superior Court, Santa Clara County under the caption *In re VIVUS, Inc. Derivative Litigation,* Master File No. 11 0 CV188439. The allegations in the state court derivative suits are substantially similar to the other lawsuits. The parties have agreed to stay these consolidated actions on the same terms as the federal derivative litigation.

The Company and its directors believe that the various shareholder lawsuits are without merit, and they intend to vigorously defend the various actions.

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Other Matters

In the normal course of business, the Company receives claims and makes inquiries regarding patent and trademark infringement and other related legal matters. The Company believes that it has meritorious claims and defenses and intends to pursue any such matters vigorously. Additionally, the Company in the normal course of business may become involved in lawsuits and subject to various claims from current and former employees including wrongful termination, sexual discrimination and employment matters. Employees may be more likely to file employment-related claims following termination of their employment. 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 it believes that an unfavorable resolution would have an adverse material impact on the operations or financial position of the Company.

Item 4. ***Mine Safety Disclosures.***

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 Select 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 Select Market.

	Three Months Ended			
	March 31	**June 30**	**September 30**	**December 31**
2012				
High	$ 25.14	$ 29.42	$ 31.21	$ 23.59
Low	9.76	21.12	17.21	9.89
2011				
High	$ 11.48	$ 9.07	$ 9.62	$ 10.80
Low	6.00	6.20	6.13	7.47

Stockholders

As of February 19, 2013, there were 100,660,029 shares of outstanding common stock that were held by 3,242 stockholders of record and no outstanding shares of preferred stock. On February 19, 2013, the last reported sales price of our common stock on the NASDAQ Global Select Market was $13.46 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.

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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, 2007 through December 31, 2012 compared with the NASDAQ Composite 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 Composite Index and 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.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*

Among VIVUS, Inc., the NASDAQ Composite Index, and the RDG SmallCap Pharmaceutical Index

*

$100 invested on 12/31/07 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				
	2012	**2011**	**2010**	**2009**	**2008**
Income Statement Data:					
Net product revenue	$ 2,012	$	$	$	$
License and other revenue				31,395	83,721
Total revenue	2,012			31,395	83,721
Operating expenses:					
Cost of goods sold	187				
Research and development	32,065	24,604	39,971	70,940	76,673
Selling, general and administrative	109,665	22,472	25,656	13,870	12,253
Total operating expenses	141,917	47,076	65,627	84,810	88,926
Loss from operations	(139,905)	(47,076)	(65,627)	(53,415)	(5,205)
Interest and other income (expense)					
Interest and other income	199	240	468	1,998	4,406
Interest expense			(4,308)	(3,693)	(659)
Other-than-temporary loss on impaired securities				(654)	(7,689)
Loss on early extinguishment of debt			(5,958)		
Total interest and other income (expense)	199	240	(9,798)	(2,349)	(3,942)
(Loss) income from continuing operations before income taxes	(139,706)	(46,836)	(75,425)	(55,764)	(9,147)
Benefit (provision) for income taxes	(27)	(190)	(9)	2,379	7
Net loss from continuing operations	(139,733)	(47,026)	(75,434)	(53,385)	(9,140)
Net income (loss) from discontinued operations, net of income taxes	(148)	886	9,369	(906)	(800)
Net loss	$ (139,881)	$ (46,140)	$ (66,065)	$ (54,291)	$ (9,940)
Basic and diluted net income (loss) per share:					
Continuing operations	$ (1.42)	$ (0.56)	$ (0.93)	$ (0.74)	$ (0.15)
Discontinued operations	$	$ 0.01	$ 0.11	$ (0.01)	$ (0.01)
Net loss per share	$ (1.42)	$ (0.55)	$ (0.82)	$ (0.75)	$ (0.16)
Shares used in per share computation:					
Basic and diluted	98,289	84,392	81,017	72,779	63,724
Balance Sheet Data (at year end):					
Working capital	$ 220,958	$ 140,764	$ 131,781	$ 200,852	$ 134,880

Total assets	$ 264,114	$ 152,056	$ 144,286	$ 230,032	$ 207,622
Long-term debt	$	$	$	$ 19,998	$ 11,177
Accumulated deficit	$ (486,146)	$ (346,265)	$ (300,125)	$ (234,060)	$ (179,769)
Stockholders' equity	$ 222,909	$ 141,084	$ 132,002	$ 186,726	$ 131,213

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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 may typically be identified by the use of forward-looking words or phrases such as "anticipate," "believe," "forecast," "estimate," "expect," "intend," "likely," "may," "plan," "potential," "predict," "opportunity" and "should," 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 limited commercial experience with Qsymia in the United States, or U.S.; (2) the timing of initiation and completion of the clinical studies required as part of the approval of Qsymia by the U. S. Food and Drug Administration, or FDA; (3) the response from the FDA to the data that VIVUS will submit relating to post-approval clinical studies; (4) the impact of the indicated uses and contraindications contained in the Qsymia label and the Risk Evaluation and Mitigation Strategy, or REMS, requirements; (5) the impact of distribution of Qsymia through a certified home delivery pharmacy network; (6) whether or not the FDA approves our amendment to the REMS for Qsymia, which, if approved, would allow dispensing through select certified retail pharmacies to increase access while meeting all requirements of the REMS; (7) that we may be required to provide further analysis of previously submitted clinical trial data; (8) the negative opinion of the European Medicines Agency's, or EMA, Committee for Medicinal Products for Human Use, or CHMP, for the Marketing Authorization Application, or MAA, for Qsymia; (9) our ability to successfully commercialize or establish a marketing partnership for avanafil, which will be marketed in the U.S. under the name STENDRA ; (10) the ability of our partners to maintain regulatory approvals to manufacture and adequately supply our products to meet demand; (11) our history of losses and variable quarterly results; (12) substantial competition; (13) risks related to the failure to protect our intellectual property and litigation in which we may become involved; (14) uncertainties of government or third-party payor reimbursement; (15) our reliance on sole source suppliers; (16) our limited sales and marketing and manufacturing experience; (17) our reliance on third parties and our collaborative partners; (18) our failure to continue to develop innovative investigational drug candidates and drugs; (19) risks related to the failure to obtain FDA or foreign authority clearances or approvals and noncompliance with FDA or foreign authority regulations; (20) our ability to demonstrate through clinical testing the safety and effectiveness of our investigational drug candidates; (21) the timing of initiation and completion of clinical trials and submissions to foreign authorities; (22) the results of post-marketing studies are not favorable; (23) compliance with post-marketing regulatory standards is not maintained; (24) the volatility and liquidity of the financial markets; (25) our liquidity and capital resources; (26) our expected future revenues, operations and expenditures and (27) 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, 2012 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.

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Overview

VIVUS is a biopharmaceutical company dedicated to commercializing and developing innovative therapies to address unmet needs in obesity, sleep apnea, diabetes and sexual health. Our drug, Qsymia (phentermine and topiramate extended-release) (formerly known as Qnexa®) was approved by the FDA for the treatment of obesity as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index, or BMI, of 30 or greater (obese), or 27 or greater (overweight) in the presence of at least one weight-related comorbidity, such as hypertension, type 2 diabetes mellitus or high cholesterol (dyslipidemia). Qsymia incorporates low doses of active ingredients from two previously approved drugs, phentermine and topiramate. Qsymia is believed to target excessive appetite and a high threshold for satiety, or the feeling of being full, the two main mechanisms that impact eating behavior. We announced the U.S. market availability of Qsymia for obesity in September 2012. On February 21, 2013, the CHMP confirmed its October 18, 2012 decision to deny the MAA for Qsiva (phentermine/topiramate extended-release) for the treatment of obesity in the European Union, or EU. We have completed Phase 2 clinical studies for Qsymia for the treatment of sleep apnea and Qsymia for the treatment of type 2 diabetes.

Our drug, STENDRA, or avanafil, was approved by the FDA for the treatment of erectile dysfunction, or ED, in the U.S. We, through collaboration arrangements with third parties, intend to market and sell STENDRA in the U.S., and if approved, under the trade name SPEDRA in the EU and other territories outside the U.S.

Our Strategy

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

- successfully commercializing Qsymia in the U.S.;
- entering into and supporting a collaboration agreement for the commercialization of STENDRA for the treatment of ED in the U.S.;
- obtaining regulatory approval for SPEDRA for the treatment of ED in the EU and other territories worldwide; and
- if approved, entering into and supporting collaboration agreements for the commercialization of SPEDRA for the treatment of ED in the EU and other territories worldwide.

It is our objective to become a leader in the development and commercialization of drugs 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 drug candidates for indications that we have studied, or plan to study, as well as in-licensing and product line extensions.

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 U.S. 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, research and development expenses, income taxes, inventories, contingencies and litigation and share-based compensation. We base our estimates on historical experience, information received from third parties and on various other

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assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

Revenue Recognition

We recognize revenue from the sale of Qsymia when: (i) persuasive evidence that an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured. Revenue from sales transactions where the customer has the right to return the product is recognized at the time of sale only if: (i) our price to the customer is substantially fixed or determinable at the date of sale, (ii) the customer has paid us, or the customer is obligated to pay us and the obligation is not contingent on resale of the product, (iii) the customer's obligation to us would not be changed in the event of theft or physical destruction or damage of the product, (iv) the customer acquiring the product for resale has economic substance apart from that provided by us, (v) we do not have significant obligations for future performance to directly bring about resale of the product by the customer, and (vi) the amount of future returns can be reasonably estimated.

Net Product Revenue and Product Revenue Allowances

Product revenue is recognized net of cash consideration paid to our customers, the certified pharmacies, for services rendered by the pharmacies in accordance with certified pharmacy services network agreements, and include a fixed rate per prescription shipped and monthly program management and data fees. These services are not deemed sufficiently separable from the customers' purchase of the product; therefore, they are recorded as a reduction of revenue at the time of revenue recognition.

Other reductions of revenue include certain prompt pay discounts and allowances offered our customers which are recognized as a reduction of revenue at the later of the date at which the related revenue is recognized or the date at which the allowance is offered.

Calculating certain of these items involves estimates and judgments based on sales or invoice data and historical experience. Amounts accrued for sales deductions are adjusted when trends, significant events, or actual results indicate that adjustment is appropriate. Revisions of estimates for sales deductions are charged to income in the period in which the information that gives rise to the revision becomes known.

Qsymia was approved by the FDA in July 2012. We sell Qsymia product in the U.S. only to select certified pharmacies through their home delivery pharmacy services networks, which are collectively, our customers. Under this arrangement, title and risk of loss transfer to our customers upon delivery of the product to their distribution facilities. They in turn, sell, dispense and ship directly to patients through their home delivery service.

We shipped initial orders of Qsymia to our customers in September 2012 and announced the availability of the product on September 17, 2012. Qsymia has a 24-month shelf life and we grant rights to our customers to return unsold product three months prior to and up to twelve months after product expiration and issue credits which may be applied against existing or future invoices. Given our limited history of selling Qsymia and the lengthy return period, we have not been able to reliably estimate expected returns of Qsymia at the time of shipment, and therefore we recognize revenue when units are shipped to patients through prescriptions, at which point, the product is not subject to return. We

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obtain the prescription shipment data directly from the pharmacies to determine the amount of revenue to recognize.

We will continue to recognize revenue for Qsymia based upon prescription sell-through until we have sufficient historical information to reliably estimate returns. As of December 31, 2012, we have recorded deferred revenue of $1.2 million related to shipments of Qsymia, which represents product shipped to our customers, but not yet shipped to patients through prescriptions. A corresponding accounts receivable is also recorded for this amount, as the payments from customers are not contingent upon the sale of product to patients.

Inventories and Related Reserves

Inventories are valued at the lower of cost or market. Cost is determined using the first-in, first-out method for all inventories, which are valued using a weighted average cost method calculated for each production batch. Inventory includes the cost of active pharmaceutical ingredients, or APIs, raw materials and third-party contract manufacturing and packaging services. Indirect overhead costs associated with production and distribution are allocated to the appropriate cost pool and then absorbed into inventory based on the units produced or distributed, assuming normal capacity, in the applicable period.

Inventory costs of product shipped to customers, but not yet shipped to patients through prescriptions, are recorded as deferred costs within inventories on the consolidated balance sheets and are subsequently recognized to cost of goods sold when shipped to patients through prescriptions.

Our policy is to write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected requirements. The estimate of excess quantities is subjective and primarily dependent on our estimates of future demand for a particular product. If the estimate of future demand is inaccurate based on actual sales, we may adjust the reserve for excess inventory for that product and record a charge to cost of goods sold.

Research and Development Expenses

Research and development, or R&D, expenses include license fees, related compensation, consultants' fees, facilities costs, accrued milestones, administrative expenses related to R&D activities and clinical trial costs incurred by clinical research organizations, or CROs, 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 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.

In addition, the Company has obtained rights to patented intellectual properties under several licensing agreements for use in research and development activities. Non-refundable licensing payments made for intellectual properties that have no alternative future use are expensed to research and development as incurred.

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Share-Based Payments

We follow the fair value method of accounting for share-based compensation arrangements in accordance with in the Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, topic 718, *Compensation Stock Compensation,* or ASC 718. Under ASC 718, the estimated fair value of share-based compensation, including stock options and restricted stock units granted under our stock option plans and purchases of common stock by employees at a discount to market price under our 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 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 share-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 our share-based payments, see Note 8: "Stock Option and Purchase Plans" to the consolidated financial statements included in this Form 10-K.

Share-based compensation expense is allocated among cost of goods sold, research and development and selling, general and administrative expenses, or included in the inventory carrying value and absorbed into inventory, based on the function of the related employee. As of December 31, 2012, unrecognized estimated compensation expense totaled $569,000 related to non-vested restricted stock units, $19.9 million related to non-vested stock options and $123,000 related to the ESPP. The weighted average remaining requisite service period of the non-vested restricted stock units was 2.1 years, of the non-vested stock options was 1.2 years and of the ESPP was 4.5 months.

Fair Value Measurements

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. ASC 820 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. ASC 820 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

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information available in the circumstances. ASC 820 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.

As of December 31, 2012, our cash and cash equivalents and available-for-sale securities measured at fair value on a recurring basis totaled $214.6 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, 2012, 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.

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, 2012, it was considered more likely than not that our 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.

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.

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RESULTS OF OPERATIONS

For the year ended December 31, 2012, we reported a net loss of $139.9 million, or $1.42 net loss per share as compared to a net loss of $46.1 million, or $0.55 net loss per share during the same period in 2011. The increase in net loss is primarily attributable to increased selling, general and administrative expenses related to commercialization and pre-commercialization activities for Qsymia.

We may have continued losses in future periods, depending on our success in commercializing Qsymia and STENDRA, the timing of our research and development expenditures, and our continued investment in the clinical development of our current research and investigational drug candidates, to bring those potential drugs to market.

Continuing operations

Net product revenue

Net product revenue was $2.0 million for the year ended December 31, 2012. We had no net product revenue from continuing operations for the year ended December 31, 2011 or 2010.

The following table reconciles gross revenue to net revenue for the year ended December 31, 2012 (in thousands):

Gross product revenue	$ 2,642
Pharmacy fees	(577)
Cash discounts	(53)
Net product revenue	$ 2,012

Pharmacy fees are based on information provided by the pharmacies and include fixed monthly management and data fees and fees incurred per prescription order shipped to patients by the pharmacies. Cash discounts for prompt payment are based on 2% of gross product revenue. We did not have any other typical gross to net items such as rebates, chargebacks or similar items for the year ended December 31, 2012 but we expect such items to be part of our net sales in the future.

On September 17, 2012, we announced the commercial availability of Qsymia in the U.S. In September 2012, we began distributing Qsymia to two of the certified home delivery pharmacies, and later in 2012, we added three more certified home delivery pharmacies to the network. We currently recognize revenue for the sales of Qsymia when the prescriptions are shipped to the patients by the pharmacies because we do not have sufficient historical information to reliably estimate returns.

At December 31, 2012, we have deferred revenue of $1.2 million, which represents Qsymia product shipped to customers but not yet shipped to patients through prescriptions, net of prompt payment discounts.

We expect Qsymia product revenue and prescriptions shipped to patients to increase in 2013 as we continue to introduce Qsymia to healthcare professionals. In addition, we have submitted a request to the FDA to modify our REMS program to include access to select certified retail pharmacies. If approved, we would be permitted to expand our distribution network which is currently limited to the certified pharmacies' home delivery networks.

Cost of goods sold

Cost of goods sold is $187,000 for the year ended December 31, 2012 and relates to our product shipments of Qsymia to patients and includes the inventory costs of APIs, third-party contract manufacturing and packaging and distribution costs, royalties, cargo insurance, freight, shipping, handling and storage costs, and overhead costs of the employees involved with production. The cost of

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goods sold associated with deferred revenue on Qsymia product shipments is recorded as deferred costs, which are included in inventories in the consolidated balance sheets, until such time as the deferred revenue is recognized.

Research and development

Drug Indication/Description	Years Ended December 31, 2012	2011	2010	% Change Increase/(Decrease) 2012 vs 2011	2011 vs 2010
	(In thousands, except percentages)				
Qsymia for obesity	$ 10,729	$ 5,762	$ 14,854	86%	(61)%
STENDRA for ED	8,601	9,467	16,968	(9)%	(44)%
Other projects	1,662	1,414	851	18%	66%
Share-based compensation	3,487	1,917	1,204	82%	59%
Overhead costs*	7,586	6,044	6,094	26%	(1)%
Total research and development expenses	$ 32,065	$ 24,604	$ 39,971	30%	(38)%

*

Overhead costs include compensation and related expenses, consulting, legal and other professional services fees relating to research and development activities, which we do not allocate to specific projects.

The increase in research and development expenses for the year ended December 31, 2012, as compared to the year ended December 31, 2011, is primarily due to start-up costs associated with the post-approval studies for Qsymia and STENDRA, partially offset by a decrease in STENDRA program costs due to the filing of the NDA in June 2011.

We anticipate that our research and development expenses in 2013 will increase significantly as compared to 2012 as we begin the post-approval cardiovascular outcomes study for Qsymia, known as ACQLAIM. The details of ACQLAIM have not yet been agreed upon with the FDA. This study could cost between $150.0 and $250.0 million and take as long as five years to complete. Enrollment is expected to begin in the fourth quarter of 2013. There are likely to be additional research and development expenses for other post-approval studies related to STENDRA and Qsymia, and for our investigational drug candidates 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.

The decrease in research and development expenses in the year ended December 31, 2011, as compared to the year ended December 31, 2010, was primarily due to the completion of the Phase 3 development programs for Qsymia and STENDRA.

Selling, general and administrative

	Years Ended December 31, 2012	2011	2010	% Change Increase/(Decrease) 2012 vs 2011	2011 vs 2010
	(In thousands, except percentages)				
Selling, general and administrative	$ 109,665	$ 22,472	$ 25,656	388%	(12)%

In the year ended December 31, 2012, the increase in selling, general and administrative expenses includes $44.7 million of increased spending primarily due to Qsymia pre-commercialization and commercialization activities (primarily related to marketing programs, market research and analytics and additional headcount), sales expenses of $17.0 million primarily related to our contract sales

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organization, which provides 150 fully dedicated sales personnel for promoting Qsymia in the U.S., medical affairs-related expenses of $8.4 million (primarily expenses related to CME grants, the Qsymia REMS program and additional headcount), increased corporate expenses of $10.1 million (primarily compensation and related expenses and professional fees), and increased share-based compensation expense of $7.0 million, as compared to the year ended December 31, 2011.

We anticipate our selling, general and administrative expenses to be significantly higher in 2013 as compared to 2012, primarily due to the additional efforts involved in the commercialization and marketing activities for Qsymia, which may include further spending for healthcare provider and patient education and awareness programs and direct-to-patient and direct-to-consumer advertising.

General and administrative expenses in the year ended December 31, 2011 decreased $3.2 million, or 12% to $22.5 million as compared to the same period in 2010. In the year ended December 31, 2011, the decrease is primarily due to lower spending on Qsymia pre-commercialization expenses of $4.9 million, partially offset by incremental increases of $0.8 million in corporate expenses (primarily compensation and related increases), $0.7 million in STENDRA pre-commercialization expenses and net increases in other general and administrative expense of $0.2 million as compared to the year ended December 31, 2010.

Interest income and expense

Interest and other income, net in the year ended December 31, 2012 was $199,000 as compared to $240,000 in the year ended December 31, 2011. Although our cash balances were higher in 2012 than in 2011, interest and other income decreased in the year ended December 31, 2012 as compared to the same period last year largely due to lower interest rates, year-over-year, on our cash, cash equivalents and available-for-sale securities and $100,000 in other income recognized in the year ended December 31, 2011.

Interest and other income, net for the year ended December 31, 2011 was $240,000 as compared to $468,000 for the year ended December 31, 2010. The decrease in interest and other income in the year ended December 31, 2011 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 partially offset by an increase in other income of $100,000 in the year ended December 31, 2011.

Interest expense for the year ended December 31, 2010 was $4.3 million. The outstanding balance on the Deerfield loan was paid off in the fourth quarter of 2010.

In addition, we recognized a $6.0 million loss on the early extinguishment of debt in connection with the payoff of the Deerfield loan in the year ended December 31, 2010.

Benefit (provision) for income taxes

We recorded a provision for income taxes in the year ended December 31, 2012 of $27,000, as compared to $190,000 in the year ended December 31, 2011. Our income tax return for the year ended December 31, 2007 is currently under examination by the California Franchise Tax Board, or FTB. Based on the progress of the audit to date, adjustments may be made in earlier years that will reduce tax attributes available to offset tax due in 2007. We recognize interest and penalties accrued on any unrecognized tax benefits as a component of our provision for income taxes. During the year ended December 31, 2012, $6,000 of interest on the unrecognized tax benefits was recorded.

In the year ended December 31, 2011, we recorded a provision for income taxes of $190,000. We increased our unrecognized tax benefits to $160,000 for the year ended December 31, 2011, based on the progress of the California Franchise Tax Board audit. During the year ended December 31, 2011, $32,000 of interest on the unrecognized tax benefits was recorded.

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In the year ended December 31, 2010, we recorded a provision for income taxes of $9,000. We increased our unrecognized tax benefits to $7,000 for the year ended December 31, 2010, based on the progress of the California Franchise Tax Board audit. During the year ended December 31, 2010, $1,000 of interest on the unrecognized tax benefits was recorded.

On January 2, 2013, the "American Taxpayer Relief Act of 2012" was signed into law. It provides for an extension of the federal research credit retroactive for 2012 and extended through 2013. The impact of the 2012 federal research credit will be reflected in our effective tax rate in the first quarter of 2013 and is estimated to be between $1.0 million - $2.0 million.

Discontinued operations

On November 5, 2010, we completed the sale of the MUSE product to Meda AB. In the years ended December 31, 2012 and 2011, we recorded some minor adjustments related to the MUSE disposition.

Total revenue for the year ended December 31, 2010 was $13.3 million. In the year ended December 31, 2010, cost of goods sold was $9.8 million, research and development expenses were $2.3 million and selling, general and administrative expenses were $5.1 million. In addition, we recognized a $13.7 million gain on the disposal of discontinued operations in the fourth quarter of 2010.

Liquidity and Capital Resources

Continuing Operations

Cash. Unrestricted cash, cash equivalents and available-for-sale securities totaled $214.6 million at December 31, 2012, as compared to $146.8 million at December 31, 2011. The increase in cash, cash equivalents and available-for-sale securities of $67.8 million is primarily the net result of cash provided by financing activities and cash used for investing and operating activities. Included in this increase are $192.0 million in net proceeds from an underwritten public offering of our common stock and $13.6 million in net proceeds from common stock option exercises and ESPP purchases during the year ended December 31, 2012.

Since inception, we have financed operations primarily from the issuance of equity securities. Through December 31, 2012, we have raised $661.0 million from financing activities, received $150.0 million from the sale of Evamist and had an accumulated deficit of $486.1 million at December 31, 2012.

At December 31, 2012, we had $58.6 million in cash and cash equivalents and $156.0 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, 2012, 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 stockholders' equity.

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Accounts Receivable. 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. We offer cash discounts to our customers, generally 2% of the sales price as an incentive for prompt payment.

Accounts receivable (net of allowance for cash discounts) at December 31, 2012 was $2.8 million, as compared to none at December 31, 2011. Currently, we do not have any significant concerns related to accounts receivable or collections. As of February 19, 2013, we had collected 70% of the accounts receivable outstanding at December 31, 2012.

Revenues from significant customers as a percentage of total revenues for the year ended December 31, 2012 is as follows:

CVS	50%
Walgreens	39%
Express Scripts, Inc.	10%

Liabilities. Total liabilities were $41.2 million at December 31, 2012, which is $30.2 million higher than at December 31, 2011. The change in total liabilities is primarily due to increased commercialization activities related to Qsymia and the timing of payments.

Operating Activities. Our operating activities used $132.2 million, $36.9 million and $64.1 million during the years ended December 31, 2012, 2011 and 2010, respectively.

During the year ended December 31, 2012, our net operating loss of $139.7 million was offset by $15.9 million in share-based compensation expense due to increased headcount and a $22.2 million net increase in accounts payable, primarily due to an increase in marketing and sales activities and startup costs for the post-approval STENDRA and Qsymia clinical trials. The increase in accounts payable was offset by a $17.7 million net increase in prepaid expenses and other assets, which primarily was comprised of prepayments related to Qsymia product liability insurance, manufacturing commitment fees, medical affairs activities for Qsymia, and prepaid product commercialization costs for sales and marketing activities in support of the commercial launch of Qsymia in the U.S. These prepayments represent probable future economic benefits obtained or controlled by us as a result of past transactions or events, which meet the definition of an asset under the FASB Concept Statement 6. As such, the costs have been deferred as prepaid expenses on the consolidated balance sheets and will be charged to expense accordingly when the related prepaid services are rendered to us. In addition, there was a net $22.1 million increase in inventories, primarily for Qsymia and pre-launch inventory for STENDRA.

During the year ended December 31, 2011, our net operating loss of $47.0 million was offset by $7.4 million in share-based compensation expense, a $0.9 million increase in accrued employee compensation and benefits and a $0.5 million increase in accounts payable. These positive cash flows to our net operating loss were in turn offset by a $1.2 million decrease in accrued research and clinical expenses.

During the year ended December 31, 2010, our net operating loss of $75.4 million was offset by $6.4 million in share-based compensation expense, $6.0 million in loss on early extinguishment of the Deerfield loan, a $2.7 million decrease in prepaid expenses and other assets, and $2.2 million in cash provided by discontinued operations. These positive cash flows to our net operating loss were in turn offset by a $3.2 million increase in inventories due to the purchase of Qsymia raw material inventory and a $5.7 million decrease in accounts payable.

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Investing Activities. Our investing activities used $54.3 million and $8.6 million and provided $84.8 million in cash during the years ended December 31, 2012, 2011 and 2010, respectively. The fluctuations from period to period are due primarily to the timing of purchases, sales and maturity of investment securities. In the year ended December 31, 2010, cash provided by investing activities for discontinued operations included $21.6 million in cash proceeds from the sale of MUSE to Meda.

Financing Activities. Financing activities provided cash of $205.6 million and $47.8 million and used cash of $24.0 million during the years ended December 31, 2012, 2011 and 2010, respectively. In the year ended December 31, 2012, cash provided by financing activities included $192.0 million in net proceeds from an underwritten public offering of our common stock. In the year ended December 31, 2011, cash provided by financing activities included $45.3 million in net proceeds from a registered direct offering of our common stock. In 2010, cash used in financing activities included $23.0 million to pay off the Deerfield loan and $4.9 million in discontinued operations to pay off the loan to Crown Bank.

Financing Activities

On March 6, 2012, we closed the underwritten public offering and sale of 9,000,000 shares of the Company's common stock. Gross proceeds to us from this sale totaled approximately $202.5 million before deduction of approximately $10.5 million in underwriting discounts and commissions and offering expenses. All of the shares of common stock were offered pursuant to the Company's effective shelf registration statement on Form S-3 (Registration No. 333-161948), including the prospectus dated September 16, 2009 (as amended on February 28, 2012) contained therein, as the same has been supplemented.

On August 24, 2011, we closed on the sale of a total of 6,889,098 shares of the Company's common stock, at a price of $6.65 per share, pursuant to a previously-reported securities purchase agreement entered into on August 23, 2011 with certain investors in connection with a registered direct offering of our common stock, or the Offering. Gross proceeds to us from the sale of the common stock in the Offering totaled approximately $45.8 million before deduction of approximately $529,000 in fees and expenses related to the Offering. All of the shares of common stock were offered pursuant to an effective shelf registration statement on Form S-3ASR (Registration No. 333-161948), including the prospectus dated September 16, 2009 contained therein.

On August 1, 2011, we filed a Form S-8 (File Number 333-175926) with the SEC registering 600,000 shares of common stock, par value $0.001 per share, under the 1994 Employee Stock Purchase Plan, as amended.

On July 14, 2010, we filed a Form S-8 (File Number 333-168106) with the SEC registering 16,615,199 shares of common stock, par value $0.001 per share, to be issued pursuant to the 2010 Equity Incentive Plan, and registering 400,000 shares of common stock, par value $0.001 per share, to be issued pursuant to the Stand-Alone Stock Option Agreement with Michael P. Miller, the Company's Senior Vice President and Chief Commercial Officer.

On February 16, 2010, we filed a Form S-8 (File Number 333-164921) 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. The funding necessary to execute our business strategies is subject to numerous uncertainties, which may adversely affect our liquidity and capital resources. Commercialization of Qsymia and STENDRA may be more costly than we planned. In addition, completion of clinical trials and approval by the FDA of investigational drug candidates 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 drug candidate. It is also important to note that if an investigational drug candidate is identified, the further development of that candidate can be halted or abandoned at any time due to a

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number of factors. These factors include, but are not limited to, funding constraints, lack of efficacy or safety or change in market demand.

We anticipate that our existing capital resources combined with anticipated future cash flows will be sufficient to support our operating needs at least through 2013. Should product sales and planned partnering activities be significantly less than internal expectations, we would need to raise additional capital to support operating activities through 2013 and beyond. We anticipate that we may require additional funding to continue our commercialization of Qsymia, to conduct post-approval clinical studies for both Qsymia and STENDRA, to conduct non-clinical and clinical research and development work to support regulatory submissions and applications for our current and future investigational drug candidates, to finance the costs involved in filing and prosecuting patent applications and enforcing or defending our patent claims, if any, to fund operating expenses, to establish additional or new manufacturing and marketing capabilities, to manufacture quantities of our drugs and investigational drug candidates and to make payments under our existing license agreements for Qsymia and STENDRA.

While some of our anticipated costs are unknown at the current time, we may need to raise additional capital to continue the funding of our commercialization efforts, product development programs and our research and development plans in future periods beyond 2013. If we require additional capital, we may seek any required additional funding through collaborations, public and private equity or debt financings, capital lease transactions or other available financing sources. Additional financing may not be available on acceptable terms, or at all. If additional funds are raised by issuing equity securities, substantial dilution to existing stockholders may result. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our commercialization or development programs or obtain funds through collaborations with others that are on unfavorable terms or that may require us to relinquish rights to certain of our technologies, product candidates or products that we would otherwise seek to develop on our own.

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2012, excluding amounts already recorded on our consolidated balance sheet as accounts payable or accrued liabilities, and the effect such obligations are expected to have on our liquidity and cash flow in future fiscal years. This table includes our enforceable, non-cancelable, and legally binding obligations and future commitments as of December 31, 2012. The amounts below do not include contingent milestone payments or royalties, and assume the agreements and commitments will run through the end of terms, as such no early termination fees or penalties are included herein:

		Payments Due by Period			
Contractual obligations	**Total**	**2013**	**2014 - 2016**	**2017 - 2018**	**Thereafter**
			(in thousands)		
Operating leases	$ 13,525	$ 1,639	$ 5,529	$ 3,780	$ 2,577
Purchase obligations:					
Manufacturing agreements	48,629	48,318	311		
Other agreements	51,455	34,252	17,203		
Total contractual obligations	$ 113,609	$ 84,209	$ 23,043	$ 3,780	$ 2,577

Operating Leases

In November 2006, we entered into a 30-month lease for our corporate headquarters located in Mountain View, California, or Castro Lease. On February 14, 2012, we entered into the most current, fourth amendment, to the Castro Lease. Under the fourth amendment to the Castro Lease, the average

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base rent for the current premises is set at $2.50 per square foot or $45,015 per month. The fourth amendment also extended the lease term for the current premises for a period of twelve months commencing August 1, 2012 and terminating July 31, 2013. In addition, the fourth amendment included a lease on an additional 4,914 square feet of office space located at 1174 Castro Street, Mountain View, California, or the Expansion Space, which is adjacent to our current corporate headquarters. The average base rent for the Expansion Space is approximately $2.75 per square foot or $13,513 per month. The lease for the Expansion Space has a term of 60 months commencing March 15, 2012, with an option to extend the term for one year from the expiration of the new lease.

We entered into a lease effective as of December 11, 2012 with SFERS Real Estate Corp. U, or the Landlord, for new principal executive offices, consisting of an approximately 45,240 square foot building, located at 351 East Evelyn Avenue, Mountain View, California, or the Evelyn Lease. The Evelyn Lease has an initial term of approximately 84 months, commencing on the later of (i) May 1, 2013 and (ii) four months following delivery of the premises, and at a starting annual rental rate of $31.20 per rentable square foot (subject to agreed increases). We will be entitled to an abatement of the monthly installments of rent for months seven through twelve of the initial term subject to the conditions detailed in the Evelyn Lease. We have one option to renew the Evelyn Lease for a term of three years at the prevailing market rate as detailed in the Evelyn Lease. In addition, we have a one-time right to accelerate the termination date of the Evelyn Lease from the expiration of the 84th full calendar month of the term to the expiration of the 60th full calendar month of the term subject to the conditions detailed in the Evelyn Lease. If this acceleration of the termination date is exercised, the following will be payable to the Landlord: (i) six months of the monthly installments of rent and our proportionate share of expenses and taxes subject to the fifth lease year and (ii) the unamortized portion of all of the leasing commissions and legal fees, the initial alterations, and the Landlord's allowance towards the cost of performing the initial alterations. We expect to occupy our new principal executive offices in the spring of 2013.

Purchase Obligations

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 product manufacturing, sales and marketing services, including for our contract sales organization, and research and development.

Manufacturing agreements

We have purchase commitments for raw material supplies for Qsymia totaling $26.6 million at December 31, 2012. In addition, in July 2012, we entered into a manufacturing agreement with Catalent Pharma Solutions, LLC, or Catalent, to supply commercial inventory for Qsymia beginning in 2012 and ending in 2016. Our remaining commitment under this agreement is to pay Catalent a minimum total of $12.5 million for the production of Qsymia in 2013. The API and the tablets for STENDRA (avanafil) are currently manufactured by MTPC. There are no minimum purchase obligations for STENDRA under our agreements with MTPC. We have placed orders with MTPC for avanafil product testing and finished goods and our remaining commitment under these purchase obligations at December 31, 2012 totaled $9.5 million.

Other agreements

On May 22, 2012, we entered into a Dedicated Sales Team Agreement, or the Sales Team Agreement, with PDI, Inc., or PDI, to provide us with promotional and commercialization support services for Qsymia. The Sales Team Agreement is effective beginning on July 30, 2012 and ending on July 29, 2014. We have the option to extend the term of the agreement for two consecutive

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twelve-month periods. Under the terms of the Sales Team Agreement, PDI provides us with 150 full-time sales representatives, three full-time field liaison managers, and one full-time account manager. In addition, under the Sales Team Agreement, PDI provides us with program personnel to collect and capture physician information, including physician target call plan reach and frequency, deactivation information related to physician accounts and physician's behavioral or attitudinal response. As of December 31, 2012, our total obligation under the Sales Team Agreement is $44.2 million, including primarily compensation costs and administrative service fees. In addition, we have remaining commitments under other various sales and marketing services and research and development agreements totaling $7.3 million at December 31, 2012.

Additional Contingent 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 clinical trial and commercial supply agreement with Tanabe Seiyaku Co., Ltd., or Tanabe, now MTPC, and hereinafter collectively 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 was our primary responsibility. The MTPC agreement contains a number of milestone payments to be made by VIVUS based on various triggering events. Through December 31, 2012, under the terms of the MTPC agreement, we have paid a total of $13.0 million to MTPC, including a $3.0 million milestone payment made in June 2012, upon FDA approval of STENDRA, or avanafil. In addition, during 2012, we purchased from MTPC $7.4 million of inventory under the supply portion of the Agreement in preparation for the commercial launch of STENDRA in the U.S. and certain other territories that use the U.S. approval.

We expect to make other substantial payments to MTPC in accordance with this agreement as we continue to develop avanafil in our territories outside of the United States and, if approved for sale, commercialize avanafil for the oral treatment of male sexual dysfunction in those territories. Potential future milestone payments include $2.0 million upon the obtainment of the first regulatory approval in any major European country and $6.0 million upon achievement of $250.0 million or more in worldwide net sales during any calendar year.

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) 10 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.

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In August 2012, we entered into an amendment to the MTPC agreement which, among other matters, allows us to manufacture the API and STENDRA tablets for avanafil and expands our rights to develop and commercialize avanafil for all indications. The amendment permits us to manufacture the API and STENDRA tablets for avanafil ourselves or through a third-party supplier at any time; however, the transition away from MTPC supply will need to occur on or before June 2015. On February 21, 2013, we entered into the third amendment to our agreement with MTPC which, among other things, expands our rights, or those of our sublicensees, to enforce the patents licensed under the MTPC agreement against alleged infringement, and clarifies the rights and duties of the parties and our sublicensees upon termination of the MTPC agreement. In addition, we are obligated to use our best commercial efforts to market STENDRA in the U.S. by December 31, 2013.

Other

In October 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 drug candidate development program for Qsymia for the treatment of obesity, obstructive sleep apnea and diabetes. The Combination Therapy and all related patent applications, or the Patents, were transferred to VIVUS with worldwide rights to develop and commercialize the Combination Therapy and exploit the Patents. Pursuant to the Assignment Agreement, through December 31, 2012, we have paid a total of $1.2 million and have issued fully vested and exercisable options to purchase 60,000 shares of VIVUS' common stock to Dr. Najarian. In addition, the Assignment Agreement 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 the Company 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 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 with Meda to sell certain of the assets related to the MUSE business to Meda, the Company agreed to indemnify Meda in connection with the representations and warranties that it made concerning its rights, liabilities and assets related to the MUSE business and its authority to enter into and consummate the MUSE Transaction. The Company also made certain covenants in the Asset Purchase Agreement which survive the closing of the MUSE Transaction, including a three year covenant not to develop, manufacture, promote or commercialize a trans-urethral erectile dysfunction drug. See Note 13: "Discontinued Operations" for additional information.

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On May 15, 2007, the Company closed its transaction with K-V Pharmaceutical Company, or K-V, for the sale of its investigational drug candidate, Evamist. At the time of the sale, Evamist was an investigational drug candidate and was not yet approved by the FDA for marketing. Pursuant to the terms of the Asset Purchase Agreement for the sale of Evamist, 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 U.S. and its territories and protectorates, with the Evamist product.

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.

Recent Accounting Pronouncements

There have been no recent accounting pronouncements or changes in accounting pronouncements during the year ended December 31, 2012 that are of significance, or potential significance to the Company.

Dividend Policy

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

Cautionary Note on Forward-Looking Statements

Our business is subject to significant risks, including but not limited to, the risks inherent in our research and development activities, including the successful completion of clinical trials, the lengthy, expensive and uncertain process of seeking regulatory approvals, uncertainties associated both with the potential infringement of patents and other intellectual property rights of third parties, and with obtaining and enforcing our own patents and patent rights, uncertainties regarding government reforms and of product pricing and reimbursement levels, technological change, competition, manufacturing uncertainties and dependence on third parties. Even if our investigational drug 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 drug 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

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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, 2012 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 would reduce the fair value of our available-for-sale securities at December 31, 2012 by approximately $453,000. In general, money market funds are not subject to market risk because the interest paid on such funds fluctuates with the prevailing interest rate.

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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, 2012 and 2011, and the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2012. 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, 2012 and 2011 , and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, 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.

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, 2012, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 26, 2013 expressed an unqualified opinion thereon.

/s/ OUM & Co. LLP

San Francisco, California
February 26, 2013

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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, 2012, 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, 2012, 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, 2012 and 2011, and the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2012 and our report dated February 26, 2013 expressed an unqualified opinion thereon.

/s/ OUM & Co. LLP

San Francisco, California
February 26, 2013

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VIVUS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except par value)

	December 31	
	2012	**2011**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 58,605	$ 39,554
Available-for-sale securities	155,981	107,282
Accounts receivable, net	2,778	
Inventories	25,353	3,107
Prepaid expenses and other assets	19,446	1,793
Total current assets	262,163	151,736
Property and equipment, net	1,951	320
Total assets	$ 264,114	$ 152,056
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 25,375	$ 2,940
Accrued and other liabilities	13,777	6,392
Deferred revenue	1,150	
Current liabilities of discontinued operations	903	1,640
Total current liabilities	41,205	10,972
Commitments and contingencies		
Stockholders' equity:		
Preferred stock; $1.00 par value; 5,000 shares authorized; no shares issued and outstanding at December 31, 2012 and 2011		
Common stock; $.001 par value; 200,000 shares authorized at December 31, 2012 and 2011; 100,659 and 88,975 shares issued and outstanding at December 31, 2012 and 2011, respectively	101	89
Additional paid-in capital	708,921	487,235
Accumulated other comprehensive income	33	25
Accumulated deficit	(486,146)	(346,265)
Total stockholders' equity	222,909	141,084
Total liabilities and stockholders' equity	$ 264,114	$ 152,056

See accompanying notes to consolidated financial statements.

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VIVUS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

	Years Ended December 31		
	2012	**2011**	**2010**
Revenue:			
Net product revenue	$ 2,012	$	$
Operating expenses:			
Cost of goods sold	187		
Research and development	32,065	24,604	39,971
Selling, general and administrative	109,665	22,472	25,656
Total operating expenses	141,917	47,076	65,627
Loss from operations	(139,905)	(47,076)	(65,627)
Interest and other income (expense):			
Interest and other income, net	199	240	468
Interest expense			(4,308)
Loss on early extinguishment of debt			(5,958)
Total interest and other income (expense)	199	240	(9,798)
Loss from continuing operations before income taxes	(139,706)	(46,836)	(75,425)
Provision for income taxes	(27)	(190)	(9)
Net loss from continuing operations	(139,733)	(47,026)	(75,434)
Net (loss) income from discontinued operations	(148)	886	9,369
Net loss	$ (139,881)	$ (46,140)	$ (66,065)
Basic and diluted net income (loss) per share:			
Continuing operations	$ (1.42)	$ (0.56)	$ (0.93)
Discontinued operations	0.00	0.01	0.11
Net loss per share	$ (1.42)	$ (0.55)	$ (0.82)
Shares used in per share computation:			
Basic and diluted	98,289	84,392	81,017

VIVUS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

Years Ended December 31

	2012	2011	2010
Net loss	$ (139,881)	$ (46,140)	$ (66,065)
Other comprehensive income unrealized gain on securities, net of taxes	8	21	7
Comprehensive loss	$ (139,873)	$ (46,119)	$ (66,058)

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, 2009	80,607	$ 81	$ 420,708	$ (3)	$ (234,060)	$ 186,726
Sale of common stock through employee stock purchase plan	48		304			304
Exercise of common stock options for cash	913	1	3,616			3,617
Share-based compensation expense			7,413			7,413
Net unrealized gain on securities				7		7
Net loss					(66,065)	(66,065)
Balances, December 31, 2010	81,568	82	432,041	4	(300,125)	132,002
Sale of common stock through employee stock purchase plan	36		211			211
Exercise of common stock options for cash	482		2,354			2,354
Share-based compensation expense			7,353			7,353
Proceeds from registered direct public offering of common stock	6,889	7	45,805			45,812
Issue costs for registered direct public offering of common stock			(529)			(529)
Net unrealized gain on securities				21		21
Net loss					(46,140)	(46,140)
Balances, December 31, 2011	88,975	89	487,235	25	(346,265)	141,084
Sale of common stock through employee stock purchase plan	35		314			314
Exercise of common stock options for cash	2,649	3	13,248			13,251
Share-based compensation expense			16,133			16,133
Proceeds from registered direct public offering of common stock	9,000	9	202,491			202,500
Issue costs for registered direct public offering of common stock			(10,500)			(10,500)
Net unrealized gain on securities				8		8
Net loss					(139,881)	(139,881)
Balances, December 31, 2012	100,659	$ 101	$ 708,921	$ 33	$ (486,146)	$ 222,909

See accompanying notes to consolidated financial statements.

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VIVUS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Years Ended December 31		
	2012	**2011**	**2010**
Cash flows from operating activities:			
Net loss from continuing operations	$ (139,733)	$ (47,026)	$ (75,434)
Adjustments to reconcile net loss from continuing operations to net cash used for operating activities from continuing operations:			
Provision for cash discounts	53		
Depreciation	271	102	138
Amortization of discount or premium on available-for-sale securities	3,958	3,118	1,655
Net realized gain on investments	(8)		(5)
Share-based compensation expense	15,938	7,353	6,443
Loss on early extinguishment of debt			5,958
Changes in assets and liabilities:			
Accounts receivable	(2,835)		
Inventories	(22,050)	118	(3,225)
Prepaid expenses and other assets	(17,653)	(145)	2,658
Accounts payable	22,202	545	(5,687)
Accrued and other liabilities	7,385	15	1,197
Deferred revenue	1,154		
Net cash used for operating activities from continuing operations	(131,318)	(35,920)	(66,302)
Net cash (used for) provided by operating activities from discontinued operations	(885)	(980)	2,195
Net cash used for operating activities	(132,203)	(36,900)	(64,107)
Cash flows from investing activities:			
Property and equipment purchases	(1,669)	(201)	(105)
Release of restricted cash			700
Purchases of available-for-sale securities	(226,654)	(137,409)	(209,759)
Proceeds from maturity of available-for-sale securities	133,250	129,000	243,900
Proceeds from sale of available-for-sale securities	40,763		28,487
Net cash (used for) provided by investing activities from continuing operations	(54,310)	(8,610)	63,223
Net cash provided by investing activities from discontinued operations			21,546
Net cash (used for) provided by investing activities	(54,310)	(8,610)	84,769
Cash flows from financing activities:			
Payments of notes payable			(23,000)
Net proceeds from exercise of common stock options	13,250	2,354	3,617
Sale of common stock through employee stock purchase plan	314	211	304
Net proceeds from issuance of common stock	192,000	45,283	
Net cash provided by (used for) financing activities from continuing operations	205,564	47,848	(19,079)
Net cash used for financing activities from discontinued operations			(4,900)
Net cash provided by (used for) financing activities	205,564	47,848	(23,979)

Net increase (decrease) in cash and cash equivalents	19,051	2,338	(3,317)
Cash and cash equivalents:			
Beginning of year	39,554	37,216	40,533
End of year	$ 58,605	$ 39,554	$ 37,216
Supplemental cash flow disclosure:			
Interest paid	$	$	$ 6,030
Income taxes paid	$ 7	$ 24	$ 41
Non-cash investing and financing activities:			
Unrealized gain on securities	$ 8	$ 21	$ 7

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 dedicated to commercializing and developing innovative therapies to address unmet needs in obesity, sleep apnea, diabetes and sexual health. The Company's drug, Qsymia™ (phentermine and topiramate extended-release) (formerly known as Qnexa®) was approved by the U.S. Food and Drug Administration, or FDA, for the treatment of obesity as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of 30 or greater (obese), or 27 or greater (overweight) in the presence of at least one weight-related comorbidity, such as hypertension, type 2 diabetes mellitus or high cholesterol (dyslipidemia). Qsymia incorporates low doses of active ingredients from two previously approved drugs, phentermine and topiramate. Although the exact mechanism of action is unknown, Qsymia is believed to target appetite and satiety, or the feeling of being full, the two main mechanisms that impact eating behavior. The Company announced the U.S. market availability of Qsymia for obesity in September 2012. On February 21, 2013, the European Medicines Agency's, or EMA, Committee for Medicinal Products for Human Use, or CHMP, confirmed its October 18, 2012 decision to deny the Marketing Authorization Application, or MAA, for Qsiva (phentermine/topiramate ER) for the treatment of obesity in the European Union, or EU. The Company has completed Phase 2 clinical studies for Qsymia for the treatment of sleep apnea and Qsymia for the treatment of type 2 diabetes.

The Company's drug, STENDRA™, or avanafil, was approved by the FDA for the treatment of erectile dysfunction, or ED, in the U.S. The Company, through collaboration arrangements with third parties, intends to market and sell STENDRA in the U.S. and, if approved, under the trade name SPEDRA™ in the EU and other territories outside the United States.

At December 31, 2012, the Company's accumulated deficit was approximately $486.1 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, 2012 will be sufficient to meet the Company's obligations at least through 2013. Should product sales and planned partnering activities be significantly less than the Company's expectations, it would need to raise additional capital to support operating activities through 2013 and beyond. 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. Management has evaluated all events and transactions that occurred after December 31, 2012 through the date these consolidated financial statements were filed. There were no events or transactions occurring during this period which require recognition or disclosure in these consolidated financial statements, except as disclosed in Note 15. The Company operates in a single segment, the development and commercialization of novel therapeutic products.

When we refer to "we," "our," "us," the "Company" or "VIVUS" in this document, we mean the current Delaware corporation, or VIVUS, Inc., and its California predecessor, as well as all of our consolidated subsidiaries.

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1. Business and Significant Accounting Policies (Continued)

Significant Accounting Policies

Reclassifications

Certain prior year amounts in the consolidated financial statements have been reclassified to conform to the current year's presentation. In particular, accrued research and clinical expenses, and accrued employee compensation and benefits have been combined with accrued and other liabilities in the consolidated balance sheets and consolidated statements of cash flows. In addition, the amortization of discount or premium on available-for-sale securities has been shown separately from proceeds from maturity of available-for-sale securities in the consolidated statement of cash flows.

Principles of Consolidation

The consolidated financial statements include the accounts of VIVUS, Inc., and its wholly owned subsidiaries: VIVUS Limited, VIVUS International LP, VIVUS Real Estate LLC, VIVUS International Limited, VIVUS U.K. Limited and VIVUS B.V. Limited. All significant intercompany 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. The Company acquired 100% of the outstanding shares of Deerfield ED Corp., a Delaware corporation, on November 5, 2010. Deerfield ED Corp. was dissolved on December 9, 2010. On July 22, 2011, VIVUS Real Estate LLC was cancelled.

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. On an ongoing basis, the Company evaluates its estimates, including critical accounting policies or estimates related to available-for-sale securities, research and development expenses, income taxes, inventories, contingencies and litigation and share-based compensation. The Company bases its estimates on historical experience, information received from third parties and on various market specific and other relevant assumptions that it believes 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 could differ significantly from those estimates under different assumptions or conditions.

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, 2012 and 2011, all cash equivalents are invested in money market funds and U.S. Treasury securities. These investments are recorded at fair value.

As of December 31, 2012 and 2011, the temporary unrealized gains (losses) on cash, cash equivalents and available-for-sale securities, net of tax, were included in accumulated other comprehensive income (loss) in the accompanying consolidated balance sheets.

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1. Business and Significant Accounting Policies (Continued)

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 Company periodically evaluates its investments to determine if impairment charges are required.

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.

Fair Value Measurements

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. FASB ASC topic 820*Fair Value Measurements and Disclosures*, or ASC 820, 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. ASC 820 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.

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1. Business and Significant Accounting Policies (Continued)

ASC 820 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.

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.

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

As of December 31, 2012, the Company's cash and cash equivalents and available-for-sale securities measured at fair value on a recurring basis totaled $214.6 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. The Company's valuation techniques used to measure the fair value of money market funds were derived from quoted market prices as active markets for these instruments exist. Investments in marketable securities are held by a custodian who obtains investment prices from a third-party pricing provider that uses standard inputs derived from or corroborated by observable market data to models that vary by asset class. There were no assets or liabilities where Level 2 or Level 3 valuation techniques were used and there were no assets and liabilities measured at fair value on a non-recurring basis.

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, in U.S. Treasury securities or diversifying its investment portfolio and placing investments with maturities that maintain safety and liquidity within the Company's liquidity needs.

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 Company offers cash discounts to its customers, generally 2% of the sales price as an incentive for prompt payment. The estimate of cash discounts is recorded at the time

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1. Business and Significant Accounting Policies (Continued)

of sale. The Company accounts for the cash discounts by reducing revenue and accounts receivable by the amount of the discounts it expects the customers to take. The accounts receivable are reported in the consolidated balance sheets, net of the allowances for doubtful accounts and cash discounts. There is no allowance for doubtful accounts at December 31, 2012 or 2011. The allowance for cash discounts is $57,000 at December 31, 2012, and $0 at December 31, 2011.

Inventories and related reserves

Inventories are valued at the lower of cost or market. Cost is determined using the first-in, first-out method for all inventories, which are valued using a weighted average cost method calculated for each production batch. Inventory includes the cost of the active pharmaceutical ingredients, or APIs, materials and third-party contract manufacturing and packaging services. Indirect overhead costs associated with production and distribution are allocated to the appropriate cost pool and then absorbed into inventory based on the units produced or distributed, assuming normal capacity, in the applicable period.

Inventory costs of product shipped to customers, but not yet shipped to patients through prescriptions, are recorded within inventories on the consolidated balance sheets and are subsequently recognized to cost of goods sold when shipped to patients through prescriptions.

The Company's policy is to write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected requirements. The estimate of excess quantities is subjective and primarily dependent on the Company's estimates of future demand for a particular product. If the estimate of future demand is inaccurate based on actual sales, the Company may adjust the reserve for excess inventory for that product and record a charge to cost of goods sold. There are no such inventory charges for the years presented in this Form 10-K.

Property and Equipment

Property and equipment is stated at cost and includes leasehold improvements, computers and software and furniture and fixtures. For financial reporting, depreciation is computed using the straight-line method over estimated useful lives of two to seven years for computers and software and furniture and fixtures. Leasehold improvements are amortized using the straight-line method over the shorter of the expected lease term or 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.

Long-lived assets, such as property 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.

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1. Business and Significant Accounting Policies (Continued)

Revenue Recognition

The Company recognizes revenue from the sale of Qsymia™ (phentermine and topiramate extended-release) when: (i) persuasive evidence that an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable, and (iv) collectability is reasonably assured. Revenue from sales transactions where the customer has the right to return the product is recognized at the time of sale only if: (i) the price to the customer is substantially fixed or determinable at the date of sale, (ii) the customer has paid the Company, or the customer is obligated to pay the Company and the obligation is not contingent on resale of the product, (iii) the customer's obligation would not be changed in the event of theft or physical destruction or damage of the product, (iv) the customer acquiring the product for resale has economic substance apart from that provided by the Company, (v) the Company does not have significant obligations for future performance to directly bring about resale of the product by the customer, and (vi) the amount of future returns can be reasonably estimated.

Net Product Revenue and Product Revenue Allowances

Product revenue is recognized net of cash consideration paid to customers for service fees in accordance with certified pharmacy services network agreements, and include a fixed rate per prescription shipped and monthly program management and data fees for certain services performed by the customer. These services are not deemed sufficiently separable from the customers' purchase of the product; therefore, they are recorded as a reduction of revenue at the time of revenue recognition.

Other reductions of revenue include certain prompt pay cash discounts and allowances offered to the customers which are recognized as a reduction of revenue at the later of the date at which the related revenue is recognized or the date at which the allowance is offered. The Company recognized $53,000 as a reduction of revenue for prompt pay cash discounts in the year ended December 31, 2012.

Calculating certain of these items involves estimates and judgments based on sales or invoice data and historical experience. Amounts accrued for sales deductions are adjusted when trends, significant events, or actual results indicate that adjustment is appropriate. Revisions of estimates for sales deductions are charged to income in the period in which the information that gives rise to the revision becomes known.

Qsymia was approved by the U.S. Food and Drug Administration, or FDA, in July 2012. The Company sells Qsymia product in the U.S. to select pharmacies through a certified home delivery pharmacy services network, which are collectively, its customers. Under this arrangement, title and risk of loss transfer to the Company's customers upon delivery of the product to their distribution facilities. They in turn, sell directly to patients through their home delivery service.

The Company shipped initial orders of Qsymia to its customers in September 2012 and announced the availability of the product on September 17, 2012. Qsymia has a 24-month shelf life and the Company grants rights to its customers to return unsold product three months prior to and up to twelve months after product expiration and issue credits which may be applied against existing or future invoices. Given the Company's limited history of selling Qsymia and the lengthy return period, it has not been able to reliably estimate expected returns of Qsymia at the time of shipment, and therefore the Company recognizes revenue when units are shipped to patients through prescriptions, at which point, the product is not subject to return.

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1. Business and Significant Accounting Policies (Continued)

The Company will continue to recognize revenue for Qsymia based upon prescription sell-through until it has sufficient historical information to reliably estimate returns.

As of December 31, 2012, the Company had recorded deferred revenue of $1.2 million related to shipments of Qsymia, which represents product shipped to customers, but not yet shipped to patients through prescriptions. A corresponding accounts receivable is also recorded for this amount, as the payments from customers are not contingent upon the sale of product to patients.

Cost of goods sold

Cost of goods sold for units shipped to patients through prescriptions includes the inventory costs of APIs, third-party contract manufacturing costs, packaging and distribution costs, royalties, cargo insurance, freight, shipping, handling and storage costs, and overhead costs of the employees involved with production.

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 incurred by clinical research organizations or CROs, and research institutions under agreements that 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 CRO 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 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.

In addition, the Company has obtained rights to patented intellectual properties under several licensing agreements for use in research and development activities. Non-refundable licensing payments made for intellectual properties that have no alternative future uses are expensed to research and development as incurred.

Advertising Expenses

Advertising expenses are charged to expense as incurred. The Company incurred $16.1 million in 2012 in advertising and sales promotion costs related to its marketed product, Qsymia.

Share-Based Payments

The Company follows the fair value method of accounting for share-based compensation arrangements in accordance with 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

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1. Business and Significant Accounting Policies (Continued)

on the date of the grant using an option-pricing model. The fair value of each option award is estimated on the grant date using a Black-Scholes option-pricing model. 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 share-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.

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, 2012, 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.

The Company recognizes interest and penalties accrued on any unrecognized tax benefits as a component of its provision for income taxes.

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1. Business and Significant Accounting Policies (Continued)

FASB ASC topic 740, *Income Taxes*, or ASC 740, prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of uncertain tax positions taken or expected to be taken in a company's income tax return, and also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. ASC 740-10 utilizes a two-step approach for evaluating uncertain tax positions. Step one, Recognition, requires a company to determine if the weight of available evidence indicates that a tax position is more likely than not to be sustained upon audit, including resolution of related appeals or litigation processes, if any. Step two, Measurement, is based on the largest amount of benefit, which is more likely than not to be realized on ultimate settlement.

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.

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 net loss per share for the years ended December 31, 2012, 2011 and 2010 are as follows:

	2012	2011	2010
	(In thousands, except per share data)		
Net loss	$ (139,881)	$ (46,140)	$ (66,065)
Net loss per share basic and diluted	$ (1.42)	$ (0.55)	$ (0.82)
Shares used in the computation of net loss per share basic and diluted	98,289	84,392	81,017

As the Company recognized a net loss from continuing operations for the years ended December 31, 2012, 2011 and 2010, 4,172,000, 5,357,000 and 4,384,000 potentially dilutive options outstanding were not included in the computation of diluted net loss, respectively, because the effect would have been anti-dilutive.

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1. Business and Significant Accounting Policies (Continued)

Recent Accounting Requirements

There have been no recent accounting pronouncements or changes in accounting pronouncements during the year ended December 31, 2012 that are of significance, or potential significance to the Company.

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, 2012 and 2011 are presented in the tables that follow.

As of December 31, 2012 (in thousands):

Cash and cash equivalents and available-for-sale securities	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash and money market funds	$ 58,605	$	$	$ 58,605
U.S. Treasury securities	155,948	33		155,981
Total	214,553	33		214,586
Less amounts classified as cash equivalents	(58,605)			(58,605)
Total available-for-sale securities	$ 155,948	$ 33	$	$ 155,981

As of December 31, 2012, all of the Company's available-for-sale securities have a contractual maturity of less than one year.

As of December 31, 2011 (in thousands):

Cash and cash equivalents and available-for-sale securities	Amortized Cost	Gross Unrealized Gains	Unrealized Losses	Estimated Fair Value
Cash and money market funds	$ 38,547	$	$	$ 38,547
U.S. Treasury securities	108,264	27	(2)	108,289
Total	146,811	27	(2)	146,836
Less amounts classified as cash equivalents	(39,554)			(39,554)
Total available-for-sale securities	$ 107,257	$ 27	$ (2)	$ 107,282

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

Fair Value Measurements

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, classified as Level 1, as of December 31, 2012 and 2011 (in thousands):

	Balance at December 31, 2012		Balance at December 31, 2011	
	Level 1	Total	Level 1	Total
Cash and cash equivalents:				
Cash and money market funds	$ 58,605	$ 58,605	$ 38,547	$ 38,547
U.S. Treasury securities			1,007	1,007
Total cash and cash equivalents	$ 58,605	$ 58,605	$ 39,554	$ 39,554

	Balance at December 31, 2012		Balance at December 31, 2011	
	Level 1	Total	Level 1	Total
Available-for-sale securities:				
U.S. Treasury securities	$ 155,981	$ 155,981	$ 107,282	$ 107,282
Total available-for-sale securities	$ 155,981	$ 155,981	$ 107,282	$ 107,282

	December 31, 2012	December 31, 2011
Reported as:		
Cash and cash equivalents	$ 58,605	$ 39,554
Available-for-sale securities	155,981	107,282
Total	$ 214,586	$ 146,836

There were no assets or liabilities where Level 2 or Level 3 valuation techniques were used and there were no assets and liabilities measured at fair value on a non-recurring basis.

Note 3. Inventories

Inventories consist of (in thousands):

	Balance as of	
	December 31, 2012	December 31, 2011
Raw materials	$ 5,139	$ 3,107
Work in process	2,635	
Finished goods	17,506	
Deferred costs	73	

Total	$	25,353	$	3,107

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 3. Inventories (Continued)

As of December 31, 2012 and 2011, the raw materials inventories consist primarily of the API for the commercialization of Qsymia. As of December 31, 2012, the finished goods inventory consists of both Qsymia and STENDRA™ (avanafil) for commercialization, while the work in process and deferred costs inventories relate exclusively to Qsymia. The deferred costs represent the costs of Qsymia product shipped to customers, but not yet shipped to patients through prescriptions, and for which recognition of revenue has been deferred.

Note 4. Prepaid expenses and other assets

Prepaid expenses and other assets consist of (in thousands):

	Balance as of	
	December 31, 2012	December 31, 2011
Interest receivable	$ 743	$ 725
Prepaid insurance	6,979	672
Prepaid sales and marketing expenses	5,735	
Manufacturing capacity commitment fees	2,300	
Prepaid medical affairs expenses	1,782	
Other prepaid expenses and assets	1,907	396
Total	$ 19,446	$ 1,793

The amounts included in prepaid expenses and other assets consist of interest receivable, deposits and prepayments for future services, primarily related to prepaid product commercialization costs for services relating to future periods in support of the commercial launch of Qsymia in the U.S., prepayments related to medical affairs activities for Qsymia and STENDRA, and manufacturing capacity commitment fees, and prepaid insurance. These amounts represent probable future economic benefits obtained or controlled by the Company as a result of past transactions or events, which meet the definition of an asset under FASB Concept Statement 6. As such, these costs have been deferred as prepaid expenses and other assets on the consolidated balance sheet and will be either (i) charged to expense accordingly when the related prepaid services are rendered to the Company, or (ii) converted to cash when the receivables are collected by the Company.

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 5. Property and Equipment

Property and equipment consist of (in thousands):

	Balance as of	
	December 31, 2012	December 31, 2011
Computers and software	$ 2,056	$ 673
Furniture and fixtures	692	413
Manufacturing equipment	269	117
Leasehold improvements	351	272
	3,368	1,475
Accumulated depreciation	(1,417)	(1,155)
Property and equipment, net	$ 1,951	$ 320

Note 6. Accrued and other liabilities

Accrued and other liabilities consist of (in thousands):

	Balance as of	
	December 31, 2012	December 31, 2011
Accrued research and clinical expenses	$ 1,372	$ 1,425
Accrued employee compensation and benefits	3,859	3,693
Accrued manufacturing costs	4,135	
Accrued sales and marketing expenses	2,908	
Other accrued liabilities	1,503	1,274
Total	$ 13,777	$ 6,392

The amounts included in accrued and other liabilities consist of obligations for past services, primarily related to accrued manufacturing and product commercialization costs for services relating to past periods in support of the commercial launch of Qsymia in the U.S., accrued employee compensation and benefits, and accrued research and clinical expenses.

Note 7. Stockholders' Equity

Common Stock

The Company is authorized to issue 200 million shares of common stock. As of December 31, 2012 and 2011, there were 100,659,000 and 88,975,000 shares, respectively, issued and outstanding.

On March 6, 2012, the Company closed the underwritten public offering and sale of 9,000,000 shares of the Company's common stock. Gross proceeds to the Company from this sale totaled approximately $202.5 million before deduction of approximately $10.5 million in underwriting discounts and commissions and offering expenses. All of the shares of common stock were offered pursuant to the Company's effective shelf registration statement on Form S-3 (Registration No. 333-161948), including the prospectus dated September 16, 2009 (as amended on February 28, 2012) contained therein, as the same has been supplemented.

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 7. Stockholders' Equity (Continued)

On August 24, 2011, the Company closed on the sale of a total of 6,889,098 shares of its common stock, at a price of $6.65 per share, pursuant to a previously-reported securities purchase agreement entered into on August 23, 2011 with certain investors in connection with a registered direct offering of the Company's common stock, or the Offering. Gross proceeds to the Company from the sale of the common stock in the Offering totaled approximately $45.8 million before deduction of approximately $529,000 in fees and expenses related to the Offering. All of the shares of common stock were offered pursuant to an effective shelf registration statement on Form S-3ASR (Registration No. 333-161948), including the prospectus dated September 16, 2009 contained therein.

On August 1, 2011, the Company filed a Form S-8 (File Number 333-175926) with the SEC registering 600,000 shares of common stock, par value $0.001 per share, under the 1994 Employee Stock Purchase Plan, as amended, or 1994 ESPP.

On July 14, 2010, the Company filed a Form S-8 (File Number 333-168106) with the SEC registering 16,615,199 shares of common stock, par value $0.001 per share, to be issued pursuant to the 2010 Equity Incentive Plan, and registering 400,000 shares of common stock, par value $0.001 per share, to be issued pursuant to the Stand-Alone Stock Option Agreement with Michael P. Miller, the Company's Senior Vice President and Chief Commercial Officer.

On February 16, 2010, the Company filed a Form S-8 (File Number 333-164921) 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.

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, 2012 and 2011, there were 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

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 7. Stockholders' Equity (Continued)

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.

Note 8. Stock Option and Purchase Plans

Stock Option Plan

On March 29, 2010, the Company's Board of Directors terminated the 2001 Stock Option Plan. In addition, the Board of Directors adopted and approved a new 2010 Equity Incentive Plan, or the 2010 Plan, with 32,000 shares remaining reserved and unissued under the 2001 Plan, subject to the approval of the Company's stockholders. The 2001 Plan, however, continues to govern awards previously granted under it. On June 25, 2010, the Company's stockholders approved the 2010 Plan at the Company's 2010 Annual Meeting of Stockholders. The 2010 Plan provides for the grant of stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares and performance units to employees, directors and consultants, to be granted from time to time as determined by the Board of Directors, the Compensation Committee of the Board of Directors, or its designees. The term of the option is determined by the Board of Directors on the date of grant but shall not be longer than 10 years. Options under this plan generally vest over four years, and all options expire after 10 years. The 2010 Plan's share reserve, which the stockholders approved, is 8,400,000 shares, plus any shares reserved but not issued pursuant to awards under the 2001 Plan as of the date of stockholder approval, or 99,975 shares, plus any shares subject to outstanding awards under the 2001 Plan that expire or otherwise terminate without having been exercised in full, or are forfeited to or repurchased by the Company, up to a maximum of 8,111,273 shares (which was the number of shares subject to outstanding options under the 2001 Plan as of March 11, 2010).

On April 30, 2010, the Company's Board of Directors granted an option to purchase 400,000 shares of the Company's common stock, or the Inducement Grant, to Michael P. Miller, the Company's Senior Vice President and Chief Commercial Officer. The Inducement Grant was granted outside of the Company's 2010 Plan and without stockholder approval pursuant to NASDAQ Listing Rule 5635(c)(4) and is subject to the terms and conditions of the Stand-Alone Stock Option Agreement between the Company and Michael P. Miller.

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 8. Stock Option and Purchase Plans (Continued)

Restricted Stock Units

Beginning in 2012, the Company began issuing restricted units under the 2010 Plan on a limited basis. There were no restricted stock units outstanding in the prior years presented in this Form 10-K. A summary of restricted stock unit award activity under the 2010 Plan is as follows:

	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, 2011				
Granted	35,000	$ 24.88		
Vested				
Forfeited				
Restricted stock units outstanding, December 31, 2012	35,000	$ 24.88	1.22	$ 469,700

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

	Years Ended December 31,					
	2012		2011		2010	
	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	8,575,434	$ 6.17	7,919,013	$ 5.71	7,553,776	$ 4.74
Options:						
Granted	2,850,118	$ 17.80	1,289,790	$ 8.72	1,729,135	$ 9.37
Exercised	(2,648,882)	$ 5.00	(482,172)	$ 4.88	(982,594)	$ 4.34
Cancelled	(265,753)	$ 9.28	(151,197)	$ 8.32	(381,304)	$ 6.66
Balance at end of year	8,510,917	$ 10.33	8,575,434	$ 6.17	7,919,013	$ 5.71
Exercisable at end of year	4,781,301	$ 6.32	6,120,210	$ 5.38	5,171,827	$ 4.82
Weighted average grant-date fair value of options granted during the year		$ 11.91		$ 5.91		$ 5.74

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 8. Stock Option and Purchase Plans (Continued)

Summary of Stock Options

At December 31, 2012, stock options were outstanding and exercisable as follows:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding at December 31, 2012	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable December 31, 2012	Weighted-Average Exercise Price
$3.13 - $6.05	3,095,998	5.0 years	$ 4.67	3,060,143	$ 4.67
$6.10 - $12.04	3,945,660	8.0 years	$ 9.99	1,698,417	$ 9.08
$18.71 - $25.74	1,469,259	9.4 years	$ 23.16	22,741	$ 22.63
$3.13 - $25.74	8,510,917	7.2 years	$ 10.33	4,781,301	$ 6.32

The aggregate intrinsic value of outstanding options as of December 31, 2012 was $40.6 million, of which $34.1 million related to exercisable options.

At December 31, 2012, 4,745,966 options remain available for grant. On January 25, 2013, awards exercisable for 1,928,132 shares were granted pursuant to the 2010 Plan. During the year ended December 31, 2012, in accordance with the terms of the 2010 Plan, the Company transferred a net total of 142,210 expired plan shares to the 2010 Plan.

Employee Stock Purchase Plan

Under the 1994 Employee Stock Purchase Plan, or the ESPP, the Company reserved 800,000 shares of common stock for issuance to employees pursuant to the ESPP, 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 ESPP to (i) extend the original term of the ESPP by an additional 10 years such that the ESPP will now expire in April 2014 (subject to earlier termination as described in the ESPP) and (ii) increase the number of shares of common stock reserved for issuance under the ESPP by 600,000 shares to a new total of 1,400,000.

On June 17, 2011, the Company's stockholders approved amendments to the Company's ESPP to increase the number of shares reserved for issuance under the ESPP by 600,000 shares to a new total of 2,000,000, to remove the Plan's 20-year term, and to include certain changes consistent with Treasury Regulations relating to employee stock purchase plans under Section 423 of the Internal Revenue Code of 1986, as amended, and other applicable law.

As of December 31, 2012, 1,398,473 shares have been issued to employees and there are 601,527 shares available for issuance under the ESPP. The weighted average fair value of shares issued under the ESPP in 2012, 2011 and 2010 was $3.72, $3.21 and $3.60 per share, respectively.

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 8. Stock Option and Purchase Plans (Continued)

Share-Based Compensation Expense

Total estimated share-based compensation expense, related to all of the Company's share-based awards, recognized for the years ended December 31, 2012, 2011 and 2010 was comprised as follows (in thousands, except per share data):

	2012	2011	2010
Continuing Operations:			
Research and development	$ 3,487	$ 1,917	$ 1,204
Selling, general and administrative	12,451	5,436	5,239
	15,938	7,353	6,443
Discontinued Operations:			
Cost of goods sold and manufacturing			810
Selling, general and administrative			160
			970
Share-based compensation expense before taxes	15,938	7,353	7,413
Related income tax benefits			
Share-based compensation expense, net of taxes	$ 15,938	$ 7,353	$ 7,413

Included in the inventory carrying value as of December 31, 2012 is $196,000 of share-based compensation which has been absorbed into inventory.

The following table summarizes share-based compensation, net of estimated forfeitures associated with each type of award (in thousands):

	2012	2011	2010
Share-based compensation, net of taxes:			
Restricted stock units	$ 292	$	$
Stock options	15,531	7,259	7,272
Employee stock purchase plan	115	94	141
	$ 15,938	$ 7,353	$ 7,413

As of December 31, 2012, unrecognized estimated compensation expense totaled $569,000 related to non-vested restricted stock units, $19.9 million related to non-vested stock options and $123,000 related to the ESPP. The weighted average remaining requisite service period of the non-vested restricted stock units was 2.1 years, of the non-vested stock options was 1.2 years and of the ESPP was 4.5 months.

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 8. Stock Option and Purchase Plans (Continued)

Valuation Assumptions

The fair value of each option is estimated on the date of grant using the Black-Scholes option pricing model, assuming no expected dividends and the following weighted average assumptions:

	2012	2011	2010
Expected life (in years)	5.54	5.93	5.82
Volatility	82.49%	77.46%	67.72%
Risk-free interest rate	1.00%	2.59%	2.59%
Dividend yield			

Note 9. Commitments

Lease Commitments

In November 2006, the Company entered into a 30-month lease for its corporate headquarters located in Mountain View, California, or Castro Lease. On February 14, 2012, the Company entered into the most current, fourth amendment to the Castro Lease. Under the fourth amendment to the Castro Lease, the average base rent for the current premises is set at $2.50 per square foot or $45,015 per month. The fourth amendment also extended the lease term for the current premises for a period of twelve months commencing August 1, 2012 and terminating July 31, 2013 and provided us one additional option to extend the term of the Castro Lease of the current premises for one year from the expiration of the Castro Lease. In addition, the fourth amendment included a new lease on an additional 4,914 square feet of office space located at 1174 Castro Street, Mountain View, California, or the Expansion Space, which is adjacent to the Company's current corporate headquarters. The average base rent for the Expansion Space is approximately $2.75 per square foot or $13,513 per month. The new lease for the Expansion Space has a term of 60 months commencing March 15, 2012, with an option to extend the term for one year from the expiration of the new lease.

The Company entered into a lease effective as of December 11, 2012 with SFERS Real Estate Corp. U, or the Landlord, for new principal executive offices, consisting of an approximately 45,240 square foot building, located at 351 East Evelyn Avenue, Mountain View, California, or the Evelyn Lease. The Evelyn Lease has an initial term of approximately 84 months, commencing on the later of (i) May 1, 2013 and (ii) four months following delivery of the premises to the Company, and at a starting annual rental rate of $31.20 per rentable square foot (subject to agreed increases). The Company will be entitled to an abatement of the monthly installments of rent for months seven through twelve of the initial term subject to the conditions detailed in the Evelyn Lease. The Company has one option to renew the Evelyn Lease for a term of three years at the prevailing market rate as detailed in the Evelyn Lease. In addition, the Company has a one-time right to accelerate the termination date of the Evelyn Lease from the expiration of the 84th full calendar month of the term to the expiration of the 60th full calendar month of the term subject to the conditions detailed in the Evelyn Lease. If this acceleration of the termination date is exercised, the following will be payable to the Landlord: (i) six months of the monthly installments of rent and the Company's proportionate share of expenses and taxes subject to the fifth lease year and (ii) the unamortized portion of all of the following: (a) any leasing commissions and legal fees, (b) the initial alterations as detailed in the Evelyn Lease, and (c) Landlord's allowance towards the cost of performing the initial alterations, which is $7.00 per rentable square foot; provided that the amount payable to the Landlord will be increased by

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 9. Commitments (Continued)

the unamortized portion of any leasing commissions, tenant improvements and allowances, or other concessions incurred by the Landlord in connection with any additional space other than the premises leased by the Company and that is subject to acceleration under the Evelyn Lease. The Company expects to occupy its new principal executive offices in the spring of 2013.

Future minimum lease payments under operating leases at December 31, 2012 were as follows (in thousands):

2013	$ 1,639
2014	1,481
2015	1,999
2016	2,049
2017	1,899
Thereafter	4,458
	$ 13,525

Rent expense under operating leases in fiscal 2012, 2011 and 2010 was as follows (in thousands):

	Years Ended December 31,		
	2012	2011	2010
Rent expense	$ 912	$ 671	$ 676

Other Contractual Obligations

The following table summarizes the Company's other contractual obligations at December 31, 2012, excluding amounts already recorded on its consolidated balance sheet as accounts payable or accrued liabilities, and the effect such obligations are expected to have on the Company's liquidity and cash flow in future fiscal years. This table includes the Company's enforceable, non-cancelable, and legally binding obligations and future commitments as of December 31, 2012. The amounts below do not include contingent milestone payments or royalties, and assume the agreements and commitments will run through the end of terms, as such no early termination fees or penalties are included herein:

	Payments Due by Period		
Other contractual obligations	**Total**	**2013**	**2014 - 2016**
		(in thousands)	
Purchase obligations:			
Manufacturing agreements	$ 48,629	$ 48,318	$ 311
Other agreements	51,455	34,252	17,203
Total other contractual obligations	$ 100,084	$ 82,570	$ 17,514

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 9. Commitments (Continued)

Purchase Obligations

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 product manufacturing, sales and marketing services, including for the contract sales organization, and research and development.

Manufacturing agreements

The Company has purchase commitments for raw material supplies for Qsymia totaling $26.6 million at December 31, 2012. In addition, in July 2012, the Company entered into a manufacturing agreement with Catalent Pharma Solutions, LLC, or Catalent, to supply commercial inventory for Qsymia beginning in 2012 and ending in 2016. The remaining commitment under this agreement is to pay Catalent a minimum total of $12.5 million for the production of Qsymia in 2013.

The API and the tablets for STENDRA (avanafil) are currently manufactured by MTPC. There are no minimum purchase obligations for STENDRA under the agreement with MTPC. The Company has placed orders with MTPC for avanafil product testing and finished goods and the remaining commitment under these purchase obligations at December 31, 2012 totaled $9.5 million.

Other agreements

On May 22, 2012, the Company entered into a Dedicated Sales Team Agreement, or the Sales Team Agreement, with PDI, Inc., or PDI, to provide it with promotional and commercialization support services for Qsymia. The Sales Team Agreement is effective beginning on July 30, 2012 and ending on July 29, 2014. The Company has the option to extend the term of the agreement for two consecutive twelve-month periods. Under the terms of the Sales Team Agreement, PDI provides the Company with 150 full-time sales representatives, three full-time field liaison managers, and one full-time account manager. In addition, under the Sales Team Agreement, PDI provides the Company with program personnel to collect and capture physician information, including physician target call plan reach and frequency, deactivation information related to physician accounts and physician's behavioral or attitudinal response. As of December 31, 2012, the total obligation under the Sales Team Agreement is $44.2 million, including primarily compensation costs and administrative service fees. In addition, the Company has remaining commitments under other various sales and marketing services and research and development agreements totaling $7.3 million at December 31, 2012.

Additional Contingent Payments

The Company 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, The Company has not included these potential future obligations in the above table.

In 2001, the Company entered into a Development, Licensing and Clinical Trial and Commercial Supply Agreement, or the Agreement, with MTPC, formerly Tanabe, for the development of avanafil, an oral phosphodiesterase type 5, or PDE5, inhibitor investigational drug candidate for the treatment of erectile dysfunction. The Agreement contains a number of milestone payments to be made by the

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 9. Commitments (Continued)

Company based on various triggering events. Through December 31, 2012, under the terms of the Agreement, the Company has paid a total of $13.0 million to MTPC, including a $3.0 million milestone payment made in June 2012, upon FDA approval of STENDRA, or avanafil. In addition, during 2012, the Company purchased from MTPC $7.4 million of finished goods inventory under the supply portion of the Agreement in preparation for the commercial launch of STENDRA in the U.S. and certain other territories that use the U.S. approval.

The Company expects to make other substantial payments to MTPC in accordance with the Agreement as the Company continues to develop avanafil in its territories outside of the United States and, if approved for sale, commercialize avanafil for the oral treatment of male sexual dysfunction in those territories. Potential future milestone payments include $2.0 million upon the obtainment of the first regulatory approval in any major European country and $6.0 million upon achievement of $250.0 million or more in worldwide net sales during any calendar year.

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) 10 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 August 2012, the Company entered into an amendment to the Agreement with MTPC which, among other matters, allows the Company to manufacture the API and STENDRA tablets for avanafil and expands its rights to develop and commercialize avanafil for all indications. The amendment permits the Company to manufacture the API and STENDRA tablets for avanafil itself or through a third-party supplier at any time; however, the transition away from MTPC supply will need to occur on or before June 2015. On February 21, 2013, the Company entered into the third amendment to its agreement with MTPC which, among other things, expands the Company's rights, or those of its sublicensees, to enforce the patents licensed under the MTPC agreement against alleged infringement, and clarifies the rights and duties of the parties and our sublicensees upon termination of the MTPC agreement. In addition, the Company is obligated to use its best commercial efforts to market STENDRA in the U.S. by December 31, 2013.

In October 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 the Company's investigational drug candidate development program for Qsymia 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, through December 31, 2012, the Company has paid a total of $1.2 million and has issued fully vested and exercisable options to purchase 60,000 shares of the Company's common stock to Dr. Najarian. In addition, the Assignment Agreement 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

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 9. Commitments (Continued)

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.

Note 10. Income Taxes

Deferred income taxes result from differences in the recognition of expenses for tax and financial reporting purposes, as well as operating loss and tax credit carryforwards. Significant components of the Company's deferred income tax assets as of December 31, 2012 and 2011 are as follows (in thousands):

	2012	2011
Deferred tax assets:		
Net operating loss carry forwards	$ 154,865	$ 107,241
Research and development credit carry forwards	13,192	14,468
Stock based compensation	9,386	
Accruals and other	5,528	13,197
Depreciation	185	790
Deferred revenue	420	
	183,576	135,696
Valuation allowance	(183,576)	(135,696)
Total	$	$

The net increase in the valuation allowance for the years ended December 31, 2012, 2011 and 2010 was $47.9 million, $22.6 million and $22.1 million, respectively. As of December 31, 2012, 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 $449.0 million and $118.1 million are available to reduce future taxable income, if any. ASC 718 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 ASC 718, the unrecognized deferred tax benefits totaled $16.0 million, of 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 $11.5 million and $2.6 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 2032. 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. Utilization of the net operating loss and tax credit carry-forwards is subject to an annual limitation due to an ownership change, as defined by the IRS code section 382, that we believe to have occurred based on the preliminary results of the Company's section 382 analysis. Although the section 382 analysis is pending final review and conclusion, none of the net operating loss or tax credit carry-forwards is anticipated to expire as a result of the ownership change. Any future changes of ownership could result in the expiration of net operating losses or credits before utilization.

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 10. Income Taxes (Continued)

The (benefit)/provision for income taxes is based upon (loss)/income from continuing operations before (benefit)/provision for income taxes as follows, for the years ended December 31, 2012, 2011 and 2010 (in thousands):

	2012	2011	2010
Loss before income taxes:			
Domestic	$ (138,599)	$ (46,836)	$ (75,425)
International	(1,107)		
Loss before taxes	$ (139,706)	$ (46,836)	$ (75,425)

The (benefit)/provision for income taxes consists of the following components for the years ended December 31, 2012, 2011 and 2010 (in thousands):

Continuing Operations:

	2012	2011	2010
Current			
Federal	$	$	$
State	27	190	9
Foreign			
Total current (benefit)/provision for income taxes	$ 27	$ 190	$ 9
Deferred			
Federal	$	$	$
State			
Foreign			
Total deferred benefit for income taxes	$	$	$
Total (benefit)/provision for income taxes from continuing operations	$ 27	$ 190	$ 9

Discontinued Operations:

	2012	2011	2010
Total (benefit)/provision for income taxes from discontinued operations	$	$	$ 29

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 10. Income Taxes (Continued)

Reconciliation between the U.S. federal statutory tax rate and the Company's effective tax rate from continuing operations is as follows, for the years ended December 31, 2012, 2011 and 2010:

	2012	2011	2010
Tax at U.S. federal statutory rate	(35)%	(35)%	(35)%
Change in valuation allowance	34	38	35
Permanent items	1	1	1
Extinguishment of debt			3
Tax credits		(4)	(4)
Effective tax rate	0%	0%	0%

The total gross unrecognized tax benefits as of December 31, 2012 is $1.2 million and relates to state tax exposures, of which $160,000 would affect the effective tax rate if recognized.

A reconciliation of the beginning and ending amount of unrecognized tax benefits in 2012 and 2011 is as follows (in thousands):

	2012	2011	2010
Unrecognized tax benefits as of January 1	$ 1,215	$ 1,171	$
Gross increase/(decrease) for tax positions of prior years		44	1,171
Gross increase/(decrease) for tax positions of current year			
Settlements			
Lapse of statute of limitations			
Unrecognized tax benefits balance at December 31	$ 1,215	$ 1,215	$ 1,171

The total unrecognized tax benefits as of December 31, 2012 of $1.2 million includes approximately $1.1 million of unrecognized tax benefits that have been netted against the related deferred tax assets. The remaining balance recorded on the Company's consolidated balance sheets as of December 31, 2012 and 2011 is as follows (in thousands):

	2012	2011
Total unrecognized tax benefits	$ 1,215	$ 1,215
Amounts netted against deferred tax assets	(1,055)	(1,055)
Unrecognized tax benefits recorded on consolidated balance sheets	$ 160	$ 160

As of January 1, 2012, the Company had accrued $33,000 for payment of interest and penalties related to unrecognized tax benefits. To the extent accrued interest and penalties do not ultimately become payable, amounts accrued will be reduced and reflected as a reduction of the overall income tax provision in the period that such determination is made. During 2012, $6,000 of interest was recognized.

Although the Company files U.S. federal, various state, and foreign tax returns, the Company's only major tax jurisdictions are the U.S., California and New Jersey. The Company's income tax return for the year ended December 31, 2007 is currently under examination by the California Franchise Tax

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 10. Income Taxes (Continued)

Board. Based on the progress of the audit to date, the Company believes adjustments may be made in early years that will reduce tax attributes available to offset tax due in 2007. Therefore, the Company has $160,000 of unrecognized tax benefits recorded on its consolidated balance sheets as of December 31, 2012.

The Internal Revenue Service completed their audit of the Company's income tax return for the years ended December 31, 2007 and 2008 with no adjustments. The Company is currently under examination by the State of New Jersey for the years ended December 31, 2007 through 2009. Because the Company used net operating loss carryforwards and other tax attributes to offset its taxable income on its 2007 income tax returns for U.S. Federal and California, such attributes can be adjusted by these taxing authorities until the statute closes on the year in which such attributes were utilized. Tax years 1991 to 2012 remain subject to examination by the appropriate governmental agencies due to tax loss carryovers from those years.

The Company is in various stages of the examination process in connection with all of its tax audits and it is difficult to determine when these examinations will be settled. It is reasonably possible that over the next twelve-month period the Company may experience an increase or decrease in its unrecognized tax benefits. It is not possible to determine either the magnitude or range of any increase or decrease at this time.

Note 11. Concentration of Customers and Suppliers

Revenues from significant customers as a percentage of total revenues for the year ended December 31, 2012 is as follows:

	2012
CVS	50%
Walgreens	39%
Express Scripts, Inc.	10%

Accounts receivable at December 31, 2012 by significant customer as a percentage of the total gross accounts receivable balance are as follows:

	2012
CVS	51%
Walgreens	44%
Express Scripts, Inc.	1%

The Company relies on third-party sole-source manufacturers to produce its clinical trial materials, raw materials and finished goods. Catalent Pharma Solutions, LLC, or Catalent, who supplied the product for the Phase 3 program for Qsymia, is the Company's sole source of clinical and commercial supplies for Qsymia. MTPC is currently the Company's sole-source supplier for the API and the tablets for STENDRA (avanafil). In August 2012, the Company entered into an amendment to its agreement with MTPC that permits the Company to manufacture the API and STENDRA tablets for avanafil itself or through third-party suppliers at any time. The transition away from MTPC supply will need to occur on or before June 2015. The Company does not have any manufacturing facilities and intends to continue to rely on third parties for the supply of the starting materials, API and tablets. Third-party

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 11. Concentration of Customers and Suppliers (Continued)

manufacturers may not be able to meet the Company's needs with respect to timing, quantity or quality.

The Company has entered into an agreement with PDI, Inc., or PDI, a third-party contract sales organization, to assist with the hiring of sales representatives and the promotion of Qsymia to physicians. Although alternative third-party contract sales organizations exist, the Company would be adversely affected if PDI does not perform its obligations under the agreement.

During the year ended December 31, 2012, the Company incurred expenses for work performed by a third-party clinical research organization, or CRO, for Qsymia and STENDRA post-approval studies which accounted for 13% of total research and development expenses. During the year ended December 31, 2011, the Company did not have any third-party CROs who accounted for ten percent or more of total research and development expenses. In the year ended December 31, 2010, the Company incurred expenses for work performed by its CROs for Qsymia Phase 3 and avanafil Phase 3 studies and for clinical supplies and formulation work provided by its third-party manufacturer which accounted for ten percent or more of total research and development expenses as shown below:

	2010
Qsymia Phase 3 studies CRO	20%
Avanafil Phase 3 studies CRO	20%
Clinical supplies and formulation work	12%

Note 12. 401(k) Plan

All of the Company's full-time employees are eligible to participate in the VIVUS 401(k) Plan. Employer-matching contributions for the years ended December 31, 2012, 2011 and 2010 were $329,000, $181,000 and $353,000, respectively. In the year ended December 31, 2010, $158,000 of the $353,000 employer-matching contribution was related to discontinued operations.

Note 13. Discontinued Operations

On November 5, 2010, the Company closed on the sale to Meda AB, or Meda, of certain rights and assets related to MUSE, transurethral alprostadil, for the treatment of erectile dysfunction, or the MUSE Transaction. Meda had been the Company's European distributor of MUSE since 2002. The assets sold in the MUSE Transaction include the U.S. and foreign MUSE patents, existing inventory, and the manufacturing facility located in Lakewood, New Jersey. The Company retained all of the liabilities associated with the pre-closing operations and products of the MUSE business and the accounts receivable for pre-closing MUSE sales. Prior to the closing of the MUSE Transaction, the Company terminated all of the rights to MUSE and avanafil held by Deerfield Management Company, L.P. and affiliates and by Crown Bank, N. A. as collateral to the Company's notes payable. Under the terms of the MUSE Transaction, the Company received an upfront payment of $22.0 million upon the closing and is eligible to receive an additional $1.5 million based on future sales of MUSE, provided that certain sales milestones are reached. The Company has not received any sales milestones to date and does not anticipate that these sales milestones will be achieved in the near future. Post-closing, Meda is responsible for the manufacturing, selling and marketing of MUSE. Meda also assumed all post-closing expenses and liabilities associated with MUSE. The Company has agreed not

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 13. Discontinued Operations (Continued)

to develop, manufacture or sell any transurethral erectile dysfunction drugs for a period of three years following the closing of the MUSE Transaction.

The sale of the MUSE product and certain related assets has been reported as discontinued operations in the consolidated statements of operations for all periods presented, because (i) the MUSE product and related assets have identifiable cash flows that are largely independent of the cash flows of other groups of assets and liabilities, (ii) the Company does not have any significant continuing involvement with the product after the close of the transaction, and (iii) the cash milestone payment to be received upon achievement of certain sales levels is considered an indirect cash flow. There are no assets related to the MUSE operations for the periods presented. The liabilities related to the MUSE operations are reported as liabilities of discontinued operations in the consolidated balance sheets for all periods presented. The extinguishment of the largest liability of the discontinued operations, accrued product returns, will be settled in accordance with the returns policy and by cash payments made to former customers for the return of expired MUSE product sold by VIVUS. The return window for expired MUSE product will end in August 2013.

Note 14. Legal Matters

Securities Related Class Action Lawsuits

The Company and two of its officers were defendants in a putative class action lawsuit captioned *Kovtun v. Vivus, Inc., et al.*, Case No. 4:10-CV-04957-PJH, in the U.S. District Court, Northern District of California. The action, filed in November 2010, alleged violations of Section 10(b) and 20(a) of the federal Securities Exchange Act of 1934 based on allegedly false or misleading statements made by the defendants in connection with the Company's clinical trials and NDA for Qsymia as a treatment for obesity. In the Amended Class Action Complaint filed on April 4, 2011, the plaintiff alleged generally that the defendants misled investors regarding the prospects for Qsymia's NDA approval, and the drug's efficacy and safety. On June 3, 2011, the defendants filed a motion to dismiss, which, after briefing and argument was granted but extending plaintiff leave to amend. On November 9, 2011, plaintiff filed his Second Amended Class Action Complaint, again generally alleging that the defendants misled investors regarding the prospects for Qsymia's NDA approval, and Qsymia's efficacy and safety. On December 30, 2011, defendants filed a motion to dismiss the Second Amended Complaint. Briefing concluded in late March 2012, and the motion was argued to the Court on April 18, 2012. On September 27, 2012, Judge Phyllis J. Hamilton granted defendants' motion to dismiss the Second Amended Complaint and dismissed the action with prejudice. She entered final judgment for defendants the same day. On October 26, 2012, plaintiff filed a Notice of Appeal to the U.S. Court of Appeals for the Ninth Circuit. Plaintiff filed his opening appellate brief on February 19, 2013. Briefing is expected to continue into April 2013.

Additionally, certain of the Company's officers and directors are defendants in a shareholder derivative lawsuit captioned *Turberg v. Logan, et al.*, Case No. CV-10-05271-PJH, pending in the same federal court. In the plaintiff's Verified Amended Shareholder Derivative Complaint filed June 3, 2011, the plaintiff largely restated the allegations of the *Kovtun* action and alleged that the directors breached fiduciary duties to the Company by purportedly permitting the Company to violate the federal securities laws as alleged in the *Kovtun* action. The parties had agreed to stay the litigation pending resolution of the defendants' second motion to dismiss in the *Kovtun* action, but have now extended that stay through resolution of the appeal. The same individuals are also named defendants in

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 14. Legal Matters (Continued)

consolidated shareholder derivative suits pending in the California Superior Court, Santa Clara County under the caption *In re VIVUS, Inc. Derivative Litigation,* Master File No. 11 0 CV188439. The allegations in the state court derivative suits are substantially similar to the other lawsuits. The parties have agreed to stay these consolidated actions on the same terms as the federal derivative litigation.

Other Matters

In the normal course of business, the Company receives claims and makes inquiries regarding patent and trademark infringement and other related legal matters. The Company believes that it has meritorious claims and defenses and intends to pursue any such matters vigorously. Additionally, the Company in the normal course of business may become involved in lawsuits and subject to various claims from current and former employees including wrongful termination, sexual discrimination and employment matters. Employees may be more likely to file employment-related claims following termination of their employment. 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 and its directors believe that the various shareholder lawsuits are without merit, and they intend to vigorously defend the various actions.

Note 15. Subsequent Events (Unaudited)

On February 21, 2013, the Company entered into the third amendment to its agreement with MTPC which, among other things, expands the Company's rights, or those of its sublicensees, to enforce the patents licensed under the MTPC agreement against alleged infringement, and clarifies the rights and duties of the parties and our sublicensees upon termination of the MTPC agreement. In addition, the Company is obligated to use its best commercial efforts to market STENDRA in the U.S. by December 31, 2013.

On February 21, 2013, the CHMP confirmed its October 18, 2012 decision to deny the MAA for Qsiva (phentermine/topiramate ER) for the treatment of obesity in the EU.

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VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 16. Selected Financial Data (Unaudited)

Selected Quarterly Financial Data (in thousands)

	Quarter Ended,			
	March 31	June 30	September 30	December 31
2012				
Total revenue	$	$	$ 41	$ 1,971
Total gross profit	$	$	$ 37	$ 1,788
Operating expenses	$ 18,772	$ 24,317	$ 40,573	$ 58,255
Net loss from continuing operations	$ (18,762)	$ (24,266)	$ (40,476)	$ (56,229)
Net income (loss) from discontinued operations	$ (16)	$ 218	$ 80	$ (430)
Basic and diluted net income (loss) per share:				
Continuing operations	$ (0.20)	$ (0.24)	$ (0.40)	$ (0.56)
Discontinued operations	$ 0.00	$ 0.00	$ 0.00	$ 0.00
2011				
Operating expenses	$ 9,908	$ 16,338	$ 8,941	$ 11,889
Net loss from continuing operations	$ (9,867)	$ (16,304)	$ (8,812)	$ (12,043)
Net income from discontinued operations	$ 14	$ 107	$ 185	$ 580
Basic and diluted net income (loss) per share:				
Continuing operations	$ (0.12)	$ (0.20)	$ (0.10)	$ (0.14)
Discontinued operations	$ 0.00	$ 0.00	$ 0.00	$ 0.01

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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)

Each of the following valuation and qualifying accounts are reported as assets and liabilities of continuing and discontinued operations in the consolidated balance sheets for all periods presented.

	Balance at Beginning of Period	Charged to Operations	Charges Utilized	Balance at End of Period
Allowance for Doubtful Accounts and Cash Discounts				
Fiscal year ended December 31, 2010	$ (114)	$ (285)	$ 399	$
Fiscal year ended December 31, 2011				
Fiscal year ended December 31, 2012		53	4	57
Inventory Reserve				
Fiscal year ended December 31, 2010	1,574	(353)	(1,221)(1)	
Fiscal year ended December 31, 2011				
Fiscal year ended December 31, 2012				
Accrued Product Returns				
Fiscal year ended December 31, 2010	3,026	906	(1,334)	2,598
Fiscal year ended December 31, 2011	2,598	(317)	(658)	1,623
Fiscal year ended December 31, 2012	1,623	(45)	(880)	698
Accrued Chargebacks Reserve				
Fiscal year ended December 31, 2010	1,617	3,103	(4,248)	472
Fiscal year ended December 31, 2011	472	(278)	(194)	
Fiscal year ended December 31, 2012	$	$ 131	$ (131)	$

(1) The Company used $98,000 of its fully reserved component parts inventory and $367,000 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***

(a.) Evaluation of disclosure 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.

(b.) Changes in internal controls. To address changes in our business in conjunction with the commercial launch of Qsymia, we have deployed new processes and systems related to our inventory, cost of goods sold, revenue, cash receipts and receivables. In doing so, we have modified and enhanced our internal control over financial reporting (as such term is defined in Exchange Act Rule 13a-15(f)) during the period covered by this Annual Report on Form 10-K as a result of the implementation of these new processes and systems. Other than the above-mentioned changes, there have been no significant changes in our internal control over financial reporting that occurred during the period covered by this Annual Report on Form 10-K that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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.

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

Management has used the framework set forth in the report entitled Internal Control Integrated Framework published by the Committee of Sponsoring Organizations of the Treadway Commission, known as COSO, to evaluate the effectiveness of the Company's internal control over financial reporting. Based on this assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2012. OUM & 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, 2012. This report, which expresses an unqualified opinion on the effectiveness of our internal controls over financial reporting as of December 31, 2012, 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***

On February 20, 2013, the Company's Board of Directors approved the amendment in its entirety of Article II, Section 2.7 of the Company's Amended and Restated Bylaws to confirm and clarify that the required vote in the election of directors shall be a plurality rather than a majority of the shares voted, such that the nominees for director receiving the highest number of affirmative votes of the shares present or represented and entitled to vote for them shall be elected as directors whether or not such affirmative votes constitute a majority of the shares voted. Amendment No. 1 to the Amended and Restated Bylaws of the Company is filed herewith as Exhibit 3.3.

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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," "Board Committees" 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 2013 Annual Meeting of Stockholders. The information required by Section 16(a) is incorporated by reference from the information under the caption "Section 16(a) Beneficial Ownership Reporting Compliance" 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 provisions 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 "Compensation Committee Interlocks and Insider Participation," "Executive Compensation" and "Report of the Compensation Committee of the Board of Directors" 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, 2012 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	8,220,917	$ 10.33	5,347,493
Equity compensation plans not approved by stockholders(b)	325,000	$ 10.19	
Total	8,545,917	$ 10.32	5,347,493

(a) Consists of two plans: our 2001 Stock Option Plan and our 2010 Stock Option Plan.

(b) On April 30, 2010, the Company's Board of Directors granted an option to purchase 400,000 shares of the Company's common stock, or the Inducement Grant, to Michael P. Miller, the Company's Senior Vice President and Chief Commercial Officer. The Inducement Grant was granted outside of the Company's 2010 Plan and without stockholder approval pursuant to NASDAQ Listing Rule 5635(c)(4) and is subject to the terms and conditions of the Stand-Alone Stock Option Agreement between the Company and Michael P. Miller.

(c) Includes 4,745,966 shares for the 2010 Stock Option Plan and 601,527 shares for the 1994 Employee Stock Purchase Plan.

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

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

The information required by this item is incorporated by reference from the information under the caption "Certain Relationships and Related Transactions" and "Board Independence" 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 Registered Public Accounting Firm" 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 88 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 Refer to Item 15(b) immediately below.

(b)

The exhibits required by Item 601 of Regulation S-K are listed in the Exhibit Index immediately preceding the exhibits and are incorporated herein.

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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: February 26, 2013

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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	February 26, 2013
/s/ MARK B. LOGAN Mark B. Logan	Chairman of the Board and Director	February 26, 2013
/s/ PETER Y. TAM Peter Y. Tam	President and Director	February 26, 2013
/s/ TIMOTHY E. MORRIS Timothy E. Morris	Sr. Vice President Finance and Global Corporate Development, Chief Financial Officer (Principal Financial Officer)	February 26, 2013
/s/ LEE B. PERRY Lee B. Perry	Vice President and Chief Accounting Officer (Principal Accounting Officer)	February 26, 2013
/s/ ERNEST MARIO Ernest Mario	Director	February 26, 2013
/s/ CHARLES J. CASAMENTO Charles J. Casamento	Director	February 26, 2013
/s/ LINDA M. DAIRIKI SHORTLIFFE, M.D. Linda M. Dairiki Shortliffe, M.D.	Director	February 26, 2013

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VIVUS, INC.
REPORT ON FORM 10-K FOR
THE YEAR ENDED DECEMBER 31, 2012
EXHIBIT INDEX

Exhibit Number	Description
2.1	Asset Purchase Agreement between the Registrant and K-V Pharmaceutical Company dated as of March 30, 2007
3.1(1)	Amended and Restated Certificate of Incorporation of the Registrant
3.2(2)	Amended and Restated Bylaws of the Registrant
3.3	Amendment No. 1 to the Amended and Restated Bylaws of the Registrant
3.4(3)	Amended and Restated Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock of the Registrant
4.1(4)	Specimen Common Stock Certificate of the Registrant
4.2(5)	Preferred Stock Rights Agreement dated as of March 27, 2007 between the Registrant and Computershare Investor Services, LLC
10.1(6)*	Form of Indemnification Agreement by and among the Registrant and the Directors and Officers of the Registrant
10.2(7)*	1994 Employee Stock Purchase Plan, as amended, Form of Subscription Agreement and Form of Notice of Withdrawal
10.3(8)*	2001 Stock Option Plan and Form of Agreement thereunder
10.4(9)*	2001 Stock Option Plan, as amended on July 12, 2006
10.5(10)*	Form of Notice of Grant and Restricted Stock Unit Agreement under the VIVUS, Inc. 2001 Stock Option Plan
10.6(11)*	2010 Equity Incentive Plan and Form of Agreement thereunder
10.7(12)*	Stand-Alone Stock Option Agreement with Michael P. Miller dated as of April 30, 2010
10.8(13)*	Employment Agreement dated December 20, 2007 between the Registrant and Leland F. Wilson
10.9(14)*	First Amendment dated January 23, 2009 to the Employment Agreement dated December 20, 2007 by and between the Registrant and Leland F. Wilson
10.10(15)*	Second Amendment dated January 21, 2011 to the Employment Agreement dated December 20, 2007 by and between the Registrant and Leland F. Wilson
10.11(16)*	Third Amendment dated January 27, 2012 to the Employment Agreement dated December 20, 2007 by and between the Registrant and Leland F. Wilson
10.12(17)*	Fourth Amendment dated January 25, 2013 to the Employment Agreement dated December 20, 2007 by and between the Registrant and Leland F. Wilson
10.13(18)*	Form of Change of Control and Severance Agreement by and between the Registrant and Certain of its Executive Officers
10.14(19)*	Change of Control and Severance Agreement dated April 30, 2010 by and between the Registrant and Michael P. Miller

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Exhibit Number	Description
10.15	Agreement effective as of December 28, 2000 between the Registrant and Tanabe Seiyaku Co., Ltd.
10.16(20)	Amendment No. 1 effective as of January 9, 2004 to the Agreement effective as of December 28, 2000 between the Registrant and Tanabe Seiyaku Co., Ltd.
10.17(21)	Termination and Release executed by Tanabe Holding America, Inc. dated May 1, 2007
10.18(22)	Second Amendment effective as of August 1, 2012 to the Agreement dated as of December 28, 2000 between the Registrant and Mitsubishi Tanabe Pharma Corporation (formerly Tanabe Seiyaku Co., Ltd.)
10.19(23)	Third Amendment effective as of February 21, 2013 to the Agreement dated as of December 28, 2000 between the Registrant and Mitsubishi Tanabe Pharma Corporation (formerly Tanabe Seiyaku Co., Ltd.)
10.20	Settlement and Modification Agreement dated July 12, 2001 between ASIVI, LLC, AndroSolutions, Inc., Gary W. Neal and the Registrant
10.21(24)	Assignment Agreement between Thomas Najarian, M.D. and the Registrant dated October 16, 2001
10.22(25)	Testosterone Development and Commercialization Agreement dated as of February 7, 2004 between the Registrant, Fempharm Pty Ltd. and Acrux DDS Pty Ltd.
10.23(26)	Estradiol Development and Commercialization Agreement dated as of February 12, 2004 between the Registrant, Fempharm Pty Ltd. and Acrux DDS Pty Ltd.
10.24(27)	Master Services Agreement dated as of September 12, 2007 between the Registrant and Medpace, Inc.
10.25(28)	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
10.26	Asset Purchase Agreement dated October 1, 2010 between the Registrant, MEDA AB and Vivus Real Estate, LLC
10.27	Transition Services Agreement dated November 5, 2010 between the Registrant and MEDA AB
10.28(29)	Commercial Manufacturing and Packaging Agreement by and between the Registrant and Catalent Pharma Solutions, LLC dated as of July 17, 2012
10.29(30)	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, The Duerkson Family Trust dated February 16, 1999, The Dutton Family Trust dated September 16, 1993, The Noel S. Schuurman Trust, The Duarte Family Partners, L.P., The Marie Antoinette Clough Revocable Living Trust dated January 11, 1989, Blue Oak Properties, Inc., and CP6CC, LLC
10.30(31)	First Amendment to Lease dated November 18, 2008 between Castro Mountain View, LLC, CP6CC, LLC and the Registrant
10.31(32)	Second Amendment to Lease effective November 12, 2009 between Castro Mountain View, LLC, CP6CC, LLC and the Registrant

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Exhibit Number	Description
10.32(33)	Third Amendment to Lease effective December 3, 2010 between Castro Mountain View, LLC, CP6CC, LLC and the Registrant
10.33(34)	Fourth Amendment to Lease effective February 14, 2012 between Castro Mountain View, LLC, CP6CC, LLC and the Registrant
10.34	Lease Agreement effective December 11, 2012 by and between the Registrant and SFERS Real Estate Corp. U
21.1	Subsidiaries of the Registrant
23.1	Consent of OUM & Co. LLP, Independent Registered Public Accounting Firm
24.1	Power of Attorney (See signature page)
31.1	Certification of Chief Executive Officer 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 pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended
32.1	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
101	The following materials from the Registrant's Quarterly Report on Form 10-K for the year ended December 31, 2012, formatted in Extensible Business Reporting Language (XBRL), include: (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Comprehensive Loss, (iv) the Consolidated Statements of Cash Flows, and (v) related notes (furnished herewith).

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.

*

Indicates management contract or compensatory plan or arrangement.

(1)

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 filed with the Commission on March 28, 1997.

(2)

Incorporated by reference to the same numbered exhibit filed with the Registrant's Current Report on Form 8-K filed with the Commission on April 20, 2012.

(3)

Incorporated by reference to Exhibit 3.3 filed with the Registrant's Registration Statement on Form 8-A filed with the Commission on March 28, 2007.

(4)

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 filed with the Commission on April 16, 1997.

(5)

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.

(6) Incorporated by reference to Exhibit 10.11 filed with the Registrant's Form 8-B filed with the Commission on June 25, 1996.

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(7) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on July 29, 2011.

(8) Incorporated by reference to Exhibit 10.44 filed with the Registrant's Registration Statement on Form S-8 filed with the Commission on November 15, 2001.

(9) 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.

(10) 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.

(11) Incorporated by reference to Exhibit 10.7 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 filed with the Commission on March 1, 2011.

(12) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on May 6, 2010.

(13) 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.

(14) 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.

(15) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on January 26, 2011.

(16) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on January 27, 2012.

(17) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on January 30, 2013.

(18) 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.

(19) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on April 30, 2010.

(20) Incorporated by reference to Exhibit 10.42A filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2004 filed with the Commission on May 7, 2004.

(21) Incorporated by reference to Exhibit 10.61 filed with the Registrant's Current Report on Form 8-K filed with the Commission on May 4, 2007.

(22)

Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on August 10, 2012.

(23)

Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on February 25, 2013.

(24)

Incorporated by reference to Exhibit 10.79 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2009 filed with the Commission on March 10, 2010.

(25)

Incorporated by reference to Exhibit 10.50 filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2004 filed with the Commission on May 7, 2004.

(26)

Incorporated by reference to Exhibit 10.51 filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2004 filed with the Commission on May 7, 2004.

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(27)

Incorporated by reference to Exhibit 10.62 filed with the Registrant's Current Report on Form 8-K filed with the Commission on September 18, 2007.

(28)

Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K/A filed with the Commission on July 15, 2009.

(29)

Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on July 23, 2012.

(30)

Incorporated by reference to Exhibit 10.60 filed with the Registrant's Current Report on Form 8-K filed with the Commission on November 7, 2006.

(31)

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.

(32)

Incorporated by reference to Exhibit 10.78 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2009 filed with the Commission on March 10, 2010.

(33)

Incorporated by reference to Exhibit 10.28 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 filed with the Commission on March 1, 2011.

(34)

Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on February 16, 2012.