

# VIVUS INC

## FORM 10-K (Annual Report)

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 10-K**

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

For the fiscal year ended December 31, 2013

OR

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

For the transition period from                      to

Commission File Number 001-33389

**VIVUS, INC.**

(Exact name of Registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**94-3136179**  
(IRS employer  
identification number)

**351 E. Evelyn Avenue**  
**Mountain View, California**  
(Address of principal executive office)

**94041**  
(Zip Code)

Registrant's telephone number, including area code: **(650) 934-5200**

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

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

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

**None**

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

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

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark 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  No

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.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer   
(Do not check if a smaller reporting company)

Smaller reporting company

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

The aggregate market value of the common equity held by non-affiliates of the Registrant as of June 30, 2013, totaled approximately \$1,262,994,990 based on the closing stock price as reported by the NASDAQ Global Market.

As of February 19, 2014, there were 103,301,701 shares of the Registrant's common stock, \$0.001 par value per share, outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

<u>Document Description</u>	<u>10-K part</u>
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, 2013, are incorporated by reference into Part III of this report.	III, ITEMS 10, 11, 12, 13, 14

**VIVUS, INC.**  
**FISCAL 2013 FORM 10-K**  
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Certification of Chief Executive Officer

Certification of Chief Financial Officer

Certification of Chief Executive Officer and Chief Financial Officer

**PART I**  
**FORWARD-LOOKING STATEMENTS**

*This Form 10-K contains "forward-looking" statements that involve risks and uncertainties. These statements typically may be identified by the use of forward-looking words or phrases such as "may," "believe," "expect," "forecast," "intend," "anticipate," "predict," "should," "planned," "likely," "opportunity," "estimated," and "potential," the negative use of these words or other similar words. All forward-looking statements included in this document are based on our current expectations, and we assume no obligation to update any such forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for such forward-looking statements. In order to comply with the terms of the safe harbor, we note that a variety of factors could cause actual results and experiences to differ materially from the anticipated results or other expectations expressed in such forward-looking statements. The risks and uncertainties that may affect the operations, performance, development, and results of our business include but are not limited to: (1) our 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 we 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 requirements; (5) our ability to continue to certify and add to the Qsymia retail pharmacy network and sell Qsymia through this network; (6) whether the Qsymia retail pharmacy network will simplify and reduce the prescribing burden for physicians, improve access and reduce waiting times for patients seeking to initiate therapy with Qsymia; (7) that we may be required to provide further analysis of previously submitted clinical trial data; (8) our assessment of the European Medicines Agency's Scientific Advice relating to our cardiovascular outcomes trial, or CVOT, and the resubmission of an application for the grant of a marketing authorization to the European Medicines Agency, or EMA, the timing of such resubmission, if any, the results of the CVOT, assessment by the EMA of the application for marketing authorization, and their agreement with the data from the CVOT; (9) our ability to successfully seek approval for Qsymia in other territories outside the U.S. and European Union, or EU; (10) whether healthcare providers, payors and public policy makers will recognize the significance of the American Medical Association officially recognizing obesity as a disease, or the new American Association of Clinical Endocrinologists guidelines; (11) our ability to successfully commercialize Qsymia including risks and uncertainties related to expansion to retail distribution, the broadening of payor reimbursement, the expansion of Qsymia's primary care presence, and the outcomes of our discussions with pharmaceutical companies and our strategic and franchise-specific pathways for Qsymia; (12) our ability to focus our promotional efforts on health-care providers and on patient education that, along with increased access to Qsymia and ongoing improvements in reimbursement, will result in the accelerated adoption of Qsymia; (13) our ability to eliminate expenses that are not essential to expanding the use of Qsymia and fully realize the anticipated benefits from a cost reduction plan, including the timing thereof; (14) the impact of lower annual net cost savings than currently expected; (15) the impact of the cost reduction plan on our business and unanticipated charges not currently contemplated that may occur as a result of the cost reduction plan; (16) our ability to ensure that the entire supply chain for Qsymia efficiently and consistently delivers Qsymia to our customers; (17) risks and uncertainties related to the timing, strategy, tactics and success of the launches and commercialization of STENDRA™ (avanafil) or SPEDRA™ (avanafil) by our sublicensees in the United States, Canada, the EU, Australia, New Zealand, Africa, the Middle East, Turkey, and the Commonwealth of Independent States, including Russia; (18) our ability to successfully complete on acceptable terms, and on a timely basis, avanafil partnering discussions for other territories under our license with Mitsubishi Tanabe Pharma Corporation in which we do not have a commercial collaboration; (19) the timing of the qualification and subsequent approval by regulatory authorities of Sanofi Chimie and Sanofi Winthrop Industrie as a qualified supplier of STENDRA/SPEDRA, Sanofi Chimie's ability to undertake worldwide manufacturing of the avanafil active pharmaceutical ingredient and Sanofi Winthrop Industrie's ability to undertake worldwide manufacturing of the tablets for avanafil; (20) whether the FDA will approve the amendment for the new*

*prescribing information we have submitted, and/or the European Commission, following an opinion by the EMA, will approve the new prescribing information we intend to submit, to include the recently announced clinical study results showing avanafil is effective for sexual activity within 15 minutes in men with erectile dysfunction; (21) the ability of our partners to maintain regulatory approvals to manufacture and adequately supply our products to meet demand; (22) our ability to accurately forecast Qsymia demand; (23) our ability to increase Qsymia sales in 2014 through growth in certified retail pharmacies, expansion of reimbursement coverage and the use of a more focused selling message; (24) the number of Qsymia prescriptions dispensed through the mail order system and through certified retail pharmacies; (25) the impact of promotional programs for Qsymia on our net product revenue and net income (loss) in future periods; (26) our history of losses and variable quarterly results; (27) substantial competition; (28) risks related to the failure to protect our intellectual property and litigation in which we may become involved; (29) uncertainties of government or third-party payor reimbursement; (30) our reliance on sole-source suppliers; (31) our reliance on third parties and our collaborative partners; (32) our failure to continue to develop innovative investigational drug candidates and drugs; (33) risks related to the failure to obtain FDA or foreign authority clearances or approvals and noncompliance with FDA or foreign authority regulations; (34) our ability to demonstrate through clinical testing the quality, safety, and efficacy of our investigational drug candidates; (35) the timing of initiation and completion of clinical trials and submissions to foreign authorities; (36) the results of post-marketing studies are not favorable; (37) compliance with post-marketing regulatory standards, post-marketing obligations or pharmacovigilance rules is not maintained; (38) the volatility and liquidity of the financial markets; (39) our liquidity and capital resources; (40) our expected future revenues, operations and expenditures; (41) potential change in our business strategy to enhance long-term stockholder value; (42) the impact, if any, of the expansion of our Board of Directors to include predominantly new members, the recent appointment of a new Chief Executive Officer and an interim Chief Financial Officer, the resignation of our President, the decision of our Chief Financial Officer to exercise his right to terminate his employment for Good Reason (as defined in his Amended and Restated Change of Control and Severance Agreement with the Company, effective as of July 1, 2013) and the assumption of the Chief Commercial Officer's duties and responsibilities by the Chief Executive Officer; and (43) other factors that are described from time to time in our periodic filings with the U.S. Securities and Exchange Commission, or the SEC, or the Commission, including those set forth in this filing as "Item 1A. Risk Factors."*

*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.*

## **Item 1. Business**

### **Overview**

VIVUS is a biopharmaceutical company with two FDA-approved therapies, Qsymia and STENDRA. Our drug Qsymia (phentermine and topiramate extended-release) was approved by the FDA on July 17, 2012, 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 a proprietary formulation combining 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 suppress appetite and increase satiety, or the feeling of being full, the two main mechanisms that impact eating behavior. On September 17, 2012, we announced the U.S. market availability of Qsymia through a certified home delivery network, which includes CVS Pharmacy, Express Scripts, Walgreens, Wal-Mart Pharmacy, and, for its members only, Kaiser Permanente. On July 1, 2013, we announced initial retail availability of Qsymia through approximately 8,000 Walgreens, Costco and Duane Reade

pharmacies nationwide. As of the date of this report, Qsymia is available in over 37,000 certified retail pharmacies nationwide. We intend to continue to certify and add new pharmacies to the Qsymia retail pharmacy network, including national and regional chains as well as independent pharmacies. In addition, Qsymia continues to be available through a certified home delivery pharmacy network for patients who prefer to receive Qsymia by mail.

In October 2012, we received the negative opinion from the EMA Committee for Medicinal Products for Human Use, or CHMP, recommending refusal of the marketing authorization for the medicinal product Qsiva<sup>TM</sup> in the EU (the approved trade name for Qsymia 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 requested that this opinion be re-examined by the CHMP. After re-examination, on February 21, 2013, the CHMP adopted a final opinion that reaffirmed the Committee's earlier negative opinion. On May 15, 2013, the European Commission issued a decision refusing the grant of marketing authorization for Qsiva in the EU. On September 20, 2013, we submitted a request to the EMA for Scientific Advice, a procedure similar to the U.S. Special Protocol Assessment process, regarding use of a pre-specified interim analysis from the AQCLAIM cardiovascular outcomes trial to support the resubmission of an application for a marketing authorization for Qsiva for treatment of obesity in accordance with the EU centralized procedure. Based on feedback from the EMA health authority, as well as various country health authorities associated with review of the AQCLAIM trial application, the protocol has been revised and resubmitted to the FDA. We also intend to seek approval for Qsymia in other territories outside the United States and EU. We intend to commercialize Qsymia in territories where we obtain approval through commercial collaboration agreements with third parties.

Our drug STENDRA, or avanafil, is an oral phosphodiesterase type 5, or PDE5, inhibitor that we have licensed from Mitsubishi Tanabe Pharma Corporation, or MTPC. STENDRA was approved by the FDA on April 27, 2012, for the treatment of erectile dysfunction, or ED, in the United States. On June 26, 2013, the European Commission, or EC, adopted the implementing decision granting marketing authorization for SPEDRA (the approved trade name for avanafil in the EU) for the treatment of ED in the EU. On July 5, 2013, we entered into an agreement with Menarini Group, through its subsidiary Berlin-Chemie AG, or Menarini, under which Menarini received an exclusive license to commercialize and promote SPEDRA for the treatment of ED in over 40 European countries, including the EU, plus Australia and New Zealand.

On October 10, 2013, we entered into an agreement with Auxilium Pharmaceuticals, Inc., or Auxilium, under which Auxilium received an exclusive license to commercialize and promote STENDRA in the United States and Canada. On December 11, 2013, we entered into an agreement with Sanofi under which Sanofi received an exclusive license to commercialize and promote avanafil for therapeutic use in humans in Africa, the Middle East, Turkey, and the Commonwealth of Independent States, or CIS, including Russia. Sanofi will be responsible for obtaining regulatory approval in its territories. Sanofi intends to market avanafil under the trade name SPEDRA or STENDRA. Under the license agreements with Menarini, Auxilium and Sanofi, avanafil is expected to be commercialized in over 100 countries worldwide. We are currently in discussions with potential collaboration partners to market and sell STENDRA for other territories under our license with MTPC in which we do not have a commercial collaboration.

Foreign regulatory approvals, including European Commission marketing authorization to market Qsiva in the EU, may not be obtained on a timely basis, or at all, and the failure to receive regulatory approvals in a foreign country would prevent us from marketing our products in that market, which could have a material adverse effect on our business, financial condition and results of operations.



We were incorporated in California in 1991 and reincorporated in Delaware in 1996. Our corporate headquarters is located at 351 E. Evelyn Avenue, Mountain View, California and our telephone number is (650) 934-5200.

***Our Strategy***

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

- establishing medical obesity treatment as a widely accepted and reimbursed, chronic category supported by treatment guidelines;
- expanding the use of Qsymia through targeted physician, payor and patient education;
- increased third-party payor coverage, continuing to lower out-of-pocket costs for patients with discount programs, and changes in public policy to obtain coverage for obesity under Medicare Part D;
- successfully expanding the certified retail pharmacy distribution channel for Qsymia in the United States;
- creating a pathway for centralized approval of Qsiva in Europe;
- finding the right partner for expanded Qsymia commercial promotion to a broader primary care physician audience;
- managing our alliances with Auxilium, Menarini and Sanofi, to help ensure the commercial success of avanafil; and
- managing costs.

**Products and Development Programs**

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

<u>Drug</u>	<u>Indication</u>	<u>Status</u>	<u>Commercial rights</u>
Qsymia (phentermine and topiramate extended-release)	Obesity	<i>United States</i>  New Drug Application, or NDA, approved July 2012; First commercial sale September 2012;  Expansion to retail pharmacies July 2013  <i>EU</i>  Marketing Authorization Application, or MAA, denied.	Worldwide
Qsymia (phentermine and topiramate extended-release)	Obstructive Sleep Apnea	Phase 2 study completed.	Worldwide
Qsymia (phentermine and topiramate extended-release)	Diabetes	Phase 2 study completed.	Worldwide
STENDRA (avanafil)	Erectile dysfunction	<i>United States</i>  NDA approved April 2012  <i>EU</i>  MAA granted in June 2013.  Commercial collaboration agreements with Menarini, Auxilium, and Sanofi.	Worldwide license from 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 cardiometabolic and other 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.

Qsymia was approved with a Risk Evaluation and Mitigation Strategy, or REMS, with a goal of informing prescribers and patients of reproductive potential regarding 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, patient brochure, voluntary healthcare provider training, distribution through certified home delivery and retail pharmacies, an implementation system and a time table for assessments.

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, known as AQCLAIM, 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 certain of these studies during 2014.

### ***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 10 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 and women (BMI 30 to 40 kg/m<sup>2</sup> 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 the timing of 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.

According to the American Diabetes Association, an estimated 79 million people have prediabetes and nearly two million will develop type 2 diabetes each year. Millions more are known to have metabolic syndrome, a cluster of symptoms that includes high blood pressure, large waist size, high levels of fats in the blood, and the body's inability to handle glucose, which collectively increase a person's chances of developing cardiovascular disease. Qsymia is not currently indicated for the treatment of hypertension, type 2 diabetes mellitus, prediabetes, stroke or heart disease.

In May 2013, the American Association of Clinical Endocrinologists introduced a new algorithm for the comprehensive management of weight in persons with prediabetes or type 2 diabetes in order to provide clinicians with a practical guide that considers the whole patient, the spectrum of risks and complications for the patient, and evidence-based approaches to treatment. In addition to advocating for glycemic control, the treatment algorithm focuses on obesity and prediabetes as the underlying risk factors for diabetes and associated complications, and specifically includes pharmacotherapy as part of the recommended treatment paradigm for managing weight.

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 experienced weight loss of approximately six to eight pounds. Newer agents recently approved for type 2 diabetes include Invokana® (canaglifozin) from Johnson & Johnson's Janssen Pharmaceuticals, a sodium glucose co-transporter 2, or SGLT2, inhibitor that has demonstrated modest, single-digit weight loss in clinical studies.

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 10 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 ( $p<0.05$ ).

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 SSRIs, or serotonin and norepinephrine reuptake inhibitors, or SNRIs, 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.

In October 2013, we announced new data published online in *Diabetes Care* demonstrating the effects of Qsymia on the progression to type 2 diabetes. In the study, high-risk overweight or obese patients with prediabetes and/or metabolic syndrome who were taking Qsymia over a two-year period experienced reductions of up to 78.7% in the annualized incidence rate of type 2 diabetes, in addition to losing weight. The American Association of Clinical Endocrinologists recognizes obesity and prediabetes as significant risk factors for progression to diabetes and associated complications.

The publication analyzed 475 high-risk overweight or obese patients with prediabetes and/or metabolic syndrome at baseline from the two-year SEQUEL study, for their progression to type 2 diabetes and their changes in cardiometabolic parameters. After 108 weeks, it was observed that patients receiving Qsymia, in conjunction with lifestyle modifications, experienced significant weight loss along with markedly reduced progression to type 2 diabetes and improvements in multiple cardiometabolic disease risk factors.

Subjects in the Qsymia recommended dose (7.5mg/46mg) and top dose (15mg/92mg) treatment groups experienced reductions of 70.5% and 78.7% in the annualized incidence rate of type 2 diabetes, respectively, versus placebo, which was related to degree of weight lost (10.9% and 12.1%, respectively, versus 2.5% with placebo; ITT-MI;  $P < 0.0001$ ). Qsymia therapy was well tolerated by this subgroup over two years.

Among patients in the study taking Qsymia, common adverse events included paraesthesia (tingling in the fingers or feet), sinusitis, dry mouth, constipation, headache, and dysgeusia (change in perception of taste). The types and severity of adverse events seen in this subgroup analysis were similar to those seen in the overall SEQUEL patient population and in other clinical trials.

We are currently contemplating the timing of 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 who 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 in the U.S. 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 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 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. These studies are currently underway.

On June 19, 2013, we announced clinical study results showing avanafil is effective for sexual activity within 15 minutes in men with ED. In the 440-patient study conducted at 30 sites in the U.S., STENDRA patients achieved statistically significant improvement versus placebo in the mean

proportion of attempts that resulted in erections sufficient for successful intercourse as early as 10 minutes for the 200-mg dose and 12 minutes for the 100-mg dose following administration. The currently approved prescribing information recommends administration approximately 30 minutes before sexual activity. On January 21, 2014, we announced that the FDA had accepted a supplemental application that proposes to revise the STENDRA prescribing information with efficacy and safety information from this study. The Prescription Drug User Fee Act, or PDUFA, date for the supplemental filing is September 20, 2014. We intend to submit the above-mentioned clinical study results to peer review journals and medical society meetings for presentations. Menarini also intends to submit an application for a variation of the marketing authorization for SPEDRA to the European Commission to reflect clinical study results showing that avanafil is effective for sexual activity within 15 minutes in men with erectile dysfunction, or ED, in the Summary of Product Characteristics and the Patient Information Leaflet for the product.

We have granted an exclusive license to Menarini to commercialize and promote SPEDRA for the treatment of erectile dysfunction in over 40 European countries, including the EU, plus Australia and New Zealand. In addition, we have granted an exclusive license to Auxilium to market STENDRA in the United States and Canada. We have also granted an exclusive license to Sanofi to commercialize avanafil in Africa, the Middle East, Turkey, and the CIS, including Russia. We are currently in discussions with potential partners to commercialize STENDRA in other territories under our license with MTPC in which we do not currently have a commercial collaboration.

### *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. 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 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. A subsequent application for approval of an additional indication must also be reviewed by the FDA under the same criteria as apply to original applications, and may be denied as well. 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.

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, commercial sales, and distribution of our investigational drug candidates. We must obtain separate approvals by the comparable regulatory authorities of foreign countries before we can commence 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 was adopted in the United States. This law substantially changes 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, rules regarding prescription drug benefits under the health insurance exchanges, expansion of the 340B program, and 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.

The Affordable Care Act made significant changes to the Medicaid Drug Rebate program. Effective March 23, 2010, rebate liability expanded from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well. With regard to the amount of the rebates owed, the Affordable Care Act increased the minimum Medicaid 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; changed the calculation of the rebate for certain innovator products that qualify as line extensions of existing drugs; and capped the total rebate amount for innovator drugs at 100% of the average manufacturer price. In addition, the Affordable Care Act and subsequent legislation changed the definition of average manufacturer price. In 2012, Centers for Medicaid and Medicare Services, or CMS, the federal agency that administers the Medicare and Medicaid Drug Rebate program, issued proposed regulations to implement the changes to the Medicaid Drug Rebate program under the Affordable Care Act but has not yet issued final regulations. CMS is currently expected to release the final regulations in 2014. Finally, the Affordable Care Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government beginning in 2011. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee of \$3.0 billion in 2014 (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.

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 coverage 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. There currently is not coverage under Medicare Part D, but this could change in the future.

The Affordable Care Act also expanded the Public Health Service's 340B drug pricing discount program. 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 Affordable Care Act expanded the 340B program to include additional types of covered entities: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by the Affordable Care Act. The Affordable Care Act also obligates the Secretary of the Department of Health and Human Services to create regulations and processes to improve the integrity of the 340B program and to ensure the agreement that manufacturers must sign to participate in the 340B program obligates a manufacturer to offer the 340B price to covered entities if the manufacturer makes the drug available to any other purchaser at any price and to report to the government the ceiling prices for its drugs. The Health Resources and Services Administration is expected to issue a comprehensive proposed regulation in 2014 that will

address many aspects of the 340B program. When that regulation is finalized, it could affect our obligations under the 340B program in ways we cannot anticipate. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting.

Some states have elected not to expand their Medicaid programs by raising the income limit to 133% of the federal poverty level as permitted under the Affordable Care Act. For each state that does not choose to expand its Medicaid program, there may 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 decide which drugs they will pay for and establish reimbursement and co-pay levels. 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 reimbursement for drugs; new or increased requirements to pay prescription drug rebates to government healthcare 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. CMS has made draft National Average Drug Acquisition Cost, or NADAC, and draft National Average Retail Price, or NARP, data publicly available on at least a monthly basis. In July 2013, CMS suspended the publication of draft NARP data, pending funding decisions. In November 2013, CMS moved to publishing final, rather than draft, NADAC data and has since made updated NADAC data publicly available on a weekly 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 CMS. These data include 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 Drug 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. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. 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 Drug Rebate program. Changes to the definition of average manufacturer price and the Medicaid Drug Rebate amount under the Affordable Care Act 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 certain federal agencies and certain federal grantees, 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. 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 innovator products that are dispensed 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 EU 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.

Once an applicant receives marketing authorization in an EU Member State, through any application route, the applicant is then required to engage in pricing discussions and negotiations with a separate pricing authority in that country. The legislators, policymakers and healthcare insurance funds in the EU Member States continue to propose and implement cost-containing measures to keep healthcare costs down, due in part to the attention being paid to healthcare cost-containment and other austerity measures in the EU. Certain of these changes could impose limitations on the prices pharmaceutical companies are able to charge for their products. The amounts of reimbursement

available from governmental agencies or third-party payors for these products may increase the tax obligations on pharmaceutical companies such as ours, or may facilitate the introduction of generic competition with respect to our products. Furthermore, an increasing number of EU Member States and other foreign countries use prices for medicinal products established in other countries as "reference prices" to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere. In addition, the ongoing budgetary difficulties faced by a number of EU Member States, including Greece and Spain, have led and may continue to lead to substantial delays in payment and payment partially with government bonds rather than cash for medicinal products, which could negatively impact our revenues and profitability. Moreover, in order to obtain reimbursement of our medicinal products in some countries, including some EU Member States, we may be required to conduct clinical trials that compare the cost-effectiveness of our products to other available therapies. There can be no assurance that our medicinal products will obtain favorable reimbursement status in any country.

## **Fraud and Abuse Laws**

The healthcare industry, and thus our business, is subject to extensive federal, state, local and foreign regulation. Some of the pertinent laws have not been definitively interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. In addition, these laws and their interpretations are subject to change. Both federal and state governmental agencies continue to subject the healthcare industry to intense regulatory scrutiny, including heightened civil and criminal enforcement efforts.

The restrictions under applicable federal and state healthcare fraud and abuse laws and 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, in cash or in kind, to induce or reward the purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any healthcare items or service for which payment may be made, in whole or in part, by federal healthcare programs such as Medicare and Medicaid. This statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and prescribers, purchasers and formulary managers on the other. Further, the Affordable Care Act, among other things, clarified that a person or entity needs not to have actual knowledge of the federal Anti-Kickback statute or specific intent to violate it. In addition, the Affordable Care Act amended the Social Security Act to provide that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Law constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Although there are a number of statutory exemptions and regulatory safe harbors to the federal Anti-Kickback Law protecting certain common business arrangements and activities from prosecution or regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exemption or safe harbor may be subject to scrutiny. We seek to comply with the 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 civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. Many pharmaceutical and other healthcare companies have been

investigated and have reached substantial financial settlements with the federal government under the civil 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 civil 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, among others, 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;
- analogous state laws and regulations, such as state anti-kickback and false claims laws, 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. In addition, California, Connecticut, 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;
- the federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, requires certain pharmaceutical manufacturers to engage in extensive tracking of payments or transfers of value to physicians and teaching hospitals, maintenance of a payments database, and public reporting of the payment data. Pharmaceutical manufacturers with products for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program are required to track and report such payments. CMS recently issued a final rule implementing the Physician Payment Sunshine Act provisions and clarified the scope of the reporting obligations, as well as that applicable manufacturers must begin tracking on August 1, 2013, and must report payment data to CMS by March 31, 2014, and annually thereafter; and



- the federal Foreign Corrupt Practices Act of 1997 and other similar anti-bribery laws in other jurisdictions generally prohibit companies and their intermediaries from providing money or anything of value to officials of foreign governments, foreign political parties, or international organizations with the intent to obtain or retain business or seek a business advantage. Recently, there has been a substantial increase in anti-bribery law enforcement activity by U.S. regulators, with more frequent and aggressive investigations and enforcement proceedings by both the Department of Justice and the U.S. Securities and Exchange Commission. A determination that our operations or activities are not, or were not, in compliance with United States or foreign laws or regulations could result in the imposition of substantial fines, interruptions of business, loss of supplier, vendor or other third-party relationships, termination of necessary licenses and permits, and other legal or equitable sanctions. Other internal or government investigations or legal or regulatory proceedings, including lawsuits brought by private litigants, may also follow as a consequence.

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 significant civil, criminal and administrative penalties, damages, fines, exclusion from government-funded 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 or regulations, 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.

## **Collaboration Agreements**

### *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., now Mitsubishi Tanabe Pharma Corporation, or 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 were our primary responsibility. The MTPC agreement contains a number of milestone payments to be made by us based on various triggering events. Through December 31, 2013, under the terms of the MTPC agreement, we have paid a total of \$15.0 million in milestone payments to MTPC, including \$2.0 million in 2013, upon the grant of a marketing authorization for SPEDRA (avanafil) in the EU and \$3.0 million in 2012, upon FDA approval of STENDRA (avanafil) in the U.S. In addition, during 2013 and 2012, we purchased \$9.9 million and \$7.4 million of product, respectively, from MTPC under the supply portion of the Agreement in preparation for the commercial launch in the U.S., the EU and certain other territories that use the U.S. approval and EU marketing authorization.

We expect to make other substantial payments to MTPC in accordance with the MTPC agreement as we continue to commercialize avanafil for the oral treatment of male sexual dysfunction in our territories. Potential future milestone payments include \$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.

In August 2012, we entered into an amendment to our agreement with MTPC that permits us to manufacture the active pharmaceutical ingredient, or API, and tablets for STENDRA ourselves or through third parties. According to the amendment, the transition of manufacturing from MTPC must occur on or before June 30, 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 were obligated to use our best commercial efforts to market STENDRA in the U.S. by December 31, 2013, which was achieved by our commercialization partner, Auxilium.

On July 23, 2013, we entered into the fourth amendment to our agreement with MTPC which, among other things, changes the definition of net sales used to calculate royalties owed by us to MTPC.

#### *Menarini Group*

On July 5, 2013, we entered into a license and commercialization agreement, or the Menarini License Agreement, and a supply agreement, or the Menarini Supply Agreement, with the Menarini Group through its subsidiary Berlin-Chemie AG, or Menarini.

Under the terms of the Menarini License Agreement, Menarini received an exclusive license to commercialize and promote our drug SPEDRA™ (avanafil) for the treatment of erectile dysfunction in over 40 European countries, including the EU, plus Australia and New Zealand. Additionally, we agreed to transfer to Menarini ownership of the marketing authorization for SPEDRA in the EU for the treatment of erectile dysfunction, which was granted by the European Commission in June 2013. Each party agreed not to develop, commercialize, or in-license any other product that operates as phosphodiesterase type-5 inhibitor for the treatment of erectile dysfunction for a limited time period, subject to certain exceptions.

We are entitled to receive upfront payments, and various approval and sales milestones, plus royalties on SPEDRA sales. Menarini will also reimburse us for payments made to cover various obligations to MTPC during the term of the Menarini License Agreement. The Menarini License Agreement will terminate on a country-by-country basis in the relevant territories upon the latest to occur of the following: (i) the expiration of the last-to-expire valid VIVUS patent covering SPEDRA; (ii) the expiration of data protection covering SPEDRA; or (iii) ten (10) years after the SPEDRA product launch. In addition, Menarini may terminate the Menarini License Agreement if certain additional regulatory obligations are imposed on SPEDRA, and we may terminate the Menarini License Agreement if Menarini challenges our patents covering SPEDRA or if Menarini commits certain legal violations. Either party may terminate the Menarini License Agreement for the other party's uncured material breach or bankruptcy.

Under the terms of the Menarini Supply Agreement, we will supply Menarini with STENDRA drug product until December 31, 2018, at the latest. Menarini also has the right to manufacture STENDRA independently, provided that it continues to satisfy certain minimum purchase obligations



to us. Following the expiration of the Menarini Supply Agreement, Menarini will be responsible for its own supply of STENDRA. Either party may terminate the Menarini Supply Agreement for the other party's uncured material breach or bankruptcy, or upon the termination of the Menarini License Agreement.

*Auxilium Pharmaceuticals, Inc.*

On October 10, 2013, we entered into a license and commercialization agreement, or the Auxilium License Agreement, and a commercial supply agreement, or the Auxilium Supply Agreement, with Auxilium Pharmaceuticals, Inc., or Auxilium.

Under the terms of the Auxilium License Agreement, Auxilium received an exclusive license to commercialize and promote our drug STENDRA for the treatment of ED in the United States and Canada and their respective territories, or the Auxilium Territory. Additionally, following the completion of certain events, we have agreed to transfer to Auxilium ownership of the product marketing authorization for STENDRA for the treatment of erectile dysfunction, which was granted by the FDA in April 2012. Each party agreed not to develop, commercialize, or in-license any other product that operates as a PDE-5 inhibitor for the treatment of erectile dysfunction in the Auxilium Territory for a limited time period, subject to certain exceptions. A PDE-5 inhibitor means any product that operates as a phosphodiesterase type-5 inhibitor.

We received an upfront license fee of \$30.0 million in October 2013, and are eligible to receive various milestone payments, plus royalty payments on STENDRA sales. We are also eligible to receive a regulatory milestone payment of \$15.0 million upon approval by the FDA of a specific time of onset claim for STENDRA in the Auxilium Territory. In addition, we are eligible to receive up to an aggregate of \$255.0 million in potential milestone payments based on certain net sales targets by Auxilium. Further, we will receive royalty payments based on tiered percentages of the aggregate annual net sales of STENDRA in the Auxilium Territory on a quarterly basis. The percentage of Auxilium's aggregate annual net sales to be paid to us increases in accordance with the achievement of specific thresholds of aggregate annual net sales of STENDRA in the Auxilium Territory. If Auxilium's net sales of STENDRA in a country are reduced by certain amounts following the entry of a generic product to the market, royalty payments will be reduced by certain percentages based on such reductions. Auxilium will also reimburse us for payments made to cover various obligations to MTPC during the term of the Auxilium License Agreement.

Auxilium will receive an exclusive license, with a right to sublicense, subject to certain limitations, under certain of our trademarks, including STENDRA, to market, sell and distribute STENDRA for the treatment of ED in the Auxilium Territory. In addition, Auxilium will receive an exclusive license, with a right to sublicense, subject to certain limitations, under certain of our patents and know-how (i) to use, distribute, import, promote, market, sell, offer for sale and otherwise commercialize STENDRA for the treatment of erectile dysfunction in the Auxilium Territory; (ii) to make and have made STENDRA anywhere in the world, with certain exceptions, where STENDRA is solely for use or sale for the treatment of erectile dysfunction in the Auxilium Territory; and (iii) to conduct certain development activities on STENDRA for the treatment of erectile dysfunction in support of obtaining regulatory approval in the Auxilium Territory.

Auxilium will obtain STENDRA exclusively from us for a mutually agreed term pursuant to the Auxilium Supply Agreement, as further described below. Auxilium may elect to transfer the control of the supply chain for STENDRA for the Auxilium Territory to itself or its designee by assigning to Auxilium our agreements with the contract manufacturer, which is referred to below as the Supply Chain Transfer.

At our sole cost and expense, we will be responsible for preparing and filing with the FDA the appropriate documents to obtain a label expansion for STENDRA referencing a specific time of onset

claim. We will use commercially reasonable efforts to obtain approval of such label expansion filing. Further, we will be responsible for conducting any post-regulatory studies of STENDRA that are required by the FDA in the Auxilium Territory. Such costs will be split equally between the parties up to a specified amount and then once the specified amount is reached, we shall be solely responsible for the remainder of the costs.

The Auxilium License Agreement will terminate on a country-by-country basis upon the later to occur of the following: (a) ten (10) years after the STENDRA product launch in such country; or (b) the expiration of the last-to-expire patents within our patents covering STENDRA in such country. In addition, Auxilium may terminate the Auxilium License Agreement (i) for any reason following the one (1) year anniversary of the STENDRA launch in the U.S upon one hundred eighty (180) days written notice, and (ii) upon the entry of a generic avanafil product into the market upon thirty (30) days written notice. We may terminate the Auxilium License Agreement (i) immediately upon written notice to Auxilium if Auxilium is excluded from participation in the U.S. federal healthcare programs and fails to cure such exclusion within one hundred twenty (120) days, and (ii) if Auxilium challenges the VIVUS patents covering STENDRA upon written notice to Auxilium. Either party may terminate the Auxilium License Agreement for the other party's uncured material breach or bankruptcy.

Under the terms of the Auxilium Supply Agreement, we will supply Auxilium with STENDRA drug product until December 31, 2018, at the latest. For 2015, and each subsequent year during the term of the Auxilium Supply Agreement, if Auxilium fails to purchase an agreed minimum purchase amount of STENDRA from us, it will reimburse us for the shortfall as it relates to our out-of-pocket costs to acquire certain raw materials needed to manufacture STENDRA. Either party may terminate the Auxilium Supply Agreement for the other party's uncured material breach or bankruptcy, or upon the termination of the License Agreement. The Auxilium Supply Agreement will automatically terminate upon completion of the Supply Chain Transfer, as described above.

### *Sanofi*

On December 11, 2013, we entered into a license and commercialization agreement, or the Sanofi License Agreement, with Sanofi. Effective as of December 11, 2013, we entered into a supply agreement, or the Sanofi Supply Agreement, with Sanofi Winthrop Industrie, a wholly owned subsidiary of Sanofi.

Under the terms of the Sanofi License Agreement, Sanofi received an exclusive license to commercialize and promote VIVUS's drug avanafil for therapeutic use in humans in Africa, the Middle East—Turkey and Eurasia, or the Sanofi Territory. During the term of the License Agreement, each party agreed not to develop, commercialize, or in-license any other product that operates as a phosphodiesterase type-5 inhibitor for therapeutic use in humans in the Sanofi Territory for a limited time period, subject to certain exceptions.

In December 2013, we received an upfront license fee of \$5.0 million and a \$1.5 million manufacturing milestone payment. We are also eligible to receive up to an additional \$3.5 million in manufacturing milestone payments, up to \$6.0 million in regulatory milestone payments, and up to \$45.0 million in sales milestone payments, plus royalties on avanafil sales based on tiered percentages of the aggregate annual net sales in the Sanofi Territory. Sanofi will also reimburse us for a portion of any sales milestone paid by us to MTPC based on the share of Sanofi's net sales in the total worldwide net sales amount triggering the payment of such sales milestone.

Royalty payment obligations under the Sanofi License Agreement will be payable for avanafil in each country in the Sanofi Territory until the later to occur of (i) the expiration of the last-to-expire valid claim within the VIVUS patents that, absent the licenses granted to Sanofi under the Sanofi License Agreement, would be infringed by the sale of avanafil in such country, and (ii) December 11,

2029, or the Sanofi Royalty Payment Term. The Sanofi License Agreement will terminate as follows: (i) as to avanafil in each country in the Sanofi Territory, upon the expiration of the Sanofi Royalty Payment Term with respect to avanafil in such country, provided however, that Sanofi's obligation to reimburse us for Sanofi's pro-rata share of any sales milestone paid by us to MTPC will survive if such sales milestone has not yet come due; and (ii) in its entirety, upon the expiration of all royalty payment obligations arising under the Sanofi License Agreement in all countries in the Sanofi Territory.

In addition, we may terminate the Sanofi License Agreement immediately upon written notice to Sanofi on a country-by-country basis if Sanofi becomes subject to certain regulatory actions or legal restrictions. We may also terminate the Sanofi License Agreement in its entirety upon written notice to Sanofi if Sanofi or any affiliate commences any action or proceeding that challenges the validity, enforceability or scope of any VIVUS patent in the Sanofi Territory or any country outside of the Sanofi Territory, or if a similar action is instituted by a sublicensee and Sanofi does not terminate the sublicense after being aware of such action for a specified period. Further, Sanofi may terminate the Sanofi License Agreement in whole or on a country-by-country basis for convenience at any time upon advance notice to us. Either party may terminate the Sanofi License Agreement for the other party's uncured material breach, or bankruptcy or related actions or proceedings. In the event of an uncured material breach by us, Sanofi may, in lieu of terminating the Sanofi License Agreement in its entirety, elect to continue the Sanofi License Agreement in full force and effect except (i) we will have no further rights to receive certain commercialization reports, and (ii) Sanofi may set off any payments or amounts due by Sanofi but not yet paid to us against all direct and undisputed damages suffered by Sanofi as a result of the breach.

Under the terms of the Sanofi Supply Agreement, we will supply Sanofi Winthrop Industrie with avanafil tablets until June 30, 2015, or in the event the obligations of MTPC to supply avanafil tablets to us are amended to extend beyond June 30, 2015, then until the expiration of the MTPC supply obligations as amended. Either party may terminate the Sanofi Supply Agreement for (i) the other party's uncured material breach or (ii) bankruptcy, insolvency, liquidation or certain receivership proceedings, or certain proceedings for reorganization under bankruptcy or comparable laws. In addition, the Sanofi Supply Agreement will automatically terminate upon the termination of the Sanofi License Agreement.

On July 31, 2013, we entered into a Commercial Supply Agreement with Sanofi Chimie to manufacture and supply the API for our drug avanafil on an exclusive basis in the United States and other territories and on a semi-exclusive basis in Europe, including the EU, Latin America and other territories. On November 18, 2013, we entered into a Manufacturing and Supply Agreement with Sanofi Winthrop Industrie to manufacture and supply the avanafil tablets on an exclusive basis in the United States and other territories and on a semi-exclusive basis in Europe, including the EU, Latin America and other territories. We intend to submit an amendment to the NDA for avanafil to the FDA, and an application for the variation of the marketing authorization for avanafil to the EMA, to include Sanofi Chimie as a qualified supplier of the avanafil API and Sanofi Winthrop Industrie as a qualified supplier of the avanafil tablets. We have minimum annual purchase commitments under these agreements for at least the initial five-year terms.

#### *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 us with worldwide rights to develop and commercialize the Combination Therapy and exploit the Patents. Pursuant to the Assignment Agreement, through December 31, 2013, we have paid a total of

\$1.2 million and have issued fully vested and exercisable options to purchase 60,000 shares of our common stock to Dr. Najarian. In addition, the Assignment Agreement requires 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 served as a Principal Scientist. In November 2013, Dr. Najarian's employment with the Company ended although he continues to work for us on a consulting basis.

### **Patents, Proprietary Technology and Data Exclusivity**

We own or are the exclusive licensee of more than 30 patents and numerous 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:

<b>QSYMIA</b>	
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 No. 8,580,299	Expiring 06/14/2029*
U.S. Patent Publication No. 2010/0105765 A1	Pending
U.S. Patent No. 8,580,298	Expiring 05/15/2029*
U.S. Patent No. 8,536,138	Expiring 06/13/2027
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
<b>STENDRA</b>	
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
<b>ERECTILE DYSFUNCTION</b>	
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

\* These expiration dates are based on the number of days of patent term adjustment, or PTA, calculated by the U.S. Patent and Trademark Office, or USPTO. An independent calculation of PTA suggested that the patents may be entitled to fewer days of PTA than determined by the USPTO.

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 European Commission, 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 after expiry of the eight years of data exclusivity, it cannot be placed on the market until the full 10-year market

exclusivity has expired. This 10-year market exclusivity may be extended 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 its authorization, is 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 collaboration agreements for the commercialization of STENDRA for territories in which we do not have a commercial collaboration 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.

As indicated above, on July 31, 2013, we entered into a Commercial Supply Agreement with Sanofi Chimie, a wholly owned subsidiary of Sanofi, pursuant to which Sanofi Chimie will manufacture and supply the active pharmaceutical ingredient for our drug avanafil. Further, as indicated above, on November 18, 2013, we entered into a Manufacturing and Supply Agreement with Sanofi Winthrop Industrie, a wholly owned subsidiary of Sanofi, pursuant to which Sanofi Winthrop Industrie will manufacture and supply the tablets for our drug avanafil.

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 additional supplier agreements or that we will be able to obtain the necessary regulatory approvals for any suppliers in a timely manner or at all.

Catalent manufactured the supply for our Phase 3b/4 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 that 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 Catalent 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.

### **Marketing and Sales**

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 management 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 rely on Cardinal Health 105, Inc., or Cardinal Health, a third-party distribution and supply-chain management company, to warehouse Qsymia and distribute it to the certified home delivery pharmacies and wholesalers that then distribute Qsymia directly to patients and certified retail pharmacies. Cardinal Health provides billing, collection and returns services. 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 wholesalers and through a broader network of certified retail pharmacies. We have contracted through a third-party vendor to certify the retail pharmacies and collect required data to support the Qsymia REMS program. In addition to providing services to support the distribution and use of Qsymia, each of the certified pharmacies has agreed to comply with the REMS program requirements and, through our third-party data collection vendor, will provide us with the necessary patient and prescribing healthcare provider, or HCP, data. In addition, we have contracted with third-party data warehouses to store this patient and HCP data 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.

### **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 engaged in the development of therapies 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 VIVUS. 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 that 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 anti-obesity compound being 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, LLC. In addition, Orexigen Therapeutics, Inc., or Orexigen, has an investigational drug under review at the FDA known as Contrave® (naltrexone/bupropion) which, according to Orexigen, could be approved and on the market in the U.S. in 2014. The company recently announced a PDUFA date of June 10, 2014, and has also expressed confidence in achieving a potential marketing authorization by the European Commission by year-end 2014. If approved, Contrave will 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. Newer agents recently approved for type 2 diabetes include Invokana (canagliflozin) from Johnson & Johnson's Janssen Pharmaceuticals, an SGLT2 inhibitor that has demonstrated modest, single-digit weight loss in clinical studies. In addition, there are several other investigational drug candidates in Phase 2 clinical trials. In January 2013, Rhythm Pharmaceuticals, or Rhythm, announced the initiation of a Phase 2 clinical trial with RM-493, a small-peptide melanocortin 4 receptor, or MC4R, agonist, for the treatment of obesity. Rhythm announced in September 2013, that RM-493 is being studied in Phase 1B for the treatment of obesity in individuals with a genetic deficiency in the MC4R pathway. There are a number of generic pharmaceutical drugs that are prescribed for obesity, predominantly phentermine, which is sold at much lower prices than we charge for Qsymia and is also widely available in retail pharmacies. The availability of branded prescription drugs, generic drugs and over-the-counter drugs could limit the demand and the price we are able to charge for Qsymia.

We may also 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 dosage 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 condition 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 in 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-promoted 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.

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.

Avanafil qualifies as an innovative medicinal product in the EU. Innovative medicinal products authorized in the EU on the basis of a full marketing authorization application (as opposed to an application for marketing authorization that relies on data in the marketing authorization dossier for another, previously approved medicinal product) are entitled to eight years' data exclusivity. During this period, applicants for approval of generics of these innovative products cannot rely on data contained in the marketing authorization dossier submitted for the innovative medicinal product. Innovative

medicinal products are also entitled to 10 years' market exclusivity. During this 10-year period no generic medicinal product can be placed on the EU market. The 10-year period of market exclusivity can be extended to a maximum of 11 years if, during the first eight years of those 10 years, the Marketing Authorization Holder for the innovative product obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. If we do not obtain extended patent protection and data exclusivity for our product candidates, our business may be materially harmed.

## **Research and Development**

We incurred \$29.7 million in 2013, \$32.1 million in 2012, and \$24.6 million in 2011, in research and development expenses, primarily to support the approval efforts and clinical programs for Qsymia and STENDRA.

## **Employees**

As of February 19, 2014, we had 98 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.

## **Geographic Area Financial Information**

For financial information concerning the geographic areas in which we operate, see Note 17: "Segment Information and Concentration of Customers and Suppliers—Geographic Information" to our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

## **Available Information**

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to reports filed pursuant to Section 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, are available on our website at [www.vivus.com](http://www.vivus.com), when such reports are available on the 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's 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**

***Changes to our management and strategic business plan may cause uncertainty regarding the future of our business, and may adversely impact employee hiring and retention, our stock price, and our revenue, operating results, and financial condition.***

In July 2013, we announced changes to our Board and management. In September and November 2013, and January 2014, we announced further changes to our management team. In November 2013, we announced a reduction in force of approximately 17%, the decision of our Chief Financial Officer to exercise his right to terminate his employment for Good Reason (as defined in his Amended and Restated Change of Control and Severance Agreement with the Company, effective as of July 1, 2013), and the appointment of our Corporate Controller as the Company's interim Chief Financial Officer. In January 2014, we announced that our Chief Executive Officer was assuming the duties and responsibilities of the Company's Chief Commercial Officer. The implementation of these changes, including the recent appointment of a new Chief Executive Officer and interim Chief Financial Officer, the expansion of our Board to include predominantly new members, the resignation of our President, the decision of our Chief Financial Officer to exercise his right to terminate his employment for Good Reason, the assumption of the Chief Commercial Officer's duties and responsibilities by the Chief Executive Officer, and the potential for additional changes to our management, organizational structure and strategic business plan, may cause speculation and uncertainty regarding our future business strategy and direction. These changes may cause or result in:

- disruption of our business or distraction of our employees and management;
- difficulty in recruiting, hiring, motivating and retaining talented and skilled personnel;
- stock price volatility; and
- difficulty in negotiating, maintaining or consummating business or strategic relationships or transactions.

If we are unable to mitigate these or other potential risks, our revenue, operating results and financial condition may be adversely impacted.

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

Our success will depend on our ability to effectively and profitably commercialize Qsymia, which will include our ability to:

- expand the use of Qsymia through targeted patient and physician education;
- find the right partner for expanded Qsymia commercial promotion to a broader primary care physician audience;

- obtain marketing authorization by the European Commission for Qsiva™ in the EU through the centralized procedure;
- manage our alliances with Auxilium, Menarini and Sanofi, to help ensure the commercial success of avanafil;
- manage costs;
- continue to certify and add to the Qsymia retail pharmacy network nationwide and sell Qsymia through this network;
- improve third-party payor coverage, lower out-of-pocket costs to patients with discount programs, and change public policy to obtain coverage for obesity under Medicare Part D;
- create market demand for Qsymia through patient and physician education, marketing and sales activities;
- achieve market acceptance and generate product sales;
- comply with the post-marketing requirements established by the U.S. Food and Drug Administration, or FDA, including Qsymia's Risk Evaluation and Mitigation Strategy, or REMS, any future changes to the 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;
- maintain and defend our patents, if challenged;
- 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 APIs 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 developing, 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 will be severely limited, which will have a material adverse impact on our business, financial condition, and results of operations. In addition, we rely on a third-party contract sales organization, PDI, to assist with the hiring of sales representatives and the promotion of Qsymia to physicians. 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.

***We may not fully realize the anticipated benefits from a cost reduction plan we announced in November 2013.***

On November 5, 2013, we announced a cost reduction plan to eliminate expenses that are not essential to expanding the use of Qsymia. The plan reduced our workforce by approximately 20 employees, not including our sales force. We substantially completed this cost reduction plan by

December 31, 2013, and incurred pre-tax non-recurring charges of \$8.0 million in the fourth quarter of 2013, including approximately \$5.7 million in employee termination costs, \$1.3 million in non-cash share-based compensation expense related to the automatic acceleration of vesting of unvested stock options held by the terminated employees, and \$1.0 million in facilities and other lease exit costs. We expect to realize approximately \$6 million to \$8 million in annual net cost savings beginning in fiscal year 2014.

Our ability to achieve the anticipated cost savings and other benefits from this cost reduction plan within the expected timeframe are subject to many estimates and assumptions, and the actual savings and timing for those savings may vary materially based on factors such as negotiations with third parties and operational requirements. These estimates and assumptions are subject to significant economic, competitive and other uncertainties, some of which are beyond our control. There can be no assurance that we will fully realize the anticipated benefits from this cost reduction plan. To the extent that we are unable to successfully implement our business plan, further cost reduction measures may be required in the future.

***We depend on our collaboration partner Auxilium to market and sell STENDRA™ (avanafil) in the United States and Canada, our collaboration partner Sanofi to gain approval, market, and sell avanafil in Africa, the Middle East, Turkey, and the Commonwealth of Independent States, and our collaboration partner Menarini to market and sell SPEDRA™ (avanafil) in over 40 European countries, including the EU, plus Australia and New Zealand.***

On December 11, 2013, we entered into a License and Commercialization Agreement with Sanofi under which Sanofi received an exclusive license to commercialize and promote avanafil for therapeutic use in humans in Africa, the Middle East, Turkey, and the Commonwealth of Independent States, or CIS, including Russia. Sanofi will be responsible for obtaining regulatory approval in its territories. Sanofi intends to market avanafil under the trade name SPEDRA™ or STENDRA™. On October 10, 2013, we entered into a License and Commercialization Agreement with Auxilium under which Auxilium received an exclusive license to commercialize and promote STENDRA for the treatment of ED in the United States and Canada. On July 5, 2013, we entered into a License and Commercialization Agreement with Menarini under which Menarini received an exclusive license to commercialize and promote SPEDRA for the treatment of ED in over 40 European countries, including the EU, plus Australia and New Zealand.

We are relying on our collaboration partners, Auxilium, Menarini, and Sanofi to successfully commercialize STENDRA or SPEDRA in their respective territories, inclusive of obtaining any necessary approvals. There can be no assurances that these collaboration partners will be successful in doing so. In general, we cannot control the amount and timing of resources that our collaboration partners devote to the commercialization of our drugs. If any of our collaboration partners fails to successfully commercialize our drug products, our business may be negatively affected. For example, if Sanofi, Auxilium or Menarini do not successfully commercialize STENDRA or SPEDRA, we may receive limited or no revenues under our agreements with them. Additionally, because we lack the resources and experience to commercialize STENDRA or SPEDRA ourselves in these territories, we would need to seek replacement licensees to undertake these commercialization efforts. We may be unable to find other licensees in a timely manner, which could delay or impair our ability to commercialize STENDRA or SPEDRA in these territories.

Under our license agreement with Mitsubishi Tanabe Pharma Corporation, or MTPC, we are obligated to ensure that Sanofi, Auxilium and Menarini, as sublicensees, comply with its terms and conditions. MTPC has the right to terminate our license rights to avanafil in the event of any uncured material breach of the license agreement. Consequently, failure by Sanofi, Auxilium or Menarini to comply with these terms and conditions could result in termination of our license rights to avanafil on a worldwide basis, which could delay, impair, or preclude our ability to commercialize avanafil.

***If we are unable to enter into agreements with collaborators for the territories that are not covered by our existing commercialization agreements, our ability to commercialize STENDRA in these territories may be impaired.***

We intend to enter into collaborative arrangements or a strategic alliance with one or more pharmaceutical partners or others to commercialize STENDRA in other territories under our license with MTPC that are not covered by our current commercial collaboration agreements. We may be unable to enter into agreements with third parties for STENDRA for these territories on favorable terms or at all, which could delay, impair, or preclude our ability to commercialize STENDRA in these territories.

***We depend on collaborative arrangements or strategic alliances for the commercialization of STENDRA or SPEDRA.***

Our dependence on collaborative arrangements or strategic alliances for the commercialization of STENDRA or SPEDRA, including our license agreements with Sanofi, Auxilium and Menarini, 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.***

In order to market products in many foreign jurisdictions, we must obtain separate regulatory approvals. Approval by the FDA in the U.S. 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, while our drug SPEDRA was approved in both the U.S. and the European Union, or EU, our drug Qsymia was approved in the U.S. but Qsiva (the approved trade name for Qsymia in the EU) was not approved 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 intend to seek approval, either directly or through our collaboration partners, for Qsymia and STENDRA in other

territories outside the United States and EU. However, we have had limited interactions with foreign regulatory authorities, and the approval procedures vary among countries and can involve additional testing. Foreign regulatory approvals may not be obtained, by us or our collaboration partners responsible for obtaining approval, on a timely basis, or at all, for any of our products. The failure to receive regulatory approvals in a foreign country would prevent us from marketing and commercializing our products in that country, which could have a material adverse effect on our business, financial condition and results of operations.

***We, together with Sanofi, Auxilium and Menarini in certain territories, intend to market STENDRA or SPEDRA outside the U.S. which will subject us to risks related to conducting business internationally.***

We, through Sanofi, Auxilium and Menarini in certain territories, intend to manufacture, market, and distribute STENDRA or SPEDRA 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 incidental 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;
- disputes may arise between us and PDI, including between the contract sales representatives, who are PDI employees, and sales management, who are VIVUS employees, that may adversely affect Qsymia 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.

***We have significant inventories on hand and, in the year ended December 31, 2013, we recorded inventory impairment and commitment fees totaling \$10.2 million, primarily to write off excess inventory related to Qsymia.***

We maintain significant inventories and evaluate these inventories on a periodic basis for potential excess and obsolescence. During the year ended December 31, 2013, we recognized total charges of \$10.2 million for Qsymia inventories on hand in excess of demand, plus a purchase commitment fee. The inventory impairment charges were based on our analysis of current Qsymia inventory on hand and remaining shelf life, in relation to our projected demand for the product. The current FDA-approved commercial product shelf life for Qsymia is 36 months. STENDRA is approved in the U.S. and SPEDRA in the EU, for 48 months commercial product shelf life.

Our write down for excess and obsolete inventory is subjective and requires accurate forecasting of the future market demand for our products. Forecasting demand for Qsymia, a drug in the obesity market in which there had been no new FDA-approved medications in over a decade prior to 2012, and for which reimbursement from third-party payors had previously been non-existent, has been difficult. Forecasting demand for STENDRA or SPEDRA, a drug that is new to the market and has no sales history, is difficult. We will continue to evaluate our inventories on a periodic basis. The value of our inventories could be impacted if actual sales differ significantly from our estimates of future demand or if any significant unanticipated changes in future product demand or market conditions occur. Any of these events, or a combination thereof, could result in additional inventory write-downs in future periods, which could be material.

***Our failure to manage and maintain our distribution network for Qsymia or compliance with certain requirements of the Qsymia REMS program could compromise the commercialization of this product.***

We rely on Cardinal Health 105, Inc., or Cardinal Health, a third-party distribution and supply-chain management company, to warehouse Qsymia and distribute it to the certified home delivery pharmacies and wholesalers that then distribute Qsymia directly to patients and certified retail pharmacies. Cardinal Health provides billing, collection and returns services. 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 wholesalers and through a broader network of certified retail pharmacies. We have contracted through a third-party vendor to certify the retail pharmacies and collect required data to support the Qsymia REMS program. In addition to providing services to support the distribution and use of Qsymia, each of the certified pharmacies has agreed to comply with the REMS program requirements and, through our third-party data collection vendor, will provide us with the necessary patient and prescribing healthcare provider, or HCP, data. In addition, we have contracted with third-party data warehouses to store this patient and HCP data 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.

We rely on the certified pharmacies to implement a number of safety procedures and report certain information to our third-party REMS data collection vendor. Failure to maintain our contracts with Cardinal Health, our third-party REMS data collection vendor, or with the third-party data warehouses, or the inability or failure of any of them to adequately perform under our contracts with them, 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 products or if we rely on sole-source suppliers, we may experience delays in commercializing our products.***

We currently do not have supply agreements for extended-release topiramate or phentermine, which are the active pharmaceutical ingredients, or 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.

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 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. 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 U.S. commercial launch, and future sales of STENDRA in the U.S. and abroad will be adversely affected, which in turn could have a detrimental

impact on our financial results and could impact our ability to enter into a collaboration agreement for the commercialization of STENDRA in other territories under our license with MTPC not covered by our agreements with Sanofi, Auxilium and Menarini.

In August 2012, we entered into an amendment to our license 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 as a supplier on or before June 30, 2015. We currently do not have any manufacturing facilities and intend to continue to rely on third parties for the supply of such API and tablets, as well as for the supply of starting materials. However, we cannot be certain that we will be able to obtain the necessary regulatory approvals for these suppliers in a timely manner or at all.

On July 31, 2013, we entered into a Commercial Supply Agreement with Sanofi Chimie to manufacture and supply the API for avanafil on an exclusive basis in the United States and other territories and on a semi-exclusive basis in Europe, including the EU, Latin America and other territories. On November 18, 2013, we entered into a Manufacturing and Supply Agreement with Sanofi Winthrop Industrie to manufacture and supply the avanafil tablets on an exclusive basis in the United States and other territories and on a semi-exclusive basis in Europe, including the EU, Latin America and other territories. We intend to submit an amendment to the New Drug Application, or NDA, for avanafil to the FDA, and the Marketing Authorization, or MA, for avanafil to the European Medicines Agency, or EMA, to include Sanofi Chimie as a qualified supplier of the avanafil API and Sanofi Winthrop Industrie as a qualified supplier of the avanafil tablets. We cannot be certain we will receive approval by regulatory authorities, or that we will be able to obtain such approval in a timely manner. The failure to receive such approval in a timely manner or at all could prevent, delay or preclude our ability to establish a reliable supply chain, which could compromise our ability to commercialize avanafil through our relationships with Sanofi, Auxilium and Menarini, or otherwise. In addition, we have entered into supply agreements with Menarini and Auxilium under which we are obligated to supply them with avanafil tablets. If we are unable to establish a reliable supply of avanafil API or tablets from Sanofi Chimie and/or Sanofi Winthrop Industrie, we may be unable to satisfy our obligations under these supply agreements in a timely manner or at all, and we may, as a result, be in breach of one or both of these agreements.

***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. We license the rights to Qsymia from Dr. Najarian. We believe we are in compliance with the material terms of our license agreements with MTPC 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 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 ability to expand the use of Qsymia through targeted patient and physician education;
- our ability to find the right partner for expanded Qsymia commercial promotion to a broader primary care physician audience;
- our ability to obtain marketing authorization by the European Commission for Qsiva in the EU through the centralized procedure;
- our ability to successfully expand the certified retail pharmacy distribution channel in the United States;
- contraindications for Qsymia and STENDRA;
- competition and timing of market introduction of competitive drugs;
- quality, safety and efficacy 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, product insert, or new REMS 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.

***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 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, or AQCLAIM, 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. We estimate the AQCLAIM study will cost between \$180 and \$250 million and the study could take as long as five to six years to complete. On September 20, 2013, we submitted to the EMA a request for Scientific Advice regarding use of a pre-specified interim analysis from the AQCLAIM cardiovascular outcomes trial to support the resubmission of the Marketing Authorization Application, or MAA, for approval of Qsiva for the treatment of obesity in accordance with the centralized marketing authorization procedure. Based on feedback from the EMA health authority, as well as various country health authorities associated with review of the AQCLAIM trial application, the protocol has been revised and resubmitted to the FDA. There can be no assurance that the FDA or EMA will not request or require us to provide additional information or undertake additional preclinical studies and clinical studies or retrospective observational studies.

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. We submitted the final report for the FORTRESS study to the FDA in the second quarter of 2013. If the FDA determines that 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 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 would differ. As a result, Qsymia may be subject to substitution by prescribing physicians, or by pharmacists, 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, both of the approved APIs (phentermine and topiramate extended-release) that are combined to produce Qsymia are 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 may be ineffective or impractical to prevent physicians from prescribing, or pharmacists from dispensing, 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. In the third quarter of 2013, Supernus Pharmaceuticals, Inc. launched Trokendi XR™, an extended-release pediatric formulation of the generic drug topiramate that is indicated for epilepsy, in the United States. 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, 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 and erectile dysfunction. 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 that 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 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 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™, an orally disintegrating tablet (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. Newer agents recently approved for type 2 diabetes include Invokana® (canagliflozin) from Johnson & Johnson's Janssen Pharmaceuticals, an SGLT2 inhibitor that has demonstrated modest, single-digit weight loss in clinical studies. In addition, there are several other investigational drug candidates in Phase 2 clinical trials for the treatment of obesity. 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 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 condition 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, which was acquired by Actavis, Inc. and is now known as Actavis plc, has licensed the U.S. rights to udenafil, a PDE5 inhibitor, from Dong-A Pharmaceutical. 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.

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 future 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.

***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 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, contract with, 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 approved drugs or investigational drug candidates 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 Pharma Solutions, LLC, or 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 an initial 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 Catalent will be successful in increasing the scale of the initial Qsymia manufacturing process, should the market demand for Qsymia expand beyond the level supportable by the current validated manufacturing process. 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 avanafil, we currently rely on MTPC to supply the API (avanafil) and the avanafil tablets for STENDRA and SPEDRA. 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 avanafil API or tablets in sufficient quantities to meet projected demand, future sales could be adversely affected, which in turn could have a detrimental impact on our financial results, our license, commercialization, and supply agreements with our collaboration partners, and our ability to enter into a collaboration agreement for the commercialization in other territories.

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 parties. According to the amendment, the transition of manufacturing from MTPC must occur on or before June 30, 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. 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, are unable to effectively transfer the technology or supply on commercially reasonable terms, partnerability and commercial success of STENDRA could be adversely impacted. Additionally, we cannot be certain that we will be successful in entering into appropriate 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.

On July 31, 2013, we entered into a Commercial Supply Agreement with Sanofi Chimie to manufacture and supply the API for avanafil on an exclusive basis in the United States and other territories and on a semi-exclusive basis in Europe, including the EU, Latin America and other territories. On November 18, 2013, we entered into a Manufacturing and Supply Agreement with Sanofi Winthrop Industrie to manufacture and supply the avanafil tablets on an exclusive basis in the United States and other territories and on a semi-exclusive basis in Europe, including the EU, Latin America and other territories. We intend to submit an amendment to the NDA for avanafil to the FDA, and the MA for avanafil to the EMA, to include Sanofi Chimie as a qualified supplier of the avanafil API and Sanofi Winthrop Industrie as a qualified supplier of the avanafil tablets. We cannot be certain we will receive approval by regulatory authorities, and the failure to receive such approval could prevent, delay, or preclude our ability to establish a reliable supply chain, which could compromise our ability to commercialize avanafil through our relationships with Sanofi, Auxilium, Menarini, or otherwise.

Any future manufacturing sites, including those of Sanofi Chimie and Sanofi Winthrop Industrie, 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 tablets in expected quantities could have a detrimental impact on our ability to commercialize STENDRA under our agreements with Sanofi, Auxilium and Menarini and our ability to enter into a collaboration agreement for the commercialization of STENDRA in other territories under our license with MTPC not covered by our agreements with Sanofi, Auxilium and Menarini.

***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.

The collection and use of personal health data in the EU is governed by the provisions of the Data Protection Directive. This Directive imposes a number of requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. The Data Protection Directive also imposes strict rules on the transfer of personal data out of the EU to the United States. Failure to comply with the requirements of the Data Protection Directive and the related national data protection laws of the EU Member States may result in fines and other administrative penalties. The draft EU Data Protection Regulation currently going through the adoption process is expected to introduce new data protection requirements in the EU and substantial fines for breaches of the data protection rules. If the draft Data Protection Regulation is adopted in its current form, it may increase our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new EU data protection rules. This may be onerous and increase our cost of doing business.

***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.***

Our arrangements with third-party payors and customers expose us to broadly applicable federal and state healthcare laws and regulations pertaining to fraud and abuse. The restrictions under applicable federal and state healthcare laws and 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, in cash or in kind, to induce or reward the purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any healthcare items or service for which payment may be made, in whole or in part, by federal healthcare programs such as Medicare and Medicaid. This statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and prescribers, purchasers and formulary managers on the other. Further, the Affordable Care Act, among other things, clarified that a person or entity needs not to have actual knowledge of the federal Anti-Kickback statute or specific intent to violate it. In addition, the Affordable Care Act amended the Social Security Act to provide that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Law constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Although there are a number of statutory exemptions and regulatory safe harbors to the federal Anti-Kickback Law protecting certain common business arrangements and activities from prosecution or regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exemption or safe harbor may be subject to scrutiny. We seek to comply with the 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 civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds or knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing, or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. Many pharmaceutical and other healthcare companies have been investigated and have reached substantial financial settlements with the federal government

under the civil 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 civil 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, among others, 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;
- analogous state laws and regulations, such as state anti-kickback and false claims laws, 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. In addition, California, Connecticut, 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;
- the federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, requires certain pharmaceutical manufacturers to engage in extensive tracking of payments or transfers of value to physicians and teaching hospitals, maintenance of a payments database, and public reporting of the payment data. Pharmaceutical manufacturers with products for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program are required to track and report such payments. Centers for Medicare and Medicaid Services, or CMS, recently issued a final rule implementing the Physician Payment Sunshine Act provisions and clarified the scope of the reporting obligations, as well as that applicable manufacturers must begin tracking on August 1, 2013, and must report payment data to CMS by March 31, 2014, and annually thereafter; and

- the federal Foreign Corrupt Practices Act of 1997 and other similar anti-bribery laws in other jurisdictions generally prohibit companies and their intermediaries from providing money or anything of value to officials of foreign governments, foreign political parties, or international organizations with the intent to obtain or retain business or seek a business advantage. Recently, there has been a substantial increase in anti-bribery law enforcement activity by U.S. regulators, with more frequent and aggressive investigations and enforcement proceedings by both the Department of Justice and the U.S. Securities and Exchange Commission. A determination that our operations or activities are not, or were not, in compliance with United States or foreign laws or regulations could result in the imposition of substantial fines, interruptions of business, loss of supplier, vendor or other third-party relationships, termination of necessary licenses and permits, and other legal or equitable sanctions. Other internal or government investigations or legal or regulatory proceedings, including lawsuits brought by private litigants, may also follow as a consequence.

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 significant civil, criminal and administrative penalties, damages, fines, exclusion from government-funded 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 or regulations, 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.

In the EU, the advertising and promotion of our products will also be subject to EU Member States' laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices, as well as other EU Member State legislation governing statutory health insurance, bribery and anti-corruption. Failure to comply with these rules can result in enforcement action by the EU Member State authorities, which may include any of the following: fines, imprisonment, orders forfeiting products or prohibiting or suspending their supply to the market, or requiring the manufacturer to issue public warnings, or to conduct a product recall.

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

The FDA, and third country authorities, including the competent authorities of the EU Member States, have 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 pharmaceutical 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 that may result in significant expense and limit our ability to commercialize Qsymia. The FDA has also required the distribution of a Medication Guide to Qsymia 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 maintain FDA approval, or receive a marketing authorization from the European Commission, 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 or EU marketing authorization may be varied, suspended or 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.

***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 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.

***If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.***

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 CMS, the federal agency that administers the Medicaid Drug Rebate program. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug.

The Affordable Care Act made significant changes to the Medicaid Drug Rebate program. Effective March 23, 2010, rebate liability expanded from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well. With regard to the amount of the rebates owed, the Affordable Care Act increased the minimum Medicaid 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; changed the calculation of the rebate for certain innovator products that qualify as line extensions of existing drugs; and capped the total rebate amount for innovator drugs at 100% of the average manufacturer price. In addition, the Affordable Care Act and subsequent legislation changed the definition of average manufacturer price. Finally, the Affordable Care Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government beginning in 2011. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee of \$3.0 billion in 2014 (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.

In 2012, CMS issued proposed regulations to implement the changes to the Medicaid Drug Rebate program under the Affordable Care Act but has not yet issued final regulations. CMS is currently expected to release the final regulations in 2014. Moreover, in the future, Congress could enact legislation that further increases Medicaid drug rebates or other costs and charges associated with participating in the Medicaid Drug Rebate program. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program has and will continue to increase our costs and the complexity of compliance, has been and will be time consuming, and could have a material adverse effect on our results of operations.

Federal law requires that any company that participates in the Medicaid Drug 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. These

340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. 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 Drug Rebate program. Changes to the definition of average manufacturer price and the Medicaid rebate amount under the Affordable Care Act 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.

The Affordable Care Act expanded the 340B program to include additional entity types: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by the Affordable Care Act. The Affordable Care Act also obligates the Secretary of the U.S. Department of Health and Human Services, or HHS, to create regulations and processes to improve the integrity of the 340B program and to update the agreement that manufacturers must sign to participate in the 340B program to obligate a manufacturer to offer the 340B price to covered entities if the manufacturer makes the drug available to any other purchaser at any price and to report to the government the ceiling prices for its drugs. The Health Resources and Services Administration, or HRSA, is expected to issue a comprehensive proposed regulation in 2014 that will address many aspects of the 340B program. When that regulation is finalized, it could affect our obligations under the 340B program in ways we cannot anticipate. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting.

Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies and the courts. The Medicaid rebate amount is computed each quarter based on our submission to CMS of our current average manufacturer prices and best prices for the quarter. If we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for a period not to exceed 12 quarters from the quarter in which the data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate program. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. Price recalculations also may affect the ceiling price at which we are required to offer our products to certain covered entities, such as safety-net providers, under the 340B drug discount program.

We are liable for errors associated with our submission of pricing data. In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted false average manufacturer price or best price information to the government, we may be liable for civil monetary penalties in the amount of \$100,000 per item of false information. Our failure to submit monthly/quarterly average manufacturer price and best price data on a timely basis could result in a civil monetary penalty of \$10,000 per day for each day the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, no federal payments would be available under Medicaid or Medicare Part B for our covered outpatient drugs.

In September 2010, CMS and the Office of the Inspector General indicated that they intend to pursue more aggressively companies that fail to report these data to the government in a timely manner. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or

paid. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect.

Federal law requires that, for a company to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs as well as to be purchased by certain federal agencies and certain federal grantees, it also must participate in the Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program. To participate, we are required to enter into an FSS contract with the VA, under which we must make our innovator "covered drugs" available to the "Big Four" federal agencies—the VA, the Department of Defense, or DoD, the Public Health Service, and the Coast Guard—at pricing that is capped pursuant to a statutory federal ceiling price, or FCP, formula set forth in Section 603 of the Veterans Health Care Act of 1992, or VHCA. The FCP is based on a weighted average wholesaler price known as the "non-federal average manufacturer price," or Non-FAMP, which manufacturers are required to report on a quarterly and annual basis to the VA. If a company misstates Non-FAMPs or FCPs it must restate these figures. Pursuant to the VHCA, knowingly providing false information in connection with a Non-FAMP filing can subject a manufacturer to penalties of \$100,000 for each item of false information.

FSS contracts are federal procurement contracts that include standard government terms and conditions, separate pricing for each product, and extensive disclosure and certification requirements. All items on FSS contracts are subject to a standard FSS contract clause that requires FSS contract price reductions under certain circumstances where pricing is reduced to an agreed "tracking customer." Further, in addition to the "Big Four" agencies, all other federal agencies and some non-federal entities are authorized to access FSS contracts. FSS contractors are permitted to charge FSS purchasers other than the "Big Four" agencies "negotiated pricing" for covered drugs that is not capped by the FCP; instead, such pricing is negotiated based on a mandatory disclosure of the contractor's commercial "most favored customer" pricing. We offer one single FCP-based FSS contract price to all FSS purchasers for all products.

In addition, pursuant to regulations issued by the DoD TRICARE Management Activity, or TMA, now Defense Health Agency, or DHA, to implement Section 703 of the National Defense Authorization Act for Fiscal Year 2008, each of our covered drugs is listed on a Section 703 Agreement with TMA under which we have agreed to pay rebates on covered drug prescriptions dispensed to TRICARE beneficiaries. Companies are required to list their innovator products on Section 703 Agreements in order for those products to be eligible for DoD formulary inclusion. The formula for determining the rebate is established in the regulations and our Section 703 Agreement and is based on the difference between the Annual Non-FAMP and the FCP (as described above, these price points are required to be calculated by us under the VHCA).

If we overcharge the government in connection with our FSS contract or Section 703 Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

***Changes in reimbursement procedures by government and other third-party payors, including changes in healthcare law and implementing regulations, may limit our ability to market and sell our approved drugs, or any future drugs, if approved, may limit our product revenues and delay profitability, and may impact our business in ways that we cannot currently predict. These changes could have a material adverse effect on our business and financial condition.***

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.

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. CMS, the federal agency that administers the Medicare and Medicaid Drug Rebate program, has made draft National Average Drug Acquisition Cost, or NADAC, and draft National Average Retail Price, or NARP, data publicly available on at least a monthly basis. In July 2013, CMS suspended the publication of draft NARP data, pending funding decisions. In November 2013, CMS moved to publishing final rather than draft NADAC data and has since made updated NADAC data publicly available on a weekly basis. Therefore, it may be difficult to project the impact of these evolving reimbursement mechanics on the willingness of payors to cover our products.

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.

In March 2010, the President signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, together the Affordable Care Act. 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, rebate liability expanded from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well. This expanded eligibility affects rebate liability for that utilization.
- With regard to the amount of the rebates owed, the Affordable Care Act increased the minimum Medicaid 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; changed the calculation of

the rebate for certain innovator products that qualify as line extensions of existing drugs; and capped the total rebate amount for innovator drugs at 100% of the average manufacturer price.

- 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 coverage 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 Affordable Care Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee of \$3.0 billion in 2014, (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.
- Some states have elected to expand their Medicaid programs by raising the income limit to 133% of the federal poverty level. For each state that does not choose to expand its Medicaid program, there may 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.

Many of the Affordable Care Act's most significant reforms do not take effect until 2014. In 2012, CMS issued proposed regulations to implement the changes to the Medicaid Drug Rebate program under the Affordable Care Act but has not yet issued final regulations. CMS is currently expected to release the final regulations in 2014. 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.

The Affordable Care Act also expanded the Public Health Service's 340B drug pricing discount program. 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 Affordable Care Act expanded the 340B program to include additional types of covered entities: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by the Affordable Care Act. The Affordable Care Act also obligates the Secretary of the Department of Health and Human Services to create regulations and processes to improve the integrity of the 340B program and to ensure the agreement that manufacturers must sign to participate in the 340B program obligates a manufacturer to offer the 340B price to covered entities if the manufacturer makes the drug available to any other purchaser at any price and to report to the government the ceiling prices for its drugs. The Health Resources and Services Administration is expected to issue a comprehensive proposed regulation in 2014 that will address many aspects of the 340B program. When that regulation is finalized, it could affect our obligations under the 340B program in ways we cannot anticipate. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting.

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 approved drugs and investigational drug candidates or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our approved drugs and 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 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, if approved, for any other indication, 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.

An increasing number of EU Member States and other foreign countries use prices for medicinal products established in other countries as "reference prices" to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere. In addition, the ongoing budgetary difficulties faced by a number of EU Member States, including Greece and Spain, have led and may continue to lead to substantial delays in payment and payment partially with government bonds rather than cash for medicinal products, which could negatively impact our revenues and profitability. Moreover, in order to obtain reimbursement of our medicinal products in some countries, including some EU Member States, we may be required to conduct clinical trials that compare the cost effectiveness of our products to other available therapies. There can be no assurance that our medicinal products will obtain favorable reimbursement status in any country.

***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 with the FDA, the European Commission, or the competent authorities of the EU Member States, 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.

***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, hindered our Qsymia sales efforts. 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 current 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 condition.

## 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, we cannot make assurances as to how much protection, if any, will be provided by our issued 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 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 has developed 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. 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 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 infringe 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 countries.***

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 approved drugs 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 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 make 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.

## 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 2014. 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:

- our ability to expand the use of Qsymia through targeted patient and physician education;
- our ability to find the right partner for expanded Qsymia commercial promotion to a broader primary care physician audience on a timely basis;
- our ability to obtain marketing authorization by the European Commission for Qsiva in the EU through the centralized procedure;
- our ability to manage costs;
- the substantial cost to expand into certified retail pharmacy locations and the cost required to maintain the REMS program for Qsymia;
- 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;
- our ability, along with our collaboration partners, to successfully commercialize STENDRA in the U.S., Canada, the EU, Australia, New Zealand, Africa, the Middle East, Turkey, and the CIS, including Russia;
- our ability to successfully commercialize STENDRA in other territories under our license with MTPC in which we do not have a commercial collaboration;
- 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 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.

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 equity and debt securities. 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.

On May 21, 2013, we closed an offering of \$220.0 million in 4.5% Convertible Senior Notes due May 1, 2020, which we refer to as the Convertible Notes. On May 29, 2013, we closed on an additional \$30.0 million of Convertible Notes upon exercise of an option by the initial purchasers of the Convertible Notes. Total net proceeds from the Convertible Notes were approximately \$241.8 million. The Convertible Notes are convertible into approximately 16,826,000 shares of our common stock under certain circumstances prior to maturity at a conversion rate of 67.3038 shares per \$1,000 principal amount of Convertible Notes, which represents a conversion price of approximately \$14.858 per share, subject to adjustment under certain conditions. The Convertible Notes are convertible at the option of the holders at any time prior to the close of business on the business day immediately preceding November 1, 2019, only under certain conditions. Investors in our common stock will be diluted to the extent the Convertible Notes are converted into shares of our common stock, rather than being settled in cash.

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. For example, on March 25, 2013, we entered into the Purchase and Sale Agreement with BioPharma, which provides for the purchase of a debt-like instrument. Under the BioPharma Agreement, we may not (i) incur indebtedness greater than a specified amount, (ii) pay a dividend or other cash distribution on our capital stock, unless we have cash and cash equivalents in excess of a specified amount, (iii) amend or restate our certificate of incorporation or bylaws unless such amendments or restatements do not affect BioPharma's interests under the BioPharma Agreement, (iv) encumber the collateral, or (v) abandon certain patent rights, in each case without the consent of BioPharma. 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 that may cause losses and affect the liquidity of these investments.***

At December 31, 2013, we had \$103.3 million in cash and cash equivalents and \$240.0 million in available-for-sale securities. While at December 31, 2013, 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 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, 2013. 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 and shareholder 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, despite the granting of the prior two motions to dismiss by the U.S. District Court for the Northern District of California in a putative class action lawsuit captioned *Kovtun v. Vivus, Inc., et al.*, Case No. 4:10-CV-04957-PJH, on October 26, 2012, plaintiff filed a Notice of Appeal to the U.S. Court of Appeals for the Ninth Circuit. Briefing of the appeal is complete, and the parties are awaiting word on whether the Court of Appeals wishes to entertain oral argument.



Additionally, certain of our 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. 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. We are named as a nominal defendant in these actions, neither of which seeks any recovery from the Company. The parties have agreed to stay the derivative lawsuits pending the outcome of the appeal of the securities class action.

Furthermore, on July 12, 2013, certain of our current and former officers and directors were named as defendants in a separate shareholder derivative lawsuit filed in the California Superior Court, Santa Clara County and captioned *Ira J. Gaines IRA, et al. v. Leland F. Wilson, et al.*, Case No.1-13-CV-249436. The lawsuit generally alleges breaches of the fiduciary duty of care in connection with the launch of Qsymia, breaches of the duty of loyalty and insider trading by some defendants for selling Company stock while purportedly being aware that the Qsymia launch would be less successful than predicted, and corporate waste. Again, we are named as a nominal defendant, and no recovery from the Company is sought. As with the other shareholder litigation, we have certain indemnification obligations to the named defendants, including to advance defense costs to the individuals. On October 21, 2013, the Company filed a demurrer seeking to have the lawsuit dismissed in its entirety for failure to make a pre-suit demand upon our Board of Directors or plead sufficient facts to show that such demand would have been futile. Briefing on the demurrer is complete and oral argument is presently scheduled for March 14, 2014.

***We have an accumulated deficit of \$660.6 million as of December 31, 2013, and we may continue to incur substantial operating losses for the future.***

We have generated a cumulative net loss of \$660.6 million for the period from our inception through December 31, 2013, 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, 2013, we had approximately \$545.1 million and \$229.1 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 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 50 percentage points over a rolling three-year period. We have not completed a recent study to assess whether any change of control has occurred or whether there have been multiple changes of control

since the Company's formation, due to the significant complexity and cost associated with the study. We have completed studies in prior periods and concluded no adjustments were required. If we have experienced a change of control at any time since our formation, our NOL carryforwards and tax credits may not be available, or their utilization could be subject to an annual limitation under Section 382. A full valuation allowance has been provided against our NOL carryforwards, and if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Accordingly, there would be no impact on the consolidated balance sheet or statement of operations.

*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;
- our ability to find the right partner for expanded Qsymia commercial promotion to a broader primary care physician audience;
- our ability to obtain marketing authorization by the European Commission for Qsiva in the EU through the centralized procedure;
- the costs, timing and outcome of post-approval clinical studies which the FDA has required us to perform as part of the approval for Qsymia and STENDRA;
- the substantial cost to expand into certified retail pharmacy locations and the cost required to maintain the REMS program for Qsymia;
- 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;

- 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. 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, although we have entered into License and Commercialization Agreements with Sanofi, Auxilium and Menarini, to commercialize avanafil for the treatment of ED on an exclusive basis in Africa, the Middle East, Turkey, and the CIS, including Russia, to commercialize and promote STENDRA for the treatment of ED in the U.S. and Canada, and to commercialize and promote SPEDRA for the treatment of ED in over 40 European countries, including the EU, plus Australia and New Zealand, respectively, we may not be successful in commercializing these drug products in these territories. 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 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 Amended and Restated 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 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 Corporation 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 former corporate headquarters located at 1172 Castro Street in Mountain View, California, or the Castro Lease. On February 14, 2012, we terminated the lease for our former corporate headquarters effective July 31, 2013. In addition, we have a lease on 4,914 square feet of office space located at 1174 Castro Street, Mountain View, California, or the Expansion Space, which is adjacent to our former corporate headquarters. 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. This Expansion Space is currently being listed for sublease.

We entered into a lease effective as of December 11, 2012, for our current 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 May 11, 2013. We have one option to renew the Evelyn Lease for a term of three years at the prevailing market rate. As part of a cost reduction plan, the first floor of the Evelyn Lease has been substantially vacated and we intend to list this unoccupied space for sublease.

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

For additional information regarding obligations under operating leases, see Note 15: "Commitments" to our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

### **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 New Drug Application, or NDA, for Qsymia as a treatment for obesity. The Court granted defendants' motions to dismiss both plaintiff's Amended Class Action Complaint and Second Amended Class Action Complaint; by order dated September 27, 2012, the latter dismissal was with prejudice, and final judgment was entered 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. Briefing of the appeal is complete, and the parties are awaiting word on whether the Court of Appeals wishes to entertain oral argument.

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 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 Company is named as a nominal defendant in these actions, neither of which seeks any recovery from the Company. The parties have agreed to stay the derivative lawsuits pending the outcome of the appeal of the securities class action.

The Company and its directors cannot predict the outcome of the various shareholder lawsuits, but they believe the various shareholder lawsuits are without merit and intend to continue vigorously defending them.

On July 12, 2013, various current and former officers and directors of the Company were named as defendants in a separate shareholder derivative lawsuit filed in the California Superior Court, Santa Clara County, and captioned *Ira J. Gaines IRA, et al. v. Leland F. Wilson, et al.*, Case No.1-13-CV-249436. The lawsuit generally alleges breaches of the fiduciary duty of care in connection with the launch of Qsymia, breaches of the duty of loyalty and insider trading by some defendants for selling Company stock while purportedly being aware that the Qsymia launch would be less successful than predicted, and corporate waste. Again, the Company is named as a nominal defendant, and no

recovery from the Company is sought. As with the other shareholder litigation, the Company does have certain indemnification obligations to the named defendants, including to advance defense costs to the individuals. The Company also maintains directors' and officers' liability insurance that it believes affords coverage for much of the anticipated cost of the proceedings, subject to the policies' terms and conditions. The individual defendants deny the material allegations and have indicated an intention to defend them vigorously. On October 21, 2013, the Company filed a demurrer seeking to have the lawsuit dismissed in its entirety for failure to make a pre-suit demand upon our Board of Directors or plead sufficient facts to show that such demand would have been futile. Briefing on the demurrer is complete and oral argument is presently scheduled for March 14, 2014.

#### *Proxy Related Lawsuit*

On July 16, 2013, First Manhattan, the owner of approximately 9.9% of the outstanding shares of common stock of the Company, commenced an action in the Court of Chancery of the State of Delaware, naming the then-serving members of the Board as defendants and the Company as a nominal defendant. The action was captioned *First Manhattan Co. v. Leland F. Wilson, et al.*, C.A. No. 8731-VCL. In its verified complaint, First Manhattan alleged that the Company's directors breached their fiduciary duties in connection with the Board's decision to adjourn the annual stockholders meeting from July 15, 2013 until July 18, 2013. The verified complaint sought declaratory and injunctive relief, including enjoining the defendants from soliciting proxies, directing the inspector of elections to certify the election of directors based on votes that were present and prepared to be voted on July 15, 2013, before the annual stockholders meeting was adjourned, and prohibiting defendants from taking any actions as directors of the Company. The verified complaint did not seek damages from the Company or the defendant board members. The parties entered into a settlement agreement on July 18, 2013, and the action was dismissed with prejudice on July 19, 2013. As part of the settlement agreement with First Manhattan, the Company paid the reasonable and documented expenses incurred by First Manhattan in connection with its proxy contest, which totaled approximately \$2.9 million.

#### *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.

## PART II

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

VIVUS's 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
2013				
High	\$ 15.54	\$ 15.62	\$ 15.40	\$ 11.64
Low	9.95	10.24	9.18	8.00
2012				
High	\$ 25.14	\$ 29.42	\$ 31.21	\$ 23.59
Low	9.76	21.12	17.21	9.89

**Stockholders**

As of February 19, 2014, there were 103,301,701 shares of outstanding common stock that were held by 3,173 stockholders of record and no outstanding shares of preferred stock. On February 19, 2014, the last reported sales price of our common stock on the NASDAQ Global Select Market was \$6.80 per share.

**Dividends**

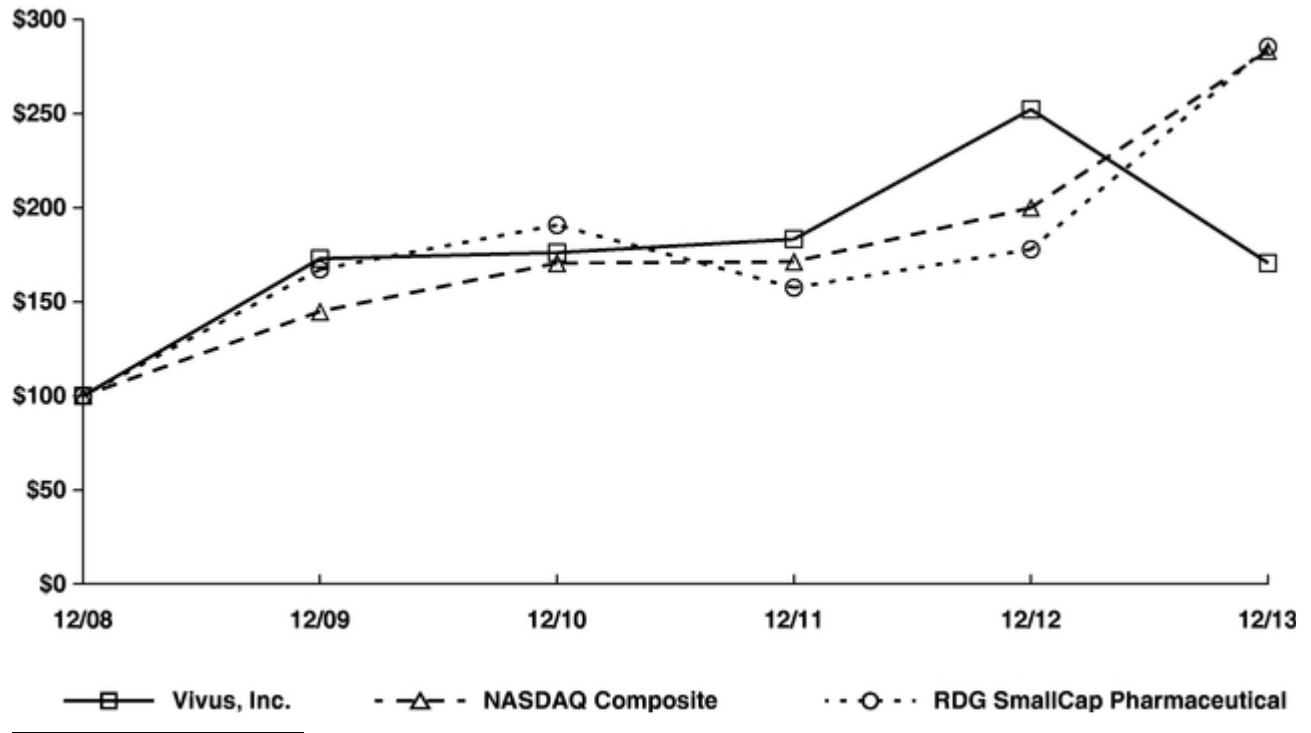
We have not paid any dividends since our inception and we do not intend to declare or pay any dividends on our common stock in the foreseeable future. Declaration or payment of future dividends, if any, will be at the discretion of our Board of Directors after taking into account various factors, including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



**Stock Performance Graph**

The following graph shows a comparison of total stockholder return for holders of our common stock from December 31, 2008 through December 31, 2013 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 small cap 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 12/31/08 in stock or index, including reinvestment of dividends. Fiscal year ending December 31.

**Item 6. Selected Financial Data**

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

**Selected Financial Data**  
(In thousands, except per share data)

**Selected Annual Financial Data**

	Year Ended December 31				
	2013	2012	2011	2010	2009
<i>Income Statement Data:</i>					
Net product revenue	\$ 25,244	\$ 2,012	\$ —	\$ —	\$ —
License and other revenue	55,838	—	—	—	31,395
Total revenue	<u>81,082</u>	<u>2,012</u>	<u>—</u>	<u>—</u>	<u>31,395</u>
Operating expenses:					
Cost of goods sold	4,868	187	—	—	—
Inventory impairment and commitment fee	10,225	—	—	—	—
Research and development	29,677	32,065	24,604	39,971	70,940
Selling, general and administrative	158,235	109,665	22,472	25,656	13,870
Other non-recurring charges	32,691	—	—	—	—
Total operating expenses	<u>235,696</u>	<u>141,917</u>	<u>47,076</u>	<u>65,627</u>	<u>84,810</u>
Loss from operations	(154,614)	(139,905)	(47,076)	(65,627)	(53,415)
Interest and other (income) expense					
Interest expense (income), net	19,532	(199)	(240)	3,840	1,695
Other expense	703	—	—	—	—
Other-than-temporary loss on impaired securities	—	—	—	—	654
Loss on early extinguishment of debt	—	—	—	5,958	—
Total interest and other (income) expense	<u>20,235</u>	<u>(199)</u>	<u>(240)</u>	<u>9,798</u>	<u>2,349</u>
Loss from continuing operations before income taxes	(174,849)	(139,706)	(46,836)	(75,425)	(55,764)
Provision (benefit) for income taxes	97	27	190	9	(2,379)
Net loss from continuing operations	(174,946)	(139,733)	(47,026)	(75,434)	(53,385)
Net income (loss) from discontinued operations, net of income taxes	490	(148)	886	9,369	(906)
Net loss	<u>\$ (174,456)</u>	<u>\$ (139,881)</u>	<u>\$ (46,140)</u>	<u>\$ (66,065)</u>	<u>\$ (54,291)</u>
Basic and diluted net income (loss) per share:					
Continuing operations	\$ (1.72)	\$ (1.42)	\$ (0.56)	\$ (0.93)	\$ (0.74)
Discontinued operations	—	—	0.01	0.11	(0.01)
Net loss per share	<u>\$ (1.72)</u>	<u>\$ (1.42)</u>	<u>\$ (0.55)</u>	<u>\$ (0.82)</u>	<u>\$ (0.75)</u>
Shares used in per share computation:					
Basic and diluted	101,174	98,289	84,392	81,017	72,779
<i>Balance Sheet Data (at year end):</i>					
Working capital	\$ 371,934	\$ 220,671	\$ 140,764	\$ 131,781	\$ 200,852
Total assets	\$ 431,796	\$ 264,114	\$ 152,056	\$ 144,286	\$ 230,032
Long-term debt	\$ 213,106	\$ —	\$ —	\$ —	\$ 19,998
Accumulated deficit	\$ (660,602)	\$ (486,146)	\$ (346,265)	\$ (300,125)	\$ (234,060)
Stockholders' equity	\$ 153,369	\$ 222,909	\$ 141,084	\$ 132,002	\$ 186,726



**Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations****Forward-Looking Statements**

*This Management's Discussion and Analysis of Financial Condition and Results of Operations and other parts of this Form 10-K contain "forward-looking" statements that involve risks and uncertainties. These statements typically may be identified by the use of forward-looking words or phrases such as "may," "believe," "expect," "forecast," "intend," "anticipate," "predict," "should," "planned," "likely," "opportunity," "estimated," and "potential," the negative use of these words or other similar words. All forward-looking statements included in this document are based on our current expectations, and we assume no obligation to update any such forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for such forward-looking statements. In order to comply with the terms of the safe harbor, we note that a variety of factors could cause actual results and experiences to differ materially from the anticipated results or other expectations expressed in such forward-looking statements. The risks and uncertainties that may affect the operations, performance, development, and results of our business include but are not limited to: (1) our 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 we 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 requirements; (5) our ability to continue to certify and add to the Qsymia retail pharmacy network and sell Qsymia through this network; (6) whether the Qsymia retail pharmacy network will simplify and reduce the prescribing burden for physicians, improve access and reduce waiting times for patients seeking to initiate therapy with Qsymia; (7) that we may be required to provide further analysis of previously submitted clinical trial data; (8) our assessment of the European Medicines Agency's Scientific Advice relating to our cardiovascular outcomes trial, or CVOT, and the resubmission of an application for the grant of a marketing authorization to the European Medicines Agency, or EMA, the timing of such resubmission, if any, the results of the CVOT, assessment by the EMA of the application for marketing authorization, and their agreement with the data from the CVOT; (9) our ability to successfully seek approval for Qsymia in other territories outside the U.S. and European Union, or EU; (10) whether healthcare providers, payors and public policy makers will recognize the significance of the American Medical Association officially recognizing obesity as a disease, or the new American Association of Clinical Endocrinologists guidelines; (11) our ability to successfully commercialize Qsymia including risks and uncertainties related to expansion to retail distribution, the broadening of payor reimbursement, the expansion of Qsymia's primary care presence, and the outcomes of our discussions with pharmaceutical companies and our strategic and franchise-specific pathways for Qsymia; (12) our ability to focus our promotional efforts on healthcare providers and on patient education that, along with increased access to Qsymia and ongoing improvements in reimbursement, will result in the accelerated adoption of Qsymia; (13) our ability to eliminate expenses that are not essential to expanding the use of Qsymia and fully realize the anticipated benefits from a cost reduction plan, including the timing thereof; (14) the impact of lower annual net cost savings than currently expected; (15) the impact of the cost reduction plan on our business and unanticipated charges not currently contemplated that may occur as a result of the cost reduction plan; (16) our ability to ensure that the entire supply chain for Qsymia efficiently and consistently delivers Qsymia to our customers; (17) risks and uncertainties related to the timing, strategy, tactics and success of the launches and commercialization of STENDRA™ (avanafil) or SPEDRA™ (avanafil) by our sublicensees in the United States, Canada, the EU, Australia, New Zealand, Africa, the Middle East, Turkey, and the Commonwealth of Independent States, including Russia; (18) our ability to successfully complete on acceptable terms, and on a timely basis, avanafil partnering discussions for other territories under our license with Mitsubishi Tanabe Pharma Corporation in which we do not have a commercial collaboration; (19) the timing of the qualification and subsequent approval by regulatory authorities of Sanofi Chimie and Sanofi Winthrop Industrie as a qualified supplier of STENDRA/SPEDRA, Sanofi Chimie's ability to undertake worldwide manufacturing of the avanafil active pharmaceutical ingredient and Sanofi Winthrop Industrie's ability to undertake worldwide*

*manufacturing of the tablets for avanafil; (20) whether the FDA will approve the amendment for the new prescribing information we have submitted, and/or the European Commission, following an opinion by the EMA, will approve the new prescribing information we intend to submit, to include the recently announced study results showing avanafil is effective for sexual activity within 15 minutes in men with erectile dysfunction; (21) the ability of our partners to maintain regulatory approvals to manufacture and adequately supply our products to meet demand; (22) our ability to accurately forecast Qsymia demand; (23) our ability to increase Qsymia sales in 2014 through growth in certified retail pharmacies, expansion of reimbursement coverage and the use of a more focused selling message; (24) the number of Qsymia prescriptions dispensed through the mail order system and through certified retail pharmacies; (25) the impact of promotional programs for Qsymia on our net product revenue and net income (loss) in future periods; (26) our history of losses and variable quarterly results; (27) substantial competition; (28) risks related to the failure to protect our intellectual property and litigation in which we may become involved; (29) uncertainties of government or third-party payor reimbursement; (30) our reliance on sole-source suppliers; (31) our reliance on third parties and our collaborative partners; (32) our failure to continue to develop innovative investigational drug candidates and drugs; (33) risks related to the failure to obtain FDA or foreign authority clearances or approvals and noncompliance with FDA or foreign authority regulations; (34) our ability to demonstrate through clinical testing the quality, safety and efficacy of our investigational drug candidates; (35) the timing of initiation and completion of clinical trials and submissions to foreign authorities; (36) the results of post-marketing studies are not favorable; (37) compliance with post-marketing regulatory standards, post-marketing obligations or pharmacovigilance rules is not maintained; (38) the volatility and liquidity of the financial markets; (39) our liquidity and capital resources; (40) our expected future revenues, operations and expenditures; (41) potential change in our business strategy to enhance long-term stockholder value; (42) the impact, if any, of the expansion of our Board of Directors to include predominantly new members, the recent appointment of a new Chief Executive Officer and an interim Chief Financial Officer, the resignation of our President, the decision of our Chief Financial Officer to exercise his right to terminate his employment for Good Reason (as defined in his Amended and Restated Change of Control and Severance Agreement with the Company, effective as of July 1, 2013) and the assumption of the Chief Commercial Officer's duties and responsibilities by the Chief Executive Officer; and (43) other factors that are described from time to time in our periodic filings with the U.S. Securities and Exchange Commission, or the SEC, or the Commission, including those set forth in this filing as "Item 1A. Risk Factors."*

*All percentage amounts and ratios were calculated using the underlying data in thousands. Operating results for the year ended December 31, 2013, are not necessarily indicative of the results that may be expected for future fiscal years. The following discussion and analysis should be read in conjunction with our historical financial statements and the notes to those financial statements that are included in Item 8 of Part II of this Form 10-K.*

## **Overview**

VIVUS is a biopharmaceutical company with two therapies approved in the U.S. by the U.S. Food and Drug Administration, or FDA: Qsymia for chronic weight management and STENDRA for erectile dysfunction.

Qsymia (phentermine and topiramate extended-release) was approved by the FDA on July 17, 2012, 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 a proprietary formulation combining low doses of active ingredients from two previously approved drugs, phentermine and topiramate.

Qsymia was approved with a Risk Evaluation and Mitigation Strategy, or REMS, with a goal of informing prescribers and patients of reproductive potential regarding 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, patient brochure, voluntary healthcare provider training, distribution (at launch) restricted to certified mail order pharmacies, an implementation system and a timetable for assessments. In April 2013, the FDA agreed to modify the Qsymia REMS to allow expanded dispensing through certified retail pharmacies. We began this broader distribution in July 2013 through approximately 8,000 certified retail pharmacies. At the date of this report, Qsymia was available through more than 37,000 certified retail pharmacies.

VIVUS commercializes Qsymia in the U.S. through a contract sales force, supported by an internal commercial team consisting of sales management, marketing and managed care professionals. Our efforts to expand the appropriate use of Qsymia include scientific publications, participation and presentations at medical conferences and development and implementation of patient-directed support programs.

In October 2012, we received a negative opinion from the European Medicines Agency, or EMA, Committee for Medicinal Products for Human Use, or CHMP, recommending refusal of the marketing authorization for the medicinal product Qsiva<sup>TM</sup> in the EU (the approved trade name for Qsymia 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 requested that this opinion be re-examined by the CHMP. After re-examination, on February 21, 2013, the CHMP adopted a final opinion that reaffirmed the Committee's earlier negative opinion. On May 15, 2013, the European Commission, or EC, issued a decision refusing the grant of marketing authorization for Qsiva in the EU. On September 20, 2013, we submitted a request to the EMA for Scientific Advice, a procedure similar to the U.S. Special Protocol Assessment process, regarding use of a pre-specified interim analysis from the AQCLAIM cardiovascular outcomes trial to support the resubmission of an application for a marketing authorization for Qsiva for treatment of obesity in accordance with the EU centralized procedure. Based on feedback from the EMA health authority, as well as various country health authorities associated with review of the AQCLAIM trial application, the protocol has been revised and resubmitted to the FDA. We also intend to seek approval for Qsymia in other territories outside the United States and EU.

We intend to commercialize Qsymia/Qsiva in territories where we obtain approval through collaboration agreements with third parties.

Our drug STENDRA (avanafil) is an oral phosphodiesterase type 5, or PDE5, inhibitor that we have licensed from Mitsubishi Tanabe Pharma Corporation, or MTPC. STENDRA was approved by the FDA on April 27, 2012, for the treatment of erectile dysfunction, or ED, in the United States. On June 26, 2013, the European Commission, or EC, adopted the implementing decision granting marketing authorization for SPEDRA (the approved trade name for avanafil in the EU) for the treatment of ED in the EU.

On July 5, 2013, we entered into an agreement with Menarini Group, through its subsidiary Berlin-Chemie AG, or Menarini, under which Menarini received an exclusive license to commercialize and promote SPEDRA for the treatment of ED in over 40 European countries, including the EU, plus Australia and New Zealand. Menarini expects to begin commercialization of SPEDRA in the EU-5 (France, Germany, Italy, Spain and the U.K.) during the first half of 2014.

On October 10, 2013, we entered into an agreement with Auxilium Pharmaceuticals, Inc., or Auxilium, under which Auxilium received an exclusive license to commercialize and promote STENDRA in the United States and Canada. Auxilium began commercializing STENDRA in December 2013.

On December 11, 2013, we entered into an agreement with Sanofi, under which Sanofi received an exclusive license to commercialize and promote avanafil in Africa, the Middle East, Turkey, and the Commonwealth of Independent States, or CIS, including Russia. Sanofi will be responsible for obtaining regulatory approval in its territories. Sanofi intends to market avanafil under the trade name SPEDRA or STENDRA.

Under the license agreements with Menarini, Auxilium and Sanofi, avanafil is expected to be commercialized in over 100 countries worldwide. We are currently in discussions with potential collaboration partners to market and sell STENDRA for other territories under our license with MTPC in which we do not have a commercial collaboration.

### **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, expenses and related disclosures. On an ongoing basis, we evaluate our estimates, including those related to available-for-sale securities, research and development expenses, income taxes, inventories, revenues, including revenues from multiple-element arrangements, contingencies and litigation and share-based compensation. We base our estimates on historical experience, information received from third parties and on various market specific and other relevant 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 significantly from these estimates under different assumptions or conditions.

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

#### *Revenue Recognition*

##### *Product Revenue*

We recognize revenue from the sales of Qsymia, and STENDRA or SPEDRA 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.

##### *Product Revenue Allowances*

Product revenue is recognized net of cash consideration paid to our customers, wholesalers and certified pharmacies, for services rendered by the wholesalers and pharmacies in accordance with the wholesalers and certified pharmacy services network agreements, and include a fixed rate per prescription shipped from home delivery pharmacies 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 product revenue allowances include certain prompt pay discounts and allowances offered to our customers, program rebates and chargebacks. These product revenue allowances 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. We also offer discount programs to patients. Calculating certain of these items involves estimates and judgments based on sales or invoice data, contractual terms, utilization rates, new information regarding changes in these programs' regulations and guidelines that would impact the amount of the actual rebates or chargebacks. We review the adequacy of product revenue allowances on a quarterly basis. Amounts accrued for product revenue allowances are adjusted when trends or significant events indicate that adjustment is appropriate and to reflect actual experience.

The following table summarizes the activity in the accounts related to Qsymia product revenue allowances (in thousands):

	Discount programs	Wholesaler/ Pharmacy fees	Cash discounts	Rebates/ Chargebacks	Total
Balance at January 1, 2012	\$ —	\$ —	\$ —	\$ —	\$ —
Current provision related to sales made during current period*	—	(577)	(57)	—	(634)
Payments	—	434	—	—	434
Balance at December 31, 2012	—	(143)	(57)	—	(200)
Current provision related to sales made during current period*	(8,801)	(5,070)	(1,050)	(280)	(15,201)
Payments	8,099	3,789	973	201	13,062
Balance at December 31, 2013	<u>\$ (702)</u>	<u>\$ (1,424)</u>	<u>\$ (134)</u>	<u>\$ (79)</u>	<u>\$ (2,339)</u>

\* Current provision related to sales made during current period includes \$14.2 million and \$630,000, for product revenue allowances related to revenue recognized during the years ended December 31, 2013 and 2012, respectively. The remaining amounts for the years ended December 31, 2013 and 2012, were recorded on the consolidated balance sheets net of deferred revenue at the end of each period, respectively.

Qsymia was approved by the FDA in July 2012. We sell Qsymia product in the U.S. to wholesalers and 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. Wholesalers, in turn, sell product to certified retail pharmacies. Both mail order and retail certified pharmacies in turn, sell and dispense directly to patients, either at their retail pharmacies or through their mail order home delivery service.

We shipped initial orders of Qsymia to our customers in September 2012, and in July 2013, we expanded our distribution network to include certified retail pharmacies in accordance with the FDA-approved amendment to our NDA for Qsymia. Qsymia has a 36-month shelf life and we grant rights to our customers to return unsold product three months prior to and up to 12 months after product expiration and issue credits that 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 dispensed to patients through prescriptions, at which point, the product is not subject to return. We obtain the prescription shipment data 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, 2013, we have recorded deferred revenue of \$10.3 million related to shipments of Qsymia, which represents product shipped to our customers, but not yet dispensed 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.

The commercialization of STENDRA was launched by our collaboration partner Auxilium in the U.S. in December 2013, and the commercialization of SPEDRA is expected to be launched in the EU-5 (France, Germany, Italy, Spain and the United Kingdom) by our collaboration partner Menarini in the first half of 2014. We sell STENDRA or SPEDRA through our commercialization partners: Auxilium in the U.S., Menarini in the EU plus Australia and New Zealand, and Sanofi in Africa, the Middle East, Turkey, and the CIS, including Russia, who are our customers. Sanofi plans to launch avanafil in their territories after regulatory approvals are received in each country, which is not expected before 2015. Our commercialization partners for STENDRA or SPEDRA sell the product through their distribution channels to patients. Under our product supply agreements, as long as product meets specified product dating criteria at the time of shipment to the partner, our commercialization partners do not have a right of return or credit for expired product. However, given STENDRA or SPEDRA's 48-month shelf life and lack of selling history, we have not been able to reliably estimate expected returns of product at the time of shipment for certain initial product supply orders under these agreements that retain a right of return or credit for product supplied that does not meet the commercialization partners' criteria. Therefore, for these orders, we recognize revenue when units are dispensed to patients through prescriptions, at which point the product is not subject to return. We obtain the prescription shipment data from our commercialization partners to determine the amount of revenue to recognize. We supplied certain initial orders of STENDRA or SPEDRA product with a right of return or credit, which did not meet the required specifications of our partners. In addition, we allocated a portion of the manufacturing milestone payment received from Sanofi in 2013 to product that was supplied in the first quarter of 2014, based on relative estimated selling prices. As a result, we had \$6.7 million in deferred revenue related to STENDRA or SPEDRA product supply as of December 31, 2013.

#### *Revenue from Multiple-Element Arrangements*

We account for multiple-element arrangements, such as license and commercialization agreements in which a customer may purchase several deliverables, in accordance with ASC Topic 605-25, *Revenue Recognition—Multiple-Element Arrangements*, or ASC 605-25. We evaluate if the deliverables in the arrangement represent separate units of accounting. In determining the units of accounting, we evaluate certain criteria, including whether the deliverables have value to our customers on a stand-alone basis. Factors considered in this determination include whether the deliverable is proprietary to us, whether the customer can use the license or other deliverables for their intended purpose without the receipt of the remaining elements, whether the value of the deliverable is dependent on the undelivered items, and whether there are other vendors that can provide the undelivered items. Deliverables that meet these criteria are considered a separate unit of accounting. Deliverables that do not meet these criteria are combined and accounted for as a single unit of accounting.

When deliverables are separable, we allocate non-contingent consideration to each separate unit of accounting based upon the relative selling price of each element. When applying the relative selling price method, we determine the selling price for each deliverable using vendor-specific objective evidence, or VSOE, of selling price, if it exists, or third-party evidence, or TPE, of selling price, if it exists. If neither VSOE nor TPE of selling price exists for a deliverable, we use best estimated selling price, or BEBP, for that deliverable. Significant management judgment may be required to determine the relative selling price of each element. Revenue allocated to each element is then recognized based

on when the following four basic revenue recognition criteria are met for each element: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) the price is fixed or determinable; and (iv) collectability is reasonably assured.

Determining whether and when some of these criteria have been satisfied often involves assumptions and judgments that can have a significant impact on the timing and amount of revenue we report. Changes in assumptions or judgments, or changes to the elements in an arrangement, could cause a material increase or decrease in the amount of revenue that we report in a particular period.

ASC Topic 605-28, *Revenue Recognition—Milestone Method* (ASC 605-28), established the milestone method as an acceptable method of revenue recognition for certain contingent, event-based payments under research and development arrangements. Under the milestone method, a payment that is contingent upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is an event: (i) that can be achieved based in whole or in part on either our performance or on the occurrence of a specific outcome resulting from our performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to us. The determination that a milestone is substantive requires judgment and is made at the inception of the arrangement. Milestones are considered substantive when the consideration earned from the achievement of the milestone is: (i) commensurate with either our performance to achieve the milestone or the enhancement of value of the item delivered as a result of a specific outcome resulting from our performance to achieve the milestone, (ii) relates solely to past performance, and (iii) is reasonable relative to all deliverables and payment terms in the arrangement.

Other contingent, event-based payments received for which payment is either contingent solely upon the passage of time or the results of a collaborative partner's performance are not considered milestones under ASC 605-28. In accordance with ASC 605-25, such payments will be recognized as revenue when all of the four basic revenue recognition criteria are met.

Revenues recognized for royalty payments are recognized as earned in accordance with the terms of the license and commercialization agreements.

### *Inventories*

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 recognized as revenue, are recorded as deferred costs within inventories on the consolidated balance sheets and are subsequently recognized to cost of goods sold when revenue recognition criteria have been met.

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 increase the write down for excess inventory for that product and record a charge to inventory impairment and commitment fee in the consolidated statements of operations. We periodically evaluate the carrying value of inventory on hand for potential excess amount over demand using the same lower of cost or market approach as that used to value the inventory. As a result of this evaluation, for the

year ended December 31, 2013, we recognized a total charge of \$10.2 million for Qsymia inventories on hand in excess of demand, plus a purchase commitment fee. There were no such charges in the year ended December 31, 2012.

### *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, we have 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.

### *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 14: "Stock Option and Purchase Plans" to our Consolidated Financial Statements included elsewhere in this Annual Report on 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, 2013, unrecognized estimated compensation expense totaled \$12.2 million related to non-vested stock options and \$66,000 related to the ESPP. The weighted average remaining requisite service period of the non-vested stock options was 1.3 years and of the ESPP was less than one month.

#### *Fair Value Measurements*

The authoritative literature for fair value measurements established a three-tier fair value hierarchy, which prioritizes the inputs in measuring fair value. These tiers are as follows: Level 1, defined as observable inputs such as quoted market prices in active markets; Level 2, defined as inputs other than the quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as significant unobservable inputs (entity developed assumptions) in which little or no market data exists.

Financial instruments include cash equivalents, available-for-sale securities, accounts receivable, accounts payable and accrued liabilities. Available-for-sale securities are carried at estimated fair value. The carrying value of cash equivalents, accounts payable and accrued liabilities approximate their estimated fair value due to the relatively short nature of these instruments. As of December 31, 2013, our cash and cash equivalents and available-for-sale securities measured at fair value on a recurring basis totaled \$343.3 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, 2013, 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 exist.

In May 2013, we closed on an offering totaling \$250.0 million in Convertible Notes. The fair value of the liability component of the Convertible Notes, excluding the conversion feature, was derived using a binomial lattice model, or Level 3 inputs. To arrive at the appropriate risk adjusted rate, or market yield, for the Convertible Notes, we performed (i) a synthetic credit rating analysis estimating the issuer level credit rating of the Company using a regression model, (ii) research on appropriate market yields using option adjusted spread indications for similar credit ratings, and (iii) considered the market yield implied for the Convertible Notes from a binomial lattice model. Using these inputs, the initial fair value of the liability component of the Convertible Notes was estimated at \$154.7 million. The Convertible Notes are described further below and in Note 12: "Long-Term Debt" to our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

Debt instruments are initially recorded at fair value, with coupon interest and amortization of debt issuance discounts recognized in the statement of operations as interest expense at each period end while such instruments are outstanding. If we issue shares to discharge the liability, the debt obligation is derecognized and common stock and additional paid-in capital are recognized on the issuance of those shares.

Our Convertible Notes contain a conversion option that is classified as equity. The fair value of the liability component of the debt instrument was deducted from the initial proceeds to determine the proceeds to be allocated to the conversion option. The excess of the proceeds received from the Convertible Notes over the initial amount allocated to the liability component, is allocated to the equity component. This excess is reported as a debt discount and subsequently amortized as non-cash interest expense, using the interest method, over the expected life of the Convertible Notes.

Issuance costs related to the equity component of the Convertible Notes were charged to additional paid-in capital. The remaining portion related to the debt component has been capitalized as a deferred charge and included in non-current assets in the consolidated balance sheets, and is being amortized and recorded as additional interest expense over the expected life of the Convertible Notes. In connection with the issuance of the Convertible Notes, we entered into capped call transactions with certain counterparties affiliated with the underwriters. The fair value of the purchased capped calls was recorded to stockholders' equity.

#### *Concentration of Credit Risk*

Financial instruments that potentially subject us to concentrations of credit risk consist primarily of cash, cash equivalents, available-for-sale-securities, and accounts receivable. We have established guidelines to limit our exposure to credit risk by placing investments with a number of high credit quality institutions, in U.S. Treasury securities or diversifying our investment portfolio and placing investments with maturities that maintain safety and liquidity within our liquidity needs.

#### *Accounts Receivable, Allowances for Doubtful Accounts and Cash Discounts*

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. The estimate of cash discounts is recorded at the time of sale. We account for the cash discounts by reducing revenue and accounts receivable by the amount of the discounts we expect our 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, 2013 or 2012.

#### *Non-Recurring Charges*

Our non-recurring charges consist of proxy contest expenses and restructuring charges, including employee severance, one-time termination benefits and ongoing benefits related to the reduction of our workforce, facilities and other exit costs. Liabilities for costs associated with a restructuring activity are recognized when the liability is incurred, as opposed to when management commits to a restructuring plan. In addition, liabilities associated with restructuring activities are measured at fair value. One-time termination benefits are expensed at the date we notify the employee, unless the employee must provide future service, in which case the benefits are expensed ratably over the future service period. Ongoing benefits are expensed when restructuring activities are probable and the benefit amounts are estimable. Other costs primarily consist of legal, consulting, and other costs related to employee terminations and are expensed when incurred. Expenses related to termination benefits are calculated in accordance with the VIVUS, Inc. Amended and Restated Change in Control and Severance Agreement or the termination benefits plan, as applicable.

#### *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, 2013, 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.

### **RESULTS OF OPERATIONS**

For the year ended December 31, 2013, net loss was \$174.5 million or \$1.72 net loss per share, as compared to a net loss of \$139.9 million, or \$1.42 net loss per share during the same period in 2012. The increase in net loss is primarily attributable to increased selling and marketing expenses related to commercialization activities for Qsymia and \$32.7 million in non-recurring charges in connection with our 2013 Annual Meeting of Stockholders and related severance charges, including \$14.1 million of non-cash share-based compensation expense. The net loss for the year ended December 31, 2013, also included higher interest expense related to the debt financings as described below under Contractual Obligations, entered into in April and May of 2013, and a total charge of \$10.2 million for Qsymia inventories on hand in excess of demand, plus a purchase commitment fee for Qsymia. These increases were partially offset by license revenue of \$55.8 million and increased product revenue of \$23.2 million.

We may have continued losses in future periods, depending on our success in commercializing Qsymia and the timing of our research and development expenditures, and our continued investment in the clinical development of our research and future investigational drug candidates, primarily related to the post-marketing study requirements for our approved drugs.

#### *Continuing operations*

##### *Net Qsymia product revenue*

We began distributing Qsymia to the certified home delivery pharmacies in our network in September 2012, and Qsymia became available in certified retail pharmacies in July 2013. As a result, for the year ended December 31, 2012, net product revenue from sales of Qsymia was minimal. We recognize net product revenue for Qsymia based on prescription sell-through by the certified retail pharmacies and home delivery pharmacy services networks to patients as we do not have sufficient historical information to reliably estimate returns. We expect to continue to recognize revenue for Qsymia using this method for the foreseeable future.

Net Qsymia product revenue was \$23.7 million for the year ended December 31, 2013, and \$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. At this time, Qsymia is only approved for sale in the U.S.; therefore, all net product revenue for Qsymia to date has been earned in the U.S.

The following table reconciles gross Qsymia product revenue to net Qsymia product revenue for the years ended December 31, 2013 and 2012 (in thousands):

	<u>2013</u>	<u>2012</u>
Gross Qsymia product revenue	\$ 37,897	\$ 2,642
Discount programs	(8,801)	—
Wholesaler/Pharmacy fees	(4,348)	(577)
Cash discounts	(750)	(53)
Rebates/Chargebacks	(280)	—
Net product revenue	<u>\$ 23,718</u>	<u>\$ 2,012</u>

In the year ended December 31, 2013, approximately 373,000 Qsymia prescriptions were dispensed, as compared to 31,000 Qsymia prescriptions dispensed in the prior year. Approximately 52% of our total prescriptions for the year ended December 31, 2013, included either a free good or discount offer, with approximately 102,000 of those prescriptions dispensed as free goods. In comparison, in the year ended December 31, 2012, approximately 7,000, or 24%, of our total prescriptions were dispensed as free goods.

At December 31, 2013, we had Qsymia deferred revenue of \$10.3 million, which represents Qsymia product shipped to the certified home delivery pharmacy services networks, wholesalers and certified retail pharmacies, but not yet dispensed to patients through prescriptions, net of prompt-payment discounts.

*Net STENDRA/SPEDRA product revenue*

We began distributing STENDRA or SPEDRA tablets to our commercialization partners in December 2013. Auxilium launched the commercialization of STENDRA in the U.S. and Canada in December 2013. We expect Menarini to launch the commercialization of SPEDRA in the EU-5 (France, Germany, Italy, Spain and the United Kingdom) in the first half of 2014. In addition, we sold avanafil API to Sanofi in December 2013, to support their technology transfer to qualify as a second supplier for avanafil API and tablets.

Net STENDRA or SPEDRA product revenue recognized for the year ended December 31, 2013, was \$1.5 million. We had no STENDRA or SPEDRA product revenue for the years ended December 31, 2012 and 2011. As of December 31, 2013, \$6.7 million of STENDRA or SPEDRA product revenue had been deferred until the product has met all required specifications and the related title and risk of loss and damages have been transferred to our commercialization partners.

For geographic information with respect to STENDRA/SPEDRA product revenue, see Note 17: "Segment Information and Concentration of Customers and Suppliers—Geographic Information" to our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

*License revenue*

For the year ended December 31, 2013, we recognized a total of \$55.8 million as license revenue, as we determined that revenue was earned upon the delivery of the license rights and related know-how. As of December 31, 2013, €8 million, or \$10.6 million, in prepayments for future royalties on sales of SPEDRA was deferred.

Under the terms of the License and Commercialization Agreement with Menarini, for the year ended December 31, 2013, we recognized \$21.0 million in license revenue related to the upfront license

fee and a regulatory milestone payment for the approval of the SPEDRA marketing authorization by the EC. In addition, in September 2013, we received another payment of €8 million, or \$10.6 million, as a prepayment for future royalties on sales of SPEDRA. As noted above, this amount has been recorded as deferred revenue as of December 31, 2013, and will be recognized as royalty income when earned.

Under the terms of the License and Commercialization Agreement with Auxilium, for the year ended December 31, 2013, we recognized license revenue of \$30.4 million related to the delivery of the license rights and related know-how.

Under the terms of the License and Commercialization Agreement with Sanofi, we recognized license revenue of \$4.4 million related to the delivery of the license rights and related know-how.

For further discussion on the revenue from our above-mentioned license and commercialization agreements, refer to Note 11: "License, Commercialization and Supply Agreements" to our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

For geographic information with respect to license revenue, see Note 17: "Segment Information and Concentration of Customers and Suppliers—Geographic Information" to our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

#### *Cost of goods sold*

Cost of goods sold was \$4.9 million for the year ended December 31, 2013, as compared to \$187,000 for the year ended December 31, 2012. Cost of goods sold relates to our product shipments of Qsymia of \$2.8 million and STENDRA of \$2.1 million. Cost of goods sold for Qsymia dispensed to patients 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. Cost of goods sold for STENDRA shipped to partners includes the inventory costs of purchased tablets, royalties, freight, shipping and handling costs. The cost of goods sold associated with deferred revenue on Qsymia and STENDRA 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.

#### *Inventory impairment and commitment fee*

Inventories are stated 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. We periodically evaluate the carrying value of inventory on hand for potential excess amount over demand using the same lower of cost or market approach as that used to value the inventory. As a result of this evaluation, for the year ended December 31, 2013, we recognized a total charge of \$10.2 million for Qsymia inventories on hand in excess of demand, plus a purchase commitment fee. No charge was required and none was taken in the years ended December 31, 2012 and 2011. We will continue to evaluate our inventories on a periodic basis and we may incur additional inventory write-downs in future periods if actual events differ materially from our current assumptions.

*Research and development*

<u>Drug Indication/Description</u>	<u>Years Ended December 31,</u>			<u>% Change Increase/(Decrease)</u>	
	<u>2013</u>	<u>2012</u>	<u>2011</u>	<u>2013 vs 2012</u>	<u>2012 vs 2011</u>
	(In thousands, except percentages)				
Qsymia for obesity	\$ 10,520	\$ 10,729	\$ 5,762	(2)%	86%
STENDRA for ED	8,391	8,601	9,467	(2)%	(9)%
Other projects	314	1,662	1,414	(81)%	18%
Share-based compensation	2,361	3,487	1,917	(32)%	82%
Overhead costs*	8,091	7,586	6,044	7%	26%
Total research and development expenses	<u>\$ 29,677</u>	<u>\$ 32,065</u>	<u>\$ 24,604</u>	<u>(7)%</u>	<u>30%</u>

\* 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 decrease in total research and development expenses in the year ended December 31, 2013, as compared to the year ended December 31, 2012, was primarily due to decreases in share-based compensation expense and other project costs.

The increase in research and development expenses for the year ended December 31, 2012, as compared to the year ended December 31, 2011, was 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 estimate the AQCLAIM study will cost between \$180 and \$250 million and the study could take as long as five to six years to complete. We submitted to the EMA a request for Scientific Advice regarding use of a pre-specified interim analysis from AQCLAIM to support the resubmission of an application for a marketing authorization for Qsiva for obesity in accordance with the EU centralized marketing authorization procedure. Based on feedback from the EMA health authority, as well as various country health authorities associated with review of the AQCLAIM trial application, the protocol has been revised and resubmitted to the FDA.

There will be additional research and development expenses for post-approval studies related to STENDRA and Qsymia. 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.

*Selling, general and administrative*

	<u>Years Ended December 31,</u>			<u>% Change Increase/(Decrease)</u>	
	<u>2013</u>	<u>2012</u>	<u>2011</u>	<u>2013 vs 2012</u>	<u>2012 vs 2011</u>
	(In thousands, except percentages)				
Selling and marketing	\$ 94,841	\$ 66,589	\$ 4,913	42%	1,255%
General and administrative	63,394	43,076	17,559	47%	145%
Total selling, general and administrative expenses	<u>\$ 158,235</u>	<u>\$ 109,665</u>	<u>\$ 22,472</u>	<u>44%</u>	<u>388%</u>

In September 2012, we began distributing Qsymia to the certified home delivery pharmacies in our network, and Qsymia became available in retail pharmacies in July 2013. As a result, the selling, general and administrative activities for the year ended December 31, 2013, increased significantly in comparison to the same period in 2012. Selling, general and administrative expenses, excluding the non-recurring charges as described below, increased by \$48.6 million for the year ended December 31, 2013, as compared to the year ended December 31, 2012, due primarily to increased Qsymia commercialization expenses—including higher marketing expenses of \$11.6 million, higher selling expenses of \$16.7 million, and higher general and administrative expenses of \$20.3 million. The increase in general and administrative spending for the year ended December 31, 2013, as compared to the year ended December 31, 2012, was primarily due to incremental increases in corporate expenses of \$10.7 million (primarily professional fees and a full year of product liability insurance), medical affairs-related expenses of \$6.1 million (primarily expenses related to Continuing Medical Education, or CME, grants, the Qsymia REMS program and additional headcount), and increased non-cash share-based compensation expense of \$3.5 million.

Selling, general and administrative expenses increased by \$87.2 million for the year ended December 31, 2012, as compared to the year ended December 31, 2011. The increase in selling and marketing expenses was primarily due to an increase of \$43.2 million in Qsymia pre-commercialization and commercialization activities (primarily related to marketing programs, market research and analytics and additional headcount) and sales expenses of \$17.0 million primarily related to our contract sales organization for the year ended December 31, 2012, as compared to the prior year. General and administrative spending increased by \$25.5 million for the year ended December 31, 2012, due to increased 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 non-cash share-based compensation expense of \$7.0 million.

### *Non-Recurring Charges*

Non-recurring charges were \$32.7 million for the year ended December 31, 2013. On July 18, 2013, we entered into a settlement agreement with First Manhattan Company in connection with a proxy contest related to our 2013 Annual Meeting of Stockholders. According to the terms of the settlement agreement, more than a majority of the members of our Board of Directors resigned and new members of our Board of Directors were appointed. The change in the majority of the members of our Board of Directors, effective July 19, 2013, triggered certain "change of control" benefits in accordance with the Amended and Restated Change of Control and Severance Agreements, or the Amended Agreements, with certain of our employees.

As part of our ongoing efforts to reduce costs by eliminating expenses that are not essential to expanding the use of Qsymia, we implemented a cost reduction plan, announced in November 2013, which reduced our workforce by approximately 20 employees, or 17%, excluding the sales force, in the year ended December 31, 2013. As of December 31, 2013, we have substantially completed this cost reduction plan.

In the year ended December 31, 2013, non-recurring charges included \$14.1 million in share-based compensation related to the automatic acceleration of vesting of unvested stock options held by certain employees per the terms of the Amended Agreements and the reduction in force announced in November 2013, \$8.5 million in employee termination costs related to the proxy contest and reduction in force, \$8.9 million in proxy contest expenses, including approximately \$2.9 million of out-of-pocket expenses that were reimbursed to First Manhattan Company, and \$1.2 million in facilities and other lease exit costs. For additional information concerning our non-recurring charges, please see Note 9: "Non-Recurring Charges" to our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

We expect to realize approximately \$6 million to \$8 million in annual net cost savings beginning in fiscal year 2014, as a result of this cost reduction plan. Our ability to achieve the anticipated cost savings and other benefits from this cost reduction plan within the expected timeframe are subject to many estimates and assumptions, and the actual savings and timing for those savings may vary materially based on factors such as negotiations with third parties and operational requirements. These estimates and assumptions are subject to significant economic, competitive and other uncertainties, some of which are beyond our control. There can be no assurance that we will fully realize the anticipated benefits from this cost reduction plan. To the extent that we are unable to successfully implement our business plan, further cost reduction measures may be required in the future.

*Interest and other expense (income)*

Interest expense (income) net was \$19.5 million in the year ended December 31, 2013, primarily due to interest expense and amortization of issuance costs and discounts from our Convertible Notes and Senior Secured Notes (as defined below under Contractual Obligations) and the amortization of the debt discount on the Convertible Notes. The Convertible Notes were issued in May 2013, and the Senior Secured Notes were issued in April 2013. Interest expense was negligible in each of the years ended December 31, 2012 and 2011. In the year ended December 31, 2013, we recorded \$896,000 in other expense relating to a loss on disposal and impairment of property and equipment which we determined would not provide any future benefits, and \$235,000 in other income for an unrealized gain on currency translation related to the refundable foreign tax withheld on payments made to us by Menarini.

*Provision for income taxes*

We recorded a provision for income taxes in the year ended December 31, 2013, of \$97,000, as compared to \$27,000 in the year ended December 31, 2012. The increase in tax expense relates to increased tax liabilities in some states.

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 for 2007. We recognize interest and penalties accrued on any unrecognized tax benefits as a component of our provision for income taxes. During the years ended December 31, 2013 and 2012, \$6,000 of interest on the unrecognized tax benefits was recorded in both years.

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.

On January 21, 2014, we received a notice of tax refund from the state of New Jersey in settlement of an audit and acceptance of a refund claim for the tax year ended December 31, 2007. As of December 31, 2013, we did not consider receiving the refund as probable and therefore had not recorded an income tax receivable. We expect to receive a refund of approximately \$357,000 (net of associated expenses) in the quarter ended March 31, 2014.

*Discontinued operations*

On November 5, 2010, we completed the sale of the MUSE product to Meda AB. For the years ended December 31, 2013, 2012 and 2011, we recorded some minor adjustments related to the MUSE disposition, primarily adjustments to our sales reserves for accrued product returns.

## LIQUIDITY AND CAPITAL RESOURCES

### Continuing Operations

*Cash.* Unrestricted cash, cash equivalents and available-for-sale securities totaled \$343.3 million at December 31, 2013, as compared to \$214.6 million at December 31, 2012. The increase of \$128.7 million is primarily due to cash provided by financing activities. In April 2013, we received a net amount of \$48.4 million through the sale of a debt-like instrument to BioPharma, or the Senior Secured Notes. On May 21, 2013, we closed an offering of \$220.0 million in 4.5% Convertible Senior Notes due May 1, 2020, or the Convertible Notes. On May 29, 2013, we closed on an additional \$30.0 million of Convertible Notes upon the exercise of an option by the initial purchasers of the Convertible Notes. Total net proceeds from the Convertible Notes were approximately \$241.8 million. In addition, in 2013, we received upfront payments totaling \$26.6 million, net of withholding taxes, under the license agreement with Menarini, \$30.0 million under the license agreement with Auxilium and \$5.0 million under the license agreement with Sanofi.

Since inception, we have financed operations primarily from the issuance of equity, debt and debt-like securities. Through December 31, 2013, we have raised approximately \$931.1 million from financing activities, received \$150 million from the sale of Evamist, and had an accumulated deficit of \$660.6 million at December 31, 2013.

At December 31, 2013, we had \$103.3 million in cash and cash equivalents and \$240.0 million in available-for-sale securities. We invest our excess cash balances in money market and marketable securities and U.S. government securities, in accordance with our investment policy. At December 31, 2013, all of our cash equivalents and available-for-sale securities were invested in either U.S. government securities or money market funds. 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. 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.

*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, 2013, was \$12.2 million, as compared to \$2.8 million at December 31, 2012. Currently, we do not have any significant concerns related to accounts receivable or collections. As of February 19, 2014, we have collected 98% of the accounts receivable outstanding at December 31, 2013.

*Liabilities.* Total liabilities were \$278.4 million at December 31, 2013, which is \$237.2 million higher than at December 31, 2012. The increase in total liabilities was primarily due to the issuances of our Convertible Notes and Senior Secured Notes and an increase in deferred revenue, mainly due to the license agreements with Menarini and Sanofi for SPEDRA, as well as Qsymia deferred product revenue.

*Operating Activities.* Our operating activities used \$135.3 million, \$131.9 million and \$36.9 million of cash during the years ended December 31, 2013, 2012 and 2011, respectively.

During the year ended December 31, 2013, our net operating loss from continuing operations of \$174.9 million was offset by \$32.4 million in non-cash share-based compensation expense due to increased headcount and the automatic acceleration of vesting of unvested stock options held by certain employees in accordance with the terms of the Amended Agreements and the termination benefits plan, \$8.4 million in amortization of debt issuance costs and discounts, and \$7.5 million due to an inventory impairment charge for Qsymia. Additional cash used in operating activities resulted from changes in assets and liabilities during the period, including a net \$30.2 million increase in inventories, primarily for Qsymia and STENDRA, an increase of \$26.5 million in deferred revenue mainly due to the license agreements with Menarini and Sanofi for SPEDRA, as well as Qsymia deferred product revenue, and a decrease in accounts payable of \$14.8 million during the year ended December 31, 2013, due to the timing of activities and vendor payments.

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 \$17.4 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. 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 and \$3.1 million in amortization of discount or premium on available-for-sale securities.

*Investing Activities.* Our investing activities used \$90.1 million, \$54.6 million and \$8.6 million in cash during the years ended December 31, 2013, 2012 and 2011, respectively. The fluctuations from period to period are due primarily to the timing of purchases, sales and maturities of investment securities.

*Financing Activities.* Financing activities provided cash of \$270.1 million, \$205.6 million and \$47.8 million during the years ended December 31, 2013, 2012 and 2011, respectively. In the year ended December 31, 2013, net cash provided by financing activities included \$290.2 million in net proceeds from debt issuances, partially offset by \$34.7 million in payments for capped call transactions. 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.

On May 21, 2013, we closed an offering of \$220.0 million in 4.5% Convertible Senior Notes due May 1, 2020. On May 29, 2013, we closed an additional \$30.0 million of Convertible Notes upon the exercise of an option by the initial purchasers of the Convertible Notes. Total net proceeds from the Convertible Notes were approximately \$241.8 million. For a further discussion of the Convertible Notes, see "Contractual Obligations—Notes Payable and Interest Payable" below.

On March 25, 2013, we entered into the Purchase and Sale Agreement with BioPharma providing for the purchase of a debt-like instrument, or the Senior Secured Notes. Under the BioPharma agreement, we received a net amount of approximately \$48.4 million, at the closing on April 9, 2013. For a further discussion of the Senior Secured Notes, see "Contractual Obligations—Notes Payable and Interest Payable" below.



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.

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 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 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 2014. However, we anticipate that we may require additional funding to expand the use of Qsymia through targeted patient and physician education, find the right partner for expanded Qsymia commercial promotion to a broader primary care physician audience, create a pathway for centralized approval of the marketing authorization application for Qsiva in the EU, continue the expansion of our distribution of Qsymia through certified retail pharmacy locations, conduct post-approval clinical studies for both Qsymia and STENDRA, conduct non-clinical and clinical research and development work to support regulatory submissions and applications for our future investigational drug candidates, finance the costs involved in filing and prosecuting patent applications and enforcing or defending our patent claims, if any, to fund operating expenses, establish additional or new manufacturing and marketing capabilities, and manufacture quantities of our drugs and investigational drug candidates and to make payments under our existing license agreements for Qsymia and STENDRA.

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, 2013, 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, 2013. 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:

<u>Contractual obligations</u>	<u>Payments Due by Period</u>				
	<u>Total</u>	<u>2014</u>	<u>2015 - 2017</u>	<u>2018 - 2019</u>	<u>Thereafter</u>
			(in thousands)		
Operating leases	\$ 12,044	\$ 1,550	\$ 5,993	\$ 3,846	\$ 655
Purchase obligations:					
Manufacturing agreements	64,439	16,143	34,830	13,466	—
Other agreements	64,743	34,824	29,919	—	—
Notes payable	300,000	—	43,571	6,429	250,000
Interest payable	96,825	20,250	48,179	22,771	5,625
<b>Total contractual obligations</b>	<b>\$ 538,051</b>	<b>\$ 72,767</b>	<b>\$ 162,492</b>	<b>\$ 46,512</b>	<b>\$ 256,280</b>

*Operating Leases*

In November 2006, we entered into a 30-month lease for our former corporate headquarters located at 1172 Castro Street in Mountain View, California, or the Castro Lease. On February 14, 2012, we terminated the lease for our former corporate headquarters effective July 31, 2013. In addition, we have a lease on 4,914 square feet of office space located at 1174 Castro Street, Mountain View, California, or the Expansion Space, which is adjacent to our former 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. The Expansion Space is currently being listed for sublease.

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 May 11, 2013, at a starting annual rental rate of \$31.20 per rentable square foot (subject to agreed increases). We are entitled to an abatement of the monthly installments of rent for months seven through 12 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. As part of a cost reduction plan, the first floor of the Evelyn Lease has been substantially vacated and we intend to list this unoccupied space for sublease.

Included in the operating lease commitments above are obligations under leases for which the Company has vacated the underlying facilities as part of a cost reduction plan. These leases expire at various dates through 2020 and represent an aggregate obligation of \$3.6 million through 2020. The Company does not currently have sublease income related to the restructured space. The Company has restructuring accruals of \$1.0 million at December 31, 2013, which represents the difference between this aggregate future obligation and expected future sublease income under estimated potential sublease agreements, as well as other facilities-related obligations. For additional information regarding this cost reduction plan, see Note 9: "Non-Recurring Charges" to our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

For additional information regarding obligations under operating leases, see Note 15: "Commitments" to our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

#### *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 \$6.4 million at December 31, 2013. 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 complete open purchase orders with Catalent for the production of Qsymia and for process improvement projects, which totaled approximately \$1.4 million at December 31, 2013.

The API and the tablets for STENDRA/SPEDRA (avanafil) are currently manufactured by MTPC. There are no minimum purchase obligations for STENDRA/SPEDRA 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, 2013, totaled \$4.4 million.

On July 31, 2013, we entered into a Commercial Supply Agreement with Sanofi Chimie pursuant to which they will manufacture and supply the API for our drug avanafil. Further, on November 18, 2013, we entered into a Manufacturing and Supply Agreement with Sanofi Winthrop Industrie pursuant to which they will manufacture and supply the avanafil tablets. We have minimum purchase commitments under these agreements to purchase API materials from 2014 through 2018, and to purchase tablets from 2015 through 2019. Our minimum purchase commitments under these agreements total approximately \$51.5 million as of December 31, 2013.

We have also entered into an agreement with a third party to perform manufacturing-related services including product stability testing on our behalf and, at December 31, 2013, our remaining commitment under this agreement totaled \$713,000.

#### 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 was effective beginning on July 30, 2012, and, on December 4, 2014, we extended the term of the agreement through December 31, 2015. 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, 2013, our total obligation under the Sales Team Agreement is \$56.1 million, including primarily compensation costs and administrative service fees. In addition, we have remaining commitments under other various marketing services agreements totaling \$407,000 at December 31, 2013.

We have entered into various agreements with clinical consultants, investigators, clinical suppliers and clinical research organizations to perform clinical trial management and clinical studies on our behalf and, at December 31, 2013, our remaining commitment under these agreements totaled \$8.2 million. We make payments to these providers based upon the number of patients enrolled and the length of their participation in the trials. These obligations, however, are contingent on future events, e.g., the rate of patient accrual in our clinical trials. Although all of these contracts could be cancelled by us, this amount represents the remaining contractual amounts that would be due in case of cancellation as of December 31, 2013, which are not included in our consolidated balance sheet at that date.

#### *Notes Payable and Interest Payable*

##### Convertible Senior Notes Due 2020

On May 21, 2013, we closed an offering of \$220.0 million in 4.5% Convertible Senior Notes due May 1, 2020. On May 29, 2013, we closed on an additional \$30.0 million of Convertible Notes upon the exercise of an option by the initial purchasers of the Convertible Notes. Total net proceeds from the Convertible Notes were approximately \$241.8 million. The Convertible Notes are governed by an indenture, dated as of May 21, 2013, between VIVUS and Deutsche Bank National Trust Company, as trustee.

The Convertible Notes are senior unsecured obligations of the Company and bear interest at a fixed rate of 4.50% per annum, payable semiannually in arrears on May 1 and November 1 of each year, beginning on November 1, 2013, unless earlier purchased or converted.

The Convertible Notes are convertible into approximately 16,826,000 unregistered shares of our common stock under certain circumstances prior to maturity at a conversion rate of 67.3038 shares per \$1,000 principal amount of the Convertible Notes, which represents a conversion price of approximately \$14.858 per share, subject to adjustment under certain conditions. The Convertible Notes are convertible at the option of the holders at any time prior to the close of business on the business day immediately preceding November 1, 2019, only under certain conditions. On or after November 1, 2019, holders may convert all or any portion of their Convertible Notes at any time at their option at the conversion rate then in effect, regardless of these conditions. Subject to certain limitations, we will settle conversions of the Convertible Notes by paying or delivering, as the case may be, cash, shares of our common stock or a combination of cash and shares of our common stock, at our election. The conversion rate of the Convertible Notes, and the corresponding conversion price, will be subject to adjustment for certain events, but will not be adjusted for accrued interest. In addition, following certain corporate transactions that occur on or prior to the maturity date for the Convertible Notes, we will increase the conversion rate for a holder that elects to convert its Convertible Notes in connection with such a corporate transaction.

Senior Secured Notes Due 2018

On March 25, 2013, we entered into the Purchase and Sale Agreement with BioPharma providing for the purchase of a debt-like instrument, or the Senior Secured Notes. Under the BioPharma agreement, we received net proceeds of approximately \$48.4 million, at the closing on April 9, 2013.

We are obligated to make scheduled quarterly payments under the BioPharma agreement. The first payment is scheduled to be made in the second quarter of 2014, and the final payment is scheduled to be made in the second quarter of 2018. The scheduled quarterly payments are subject to the net sales of (i) Qsymia (and any derivative or improvement thereof, including Qsiva as it relates to the EU), or the Product, and (ii) any other obesity agent developed or marketed by us or our affiliates or licensees. The scheduled quarterly payments, other than the payment (s) scheduled to be made in the second quarter of 2018, are capped at the lower of the scheduled payment amounts or 25% of the net sales of (i) and (ii) above. Accordingly, if 25% of the net sales is less than the scheduled quarterly payment, then 25% of the net sales is due for that quarter, with the exception of the payment(s) scheduled to be made in the second quarter of 2018, when any unpaid scheduled quarterly payments plus any accrued and unpaid make-whole premiums must be paid. Any quarterly payment less than the scheduled quarterly payment amount will be subject to a make-whole premium equal to the applicable scheduled quarterly payment of the preceding quarter less the actual payment made to BioPharma for the preceding quarter multiplied by 1.03. Regardless, we may pay scheduled quarterly payments out of any available funds notwithstanding Product net sales. We also have the option to prepay all scheduled quarterly payments as specified in the BioPharma agreement.

To secure our obligations in connection with the BioPharma agreement, we granted BioPharma a security interest to (i) the purchased receivables which are defined in the BioPharma agreement as the scheduled quarterly payments, any underpayments of such payments based on an audit of our records and any interest due on the foregoing amounts, and (ii) our patents, trademarks, copyrights and regulatory filings related to the Product, or the Additional Collateral.

***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., now 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 were 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, 2013, under the terms of the MTPC agreement, we have paid a total of \$15.0 million to MTPC in milestone payments, including \$2.0 million in 2013, upon approval of SPEDRA (avanafil) in the EU, and \$3.0 million in 2012, upon FDA approval of STENDRA (avanafil). In addition, during 2013 and 2012, we purchased from MTPC

\$10.0 million and \$7.4 million of product, respectively, under the supply portion of the Agreement in preparation for the commercial launch in the U.S., the EU and certain other territories that use the U.S. and EU approvals.

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 \$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.

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 parties. According to the amendment, the transition of manufacturing from MTPC must occur on or before June 30, 2015. As mentioned above, on July 31, 2013, we entered into a Commercial Supply Agreement with Sanofi Chimie to manufacture and supply the API for avanafil on an exclusive basis in the United States and other territories and on a semi-exclusive basis in Europe, including the EU, Latin America and other territories. Further, as mentioned above, on November 18, 2013, we entered into a Manufacturing and Supply Agreement with Sanofi Winthrop Industrie to manufacture and supply the avanafil tablets on an exclusive basis in the United States and other territories and on a semi-exclusive basis in Europe, including the EU, Latin America and other territories. We intend to submit an amendment to the NDA for avanafil to the FDA, and a variation to the marketing authorization, or MA, for avanafil to the EMA, to include Sanofi Chimie as a qualified supplier of the avanafil API and Sanofi Winthrop Industrie as a qualified supplier of the avanafil tablets.

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 were obligated to use our best commercial efforts to market STENDRA in the U.S. by December 31, 2013, which was achieved by our commercialization partner, Auxilium. On July 23, 2013, we entered into the fourth amendment to our agreement with MTPC which, among other things, changes the definition of net sales used to calculate royalties owed by us to MTPC.

#### *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 us with worldwide rights to develop and commercialize the Combination Therapy and exploit the Patents. Pursuant to the Assignment Agreement, through December 31, 2013, we have paid a total of \$1.2 million and have issued fully vested and exercisable options to purchase 60,000 shares of VIVUS's common stock to Dr. Najarian. In addition, the Assignment Agreement requires 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 served as a Principal Scientist. In November 2013, Dr. Najarian's employment with the Company ended although he continues to work for us on a consulting basis.

### *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.

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, 2013 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 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, 2013, 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, 2013, by approximately \$1.3 million. In general, money market funds are not subject to market risk because the interest paid on such funds fluctuates with the prevailing interest rate.

**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:

Reports of Independent Registered Public Accounting Firm	102
Consolidated Balance Sheets as of December 31, 2013 and 2012	104
Consolidated Statements of Operations for the years ended December 31, 2013, 2012 and 2011	105
Consolidated Statements of Comprehensive Loss for the years ended December 31, 2013, 2012 and 2011	105
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2013, 2012 and 2011	106
Consolidated Statements of Cash Flows for the years ended December 31, 2013, 2012 and 2011	107
Notes to Consolidated Financial Statements	108
Financial Statement Schedule II	153

**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, 2013 and 2012, 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, 2013. In connection with our audits of the financial statements, we have also audited the financial statement schedule 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, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements and schedule. 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, 2013 and 2012, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2013, in conformity with U.S. generally accepted accounting principles.

Also, in our opinion, the financial statement schedule, when considered in relation to the basic consolidated 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, 2013, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated February 27, 2014 expressed an unqualified opinion thereon.

/s/ OUM & Co. LLP

San Francisco, California  
February 27, 2014

**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, 2013, 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 the accompanying Item 9A, *Management's Annual Report on Internal Control Over Financial Reporting*. 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, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included 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, 2013, 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, 2013 and 2012, 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, 2013 and our report dated February 27, 2014 expressed an unqualified opinion thereon.

/s/ OUM & Co. LLP

San Francisco, California  
February 27, 2014

## VIVUS, INC.

## CONSOLIDATED BALANCE SHEETS

(In thousands, except par value)

	December 31	
	2013	2012
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 103,262	\$ 58,605
Available-for-sale securities	240,024	155,981
Accounts receivable, net	12,214	2,778
Inventories, net	48,503	25,353
Prepaid expenses and other assets	19,938	19,159
Total current assets	<u>423,941</u>	<u>261,876</u>
Property and equipment, net	1,954	1,951
Non-current assets	5,901	287
Total assets	<u>\$ 431,796</u>	<u>\$ 264,114</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 10,759	\$ 25,375
Accrued and other liabilities	23,993	14,680
Deferred revenue	17,255	1,150
Total current liabilities	<u>52,007</u>	<u>41,205</u>
Long-term debt	213,106	—
Deferred revenue—net of current portion	10,360	—
Non-current accrued and other liabilities	2,954	—
Total liabilities	<u>278,427</u>	<u>41,205</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock; \$1.00 par value; 5,000 shares authorized; no shares issued and outstanding at December 31, 2013 and 2012	—	—
Common stock; \$.001 par value; 200,000 shares authorized at December 31, 2013 and 2012; 103,161 and 100,659 shares issued and outstanding at December 31, 2013 and 2012, respectively	103	101
Additional paid-in capital	813,802	708,921
Accumulated other comprehensive income	66	33
Accumulated deficit	(660,602)	(486,146)
Total stockholders' equity	<u>153,369</u>	<u>222,909</u>
Total liabilities and stockholders' equity	<u>\$ 431,796</u>	<u>\$ 264,114</u>

See accompanying notes to consolidated financial statements.

## VIVUS, INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

	Years Ended December 31		
	2013	2012	2011
Revenue:			
Net product revenue	\$ 25,244	\$ 2,012	\$ —
License revenue	55,838	—	—
Total revenue	81,082	2,012	—
Operating expenses:			
Cost of goods sold	4,868	187	—
Inventory impairment and commitment fee	10,225	—	—
Research and development	29,677	32,065	24,604
Selling, general and administrative	158,235	109,665	22,472
Non-recurring charges	32,691	—	—
Total operating expenses	235,696	141,917	47,076
Loss from operations	(154,614)	(139,905)	(47,076)
Interest and other expense (income):			
Interest expense (income), net	19,532	(199)	(240)
Other expense	703	—	—
Total interest and other income (expense)	20,235	(199)	(240)
Loss from continuing operations before income taxes	(174,849)	(139,706)	(46,836)
Provision for income taxes	97	27	190
Loss from continuing operations	(174,946)	(139,733)	(47,026)
Income (loss) from discontinued operations, net of tax	490	(148)	886
Net loss	\$ (174,456)	\$ (139,881)	\$ (46,140)
Basic and diluted net loss per share:			
Continuing operations	\$ (1.72)	\$ (1.42)	\$ (0.56)
Discontinued operations	0.00	0.00	0.01
Net loss per share	\$ (1.72)	\$ (1.42)	\$ (0.55)
Shares used in per share computation:			
Basic and diluted	101,174	98,289	84,392

## VIVUS, INC.

## CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

	Years Ended December 31		
	2013	2012	2011
Net loss	\$ (174,456)	\$ (139,881)	\$ (46,140)
Other comprehensive income—unrealized gain on securities, net of taxes	33	8	21
Comprehensive loss	\$ (174,423)	\$ (139,873)	\$ (46,119)

See accompanying notes to consolidated financial statements.

## VIVUS, INC.

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amount				
Balances, December 31, 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
Sale of common stock through employee stock purchase plan	103	—	860	—	—	860
Exercise of common stock options for cash	2,366	2	13,704	—	—	13,706



Vesting of restricted stock units	33	—	—	—	—	—
Share-based compensation expense	—	—	32,877	—	—	32,877
Equity component of convertible debt	—	—	95,262	—	—	95,262
Offering cost allocated to equity	—	—	(3,113)	—	—	(3,113)
Purchase of capped call transaction	—	—	(34,709)	—	—	(34,709)
Net unrealized gain on securities	—	—	—	33	—	33
Net loss	—	—	—	—	(174,456)	(174,456)
Balances, December 31, 2013	<u>103,161</u>	<u>\$ 103</u>	<u>\$ 813,802</u>	<u>\$ 66</u>	<u>\$ (660,602)</u>	<u>\$ 153,369</u>

See accompanying notes to consolidated financial statements.

## VIVUS, INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Years Ended December 31		
	2013	2012	2011
<b>Cash flows from operating activities:</b>			
Net loss from continuing operations	\$(174,946)	\$(139,733)	\$ (47,026)
Adjustments to reconcile net loss from continuing operations to net cash used for operating activities from continuing operations:			
Depreciation	973	271	102
Amortization of debt issuance costs and discounts	8,369	—	—
Amortization of discount or premium on available-for-sale securities	2,635	3,950	3,118
Share-based compensation expense	32,397	15,938	7,353
Unrealized foreign currency remeasurement gain	(235)	—	—
Loss on disposal and impairment of property and equipment	896	—	—
Inventory impairment	7,525	—	—
Changes in assets and liabilities:			
Accounts receivable	(9,436)	(2,778)	—
Inventories	(30,195)	(22,050)	118
Prepaid expenses and other assets	2,086	(17,366)	(145)
Accounts payable	(14,821)	22,202	545
Accrued and other liabilities	13,170	7,385	15
Deferred revenue	26,465	1,150	—
Net cash used for operating activities from continuing operations	(135,117)	(131,031)	(35,920)
Net cash used for operating activities from discontinued operations	(208)	(885)	(980)
Net cash used for operating activities	<u>(135,325)</u>	<u>(131,916)</u>	<u>(36,900)</u>
<b>Cash flows from investing activities:</b>			
Property and equipment purchases	(1,795)	(1,669)	(201)
Purchases of available-for-sale securities	(329,145)	(226,654)	(137,409)
Proceeds from maturity of available-for-sale securities	242,500	133,250	129,000
Proceeds from sale of available-for-sale securities	—	40,763	—
Non-current assets	(1,681)	(287)	—
Net cash used for investing activities	<u>(90,121)</u>	<u>(54,597)</u>	<u>(8,610)</u>
<b>Cash flows from financing activities:</b>			
Net proceeds from debt issuances	290,247	—	—
Payments for capped call transactions	(34,709)	—	—
Net proceeds from exercise of common stock options	13,706	13,250	2,354
Sale of common stock through employee stock purchase plan	859	314	211
Net proceeds from issuance of common stock	—	192,000	45,283
Net cash provided by financing activities from continuing operations	<u>270,103</u>	<u>205,564</u>	<u>47,848</u>
<b>Net increase in cash and cash equivalents</b>	<u>44,657</u>	<u>19,051</u>	<u>2,338</u>
<b>Cash and cash equivalents:</b>			
Beginning of year	58,605	39,554	37,216
End of year	<u>\$ 103,262</u>	<u>\$ 58,605</u>	<u>\$ 39,554</u>
<b>Supplemental cash flow disclosure:</b>			
Interest paid	<u>\$ 5,000</u>	<u>\$ —</u>	<u>\$ —</u>
Income taxes paid	<u>\$ 32</u>	<u>\$ 7</u>	<u>\$ 24</u>
<b>Non-cash investing activities:</b>			
Unrealized gain on securities	<u>\$ 33</u>	<u>\$ 8</u>	<u>\$ 21</u>

See accompanying notes to consolidated financial statements.

VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**Note 1. Business and Significant Accounting Policies**

**Business**

VIVUS is a biopharmaceutical company with two U.S. Food and Drug Administration, or FDA, approved therapies, Qsymia® and STENDRA™. The Company's drug Qsymia (phentermine and topiramate extended-release) was approved by the FDA on July 17, 2012, 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 a proprietary formulation combining 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 suppress appetite and increase satiety, or the feeling of being full, the two main mechanisms that impact eating behavior. On September 17, 2012, the Company announced the U.S. market availability of Qsymia through a certified home delivery network, which includes CVS Pharmacy, Express Scripts, Walgreens, Wal-Mart Pharmacy, and, for its members only, Kaiser Permanente. On July 1, 2013, the Company announced initial retail availability of Qsymia through approximately 8,000 Walgreens, Costco and Duane Reade pharmacies nationwide. As of the date of this report, Qsymia is available in over 37,000 certified retail pharmacies nationwide. The Company intends to continue to certify and add new pharmacies to the Qsymia retail pharmacy network, including national and regional chains as well as independent pharmacies. In addition, Qsymia continues to be available through a certified home delivery pharmacy network for patients who prefer to receive Qsymia by mail.

In October 2012, the Company received the negative opinion from the European Medicines Agency, or EMA, Committee for Medicinal Products for Human Use, or CHMP, recommending refusal of the marketing authorization for the medicinal product Qsiva™ in the European Union, or EU, (the approved trade name for Qsymia 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. The Company requested that this opinion be re-examined by the CHMP. After re-examination, on February 21, 2013, the CHMP adopted a final opinion that reaffirmed the Committee's earlier negative opinion. On May 15, 2013, the European Commission issued a decision refusing the grant of marketing authorization for Qsiva in the EU. On September 20, 2013, the Company submitted a request to the EMA for Scientific Advice, a procedure similar to the U.S. Special Protocol Assessment process, regarding use of a pre-specified interim analysis from the AQCLAIM cardiovascular outcomes trial to support the resubmission of an application for a marketing authorization for Qsiva for treatment of obesity in accordance with the EU centralized procedure. Based on feedback from the EMA health authority, as well as various country health authorities associated with review of the AQCLAIM trial application, the protocol has been revised and resubmitted to the FDA. The Company also intends to seek approval for Qsymia in other territories outside the United States and EU. The Company intends to commercialize Qsymia in territories where it obtains approval through collaboration agreements with third parties.

The Company's drug STENDRA, or avanafil, is an oral phosphodiesterase type 5, or PDE5, inhibitor that the Company has licensed from Mitsubishi Tanabe Pharma Corporation, or MTPC. STENDRA was approved by the FDA on April 27, 2012, for the treatment of erectile dysfunction, or ED, in the United States. On June 26, 2013, the European Commission, or EC, adopted the implementing decision granting marketing authorization for SPEDRA™ (the approved trade name for avanafil in the EU) for the treatment of ED in the EU. On July 5, 2013, the Company entered into an

VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

agreement with Menarini Group, through its subsidiary Berlin-Chemie AG, or Menarini, under which Menarini received an exclusive license to commercialize and promote SPEDRA for the treatment of ED in over 40 European countries, including the EU, plus Australia and New Zealand.

On October 10, 2013, the Company entered into an agreement with Auxilium Pharmaceuticals, Inc., or Auxilium, under which Auxilium received an exclusive license to commercialize and promote STENDRA in the United States and Canada. On December 11, 2013, the Company entered into an agreement with Sanofi under which Sanofi received an exclusive license to commercialize and promote avanafil for therapeutic use in humans in Africa, the Middle East, Turkey, and the Commonwealth of Independent States, or CIS, including Russia. Sanofi will be responsible for obtaining regulatory approval in its territories. Sanofi intends to market avanafil under the trade name SPEDRA or STENDRA. Under the license agreements with Menarini, Auxilium and Sanofi, avanafil is expected to be commercialized in over 100 countries worldwide. The Company is currently in discussions with potential collaboration partners to market and sell STENDRA for other territories under its license with MTPC in which it does not have a commercial collaboration.

At December 31, 2013, the Company's accumulated deficit was approximately \$660.6 million. Based on current plans, management expects to incur further losses for the foreseeable future. Management believes that the Company's existing capital resources combined with anticipated future cash flows will be sufficient to support its operating needs at least through 2014. 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 2014 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, 2013, through the date these consolidated financial statements were filed. There were no events or transactions occurring during this period that require recognition or disclosure in these consolidated financial statements, except as disclosed in Note 20. 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.

**Significant Accounting Policies**

*Reclassifications*

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

*Principles of Consolidation*

The consolidated financial statements include the accounts of VIVUS, Inc., and its wholly owned subsidiaries: 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 July 22, 2011, VIVUS Real Estate LLC was cancelled.

VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

*Use of Estimates*

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, the Company evaluates its estimates, including critical accounting policies or estimates related to available-for-sale securities, debt instruments, 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, 2013 and 2012, 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, 2013 and 2012, the temporary unrealized gains (losses) on cash equivalents and available-for-sale securities, net of tax, were included in accumulated other comprehensive income (loss) in the accompanying consolidated balance sheets.

*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

VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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 include cash equivalents, available-for-sale securities, accounts receivable, accounts payable and accrued liabilities. Available-for-sale securities are carried at estimated fair value. The carrying value of cash equivalents, accounts payable and accrued liabilities approximate their estimated fair value due to the relatively short-term nature of these instruments.

Debt instruments are initially recorded at fair value, with coupon interest and amortization of debt issuance discounts recognized in the statement of operations as interest expense at each period end while such instruments are outstanding. If the Company issues shares to discharge the liability, the debt obligation is derecognized and common stock and additional paid-in capital are recognized on the issuance of those shares.

The Company's Convertible Notes contain a conversion option that is classified as equity. The Company determined the fair value of the liability component of the debt instrument and allocated the excess amount from the initial proceeds to the conversion option. The fair value of the debt component was determined by estimating a risk adjusted interest rate, or market yield, at the time of issuance for similar notes that do not include the conversion feature, or equity component. This excess is reported as a debt discount and is amortized as non-cash interest expense, using the interest method, over the expected life of the Convertible Notes.

Issuance costs related to the equity component of the Convertible Notes were charged to additional paid-in capital. The remaining portion related to the debt component is being amortized and recorded as additional interest expense over the expected life of the Convertible Notes. In connection with the issuance of the Convertible Notes, the Company entered into capped call transactions with certain counterparties affiliated with the underwriters. The fair value of the purchased capped calls was recorded to stockholders' equity.

*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

VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

sales price, as an incentive for prompt payment. The estimate of cash discounts is recorded at the time 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, 2013 or 2012. The allowance for cash discounts is \$134,000 at December 31, 2013, and \$57,000 at December 31, 2012.

*Inventories*

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, 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 recognized as revenue, are recorded within inventories on the consolidated balance sheets and are subsequently recognized to cost of goods sold when revenue recognition criteria have been met.

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 increase the write down for excess inventory for that product and record a charge to inventory impairment and commitment fee in the accompanying consolidated statements of operations. The Company periodically evaluates the carrying value of inventory on hand for potential excess amount over demand using the same lower of cost or market approach as that used to value the inventory. As a result of this evaluation, for the year ended December 31, 2013, the Company recognized a total charge of \$10.2 million for Qsymia inventories on hand in excess of demand, plus a purchase commitment fee. There were no such charges in the year ended December 31, 2012.

*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, software, 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.



VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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 for the amount by which the carrying amount of the asset exceeds the fair value of the asset.

*Deferred Financing Costs*

Deferred financing costs, which are included in other assets, are amortized as interest expense over the contractual terms of the related credit facilities.

*Revenue Recognition*

*Product Revenue:*

The Company recognizes revenue from the sales of Qsymia, and STENDRA or SPEDRA 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 Company's 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 to the Company 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.

*Product Revenue Allowances:*

Product revenue is recognized net of cash consideration paid to the Company's customers, wholesalers and certified pharmacies, for services rendered by the wholesalers and pharmacies in accordance with the wholesalers and certified pharmacy services network agreements, and include a fixed rate per prescription shipped from home delivery pharmacies 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 product revenue allowances include certain prompt pay discounts and allowances offered to the Company's customers, program rebates and chargebacks. These product revenue allowances 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 also offers discount programs to patients. Calculating certain of these items involves estimates and judgments based on sales or invoice data, contractual terms, utilization rates, new information regarding changes in these programs' regulations and guidelines that would impact the amount of the actual rebates or chargebacks. The Company reviews the adequacy of product revenue allowances on a quarterly basis. Amounts accrued for product revenue allowances are adjusted when trends or significant events indicate that adjustment is appropriate and to reflect actual experience.

## VIVUS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

Qsymia was approved by the FDA in July 2012. The Company sells Qsymia product in the U.S. to wholesalers and select certified pharmacies through their home delivery pharmacy services networks, 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. Wholesalers, in turn, sell product to certified retail pharmacies. Both mail order and retail certified pharmacies in turn, sell and dispense directly to patients either at their retail pharmacies or through their mail order home delivery service.

The Company shipped initial orders of Qsymia to its customers in September 2012, and in July 2013 the Company expanded its distribution network to include certified retail pharmacies in accordance with the FDA-approved amendment to the Company's NDA for Qsymia. Qsymia has a 36-month shelf life and the Company grants rights to its customers to return unsold product three months prior to and up to 12 months after product expiration and issue credits that may be applied against existing or future invoices. Given the Company's limited history of selling Qsymia and the lengthy return period, the Company has not been able to reliably estimate expected returns of Qsymia at the time of shipment, and therefore it recognizes revenue when units are dispensed to patients through prescriptions, at which point, the product is not subject to return. The Company obtains the prescription shipment data from the pharmacies to determine the amount of revenue to recognize.

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, 2013, the Company had recorded deferred revenue of \$10.3 million related to shipments of Qsymia, which represents product shipped to its customers, but not yet dispensed 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.

The commercialization of STENDRA was launched by the Company's collaboration partner Auxilium in the U.S. in December 2013, and the commercialization of SPEDRA is expected to be launched in the EU-5 (France, Germany, Italy, Spain and the United Kingdom), by the Company's collaboration partner Menarini in the first half of 2014. The Company sells STENDRA or SPEDRA through its commercialization partners: Auxilium in the U.S., Menarini in the EU plus Australia and New Zealand, and Sanofi in Africa, the Middle East, Turkey, and the CIS, including Russia, who are its customers. The Company's commercialization partners for STENDRA or SPEDRA sell product through their distribution channels to patients. Under the Company's product supply agreements, as long as product meets specified product dating criteria at the time of shipment to the partner, the Company's commercialization partners do not have a right of return or credit for expired product. However, given STENDRA or SPEDRA's 48-month shelf life and lack of selling history, the Company has not been able to reliably estimate expected returns of product at the time of shipment for certain initial product supply orders under these agreements that retain a right of return or credit for product supplied that does not meet the commercialization partners' criteria. Therefore, for these orders, the Company recognizes revenue when units are dispensed to patients through prescriptions, at which point, the product is not subject to return. The Company obtains the prescription shipment data from its commercialization partners to determine the amount of revenue to recognize. The Company supplied certain initial orders of STENDRA or SPEDRA product with a right of return or credit, which did not meet the required specifications of its partners. In addition, the Company allocated a portion of the manufacturing milestone payment received from Sanofi in 2013 to product that was supplied in the first quarter of 2014, based on relative estimated selling prices. As a result, the

VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

Company had \$6.7 million in deferred revenue related to STENDRA or SPEDRA product supply as of December 31, 2013.

*Revenue from Multiple-Element Arrangements:*

The Company accounts for multiple-element arrangements, such as license and commercialization agreements in which a customer may purchase several deliverables, in accordance with ASC Topic 605-25, *Revenue Recognition—Multiple-Element Arrangements*, or ASC 605-25. The Company evaluates if the deliverables in the arrangement represent separate units of accounting. In determining the units of accounting, management evaluates certain criteria, including whether the deliverables have value to its customers on a stand-alone basis. Factors considered in this determination include whether the deliverable is proprietary to the Company, whether the customer can use the license or other deliverables for their intended purpose without the receipt of the remaining elements, whether the value of the deliverable is dependent on the undelivered items, and whether there are other vendors that can provide the undelivered items. Deliverables that meet these criteria are considered a separate unit of accounting. Deliverables that do not meet these criteria are combined and accounted for as a single unit of accounting.

When deliverables are separable, the Company allocates non-contingent consideration to each separate unit of accounting based upon the relative selling price of each element. When applying the relative selling price method, the Company determines the selling price for each deliverable using vendor-specific objective evidence, or VSOE, of selling price, if it exists, or third-party evidence, or TPE, of selling price, if it exists. If neither VSOE nor TPE of selling price exists for a deliverable, the Company uses best estimated selling price, or BESP, for that deliverable. Significant management judgment may be required to determine the relative selling price of each element. Revenue allocated to each element is then recognized based on when the following four basic revenue recognition criteria are met for each element: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) the price is fixed or determinable; and (iv) collectability is reasonably assured.

Determining whether and when some of these criteria have been satisfied often involves assumptions and judgments that can have a significant impact on the timing and amount of revenue the Company reports. Changes in assumptions or judgments, or changes to the elements in an arrangement, could cause a material increase or decrease in the amount of revenue reported in a particular period.

ASC Topic 605-28, *Revenue Recognition—Milestone Method* (ASC 605-28), established the milestone method as an acceptable method of revenue recognition for certain contingent, event-based payments under research and development arrangements. Under the milestone method, a payment that is contingent upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is an event: (i) that can be achieved based in whole or in part on either the Company's performance or on the occurrence of a specific outcome resulting from the Company's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to the Company. The determination that a milestone is substantive requires judgment and is made at the inception of the arrangement. Milestones are considered substantive when the consideration earned from the achievement of the milestone is: (i) commensurate with either the Company's

VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

performance to achieve the milestone or the enhancement of value of the item delivered as a result of a specific outcome resulting from the Company's performance to achieve the milestone, (ii) relates solely to past performance, and (iii) is reasonable relative to all deliverables and payment terms in the arrangement.

Other contingent, event-based payments received for which payment is either contingent solely upon the passage of time or the results of a collaborative partner's performance are not considered milestones under ASC 605-28. In accordance with ASC 605-25, such payments will be recognized as revenue when all of the four basic revenue recognition criteria are met.

Revenues recognized for royalty payments are recognized as earned in accordance with the terms of the license and commercialization agreements.

*Cost of Goods Sold*

Cost of goods sold for units dispensed to patients through prescriptions, or shipped to customers without a right of return or credit, 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. Specifically, cost of goods sold for Qsymia dispensed to patients includes the inventory costs of the 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; while cost of goods sold for STENDRA shipped to partners includes the inventory costs of purchased tablets, royalties, freight, shipping and handling costs. The cost of goods sold associated with deferred revenue on Qsymia and STENDRA 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 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.

VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

*Advertising Expenses*

Advertising expenses are charged to expense as incurred. The Company incurred \$26.1 million in 2013 and \$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 on the date of the grant using the Black-Scholes 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's 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.

*Non-Recurring Charges*

The Company's non-recurring charges consist of proxy contest expenses and restructuring charges including employee severance, one-time termination benefits and ongoing benefits related to the reduction of its workforce, facilities and other exit costs. Liabilities for costs associated with a restructuring activity are recognized when the liability is incurred, as opposed to when management commits to a restructuring plan. In addition, liabilities associated with restructuring activities are measured at fair value. One-time termination benefits are expensed at the date the entity notifies the employee, unless the employee must provide future service, in which case the benefits are expensed ratably over the future service period. Ongoing benefits are expensed when restructuring activities are probable and the benefit amounts are estimable. Other costs primarily consist of legal, consulting, and other costs related to employee terminations and are expensed when incurred. Termination benefits are calculated in accordance with the VIVUS, Inc. Amended and Restated Change in Control and Severance Agreement or the termination benefits plan, as applicable.

*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

VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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, 2013, 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.

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.

*Discontinued operations*

On November 5, 2010, the Company completed the sale of the MUSE product to Meda AB. For the years ended December 31, 2013, 2012 and 2011, the Company recorded some minor adjustments related to the MUSE disposition, primarily adjustments to its sales reserves for accrued product returns.

*Foreign Currency Transactions*

Transactions in foreign currencies are initially recorded at the rates of exchange prevailing on the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies are retranslated into the Company's functional currency at the rates prevailing on the balance sheet date.

## VIVUS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

Non-monetary items carried at fair value that are denominated in foreign currencies are retranslated at the rates prevailing on the initial transaction dates.

Exchange differences arising on the settlement of monetary items, and on the retranslation of monetary items, are included in the profit and loss account for the period. Exchange differences arising on the retranslation of non-monetary items carried at fair value are included in other expense in the accompanying consolidated statements of operations for the period.

*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 or upon a net share settlement of the Company's Convertible Notes. 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. As discussed in Note 12, the triggering conversion conditions that allow holders of the Convertible Notes to convert have not been met. If such conditions are met and the note holders opt to convert, the Company may choose to settle in cash, common stock, or a combination thereof; however, if this occurs, the Company has the intent and ability to net share settle this debt security; thus the Company uses the treasury stock method for earnings per share purposes. Due to the effect of the capped call instrument purchased in relation to the Convertible Notes, there would be no net shares issued until the market value of the Company's stock exceeds \$20 per share, and thus there would be no impact on diluted net income per share. Further, 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, 2013, 2012 and 2011, are as follows:

	<u>2013</u>	<u>2012</u>	<u>2011</u>
	(In thousands, except per share data)		
Net loss	\$ (174,456)	\$ (139,881)	\$ (46,140)
Net loss per share—basic and diluted	\$ (1.72)	\$ (1.42)	\$ (0.55)
Shares used in the computation of net loss per share—basic and diluted	<u>101,174</u>	<u>98,289</u>	<u>84,392</u>



## VIVUS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

As the Company recognized a net loss from continuing operations for the years ended December 31, 2013, 2012 and 2011, 7,027,000, 4,172,000 and 5,357,000 potentially dilutive options outstanding were not included in the computation of diluted net loss, respectively, because the effect would have been anti-dilutive.

*Recent Accounting Requirements*

There have been no recent accounting pronouncements or changes in accounting pronouncements during the year ended December 31, 2013 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, 2013 and 2012, are presented in the tables that follow.

As of December 31, 2013 (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	\$ 103,262	\$ —	\$ —	\$ 103,262
U.S. Treasury securities	239,959	69	(4)	240,024
Total	343,221	69	(4)	343,286
Less amounts classified as cash equivalents	(103,262)	—	—	(103,262)
Total available-for-sale securities	<u>\$ 239,959</u>	<u>\$ 69</u>	<u>\$ (4)</u>	<u>\$ 240,024</u>

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	<u>\$ 155,948</u>	<u>\$ 33</u>	<u>\$ —</u>	<u>\$ 155,981</u>

As of December 31, 2013, the Company's available-for-sale securities have original contractual maturities up to 23 months. However, 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. Due to their short-term maturities, the Company believes that the fair value of its bank deposits, accounts payable and accrued expenses approximate their carrying value.

## VIVUS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

The authoritative literature for fair value measurements established a three-tier fair value hierarchy, which prioritizes the inputs in measuring fair value. These tiers are as follows: Level 1, defined as observable inputs such as quoted market prices in active markets; Level 2, defined as inputs other than the quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as significant unobservable inputs (entity developed assumptions) in which little or no market data exists.

As of December 31, 2013, and December 31, 2012, all of the Company's cash and cash equivalents and available-for-sale securities were measured at fair value on a recurring basis, and classified as Level 1 in the fair value hierarchy. There were no assets or liabilities measured on a recurring basis where Level 2 or Level 3 valuation techniques were used.

**Note 3. Inventories**

Inventories, net of \$7.5 million in write downs, consist of (in thousands):

	<b>Balance as of</b>	
	<b>December 31, 2013</b>	<b>December 31, 2012</b>
Raw materials	\$ 28,545	\$ 5,139
Work in process	12	2,635
Finished goods	14,793	17,506
Deferred costs	5,153	73
Inventories, net	<u>\$ 48,503</u>	<u>\$ 25,353</u>

As of December 31, 2013 and 2012, the raw materials inventories consist primarily of the active pharmaceutical ingredients, or API, for the commercialization of Qsymia® (phentermine and topiramate extended-release) capsules CIV, the finished goods and deferred costs inventories consist of both Qsymia and STENDRATM (avanafil), while the work in process inventory relates exclusively to Qsymia. The deferred costs represent the costs of product shipped to wholesalers, certified retail pharmacies, certified mail order pharmacies, and commercialization partners but not yet dispensed to patients through prescriptions, and for which recognition of revenue has been deferred.

Inventories are stated 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. The Company periodically evaluates the carrying value of inventory on hand for potential excess amount over demand using the same lower of cost or market approach as that used to value the inventory. As a result of this evaluation, for the year ended December 31, 2013, the Company recognized a total charge of \$10.2 million for Qsymia inventories on hand in excess of demand, plus a purchase commitment fee. No such charge was recorded in the year ended December 31, 2012.

## VIVUS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## Note 4. Prepaid Expenses and Other Assets

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

	Balance as of	
	December 31, 2013	December 31, 2012
Prepaid insurance	\$ 3,617	\$ 6,979
Prepaid sales and marketing expenses	5,187	5,735
Prepaid medical affairs expenses	444	1,782
Manufacturing capacity commitment fees	461	2,300
Withholding tax receivable	5,560	—
Debt issuance costs	1,247	—
Other prepaid expenses and assets	3,422	2,363
Total	<u>\$ 19,938</u>	<u>\$ 19,159</u>

The amounts included in prepaid expenses and other assets consist primarily of prepaid insurance, deposits and prepayments for future services, primarily related to prepaid product commercialization costs for services relating to future periods in support of the sales and marketing of Qsymia in the U.S., prepayments related to medical affairs activities for Qsymia and STENDRA, current portion of debt issuance costs, interest income receivable, withholding tax receivable and manufacturing capacity commitment fees. The withholding tax receivable represents refundable foreign tax withheld on payments Menarini Group, through its subsidiary Berlin-Chemie AG, or Menarini, made to the Company. 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 condensed consolidated balance sheets 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.

## Note 5. Property and Equipment

Property and equipment consist of (in thousands):

	Balance as of	
	December 31, 2013	December 31, 2012
Computers and software	\$ 2,301	\$ 2,056
Furniture and fixtures	936	692
Manufacturing equipment	213	269
Leasehold improvements	758	351
	4,208	3,368
Accumulated depreciation	(2,254)	(1,417)
Property and equipment, net	<u>\$ 1,954</u>	<u>\$ 1,951</u>

## VIVUS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 6. Non-Current Assets**

Non-current assets consist of (in thousands):

	Balance as of	
	December 31, 2013	December 31, 2012
Debt issuance costs	\$ 4,620	\$ —
Other non-current assets	1,281	287
Total	<u>\$ 5,901</u>	<u>\$ 287</u>

The amounts included in non-current assets consist of debt issuance costs relating to the Convertible Notes and the Senior Secured Notes Due 2018 (see Note 12), which primarily consist of investment banker, legal and other professional fees, and other assets which are not expected to be realized in the next 12 months.

**Note 7. Accrued and Other Liabilities**

Accrued and other liabilities consist of (in thousands):

	Balance as of	
	December 31, 2013	December 31, 2012
Accrued employee compensation and benefits	\$ 3,408	\$ 3,859
Accrued manufacturing costs	4,071	4,135
Accrued sales and marketing expenses	970	2,908
Accrued interest on debt (see Note 12)	5,541	—
Accrued research and clinical expenses	1,755	1,372
Accrued restructuring costs (see Note 9)	4,577	—
Other accrued liabilities	3,671	1,503
Liabilities of discontinued operations	—	903
Total	<u>\$ 23,993</u>	<u>\$ 14,680</u>

The amounts included in accrued and other liabilities consist of obligations for past services, primarily related to accrued employee compensation and benefits, 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 interest on debt, and accrued research and clinical expenses.

**Note 8. Non-Current Accrued and Other Liabilities**

Non-current accrued and other liabilities at December 31, 2013 of \$3.0 million, consist of employee severance and benefits related to a cost reduction plan that was substantially completed in the year ended December 31, 2013 and lease exit costs that will be paid out in excess of the next 12 months (see Note 9).

## VIVUS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## Note 9. Non-Recurring Charges

On July 18, 2013, the Company entered into a settlement agreement with First Manhattan in connection with a proxy contest related to the Company's 2013 Annual Meeting of Stockholders. According to the terms of the settlement agreement, more than a majority of the members of the Company's Board of Directors resigned and new members were appointed. The change in the majority of the members of the Company's Board of Directors, effective July 19, 2013, triggered certain "change of control" benefits in accordance with the Amended Agreements with certain of the Company's employees. Under the Amended Agreements, all unvested stock options held by these employees automatically vested in full and became immediately exercisable. In addition, the resignations of both the Company's Chief Executive Officer and President resulted in severance charges under the Amended Agreements. As part of the settlement agreement with First Manhattan, the Company paid the reasonable and documented expenses incurred by First Manhattan in connection with its proxy contest, which totaled approximately \$2.9 million.

As part of the Company's ongoing efforts to reduce costs by eliminating expenses that are not essential to expanding the use of Qsymia, the Company implemented a cost reduction plan that reduced the Company's workforce by approximately 20 employees, or 17%, excluding the sales force, in the year ended December 31, 2013. As of December 31, 2013, this cost reduction plan was substantially complete.

The following table sets forth activity for the proxy contest and cost reduction plan (the restructuring accrual) for the year ended December 31, 2013, the balance of which is primarily comprised of employee severance costs (in thousands):

	<u>Proxy contest costs</u>	<u>Employee severance costs</u>	<u>Facilities- related costs</u>	<u>Total Cash Expense</u>
Balance of accrued employee severance and facilities-related costs at December 31, 2012	\$ —	\$ —	\$ —	\$ —
Charges	8,862	8,546	1,211	18,619
Payments	<u>(8,862)</u>	<u>(2,037)</u>	<u>(189)</u>	<u>(11,088)</u>
Balance of accrued employee severance and facilities-related costs at December 31, 2013	<u>\$ —</u>	<u>\$ 6,509</u>	<u>\$ 1,022</u>	<u>\$ 7,531</u>

\* In addition to the above non-recurring charges, as previously described, the Company incurred \$14.1 million in non-cash share-based compensation expense for an aggregated total of \$32.7 million in non-recurring charges for the year ended December 31, 2013.

The accrued employee severance costs represent severance and benefit costs to be paid out.

The accrued facilities-related costs at December 31, 2013, represent estimated losses, net of subleases, on space vacated as part of the Company's restructuring plan. The leases, and payments against the amounts accrued, extend through May 2020 unless the Company is able to negotiate earlier terminations.

Of the total accrued employee severance and facilities-related costs, \$4.6 million is included in "Accrued and other liabilities" and \$3.0 million is included in "Non-current accrued and other liabilities" in the Company's consolidated balance sheet at December 31, 2013. The balance of the

## VIVUS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 9. Non-Recurring Charges (Continued)**

accrued employee severance and facilities-related costs at December 31, 2013, is anticipated to be fully paid by May 2020.

The balance of the accrued employee severance and facilities-related costs at December 31, 2013 is anticipated to be paid out as follows (in thousands):

2014	\$ 4,705
2015	2,581
2016	80
2017	55
2018	46
Thereafter	64
	<u>\$ 7,531</u>

**Note 10. Deferred Revenue***Qsymia Deferred Revenue*

At December 31, 2013, the Company had \$10.3 million in current deferred revenue, which represents Qsymia product shipped to the Company's certified home delivery pharmacy services networks, wholesalers and certified retail pharmacies, but not yet dispensed to patients through prescriptions, net of prompt payment discounts.

*STENDRA™ or SPEDRA™ Deferred Revenue*

As further discussed in Note 11 below, in 2013, the Company received €6.7 million, (€8 million net of approximately 16% reimbursable withholding tax) from Menarini as a prepayment for future royalties on sales of SPEDRA. The gross prepayment amount of €8 million, or \$10.6 million, is recorded as non-current deferred revenue as of December 31, 2013, and will be recognized through future earnings and deducted by Menarini against future royalties owed to the Company until such amount, plus interest cost, is depleted in full.

The Company supplied certain initial orders of STENDRA or SPEDRA product with a right of return or credit, which did not meet the required specifications of its partners. As such, the Company recorded these shipments as deferred revenue as of December 31, 2013. Under the Company's product supply agreements, as long as product meets specified product dating criteria at the time of shipment to the partner, the Company's commercialization partners do not have a right of return or credit for expired product. However, given STENDRA or SPEDRA's 48-month shelf life and lack of selling history, the Company has not been able to reliably estimate expected returns of product at the time of shipment for certain initial product supply orders under these agreements that retain a right of return or credit for product supplied that does not meet the commercialization partners' criteria. Therefore, for these orders, the Company recognizes revenue when units are dispensed to patients through prescriptions, at which point, the product is not subject to return. In addition, the Company allocated a portion of the manufacturing milestone payment received from Sanofi in 2013 to product that was supplied in the first quarter of 2014, based on relative estimated selling prices. As a result, the Company had \$6.7 million in non-current deferred revenue related to STENDRA or SPEDRA product supply as of December 31, 2013.

VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 11. License, Commercialization and Supply Agreements**

*Menarini Group*

On July 5, 2013, the Company entered into a License and Commercialization Agreement, or the Menarini License Agreement, with Menarini Group through its subsidiary Berlin-Chemie AG, or Menarini, to commercialize and promote SPEDRA for the treatment of ED in over 40 European countries, including the EU, plus Australia and New Zealand. VIVUS and Menarini also entered into a Commercial Supply Agreement, or the Menarini Supply Agreement, whereby VIVUS will supply Menarini with SPEDRA drug product.

The Company agreed to transfer to Menarini ownership of the European Union marketing authorization for SPEDRA for the treatment of erectile dysfunction, which was granted by the European Commission in June 2013. Each party agreed not to develop, commercialize, or in-license any other product that operates as phosphodiesterase type-5 inhibitor for the treatment of erectile dysfunction for a limited time period, subject to certain exceptions.

Under the Menarini License Agreement, the Company is entitled to receive upfront payments, and various approval and sales milestones, plus royalties on SPEDRA sales. Menarini will also reimburse the Company for payments made to cover various obligations to MTPC during the term of the Menarini License Agreement. The Menarini License Agreement will terminate on a country-by-country basis in the relevant territories upon the latest to occur of the following: (i) the expiration of the last-to-expire valid VIVUS patent covering SPEDRA; (ii) the expiration of data protection covering SPEDRA; or (iii) ten (10) years after the SPEDRA product launch. In addition, Menarini may terminate the Menarini License Agreement if certain additional regulatory obligations are imposed on SPEDRA, and the Company may terminate the Menarini License Agreement if Menarini challenges VIVUS's patents covering SPEDRA or if Menarini commits certain legal violations. Either party may terminate the Menarini License Agreement for the other party's uncured material breach or bankruptcy.

Under the terms of the Menarini Supply Agreement, the Company will supply Menarini with STENDRA drug product until December 31, 2018, at the latest. Menarini also has the right to manufacture STENDRA independently, provided that it continues to satisfy certain minimum purchase obligations to VIVUS. Following the expiration of the Menarini Supply Agreement, Menarini will be responsible for its own supply of STENDRA. Either party may terminate the Menarini Supply Agreement for the other party's uncured material breach or bankruptcy, or upon the termination of the Menarini License Agreement.

Upon the signing of the Menarini License Agreement, the Company received a payment of €6.7 million, (€8 million, net of approximately 16% reimbursable withholding tax), for the non-refundable, non-creditable license fee, as well as a payment of €6.7 million, (€8 million, net of approximately 16% reimbursable withholding tax), for a regulatory milestone payment, related to the approval of the SPEDRA marketing authorization by the European Commission. Although this payment was described in the Menarini License Agreement as a regulatory milestone payment for obtaining marketing authorization in the EU, it is essentially an additional license fee because the approval by the European Commission was obtained prior to the final execution of the Menarini License Agreement. In addition, in October 2013, VIVUS received another payment of €6.7 million, (€8 million, net of approximately 16% reimbursable withholding tax), as a prepayment for future royalties on sales of SPEDRA. This prepayment amount of €8 million, or \$10.6 million, has been



VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 11. License, Commercialization and Supply Agreements (Continued)**

recorded as deferred revenue as of December 31, 2013, and will be recognized as royalty income when earned.

For the year ended December 31, 2013, VIVUS recognized €16.0 million, or \$21.0 million, as license revenue, as the Company determined that revenue was earned upon the delivery of the license rights and related know-how. Under the Menarini Supply Agreement, VIVUS will supply the SPEDRA drug product to Menarini on a cost-plus basis.

In accordance with ASC 605-25, VIVUS identified the license and related know-how and supply services as separate deliverables under the agreements. The Company determined that the license and related know-how and supply services individually represent separate units of accounting because each deliverable has stand-alone value. The Company determined that the license and related know-how have stand-alone value based on various facts and circumstances in the arrangement, including Menarini's option to sublicense. Although Menarini is precluded from reselling the license, Menarini's ability to use the delivered license and related know-how for its intended purpose without the receipt of the remaining deliverable indicated that the license and related know-how have stand-alone value.

VIVUS determined that the supply services have stand-alone value because: (i) the manufacturing process is not proprietary to the Company; (ii) a third-party manufacturer produces the product, and (iii) Menarini may at any time with notice to the Company elect to accept assignment of VIVUS's agreements with the third-party manufacturer, or manufacture the licensed product itself or contract with a third-party manufacturer to produce it.

The Company allocated the non-contingent consideration relating to the stand-alone, non-contingent deliverables on the basis of relative selling price, which is BESP because VSOE or TPE are unavailable for these deliverables. The objective of BESP is to determine the price at which the Company would transact a sale if the product or service were sold on a stand-alone basis. BESP for the license is based on discounted future projected cash flows relating to the licensed territories. Revenue related to the license was recognized in 2013 when the license and all related knowledge and data had been transferred. BESP for the supply services is based on third-party costs to manufacture the licensed product, plus a mark-up consistent with similar agreements. Revenues allocated to the supply services will be recognized when the product has met all required specifications and the related title and risk of loss and damages have been transferred to Menarini. The Company has determined that achievement of any and all of the milestones is dependent solely upon the results of Menarini and therefore none of the milestones are deemed to be substantive. Royalties to be received from Menarini will be recognized by the Company based upon the net sales of the product by Menarini. As of December 31, 2013, \$5.1 million in revenue from the initial product delivered in 2013 under the Menarini Supply Agreement has been deferred until the product has met all required specifications and the related title and risk of loss and damages have been transferred.

*Auxilium Pharmaceuticals, Inc.*

On October 10, 2013, the Company entered into a license and commercialization agreement, or the Auxilium License Agreement, and a commercial supply agreement, or the Auxilium Supply Agreement, whereby VIVUS will supply Auxilium with STENDRA drug product. Under the terms of the Auxilium License Agreement, Auxilium received an exclusive license to commercialize and promote VIVUS's drug STENDRA (avanafil) for the treatment of erectile dysfunction in the United States and Canada and their respective territories, or the Auxilium Territory.

VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 11. License, Commercialization and Supply Agreements (Continued)**

Each party agreed not to develop, commercialize, or in-license any other product that operates as a PDE5 inhibitor for the treatment of erectile dysfunction in the Territory for a limited time period, subject to certain exceptions. A PDE5 inhibitor means any product that operates as a phosphodiesterase type 5 inhibitor.

Auxilium received an exclusive license, with a right to sublicense, subject to certain limitations, under certain of VIVUS's trademarks, including STENDRA, to market, sell and distribute STENDRA for the treatment of erectile dysfunction in the Auxilium Territory. In addition, Auxilium received an exclusive license, with a right to sublicense, subject to certain limitations, under certain of VIVUS's patents and know-how (i) to use, distribute, import, promote, market, sell, offer for sale and otherwise commercialize STENDRA for the treatment of erectile dysfunction in the Auxilium Territory; (ii) to make and have made STENDRA anywhere in the world, with certain exceptions, where STENDRA is solely for use or sale for the treatment of erectile dysfunction in the Auxilium Territory; and (iii) to conduct certain development activities on STENDRA for the treatment of erectile dysfunction in support of obtaining regulatory approval in the Auxilium Territory.

Auxilium will obtain STENDRA exclusively from VIVUS for a mutually agreed term pursuant to the Auxilium Supply Agreement, as further described below. Auxilium may elect to transfer the control of the supply chain for STENDRA for the Territory to itself or its designee by assigning to Auxilium VIVUS's agreements with the contract manufacturer, which is referred to below as the Supply Chain Transfer.

At VIVUS's sole cost and expense, VIVUS shall be responsible for preparing and filing with the FDA the appropriate documents to obtain a label expansion for STENDRA referencing a specific time of onset claim. VIVUS shall use commercially reasonable efforts to obtain approval of such label expansion filing. Further, VIVUS shall be responsible for conducting any post-regulatory studies of STENDRA that are required by the FDA in the Territory. Such costs will be split equally between the parties up to a specified amount and then, once the specified amount is reached, VIVUS shall be solely responsible for the remainder of the costs.

The Auxilium License Agreement will terminate on a country-by-country basis upon the later to occur of the following: (a) ten (10) years after the STENDRA product launch in such country; or (b) the expiration of the last-to-expire patents within the VIVUS patents covering STENDRA in such country. In addition, Auxilium may terminate the Auxilium License Agreement (i) for any reason following the one (1) year anniversary of the STENDRA launch in the U.S upon one hundred eighty (180) days written notice; and (ii) upon the entry of a generic avanafil product into the market upon thirty (30) days written notice. VIVUS may terminate the Auxilium License Agreement (i) immediately upon written notice to Auxilium if Auxilium is excluded from participation in the U.S. federal healthcare programs and fails to cure such exclusion within one hundred twenty (120) days; and (ii) if Auxilium challenges the VIVUS patents covering STENDRA upon written notice to Auxilium. Either party may terminate the Auxilium License Agreement for the other party's uncured material breach or bankruptcy.

Under the terms of the Auxilium Supply Agreement, VIVUS will supply Auxilium with STENDRA drug product until December 31, 2018, at the latest. For 2015 and each subsequent year during the term of the Auxilium Supply Agreement, if Auxilium fails to purchase an agreed minimum purchase amount of STENDRA from VIVUS, it will reimburse VIVUS for the shortfall as it relates to VIVUS's out-of-pocket costs to acquire certain raw materials needed to manufacture STENDRA. Either party

VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 11. License, Commercialization and Supply Agreements (Continued)**

may terminate the Auxilium Supply Agreement for the other party's uncured material breach or bankruptcy, or upon the termination of the Auxilium License Agreement. The Auxilium Supply Agreement will automatically terminate upon completion of the Supply Chain Transfer, as described above.

Under the terms of the Auxilium License Agreement, VIVUS received an upfront license fee of \$30.0 million. The Company is eligible to receive a regulatory milestone payment of \$15.0 million upon approval by the FDA of a specific time of onset claim for STENDRA in the Auxilium Territory. In addition, the Company is eligible to receive up to an aggregate of \$255.0 million in potential milestone payments based on certain net sales targets by Auxilium. Further, the Company will receive royalty payments based on tiered percentages of the aggregate annual net sales of STENDRA in the Auxilium Territory on a quarterly basis. The percentage of Auxilium's aggregate annual net sales to be paid to the Company increases in accordance with the achievement of specific thresholds of aggregate annual net sales of STENDRA in the Auxilium Territory. If Auxilium's net sales of STENDRA in a country are reduced by certain amounts following the entry of a generic product to the market, royalty payments will be reduced by certain percentages based on such reductions. Auxilium will also reimburse the Company for payments made to cover various obligations to MTPC during the term of the Auxilium License Agreement.

For the year ended December 31, 2013, VIVUS recognized \$30.4 million as license revenue, as the Company determined that revenue was earned upon the delivery of the license rights and related know-how. Under the Auxilium Supply Agreement, VIVUS supplies the STENDRA drug product to Auxilium on a cost-plus basis.

In accordance with ASC 605-25, VIVUS identified the license and related know-how and supply services as separate deliverables under the agreements. The Company determined that the license and related know-how and supply services individually represent separate units of accounting because each deliverable has stand-alone value. The Company determined that the license and related know-how have stand-alone value based on various facts and circumstances in the arrangement, including Auxilium's option to sublicense. Although Auxilium is precluded from reselling the license, Auxilium's ability to use the delivered license and related know-how for its intended purpose without the receipt of the remaining deliverable indicated that the license and related know-how have stand-alone value.

VIVUS determined that the supply services have stand-alone value because: (i) the manufacturing process is not proprietary to the Company; (ii) a third-party manufacturer produces the product, and (iii) Auxilium may at any time with notice to the Company elect to accept assignment of VIVUS's agreements with the third-party manufacturer, or manufacture the licensed product itself or contract with a third-party manufacturer to produce it.

The Company allocated the non-contingent consideration relating to the stand-alone non-contingent deliverables on the basis of relative selling price, which is BESP because VSOE or TPE are unavailable for these deliverables. The objective of BESP is to determine the price at which the Company would transact a sale if the product or service were sold on a stand-alone basis. BESP for the license is based on discounted future projected cash flows relating to the licensed territories. Revenue related to the license was recognized in the fourth quarter of 2013, when the license and all related knowledge and data had been transferred. BESP for the supply services is based on third-party costs to manufacture the licensed product, plus a mark-up consistent with similar agreements. Revenues allocated to the supply services will be recognized when the product has met all required specifications

## VIVUS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 11. License, Commercialization and Supply Agreements (Continued)**

and the related title and risk of loss and damages have been transferred to Auxilium. The Company has determined that the achievement of the regulatory milestone payment of \$15.0 million upon approval by the FDA of a specific time of onset claim for STENDRA is contingent upon both the Company's completion of the study reports and upon FDA approval of the label expansion filing, resulting from the Company's efforts. At the time of the agreement, there was substantive uncertainty that the time of onset claim and label expansion filing would be approved, which are required for the additional milestone payment. In addition, the Company has determined that achievement of any and all of the potential net sales milestones is dependent solely upon the results of Auxilium and therefore none of the net sales milestones are deemed to be substantive. Royalties to be received from Auxilium will be recognized by the Company based upon the net sales of the product by Auxilium. For the year ended December 31, 2013, \$1.1 million in net product revenue was recognized from initial product delivered under the Auxilium Supply Agreement.

*Sanofi*

On December 11, 2013, the Company entered into a license and commercialization agreement, or the Sanofi License Agreement, with Sanofi. Effective as of December 11, 2013, the Company entered into a supply agreement, or the Sanofi Supply Agreement, with Sanofi Winthrop Industrie, a wholly owned subsidiary of Sanofi. Under the terms of the Sanofi License Agreement, Sanofi received an exclusive license to commercialize and promote VIVUS's drug avanafil for therapeutic use in humans in Africa, the Middle East—Turkey and Eurasia, or the Sanofi Territory. During the term of the License Agreement, each party agreed not to develop, commercialize, or in-license any other product that operates as a phosphodiesterase type-5 inhibitor for therapeutic use in humans in the Sanofi Territory for a limited time period, subject to certain exceptions.

In December 2013, the Company received an upfront license fee of \$5.0 million and a \$1.5 million manufacturing milestone payment. The Company is also eligible to receive up to an additional \$3.5 million in manufacturing milestone payments, up to \$6.0 million in regulatory milestone payments, and up to \$45.0 million in sales milestone payments, plus royalties on avanafil sales based on tiered percentages of the aggregate annual net sales in the Sanofi Territory. Sanofi will also reimburse the Company for a portion of any sales milestone paid by VIVUS to MTPC based on the share of Sanofi's net sales in the total worldwide net sales amount triggering the payment of such sales milestone.

Royalty payment obligations under the Sanofi License Agreement will be payable for avanafil in each country in the Sanofi Territory until the later to occur of (i) the expiration of the last-to-expire valid claim within the VIVUS patents that, absent the licenses granted to Sanofi under the Sanofi License Agreement, would be infringed by the sale of avanafil in such country; and (ii) December 11, 2029, or the Sanofi Royalty Payment Term. The Sanofi License Agreement will terminate as follows: (i) as to avanafil in each country in the Sanofi Territory, upon the expiration of the Sanofi Royalty Payment Term with respect to avanafil in such country, provided however, that Sanofi's obligation to reimburse VIVUS for Sanofi's pro-rata share of any sales milestone paid by the Company to MTPC will survive if such sales milestone has not yet come due; and (ii) in its entirety, upon the expiration of all royalty payment obligations arising under the Sanofi License Agreement in all countries in the Sanofi Territory.

In addition, the Company may terminate the Sanofi License Agreement immediately upon written notice to Sanofi on a country-by-country basis if Sanofi becomes subject to certain regulatory actions or

## VIVUS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 11. License, Commercialization and Supply Agreements (Continued)**

legal restrictions. The Company may also terminate the Sanofi License Agreement in its entirety upon written notice to Sanofi if Sanofi or any affiliate commences any action or proceeding that challenges the validity, enforceability or scope of any VIVUS patent in the Sanofi Territory or any country outside of the Sanofi Territory, or if a similar action is instituted by a sublicensee and Sanofi does not terminate the sublicense after being aware of such action for a specified period. Further, Sanofi may terminate the Sanofi License Agreement in whole or on a country-by-country basis for convenience at any time upon advance notice to the Company. Either party may terminate the Sanofi License Agreement for the other party's uncured material breach, or bankruptcy or related actions or proceedings. In the event of an uncured material breach by the Company, Sanofi may, in lieu of terminating the Sanofi License Agreement in its entirety, elect to continue the Sanofi License Agreement in full force and effect except (i) the Company will have no further rights to receive certain commercialization reports, and (ii) Sanofi may set off any payments or amounts due by Sanofi but not yet paid to the Company against all direct and undisputed damages suffered by Sanofi as a result of the breach.

Under the terms of the Sanofi Supply Agreement, the Company will supply Sanofi Winthrop Industrie with avanafil tablets until June 30, 2015, or in the event the obligations of MTPC to supply avanafil tablets to us are amended to extend beyond June 30, 2015, then until the expiration of the MTPC supply obligations as amended. Either party may terminate the Sanofi Supply Agreement for (i) the other party's uncured material breach, or (ii) bankruptcy, insolvency, liquidation or certain receivership proceedings, or certain proceedings for reorganization under bankruptcy or comparable laws. In addition, the Sanofi Supply Agreement will automatically terminate upon the termination of the Sanofi License Agreement.

For the year ended December 31, 2013, VIVUS recognized \$4.4 million in license revenue, as the Company determined that revenue was earned upon the delivery of the license rights and related know-how. Under the Sanofi Supply Agreement, VIVUS supplies the SPEDRA drug product to Sanofi on a cost-plus basis. For the year ended December 31, 2013, \$446,000 in net product revenue was recognized from initial product delivered under the Sanofi Supply Agreement. As of December 31, 2013, the Company deferred \$1.6 million of the manufacturing milestone payment received in 2013 from Sanofi, allocable to non-contingent product deliverables based on relative estimated selling prices, which were later supplied in the first quarter of 2014.

In accordance with ASC 605-25, VIVUS identified the license and related know-how and supply services as separate deliverables under the agreements. The Company determined that the license and related know-how and supply services individually represent separate units of accounting because each deliverable has stand-alone value. The Company determined that the license and related know-how have stand-alone value based on various facts and circumstances in the arrangement, including Sanofi's option to sublicense. Although Sanofi is precluded from reselling the license, Sanofi's ability to use the delivered license and related know-how for its intended purpose without the receipt of the remaining deliverable indicated that the license and related know-how have stand-alone value.

VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 11. License, Commercialization and Supply Agreements (Continued)**

The Company determined that the supply services have stand-alone value because: (i) the manufacturing process is not proprietary to the Company; (ii) a third-party manufacturer produces the product, and (iii) Sanofi may at any time with notice to the Company elect to accept assignment of the Company's agreements with the third-party manufacturer (including agreements with Sanofi subsidiaries), or manufacture the licensed product itself, or contract with a third-party manufacturer to produce it.

The Company allocated the non-contingent consideration relating to the stand-alone non-contingent deliverables on the basis of relative selling price, which is BESP because VSOE or TPE are unavailable for these deliverables. The objective of BESP is to determine the price at which the Company would transact a sale if the product or service were sold on a stand-alone basis. BESP for the license is based on discounted future projected cash flows relating to the licensed territories. Revenue related to the license was recognized in the fourth quarter of 2013, when the license and all related knowledge and data had been transferred. BESP for the supply services is based on third-party costs to manufacture the licensed product, plus a mark-up consistent with similar agreements. Revenues allocated to the supply services will be recognized when the product has met all required specifications and the related title and risk of loss and damages have been transferred to Sanofi. The Company has determined that achievement of any and all of the milestones is dependent solely upon the results of Sanofi and therefore none of the milestones are deemed to be substantive. Royalties to be received from Sanofi will be recognized by the Company based upon the net sales of the product by Sanofi.

On July 31, 2013, VIVUS entered into a Commercial Supply Agreement with Sanofi Chimie, a wholly owned subsidiary of Sanofi, or the Sanofi Chimie Supply Agreement, pursuant to which Sanofi Chimie will manufacture and supply the active pharmaceutical ingredient for VIVUS's drug avanafil.

Under the terms of the Sanofi Chimie Supply Agreement, Sanofi Chimie will manufacture and supply the active pharmaceutical ingredient, or API, for VIVUS's drug avanafil on an exclusive basis in the United States and other territories and on a semi-exclusive basis in Europe, including the EU, and Latin America. Each year, VIVUS must purchase a minimum quantity of API from Sanofi Chimie.

The Sanofi Chimie Supply Agreement has an initial five year term commencing on January 1, 2014 and will auto-renew for additional two-year periods unless either party makes a timely election not to renew. Either party may terminate the Sanofi Chimie Supply Agreement for the other party's uncured material breach or bankruptcy or in the event of a persistent force majeure event.

On November 18, 2013, the Company entered into a Manufacturing and Supply Agreement, effective as of September 1, 2013, with Sanofi Winthrop Industrie, or Sanofi Winthrop, a wholly owned subsidiary of Sanofi, or the Sanofi Winthrop Supply Agreement. Under the terms of the Sanofi Winthrop Supply Agreement, Sanofi Winthrop will manufacture and supply the tablets for VIVUS's drug avanafil on an exclusive basis in the United States and other territories and on a semi-exclusive basis in Europe, including the EU, Latin America and other territories. Beginning in 2015, VIVUS must purchase a minimum quantity of tablets each year for its drug avanafil from Sanofi Winthrop.

The Sanofi Winthrop Supply Agreement has an initial term commencing on September 1, 2013 and continuing for a period of five years after the date of the first commercial sale, and will auto-renew for additional two-year periods unless either party makes a timely election not to renew. Either party may terminate the Sanofi Winthrop Supply Agreement for the other party's uncured material breach or bankruptcy or in the event of a persistent force majeure event. In addition, the parties may mutually

VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 11. License, Commercialization and Supply Agreements (Continued)**

agree to terminate the Sanofi Winthrop Supply Agreement if (i) Sanofi Winthrop is unable to manufacture and deliver the required number of validation batches meeting the specifications within the time period specified in the technology transfer master plan, or (ii) registration of Sanofi Winthrop as the manufacturer and supplier for the tablets for VIVUS's drug avanafil fails.

*Mitsubishi Tanabe Pharma Corporation*

In January 2001, the Company entered into an exclusive development, license and clinical trial and commercial supply agreement with 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. The Company agreed to grant MTPC an exclusive, royalty-free license within those countries for oral products that it develops containing avanafil. In addition, the Company agreed to grant MTPC an exclusive option to obtain an exclusive, royalty-bearing license within those countries for non-oral products that it develops containing avanafil. MTPC agreed to manufacture and supply VIVUS with avanafil for use in clinical trials, which were the Company's primary responsibility. The MTPC agreement contains a number of milestone payments to be made by the Company based on various triggering events. Through December 31, 2013, under the terms of the MTPC agreement, the Company has paid a total of \$15.0 million in milestone payments to MTPC, including \$2.0 million in 2013 upon approval of SPEDRA (avanafil) in the EU and \$3.0 million in 2012 upon FDA approval of STENDRA (avanafil) in the U.S. In addition, during 2013 and 2012, the Company purchased \$9.9 million and \$7.4 million, respectively, of product from MTPC under the supply portion of the Agreement in preparation for the commercial launch in the U.S., the EU and certain other territories that use the U.S. and EU approvals.

The Company expects to make other substantial payments to MTPC in accordance with the MTPC agreement as VIVUS and its sublicensees continue to commercialize avanafil for the oral treatment of male sexual dysfunction in its territories. Potential future milestone payments include \$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 VIVUS'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 its agreement with MTPC that permits VIVUS to manufacture the API and tablets for STENDRA itself or through third parties. According to the amendment, the transition of manufacturing from MTPC must occur on or before June 30, 2015. On July 31, 2013, as mentioned above, VIVUS entered into a Commercial Supply Agreement with Sanofi Chimie to manufacture and supply the API for avanafil on an exclusive basis in the United States and other territories and on a semi-exclusive basis in Europe, including the EU,



## VIVUS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 11. License, Commercialization and Supply Agreements (Continued)**

Latin America and other territories. Further, as mentioned above, on November 18, 2013, the Company entered into a Manufacturing and Supply Agreement with Sanofi Winthrop Industrie to manufacture and supply the avanafil tablets on an exclusive basis in the United States and other territories and on a semi-exclusive basis in Europe, including the EU, Latin America and other territories. The Company intends to submit an amendment to the NDA for avanafil to the FDA, and the marketing authorization, or MA, for avanafil to the EMA, to include Sanofi Chimie as a qualified supplier of the avanafil API and Sanofi Winthrop Industrie as a qualified supplier of the avanafil tablets.

On February 21, 2013, the Company entered into the third amendment to its agreement with MTPC which, among other things, expands VIVUS's rights, or those of VIVUS's sublicensees, to enforce the patents licensed under the MTPC agreement against alleged infringement, and clarifies the rights and duties of the parties and VIVUS's sublicensees upon termination of the MTPC agreement. In addition, the Company was obligated to use its best commercial efforts to market STENDRA in the U.S. by December 31, 2013, which was achieved by its commercialization partner, Auxilium. On July 23, 2013, the Company entered into the fourth amendment to its agreement with MTPC which, among other things, changes the definition of net sales used to calculate royalties owed by the Company to MTPC.

*Other*

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 VIVUS with worldwide rights to develop and commercialize the Combination Therapy and exploit the Patents. Pursuant to the Assignment Agreement, through December 31, 2013, the Company has paid a total of \$1.2 million and has issued fully vested and exercisable options to purchase 60,000 shares of VIVUS's common stock to Dr. Najarian. In addition, the Assignment Agreement requires the Company to pay royalties on worldwide net sales of a product for the treatment of obesity that is based upon the Combination Therapy and Patents until the last-to-expire of the assigned Patents. To the extent that the Company decides not to commercially exploit the Patents, the Assignment Agreement will terminate and the Combination Therapy and Patents will be assigned back to Dr. Najarian. In 2006, Dr. Najarian joined the Company as a part-time employee and served as a Principal Scientist. In November 2013, Dr. Najarian's employment with the Company ended although he continues to work for VIVUS on a consulting basis.

**Note 12. Long-Term Debt***Convertible Senior Notes Due 2020*

On May 21, 2013, the Company closed an offering of \$220.0 million in 4.5% Convertible Senior Notes due May 1, 2020, or the Convertible Notes. The Convertible Notes are governed by an indenture, dated as of May 21, 2013 between the Company and Deutsche Bank National Trust Company, as trustee. On May 29, 2013, the Company closed on an additional \$30.0 million of

## VIVUS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 12. Long-Term Debt (Continued)**

Convertible Notes upon exercise of an option by the initial purchasers of the Convertible Notes. Total net proceeds from the Convertible Notes were approximately \$241.8 million.

The Convertible Notes are senior unsecured obligations of the Company and bear interest at a fixed rate of 4.50% per annum, payable semiannually in arrears on May 1 and November 1 of each year, beginning on November 1, 2013, unless earlier purchased or converted.

The Convertible Notes are convertible into approximately 16,826,000 shares of the Company's common stock under certain circumstances prior to maturity at a conversion rate of 67.3038 shares per \$1,000 principal amount of Convertible Notes, which represents a conversion price of approximately \$14.858 per share, subject to adjustment under certain conditions. The Convertible Notes are convertible at the option of the holders at any time prior to the close of business on the business day immediately preceding November 1, 2019 only under certain conditions. On or after November 1, 2019, holders may convert all or any portion of their Convertible Notes at any time at their option at the conversion rate then in effect regardless of these conditions. Subject to certain limitations, the Company will settle conversions of the Convertible Notes by paying or delivering, as the case may be, cash, shares of its common stock or a combination of cash and shares of its common stock, at its election. The conversion rate of the Convertible Notes, and the corresponding conversion price, will be subject to adjustment for certain events, but will not be adjusted for accrued interest. In addition, following certain corporate transactions that occur on or prior to the maturity date for the Convertible Notes, the Company will increase the conversion rate for a holder that elects to convert its Convertible Notes in connection with such a corporate transaction. The Convertible Notes were issued to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended, or the Securities Act. Neither the Convertible Notes nor any shares of VIVUS's common stock issuable upon conversion of the Convertible Notes have been or are expected to be registered under the Securities Act or under any state securities laws.

The Convertible Notes are accounted for in accordance with ASC 470-20, *Debt with Conversion and Other Options*. Under ASC 470-20, issuers of convertible debt instruments that may be settled in cash upon conversion, including partial cash settlement, are required to separately account for the liability (debt) and equity (conversion option) components. The Company analyzed the conversion feature to determine if it was required to be bifurcated and treated as a derivative liability and determined that it did not. Rather, the Company is required to separately account for the liability and equity components of the convertible debt instrument. The Company determined the fair value of the liability component by estimating a risk adjusted interest rate, or market yield, at the time of issuance for similar notes that do not include the equity component. To arrive at the appropriate risk adjusted rate, or market yield, for the Convertible Notes, the Company performed (i) a synthetic credit rating analysis estimating the issuer level credit rating of the Company using a regression model; (ii) research on appropriate market yields using option adjusted spread indications for similar credit ratings, and (iii) considered the market yield implied for the Convertible Notes from a binomial lattice model, or Level 3 inputs. The risk adjusted interest rate was used to compute the initial fair value of the liability component of \$154.7 million. The excess of the proceeds received from the Convertible Notes over the amount allocated to the liability component, of \$95.3 million, is allocated to the equity component and recorded to additional paid-in capital. This excess is reported as a debt discount and is amortized as non-cash interest expense, using the interest method, over the expected life of the Convertible Notes. The conversion option will not be subsequently remeasured as long as it continues to meet conditions for equity classification.

## VIVUS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 12. Long-Term Debt (Continued)**

In connection with the issuance of the Convertible Notes, the Company incurred \$8.2 million of issuance costs, which primarily consisted of investment banker, legal and other professional fees. The portion of the costs related to the equity component of \$3.1 million was charged to additional paid-in capital. The remaining portion related to the debt component of \$5.1 million was recorded as a deferred charge and included in non-current assets, and is being amortized and recorded as additional interest expense over the expected life of the Convertible Notes.

The combined effective interest rate on the liability component was 15.2%. Total interest expense of \$14.3 million was recognized during the year ended December 31, 2013, which includes \$8.4 million of amortization of the debt discount and \$444,000 amortization of deferred financing costs during the year ended December 31, 2013. The remaining expected life of the Convertible Notes at December 31, 2013, is 4.9 years. As of December 31, 2013, the Convertible Notes were not convertible and the if-converted value did not exceed their principal amount.

In connection with the issuance of the Convertible Notes, the Company entered into capped call transactions with certain counterparties affiliated to the underwriters. The capped call transactions are expected to reduce potential dilution of earnings per share upon conversion of the Convertible Notes. Under the capped call transactions, the Company purchased capped call options that in the aggregate relate to the total number of shares of the Company's common stock underlying the Convertible Notes, with a strike price equal to the conversion price of the notes and with a cap price equal to \$20 per share. The fair value of the purchased capped calls of \$34.7 million was recorded to stockholders' equity.

*Senior Secured Notes Due 2018*

On March 25, 2013, the Company entered into the Purchase and Sale Agreement, or the Agreement, between the Company and BioPharma Secured Investments III Holdings Cayman LP, a Cayman Islands exempted limited partnership, or BioPharma, providing for the purchase of a debt-like instrument, or the Senior Secured Notes. Under the Agreement, the Company received \$50 million, less \$500,000 in funding and facility payments, at the initial closing on April 9, 2013. The Company elected not to exercise its option to receive an additional \$60 million, less \$600,000 in a funding payment, at a secondary closing no later than January 15, 2014. The Company was responsible for all reasonable and documented out-of-pocket legal costs and fees incurred by BioPharma related to the Agreement, subject to a cap of \$300,000.

Net proceeds from the financing were approximately \$48.4 million. The Company is obligated to make scheduled quarterly payments. The first payment is scheduled to be made in the second quarter of 2014 and the final payment is scheduled to be made in the second quarter of 2018. The scheduled quarterly payments are subject to the net sales of (i) Qsymia® (and any derivative or improvement thereof, including Qsiva™ as it relates to the European Union), or the Product, and (ii) any other obesity agent developed or marketed by the Company or its affiliates or licensees. The scheduled quarterly payments, other than the payment(s) scheduled to be made in the second quarter of 2018, are capped at the lower of the scheduled payment amounts or 25% of the net sales of (i) and (ii) above. Accordingly, if 25% of the net sales is less than the scheduled quarterly payment, then 25% of the net sales is due for that quarter, with the exception of the payment(s) scheduled to be made in the second quarter of 2018, when any unpaid scheduled quarterly payments plus any accrued and unpaid make-whole premiums must be paid. Any quarterly payment less than the scheduled quarterly payment

## VIVUS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 12. Long-Term Debt (Continued)**

amount will be subject to a make-whole premium equal to the applicable scheduled quarterly payment of the preceding quarter less the actual payment made to BioPharma for the preceding quarter multiplied by 1.03. Regardless, the Company may pay scheduled quarterly payments out of any available funds notwithstanding Product net sales. The Company also has the option to prepay all scheduled quarterly payments as specified in the Agreement. Assuming all scheduled quarterly payments are made timely and in full, the annual implied effective interest rate is 13.38% per annum. The imputed interest for the Senior Secured Notes was \$5.2 million, including \$329,000 amortization of deferred financing costs during the year ended December 31, 2013.

To secure its obligations in connection with the Agreement, the Company granted BioPharma a security interest to (i) the purchased receivables which are defined in the Agreement as the scheduled quarterly payments, any underpayments of such payments based on an audit of the Company's records and any interest due on the foregoing amounts, and (ii) the Company's patents, trademarks, copyrights and regulatory filings related to the Product, or the Additional Collateral.

In connection with the issuance of the Senior Secured Notes, the Company incurred \$1.6 million of issuance costs, which primarily consisted of funding and facility fees, legal and other professional fees. These costs are being amortized and recorded as additional interest expense using the interest method through 2018.

The following table summarizes information on the debt (in thousands) as of:

	<b>December 31, 2013</b>
<b>Convertible Senior Notes due 2020:</b>	
Fair value of the liability component	\$ 154,737
Accumulated accretion of discount	8,369
Net carrying value	<u>\$ 163,106</u>
<b>Senior Secured Notes due 2018:</b>	
Carrying value	<u>\$ 50,000</u>
<b>Total Notes:</b>	
Fair value of the liability component	\$ 204,737
Accumulated accretion of discount	8,369
Net carrying amount (Long-term debt)	<u>\$ 213,106</u>

There is no short term portion of long-term debt as of December 31, 2013.

**Note 13. Stockholders' Equity***Common Stock*

The Company is authorized to issue 200 million shares of common stock. As of December 31, 2013 and 2012, there were 103,161,000 and 100,659,000 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

VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 13. Stockholders' Equity (Continued)**

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, 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.

*Preferred Stock*

The Company is authorized to issue five million shares of undesignated preferred stock with a par value of \$1.00 per share. As of December 31, 2013 and 2012, 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 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.

## VIVUS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## Note 14. 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.

*Restricted Stock Units*

Beginning in 2012, the Company began issuing restricted units under the 2010 Plan on a limited basis. A summary of restricted stock unit award activity under the 2010 Plan is as follows:

	<u>Number of Restricted Stock Units</u>	<u>Weighted Average Grant Date Fair Value</u>
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
Granted	144,500	\$ 12.63
Vested	(33,296)	(14.15)
Forfeited	(146,204)	(13.83)
Restricted stock units outstanding, December 31, 2013	<u>—</u>	<u>\$ —</u>

## VIVUS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## Note 14. Stock Option and Purchase Plans (Continued)

## Stock Options

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

	Years Ended December 31,					
	2013		2012		2011	
	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	8,510,917	\$ 10.33	8,575,434	\$ 6.17	7,919,013	\$ 5.71
Options:						
Granted	4,166,292	\$ 12.86	2,850,118	\$ 17.80	1,289,790	\$ 8.72
Exercised	(2,375,688)	\$ 5.79	(2,648,882)	\$ 5.00	(482,172)	\$ 4.88
Cancelled	(1,395,070)	\$ 14.54	(265,753)	\$ 9.28	(151,197)	\$ 8.32
Balance at end of year	8,906,451	\$ 12.06	8,510,917	\$ 10.33	8,575,434	\$ 6.17
Exercisable at end of year	6,616,555	\$ 11.00	4,781,301	\$ 6.32	6,120,210	\$ 5.38
Weighted average grant-date fair value of options granted during the year		\$ 8.32		\$ 11.91		\$ 5.91

At December 31, 2013, stock options were outstanding and exercisable as follows:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding at December 31, 2013	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable December 31, 2013	Weighted-Average Exercise Price
\$3.13 - \$10.19	3,318,235	3.4 years	\$ 7.23	3,296,690	\$ 7.22
\$12.04 - \$12.84	3,215,931	5.2 years	\$ 12.29	2,466,649	\$ 12.22
\$12.90 - \$25.74	2,372,285	7.1 years	\$ 18.52	853,216	\$ 22.08
\$3.13 - \$25.74	8,906,451	5.1 years	\$ 12.06	6,616,555	\$ 11.00

The aggregate intrinsic value of outstanding options as of December 31, 2013, was \$6.6 million, of which \$6.6 million related to exercisable options.

At December 31, 2013, 1,976,823 options remained available for grant. In January 2014, awards exercisable for 1,128,100 shares were granted pursuant 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.



## VIVUS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## Note 14. Stock Option and Purchase Plans (Continued)

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, 2013, 1,501,905 shares have been issued to employees and there are 498,095 shares available for issuance under the ESPP. The weighted average fair value of shares issued under the ESPP in 2013, 2012 and 2011 was \$3.53, \$3.72 and \$3.21 per share, respectively.

*Share-Based Compensation Expense*

Total estimated share-based compensation expense, related to all of the Company's share-based awards, recognized for the years ended December 31, 2013, 2012 and 2011 was comprised as follows (in thousands, except per share data):

	<u>2013</u>	<u>2012</u>	<u>2011</u>
Research and development	\$ 2,361	\$ 3,487	\$ 1,917
Selling, general and administrative	15,964	12,451	5,436
Non-recurring charges	14,072	—	—
Share-based compensation expense before taxes	32,397	15,938	7,353
Related income tax benefits	—	—	—
Share-based compensation expense, net of taxes	<u>\$ 32,397</u>	<u>\$ 15,938</u>	<u>\$ 7,353</u>

On July 18, 2013, the Company entered into a settlement agreement with First Manhattan Company, or First Manhattan, in connection with a proxy contest related to the Company's 2013 Annual Meeting of Stockholders. According to the terms of the settlement agreement, more than a majority of the members of the Company's Board of Directors resigned and new members were appointed. The change in the majority of the members of the Company's Board of Directors, effective July 19, 2013, triggered certain "change of control" benefits in accordance with the Amended and Restated Change of Control and Severance Agreements, or the Amended Agreements, with certain of the Company's employees; specifically, all unvested stock options held by these employees automatically vested in full and became immediately exercisable. In accordance with ASC 718, all unamortized expense for options that were expected to vest on the date of grant and the modified fair value of the options that were not expected to vest on the date of grant (due to expected forfeitures) were immediately expensed. As a result, in the year ended December 31, 2013, the Company recognized approximately \$12.9 million in additional share-based compensation expense related to this event.

## VIVUS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 14. Stock Option and Purchase Plans (Continued)**

As part of the Company's ongoing efforts to reduce costs by eliminating expenses that are not essential to expanding the use of Qsymia, the Company implemented a cost reduction plan that reduced the Company's workforce by approximately 20 employees, or 17% of its workforce, excluding the sales force, in the year ended December 31, 2013. As a result, the Company incurred \$1.2 million in additional share-based compensation expense in the year ended December 31, 2013, related to the automatic acceleration of vesting of unvested stock options held by the terminated employees.

Total share-based compensation cost capitalized as part of the cost of inventory was \$480,000 and \$196,000 for the years ended December 31, 2013 and 2012, respectively.

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

	2013	2012	2011
Share-based compensation, net of taxes:			
Restricted stock units	\$ 471	\$ 292	\$ —
Stock options	31,610	15,531	7,259
Employee stock purchase plan	316	115	94
	<u>\$ 32,397</u>	<u>\$ 15,938</u>	<u>\$ 7,353</u>

As of December 31, 2013, unrecognized estimated compensation expense totaled \$12.2 million related to non-vested stock options and \$66,000 related to the ESPP. The weighted average remaining requisite service period of the non-vested stock options was 1.3 years and of the ESPP was less than one month.

*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:

	2013	2012	2011
Expected life (in years)	4.88	5.54	5.93
Volatility	83.35%	82.49%	77.46%
Risk-free interest rate	1.12%	1.00%	2.59%
Dividend yield	—	—	—

**Note 15. Commitments***Lease Commitments*

In November 2006, the Company entered into a 30-month lease for its former 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 lease term for the headquarters' premises terminated July 31, 2013. The fourth amendment also 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 former corporate headquarters. The average base rent for the Expansion

## VIVUS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## Note 15. Commitments (Continued)

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 Expansion Space is currently being listed for sublease.

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 May 11, 2013, and at a starting annual rental rate of \$31.20 per rentable square foot (subject to agreed increases). The Company is entitled to an abatement of the monthly installments of rent for months seven through 12 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 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. As part of a cost reduction plan, the first floor of the Evelyn Lease has been substantially vacated and the Company intends to list this unoccupied space for sublease.

Future minimum lease payments under operating leases at December 31, 2013, were as follows (in thousands):

2014	\$ 1,550
2015	2,013
2016	2,063
2017	1,917
2018	1,899
Thereafter	2,602
	<u>\$ 12,044</u>

Included in the operating lease commitments above are obligations under leases for which the Company has vacated the underlying facilities as part of a cost reduction plan. These leases expire at various dates through 2020 and represent an aggregate obligation of \$3.6 million through 2020. The Company does not currently have sublease income related to the restructured space. The Company has restructuring accruals of \$1.0 million at December 31, 2013, which represents the difference between this aggregate future obligation and expected future sublease income under estimated potential sublease agreements, as well as other facilities-related obligations (see Note 9).

## VIVUS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## Note 15. Commitments (Continued)

Rent expense under operating leases in fiscal 2013, 2012 and 2011, was as follows (in thousands):

	Years Ended December 31,		
	2013	2012	2011
Rent expense	\$ 2,867	\$ 912	\$ 671

## Note 16. 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, 2013 and 2012, are as follows (in thousands):

	2013	2012
Deferred tax assets:		
Net operating loss carry forwards	\$ 202,289	\$ 154,865
Research and development credit carry forwards	16,659	13,192
Stock-based compensation	15,476	9,386
Accruals and other	18,927	5,528
Depreciation	218	185
Deferred revenue	4,009	420
	<u>257,578</u>	<u>183,576</u>
Valuation allowance	(257,578)	(183,576)
Total	\$ <u>—</u>	\$ <u>—</u>

The net increase in the valuation allowance for the years ended December 31, 2013, 2012 and 2011, was \$74.0 million, \$47.9 million and \$22.6 million, respectively. As of December 31, 2013, 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 \$545.1 million and \$229.1 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 \$18.1 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 \$13.9 million and \$4.3 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 2033. 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. The Company has not completed a recent study to assess whether any change of control has occurred or whether there have

## VIVUS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## Note 16. Income Taxes (Continued)

been multiple changes of control since the Company's formation, due to the significant complexity and cost associated with the study. The Company has completed studies in prior periods and concluded no adjustments were required. If the Company has experienced a change of control at any time since its formation, its NOL carryforwards and tax credits may not be available, or their utilization could be subject to an annual limitation under Section 382. A full valuation allowance has been provided against the Company's NOL carryforwards, and if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Accordingly, there would be no impact on the consolidated balance sheet or statement of operations.

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, 2013, 2012 and 2011 (in thousands):

	<u>2013</u>	<u>2012</u>	<u>2011</u>
Loss before income taxes:			
Domestic	\$ (174,083)	\$ (138,599)	\$ (46,836)
International	(766)	(1,107)	—
Loss before taxes	<u>\$ (174,849)</u>	<u>\$ (139,706)</u>	<u>\$ (46,836)</u>

The (benefit)/provision for income taxes consists of the following components for the years ended December 31, 2013, 2012 and 2011 (in thousands):

## Continuing Operations:

	<u>2013</u>	<u>2012</u>	<u>2011</u>
Current			
Federal	\$ —	\$ —	\$ —
State	97	27	190
Foreign	—	—	—
Total current (benefit)/provision for income taxes	<u>\$ 97</u>	<u>\$ 27</u>	<u>\$ 190</u>
Deferred			
Federal	\$ —	\$ —	\$ —
State	—	—	—
Foreign	—	—	—
Total deferred benefit for income taxes	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>
Total (benefit)/provision for income taxes from continuing operations	<u>\$ 97</u>	<u>\$ 27</u>	<u>\$ 190</u>

## VIVUS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## Note 16. 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, 2013, 2012 and 2011:

	<u>2013</u>	<u>2012</u>	<u>2011</u>
Tax at U.S. federal statutory rate	(35)%	(35)%	(35)%
Change in valuation allowance	35	34	38
Permanent items	2	1	1
Tax credits	(1)	—	(4)
Other	(1)	—	—
Effective tax rate	<u>0%</u>	<u>0%</u>	<u>0%</u>

The total gross unrecognized tax benefits as of December 31, 2013, is \$1.7 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 2013 and 2012, is as follows (in thousands):

	<u>2013</u>	<u>2012</u>	<u>2011</u>
Unrecognized tax benefits as of January 1	\$ 1,215	\$ 1,215	\$ 1,171
Gross increase/(decrease) for tax positions of prior years	447	—	44
Gross increase/(decrease) for tax positions of current year	—	—	—
Settlements	—	—	—
Lapse of statute of limitations	—	—	—
Unrecognized tax benefits balance at December 31	<u>\$ 1,662</u>	<u>\$ 1,215</u>	<u>\$ 1,215</u>

The total unrecognized tax benefits as of December 31, 2013, of \$1.7 million includes approximately \$1.5 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, 2013 and 2012, is as follows (in thousands):

	<u>2013</u>	<u>2012</u>
Total unrecognized tax benefits	\$ 1,662	\$ 1,215
Amounts netted against deferred tax assets	(1,502)	(1,055)
Unrecognized tax benefits recorded on consolidated balance sheets	<u>\$ 160</u>	<u>\$ 160</u>

As of December 31, 2013, the Company had accrued \$45,000 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 2013, \$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

## VIVUS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 16. 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, 2013.

The Internal Revenue Service completed its 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 2013 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 12-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 17. Segment Information and Concentration of Customers and Suppliers**

The Company operates in one business segment—the development and commercialization of novel therapeutic products. Therefore, results of operations are reported on a consolidated basis for purposes of segment reporting, consistent with internal management reporting. Disclosures about product revenues by geographic area; revenues and accounts receivable from major customers, and major suppliers are presented below.

*Revenue*

Revenue was as follows for the years ended December 31, 2013, 2012 and 2011 (in thousands):

	<u>2013</u>	<u>2012</u>
Net product revenue:		
Qsymia	\$ 23,718	\$ 2,012
STENDRA or SPEDRA	1,526	—
Total net product revenue	<u>25,244</u>	<u>2,012</u>
License revenue	55,838	—
Total revenue	<u>\$ 81,082</u>	<u>\$ 2,012</u>

*Geographic Information*

Outside the United States, the Company sells products principally in the EU. The geographic classification of product sales was based on the location of the customer. The geographic classification of all other revenues was based on the domicile of the entity from which the revenues were earned.



## VIVUS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## Note 17. Segment Information and Concentration of Customers and Suppliers (Continued)

Certain geographic information with respect to revenues was as follows (in thousands):

Total revenue by geographic region for the years ended December 31, 2013 and 2012, was as follows (in thousands):

	Years Ended December 31,			
	2013		2012	
	U.S.	ROW	U.S.	ROW
Qsymia—Net product revenue	\$ 23,718	\$ —	\$ 2,012	\$ —
STENDRA/SPEDRA—Net product revenue	1,080	446	—	—
Total net product revenue	24,798	446	2,012	—
STENDRA/SPEDRA—License revenue	30,393	25,445(1)	—	—
Total revenue	\$ 55,191	\$ 25,891	\$ 2,012	\$ —

(1) \$21.0 million of which is attributable to Germany.

*Major customers*

Revenues from significant customers as a percentage of total revenues for the year ended December 31, 2013 and 2012, is as follows:

	2013	2012
Auxilium	39%	—%
Menarini	26%	—%
CVS	9%	50%
Walgreens	6%	39%
Express Scripts, Inc.	3%	10%

Accounts receivable at December 31, 2013 and 2012 by significant customer as a percentage of the total gross accounts receivable balance are as follows:

	2013	2012
Menarini	41%	—%
Amerisource Bergen	26%	—%
McKesson	13%	—%
Cardinal Health, Inc.	12%	—%
CVS	1%	51%
Walgreens	1%	44%
Express Scripts, Inc.	1%	1%

*Major suppliers*

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, which supplied the product for the Phase 3b/4 program for Qsymia, is the Company's sole source of clinical and

VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 17. Segment Information and Concentration of Customers and Suppliers (Continued)**

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 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 years ended December 31, 2013 and 2012, the Company incurred expenses for work performed by a third-party clinical research organization, or CRO, for Qsymia and STENDRA post-approval studies that accounted for 29% and 13%, respectively, of total research and development expenses. During the year ended December 31, 2011, the Company did not have any third-party CROs that accounted for 10% or more of total research and development expenses.

**Note 18. 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, 2013, 2012 and 2011 were \$565,000, \$329,000 and \$181,000, respectively.

**Note 19. 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. The Court granted defendants' motions to dismiss both plaintiff's Amended Class Action Complaint and Second Amended Class Action Complaint; by order dated September 27, 2012, the latter dismissal was with prejudice and final judgment was entered 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. Briefing of the appeal is complete, and the parties are awaiting word on whether the Court of Appeals wishes to entertain oral argument.

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 same individuals are also named defendants in

VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 19. 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 Company is named as a nominal defendant in these actions, neither of which seeks any recovery from the Company. The parties have agreed to stay the derivative lawsuits pending the outcome of the appeal of the securities class action.

The Company and its directors cannot predict the outcome of the various shareholder lawsuits, but they believe the various shareholder lawsuits are without merit and intend to continue vigorously defending them.

On July 12, 2013, various current and former officers and directors of the Company were named as defendants in a separate shareholder derivative lawsuit filed in the California Superior Court, Santa Clara County, and captioned *Ira J. Gaines IRA, et al. v. Leland F. Wilson, et al.*, Case No.1-13-CV-249436. The lawsuit generally alleges breaches of the fiduciary duty of care in connection with the launch of Qsymia, breaches of the duty of loyalty and insider trading by some defendants for selling Company stock while purportedly being aware that the Qsymia launch would be less successful than predicted and corporate waste. Again, the Company is named as a nominal defendant, and no recovery from the Company is sought. As with the other shareholder litigation, the Company does have certain indemnification obligations to the named defendants, including to advance defense costs to the individuals. The Company also maintains directors' and officers' liability insurance that it believes affords coverage for much of the anticipated cost of the proceedings, subject to the policies' terms and conditions. The individual defendants deny the material allegations and have indicated an intention to defend them vigorously. On October 21, 2013, the Company filed a demurrer seeking to have the lawsuit dismissed in its entirety for failure to make a pre-suit demand upon the Company's Board of Directors or plead sufficient facts to show that such demand would have been futile. Briefing on the demurrer is complete and oral argument is presently scheduled for March 14, 2014.

*Proxy Related Lawsuit*

On July 16, 2013, First Manhattan, the owner of approximately 9.9% of the outstanding shares of common stock of the Company, commenced an action in the Court of Chancery of the State of Delaware, naming the then-serving members of the board of directors of the Company as defendants and the Company as a nominal defendant. The action was captioned *First Manhattan Co. v. Leland F. Wilson, et al.*, C.A. No. 8731-VCL. In its verified complaint, First Manhattan alleged that the Company's directors breached their fiduciary duties in connection with the Board's decision to adjourn the annual stockholders meeting from July 15, 2013 until July 18, 2013. The verified complaint sought declaratory and injunctive relief, including enjoining the defendants from soliciting proxies, directing the inspector of elections to certify the election of directors based on votes that were present and prepared to be voted on July 15, 2013, before the annual stockholders meeting was adjourned, and prohibiting defendants from taking any actions as directors of the Company. The verified complaint did not seek damages from the Company or the defendant board members. The parties entered into a settlement agreement on July 18, 2013, and the action was dismissed with prejudice on July 19, 2013. As part of the settlement agreement with First Manhattan, the Company paid the reasonable and documented expenses incurred by First Manhattan in connection with its proxy contest, which totaled approximately \$2.9 million.

VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Note 19. Legal Matters (Continued)**

*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 20. Subsequent Events (Unaudited)**

On January 21, 2014, the Company received a notice of tax refund from the state of New Jersey in settlement of an audit and acceptance of a refund claim for the tax year ended December 31, 2007. As of December 31, 2013, the Company did not consider receiving the refund as probable and therefore had not recorded an income tax receivable. The Company expects to receive a refund of approximately \$357,000 (net of expenses) in the quarter ended March 31, 2014.

## VIVUS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## Note 21. Selected Financial Data (Unaudited)

## Selected Quarterly Financial Data (in thousands)

	Quarter Ended,			
	March 31	June 30	September 30	December 31
2013				
Total revenue	\$ 4,112	\$ 5,534	\$ 27,379	\$ 44,057
Total gross profit (loss)	\$ (2,055)	\$ 514	\$ 26,638	\$ 40,892
Operating expenses	\$ 57,909	\$ 56,979	\$ 68,056	\$ 52,752
Net loss from continuing operations	\$ (53,768)	\$ (55,635)	\$ (48,379)	\$ (17,164)
Net income from discontinued operations	\$ 192	\$ 123	\$ 175	\$ —
Basic and diluted net (loss) per share:				
Continuing operations	\$ (0.53)	\$ (0.55)	\$ (0.48)	\$ (0.17)
Discontinued operations	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00
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

## 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
<b>Allowance for Cash Discounts</b>				
Fiscal year ended December 31, 2011	\$ —	\$ —	\$ —	\$ —
Fiscal year ended December 31, 2012	\$ —	\$ 57	\$ —	\$ 57
Fiscal year ended December 31, 2013	\$ 57	\$ 1,050	\$ (973)	\$ 134

\* Amount charged to operations during fiscal years ended December 31, 2013 and 2012, includes \$750,000 and \$53,000, respectively, for cash discount allowances related to revenue recognized during each fiscal year. The remaining amounts for the years ended December 31, 2013 and 2012, were recorded on the consolidated balance sheets net of deferred revenue at the end of each period, respectively.

**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. None.

**Management's Annual Report on Internal Control Over Financial Reporting**

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

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

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



eliminate, this risk. Management is responsible for establishing and maintaining adequate internal control over financial reporting for the company.

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, 2013. 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, 2013. This report, which expresses an unqualified opinion on the effectiveness of our internal controls over financial reporting as of December 31, 2013, is included herein.

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

**Item 9B. *Other Information***

None.

## PART III

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

The information required by this item is hereby incorporated by reference from the information under the captions "Election of Directors," "Board of Directors Meetings and Committees—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 2014 Annual Meeting of Stockholders. The information required by Section 16(a) is incorporated by reference from the information under the caption "Security Ownership of Certain Beneficial Owners and Management—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](http://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 "Board of Directors Meetings and Committees—Compensation Committee Interlocks and Insider Participation," "Executive Compensation" and "Executive Compensation—Compensation Committee Report" 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 Plan Information**

Information about our equity compensation plans at December 31, 2013, that were approved by our stockholders was as follows:

<u>Plan Category</u>	<u>Number of Shares to be issued Upon Exercise of Outstanding Options and Rights(a)</u>	<u>Weighted Average Exercise Price of Outstanding Options</u>	<u>Number of Shares Remaining Available for Future Issuance(c)</u>
Equity compensation plans approved by stockholders	8,581,451	\$ 12.14	2,474,918
Equity compensation plans not approved by stockholders(b)	325,000	\$ 10.19	—
<b>Total</b>	<b>8,906,451</b>	<b>\$ 12.07</b>	<b>2,474,918</b>

- (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 1,976,823 shares for the 2010 Stock Option Plan and 498,095 shares for the 1994 Employee Stock Purchase Plan.

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

**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 of Directors Meetings and Committees—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.

## PART IV

**Item 15. Exhibits and Financial Statement Schedules****(a) Documents filed as part of this report.****1. Financial Statements**

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

***Index to Consolidated Financial Statements***

Reports of Independent Registered Public Accounting Firm	102
Consolidated Balance Sheets as of December 31, 2013 and 2012	104
Consolidated Statements of Operations for the years ended December 31, 2013, 2012 and 2011	105
Consolidated Statements of Comprehensive Loss for the years ended December 31, 2013, 2012 and 2011	105
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2013, 2012 and 2011	106
Consolidated Statements of Cash Flows for the years ended December 31, 2013, 2012 and 2011	107
Notes to Consolidated Financial Statements	108

**2. Financial Statement Schedules**

The following financial statement schedule of VIVUS, Inc. as set forth on page 121 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.



**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Seth H. Z. Fischer and Svai S. Sanford 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:

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ SETH H. Z. FISCHER</u> Seth H. Z. Fischer	Chief Executive Officer (Principal Executive Officer) and Director	February 27, 2014
<u>/s/ MICHAEL J. ASTRUE</u> Michael J. Astrue	Non-executive Chairman of the Board of Directors and Director	February 27, 2014
<u>/s/ SVAI S. SANFORD</u> Svai S. Sanford	Chief Financial Officer (Principal Financial and Accounting Officer)	February 27, 2014
<u>/s/ J. MARTIN CARROLL</u> J. Martin Carroll	Director	February 27, 2014
<u>/s/ SAMUEL F. COLIN, M.D.</u> Samuel F. Colin, M.D.	Director	February 27, 2014
<u>/s/ ALEXANDER J. DENNER, PH.D.</u> Alexander J. Denner, Ph.D.	Director	February 27, 2014
<u>/s/ JOHANNES J. P. KASTELEIN</u> Johannes J. P. Kastelein	Director	February 27, 2014
<u>/s/ MARK B. LOGAN</u> Mark B. Logan	Director	February 27, 2014

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ DAVID Y. NORTON</u> David Y. Norton	Director	February 27, 2014
<u>/s/ JORGE PLUTZKY, M.D.</u> Jorge Plutzky, M.D.	Director	February 27, 2014
<u>/s/ HERMAN ROSENMAN</u> Herman Rosenman	Director	February 27, 2014
<u>/s/ ROBERT N. WILSON</u> Robert N. Wilson	Director	February 27, 2014



**VIVUS, INC.**  
**REPORT ON FORM 10-K FOR**  
**THE YEAR ENDED DECEMBER 31, 2013**

**EXHIBIT INDEX**

<u>Exhibit Number</u>	<u>Description</u>
2.1(1)†	Asset Purchase Agreement between the Registrant and K-V Pharmaceutical Company dated as of March 30, 2007
2.2(2)†	Asset Purchase Agreement dated October 1, 2010, between the Registrant, MEDA AB and Vivus Real Estate, LLC
3.1(3)	Amended and Restated Certificate of Incorporation of the Registrant
3.2(4)	Amended and Restated Bylaws of the Registrant
3.3(5)	Amendment No. 1 to the Amended and Restated Bylaws of the Registrant
3.4(6)	Amendment No. 2 to the Amended and Restated Bylaws of the Registrant
3.5(7)	Amendment No. 3 to the Amended and Restated Bylaws of the Registrant
3.6(8)	Amendment No. 4 to the Amended and Restated Bylaws of the Registrant
3.7(9)	Amended and Restated Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock of the Registrant
4.1(10)	Specimen Common Stock Certificate of the Registrant
4.2(11)	Preferred Stock Rights Agreement dated as of March 27, 2007, between the Registrant and Computershare Investor Services, LLC
4.3(12)	Indenture dated as of May 21, 2013, by and between the Registrant and Deutsche Bank Trust Company Americas, as trustee
4.4(13)	Form of 4.50% Convertible Senior Note due May 1, 2020
10.1(14)*	Form of Indemnification Agreement by and among the Registrant and the Directors and Officers of the Registrant
10.2(15)*	1994 Employee Stock Purchase Plan, as amended, Form of Subscription Agreement and Form of Notice of Withdrawal
10.3(16)*	2001 Stock Option Plan and Form of Agreement thereunder
10.4(17)*	2001 Stock Option Plan, as amended on July 12, 2006
10.5(18)*	Form of Notice of Grant and Restricted Stock Unit Agreement under the VIVUS, Inc. 2001 Stock Option Plan
10.6(19)*	2010 Equity Incentive Plan and Form of Agreement thereunder
10.7(20)*	Stand-Alone Stock Option Agreement with Michael P. Miller dated as of April 30, 2010
10.8(21)*	Employment Agreement dated December 20, 2007, between the Registrant and Leland F. Wilson
10.9(22)*	First Amendment dated January 23, 2009, to the Employment Agreement dated December 20, 2007, by and between the Registrant and Leland F. Wilson



Exhibit Number	Description
10.10(23)*	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(24)*	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(25)*	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(26)†	Agreement effective as of December 28, 2000, between the Registrant and Tanabe Seiyaku Co., Ltd.
10.14(27)	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.
10.15(28)	Termination and Release executed by Tanabe Holding America, Inc. dated May 1, 2007
10.16(29)†	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.)
10.17(30)†	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.)
10.18(31)†	Settlement and Modification Agreement dated July 12, 2001, between ASIVI, LLC, AndroSolutions, Inc., Gary W. Neal and the Registrant
10.19(32)†	Assignment Agreement between Thomas Najarian, M.D. and the Registrant dated October 16, 2001
10.20(33)†	Testosterone Development and Commercialization Agreement dated as of February 7, 2004, between the Registrant, Fempharm Pty Ltd. and Acrux DDS Pty Ltd.
10.21(34)†	Estradiol Development and Commercialization Agreement dated as of February 12, 2004, between the Registrant, Fempharm Pty Ltd. and Acrux DDS Pty Ltd.
10.22(35)†	Master Services Agreement dated as of September 12, 2007, between the Registrant and Medpace, Inc.
10.23(36)†	Exhibit A: Medpace Task Order Number: 06 dated as of December 15, 2008, pursuant to that certain Master Services Agreement, between the Registrant and Medpace, Inc., dated as of September 12, 2007
10.24(37)†	Transition Services Agreement dated November 5, 2010, between the Registrant and MEDA AB
10.25(38)†	Commercial Manufacturing and Packaging Agreement by and between the Registrant and Catalent Pharma Solutions, LLC dated as of July 17, 2012
10.26(39)	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

Exhibit Number	Description
10.27(40)	First Amendment to Lease dated November 18, 2008, between Castro Mountain View, LLC, CP6CC, LLC and the Registrant
10.28(41)	Second Amendment to Lease effective November 12, 2009, between Castro Mountain View, LLC, CP6CC, LLC and the Registrant
10.29(42)	Third Amendment to Lease effective December 3, 2010, between Castro Mountain View, LLC, CP6CC, LLC and the Registrant
10.30(43)	Fourth Amendment to Lease effective February 14, 2012, between Castro Mountain View, LLC, CP6CC, LLC and the Registrant
10.31(44)	Lease Agreement effective December 11, 2012, by and between the Registrant and SFERS Real Estate Corp. U
10.32(45)†	Purchase and Sale Agreement effective as of March 25, 2013, between the Registrant and BioPharma Secured Investments III Holdings Cayman LP
10.33(46)	Capped Call Confirmation dated May 15, 2013, by and between the Registrant and Deutsche Bank AG, London Branch
10.34(47)*	Form of Amended and Restated Change of Control and Severance Agreement
10.35(48)†	License and Commercialization Agreement dated July 5, 2013, between the Registrant and Berlin-Chemie AG
10.36(49)†	Commercial Supply Agreement dated as of July 5, 2013, between the Registrant and Berlin-Chemie AG
10.37(50)	Agreement dated July 18, 2013, by and between the Registrant and First Manhattan Co.
10.38(51)*	Letter Agreement dated July 18, 2013, by and among the Registrant, First Manhattan Co. and Peter Y. Tam
10.39(52)	Fourth Amendment to the Agreement dated as of December 28, 2000, between the Registrant and Mitsubishi Tanabe Pharma Corporation (formerly Tanabe Seiyaku Co., Ltd.), effective as of July 1, 2013
10.40(53)†	Commercial Supply Agreement dated July 31, 2013, by and between the Registrant and Sanofi Chimie
10.41(54)*	Employment Agreement dated September 3, 2013, by and between the Registrant and Seth H. Z. Fischer
10.42(55)†	License and Commercialization Agreement dated as of October 10, 2013, by and between the Registrant and Auxilium Pharmaceuticals, Inc.
10.43(56)†	Commercial Supply Agreement dated as of October 10, 2013, by and between the Registrant and Auxilium Pharmaceuticals, Inc.
10.44(57)*	Letter Agreement dated November 4, 2013, by and between the Registrant and Timothy E. Morris
10.45††	Manufacturing and Supply Agreement dated November 18, 2013, by and between the Registrant and Sanofi Winthrop Industrie
10.46††	License and Commercialization Agreement dated December 11, 2013, by and between the Registrant and Sanofi

Exhibit Number	Description
10.47††	Supply Agreement effective as of December 11, 2013, by and between the Registrant and Sanofi Winthrop Industrie
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, 2013, 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

† 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 2.1 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2012, filed with the Commission on February 26, 2013.
- (2) Incorporated by reference to Exhibit 2.2 filed with the Registrant's Annual Report on Form 10-K/A for the fiscal year ended December 31, 2012, filed with the Commission on June 12, 2013.
- (3) 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.
- (4) Incorporated by reference to Exhibit 3.2 filed with the Registrant's Current Report on Form 8-K filed with the Commission on April 20, 2012.
- (5) Incorporated by reference to Exhibit 3.3 filed with the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2013, filed with the Commission on May 8, 2013.
- (6) Incorporated by reference to Exhibit 3.4 filed with the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2013, filed with the Commission on May 8, 2013.
- (7) Incorporated by reference to Exhibit 3.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on May 13, 2013.

- (8) Incorporated by reference to Exhibit 3.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on July 24, 2013.
- (9) 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.
- (10) Incorporated by reference to Exhibit 4.1 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.
- (11) 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.
- (12) Incorporated by reference to Exhibit 4.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on May 21, 2013.
- (13) Incorporated by reference to Exhibit 4.2 filed with the Registrant's Current Report on Form 8-K filed with the Commission on May 21, 2013.
- (14) Incorporated by reference to Exhibit 10.11 filed with the Registrant's Form 8-B filed with the Commission on June 25, 1996.
- (15) 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.
- (16) 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.
- (17) 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.
- (18) 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.
- (19) 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.
- (20) 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.
- (21) 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.
- (22) 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.
- (23) 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.
- (24) 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.
- (25) 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.
- (26) Incorporated by reference to Exhibit 10.15 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2012, filed with the Commission on February 26, 2013.

- (27) Incorporated by reference to Exhibit 10.42A filed with the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2004, filed with the Commission on May 7, 2004.
- (28) 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.
- (29) 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.
- (30) 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.
- (31) Incorporated by reference to Exhibit 10.20 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2012, filed with the Commission on February 26, 2013.
- (32) 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.
- (33) Incorporated by reference to Exhibit 10.50 filed with the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2004, filed with the Commission on May 7, 2004.
- (34) Incorporated by reference to Exhibit 10.51 filed with the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2004, filed with the Commission on May 7, 2004.
- (35) Incorporated by reference to Exhibit 10.2 filed with the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2013, filed with the Commission on May 8, 2013.
- (36) 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.
- (37) Incorporated by reference to Exhibit 10.27 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2012, filed with the Commission on February 26, 2013.
- (38) 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.
- (39) 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.
- (40) 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.
- (41) 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.
- (42) 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.
- (43) 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.

- (44) Incorporated by reference to Exhibit 10.34 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2012, filed with the Commission on February 26, 2013.
- (45) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2013, filed with the Commission on May 8, 2013.
- (46) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on May 16, 2013.
- (47) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on July 5, 2013.
- (48) Incorporated by reference to Exhibit 10.3 filed with the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2013, filed with the Commission on August 8, 2013.
- (49) Incorporated by reference to Exhibit 10.4 filed with the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2013, filed with the Commission on August 8, 2013.
- (50) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on July 19, 2013.
- (51) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on July 24, 2013.
- (52) 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, 2013.
- (53) Incorporated by reference to Exhibit 10.8 filed with the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2013, filed with the Commission on August 8, 2013.
- (54) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on September 4, 2013.
- (55) Incorporated by reference to Exhibit 10.9 filed with the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2013, filed with the Commission on November 7, 2013.
- (56) Incorporated by reference to Exhibit 10.10 filed with the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2013, filed with the Commission on November 7, 2013.
- (57) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on November 5, 2013.





**\*\*\* INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

### **MANUFACTURING AND SUPPLY AGREEMENT**

**THIS MANUFACTURING AND SUPPLY AGREEMENT** (this “**Agreement**”) is entered into and effective as of September 1<sup>st</sup>, 2013 (the “**Effective Date**”) by and between VIVUS, Inc., a Delaware corporation with its principal place of business at 351 E. Evelyn Avenue, Mountain View, CA 94041 (“**Purchaser**”) and SANOFI WINTHROP INDUSTRIE, a French corporation having its principal offices at 20, avenue Raymond Aron, 92165 Antony Cedex, France, acting for itself and on behalf of its Affiliates as hereinafter defined (“**SWI**”). SWI and Purchaser are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**”.

### **RECITALS**

Purchaser owns or has a license to certain patent rights and other intellectual property rights relating to a therapeutic drug known as avanafil.

Purchaser has received regulatory approval for avanafil in the United States and in Europe for the treatment of male erectile dysfunction (under the trade names Stendra<sup>TM</sup> and Spedra<sup>TM</sup>).

Purchaser desires to have SWI, and SWI desires to, manufacture and supply the Product (as hereinafter defined), on the terms and subject to the conditions of this Agreement.

**NOW, THEREFORE**, in consideration of the mutual covenants and promises set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

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## 1. DEFINITIONS

“ **Act** ” shall mean the United States Federal Food, Drug, and Cosmetic Act, as it may be amended from time to time.

“ **Affiliate(s)** ” shall mean any corporation or business entity which is controlled by, controls, or is under common control of a Party. For this purpose, the meaning of the word “control” shall include, without limitation, direct or indirect ownership of more than fifty percent (50%) of the voting shares of interest of such corporation or business entity.

For SWI, the term Affiliate shall include any company, which, directly or indirectly, is controlled or is under common control with SANOFI — a French corporation registered in the Company and Trade Register of Paris under N° 395 030 844, having its registered office at 54, rue La Boétie, 75008 Paris, France .

“ **Applicable Laws** ” means any and all laws, statutes, ordinances, regulations, permits, orders, decrees, judgments, directives, or rules of any kind whatsoever that are promulgated by a federal, state, or other governmental authority, in each case pertaining to any of the activities contemplated by this Agreement, all as amended from time to time. Notwithstanding the foregoing, nothing herein shall require SWI to comply with any Applicable Law outside France, other than cGMP, unless SWI agrees in advance in a written agreement that specifies the applicable law, statute, ordinance, regulation, permit, order, decree, judgment, directive, or rule.

“**Background Technology**” shall mean, as the case may be, Purchaser’s or SWI’s and/or its Affiliates’ intellectual property used to perform the Agreement including any patented technology, know-how, trade secrets, and proprietary information that was in the Party’s possession prior to its disclosure or, is later generated or, acquired independently by a Party outside the scope of the Agreement and without the use of the other Party’s Confidential Information.

“**Batch**” means a quantity of Product manufactured under the batch size specified in Exhibit F attached hereto.

“**Business Day**” means each day of the week excluding Saturday, Sunday or a day on which banking institutions in New York, New York or Paris, France, are closed.

“**Calendar Quarter**” shall mean any consecutive 3-month period ending March 31, June 30, September 30 or December 31.

“**Calendar Year**” shall mean a twelve (12) month period commencing January 1.

“ **cGMP** ” shall mean (a) current good manufacturing practices for the methods to be used in, and the facilities and controls to be used for, the manufacture, processing, packing, testing, shipping, and holding of drug active ingredients, as promulgated by the FDA (including 21

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C.F.R. Parts 210 and 211), including all amendments and supplements thereto during the term of this Agreement and (b) comparable laws or regulations applicable to the manufacture, processing, packing, testing, shipping, and holding of drug active ingredients in the European Union, as they may be updated from time to time, including applicable guidelines promulgated under the International Conference on Harmonization.

“**Commercialization Partner**” means any third party to which Purchaser has agreed to transfer all or any of its rights to commercialize Purchaser’s Product in all or any portion of the Purchaser Territory.

“**Commercially Reasonable Efforts**” means with respect to the efforts to be expended by any Party with respect to any action, objective or obligation, those reasonable, diligent, good faith efforts to accomplish such action, objective, or obligation as a Person engaged in the relevant business activity for its own account would normally use to accomplish a similar action, objective, or obligation under similar circumstances.

“**Compound**” means the compound identified by the International Non-Proprietary Name avanafil and chemically known as (S)-4-(3-Chloro-4-methoxybenzylamino)-2-(2-hydroxymethylpyrrolidin-1-yl)-N-pyrimidin-2-ylmethyl-5-pyrimidinecarboxamide.

“**Confidential Information**” means, with respect to a Party, all proprietary Information of such Party that is disclosed to or accessed by the other Party under this Agreement.

“**EMA**” means the European Medicines Agency or its successor.

“**Exclusive Territory**” shall mean all countries in the Purchaser Territory, excluding the Semi-Exclusive Territory.

“**FDA**” means the United States Food and Drug Administration or its successor.

“**Forecast**” shall have the meaning set forth in Section 2.5.

“**License Agreement**” shall mean the License and Commercialization Agreement to be executed promptly after the date hereof between Purchaser and SANOFI regarding Purchaser’s Product, as such agreement may be amended from time to time.

“**MAA**” means an application for Regulatory Approval filed with the EMA.

“**Manufacturing Technology**” shall the meaning set forth in Section 2.2

“**MTPC**” means Mitsubishi Tanabe Pharma Corporation.

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“**MTPC Agreement**” means that certain Agreement between SWI and MTPC (as successor in interest to Tanabe Seiyaku Co., Ltd.), effective as of December 28, 2000, as amended pursuant to the Amendment No. 1 to Agreement dated as of January 9, 2004 and the Second Amendment to Agreement dated as of August 1, 2012, the Third Amendment to Agreement dated as of February 21, 2013, and as otherwise amended from time to time.

“**NDA**” means a New Drug Application, as defined in the Act.

“**Non-Severable Improvements**” shall mean such improvement and enhancements to the Manufacturing Technology, whether patentable or not, generated by or on behalf of SWI during the course of the performance of the Agreement which \*\*\*.

“**Price**” means the toll fee to be paid by Purchaser as described in Exhibit B.

“**Product**” means formulated tablets containing Compound in bulk tablet form . Product will be ordered and supplied at three different dosage strengths: 50 mg, 100 mg, and 200 mg.

“**Product Shortage**” means a circumstance that is not the result of a force majeure in which SWI is unable to supply Product to Purchaser in compliance with the terms and conditions of this Agreement in the quantities sufficient to meet Purchaser’s requirements of Product as set forth in outstanding Purchase Orders and/or the Binding Forecast.

“**Purchase Order**” shall have the meaning set forth in Section 2.6.

“**Purchaser’s Product**” shall mean any composition containing the Compound, alone or in combination with one or more active ingredient(s), in all dosage strengths whether packaged and labeled or in bulk form, commercialized by Purchaser or its Commercialization Partners.

“**Purchaser Territory**” means all countries in the world in which Purchaser has a right under the MTPC Agreement to sell the Product, other than the countries of the Sanofi Territory.

“**Quality Agreement**” shall have the meaning set forth in Section 5.4.

“**Regulatory Approval**” means all approvals necessary for the manufacture, marketing, importation and sale of a Product for one or more indications in a country or regulatory jurisdiction, which may include satisfaction of all applicable regulatory and notification requirements.

“**Regulatory Authority**” means, in a particular country or regulatory jurisdiction, any applicable governmental authority involved in granting Regulatory Approval.

“**Sanofi Territory**” means all the countries of Africa, the Middle East-Turkey, and Eurasia, as detailed in Exhibit E, which list of territories shall be deemed automatically amended

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from time to time upon any amendment to the definition of “Sanofi Territory” in the License Agreement.

“**Semi-Exclusive Territory**” shall mean the following countries: Albania, Andorra, Argentina, Australia, Austria, Belgium, Bosnia Herzegovina, Brazil, Bulgaria, Chile, Colombia, Costa Rica, Croatia, Cuba, Cyprus, Czech Republic, Denmark, Dominican Republic, Ecuador, El Salvador, Estonia, Finland, France, Germany, Greece, Guatemala, Honduras, Hungary, Iceland, India, Ireland, Italy, Jamaica, Latvia, Lichtenstein, Lithuania, Luxembourg, Kosovo, Malta, Mexico, Montenegro, the Netherlands, New Zealand, Nicaragua, Norway, Panama, Paraguay, Peru, Poland, Portugal, Republic of Macedonia, Republic of Serbia, Romania, San Marino Republic, Slovakia, Slovenia, Spain, Sweden, Switzerland, Trinidad & Tobago, the United Kingdom, Uruguay, Vatican City, and Venezuela.

“**Severable Improvements**” shall mean such improvements and enhancements to the Manufacturing Technology, generated by or on behalf of SWI during the course of the performance of the Agreement that are not Non-Severable Improvements.

“**Specifications**” means the specifications, standards, limits, criteria and other requirements for or related to the Product provided hereunder, as set forth in Exhibit A or otherwise agreed to by the Parties in writing.

“**Term**” shall have the meaning set forth in Section 9.1.

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## 2. SUPPLY OF PRODUCTS

### 2.1 Supply of Product.

(a) Supply and Purchase of Product. Subject to the provisions herein, the successful completion of the validation protocol and the approval of SWI by Regulatory Authorities to supply Product, SWI agrees, during the Term, to manufacture, test, and supply the Product to Purchaser or its designee and Purchaser agrees to purchase the Product from SWI, pursuant to Purchase Orders submitted to SWI by Purchaser, from time to time in accordance with Section 2.3.

(b) Minimum Quantities. For the duration of this Agreement, subject to the terms and conditions of this Agreement, SWI undertakes to supply, and Purchaser undertakes to purchase and be delivered: (i) exclusively from SWI its total needs of Product for the manufacture of Purchaser's Product to be commercialized in the Exclusive Territory; and

(ii) each Calendar Year, \*\*\*% of Purchaser's global annual demand of Product for the manufacture of Purchaser's Product to be commercialized in the Semi-Exclusive Territory

(for purposes of this Section 2.1(b)(ii), the purchase of \*\*\*% of Purchaser's global annual demand during a particular Calendar Year shall be calculated based on \*\*\* of Product for the manufacture of Purchaser's Product to be commercialized in the Semi-Exclusive Territory, in each case submitted as of \*\*\* and requesting delivery by Purchaser no later than \*\*\*); and

(iii) minimum yearly quantities of Product through the term of the Agreement, \*\*\* as follows: - SWI's \*\*\*;  
- SWI's \*\*\*, but in each case \*\*\*;

\*\*\* collectively referred to herein as the "Minimum Yearly Quantities".

Purchaser undertakes to purchase the Minimum Yearly Quantities, which shall not be subject to any reduction whatsoever. Remedies for failure to comply with such undertaking are described below. Promptly after \*\*\* of each Calendar Year during the term of this Agreement, Purchaser shall provide to SWI a report indicating (a) the quantities of Product ordered by Purchaser from SWI during such Calendar Year and delivered to Purchaser during \*\*\* or having a requested delivery date before \*\*\*, including a separate report of quantities of such Product to be commercialized in the Semi-Exclusive Territory, and (b) the quantities of Product ordered by Purchaser from a third-party supplier during such Calendar Year and delivered to Purchaser during \*\*\* or having a requested delivery date before \*\*\* for the commercialization of the Product in the Semi-Exclusive Territory. If SWI failed to supply any portion of Purchaser's firm orders during such Calendar Year, the quantity of Product that SWI failed to supply shall, for purposes of determining whether Purchaser satisfied its obligations and/or calculating any payments under this section, be deemed to have been ordered and delivered to Purchaser.

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Purchaser shall keep complete and accurate records of the aggregate quantities of Product bought from SWI or from any other supplier for the commercialization of Purchaser's Product in the Purchaser Territory. All such records shall be retained for at least \*\*\* years following the Calendar Year in which they are generated. At SWI's request, such records shall be available for review not more than once each Calendar Year (during normal business hours on a mutually agreed date with reasonable advance notice) by an independent auditor mutually agreed upon by the Parties and subject to confidentiality and non-use obligations no less stringent than those set forth in Article 13 for the sole purpose of verifying the respect of Purchaser's commitment pursuant to Section 2.1(b). The expense of such auditor shall be borne by SWI unless the audit report reveals a breach of such commitments by Purchaser, in which case, Purchaser shall reimburse SWI the expense of such independent auditor. Such auditor shall not disclose Purchaser's Confidential Information to SWI, except to the extent such disclosure is necessary to verify the accuracy of the reports furnished by Purchaser.

In the event that as determined from the reports specified in this Section the quantities of Product purchased by Purchaser are below the Minimum Yearly Quantity applicable for a given Calendar Year (a "Minimum Yearly Quantity Shortfall"), not caused by a force majeure occurrence, then Purchaser shall either (i) promptly (but in any event no later than \*\*\*) submit to SWI a purchase order for the amount of the Minimum Yearly Quantity Shortfall, requesting delivery of the Shortfall Quantity on or before \*\*\*, or (ii) pay a penalty corresponding to the amount of the Minimum Yearly Quantity Shortfall.

This Section describes Purchaser's sole obligations, and SWI's sole remedies, for Purchaser's failure to comply with its obligations under Section 2.1(b).

**2.2 Technology Transfer.** Prior to manufacturing the Product, a technology transfer of the manufacturing process will be performed from Purchaser to SWI. Purchaser shall disclose (and provide copies, as applicable) to SWI all information related to the manufacture of the Product in Purchaser's possession, that is required for the manufacture of the Product by SWI (collectively "Manufacturing Technology"); provided that any such information is used solely for the purpose of manufacturing the Product in accordance with this Agreement. SWI acknowledges that such Manufacturing Technology is and shall remain the sole property of Purchaser and/or its Affiliates, and nothing herein shall be deemed to convey to SWI any right therein except as required for the purpose of manufacturing the Product in accordance with this Agreement. The steps, planning and obligations of the Parties regarding the transfer of the Manufacturing Technology for such Product are set forth in the technology transfer master plan attached in Exhibit D (the "Technology Transfer Master Plan"). Provided that Purchaser supply SWI with the needed amount of Compound at \*\*\* to SWI, SWI will manufacture the required number of Batches as outlined in the Technology Transfer Master Plan and a minimum of \*\*\* validation Batches of Product. Purchaser shall be responsible for any and all regulatory requirements with respect to the Product. SWI shall provide to Purchaser data required by Purchaser to qualify SWI's facility as per the Technology Transfer Master Plan.

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Upon request, Purchaser will provide SWI with, assistance or on-site support as may be reasonably required by SWI in connection with the transfer of the manufacturing technology. Such assistance will be provided \*\*\* for a number of days as set forth in the Technology Transfer Master Plan.

Purchaser shall support the one-time costs as described in the Technology Transfer Master Plan and purchase from SWI each validation Batch that meets the Specifications at the Price set forth in Exhibit B. If any of the validation Batches of a Product does not comply with the Specifications, Supplier shall have \*\*\* (\*\*\*) months to re-manufacture and deliver the number of validation Batch(es) that failed to meet the Specifications. If SWI is unable within that \*\*\* (\*\*\*)-month period to manufacture and deliver to Purchaser the validation Batch(es), Section 9.2 (c) shall apply. Purchaser will be reimbursed for \*\*\* any validation Batches that fail to meet the Specifications, in the event that such failure is due to SWI's mistake, negligence or failure to follow Purchaser's instructions.

In the event any validation batches fail to meet the Specifications for any other reason, except for Purchaser's mistake, negligence or failure to provide SWI with any portion of the Manufacturing Technology, SWI will \*\*\*.

**2.3 Supply of Compound.** Purchaser shall, \*\*\*, provide Supplier with adequate quantities of Compound necessary to manufacture the number of Batches set out in each Purchase Order at least \*\*\* prior to the Delivery date mentioned in each Purchase Order. SWI shall be responsible for the storage of the Compound while in its possession. The storage of the Compound by SWI shall comply with Applicable Laws and the specifications for the Compound.

In addition to the above, and at any time during the Term, upon the Parties mutual agreement, Purchaser shall make reasonable efforts to establish and maintain at SWI's facility, \*\*\*, an inventory of Compound corresponding to \*\*\* demand of Product as determined by mutual agreement of the parties. SWI shall not charge any storage fees for such inventory, and shall be responsible for any loss of such inventory.

SWI shall keep all Compound segregated from other materials within its reasonable control in order to maintain the integrity of the substance and shall not allow any samples of the substance to be used or tested by any person who is not under its direct supervisory control for any purposes. SWI shall perform only such tests and analysis as is necessary to meet its obligations under this Agreement and shall maintain the confidentiality of the results of such test in compliance with the terms of this Agreement.

#### **2.4 Prescribed Yield.**

(a) Generally. Based on the results of the \*\*\* of commercial Batches of the Product manufactured hereunder, the Parties shall mutually determine and specify an allowable range of quantities of Product to result from a specified quantity of Compound after having deducted the samples required for quality control and the samples to be retained by SWI (such range being

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hereinafter referred to as the “**Prescribed Yield**”) for the next Calendar Year. The parties shall reevaluate and, if necessary, re-determine the Prescribed Yield during each subsequent Calendar Year.

(b) **Shortfalls.** To the extent that all Batches of Product in the aggregate fall below the Prescribed Yield for the relevant Calendar Year and such event is not directly attributable to any information or improper materials supplied by Purchaser or any other acts or omissions by Purchaser (a “**Yield Shortfall**”), SWI shall reimburse Purchaser \*\*\*.

(c) **Excess.** To the extent that all Batches of Product in the aggregate exceed the Prescribed Yield for the relevant Calendar Year (a “**Yield Excess**”), the Parties shall \*\*\* resulting from such Yield Excess.

**2.5 Forecasts.** Purchaser shall submit to SWI, no later than the \*\*\* of the \*\*\* preceding the start of every \*\*\* during the Term, a rolling forecast (“Forecast”) setting forth an estimate of the total quantity of Product that Purchaser reasonably believes it will purchase during the \*\*\* commencing with the beginning of the subsequent \*\*\*, along with estimated shipment dates.

In addition, Purchaser shall submit to SWI for information purpose, on \*\*\* of each Calendar Year, a non-binding forecast setting forth an estimate of the \*\*\* quantity of Product that Purchaser reasonably believes it will purchase during the next \*\*\* (\*\*\*) Calendar Years.

**2.6 Purchase Orders.** Purchaser shall purchase Product by written purchase orders (“Purchase Orders”), submitted to SWI at least \*\*\* in advance of the desired shipment date specified therein. For each \*\*\*, Purchaser shall be required to submit Purchase Orders for at least \*\*\* percent (\*\*\*) of the quantities in the Forecast for such \*\*\* submitted by Purchaser to SWI \*\*\* prior to the start of such \*\*\* (the “Binding Forecast”), and SWI will have no obligation to supply Product in excess of \*\*\* percent (\*\*\*) of the quantity specified in such Binding Forecast. Each Purchase Order shall specify, at a minimum, the applicable volume of each dosage strength in full Batch increments and of each form of Product ordered, and the requested delivery date. Upon receipt of a Purchase Order, subject to the provisions of Section 2.1, SWI shall supply the Product in such quantities and deliver the Product to Purchaser (or Purchaser’s designee) on such delivery dates. SWI is not obligated to accept verbal orders of any kind for the supply of Product hereunder. To the extent there is any conflict or inconsistency between this Agreement and any Purchase Order, this Agreement shall govern.

The Parties agree that during \*\*\*, Purchaser will make its commercially reasonable efforts to respect the deadlines mentioned in this Section 2.6, but shall not be considered in breach in case such deadlines are not respected. SWI will make its commercially reasonable efforts to deliver the Product with the requested Delivery date but shall not be considered in breach in case of late delivery as long as the Product is delivered within the \*\*\* days period from the date Purchaser has placed its Purchase Order.

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**2.7 Initial Order.** Purchaser hereby submits a binding order for the \*\*\* validation Batches of Product as per the Technology Transfer Master Plan.

**2.8 Delivery and Shipping Terms.** Product shall be shipped FCA (Incoterms® 2010) SWI’s distribution site Croissy-Beaubourg - Z.I. Paris Est/18, rue des Vieilles Vignes/77435 Marne-la-Vallée CEDEX 2/France. Risk of loss of the Product shall pass to Purchaser at the time of delivery of the Product to the applicable Third Party shipper at the loading dock SWI’s distribution center, and Purchaser shall be responsible for obtaining such insurance as Purchaser deems necessary with respect to the shipment at Purchaser’s expense. Purchaser shall arrange for, and pay for, all shipping, freight, custom duties, and other charges associated with the shipment of the Product to Purchaser’s designated destination. Purchaser shall be responsible for obtaining any necessary export and/or import licenses, or other similar official authorizations, and for carrying out all customs formalities for the exportation and importation of the Product. SWI shall issue (or shall have its manufacturer issue) a certificate of analysis (“COA”) for shipment of Product sent to Purchaser.

**2.9 Packaging and Labeling.** SWI will supply Product to Purchaser in the form of bulk tablets. Purchaser shall be responsible, at its sole expense, for packaging and labeling the Product for commercial sale. SWI’s name will not appear on the label or anywhere else on the commercial packaging of the Product unless: (i) required by any Applicable Laws; or (ii) SWI consents in writing to the use of its name.

**2.10 Product Shortage.** If SWI becomes aware of any circumstances that may give rise to a Product Shortage for any Calendar Quarter, SWI shall provide Purchaser with prompt written notice thereof. In the event of a Product Shortage, without prejudice to any other remedy Purchaser may have under this Agreement, SWI shall be permitted to allocate the available Product among Purchaser and SANOFI, \*\*\* based on the volume of Product orders of Purchaser and such other licensees and distributors. The “volume of Product orders” will be calculated based on (a) orders for Product that were delivered during the preceding \*\*\* or that are then in transit (excluding in each case any orders where payment therefor is delinquent), and (b) the binding portion of any outstanding purchase orders or forecasts.

### **3. PRICE; PAYMENT**

**3.1 Prices for Product.** Purchaser shall pay to SWI the Price for the units of Product supplied to Purchaser pursuant to this Agreement.

**3.2 Payment.** SWI shall provide to Purchaser written invoices setting forth the amount payable by Purchaser with respect to quantities of Product sold hereunder, including the Price applied by SWI to each dosage strength of Product. Purchaser shall pay SWI for Product in the amount invoiced by SWI, without deduction, deferment, set-off, lien, or counterclaim of any nature, within \*\*\* (\*\*\*) days from the date of the invoice. All payments to be made by Purchaser to SWI under this Agreement represent net amounts SWI is entitled to receive. If such

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payments become subject to taxes, duties, assessments, or fees of any kind (other than as a result of such payments constituting net income of SWI or as a result of a tax on SWI's property), then such payments and related withholdings shall be increased to the extent necessary for SWI to receive the actual net amounts due under this Agreement.

#### 4. REPRESENTATIONS AND WARRANTIES

**4.1 Mutual Representations.** Each Party hereby represents, warrants, and covenants (as applicable) to the other Party as follows, as of the Effective Date:

(a) Corporate Existence and Power. It is a corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has all requisite power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement.

(b) Authority and Binding Agreement. It has the requisite power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; it has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and this Agreement has been duly executed and delivered on its behalf, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms, subject as to enforcement of remedies to applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting generally the enforcement of creditors' rights and subject to a court's discretionary authority with respect to the granting of a decree ordering specific performance or other equitable remedies.

(c) Consents. All necessary consents, approvals and authorizations of all governmental authorities and other Third Parties required to be obtained by it in connection with the execution, delivery and performance of this Agreement have been obtained by it.

(d) Representations regarding Debarment and Compliance.

(i) Each Party represents, warrants and covenants that as of the Effective Date and during the Term, neither it nor its Affiliates nor, to its knowledge based upon reasonable inquiry, any of their respective directors, officers, or employees:

(A) is debarred under Section 306(a) or 306(b) of the Act;

(B) has been charged with, or convicted of, any felony or misdemeanor under Applicable Laws related to any of the following: (1) the development or approval of any drug product or the regulation of any drug product under the Act; Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, Directive 2001/20/EC of the European Parliament and of the

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Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, the national laws of individual EU Member States implementing the provisions of these Directives into their national law, Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, or any similar Applicable Laws; (2) a conspiracy to commit, aid or abet the development or approval of any drug product or regulation of any drug product; (3) health care program-related crimes (involving Medicare or any state health care program); (4) patient abuse, controlled substances, bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records; (5) interference with, obstruction of an investigation into, or prosecution of, any criminal offense; or (6) a conspiracy to commit, aid or abet any of these listed felonies or misdemeanors; or

(C) are excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any United States federal or state health care programs (including convicted of a criminal offense that falls within the scope of 42 U.S.C. §1320a-7 but not yet excluded, debarred, suspended, or otherwise declared ineligible), or excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any United States federal procurement or non-procurement programs.

(ii) Each Party will notify the other Party promptly, but in no event later than \*\*\* days, after knowledge of any exclusion, debarment, suspension or other ineligibility set forth in Section 4.1(d)(i) occurring during the Term, or if such Party concludes based on its good faith business judgment that a pending action or investigation is likely to lead to the exclusion, debarment, suspension or other ineligibility of such Party.

(iii) Each Party will conduct itself and undertake the arrangements contemplated by this Agreement in a manner which is consistent with good business ethics and all applicable anti-bribery legislation (national and foreign), including but not limited to the OECD Convention dated 17<sup>th</sup> December 1997 on combating bribery of public officials in international business and the United States Foreign Corrupt Practices Act, as amended. Failure of a Party to comply with the provisions of this Article will be deemed a material breach of a material provision of this Agreement by the other Party.

#### **4.2 Product Warranties of SWI.**

(a) SWI warrants that at the time of shipment, the Product shall: (i) comply with the Specifications, and (ii) be manufactured in compliance with cGMP.

(b) The foregoing warranty shall not apply to damaged Product to the extent such damage is directly caused in whole or in part by Purchaser's breach of this Agreement or use,

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handling, or storage that is not in accordance with SWI's instructions or that constitutes improper treatment.

(c) SWI's obligations as provided in Section 10.1 and Section 6.2 shall be the sole and exclusive remedies available to Purchaser with respect to Product that fails to meet the product warranties set forth in Section 4.2(a).

**4.3 No Other Representations or Warranties.** EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 4, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF SWI. EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 4, ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

## 5. QUALITY

**5.1 General.** SWI shall be responsible for establishing and maintaining such procedures for implementing corrective and preventive actions with respect to the manufacturing of the Product as it deems necessary in compliance with Applicable Law. SWI shall cooperate with Purchaser at SWI's expense in determining the cause of any quality problems involving the Product, identifying corrective actions, and ensuring the implementation and effectiveness thereof. Upon Purchaser's request, SWI shall \*\*\* to \*\*\* with respect to the Product, and shall provide Purchaser with written confirmation upon the completion thereof.

**5.2 Notice of Failure to Meet Specifications.** SWI shall notify Purchaser promptly after the discovery that any lot of Product shipped to Purchaser, which had previously been approved in accordance with procedures set forth herein, fails to comply with its applicable Specifications. SWI will make, at its expense, such further internal investigation of any failure to meet the Specifications SWI deems appropriate under the circumstances and otherwise consistent with its obligations hereunder. Should such failure is determined to be a result of a defect in the Compound supplied by Purchaser from MTPC, then Purchaser shall (i) reimburse SWI the costs of such investigation, and the costs of destruction of the Product, if any, (ii) pay the Price of the Product which failed to meet the Specifications due to a defect in the Compound, and (iii) replace the quantity of Compound necessary to manufacture the replacement batch(es) of Product. In the event of a dispute in regards to a defect in the Compound, then Section 6.2(b) shall apply.

In the event of a dispute in regards to a defect in the Compound manufactured by Sanofi Chimie under the Commercial Supply Agreement signed on July 24<sup>th</sup>, 2013, then such agreement shall apply.

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### 5.3 Changes to Specifications.

(a) Changes Requested by Purchaser. SWI shall consider in good faith any reasonable requests by Purchaser to change the manufacturing process, Specifications, or any testing method with respect to the Product; provided, however that SWI shall in no event be obligated to implement any such change unless SWI, in its sole discretion, agrees to do so at Purchaser's costs.

(b) Changes Requested by SWI. SWI shall have the right, in its sole discretion, to change any procedures, Specifications, methods (including testing methods) or standard operating procedures relating to the manufacture or supply of the Product. Notwithstanding the foregoing, SWI shall not implement any such change that is (i) inconsistent with the then-current MAA or NDA for the Product or (ii) reasonably likely to have a material adverse effect on SWI's ability to comply with the terms of this Agreement, including any Product delivery timelines hereunder.

**5.4 Quality Agreement**. Within \*\*\* (\*\*\*) days following execution of this Agreement, the Parties will enter into a quality agreement governing the agreed-upon Specifications and other technical aspects of supply of Products to Purchaser hereunder (the "**Quality Agreement**"). In the event of any inconsistency between this Agreement and the Quality Agreement, this Agreement shall control.

## 6. ACCEPTANCE AND REJECTION PROCEDURES

**6.1 Inspection**. Purchaser or its designee shall promptly, upon arrival on its site, carefully inspect each shipment of Product for transport damages, losses and shortfalls. Apparent defects like for instance damaged containers or missing packages of Product have to be notified to the carrier promptly upon arrival of the shipment and the freight documents at Purchaser or its designee and, where possible, countersigned by the carrier's representative. Failure of Purchaser or its designee to notify such visually detectable defects to the carrier promptly upon arrival of the concerned shipment and freight documents shall exclude any liability of SWI for such defects.

Purchaser or its designee shall have \*\*\* (\*\*\*) days after receipt of a shipment of Product to determine if such Product complies with the warranties set forth in Section 4.2(a) (the "Inspection Period"). Purchaser shall notify SWI of any such non-compliance prior to the end of the Inspection Period, describing in detail the non-compliance. Notwithstanding the preceding provisions of this Section 6.1, if with respect to any unexpired Product, the non-compliance could not reasonably be expected to have been found by diligent and adequate inspection during the Inspection Period and Purchaser notifies SWI of such non-compliance, describing the Latent Defect in detail, within \*\*\* (\*\*\*) days of the discovery of the Latent Defect and within the shelf life of the Product, such non-compliance shall be deemed to be a "Latent Defect" hereunder. Purchaser's notification of SWI of a Defect during the Inspection Period or of a Latent Defect in the period permitted above shall be referred to herein as a "Claim." Purchaser shall be deemed to have accepted any Product if it fails to give a Claim in the periods permitted above.

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**6.2 Remedies.** Except for Claims disputed pursuant to Section 6.2(b) hereof, if Purchaser submits a Claim, then as promptly as practicable after the submission of the Claim to SWI, SWI shall instruct Purchaser whether to return or destroy the Product in question and provide Purchaser with replacement Product. In the event that:

(a) SWI agrees with the Claim, then SWI shall pay for all out-of-pocket costs of returning or destroying Product that is the subject of any accepted Claim. SWI shall bear the risk of loss for such Product, beginning at such time as they are taken at Purchaser's premises for return delivery.

(b) SWI does not agree with the Claim, then the Parties agree to submit the Product in question to a mutually agreed independent Third Party that has the capability of testing the Product to determine whether or not it complies with the Specifications. The losing Party shall bear all costs and expenses related to such testing and pay for all shipping costs of returning the Product and/or sending the replacement Product, as the case may be.

## **7. RECALLS**

In the event a recall of the Product is required by a governmental agency or authority of competent jurisdiction or by Applicable Law, or if a recall of the Product is jointly deemed advisable by the Parties, or deemed advisable solely by Purchaser, such recall shall be promptly implemented and administered by Purchaser at Purchaser's costs in a manner which is appropriate and reasonable under the circumstances and in conformity with accepted trade practices.

Should it be duly evidenced by Purchaser that the recall of the Product results from a manufacturing defect (i.e. non conformance to the warranties set forth in Section 4.2(a)), SWI shall be solely responsible for replacement of such recalled Product according to Section 6.2 above, it being understood that any dispute regarding the existence of a such a defect shall be handled according to the provisions of Section 6.2(b).

## **8. RECORD-KEEPING; INSPECTION; AUDIT**

**8.1 Recordkeeping.** SWI will keep records of the manufacture and testing of the Product, and retain samples of Product sold hereunder as are necessary to comply with Applicable Laws, as well as to assist with resolving Product complaints and other similar investigations. Copies of the records and samples will be retained for a period of \*\*\* following the date of Product expiry, or longer if required by Applicable Laws. Purchaser is responsible for retaining samples of the Product necessary to comply with the legal/regulatory requirements applicable to Purchaser.

**8.2 Audits.** From and after the commencement of supply hereunder and through Purchaser's personnel or through an independent auditor reasonably acceptable to SWI, Purchaser shall have the right, upon reasonable advance notice and during regular business hours, to cause an inspection and audit of the facilities being used by SWI for the production of Product

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by Purchaser's personnel or an independent Third Party auditor to assure compliance by SWI with cGMPs .

**8.3 Procedure.** The inspection and audit provided for under Section 8.2 shall not be carried out by Purchaser more than \*\*\* per \*\*\* over \*\*\*. Each inspection and audit shall be conducted in a manner so as to minimize disruption of the business operations of SWI. The independent auditor shall enter into a written confidentiality agreement with SWI containing provisions regarding the disclosure of information obtained during the inspection and audit that are at least as restrictive as the provisions of Section 13 of this Agreement; provided that, the independent auditor will be permitted to disclose to Purchaser whether and to what extent SWI failed to comply with the requirements of Section 8.1 (and shall not be permitted to disclose to Purchaser any other information). A copy of any such disclosure to Purchaser shall also be provided to SWI.

**8.4 Results.** If an inspection or audit reveals a failure to comply with cGMP in all material respects, then Purchaser shall promptly provide to SWI written notice of such fact, which notice shall contain in reasonable detail the deficiencies found in the applicable facilities and, if practicable, those steps Purchaser believes should be undertaken in order to remedy such deficiencies. The Parties shall discuss in good faith the proposed deficiencies and, to the extent there is agreement on the proposed deficiencies, SWI shall use reasonable efforts to remedy such deficiencies, or implement a plan to remedy such deficiencies, as soon as reasonably practical following receipt of the notification thereof.

## **9. TERM; TERMINATION**

**9.1 Term.** The term of this Agreement (the "Term") will commence on the Effective Date and, unless earlier terminated pursuant to this Article 9, shall remain in full force and effect for a period of five (5) years after the date of the first commercial sale. Thereafter, it shall be automatically renewed for successive period of two (2) years, unless SWI provides notice of desire not to renew \*\*\* in advance of end of the current term or Purchaser provides \*\*\* notice.

### **9.2 Termination**

(a) Termination for Default. Either Party may terminate the Agreement without prejudice to any claim for damages, if the other Party commits a material breach and fails to remedy such material breach within \*\*\* (\*\*\*) calendar days of receipt of a registered letter with return receipt requested, specifying the breach. The termination will become effective on the date of first presentation of a second registered letter with return receipt requested, notifying the decision of termination.

(b) Termination for bankruptcy or Force Majeure. Either Party may immediately terminate the Agreement, by registered letter with return receipt requested in case (i) the other Party is declared insolvent or bankrupt by a court of competent jurisdiction, or a voluntary petition in bankruptcy is filed in any court of competent jurisdiction, or the other Party makes or

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executes any assignment for the benefit of creditor, in accordance with the Applicable Laws; or (ii) a force majeure event occurs and persists over \*\*\* (\*\*\*) calendar days, according to the provisions of Section 16.3 hereof.

(c) Termination for validation failure. The Parties may mutually agree to terminate the Agreement by registered letter with return receipt requested, in case SWI is unable to manufacture and deliver the required number of validation batches meeting the Specifications within the time period specified in the Technology Transfer Master Plan, or if registration of SWI as Product manufacturer and supplier fails.

**9.3 Effects of Termination.** Upon expiration or termination of this Agreement, SWI shall manufacture and supply, and Purchaser shall purchase from SWI (a) any and all quantities of Product ordered by Purchaser pursuant to this Agreement prior to the date on which such notice is given, for the applicable Price, and (b) any and all excipients and materials held by SWI specifically for use in the manufacture of the Product based on Forecasts provided by Purchaser. Termination or expiration of this Agreement will not affect any outstanding obligations due hereunder prior to the termination or expiration.

**9.4 Survival.** Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to the effective date of such expiration or termination. The following sections shall survive termination or expiration of this Agreement for any reason: Sections 9, 10, 11, 13, 14, 15, 16.4, 16.6, 16.7, and 16.8.

## **10. INDEMNIFICATION**

**10.1 Indemnification by SWI.** SWI agrees to defend and indemnify and hold Purchaser, its Affiliates, and their respective directors, officers and employees (the “**Purchaser Indemnified Parties**”) harmless against any and all Third Party claims, suits or proceedings, and all associated expenses, recoveries and damages, including court costs and reasonable attorneys’ fees and expenses, arising out of, based on, or caused by the breach by SWI of any representation, warranty, or covenant contained in this Agreement, except in each case to the extent that such claims, suits, proceedings, expenses, recoveries or damages arise from the breach by Purchaser of any representation, warranty, or covenant contained in this Agreement or any negligence or willful misconduct by a Purchaser Indemnified Party.

**10.2 Indemnification by Purchaser.** Purchaser agrees to defend and indemnify and hold SWI, its Affiliates, and their respective directors, officers and employees (the “**SWI Indemnified Parties**”) harmless against any and all Third Party claims, suits, proceedings, and all associated expenses, recoveries, and damages including court costs and reasonable attorneys’ fees and expenses, arising out of, based on, or caused by (i) the storage, sale, shipment, promotion or distribution of the Product by Purchaser or its licensees, or (ii) the breach by Purchaser of any representation or warranty or covenant contained in this Agreement, except in each case to the extent that such claims, suits, proceedings, expenses, recoveries or damages arise from the breach by SWI of any representation or warranty or covenant contained in this

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Agreement or any negligence or willful misconduct by a SWI Indemnified Party.

**10.3 Indemnification Procedures.** The Party claiming indemnity under this Article 10 (the “ **Indemnified Party** ”) shall give written notice to the Party from whom indemnity is being sought (the “ **Indemnifying Party** ”) as soon as reasonably practicable after learning of a written claim (“ **Indemnified Claim** ”). Failure by an Indemnified Party to give notice of an Indemnified Claim as soon as reasonably practicable after receiving a writing reflecting such Claim shall not relieve the Indemnifying Party of its indemnification obligations hereunder except and solely to the extent that such Indemnifying Party is actually prejudiced as a result of such failure to give such notice. The indemnifying Party shall have the right to assume the conduct and defense of the Indemnified Claim with counsel of its choice; provided that, the Indemnifying Party shall not have the right to assume any Indemnified Claim if (i) the Indemnifying Party fails to provide reasonable evidence of its ability and willingness to satisfy such claim, or (ii) such claim involves criminal or regulatory enforcement action. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance in connection with the defense of the Indemnified Claim. The Indemnified Party may monitor such defense with counsel of its own choosing at its sole expense. The Indemnifying Party may not settle the Indemnified Claim without the prior written consent of the Indemnified Party, unless such settlement provides an unconditional and full release of the Indemnified Party; such consent shall not be unreasonably withheld, delayed or conditioned. If the Indemnifying Party does not assume and conduct the defense of the Indemnified Claim as provided above: (a) the Indemnified Party may assume and conduct the defense of the Indemnified claim at the Indemnifying Party’s expense; (b) the Indemnified Party may consent to the entry of any judgment or enter into any settlement with respect to the Indemnified Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith); and (c) the Indemnifying Party will remain responsible to indemnify the Indemnified Party for Indemnified Claims as provided in this Article 10.

## **11. LIMITATION OF LIABILITY**

(a) Liability for non-conforming Product. The liability of SWI for any delivery of Product not compliant with the Specifications and the related Quality Agreement (hereinafter the “Non-Conforming Product”) shall be limited toward Purchaser to, at Purchaser’s election, the replacement of the Non-Conforming Product as soon as technically possible, at no additional cost for Purchaser, or the reimbursement of Purchaser for the Non-Conforming Product, including reimbursement for the Compound used in producing the Non-Conforming Product.

(b) NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY EXEMPLARY, SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES, COSTS OR EXPENSES (INCLUDING LOST PROFITS, LOST REVENUES AND/OR LOST SAVINGS) ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTHING IN THE PRECEDING SENTENCE IS INTENDED TO OR SHALL

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LIMIT OR RESTRICT (A) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY IN CONNECTION WITH THIRD PARTY CLAIMS UNDER SECTION 10.1 OR 10.2, (B) DAMAGES OR INJUNCTIVE RELIEF AVAILABLE FOR A PARTY'S BREACH OF ARTICLE 13, (C) DAMAGES TO THE EXTENT ARISING FROM OR RELATING TO WILLFUL MISCONDUCT OR FRAUDULENT ACTS OR OMISSIONS OF A PARTY. IN NO EVENT SHALL SWI'S AGGREGATE LIABILITY ARISING OUT OF OR RELATING TO THIS AGREEMENT UNDER ANY THEORY OF LIABILITY (WHETHER IN CONTRACT, TORT, STATUTORY OR OTHERWISE) EXCEED, ON A CUMULATIVE BASIS, THE LESSER OF THE TOTAL AMOUNT INVOICED BY SWI TO PURCHASER HEREUNDER DURING \*\*\* OR \*\*\* EUROS (EUR. \*\*\*), EXCEPT IN CASES OF GROSS NEGLIGENCE OR WILLFUL MISCONDUCT.

(c) *Allocation of Risks*. The limitation of liability set forth in this Article 11 reflects a deliberate and bargained for allocation of risks between Purchaser and SWI and is intended to be independent of any exclusive remedies available under this Agreement, including any failure of such remedies to achieve their essential purpose.

(d) *Essential Part of the Bargain*. The Parties acknowledge that the limitations of liability set forth in this Article 11 are an essential element of this Agreement between the Parties and that the Parties would not have entered into this Agreement without such limitations of liability.

(e) *Duty to Mitigate*. Each Party shall use reasonable efforts to mitigate any damages incurred by such Party hereunder.

## 12. INSURANCE

Each Party shall procure and maintain insurance or self-insure during the Term of this Agreement, adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situated. Such insurance shall be written by insurance companies of good international reputation.

It is understood that the insurance requirements above shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under Article 10. Each Party shall provide the other Party with written evidence of such insurance upon request.

## 13. CONFIDENTIALITY; PROPRIETARY RIGHTS

**13.1 Confidentiality.** Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each Party agrees that, for the Term and for \*\*\* (\*\*\*) years thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement any Confidential Information of the other Party except for that portion of such information or materials that the receiving Party can demonstrate by competent proof:

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(a) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure by the other Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) is subsequently disclosed to the receiving Party or its Affiliate by a Third Party without obligations of confidentiality with respect thereto; or

(e) is subsequently independently discovered or developed by the receiving Party or its Affiliate without the aid, application, or use of Confidential Information.

Notwithstanding the foregoing, the receiving Party may disclose without violation of this Agreement such portion of the Confidential Information as is required or permitted to be disclosed if, on the advice of counsel, it is required under Applicable Law or pursuant to legal process to disclose such Confidential Information of the other Party; provided that unless otherwise prohibited by Applicable Law, the receiving Party first advises the disclosing Party of such intended disclosure and provides the disclosing Party with the opportunity to seek appropriate judicial or administrative relief to avoid, or obtain confidential treatment of, such disclosure at the disclosing Party's sole cost and expense.

**13.2 Authorized Disclosures.** Each Party may disclose Confidential Information belonging to the other Party to the extent such Party determines such disclosure is reasonably necessary in the following situations:

(a) prosecuting or defending litigation relating to this Agreement;

(b) in the case of Purchaser as the receiving Party, disclosure to MTPC as required pursuant to the MTPC Agreement;

(c) in the case of Purchaser as the receiving Party, disclosure to its licensees, sublicensees, and collaborators with respect to the Product, but solely to the extent that such Confidential Information (i) raises any material concerns regarding the safety or efficacy of the Product; (ii) indicates or suggests a potential material liability of either Purchaser or the applicable licensee, sublicensee, or collaborator to Third Parties in connection with the Product; (iii) is reasonably likely to lead to a recall or market withdrawal of the Product; or (iv) relates to any Product and is reasonably likely to have a material impact on a Regulatory Approval of the Product in such licensee's, sublicensee's, or collaborator's territory; provided that each disclosee must be bound by obligations of confidentiality and non-use no less stringent than those set forth in Section 13.1 and this Section 13.2 prior to any such disclosure (it being understood that

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receiving Party shall be liable for any breach of such confidentiality and non-use obligations by any such disclosee) and further provided that Purchaser shall cause any of its licensees to commit to the same obligations and shall disclose to SWI any confidential information received from any licensee in order to enable SWI, its Affiliates and licensees to address adequately the situations set forth in the sub-sections (i) to (iv) of this Section 13.2 (c).

(d) disclosure to its and its Affiliates' respective directors, officers, employees, consultants, attorneys, professional advisors, lenders, insurers, sublicensees, suppliers, and distributors only on a need-to-know basis and solely as necessary in connection with this Agreement; provided that each disclosee must be bound by obligations of confidentiality and non-use no less stringent than those set forth in Section 13.1 and this Section 13.2 prior to any such disclosure (it being understood that receiving Party shall be liable for any breach of such confidentiality and non-use obligations by any such disclosee); and

(e) disclosure to any bona fide potential or actual investor, acquirer, merger partner, or other potential or actual financial partner (and/or their respective consultants, attorneys, and professional advisors) on a need-to-know basis and solely for the purpose of evaluating a potential investment, acquisition, merger, or similar transaction; provided that each disclosee must be bound by obligations of confidentiality and non-use no less stringent than those set forth in Section 13.1 and this Section 13.2 prior to any such disclosure (it being understood that the receiving Party shall be liable for any breach of such confidentiality and non-use obligations by any such disclosee).

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13.3 **Intellectual Property.** SWI expressly agrees that all Purchaser's Background Technology is and shall remain the sole property of Purchaser, and, nothing herein contained shall be deemed to convey to SWI any right, including a property right, relating to any Purchaser's Background Technology, nor to grant SWI any right in and to Purchaser's patents and patent applications, know-how, patterns or trademarks relating to the Products, in any country, during the term of this Agreement or at any time thereafter, except as otherwise provided for hereunder for the purpose of this Agreement.

Purchaser expressly agrees that, all SWI's Background Technology is and shall remain the sole property of SWI and/or its Affiliates, and, nothing herein contained shall be deemed to transfer to Purchaser any right, including property rights, under any SWI's Background Technology, nor to grant Purchaser any right in and to SWI's patents and patent applications, know-how, patterns or trademarks relating to SWI's and/or its Affiliates' equipment or know-how together with related developments in any country, during the term of this Agreement or at any time thereafter, except as otherwise provided for hereunder for the purpose of this Agreement.

Each Party agrees to have its know-how as of the Effective Date archived in such a way as to provide reliable evidence as to their content on the Effective Date and that such archives shall be made available to an independent expert mutually appointed by both Parties as may be required in case of disagreement between the Parties as to the extent of know-how that is effectively developed after the Effective Date pursuant to this Agreement.

13.4 **Non-Severable Improvements / Severable Improvements.**

(a) Subject to Section 13.5, the Parties hereto acknowledge and agree that the Non-Severable Improvements shall be and remain at all times, both during and after the expiry or termination date of this Agreement, the exclusive property of Purchaser, which may file in its sole name and at its sole expenses, any and all patents and/or any and all intellectual property rights claiming all or part of such Non-Severable Improvements.

SWI agrees to execute, and cause its Affiliates to execute, all documents and to take all actions necessary or advisable to assign and transfer the Non-Severable Improvements to Purchaser and, upon Purchaser's request, to assist Purchaser, at Purchaser's reasonable costs and expenses, in obtaining patent protection or other forms of protection for the Non-Severable Improvements.

(b) The Parties hereto acknowledge and agree that Severable Improvements shall be and remain at all times, both during and after the expiry or termination date of this Agreement, the exclusive property of SWI and/or its Affiliates which may file in its own name and sole expenses, any and all patents and/or any and all intellectual property rights claiming all or part of the Severable Improvements.

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13.5 SWI shall grant and hereby grants to Purchaser a non-exclusive and worldwide license, with right to grant sublicense, in and to such (i) SWI and/or its Affiliates' Background Technology and (ii) Severable Improvements, which SWI incorporates in the manufacture of Products or which is necessary to the manufacture of Products for the sole and limited purpose of use and sale of Products by or on behalf of Purchaser or its Commercialization Partners.

Such license shall be \*\*\* during the Term of this Agreement. Upon expiration or termination of this Agreement, the above license shall be granted on a royalty-bearing basis to be negotiated in good faith.

In the case of any sub-license in and to such SWI and/or its Affiliates Background Technology and Severable Improvements, if any, Purchaser (a) shall include a provision in all sublicense agreements with Commercialization Partners for the use or sale of Products that clearly states that such sublicensee's rights to the use of said Background Technology and/or any Severable Improvements is exclusively limited to the sole purpose of using and/or selling the Products and (b) shall be responsible for ensuring that its sublicensee right to use said Background Technology and/or any Severable Improvements are terminated in case of breach by sublicensees.

In the event Purchaser becomes aware of any suspected infringement of any sublicensed Background Technology and/or Severable Improvements, Purchaser shall promptly notify SWI and provide it with all details of such infringement of which it is aware.

Purchaser shall assist and cooperate with SWI as the latter may reasonably request from time to time, including by providing access to relevant documents and other evidence and making its employees available at reasonable business hours; provided that Purchaser shall not be required to disclose legally privileged information unless and until procedures reasonably acceptable to Purchaser are in place to protect such privilege.

13.6 For the sole purpose of performing its obligations hereunder, Purchaser hereby grants to SWI and/or its Affiliates a royalty-free, non-exclusive license, to use, subject to the terms of this Agreement, any and all Purchaser's Background Technology, Information, and Non-Severable Improvements and such relevant information relating to the Products, in order for SWI to manufacture the Product. Such licensed rights shall only be used by SWI and its Affiliated Companies, in the name and on behalf of SWI solely for the purpose of this Agreement.

#### **14. DISPUTE RESOLUTION**

**14.1 Disputes.** The Parties recognize that disputes as to certain matters may from time to time arise during the Term which relate to either Party's rights and/or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to meet and discuss in good faith any disputes, controversies or differences which may arise between the Parties out of or in relation to or in connection with this Agreement, including any alleged failure to perform, or breach, of this

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Agreement, or any issue relating to the interpretation or application of this Agreement. Such good faith efforts shall include at least one in-person meeting between the executive officers of each Party. If the matter is not resolved within \*\*\* (\*\*\*) days following the request for discussions, either Party may then invoke the provisions of Section 14.2.

#### **14.2 Arbitration.**

(a) Claims. Subject to Section 14.3 below, any claim, dispute, or controversy of whatever nature arising out of or relating to this Agreement that is not resolved under Section 14.1 within the required \*\*\* (\*\*\*) day period, including, without limitation, any claim concerning the interpretation, effect, termination, validity, performance and/or breach of this Agreement shall be resolved by final and binding arbitration administered by the International Chamber of Commerce (“ICC”). The arbitration and all associated discovery proceedings and communications shall be conducted in English, and the arbitration shall be held in New York, New York, USA.

(b) English Language. All proceedings shall be held in English and a transcribed record prepared in English. Documents submitted in the arbitration (the originals of which are not in English) shall be submitted together with a reasonably complete and accurate English translation.

(c) Selection of Arbitrators. The Parties shall each choose one arbitrator within \*\*\* (\*\*\*) days of receipt of notice of the intent to arbitrate and the said two arbitrators shall select by mutual agreement a third arbitrator within \*\*\* (\*\*\*) days after they have been selected as arbitrators. If no arbitrator is appointed within the times herein provided or any extension of time that is mutually agreed on, the ICC shall make such appointment (i.e. shall appoint three arbitrators) within \*\*\* (\*\*\*) days of such failure.

(d) Arbitrators’ Award. The arbitrators’ award shall include a written statement describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The arbitrators shall, in rendering their decision, apply the substantive laws of the State of New York, without giving effect to its conflicts of laws principles. The arbitrators’ authority to award special, incidental, consequential or punitive damages shall be subject to the limitation set forth in Article 11. The award rendered by the arbitrators shall be final, binding and non-appealable, and judgment may be entered upon it in any court of competent jurisdiction.

(e) Costs. Each Party shall bear its own attorney’s fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the arbitrators; provided, however, the arbitrators shall be authorized to determine whether a Party is the prevailing party, and if so, to award to that prevailing party reimbursement for any or all of its reasonable attorneys’ fees, costs and disbursements (including, for example, expert witness fees and expenses, photocopy charges, travel expenses, etc.), and/or the fees and costs of the ICC and the arbitrators.

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**14.3 Court Actions.** Nothing contained in this Agreement shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, including but not limited to a breach or threatened breach of any confidentiality provision herein, and such an action may be filed and maintained notwithstanding any ongoing discussions between the Parties or any ongoing arbitration proceeding. In addition, either Party may bring an action in any court of competent jurisdiction to resolve disputes pertaining to the validity, construction, scope, enforceability, infringement or other violations of patents or other intellectual property rights, and no such claim shall be subject to arbitration pursuant to Section 14.2.

**15. PRESS RELEASES; USE OF NAMES**

**15.1 Press Releases.** The form and content of any public announcement to be made by one Party regarding this Agreement, or the subject matter contained herein, shall be subject to the prior written consent of the other Party (which consent shall not be unreasonably withheld, conditioned, or delayed), except as may be required by applicable law in which event the Party required to make such announcement shall, to the extent possible, provide to the other Party a written copy of any such required announcement at least \*\*\* (\*\*\*) business days prior to disclosure to give the other Party reasonable advance notice and review of any such announcement. Notwithstanding the foregoing, either Party may publicly disclose without violation of this Agreement, such terms of this Agreement as are, on the advice of such Party's counsel, required by the rules and regulations of the SEC or any other applicable entity having regulatory authority over such Party's securities; provided that such Party shall advise Purchaser of such intended disclosures and requests confidential treatment of certain commercial terms and technical terms hereof to the extent such confidential treatment is reasonably available to such Party. In the event of any such filing, such Party will provide the other Party, a reasonable time prior to filing, with a copy of the Agreement marked to show provisions for which such Party intends to seek confidential treatment and shall reasonably consider and incorporate the other Party's comments thereon to the extent consistent with the legal requirements applicable to such Party and that govern redaction of information from material agreements that must be publicly filed. The other Party shall provide any such comments as promptly as practicable.

**15.2 Use of Names.** Except as otherwise required by law or by the terms of this Agreement or as mutually agreed upon by the Parties, neither Party shall make any use of the name of the other Party in any advertising or promotional material, or otherwise, without the prior written consent of the other Party, which consent shall not be unreasonably withheld.

**16. MISCELLANEOUS**

**16.1 Entire Agreement; Amendment.** This Agreement, including the Exhibits hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior

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agreements and understandings between the Parties with respect to the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

Notwithstanding the foregoing, any prior Confidentiality Agreement between the Parties remains in full force and effect.

**16.2 Relationship of the Parties.** The relationship between SWI and Purchaser is that of independent contractors and nothing herein shall be deemed to constitute the relationship of partners, joint venturers, or principal and agent between SWI and Purchaser. Neither Party shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement, or undertaking with any Third Party.

**16.3 Force Majeure.** Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall include conditions beyond the control of the Parties, including an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, and failure of plant or machinery (provided that such failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances). Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a force majeure affecting such Party.

**16.4 Notices.** Any notice required or permitted to be given under this Agreement shall be deemed to have been sufficiently given if mailed by registered mail, postage prepaid, or sent by fax or electronic mail, addressed to the Party to be notified, at its address stated in this Agreement or at such other address as may hereafter be provided in an Amendment (or in any other document exchanged between the Parties) and shall be deemed to have been served \*\*\* after mailing in the case of mail, and \*\*\* after dispatch in the case of fax or electronic mail.

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If to Purchaser: VIVUS, Inc.  
351 E. Evelyn Ave.  
Mountain View, CA 94041  
Attention: General Counsel

With a copy to: Hogan Lovells US LLP  
525 University Avenue  
3rd Floor  
Palo Alto, CA 94301  
Attention: Shane Albright, Partner  
Fax: (650) 463-4199

If to SWI: SANOFI WINTHROP INDUSTRIE  
CEPiA US Manager  
55 Corporate Dr.  
Bridgewater, NJ 08807

With a copy to: SANOFI WINTHROP INDUSTRIE  
Industrial Affairs Legal Department  
20, avenue Raymond Aron,  
92165 ANTONY Cedex — FRANCE  
Fax: +33 1 55 71 61 31

**16.5 No Strict Construction; Headings; Interpretation.** This Agreement has been prepared jointly and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section. The definitions of the terms herein apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun will include the corresponding masculine, feminine and neuter forms. The words “include”, “includes” and “including” will be deemed to be followed by the phrase “without limitation.” Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (b) any reference to any laws herein will be construed as referring to such laws and any rules or regulations promulgated thereunder as from time to time enacted, repealed or amended, (c) any reference herein to any person will be construed to include the person’s successors and assigns, (d) the words “herein”, “hereof” and “hereunder”, and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (e) any reference herein to the words

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“mutually agree” or “mutual written agreement” will not impose any obligation on either Party to agree to any terms relating thereto or to engage in discussions relating to such terms except as such Party may determine in such Party’s sole discretion, except as expressly provided in this Agreement, (f) as applied to a Party, the word “will” shall be construed to have the same meaning and effect as the word “shall,” and (g) all references herein without a reference to any other agreement to Articles, Sections, or Exhibits will be construed to refer to Articles, Sections, and Exhibits of or to this Agreement.

**16.6 Assignment.** Neither Party may subcontract, assign, extend or transfer any of its rights and obligations under this Agreement, without the express and prior written consent of the other Party, such consent not to be unreasonably withheld. Notwithstanding the foregoing, SWI may subcontract, transfer or assign its rights and obligations under this Agreement to its Affiliates and/or any third party acquiring the manufacturing site, and that Purchaser may transfer or assign its rights and obligations under this Agreement, in whole or in part, to its Affiliates and/or its Commercialization Partners.

No assignment nor transfer of this Agreement or of any rights hereunder shall relieve the assigning Party of any of its obligations and liability hereunder, unless the assignee undertakes in writing to, and can reasonably, assume such obligations and liabilities. Any assignment or attempted assignment in violation of the terms of this Section 16.6 shall be null, void and of no legal effect.

**16.7 Governing Law.** Resolution of all disputes arising out of or related to this Agreement or the validity, construction, interpretation, enforcement, breach, performance, application or termination of this Agreement and any remedies relating thereto, shall be governed by and construed under the substantive laws of the State of New York, United States of America, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

**16.8 Successors and Assigns; No Third Party Beneficiaries.** This Agreement will be binding upon and inure to the benefit of the Parties and their successors and permitted assigns. No provision of this Agreement, express or implied, is intended to or will be deemed to confer upon Third Parties any right, benefit, remedy, claim, liability, reimbursement, claim of action or other right of any nature whatsoever under or by reason of this Agreement other than the Parties and, to the extent provided in Sections 10.1 and 10.2, the Indemnified Parties. Without limitation of the foregoing, this Agreement will not be construed so as to grant employees of either Party in any country any rights against the other Party pursuant to the laws of such country.

**16.9 Severability.** If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

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**16.10 No waiver.** Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

**16.11 Performance by Affiliates and/or Subcontractors.** Any obligation of SWI under or pursuant to this Agreement may be satisfied, met or fulfilled, in whole or in part, at SWI's sole and exclusive option, either by SWI directly or by any Affiliate or any third party acquiring the manufacturing site that SWI causes to satisfy, meet or fulfill such obligation, in whole or in part. Any obligation of Purchaser under or pursuant to this Agreement may be satisfied, met or fulfilled, in whole or in part, at Purchaser's sole and exclusive option, either by Purchaser directly or by any Affiliate of Purchaser that Purchaser causes to satisfy, meet or fulfill such obligation, in whole or in part. Each of the Parties guarantees the performance of all actions, agreements and obligations to be performed by any Affiliates of such Party under the terms and conditions of this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate .

**16.12 Counterparts.** This Agreement may be executed in one (1) or more counterparts, including by facsimile or other electronic transmission, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

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IN WITNESS WHEREOF, the Parties have caused this Agreement to be duly executed as of the date first above written.

**SANOFI WINTHROP INDUSTRIE**

By: /s/ Jacques Tavernier  
Name: Jacques Tavernier  
Title: VP CEPiA  
Date: November 18, 2013

By: /s/ Alain Davidou  
Name: Alain Davidou  
Title: Director Business Development & Service, CEPiA  
Date: November 18, 2013

**VIVUS, Inc.**

By: /s/ Timothy E. Morris  
Name: Timothy E. Morris  
Title: SVP Finance, Chief Financial Officer  
Date: October 24, 2013

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**EXHIBIT A**

**Specifications**

**Release Specifications for Avanafil Tablets**

\*\*\*

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**EXHIBIT B**

**Prices**

The Price for each dosage form of the Product is as follows:

<b>Dosage forms</b>	<b>Fixed Manufacturing Cost (per tablet)</b>
***	***
***	***
***	***

As from January 1st, 2014 for the first time, and thereafter on a \*\*\* basis, the purchase price defined above shall be reviewed according to the latest available \*\*\*.

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**EXHIBIT C**

**Quality Agreement**

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**EXHIBIT D**

**Transfer Master Plan**

\*\*\*

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## EXHIBIT E

### Sanofi Territory

#### Africa :

Egypt  
Sudan  
Algeria  
Morocco  
South Africa  
Tunisia  
Libya  
Burkina Faso  
Gambia  
Guinea  
Mali  
Mauritania  
Sao Tome  
Senegal  
Benin  
Ivory Coast  
Togo  
Niger  
Tchad  
Kenya  
Mauritius  
Ethiopia  
Uganda  
Tanzania  
Eritrea  
Somalia  
Seychelles Island  
Burundi  
Rwanda  
Cameroon  
Gabon  
Congo  
Madagascar  
Democratic Republic of Congo  
Djibouti  
Central African Republic

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Islamic Republic of Comoros  
Republic of Equatorial Guinea  
Nigeria  
Ghana  
Liberia  
Sierra Leone  
Angola  
Mozambique  
Zambia  
Zimbabwe  
Malawi  
Botswana  
Namibia

**Middle East — Turkey :**

Turkey  
Saudi Arabia  
Yemen  
Qatar  
Bahrain  
United Arab Emirates  
Oman  
Kuwait  
Lebanon  
Syria  
Jordan  
Palestine  
Iraq  
Iran  
Israel

**Eurasia :**

Azerbaijan  
Kazakhstan  
Kirghizstan  
Uzbekistan  
Georgia  
Armenia  
Russia  
Ukraine  
Byelorussia

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PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

**EXHIBIT F**

**Batch size**

<b>Dosage form</b>		<b>Batch size: ***</b>
	***	***
	***	***
	***	***

\*\*\*

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**LICENSE AND COMMERCIALIZATION AGREEMENT**

**by and between**

**VIVUS, INC.**

**and**

**SANOFI**

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## LICENSE AND COMMERCIALIZATION AGREEMENT

**THIS LICENSE AND COMMERCIALIZATION AGREEMENT** (the “**Agreement**”) is entered into as of the 11th day of December, 2013 (the “**Effective Date**”) by and between Vivus, Inc., a corporation with its principal office at 351 E. Evelyn Avenue, California, 94041, United States of America (referred to herein as “**Vivus**”), and **Sanofi**, a French corporation having a place of business at 54 rue la Boétie, 75008, Paris, France (referred to herein as “**Sanofi**”). Vivus and Sanofi are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**”.

### RECITALS

Vivus owns or has a license to certain patent rights and other intellectual property rights relating to a therapeutic drug known as avanafil.

Vivus has received regulatory approval for avanafil in the United States for the treatment of male erectile dysfunction (under the trade name Stendra™) and has filed for European regulatory approval for avanafil for the same indication (under the trade name Spedra™).

Vivus desires to grant to Sanofi, and Sanofi desires to receive, an exclusive license for the development, manufacture and commercialization of avanafil in the Field (as hereinafter defined) in certain territories as defined herein.

**NOW THEREFORE**, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties agree as follows:

### ARTICLE 1 DEFINITIONS

As used in this Agreement, the following initially capitalized terms, whether used in the singular or plural form, shall have the meanings set forth in this Article 1.

1.1 “**Action Date**” means, with respect to a legal action in connection with a Product Infringement, the date that is the earlier of (a) \*\*\* following notice pursuant to Section 8.5(a) of a Product Infringement, and (b) \*\*\* before the date after which a legal action would be substantively limited or compromised with respect to the remedies available against the alleged Third Party infringer. Notwithstanding the foregoing, the Action Date shall in no event be earlier than \*\*\* after notice pursuant to Section 8.5(a) of a Product Infringement.

1.2 “**Affiliate**” means, with respect to a particular Party, any person, firm, trust, corporation, company, partnership, or other entity or combination thereof that directly or indirectly controls, is controlled by or is under common control with such Party. For the

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purposes of this definition, the word “control” (including, with correlative meaning, the terms “controlled by” or “under the common control with”) means (a) ownership of fifty percent (50%) or more of the voting and equity rights of such person, firm, trust, corporation, company, partnership or other entity or combination thereof, or (b) the power to direct the management of such person, firm, trust, corporation, company, partnership, or other entity or combination thereof.

1.3 “**Alliance Managers**” has the meaning set forth in Section 3.1.

1.4 “**API**” has the meaning set forth in Section 6.1.

1.5 “**Applicable Law**” means any and all laws, statutes, ordinances, regulations, permits, orders, decrees, judgments, directives, or rules of any kind whatsoever that are promulgated by a federal, state, or other governmental authority, including, without limitation, any regulations promulgated by any Regulatory Authority in the Sanofi Territory, all as amended from time to time.

1.6 “**Anti-Bribery Laws**” means any applicable anti-bribery and good business ethics legislation, regulations and/or codes, both national and foreign, including but not limited to, the United States Foreign Corrupt Practices Act of 1977, the United Kingdom Bribery Act, and national laws adopted and implemented pursuant to the Convention on Combating Bribery of Foreign Public Officials in International Business Transactions .

1.7 “**Bankrupt Party**” has the meaning set forth in Section 12.7.

1.8 “**Business Day**” means each day of the week excluding Saturday, Sunday or a day on which banking institutions in New York, New York or Paris, France, are closed.

1.9 “**Calendar Quarter**” shall mean any consecutive 3-month period ending March 31, June 30, September 30 or December 31.

1.10 “**Calendar Year**” shall mean a twelve (12) month period commencing January 1.

1.11 “**Claim**” means all investigations, claims, suits, actions, cross-complaints, demands, rights, requests, causes of action, or proceedings, whether at law, equity or otherwise, or whether sounding in tort, contract, equity, strict liability or any statutory or common law cause of action of any sort.

1.12 “**Commercialization**” means the marketing, Promotion, sale, offering for sale, importation and/or distribution of Product. “**Commercialize**” has a correlative meaning.

1.13 “**Commercialization and Medical Affairs Plan**” has the meaning set forth in Section 4.3(a).

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1.14 **“Commercially Reasonable Efforts”** means, with respect to a Party’s obligations under this Agreement, the reasonable and good faith efforts normally used by a similarly situated company in the pharmaceutical industry for a product that is of similar market potential and at a similar stage in its development or product life as the Product, which level of effort is at least commensurate with the level of effort that such Party would devote to its own internally discovered compounds or products that are of similar market potential and at a similar stage of development or product life as the Product.

1.15 **“Competing Product”** means a PDE-5 Inhibitor other than the Product.

1.16 **“Compound”** means the compound identified by the International Non-Proprietary Name avanafil and chemically known as (S)-4-(3-Chloro-4-methoxybenzylamino)-2-(2-hydroxymethylpyrrolidin-1-yl)-N-pyrimidin-2-ylmethyl-5-pyrimidinecarboxamide, including any metabolites, polymorphs, salts, esters, free acid forms, free base forms, pro-drug forms, racemates and all optically active forms thereof (each, a “Compound” and collectively, the “Compounds”).

1.17 **“Confidential Information”** means, with respect to a Party, all proprietary Information of such Party that is disclosed to or accessed by the other Party under this Agreement.

1.18 **“Control”** means, with respect to any material, Information, or intellectual property right, that a Party and/or its Affiliates owns or has a license or right to such material, Information, or intellectual property right and has the ability to grant to the other Party access, a license, or a sublicense (as applicable) to such material, Information, or intellectual property right on the terms and conditions set forth herein without violating the terms of any then-existing agreement or other arrangement with any Third Party.

1.19 **“Core Indication”** means the treatment of male erectile dysfunction.

1.20 **“Cover”, “Covered” or “Covering”** means, with respect to Vivus Patents, Sanofi Patents or Joint Patents that, but for a license granted thereunder, the use, manufacture, import, or sale of a Product would infringe a Valid Claim included in such Vivus Patents, Sanofi Patents or Joint Patents, or in the case of Vivus Patents, Sanofi Patents or Joint Patents that are patent applications, would infringe a claim in such patent applications if it were to issue as a Valid Claim.

1.21 **“Detail” or “Detailing”** means each separate face-to-face contact by a professional sales representative with a physician or other professional with authority to write prescriptions during which time the promotional message involving the Product is presented and is a topic of discussion. When used as a verb, **“Detail”** shall mean to engage in a Detail.

1.22 **“Development”** means all activities that relate to obtaining, maintaining or expanding Regulatory Approval of Product. This includes (a) preclinical and clinical studies,

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including formulation and CMC activities on Product; (b) preparation, submission, review, and development of data or information for the purpose of submission to a Regulatory Authority to obtain, maintain and/or expand Regulatory Approval of Product; and (c) post-Regulatory Approval product support for Product (including laboratory and clinical efforts directed toward the further understanding of the safety and efficacy of Product). For clarity, Development includes phase IV clinical trials and other post-Regulatory Approval clinical trials of Product. **“Develop”** and **“Developed”** have correlative meanings.

1.23 **“EMA”** means the European Medicines Agency or its successor.

1.24 **“Existing Confidentiality Agreement”** means the Confidentiality Agreement entered into by the Parties, dated August 30, 2011.

1.25 **“Existing PDE-5 Inhibitor”** means any of the generic PDE-5 Inhibitors listed on Exhibit A hereto, each of which, as of the Effective Date, is being developed or is planned to be registered by Sanofi or any of its Affiliates for sale in the Sanofi Territory or is sold by Sanofi or any of its Affiliates or sublicensees in the Sanofi Territory.

1.26 **“FDA”** means the United States Food and Drug Administration or its successor.

1.27 **“FD&C Act”** means the United States Federal Food, Drug and Cosmetic Act.

1.28 **“Federal Arbitration Act”** has the meaning set forth in Section 13.2.

1.29 **“Field”** means any therapeutic use in humans.

1.30 **“Generic Product”** means, with respect to the \*\*\* in a given \*\*\* of the \*\*\*, a product \*\*\* in such \*\*\* by a Third Party (other than a \*\*\* or any other Third Party \*\*\* such \*\*\* by, or otherwise in the \*\*\* of, \*\*\*) that (a) contains the \*\*\* as the \*\*\*, or any \*\*\* of such \*\*\* (but no more \*\*\* than is contained in the \*\*\*), and (b) is \*\*\* or \*\*\* in such \*\*\* pursuant to any \*\*\* based solely on (A) (x) \*\*\* to a \*\*\* for such \*\*\* held by \*\*\* in such \*\*\*, and/or (y) \*\*\* to other \*\*\* with respect to such \*\*\* generated by \*\*\*, and (B) a \*\*\* of \*\*\* to such \*\*\*. With respect to a \*\*\* that is \*\*\* as \*\*\* of a \*\*\* with \*\*\* (collectively “the \*\*\*”), a Generic Product shall, for purposes of this paragraph, \*\*\* as \*\*\* the same \*\*\* as \*\*\* in such \*\*\*, or any \*\*\* thereof, and meet the conditions defined in (b) above.

1.31 **“IFRS”** means the International Financial Reporting System as adopted by the European Union, consistently applied by Sanofi.

1.32 **“IND”** means an Investigational New Drug Application, as defined in the FD&C Act, or a similar application filed with an applicable Regulatory Authority outside of the United States such as a clinical trial application (CTA) or a clinical trial exemption (CTX).

1.33 **“Indemnified Claim”** has the meaning set forth in Section 11.3.

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1.34 **“Indemnified Party”** has the meaning set forth in Section 11.3.

1.35 **“Indemnifying Party”** has the meaning set forth in Section 11.3.

1.36 **“Information”** means any data, results, and information of any type whatsoever, in any tangible or intangible form, including know-how, trade secrets, practices, techniques, methods, processes, procedures, inventions, developments, specifications, formulations, formulae, software, algorithms, marketing reports, expertise, stability, technology, pharmacological, biological, chemical, biochemical, toxicological, and clinical test data, analytical and quality control data, and stability data.

1.37 **“Invention”** means any new or useful process, machine, manufacture, use, method of use or composition of matter, whether patentable or not.

1.38 **“Joint Invention”** has the meaning set forth in Section 8.1.

1.39 **“Joint Patent”** has the meaning set forth in Section 8.3(b).

1.40 **“Liquidated Damages”** shall have the meaning set forth in Section 6.2.

1.41 **“Losses”** means (a) all damages (including compensatory damages, monetary damages, statutory damages, punitive and exemplary damages and any pre-judgment and post-judgment interest), judgments, or settlements payable to Third Parties; and (b) all legal expenses (including attorneys’ fees and disbursements, expert and witness fees, fees and costs associated with any investigations, court costs and appeal bonds).

1.42 **“Major Market Countries”** means \*\*\*.

1.43 **“Manufacture”** or **“Manufacturing”** shall mean all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, inspection, receiving, holding and shipping of the Product or any constituents (including without limitation the Product’s API) or packaging materials with respect thereto, or any intermediate of any of the foregoing (such as the Product in the form of bulk tablets), including process and cost optimization, process qualification and validation, release, testing, quality assurance and quality control. When used as a verb, “Manufacture” shall mean to engage in Manufacture.

1.44 **“Marketing Authorization Application”** or **“MAA”** means an application to the appropriate Regulatory Authority for approval to sell the Product in any particular jurisdiction in the Sanofi Territory.

1.45 **“MTPC”** means Mitsubishi Tanabe Pharma Corporation, formerly known as Tanabe Seiyaku Co., Ltd..

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1.46 “**MTPC Agreement**” means that certain Agreement between Vivus and MTPC (as successor in interest to Tanabe Seiyaku Co., Ltd.), effective as of December 28, 2000, as successively amended by Amendment N°1 dated January 9, 2004, Amendment N°2 dated August 1, 2012, Amendment N°3 dated February 21, 2013 and excluding any further amendment that may be agreed between Vivus and MTPC, their Affiliates and/or successors in interest.

1.47 “**MTPC Supply Obligations**” has the meaning set forth in Section 6.2.

1.48 “**NDA**” means a New Drug Application, as defined in the FD&C Act.

1.49 “**Net Sales**” means the amount invoiced or otherwise billed by Sanofi or its Affiliate or Sublicensee for sales or other commercial disposition of the Product, in the Sanofi Territory, to a Third Party purchaser, less the following, to the extent included in such billing or otherwise actually allowed or incurred with respect to such sales: (a) discounts, including cash, trade and quantity discounts, price reduction programs, retroactive price adjustments with respect to sales of the Product, charge-back payments and rebates granted to managed health care organizations or to federal, state and local governments (or their respective agencies, purchasers and reimbursers) or to trade customers, including but not limited to, wholesalers and chain and pharmacy buying groups; (b) credits or allowances actually granted upon rejections or returns of Product, including for recalls or damaged goods; (c) freight, postage, shipping and insurance charges actually allowed or paid for delivery of Product, to the extent billed; (d) customs duties, surcharges and other governmental charges incurred in connection with the exportation or importation of a Product; (e) bad debts relating to sales of Product that are actually written off by Sanofi in accordance with IFRS, consistently applied, during the applicable royalty calculation period; and (f) taxes, duties or other governmental charges levied on, absorbed or otherwise imposed on sale of Product, including value-added taxes, or other governmental charges otherwise measured by the billing amount, when included in billing, as adjusted for rebates and refunds, but specifically excluding taxes based on net income of the seller; provided that all of the foregoing deductions are calculated in accordance with IFRS. Such amounts shall be determined from the books and records of Sanofi, its Affiliates or its Sublicensees, as the case may be, maintained in accordance with Sanofi’s normal practices. Notwithstanding the foregoing, in the event a Product is sold in combination or conjunction with one or more active ingredients, so as to be a combination product (whether packaged together and sold as one (1) stock keeping unit or in the same therapeutic formulation), Net Sales of the Product shall be calculated by multiplying the Net Sales of such combination product by a fraction, the numerator of which shall be the fair market value of the Product as if sold separately (determined in accordance with generally accepted accounting principles), and the denominator of which shall be the aggregate fair market value of all the proprietary active components of such combination product, including the Product, as if sold separately. In the event no such separate sales are made by Sanofi, its Affiliates or Sublicensees, Net Sales of the combination product shall be calculated in a manner to be negotiated and agreed upon by the Parties, reasonably and in good faith, prior to any sale of such combination product, which shall be based upon the respective estimated commercial values of the proprietary active components of such combination product. Sanofi’s or any of its

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Affiliate's transfer of Product to an Affiliate or Sublicensee shall not result in any Net Sales, unless such Product is consumed by such Affiliate or Sublicensee in the course of its commercial activities. Further, the disposition of a Product for, or the use of Product in, pre-clinical or clinical (Phase I — III) trials, other market-focused (Phase IV or V) trials, or Regulatory Approvals or free samples shall not result in any Net Sales.

1.50 **“Patents”** shall mean issued patents and patent applications, including provisional applications, continuations, continuations-in-part, continued prosecution applications, divisions, substitutions, reissues, additions, renewals, reexaminations, extensions, term restorations, confirmations, registrations, revalidations, revisions, priority rights, requests for continued examination and supplementary protection certificates granted in relation thereto, as well as utility models, innovation patents, petty patents, patents of addition, inventor's certificates, and equivalents in any country or jurisdiction.

1.51 **“Payment”** has the meaning set forth in Section 10.6

1.52 **“PDE-5 Inhibitor”** means any product that operates as a phosphodiesterase type-5 inhibitor.

1.53 **“Product”** means any composition containing a Compound as API, alone or in combination with one or more other active ingredient(s), in all dosage strengths, whether packaged and labeled or in bulk form, \*\*\* .

1.54 **“Product Infringement”** has the meaning set forth in Section 8.5(a).

1.55 **“Product Launch”** means the first sale of Product by Sanofi or its Affiliate or sublicensee after the Effective Date to an unrelated Third Party in a bona fide arms-length transaction for use, consumption, or commercial distribution in the Field in the Sanofi Territory, excluding any transfer of Product for research, test marketing, clinical trial purposes, compassionate use, or named patient arrangements, or for warehousing or staging in advance of release of the Product for commercial sale.

1.56 **“Promotion”** means those activities, including advertising, Detailing, and distributing samples of a product, normally undertaken by a pharmaceutical company that are aimed at legally marketing and promoting, and encouraging the appropriate use of, a particular prescription pharmaceutical product. **“Promote”** and **“Promotional”** have correlative meanings.

1.57 **“Promotional Materials”** means all training materials and all written, printed, graphic, electronic, audio or video matter, including journal advertisements, sales visual aids, leave items, formulary binders, reprints, direct mail, direct-to-consumer (**“DTC”**) advertising, Internet postings and broadcast advertisements, in each case created by Sanofi or on its behalf, and used or intended for use in connection with any Promotion of the Product in the Sanofi Territory under this Agreement.

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1.58 “**Prosecuting Party**” has the meaning set forth in Section 8.3(b).

1.59 “**PV Agreement**” has the meaning set forth in Section 5.5.

1.60 “**Regulatory Approval**” means all approvals necessary for the manufacture, marketing, importation and sale of the Product for one or more indications in a country or regulatory jurisdiction, which may include satisfaction of all applicable regulatory and notification requirements. For the avoidance of doubt, Regulatory Approval includes any pricing approval that may be required by Applicable Law.

1.61 “**Regulatory Authority**” means, in a particular country or regulatory jurisdiction, any applicable governmental authority involved in granting Regulatory Approval.

1.62 “**Regulatory Materials**” means regulatory applications, submissions, notifications, registrations, and/or other filings made to or with a Regulatory Authority that are necessary or reasonably desirable in order to Develop, manufacture, market, sell or otherwise Commercialize the Product in a particular country or regulatory jurisdiction, along with any documents of Regulatory Approval issued by a Regulatory Authority in a particular country or regulatory jurisdiction. Regulatory Materials include INDs and MAAs for the relevant country or regulatory jurisdiction.

1.63 “**Required Notice Date**” has the meaning set forth in Section 2.6(d).

1.64 “**Right of First Negotiation**” has the meaning set forth in Section 2.7.

1.65 “**Royalty Payment Term**” has the meaning set forth in Section 7.4 (b).

1.66 “**Sales Force**” means Sanofi’s sales personnel that Detail Product in the Sanofi Territory, including employees of, and contract sales organizations engaged by, Sanofi who are qualified to do so pursuant to the terms and conditions of this Agreement.

1.67 “**Sample Distribution**” means the distribution to a physician’s office of (a) a voucher for free Product or (b) free Product packaged as a complimentary trial for use by patients in the Sanofi Territory and in accordance with Applicable Law.

1.68 “**Sanofi API Supply Agreement**” means that certain Commercial Supply Agreement, between Vivus and Sanofi Chimie, effective as of January 1, 2014.

1.69 “**Sanofi Background Technology**” means Sanofi’s intellectual property used by Sanofi or its Affiliates in exercising their rights and/or performing their obligations hereunder or under the Technology Transfer and Development Services Agreement, including any patented technology, know-how, trade secrets that was in Sanofi’s possession prior to the disclosure by Vivus of the Vivus Know-How or Vivus’ Confidential Information, is later generated or acquired by Sanofi outside the scope of this Agreement, independently from and without use of or

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reference to the Vivus Technology.

1.70 “**Sanofi Indemnitees**” has the meaning set forth in Section 10.1.

1.71 “**Sanofi Know-How**” means all Information (excluding any patents and patent applications) that is Controlled by Sanofi or any Affiliate as of the Effective Date or during the Term and is necessary for the Development of the Product in the Field, provided however that, as used in this Agreement, the term “Sanofi Know-How” shall exclude the Sanofi Background Technology and the Sanofi Severable Improvements. For clarity, Sanofi Know-How shall also exclude the Vivus Know-How licensed to Sanofi hereunder.

1.72 “**Sanofi Manufacturing Territory**” shall mean the entire world except the Democratic People’s Republic of Korea (North Korea), the Republic of Korea (South Korea), Singapore, Malaysia, Thailand, Vietnam and the Philippines.

1.73 “**Sanofi Patents**” means all Patents (a) that are Controlled by Sanofi or any Affiliate as of the Effective Date or during the Term and (b) that Cover the Product. As used in this Agreement, the Sanofi Patents do not include: (a) any Patent Covering the Sanofi Background Technology and/or the Sanofi Severable Improvements; (b) the Vivus Patents licensed to Sanofi hereunder and (c) Sanofi’s ownership interest in any Joint Patent.

1.74 “**Sanofi Product Manufacturing Agreement**” means that certain Manufacturing and Supply Agreement between Vivus and Sanofi Winthrop Industrie that, as of the Effective Date, is being negotiated between the Parties.

1.75 “**Sanofi Severable Improvements**” means improvements to the Manufacturing process(es) of the Product that are made by or on behalf of Sanofi or its Affiliates and that are not Product-specific but can be used for other products .

1.76 “**Sanofi Technology**” means the Sanofi Patents and Sanofi Know-How.

1.77 “**Sanofi Territory**” means all the countries of Africa, the Middle East-Turkey, and Eurasia, as detailed in Exhibit B.

1.78 “**Sanofi Territory Approvals**” has the meaning set forth in Section 4.1(a).

1.79 “**Sanofi Trademarks**” has the meaning set forth in Section 8.8.

1.80 “**SEC**” means the United States Securities and Exchange Commission or any successor.

1.81 “**Service Provider**” shall mean any Third Party service providers such as contract research organizations, clinical research organizations, contract manufacturing organizations, consultants, subcontractors or other independent contractors performing on behalf of a Party (or

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MTPC) such Party’s obligations under this Agreement (or in the case of MTPC, MTPC’s obligations under the MTPC Agreement).

1.82 “**Sole Inventions**” has the meaning set forth in Section 8.1.

1.83 “**Technology Transfer and Development Services Agreement**” shall have the meaning set forth in Section 6.1.

1.84 “**Term**” has the meaning set forth in Section 13.1.

1.85 “**Third Party**” means any person, entity, or organization other than Vivus, Sanofi or an Affiliate of either Party.

1.86 “**Trademarks**” means trademarks and all registrations or applications for registration thereof.

1.87 “**Valid Claim**” means a claim of any examined and issued patent that has not been revoked or held invalid or unenforceable by final decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and that is not admitted to be invalid or unenforceable through reissue, disclaimer or otherwise.

1.88 “\*\*\*\*” shall have the meaning set forth in Section 6.5.

1.89 \*\*\* .

1.90 “**Vivus Indemnitees**” has the meaning set forth in Section 10.2.

1.91 “**Vivus Know-How**” means all Information (excluding any patents and patent applications) that (a) is Controlled as of the



Effective Date or during the Term by Vivus or its Affiliates and (b) is reasonably necessary or useful for the Development, Manufacture, use, or Commercialization of the Product in the Field. Information within the Vivus Know-How shall include data and reports arising out of any study performed as part of post-approval commitments to the Regulatory Authorities in the Vivus Territory. Notwithstanding the foregoing, the Vivus Know-How shall not include any Information to the extent such Information relates specifically to active pharmaceutical ingredients other than a Compound unless Sanofi exercises its Right of First Negotiation pursuant to Section 2.7 with respect to a \*\*\*, in which case the Vivus Know-How shall include Information (excluding any patents and patent applications) that relates to the other active pharmaceutical ingredients included in the \*\*\* and that otherwise satisfies the requirements set forth in subsections (a) and (b) above.

1.92 **“Vivus License”** has the meaning set forth in Section 2.2(a).

1.93 **“Vivus Patents”** means (a) the Patents that are listed in Exhibit C; (b) any Patents Controlled by Vivus or its Affiliates as of the Effective Date or during the Term (excluding

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Vivus' ownership interest in any Joint Patent) Covering (x) the Development, use, Manufacture and import of the Product in the Field and in the Sanofi Territory (y) the Manufacture of the Product in the Field in the Sanofi Manufacturing Territory. Notwithstanding the foregoing, Vivus Patents shall exclude any claim that specifically relate to the composition of matter, use or manufacture of active pharmaceutical ingredients other than a Compound unless Sanofi exercises the Right of First Negotiation pursuant to Section 2.7, in which case the Vivus Patents shall include claims that relate to the composition of matter, use or manufacture of the other active pharmaceutical ingredients included in the \*\*\* and that otherwise satisfy the requirements set forth in subsections (a) or (b) above .

- 1.94 “**Vivus Supply Agreement**” has the meaning set forth in Section 6.3.
- 1.95 “**Vivus Tablet Supply Obligations**” shall have the meaning set forth in Section 6.2.
- 1.96 “**Vivus Technology**” means the Vivus Patents and Vivus Know-How.
- 1.97 “**Vivus Territory**” means all countries in the world other than the countries of the Sanofi Territory.
- 1.98 “ **Vivus Territory Regulatory Approval Holder** ” has the meaning set forth in Section 5.1(a).

1.99 “**Vivus Trademarks**” means the Trademarks “Stendra<sup>TM</sup>” and “Spedra<sup>TM</sup>”, all designs and styles used by Vivus in the depiction of the foregoing Trademark, and any copyrights therein, and all goodwill appurtenant to any of the foregoing, in each case Controlled by Vivus as of the Effective Date or during the Term, provided however that if the registration of any of the Vivus Trademarks is refused by any Regulatory Authority or trademark office in the Sanofi Territory and by mutual agreement of the Parties another Trademark owned by or licensed to Vivus or its Affiliates is selected to be used by Sanofi with respect to the Manufacture and Commercialization of the Product in the Sanofi Territory, such other Trademark shall also be included in Vivus Trademarks.

- 1.100 “ \*\*\* ” has the meaning set forth in Section 6.2.

## **ARTICLE 2 LICENSES**

### **2.1 Licenses to Sanofi .**

(a) **License under Vivus Technology** . Subject to the terms and conditions of this Agreement, Vivus hereby grants to Sanofi, under the Vivus Technology: (i) an exclusive (even as to Vivus), royalty-bearing, sublicensable license to Develop, have Developed, use,

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Commercialize the Product and to Manufacture or have Manufactured the Product and API in the Field in the Sanofi Territory and (ii) a non-exclusive, royalty-bearing, sublicensable license to Manufacture or have Manufactured the Product and/or API in the Sanofi Manufacturing Territory. For clarity, the rights granted to Sanofi to Manufacture and have Manufactured Product are not intended to, and shall not, limit or extend any Manufacturing rights granted to Sanofi in the Sanofi API Supply Agreement or the Sanofi Product Manufacturing Agreement.

(b) **License under Vivus Trademarks** . Subject to the terms and conditions of this Agreement including the terms set forth in Section 8.7, Vivus hereby grants to Sanofi an exclusive (even as to Vivus), sublicensable (subject to Section 2.5) license to use the Vivus Trademarks solely in connection with the Manufacture, Development, and Commercialization of the Product in the Field within the scope of the licenses granted in Section 2.1(a). In recognition of Vivus' desire to develop a consistent worldwide brand for the Product, the foregoing license to the Vivus Trademarks shall be subject to Sanofi's compliance with Vivus' quality control provisions, as set-forth in Exhibit D to this Agreement, as may be amended from time to time by mutual agreement of the Parties.

(c) **Vivus Retained Rights** . Notwithstanding the rights granted to Sanofi in Section 2.1(a) and Section 2.1(b), Vivus retains under the Vivus Technology (i) the right to conduct those responsibilities assigned to Vivus under this Agreement and (ii) the right to conduct research, Development, and Manufacturing activities in the Sanofi Territory (as well as Manufacturing activities in the rest of the Sanofi Manufacturing Territory) in support of the Regulatory Approvals or Commercialization of Products in the Vivus Territory. For clarity, these retained rights are subject to any exclusive Manufacturing rights granted to Sanofi in the Sanofi API Supply Agreement or the Sanofi Product Manufacturing Agreement.

## 2.2 **License Grant to Vivus.**

(a) Subject to the terms and conditions of this Agreement, Sanofi hereby grants to Vivus a non-exclusive, royalty-free, non-transferable (except in accordance with Section 15.5), sublicensable (subject to Section 2.5) license under the Sanofi Technology solely to the extent pertaining to the Product containing a Compound as its sole active ingredient, and solely to the extent necessary to (i) fulfill its obligations under this Agreement; and (ii) conduct Development and Manufacturing of Product in the Sanofi Territory solely in support of the Regulatory Approval of Products in the Core Indication in the Vivus Territory (the "**Vivus License** "). Vivus shall obtain from its licensees under the Vivus Technology outside the Sanofi Territory a license grant, with a right to sublicense, of similar scope as the Vivus License. If Vivus is unable to obtain such a license grant from a licensee, then as Sanofi's sole remedy, the Vivus License shall cease to be sublicensable to such licensee unless and until such license grant is obtained.

(b) For the avoidance of doubt, the scope of Vivus License shall not extend to: (i) any Product containing a Compound in combination or association with one or more active ingredients and/or (ii) any indication other than the Core Indication. Upon Vivus' request in

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writing, Sanofi may consider the grant to Vivus of a royalty bearing license under the Sanofi Technology to Develop and Commercialize in the Vivus Territory: (i) any Product Developed by Sanofi containing a Compound in combination or association with one or more active ingredients and/or (ii) the Product in any indication other than the Core Indication, subject to the good-faith negotiations between the Parties of the terms and conditions applying to such license.

2.3 **No Other Licenses.** Neither Party grants to the other Party any rights, licenses or covenants in or to any intellectual property, whether by implication, estoppel, or otherwise, other than the license rights that are expressly granted under this Agreement.

2.4 **Sublicensing by Sanofi.** Sanofi acknowledges that the licenses granted to Sanofi in Section 2.1 include sublicenses under the rights licensed to Vivus under the MTPC Agreement and that Vivus is required to notify and consult with MTPC with respect to the selection of sublicenses. Consequently, the licenses granted by Vivus to Sanofi in Section 2.1 may be further sublicensed by Sanofi to a Third Party only with the prior written consent of Vivus, which shall not be unreasonably withheld. Any agreement granting a sublicense under the licenses granted by Vivus to Sanofi in Section 2.1 shall be consistent with the terms of this Agreement and shall include confidentiality and non-use obligations no less stringent than those set forth in Article 12. Notwithstanding the foregoing, Sanofi shall have the right to sublicense all rights granted by Vivus to Sanofi pursuant to Section 2.1 to any of its Affiliates, Service Providers or Third Party agents or distributors in relation to the Development, Manufacture or Commercialization of the Product without the prior consent of Vivus.

2.5 **Sublicensing by Vivus .** The licenses granted by Sanofi to Vivus in Section 2.2(a) may be freely sublicensed by Vivus to Vivus' Affiliates or to any of Vivus' licensees or sublicensees through one or multiple tiers.

2.6 **Mutual Non-Compete.**

(a) Except for its activities with respect to the Product under this Agreement and subject to the following subsections of this Section 2.6, for a period of \*\*\* following the Effective Date (the "Restricted Period"), each Party hereby covenants that neither it nor its Affiliates or will, directly or indirectly, develop, commercialize, or in-license any product that it knows to be a Competing Product in the Sanofi Territory in the Field, provided however that \*\*\*. For clarity, the foregoing is not intended to limit Vivus' covenant set forth in last sentence of Section 2.2(a).

(b) Notwithstanding Section 2.6(a), if Vivus or any of its Affiliates, \*\*\* that \*\*\* or \*\*\* to, a \*\*\* that does not \*\*\*, then Vivus and/or its Affiliates (or the \*\*\*, as applicable) shall have the right to \*\*\* provided that Vivus or its Affiliate (or the \*\*\*, as applicable) (i) notifies Sanofi of such \*\*\* in writing no later than the Required Notice Date (as defined below) \*\*\* (ii) does not use the \*\*\* or any \*\*\* (including, but not limited to, the \*\*\* that qualifies as \*\*\*) in connection with the \*\*\* of such \*\*\*.

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(c) In the event that, \*\*\*, either Sanofi or any of its Affiliates \*\*\* that \*\*\* or \*\*\* to a \*\*\* then Sanofi (or the \*\*\*, as applicable) shall (x) notify Vivus of such \*\*\* in writing no later than the Required Notice Date (as defined below); (y) not use any \*\*\* in connection with the \*\*\* of such \*\*\*; and (z) \*\*\* one of the following \*\*\* under \*\*\* (and specify which of the following it will \*\*\* in the notice provided pursuant to subsection (x), which decision shall be final and binding):

(i) \*\*\* and notify Vivus in writing of such \*\*\*; *provided* that such \*\*\* shall be \*\*\*; or

(ii) \*\*\* (in which case the notice delivered pursuant to subsection (i) above shall be deemed to be a \*\*\*); or

(iii) \*\*\* such that neither Sanofi nor any Sanofi Affiliates have \*\*\* with respect to such \*\*\*; *provided* such \*\*\*; and it being understood, for the avoidance of doubt, that as of the \*\*\* Sanofi shall have \*\*\*, to \*\*\* any \*\*\*; or

(iv) \*\*\* for purposes of \*\*\*.

(d) As used herein, “**Required Notice Date**” means the date that is \*\*\*; *provided* that the Required Notice Date shall in no event be \*\*\* following the consummation of the transaction described in \*\*\*, as applicable.

## 2.7 **Right of First Negotiation .**

(a) **Right of First Negotiation Generally .** In the event Vivus or its Affiliates, either by themselves or as part of a collaboration with any Third Party, develop a \*\*\*, Sanofi shall have a right of first negotiation to obtain an exclusive license under any intellectual property rights under the Control of Vivus or its Affiliates that are necessary and/or useful to develop, and/or Manufacture, and/or Commercialize such \*\*\* (the “**Right of First Negotiation**”). Sanofi may exercise the Right of First Negotiation at any time during the development of any such \*\*\*, but in no event later than \*\*\* after the receipt from Vivus of the report of \*\*\* for such Vivus Combination (the “**Option Period**”). If Sanofi exercises the Right of First Negotiation during the Option Period by providing written notice of such exercise to Vivus (the “**Sanofi ROFN Notice**”), then for a period of \*\*\* after VIVUS receives the Sanofi ROFN Notice (or such longer period as the Parties may mutually agree) (the “**Negotiation Period**”), the Parties shall negotiate in good faith the commercially reasonable terms under which \*\*\*.

(b) **Exercise of the Right of First Negotiation.** Sanofi shall have the right to exercise the Right of First Negotiation at any time during the Option Period. Vivus (or its Affiliates) shall not enter into any discussions with any Third Party with regard to the development and/or Manufacturing and/or Commercialization of any \*\*\* during the Option Period and/or, if applicable, the Negotiation Period. Vivus shall periodically report to Sanofi on the progress of all \*\*\*, and, in any event, shall report to Sanofi at \*\*\*, and provide Sanofi with the final

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development reports for such \*\*\* of development and, upon request, with all \*\*\*. Until such time as Sanofi exercises the Right of First Negotiation, Vivus and its Affiliates shall be free to continue development of such \*\*\* on their own and at own expense. In the event Sanofi does not elect to exercise the Right of First Negotiation during the Option Period, or Sanofi elects to exercise the Right of First Negotiation, but the Parties fail to mutually agree on commercially reasonable terms during the Negotiation Period, then, in each case, after the Option Period or Negotiation Period (respectively), Vivus shall be free to grant licenses to one or more Third Parties with respect to the development, Manufacturing and Commercialization rights relating to the \*\*\* that is the subject of the Right of First Negotiation, without any further obligations to Sanofi; provided, however, that Vivus shall not enter into any such license unless the terms thereof are, in the aggregate, less favorable to Vivus than the last terms offered by Sanofi.

(d) **Mutual Agreement of the Parties.** In the event Sanofi exercises its Right of First Negotiation and the Parties mutually agree to commercially reasonable terms under which the definition of Product hereunder would be expanded to include the applicable \*\*\* (as evidenced by a written document signed by both Parties), this Agreement shall be amended to incorporate such financial terms and conditions; the definition of Products shall thereafter be deemed to include such \*\*\*; and the Agreement shall otherwise remain unchanged and in full force and effect provided that the definition of Vivus Patents shall be expanded by the inclusion by Vivus in Exhibit C of any Patent(s) in respect to any such \*\*\*.

### **ARTICLE 3 ALLIANCE MANAGEMENT**

3.1 **Appointment.** Each of the Parties shall appoint a single individual to act as a single point of contact between the Parties (each, an “**Alliance Manager**”) during the Term. Each Party may change its designated Alliance Manager from time to time upon written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager by written notice to the other Party.

3.2 **Responsibilities.** Each Alliance Manager: (i) will be the point of first referral in all matters of conflict resolution; (ii) will coordinate the relevant functional representatives of the Parties in developing and executing strategies and plans for the Product in the Sanofi Territory in an effort to ensure consistency and efficiency with similar efforts in the Vivus Territory; (iii) will provide a single point of communication for seeking consensus both internally within the respective Parties’ organizations and between the Parties regarding key strategy and plan issues; (iv) will identify and bring disputes to the attention of the Parties’ in a timely manner; and (v) will plan and coordinate cooperative efforts and internal and external communications.

3.3 **Meetings.** Upon the reasonable request of Sanofi, the Alliance Managers shall organize ad hoc meetings with appropriate representatives from each Party having expertise in

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the matter discussed, and, as may be needed or requested by Sanofi, Vivus will seek the participation of representatives of Vivus' licensees for the Product in the Vivus Territory, to facilitate the coordination efforts set forth in Section 3.2 above.

3.4 **Independence.** Subject to the terms of this Agreement, the activities and resources of each Party shall be managed by such Party, acting independently and in its individual capacity. The relationship between Vivus and Sanofi is that of independent contractors and neither Party shall have the power to bind or obligate the other Party in any manner.

#### **ARTICLE 4 DEVELOPMENT AND COMMERCIALIZATION**

##### **4.1 Development .**

(a) **Obtaining Regulatory Approval.** Sanofi shall be responsible for filing Regulatory Materials that are necessary for obtaining the Regulatory Approvals of the Product in the Sanofi Territory in the Field (“**Sanofi Territory Approvals**”), including performing any and all Development activities in the Sanofi Territory in connection therewith. Sanofi shall file for the Sanofi Territory Approvals in such countries in the Sanofi Territory at its cost and expense and on such schedule, in each case, that are consistent with Commercially Reasonable Efforts and Sanofi's diligence obligations as set forth in Section 4.5. For clarity, the Regulatory Materials for which Sanofi is responsible hereunder include INDs and MAAs that are specific for countries or regions in the Sanofi Territory, but expressly exclude any Regulatory Materials filed with the FDA or EMA.

(b) **Post-Approval Studies .** Sanofi shall be responsible, at Sanofi's sole expense, for conducting any clinical or non-clinical studies of Product that are required by any of the individual countries in the Sanofi Territory, whether such studies are conducted prior to or after receipt of the Sanofi Territory Approvals. Sanofi shall conduct such studies using Commercially Reasonable Efforts.

(c) **Use of Data.** Subject to the limitations set forth in Section 2.2, Vivus shall have the right, without any additional payment, to use the Sanofi Know-How in support of Regulatory Approval of Product in the Vivus Territory. Sanofi shall have the right, without any additional payment, to use the Vivus Know-How in support of Regulatory Approval of Product in the Field in the Sanofi Territory.

(d) **Other Development .** Sanofi shall have the sole right to conduct any further Development (including clinical trials) on the Product in the Field in the Sanofi Territory, at its sole discretion. Sanofi shall be responsible for all of its costs in connection with any further Development activities that it conducts, unless otherwise mutually agreed by the Parties.

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4.2 **Commercialization — General.** Subject to the terms of this Agreement, Sanofi shall have sole responsibility and decision-making authority for Commercialization activities for the Sanofi Territory. Sanofi shall be responsible for all costs and expenses associated with such Commercialization activities.

4.3 **Diligent Commercialization by Sanofi.** Sanofi, itself or through its Affiliates or sublicensees, shall use Commercially Reasonable Efforts to seek Regulatory Approval for and Commercialize the Product in the Core Indication in the Sanofi Territory and to launch the Product in each of the Major Market Countries within a period of six (6) months following Regulatory Approval in such country.

4.4 **Sales Force .**

(a) **General .** Sanofi shall at all times during the Term maintain a Sales Force containing a reasonable number of sales representatives in order to meet Sanofi's obligations under Section 4.4. The Sales Force may consist of employees of Sanofi or a contract sales force (or a combination thereof); provided that Sanofi shall remain responsible for the management, supervision, and performance of such contract sales force.

(b) **Qualifications.** Unless otherwise agreed by the Parties, Sanofi shall subject the members of its Sales Force to substantially the same minimum qualifications that it applies to its sales forces for its other products in the Sanofi Territory.

(c) **Compensation .** Sanofi shall be solely responsible for all costs and expenses of recruiting, hiring, maintaining and compensating its Sales Force, including salaries, benefits and incentive compensation, provided that (i) the compensation structure for the Sales Force shall include elements that are tied to effective Promotion of Product; and (ii) the incentive compensation for the Sales Force shall not be structured in a manner that would reasonably be expected to inappropriately motivate such individuals to engage in the improper Detailing, Promotion, or sales of Product.

4.5 **Promotional Materials .**

(a) Sanofi shall be responsible, at its expense, for preparing and producing the Promotional Materials. The Promotional Materials used by Sanofi or its Affiliates or sublicensees in a particular market in the Sanofi Territory shall be consistent with any Regulatory Approval in the Sanofi Territory that is applicable to such market and shall in any event comply with Applicable Law.

(b) Sanofi shall be solely responsible for timely submitting, as applicable, any Promotional Materials to Regulatory Authorities in the Sanofi Territory (including any applicable governmental authorities in individual countries in the Sanofi Territory). Sanofi shall use and distribute the Promotional Materials in accordance with the terms of this Agreement.

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(c) Sanofi shall not use or distribute in connection with Promotion of the Product any materials bearing Vivus' name or trademarks without Vivus' prior written approval. Notwithstanding the foregoing, Sanofi shall be permitted to use the Vivus Trademarks in accordance with the license granted in Section 2.1(b).

#### 4.6 **Compliance.**

(a) In performing its duties hereunder, Sanofi shall and shall cause its Sales Force to: (i) Commercialize the Product in conformity with its approved labeling; and (ii) comply with all Applicable Laws, including all laws and regulations and other guidelines concerning the sale, promotion, and advertising of prescription drug products that are applicable to the Sanofi Territory.

(b) Sanofi shall Commercialize the Product in a professional, ethical and competent manner and shall ensure that the systems, processes, and standard operating procedures being used by Sanofi or its Affiliates in connection with the Commercialization of Product in the Sanofi Territory (including procedures for collecting and reporting adverse events) comply with Applicable Law and industry practice. Without limiting the generality of the foregoing, Sanofi shall ensure that each of its employees and Sales Force representatives does not make any representation, statement, warranty or guaranty with respect to the Product that is inconsistent with its current labeling, that is deceptive or misleading, or that disparages the Product or the good name, goodwill or reputation of Vivus or its Affiliates.

4.7 **Re-Sale Price.** Sanofi shall be free to determine the price(s) at which it sells Products in the Sanofi Territory, subject to any pricing approvals or other requirements imposed by Applicable Law.

4.8 **Commercialization Reports.** Sanofi shall keep Vivus reasonably informed regarding the material progress and results of its Commercialization activities and those of its Affiliates, sublicensees, including providing the following:

(a) On a \*\*\* basis during the Term, an email reporting (i) the Net Sales of Products in the Sanofi Territory, on a country-by-country basis, booked during the preceding calendar month and (ii) the aggregate Net Sales in the Sanofi Territory during the ongoing calendar year. Within \*\*\* days after the end of each \*\*\* during the Term following Product Launch, Sanofi shall provide to Vivus a written report summarizing Sanofi's material Commercialization activities pursuant to this Agreement for such \*\*\* and on a calendar year-to-date basis, including: (i) the number of Details made; (ii) the total number of Sample Distributions delivered and/or redeemed, and (iii) Information in Sanofi's possession regarding any direct mail advertising, journal advertising and DTC advertising.

(b) Any report submitted to Vivus by Sanofi under this Agreement shall be in a reasonable format, as determined by Sanofi in its discretion. Each such report shall be considered Sanofi's Confidential Information.

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4.9 **Sanofi Records and Audits.** Sanofi shall keep complete and accurate records of (a) the number of Details delivered by sales representatives under Sanofi's control, (b) the total number of Sample Distributions distributed and/or redeemed, and (d) Information regarding any direct mail advertising, journal advertising and DTC advertising. All such records shall be retained for at least \*\*\* years following the Calendar Year in which they are generated, or longer if required by Applicable Laws. At Vivus' request, such records and Sanofi's Detail and Sample Distribution activity reporting system shall be available for review at Sanofi facilities in the Sanofi Territory not more than once each calendar year (during normal business hours on a mutually agreed date with reasonable advance notice) by an independent Third Party auditor mutually agreed upon by the Parties and subject to confidentiality and non-use obligations no less stringent than those set forth in Article 12 for the sole purpose of verifying for Vivus the accuracy of the reports furnished by Sanofi pursuant to this Section. The expense of such auditor shall be borne solely by Vivus unless such audit reveals a numerical reporting error of \*\*\* percent (\*\*\*) or more during the applicable audit period, in which case Sanofi shall bear the full cost of such audit. Such auditor shall not disclose Sanofi's confidential information to Vivus, except to the extent such disclosure is necessary to verify the accuracy of the reports furnished by Sanofi.

4.10 **Cross-Territory Sales .** Sanofi shall not directly solicit, advertise, sell, distribute, ship, consign, or otherwise Promote the Product outside the Sanofi Territory. Sanofi shall use Commercially Reasonable Efforts to ensure that Products sold in the Sanofi Territory are not used outside the Sanofi Territory. Without limiting the generality of the foregoing, Sanofi shall not sell any Product to a purchaser if Sanofi knows, or has reason to believe, that such purchaser intends to remove such Product from the Sanofi Territory or otherwise intends to facilitate the use of such Product outside the Sanofi Territory. Sanofi shall use Commercially Reasonable Efforts to ensure that its sublicensees, distributors, and wholesalers comply with all of the foregoing obligations.

## **ARTICLE 5 REGULATORY**

### **5.1 Regulatory Materials and Regulatory Approvals .**

(a) **Ownership and Responsibility .** Sanofi, its Affiliates, sublicensees or, if required by Applicable Laws in the Sanofi Territory, their distributors or agents, shall be the legal and beneficial owner of all Sanofi Territory Approvals, and Regulatory Materials relating to the Sanofi Territory Approvals shall be filed by, and in the name of, Sanofi, its Affiliates or sublicensees or if required by Applicable Laws in the Sanofi Territory, their distributors or agents. If Applicable Laws of any country in the Sanofi Territory require that, in such country, Regulatory Approvals be held by the Regulatory Approval holder of a specific country in the Vivus Territory (a "**Vivus Territory Regulatory Approval Holder**"), Vivus shall or, if Vivus is not the Vivus Territory Regulatory Approval Holder, shall use Commercially Reasonable Efforts to cause any such Vivus Territory Regulatory Approval Holder to: (i) execute all instruments that

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shall be deemed necessary by Regulatory Authorities of such country in the Sanofi Territory in this respect and/or (ii) execute any agreement with Sanofi or its Affiliates for the purpose of transferring to Sanofi or its Affiliates certain responsibilities that the Vivus Territory Regulatory Approval Holder may incur by holding the Regulatory Approval in such country of the Sanofi Territory, all at Sanofi's expense. For clarity, as used in the preceding sentence, "Commercially Reasonable Efforts" shall not require that Vivus incur any out-of-pocket costs or otherwise amend its agreement with the applicable Vivus Territory Regulatory Approval Holder in any manner that adversely impacts Vivus to a material degree.

(b) **Notifications.** During the Term, Sanofi shall keep Vivus reasonably and regularly informed of the submission to Regulatory Authorities of all material Regulatory Materials, meetings with Regulatory Authorities, and receipt of, or any material changes to existing, Regulatory Approvals, in each case for the Product in the Sanofi Territory.

### **5.2 Reporting Obligations .**

(a) Each Party shall keep the other informed, in a timely manner consistent the other Party's reporting requirements to Regulatory Authorities, of any Information that such Party receives (directly or indirectly) that (i) raises any material concerns regarding the safety or efficacy of the Product; (ii) indicates or suggests a potential material liability of either Party to Third Parties in connection with the Product; (iii) is reasonably likely to lead to a recall or market withdrawal of the Product; or (iv) relates to the Product and is reasonably likely to have a material impact on a Regulatory Approval or the Commercialization of the Product .

(b) Each Party shall fully cooperate with and assist the other Party (the requesting Party) in complying with any of the requesting Party's regulatory obligations with respect to the Product in its Territory, including by providing to the requesting Party, within \*\*\* (or sooner if reasonably required for such Party to meet a deadline set by the relevant Regulatory Authority or by Applicable Law), such information and documentation in its possession as may be necessary or helpful for the requesting Party to prepare a response to an inquiry from a Regulatory Authority.

(c) Neither Party shall communicate with any Regulatory Authority of the other Party's Commercialization territory regarding any Product unless explicitly requested or permitted in writing to do so by the other Party, or unless so ordered by such Regulatory Authority or otherwise required by Applicable Law, in which case either Party shall immediately provide notice of such order or legal

requirement to the other .

5.3 **Vivus Obligations.**

(a) **Transfer of Vivus Know-How and Information.** For the purpose of this Agreement, Vivus shall, and shall cause MTPC and its Service Providers, as the case may be, at no additional cost to Sanofi, to: (i) provide Sanofi in a timely manner with all Vivus Know-How that shall be required with respect to the Manufacture of the Product inside or outside the

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Territory; (ii) provide Sanofi with all Vivus Know-How that shall be required by Regulatory Authorities or that may be reasonably useful for obtaining the Sanofi Territory Approvals, including but not limited to any Information relating to manufacturing facilities wherein the Product is manufactured (to the extent such Information is Controlled by Vivus or its Affiliates or is in the possession of the Service Providers of Vivus or its Affiliates); (iii) permit the inspection of such manufacturing facilities by Sanofi, its Affiliates or any Regulatory Authority of a country within the Sanofi Territory, during normal business hours on a mutually agreed date with reasonable advance notice; (iv) at Sanofi's request, provide to Sanofi or its Affiliates timely assistance to answer any query from Regulatory Authorities; (v) carry-out any additional or specific stability studies on the Product that are required or reasonably advisable for the Major Market Countries; (vi) provide Sanofi, within \*\*\* after the Effective Date, with Regulatory Material under CTD/ICH format and content (including any additional country specific CMC documentation), as and to the extent such dossiers and documentation exist and are in Vivus' Control at the time of transfer; (vii) upon Sanofi's request, provide Sanofi or its Affiliates with (A) reasonable quantities of Product (either in finished form, bulk form or as API) for Development purposes, in accordance with terms and conditions to be negotiated in good faith between the Parties, provided however that any reasonable quantities requested by the Regulatory Authorities in the Sanofi Territory for registration purposes shall be supplied to Sanofi free of charge; and (B) the Product's core labeling documents and Vivus' Company Core Data Sheet ("CCDS"), including such CCDS prospective update(s). For clarity, Vivus shall have no obligation hereunder to transfer (or cause to be transferred, as the case may be) to Sanofi any Vivus Know-How that is already in Sanofi's or its Affiliate's possession as of the Effective Date.

(b) **Regulatory Updates** . Vivus shall keep Sanofi informed in a timely manner of any updates of a Regulatory Approval with respect to the Product in the United States or such countries of Europe that are used as countries of reference for the Sanofi Territory Approvals. Such updates shall be provided within \*\*\* from the date of any such Regulatory Approval update.

5.4 **Rights of Reference** . Vivus hereby grants to Sanofi an exclusive right of reference to all Regulatory Materials and Regulatory Approvals owned or Controlled by Vivus solely for the purpose of obtaining or maintaining the Sanofi Territory Approvals during the Term.

#### 5.5 **Regulatory Actions.**

(a) **Notice of Non-Compliance**. Each Party promptly disclose to the other any information pertaining to notices from Regulatory Authorities of non-compliance with Applicable Laws in connection with the Product.

(b) **Inspection or Audit**. If a Regulatory Authority in the Vivus Territory desires to conduct an inspection or audit of Sanofi's facility or a facility under contract with Sanofi with regard to the Product, Sanofi shall cooperate and cause the contract facility to

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cooperate with such Regulatory Authority during such inspection or audit. To the extent that Sanofi, rather than Vivus, receives the inspection or audit observations of such Regulatory Authority, Sanofi shall promptly provide a copy of such observations to Vivus. Sanofi shall prepare the response to any such observations, but the submission of the response to the applicable Regulatory Authority shall be subject to Vivus' final approval of response, which approval shall not be unreasonably withheld. Sanofi agrees to conform its activities under this Agreement to any commitments made in such a response, except to the extent it believes in good faith that such commitments violate Applicable Laws.

(c) **Product Withdrawals and Recalls.** The Parties shall exchange their internal standard operating procedures ( "SOPs" ) for conducting product recalls reasonably in advance of Product Launch, and shall discuss and resolve any conflicts between such SOPs and issues relating thereto promptly after such exchange. In the event of any disagreement as to how to resolve any such conflicts, Vivus' SOP shall control. If either Party becomes aware of information relating to the Product that indicates that a unit or batch of the Product in the Sanofi Territory may not conform to the specifications therefor, or that potential adulteration, misbranding, and/or other issues have arisen that relate to the safety or efficacy of the Product in the Sanofi Territory, it shall promptly so notify the other Party. To the extent practicable, the Parties shall discuss the circumstances of any potential product recall, field correction, or withdrawal of any Product in the Sanofi Territory and possible appropriate courses of action. If Sanofi decides to initiate a recall, field correction, or withdrawal of Product in the Sanofi Territory, Sanofi shall have the right and responsibility, at its expense, to control such recall, field correction, or withdrawal in a manner consistent with its internal SOPs (as revised pursuant to the first sentence of this Section 5.4(c), if applicable); provided, however, Sanofi shall consider in good faith the views of Vivus as to whether a recall, field correction, or withdrawal is necessary or appropriate. If (i) a Regulatory Authority or other Applicable Law requires a recall, field correction, or withdrawal of Product in the Sanofi Territory, and (ii) Sanofi fails to initiate such recall, field correction, or withdrawal within \*\*\* of being notified of such requirement, Vivus shall have the right (but not the obligation), at its expense, to control such recall, field correction, or withdrawal in a manner consistent with its internal SOPs (as revised pursuant to the first sentence of this Section 5.4(c), if applicable); provided, however, Vivus shall consider in good faith the views of Sanofi as to whether a recall, field correction, or withdrawal is necessary or appropriate. For clarity, as between the Parties, Vivus shall have the right (but not the obligations), at its expense, to control all recalls, field corrections, and withdrawals of any Product in the Vivus Territory. Each Party shall maintain complete and accurate records of any recall, field correction, or withdrawal in its territory for such periods as may be required by Applicable Laws, but in no event for less than \*\*\*.

5.6 **Pharmacovigilance Agreement .** Prior to the grant of the first Regulatory Approval required for the marketing of the Product in the Sanofi Territory, the Parties (or their Affiliates) shall enter into a separate pharmacovigilance agreement (the " **PV Agreement** " or Safety Data Exchange Agreement (the " **SDEA** ")) to be negotiated by their respective pharmacovigilance departments. Such SDEA shall contain specific terms, conditions and

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obligations for the Parties to ensure worldwide safety surveillance, signal detection and risk management for the Product during the Term and as long as either Party has safety reporting obligations. Notwithstanding the foregoing, Vivus, shall, as of the Effective Date, and prior to the grant of any Regulatory Approval, communicate promptly to Sanofi any safety issue relating to the Product that comes to its knowledge.

## ARTICLE 6 MANUFACTURING & SUPPLY

6.1 **Manufacturing Generally.** Subject to Sections 6.2, 6.3, and 6.5, Sanofi shall be responsible, during the term of this Agreement, for the Manufacture, under its sole authority, of all of its requirements of Product and Product's active pharmaceutical ingredient ("API"), for use by Sanofi, its Affiliates and their sublicensees in the Sanofi Territory. On March 25, 2013, Vivus and Sanofi Chimie, an Affiliate of Sanofi executed a Technology Transfer and Development Services Agreement (the "**Technology Transfer and Development Services Agreement**") for the transfer to Sanofi Chimie of the manufacturing process for the API described in the Product's active substance master file existing as of the Effective Date.

6.2 **Vivus Tablet Supply Obligations.** Until June 30, 2015, or, in the event that MTPC's obligations to supply Product to Vivus (the "**MTPC Supply Obligations**") are amended such that the term thereof is extended beyond June 30, 2015, until the expiration of the MTPC Supply Obligations as amended, Vivus shall supply to Sanofi or its designee(s) Sanofi's requirements of Product in the form of bulk drug tablet (s) for use by Sanofi, its Affiliates and their sublicensees (such supply, the "**Vivus Tablet Supply Obligations**"). The Vivus Tablet Supply Obligations shall also include the \*\*\* that Vivus has agreed to supply to Sanofi, as described in the Vivus Supply Agreement \*\*\*. In order to comply with the Vivus Tablet Supply Obligations, Vivus may subcontract the Manufacture of Sanofi's requirements of Product to \*\*\*. Vivus understands and acknowledges that \*\*\* of the \*\*\* would be a \*\*\* of \*\*\* and would \*\*\*. Notwithstanding anything in this Agreement or the Vivus Supply Agreement to the contrary, Vivus undertakes to \*\*\*. Should Vivus be in breach of the foregoing undertaking, then (A) Vivus would pay Sanofi, \*\*\* an amount of \*\*\* within \*\*\* of Sanofi's written notification to Vivus of its breach and (B) Sanofi would be relieved of its obligation to \*\*\*. Should Vivus fail to make the \*\*\*, The Parties agree that it would be extremely difficult and impracticable to determine precisely the amount of actual damages that would be suffered by Sanofi as a result of Vivus' failure to \*\*\*. The Parties further agree that the \*\*\* set forth in this Section 6.2 \*\*\* and that such \*\*\* constitute a penalty. The \*\*\* of the \*\*\* shall be \*\*\*, for \*\*\* the \*\*\*.

6.3 **Vivus Supply Agreement.** Within \*\*\* following the Effective Date, Vivus and Sanofi (or one of its Affiliates) shall execute a supply agreement substantially in the form of Exhibit E (the "**Vivus Supply Agreement**"), whereby, at the request of Sanofi, Vivus will perform the Vivus Tablet Supply Obligations. Within \*\*\* months of the date of execution of the Vivus Supply Agreement by the latest of the parties, the parties to such Vivus Supply Agreement

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shall also enter into a quality agreement governing the agreed-upon specifications and other technical aspects of supply of the Product for Commercialization in the Sanofi Territory (the “**Quality Agreement**”).

6.4 **Sanofi Manufacturing Responsibility.** On June 30, 2015, Vivus Tablet Supply Obligations shall expire and Sanofi shall then be solely responsible for the Manufacture of its requirements of Product and API under this Agreement.

6.5 **\*\*\***. Vivus shall **\*\*\*** no less than **\*\*\*** conforming to the **\*\*\*** as set forth in the **\*\*\***, on a **\*\*\***, pursuant to the following schedule **\*\*\***. In order to comply with the **\*\*\***, Vivus may **\*\*\***.

## **ARTICLE 7 FINANCIALS**

### **7.1 License Fee .**

(a) No later than **\*\*\*** after the Effective Date, Sanofi shall pay to Vivus a one-time license fee of five million U.S. dollars (US\$5,000,000) by wire transfer of immediately available funds to the following account:

**\*\*\***

(b) Subject to the timely performance of all **\*\*\***, Sanofi shall pay to Vivus a one-time, non-refundable additional fee of five million U.S. dollars (US\$5,000,000) by wire transfer of immediately available funds to the account mentioned in Section 7.1(a) above, in accordance with the following terms and conditions:

(i) Sanofi shall pay Vivus **\*\*\*** U.S. dollars (US\$**\*\*\***) no later than **\*\*\*** following the delivery of the quantities specified in subsections (i) of Section 6.5, within the timeframe set forth therein.

(ii) Sanofi shall pay Vivus **\*\*\*** U.S. dollars (US\$**\*\*\***) no later than **\*\*\*** following the **\*\*\*** of Section 6.5. Should the **\*\*\*** be delayed, then Sanofi’s payment under this Section 7.1(b)(ii) shall be reduced as follows: **\*\*\***. This Section 7.1(b)(ii) states VIVUS’s sole liability, and Sanofi’s sole remedy, for any delay in **\*\*\***, but not for **\*\*\***.

7.2 **Regulatory Milestone Payments .** In partial consideration of the licenses granted by Vivus to Sanofi pursuant to Section 2.1 (a) and (b) of this Agreement, Sanofi shall make each of the milestone payments indicated below to Vivus:

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Milestone Event		Payment	
***		US\$	***
***		US\$	***
***		US\$	***
***		US\$	***

Each regulatory milestone payment in this Section 7.2 shall be paid once in the Field for the first indication for which Regulatory Approval is obtained in the applicable country and shall not be payable for any other indication for which Regulatory Approval may be obtained in such country. The maximum total amount of payment to Vivus pursuant to this Section 7.2 shall be six million U.S. dollars (US\$6,000,000). Each such payment shall be made by wire transfer of immediately available funds into the account designated in Section 7.1. Each such payment is nonrefundable and noncreditable against any other payments due hereunder. For clarity, in the event that Sanofi or sublicensee commences commercial sales of Product in a country listed in the table above prior to receipt of any Regulatory Approval in such country (i.e., prior to Regulatory Approval in the first indication), the Regulatory Approval milestone payment for such country shall become immediately due and payable, whether or not such Regulatory Approval is ever received.

7.3 **Sales Milestone Payments.** In partial consideration of the licenses granted by Vivus to Sanofi pursuant to Section 2.1(a) and (b) of this Agreement, Sanofi shall make each of the sales milestone payments indicated below to Vivus when aggregate Net Sales of all Products in any calendar year in the Sanofi Territory reach the specified dollar values.

Aggregate Net Sales in a Calendar Year		Payment	
US\$	***	US\$	***
US\$	***	US\$	***
US\$	***	US\$	***

Each sales milestone payment in this Section 7.3 shall be paid only once. The maximum total amount of payment to Vivus pursuant to this Section 7.3 shall be forty-five million U.S. dollars (US\$45 million). Sanofi shall notify and pay to Vivus the amounts set forth in this Section 7.3 together with the delivery of the quarterly report pursuant to Section 7.6 for the \*\*\* in which the applicable event was achieved. For clarity, in the event that more than one of the aggregate Net Sales thresholds is achieved in a \*\*\*, Sanofi shall owe each of the corresponding payments. Each such payment shall be made by wire transfer of immediately available funds into an account designated by Vivus. Each such payment is nonrefundable and noncreditable against any other payments due hereunder.

7.4 **Royalty to Vivus.**

(a) **Royalties Generally.** In partial consideration of the licenses granted by Vivus to Sanofi pursuant to Section 2.1 (a) and (b) of this Agreement, Sanofi shall pay to Vivus royalties on Net Sales of the Product in the Sanofi Territory as follows:

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**Aggregate Net Sales of the Product in a calendar year  
in the Sanofi Territory**

	<b>Royalty Rate</b>
Portion of Net Sales less than or equal to US\$***	***%
Portion of Net Sales greater than US\$*** and less than or equal to US\$***	***%
Portion of Net Sales greater than US\$***	***%

For purposes of illustration only, if Net Sales in the Sanofi Territory for each of the \*\*\* in a calendar year was \$\*\*\*, the royalties due to Vivus hereunder would be as follows: for the first \*\*\*, \$\*\*\*; for the second \*\*\*, \$\*\*\*; for the third \*\*\*, \$\*\*\*; and for the fourth \*\*\*, \$\*\*\*.

(b) **Royalty Payment Term.** The above royalties shall be payable for each Product in each country of the Sanofi Territory until the later to occur of (i) the expiration of the last to expire Valid Claim within the Vivus Patents that, absent the licenses granted to Sanofi hereunder, would be infringed by the sale of such Product in such country, and (ii) the sixteenth anniversary of the Effective Date (the “Royalty Payment Term”).

(c) **Third Party Royalties.** If a Third Party’s Patent exists in any country of the Sanofi Territory during the Royalty Payment Term defined in Section 7.4(b), which would make it impractical or impossible for Sanofi, its Affiliates or its sublicensees to Commercialize the Product in such country without obtaining a license for such Third Party Patent in such country, then Sanofi shall be entitled to a deduction from the royalty payments otherwise due to Vivus upon Net Sales of such Product in the applicable country, of an amount equal to \*\*\* percent (\*\*\*) of the royalty, license fee and/or other amount paid to such Third Party for such license in such country during the applicable reporting period (notwithstanding Section 7.4(e)).

(d) **Generic Competition .**

(i) If, in a country where Sanofi has an obligation to pay Vivus royalties on Net Sales of the Product, (A) Generic Products are being sold by one or more Third Parties who are not Affiliates or sublicensees of Sanofi or otherwise in Sanofi’s, its Affiliate’s or its sublicensee’s chain of distribution, and (B) \*\*\* by \*\*\* for a Calendar Quarter \*\*\* by \*\*\* for such \*\*\* across the \*\*\*, the royalty owed to Vivus for Net Sales of such Product in such country may be reduced by \*\*\* percent (\*\*\*) (subject to Section 7.4(e)), but only for so long as the conditions set forth in subclauses (A) and (B) of this Section 7.4(d)(i) continue to be satisfied.

(ii) If, in a country where Sanofi has an obligation to pay Vivus royalties on Net Sales of the Product, (A) Generic Products are being sold by one or more Third Parties who are not Affiliates or sublicensees of Sanofi or otherwise in Sanofi’s, its Affiliate’s or its sublicensee’s chain of distribution and (B) \*\*\* by \*\*\* for a Calendar Quarter \*\*\* by \*\*\* across the \*\*\* for Net Sales of such Product in such country (subject to Section 7.4(e)), but only for so

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long as the conditions set forth in subclauses (A) and (B) of this Section 7.4(d)(ii) continue to be satisfied.

(iii) Notwithstanding subsections (i) and (ii) above, if one or more Generic Product(s) is/are \*\*\*, then, during any Calendar Quarters in which the \*\*\* in such \*\*\* is \*\*\*. As used herein, “\*\*\*” of the Product means, with respect to a particular country and time period, the \*\*\*, as evidenced by \*\*\*.

(e) **Royalty Floor** . Notwithstanding Sections 7.4(b) and 7.4(d), no reduction in, or deduction or offset against, royalties hereunder shall cause the royalty payable to Vivus hereunder for a given \*\*\* to be less than \*\*\* percent (\*\*\*) of Sanofi and its sublicensees’ Net Sales.

7.5 **Payments to MTPC** . Vivus shall be responsible for paying all milestone, royalty and other payments owed by Vivus to MTPC under the MTPC Agreement on account of the activities of Sanofi or its Affiliates or sublicensees, except that Sanofi shall reimburse Vivus a portion of any sales milestone paid by Vivus to MTPC pursuant to the MTPC Agreement, based on the share of Sanofi’s Net Sales in the worldwide net sales amount reported by Vivus to MTPC triggering the payment of such sales milestone. Such reimbursement shall be made within \*\*\* days following the receipt of an undisputed invoice from Vivus detailing the calculation of such reimbursement. To the extent Sanofi’s reimbursement to Vivus under this Section 7.5 exceeds \$\*\*\* Sanofi may credit any such excess (to the extent actually paid by Sanofi) against any future payments owed by Sanofi under Section 7.3.

7.6 **Quarterly Reports and Payments** . Within \*\*\* days after the end of each \*\*\*, Sanofi shall provide Vivus with a full and accurate accounting for such \*\*\* of (a) satisfaction of any regulatory or sales milestone payment due pursuant to Section 7.2 or Section 7.3; and (b) on a country-by-country basis, the amount of Net Sales and royalty payment due on such Net Sales pursuant to Section 7.4. Vivus shall invoice Sanofi for all royalties and other payment hereunder and Sanofi shall pay all such royalties and other payments that are due no later than \*\*\* days after receipt of the applicable invoice from Vivus, except as otherwise provided in this Agreement. If any portion of a payment owed hereunder is subject to a good faith dispute between the Parties, Sanofi may withhold the disputed portion of such payment, pending resolution of such dispute pursuant to Article 14, provided that it timely pays any undisputed portions. All amounts payable to Vivus under this Section 7.6 shall be paid in United States dollars by wire transfer of immediately available funds into an account designated by Vivus. If Sanofi, its Affiliates or a sub-licensee receives payment from a Third Party in a currency other than United States dollars for which a royalty or fee is owed under this Agreement, then conversion of sales recorded in local currencies to United States dollars shall be performed in a manner consistent with Sanofi’s normal practices used to prepare its audited financial statements for external reporting purposes, which uses a widely accepted source of published exchange rates.

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7.7 **Taxes.** Vivus shall pay any and all Taxes levied on account of any payments made to it under this Agreement. If Sanofi is legally required to withhold any Taxes from payments due hereunder, Sanofi shall (a) deduct such Taxes from the payment made to Vivus, (b) timely pay the taxes to the proper taxing authority, and (c) send proof of payment to Vivus. If Sanofi had a duty to withhold Taxes in connection with any payment it made to Vivus under this Agreement but Sanofi failed to withhold, and such Taxes were assessed against and paid by Sanofi, then Vivus will reimburse Sanofi for such Taxes (excluding interest and penalties), upon delivery by Sanofi of the documents evidencing Sanofi payment of the Taxes and the basis for such payment. Each Party agrees to cooperate with the other Party in claiming exemptions from such deductions or withholdings under any agreement or treaty from time to time in effect. Solely for purposes of this Section 7.7, “ **Taxes** ” means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including interest, penalties and additions thereto) that are imposed by the applicable government or other taxing authority.

7.8 **Late Payments.** If a Party does not receive payment of any sum due to it on or before the due date, simple interest shall thereafter accrue on the sum due to such Party from the due date until the date of payment at the rate of \*\*\* percent (\*\*\*) per month or the maximum annual rate allowable by Applicable Law, whichever is less.

7.9 **Sanofi Records; Audits by Vivus.** Sanofi shall maintain complete and accurate books and records in accordance with IFRS in sufficient detail to permit Vivus to confirm the accuracy of milestone payments, royalty payments, and any other compensation payable under this Agreement for a period of \*\*\* years from the creation of individual records or any longer period required by Applicable Law. At Vivus’ request, such records shall be available for review not more than once each \*\*\* (during normal business hours on a mutually agreed date with reasonable advance notice) at a single location in France by an independent Third Party auditor selected by Vivus and approved by Sanofi (such approval not to be unreasonably withheld, conditioned, or delayed) and subject to confidentiality and non-use obligations no less stringent than those set forth in Article 12 for the sole purpose of verifying for Vivus the accuracy of the financial reports furnished by Sanofi pursuant to this Agreement during the \*\*\* preceding years or of any payments made by Sanofi to Vivus pursuant to this Agreement during the \*\*\* preceding years. Any such auditor shall not disclose Sanofi’s Confidential Information to Vivus, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by Sanofi or the amount of payments due by Sanofi under this Agreement. Any amounts shown to be owed but unpaid shall be paid within \*\*\* days from the accountant’s report, plus interest (as set forth in Section 7.9) from the original due date. Any amounts shown to have been overpaid may be credited by Sanofi against future payments to Vivus hereunder. No payment to Vivus shall be reduced by more than \*\*\* percent (\*\*\*) as a result of such credit, and Sanofi may carry forward any unused credits to future Calendar Quarters. Vivus shall bear the full cost of such audit unless such audit reveals a payment or reporting error of \*\*\* percent (\*\*\*) or more during the applicable audit period, in which case Sanofi shall bear the full cost of such audit.

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7.10 **Vivus Records; Audits by Sanofi.** Vivus shall maintain complete and accurate books and records in accordance with GAAP in sufficient detail to permit Sanofi to confirm the accuracy of Vivus' calculation of any reimbursement payments owed by Sanofi pursuant to Section 7.5 for a period of \*\*\* years from the creation of individual records or any longer period required by Applicable Law. At Sanofi' request, such records shall be available for review not more than once each \*\*\* (during normal business hours on a mutually agreed date with reasonable advance notice) at a single location in the United States by an independent Third Party auditor selected by Sanofi and approved by Vivus (such approval not to be unreasonably withheld, conditioned, or delayed) and subject to confidentiality and non-use obligations no less stringent than those set forth in Article 12 for the sole purpose of verifying for Sanofi the accuracy of Vivus' calculation of any reimbursement payments owed by Sanofi pursuant to Section 7.5 during the \*\*\* preceding years. Any such auditor shall not disclose Vivus' Confidential Information to Sanofi, except to the extent such disclosure is necessary to verify the accuracy of such calculations. Any amounts shown to be owed by Sanofi but unpaid shall be paid within \*\*\* days from the accountant's report, plus interest (as set forth in Section 7.9) from the original due date. Any amounts shown to have been overpaid by Sanofi may be credited by Sanofi against future payments to Vivus hereunder. No payment to Vivus shall be reduced by more than \*\*\* percent (\*\*\*) as a result of such credit, and Sanofi may carry forward any unused credits to future Calendar Quarters. Sanofi shall bear the full cost of such audit unless such audit reveals a calculation error of \*\*\* percent (\*\*\*) or more during the applicable audit period, in which case Vivus shall bear the full cost of such audit.

## **ARTICLE 8 INTELLECTUAL PROPERTY**

8.1 **Ownership of Inventions.** Each Party shall own all Inventions made solely by its or its Affiliates' employees, agents, and independent contractors in the course of conducting its activities under this Agreement (collectively, "**Sole Inventions**"), along with any Patents covering such Sole Inventions. All Inventions that are made jointly by employees, Affiliates, agents, or independent contractors of both Parties in the course of performing activities under this Agreement (collectively, "**Joint Inventions**"), along with any Joint Patents, shall be owned jointly by the Parties. Subject to any exclusive licenses granted pursuant to Section 2.1 or 2.2, each Party shall have the right to practice, license and exploit the Joint Inventions and Joint Patents worldwide, without consent of the other Party (and where consent is required by law, such consent is hereby deemed granted; and the Parties shall execute all instruments and documents and otherwise take all actions as shall be necessary to effectuate such consent ) and without a duty of accounting to the other Party. For the avoidance of doubt, the ownership of Sole Inventions and Joint Inventions shall be determined according to US patent law.

8.2 **Disclosure of Inventions.** Each Party shall promptly disclose to the other all Sole Inventions or Joint Inventions relating to Product or its composition, formulation, manufacture,

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or use, including all invention disclosures or other similar documents submitted to such Party by its Affiliates', employees, agents or independent contractors describing such Sole Inventions or Joint Inventions. Such Party shall also respond promptly to reasonable requests from the other Party for more Information relating to such inventions.

### 8.3 **Prosecution of Patents.**

(a) **Vivus Patents.** Sanofi acknowledges that, under the terms of the MTPC Agreement, MTPC has the sole right to prosecute and maintain the Vivus Patents.

(b) **Joint Patents.** With respect to any potentially patentable Joint Invention, the Parties shall agree whether a Party or any external counsel to be jointly appointed by the Parties (the "**Joint Patent Outside Counsel**"), shall prepare, file, prosecute (including any interferences, reissue proceedings and reexaminations) and maintain patent applications and patents covering such Joint Invention (a "**Joint Patent**") in jurisdictions as mutually agreed by the Parties. Patent expenses for such Joint Patent will be equally shared by the Parties. For clarity, patent expenses include any out-of-pocket expenses (such as, without limitation, the fees of the Joint Patent Outside Counsel), but shall exclude any internal cost (such as salaries) incurred by the Parties. If the Parties do not appoint any Joint Patent Outside Counsel with respect to a Joint Patent: (i) the Party that prosecutes such Joint Patent (the "**Prosecuting Party**") shall provide the other Party reasonable opportunity to review and comment on such prosecution efforts regarding the applicable Joint Patent in the particular jurisdictions and such other Party shall provide the Prosecuting Party reasonable assistance in such efforts; (ii) the Prosecuting Party shall provide the other Party with a copy of all material communications from any patent authority in the applicable jurisdictions regarding the Joint Patent being prosecuted by such Party, and shall provide drafts of any material filings or responses to be made to such patent authorities a reasonable amount of time in advance of submitting such filings or responses; and (iii) the Prosecuting Party shall provide the other Party with all information necessary or desirable to enable the other Party to comply with the duty of candor/duty of disclosure requirements of any patent authority. Either Party may determine that it is no longer interested in supporting the continued prosecution or maintenance of a particular Joint Patent in a country or jurisdiction, in which case the disclaiming Party shall provide the other Party with written notice of such determination at least \*\*\* days before any deadline for taking action to avoid abandonment and shall provide the other Party with the opportunity to have the disclaiming Party's interest in such Joint Patent in such country or jurisdiction assigned to the other Party (the "**Assignee**"); provided that the costs relating to the transfer of rights from the disclaiming Party to the Assignee shall be borne by the disclaiming Party. For the avoidance of doubt, as from the date the other Party's interest in such Joint Patent in such country or jurisdiction is assigned to the Assignee, the Assignee shall bear all cost and expenses relating to the maintenance and prosecution of such Patent in such country or jurisdiction, which shall no longer be deemed to be a Joint Patent for the

purpose of this Agreement.

(c) **Sanofi Patents.** Sanofi shall have the sole right, but not the obligation, to

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prepare, file, maintain and prosecute all Sanofi Patents (and control any interferences, reissue proceedings and reexaminations in connection therewith) in the Sanofi Territory and the Vivus Territory, at its sole cost and expense.

8.4 **Cooperation of the Parties.** Each Party shall provide the other Party all reasonable assistance and cooperation in the preparation, filing, prosecution and maintenance of Patents under Sections 8.3(b) and 8.3(c), at the request and expense of the prosecuting Party. Such cooperation includes, but is not limited to: (i) executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, so as to effectuate the ownership of Inventions set forth in Section 8.1, and Patents claiming or disclosing such Inventions, and to enable the other party to apply for and to prosecute Patent in any country as permitted by Section 8.3 and (ii) promptly informing the other Party of any matters coming to such party's attention that may affect the preparation, filing, prosecution or maintenance of any such Patent.

8.5 **Enforcement of Patents.**

(a) **Notification .** If a Party becomes aware of any infringement, threatened infringement, or alleged infringement of a Vivus Patent, a Sanofi Patent or a Joint Patent on account of a Third Party's manufacture, use or sale of Product (in each case, a **"Product Infringement"** ), then such Party shall promptly notify the other Party in writing of such Product Infringement, including any evidence in such Party's possession demonstrating such Product Infringement. Any certification or filing with a governmental authority that asserts that a Product Infringement will not arise from the manufacture, use or sale of Product by a Third Party or that asserts that any claims of a Vivus Patent, Sanofi Patent or Joint Patent covering Product is invalid or unenforceable shall be deemed to be a Product Infringement hereunder, and each Party shall provide written notice to other Party of any such filed certification promptly upon becoming aware thereof.

(b) **Enforcement Rights .** During the Term and subject to the remainder of this Section 8.5(b), Sanofi shall have the first right to initiate, prosecute and control legal proceedings against any person or entity engaged in a Product Infringement of the Vivus Patents in the Sanofi Territory (the **" Enforcement Right "**). The foregoing exercise of the Enforcement Right shall be at Sanofi's sole expense. If Sanofi decides not to bring such legal action, or if Sanofi fails to initiate such legal action by the Action Date, Vivus shall have the right, but not the obligation, to commence a suit or take action to enforce the applicable Vivus Patent or Joint Patent with respect to such Product Infringement in the Sanofi Territory, at its own expense. Each Party shall provide to the Party enforcing any such rights under this Section 8.5(b) reasonable assistance in such enforcement, at the request of and expense of such enforcing Party, including joining such action as a party plaintiff if required by Applicable Law to pursue such action. Additionally, to the extent requested by Sanofi, Vivus agrees to exercise its right under the MTPC Agreement to require MTPC to cooperate in any enforcement by or on behalf of Sanofi pursuant to Section 8.5(b), including being joined as a party to such action if necessary.

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The enforcing Party shall keep the other Party reasonably and regularly informed of the status and progress of such enforcement efforts, and shall reasonably consider the other Party's comments on any such efforts. The non-enforcing Party shall have the right to be represented in any action brought under this Section 8.5(b) by counsel of its choice and at its own expense. For clarity, as between the Parties, Vivus shall have the exclusive right to bring, control, and/or settle any legal action, at its own expense, as it reasonably determines appropriate and by counsel of its own choice, in connection with any actual, alleged, or threatened infringement of any Patent Controlled by Vivus that occurs in the Vivus Territory. In the event Vivus elects to bring any legal action in connection with any actual, alleged, or threatened infringement of a Vivus Patent that occurs in the Sanofi Territory but is not a Product Infringement, Vivus shall (i) use counsel that is approved by Sanofi, such approval not to be unreasonably withheld, and (ii) prior to bringing any such action in the Sanofi Territory, obtain Sanofi's agreement, not to be unreasonably withheld, on legal strategies and defenses for such action.

(c) **Joint Patents** . With respect to any infringement of a Joint Patent by infringing activity other than a Product Infringement, the Parties shall mutually agree on a case-by-case basis whether to initiate and prosecute any legal action to enforce any such Joint Patent and, if the Parties agree to initiate and prosecute any such action, which party will be responsible for initiating and prosecuting such action, and how costs and recoveries will be allocated between the parties.

(d) **Settlement** . Neither Party shall enter into any settlement or compromise of any action under this Section 8.5 with respect to Product Infringement in the Sanofi Territory without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, in the event that (A) Sanofi decides not to bring a legal action against Product Infringement in the Sanofi Territory, or if Sanofi fails to initiate such legal action by the Action Date, and (B) thereafter MTPC (or a licensee or designee of MTPC other than VIVUS) brings an action under the VIVUS Patents against such Product Infringement, settlement of such action shall be at MTPC's sole discretion and shall not require the consent of Sanofi.

(e) **Recoveries; Damages** . Except as otherwise agreed by the Parties in connection with a cost-sharing arrangement, any recoveries resulting from an action brought by a Party relating to a claim of Product Infringement in the Sanofi Territory shall be first applied against payment of each Party's costs and expenses in connection therewith. Any such recoveries in excess of such costs and expenses (the "**Remainder**") will be retained by the enforcing Party, provided that if Sanofi is the enforcing Party, the Remainder shall be included in Net Sales for purposes of calculating royalties owed to Vivus hereunder.

8.6 **Infringement of Third Party Rights**. Each Party shall promptly notify the other in writing of any allegation by a Third Party that the activity of either of the Parties pursuant to this Agreement infringes or may infringe the intellectual property rights of such Third Party. Subject to Article 10, Vivus shall have the sole right to control any defense of any such claim

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involving alleged infringement of Third Party rights by Vivus' activities at its own expense and by counsel of its own choice. Subject to Article 10, Sanofi shall have the sole right to control any defense of any such claim involving alleged infringement of Third Party rights by Sanofi's activities at its own expense and by counsel of its own choice. Neither Party shall have the right to settle any litigation under this Section 8.6 in a manner that diminishes the rights or interests of the other Party without the written consent of such other party (which shall not be unreasonably withheld).

8.7 **Patent Marking** . Sanofi shall, and shall require its Affiliates and sublicensees, to mark Products sold by it hereunder with appropriate patent numbers or indicia to the extent permitted by Applicable Law.

8.8 **Trademarks.**

(a) **General** . Sanofi shall, at its discretion, have the right to either use any of the Vivus Trademarks or Trademarks selected and owned by Sanofi (the "**Sanofi Trademarks**") with respect to the Manufacture and Commercialization of the Product in the Sanofi Territory. Sanofi shall use Commercially Reasonable Efforts to inform Vivus of its decision within a reasonable timeline. Sanofi may include its company name and associated logos on all Product packaging and Promotional Materials for the Sanofi Territory.

(b) **Vivus Trademarks** . If Sanofi elects to use the Vivus Trademarks to Commercialize the Product across the Sanofi Territory pursuant to Section 8.8(a), the following shall apply:

(i) Sanofi's use of the Vivus Trademarks shall be limited to the Manufacture and the Commercialization of the Product in the Sanofi Territory;

(ii) Sanofi shall not at any time register or cause to be registered any other trademark, name or design confusingly similar to any of the Vivus Trademarks without the express consent of Vivus, which consent shall not be unreasonably withheld, conditioned or delayed;

(iii) Sanofi shall properly designate the Vivus Trademarks on the packaging of the final Product, to the extent required or permissible by the applicable Regulatory Approvals. All rights arising from the use of the Vivus Trademarks in the Sanofi Territory during the Term shall inure to Vivus' benefit. Sanofi agrees that the Products with which the Vivus Trademarks are used shall conform to all requirements of the Regulatory Authority in the Sanofi Territory;

(iv) Vivus shall be responsible for and carry out all proceedings reasonably necessary to ensure the defense of the Vivus Trademarks in the Sanofi Territory during the Term at its own costs and expense;

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(v) Vivus shall use Commercially Reasonable Efforts, at its own costs and expense, to have the Vivus Trademarks registered in all countries of the Sanofi Territory and shall keep Sanofi regularly informed of the completion of such registration process and provide Sanofi with an updated list of Vivus Trademarks numbers;

(vi) Vivus shall use Commercially Reasonable Efforts to maintain the registrations of the Vivus Trademarks in each Country of the Sanofi Territory during the Term at its own costs and expense.

(c) **Infringement of Vivus Trademarks.** If Sanofi elects to use the Vivus Trademarks to Commercialize the Product pursuant to Section 8.8(a), Sanofi shall, as soon as practicable after receiving notice of any potential infringement of a Vivus Trademark in the Sanofi Territory, inform Vivus of any such potential infringement. Vivus shall have the first right and discretion to bring infringement or unfair competition proceedings involving the Vivus Trademark in the Sanofi Territory and Vivus shall bear all costs in connection with any such proceedings. Sanofi shall cooperate with Vivus in any such proceedings at its own expense including by giving testimony and producing documents and materials supporting the Vivus Trademark, and shall endeavour to cause the employees of Sanofi, as appropriate, to cooperate with Vivus, all at Vivus' expense. Any recoveries obtained as a result of any infringement litigation undertaken by Vivus alone or in settlement of such infringement shall be retained by Vivus. Sanofi shall have the right, but shall not be obliged, to participate with Vivus as a party plaintiff in any infringement or unfair competition action undertaken by Vivus hereunder in the Sanofi Territory, at Sanofi's costs and expense, and any recovery obtained shall be shared between Vivus and Sanofi in proportion to incurred expenses, except that any recovery with respect to unfair competition claims in the Sanofi Territory shall be retained solely by Sanofi. Should Vivus fail to institute infringement proceedings in the Sanofi Territory, Sanofi, if it deems necessary, shall have the right but shall not be obligated, to bring suit for such infringement under its name and at its own costs and expenses. Vivus shall cooperate with Sanofi in any such proceedings at its own expense including giving testimony and producing document and material supporting the Vivus Trademark and shall endeavour to cause the employees of Vivus, as appropriate, to cooperate with Sanofi, all at Sanofi's expense. Any recoveries obtained in suit for trademark infringement litigation or in settlement of such infringement undertaken without Vivus' involvement shall be retained by Sanofi.

(d) **Sanofi Trademarks .** To the extent Sanofi elects to use a Sanofi Trademark in addition or, pursuant to Section 8.8 (a), as an alternative to the Vivus Trademarks in connection with the Manufacture and the Commercialization of the Products in the Sanofi Territory, Sanofi shall be responsible for the selection, adoption, registration, maintenance and defense of such Sanofi Trademarks, as well as all expenses associated therewith. Sanofi shall own all Sanofi Trademarks and all rights arising from the use of the Sanofi Trademarks in the Sanofi Territory shall inure to Sanofi's benefit. Sanofi shall also choose at its own discretion the related packaging and trade dress.

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(e) **No Similar Trademarks.** Vivus shall not at any time register or cause to be registered, anywhere in the world, any trademark, name or design identical or confusingly similar to any of the Sanofi Trademarks in the Sanofi Territory or outside of the Sanofi Territory without the express consent of Sanofi. Sanofi shall not at any time register or cause to be registered, anywhere in the world, any other trademark, name or design identical to or confusingly similar to any of the Vivus Trademarks without the express consent of Vivus, which consent shall not be unreasonably withheld, conditioned or delayed.

(f) **Further Acts.** Vivus shall execute, acknowledge and deliver such instruments and do all such other acts as may be necessary or appropriate in order to have this Agreement recorded by any authority operating as a trademark office in the Sanofi Territory or in order to ascertain or confirm Sanofi's right to use the Vivus Trademarks.

(g) **Infringement of Third Party rights by the Vivus Trademarks.** Notwithstanding the provisions of Section 8.6, Vivus shall: (i) defend, through counsel of its choosing, at its own cost and expense, any Claim from a Third Party that claims that the Vivus Trademarks infringe such Third Party's intellectual Property in the Sanofi Territory; (ii) consult with Sanofi, take into consideration Sanofi's comments, incorporate and act on such comments to the extent reasonable in defending against any such Claim; and (iii) release and hold Sanofi, its Affiliates and sublicensees harmless from any liabilities arising from or connected with any such Claim.

## **ARTICLE 9 MTPC AGREEMENT**

9.1 **Representations and Warranties of Vivus with respect to the MTPC Agreement .** Vivus represents and warrants to Sanofi that, as of the Effective Date:

(a) The MTPC Agreement is in full force and effect and has not been modified or amended; and

(b) Neither Vivus nor, to the best of Vivus' knowledge and belief, MTPC, is in default with respect to any obligation under, and neither of Vivus or MTPC has claimed that the other party is in default with respect to any obligation under the MTPC Agreement; and

(c) The rights that MTPC has licensed to Vivus pursuant to the MTPC Agreement are not subject to any contractual restrictions or limitations in the MTPC Agreement (or any other agreement between Vivus and MTPC) that would reasonably be expected to restrict or limit (beyond any restrictions or limitations expressly set forth herein) the rights granted by Vivus to Sanofi pursuant to this Agreement; and

(d) Vivus has not waived or terminated any of its rights under the MTPC

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Agreement, and to Vivus' knowledge, no such rights under the MTPC Agreement have otherwise lapsed, expired, or been terminated.

9.2 **Vivus Obligations with respect to the MTPC Agreement** . Vivus agrees that during the term of this Agreement:

(a) Vivus shall not breach the MTPC Agreement in any matter that would reasonably be expected to adversely affect Sanofi or its rights hereunder; and

(b) Vivus shall not enter into any subsequent agreement with MTPC that modifies or amends the MTPC Agreement in any way that would reasonably be expected to adversely affect Sanofi's rights under this Agreement without Sanofi's prior written consent, and shall provide Sanofi with a copy of all executed modifications to or amendments of the MTPC Agreement, regardless of whether Sanofi's consent was required with respect thereto; and

(c) Vivus shall not terminate, nor take or fail to take any action that would reasonably be expected to terminate, the MTPC Agreement in whole or in part, directly or indirectly, without Sanofi's prior written consent; and

(d) Vivus shall furnish Sanofi with copies of all notices received by Vivus relating to any alleged breach or default of any obligation by Vivus under the MTPC Agreement within \*\*\* after Vivus' receipt thereof.

9.3 **Consequences of Termination of MTPC Agreement; Letter Agreement** . A letter, signed by \*\*\*, addressing \*\*\* is here-attached as Exhibit F to this Agreement (the "**Letter Agreement** "). No further consent of Vivus shall be required for Sanofi to receive the benefit of the Letter Agreement, and Sanofi shall have the right to \*\*\* as a consequence of \*\*\* in the Letter Agreement being \*\*\*.

## **ARTICLE 10 OTHER REPRESENTATIONS, WARRANTIES AND COVENANTS**

10.1 **Mutual Representations and Warranties** . Each Party hereby represents, warrants, and covenants (as applicable) to the other Party as follows, as of the Effective Date:

(a) **Corporate Existence and Power** . It is a corporation or limited partnership, as applicable, duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated or formed, and has all requisite power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including the right to grant the licenses granted by it hereunder.

(b) **Authority and Binding Agreement** . It has the requisite power and

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authority and the legal right to enter into this Agreement and perform its obligations hereunder; it has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and this Agreement has been duly executed and delivered on its behalf, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms, subject as to enforcement of remedies to applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting generally the enforcement of creditors' rights and subject to a court's discretionary authority with respect to the granting of a decree ordering specific performance or other equitable remedies.

(c) **Consents** . All necessary consents, approvals and authorizations of all governmental authorities and other Third Parties required to be obtained by it in connection with the execution, delivery and performance of this Agreement have been obtained by it.

(d) **No Conflict** . The execution and delivery of this Agreement, the performance of such Party's obligations hereunder and the licenses and sublicenses to be granted pursuant to this Agreement (i) do not and will not conflict with or violate any requirement of Applicable Law existing as of the Effective Date, (ii) do not and will not conflict with or violate the certificate of incorporation, certificate of formation, by-laws, limited partnership agreement or other organizational documents of such Party, and (iii) do not and will not conflict with, violate, breach or constitute a default under any contractual obligations of such Party or any of its Affiliates existing as of the Effective Date.

10.2 **Vivus Technology** . Vivus hereby represents and warrants to Sanofi as of the Effective Date that:

(a) Vivus Controls the Vivus Patents in the Sanofi Territory;

(b) Vivus has not granted rights to any Third Party under the Vivus Technology with respect to the Commercialization of the Product in the Field in the Sanofi Territory;

(c) To Vivus' knowledge as of the Effective Date, the manufacture and commercialization of the Product in the Field in the Sanofi Territory does not infringe any valid and enforceable Third Party Patents in the Sanofi Territory.

(d) Vivus has not received any written notice from any Third Party asserting or alleging that the research, development, making or using of the Product by Vivus prior to the Effective Date has infringed or otherwise violated, or that the Commercialization of the Product in the Sanofi Territory will infringe or otherwise violate, the intellectual property rights of such Third Party;

(e) other than the MTPC Agreement, there are no agreements in effect as of the Effective Date between Vivus and a Third Party under which intellectual property right or

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trade secrets within the Vivus Technology are being licensed to Vivus;

(f) Vivus has taken reasonable measures to protect the confidentiality of any confidential Information in the Vivus Know-How;

(g) Vivus has the right to license and disclose the Vivus Know-How to Sanofi as contemplated by this Agreement and Vivus Know-How was not obtained by Vivus in violation of any contractual or fiduciary obligation to which Vivus or any of its employees or staff members are or were bound, or by the misappropriation of the trade secrets of any Third Party;

(h) To Vivus' knowledge, there is no use, infringement or misappropriation of the Vivus Technology in derogation of the rights granted to Sanofi in this Agreement; and

(i) Exhibit C attached hereto accurately and completely identifies all Vivus Patents that have been filed or have issued as of the Effective Date; and

(j) To Vivus' knowledge, each of the Vivus Patents listed in Exhibit C hereto, has been prosecuted in material compliance with all applicable rules, policies and procedures of the jurisdiction in which such Vivus Patent was filed and is subsisting and in good standing. Vivus is not aware of any material prior art or other facts that are likely to render any claims in the Vivus Patents unpatentable, invalid or unenforceable. All renewable and maintenance fees due as of the Effective Date with respect to the prosecution and maintenance of the Vivus Patents have been paid;

(k) Vivus is not a party to any legal Action relating to the Vivus Technology or any Compound or Product, nor has Vivus received any written communication from any Third Party, including, without limitation, any Regulatory Authority or other government agency, threatening such action, suit or proceeding;

(l) To Vivus' knowledge, the research and development of the Compound and Product prior to the Effective Date by Vivus, its Affiliates, Service Providers and any Third Party, was conducted in compliance, in all material respects, with all applicable laws and regulations, including all public health, environmental and safety provisions thereof;

(n) To Vivus' knowledge, all of the Information that Vivus has provided to Sanofi prior to the Effective Date relating to the Product is materially accurate, and Vivus has not omitted therefrom any material data or material Information in Vivus' possession or Control prior to the Effective Date relating to the Product that Vivus reasonable believes would be material to Sanofi's decision to enter into this Agreement.

10.3 **Vivus Trademarks** . Vivus hereby represents and warrants to Sanofi as of the Effective Date that:

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- (a) it has all right, title, and interest in and to the Vivus Trademarks existing on the Effective Date;
- (b) it has pending registrations for the Vivus Trademarks in Algeria, Bahrain, Kuwait, Oman, Qatar, Russia, Saudi Arabia, Turkey, and the United Arab Emirates;
- (c) to the best knowledge of Vivus, there is no Third Party using or infringing any of the Vivus Trademarks in the Sanofi Territory in material derogation of the rights granted to Sanofi in this Agreement;
- (d) Vivus has not received notice of any opposition, cancellation action or pending litigation or any communication which expressly threatens an opposition or cancellation action, or other litigation, before any trademark office, court or any other governmental entity in the Sanofi Territory with respect to any of the Vivus Trademarks;
- (e) the Vivus Trademarks are the only Trademarks owned, held, Controlled, licensed or otherwise used (or intended to be used) by Vivus or its Affiliates with respect to the Product in the Field in the Sanofi Territory (other than Vivus' corporate name and/or logo);
- (f) to the best knowledge of Vivus, Vivus has all rights to use the Vivus Trademarks with respect to the Product in the Sanofi Territory and to license the Vivus Trademarks to Sanofi hereunder; and
- (g) to the best knowledge of Vivus, Vivus has not infringed, misappropriated, diluted or otherwise violated any Trademark of any Third Party by registering or using the Vivus Trademarks in the Sanofi Territory; and
- (h) to the knowledge of Vivus, no claims or proceedings, asserting that the Vivus Trademarks infringe the right of any Third Party, are pending or threatened.

10.4 **Compliance with Law** . Each Party shall, and shall ensure that its Affiliates and sublicensees shall, comply with all Applicable Laws in exercising their rights and fulfilling their obligations under this Agreement.

10.5 **Representations regarding Debarment and Compliance.**

- (a) Each Party represents warrants and covenants that as of the Effective Date and during the Term, neither it nor its Affiliates nor any of their respective directors, officers, employees, to its knowledge based upon reasonable inquiry:
  - (i) is debarred under Section 306(a) or 306(b) of the FD&C Act or under any similar Applicable Laws;

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(ii) has been charged with, or convicted of, any felony or misdemeanor under Applicable Laws related to any of the following: (A) the development or approval of any drug product or the regulation of any drug product under the FD&C Act; Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, the national laws of individual EU Member States implementing the provisions of these Directives into their national law, Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, or any similar Applicable Laws; (B) a conspiracy to commit, aid or abet the development or approval of any drug product or regulation of any drug product; (C) health care program-related crimes (involving Medicare, any state health care program, or any healthcare program in any country in the European Union or the Sanofi Territory) or provision of illegal inducements to physicians or healthcare institutions to recommend, endorse, prescribe, order, supply, purchase, use or administer any drug product; (D) patient abuse, controlled substances, bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records; (E) interference with, obstruction of an investigation into, or prosecution of, any criminal offense; or (F) a conspiracy to commit, aid or abet any of these listed felonies or misdemeanors; and

(iii) is excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any United States federal or state health care programs (including convicted of a criminal offense that falls within the scope of 42 U.S.C. §1320a-7 but not yet excluded, debarred, suspended, or otherwise declared ineligible), excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any healthcare program in any country in the European Union or the Sanofi Territory, or excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any United States federal procurement or non-procurement programs or procurement or non-procurement programs in any country in the European Union or the Sanofi Territory.

(b) Each Party will notify the other Party promptly, but in no event later than \*\*\* days, after knowledge of any exclusion, debarment, suspension or other ineligibility set forth in Section 10.5(a)(iii) occurring during the Term, or if such Party concludes based on its good faith business judgment that a pending action or investigation is likely to lead to the exclusion, debarment, suspension or other

ineligibility of such Party an Affiliate of such Party or any of such Party's or such Party's Affiliates' directors, officers, employees, or consultants.

10.6 **Representations Regarding Anti-Bribery Laws** . Each Party represents and warrants that, on or before the Effective Date, to its knowledge based upon reasonable inquiry , neither it, its Affiliates nor any of their respective directors, officers, employees: (a) has made or

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agreed any payment or any offer or promise for payment, either directly or indirectly, of money or other assets, or transfer anything of value (a "Payment"), to government or political party officials (where "government official" shall, for purposes of this Section 10.6, include without limitation health care providers in state-run hospitals and health care systems and decision-makers in state-owned or -controlled enterprises) , officials of international organizations, candidates for public office, or representatives of other businesses or persons action on behalf of any of the foregoing for the purpose of influencing decisions or actions or where such Payment would constitute violation of any applicable Anti-Bribery Laws; and (b) has accepted any Payment for the purpose of influencing any decisions or actions to help anyone (including but not limited to any of the Parties) obtain or maintain business where such Payment would constitute violation of any Anti-Bribery Laws. Each Party covenants that during the Term, it will ensure that neither it, its Affiliates, nor any of their respective directors, officers and employees will make, agree to, offer or accept any of the Payment described in (a) and (b).

10.7 **No Other Representations or Warranties** . EXCEPT FOR THE EXPRESS WARRANTIES THAT ARE EXPLICITLY SET FORTH IN ARTICLE 9 AND THIS ARTICLE 10, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, IS MADE OR GIVEN BY OR ON BEHALF OF A PARTY. ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

## **ARTICLE 11 INDEMNIFICATION**

11.1 **Indemnification by Vivus.** Vivus shall defend, indemnify, and hold harmless Sanofi, its Affiliates, and their respective officers, directors, employees, consultants and authorized agents and their respective successors and assigns or heirs, as the case may be (the "**Sanofi Indemnitees**") from and against any and all Losses to the extent resulting from any Claim of a Third Party against such Sanofi Indemnitee based on or arising out of:

(a) any misrepresentation or breach of any of Vivus' representations, warranties, covenants or obligations under this Agreement \*\*\*; or

(b) the negligence or willful misconduct of, or violation of Applicable Law by, Vivus, its Affiliates, licensees, licensors, distributors or their respective officers, directors, employees, consultants or authorized agents under this Agreement \*\*\*; or

The foregoing indemnity obligations shall not apply to the extent that the Losses of such Sanofi Indemnitee were caused by: (i) a breach of any of Sanofi's representations, warranties, covenants,

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or obligations under this Agreement; or (ii) the negligence or willful misconduct of, or violation of Applicable Law by any Sanofi Indemnitee.

11.2 **Indemnification by Sanofi.** Sanofi shall defend, indemnify and hold harmless Vivus, its Affiliates, and their respective officers, directors, employees, consultants and authorized agents and their respective successors and assigns or heirs, as the case may be (the “**Vivus Indemnitees**” ) from and against any and all Losses to the extent resulting from any Claim of a Third Party against such Vivus Indemnitee based on or arising out of:

- (a) any misrepresentation or breach of any of Sanofi’s representations, warranties, covenants or obligations under this Agreement; or
- (b) the negligence or willful misconduct of, or violation of Applicable Law by, Sanofi, its Affiliates, licensees, distributors or their respective officers, directors, employees, consultants or authorized agents under this Agreement.
- (c) the Commercialization of any Product by Sanofi, its Affiliates, and sublicensees.

The foregoing indemnity obligation shall not apply to the extent that the Losses of such Vivus Indemnitee were caused by: (i) a breach of any of Vivus’ representations, warranties, covenants, or obligations under the Agreement \*\*\*; or (ii) the negligence or willful misconduct of, or violation of Applicable Law by any Vivus Indemnitee.

11.3 **Indemnification Procedures.** The Party claiming indemnity under this Article 11 (the “**Indemnified Party**” ) shall give written notice to the Party from whom indemnity is being sought (the “**Indemnifying Party**” ) as soon as reasonably practicable after learning of a written Claim (“ **Indemnified Claim** ”). Failure by an Indemnified Party to give notice of an Indemnified Claim as soon as reasonably practicable after receiving a writing reflecting such Claim shall not relieve the Indemnifying Party of its indemnification obligations hereunder except and solely to the extent that such Indemnifying Party is actually prejudiced as a result of such failure to give such notice. The Indemnifying Party shall have the right to assume the conduct and defense of the Indemnified claim with counsel of its choice. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance in connection with the defense of the Indemnified Claim. The Indemnified Party may monitor such defense with counsel of its own choosing at its sole expense. The Indemnifying Party may not settle the Indemnified Claim without the prior written consent of the Indemnified Party, such consent shall not be unreasonably withheld, delayed or conditioned. If the Indemnifying Party does not assume and conduct the defense of the Indemnified Claim as provided above: (a) the Indemnified Party may assume and conduct the defense of the Indemnified claim at the Indemnifying Party’s expense; (b) the Indemnified Party may consent to the entry of any judgment or enter into any settlement with respect to the Indemnified Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party

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in connection therewith); and (c) the Indemnifying Party will remain responsible to indemnify the Indemnified Party for Losses as provided in this Article 11.

11.4 **Limitation of Liability.** NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY EXEMPLARY, SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES, COSTS OR EXPENSES (INCLUDING LOST PROFITS, LOST REVENUES AND/OR LOST SAVINGS) ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 11.4 IS INTENDED TO OR SHALL LIMIT OR RESTRICT (A) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY IN CONNECTION WITH THIRD PARTY CLAIMS UNDER SECTION 11.1 OR 11.2, (B) DAMAGES AVAILABLE FOR A PARTY'S BREACH OF ARTICLE 2, OR THE \*\*\* AVAILABLE FOR SANOFI AS SET FORTH IN SECTION 6.2 OR (C) DAMAGES TO THE EXTENT ARISING FROM OR RELATING TO WILLFUL MISCONDUCT OR FRAUDULENT ACTS OR OMISSIONS OF A PARTY.

11.5 **Insurance.** Each Party shall procure and maintain insurance (or self-insure) adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situated. Such insurance shall be written by insurance companies of good international reputation. Without limiting the generality of the foregoing, Sanofi's insurance shall include, at minimum, the following coverages:

- (a) commercial general liability coverage with minimum per claim limits of at least \$\*\*\* per occurrence and \$\*\*\* annual aggregate;
- (b) excess liability/umbrella coverage with minimum per claim limits of at least \$\*\*\* per occurrence and annual aggregate;
- (c) products liability coverage with minimum per claim limits of at least \$\*\*\* per occurrence and annual aggregate; and

It is understood that the insurance requirements above shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 11. Each Party shall provide the other Party with written evidence of such insurance upon request.

## **ARTICLE 12 CONFIDENTIALITY**

12.1 **Confidentiality.** Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each Party agrees that, for the Term and for \*\*\* years thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement any Confidential Information of the

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other Party except for that portion of such information or materials that the receiving Party can demonstrate by competent proof:

- (a) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure by the other Party;
- (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;
- (c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;
- (d) is subsequently disclosed to the receiving Party or its Affiliate by a Third Party without obligations of confidentiality with respect thereto; or
- (e) is subsequently independently discovered or developed by the receiving Party or its Affiliate without the aid, application, or use of Confidential Information.

Notwithstanding the foregoing, the receiving Party may disclose without violation of this Agreement such portion of the Confidential Information as is required or permitted to be disclosed if, on the advice of counsel, it is required under Applicable Law or pursuant to legal process to disclose such Confidential Information of the other Party; provided that unless otherwise prohibited by Applicable Law, the receiving Party first advises the disclosing Party of such intended disclosure and provides the disclosing Party with the opportunity to seek appropriate judicial or administrative relief to avoid, or obtain confidential treatment of, such disclosure at the disclosing Party's sole cost and expense.

The confidentiality provisions set forth herein shall supersede and replace the Existing Confidentiality Agreement and shall be deemed to cover all confidential information disclosed or obtained under the Existing Confidentiality Agreement.

12.2 **Authorized Disclosure.** Each Party may disclose Confidential Information belonging to the other Party to the extent such Party determines such disclosure is reasonably necessary in the following situations:

- (a) prosecuting or defending litigation relating to this Agreement;
- (b) in the case of Vivus, disclosure to MTPC as required pursuant to the MTPC Agreement;
- (c) in the case of Vivus as the receiving Party, disclosure to its licensees, sublicensees, and collaborators with respect to the Product outside the Sanofi Territory or outside the Field, but solely to the extent that such Confidential Information (i) raises any material

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concerns regarding the safety of any Product; (ii) indicates or suggests a potential material liability of either Vivus or the applicable licensee, sublicensee, or collaborator to Third Parties in connection with any Product; (iii) is reasonably likely to lead to a recall or market withdrawal of any Product; or (iv) relates to any Product and is reasonably likely to have a material impact on a Regulatory Approval of any Product in such licensee's, sublicensee's, or collaborator's territory; *provided* that each such disclosee must be bound by obligations of confidentiality and non-use no less stringent than those set forth in Sections 12.1 and 12.2 prior to any such disclosure and further provided that Vivus shall cause any of its licensees to commit to the same obligations and shall disclose to Sanofi any confidential information received from any licensee of the Vivus Technology in order to enable Sanofi, its Affiliates and licensees to address adequately the situations set forth in the sub-sections (i) to (iv) of this Section 12.2 (c);

(d) disclosure to its and its Affiliates' respective directors, officers, employees, consultants, attorneys, professional advisors, lenders, insurers, Service Providers and sublicensees only on a need-to-know basis and solely as necessary in connection with this Agreement, provided that each disclosee must be bound by obligations of confidentiality and non-use no less stringent than those set forth in Sections 12.1 and 12.2 prior to any such disclosure; and

(e) disclosure to any bona fide potential or actual investor, acquirer, merger partner, or other potential or actual financial partner (and/or their respective consultants, attorneys, professional advisors) on a need-to-know basis and solely for the purpose of evaluating a potential investment, acquisition, merger, or similar transaction; provided that each disclosee must be bound by obligations of confidentiality and non-use no less stringent than those set forth in Sections 12.1 and 12.2 prior to any such disclosure. The receiving Party shall be liable for any breach of such confidentiality and non-use obligations by any such Third Party.

### 12.3 **Publicity; Terms of Agreement.**

(a) The Parties agree that the material terms of this Agreement are the Confidential Information of both Parties, subject to the authorized disclosure provisions set forth in Section 12.2 and this Section 12.3.

(b) Each Party shall have the right to make an individual public announcement of the execution of this Agreement, the content and timing of which shall be mutually agreed upon by the Parties. After release of the press release announcing this Agreement, if either Party desires to make a public announcement concerning the material terms of this Agreement, such Party shall give reasonable prior advance notice of the proposed text of such announcement to the other Party for its prior review and approval, such approval not to be unreasonably withheld, conditioned or delayed. A Party commenting on such a proposed press release shall provide its comments, if any, within \*\*\* after receiving the press release for review. Neither Party shall be required to seek the permission of the other Party to disclose any information already disclosed or otherwise in the public domain, provided such information

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remains accurate.

(c) Vivus may publicly disclose without violation of this Agreement, such terms of this Agreement as are, on the advice of Vivus' counsel, required by the rules and regulations of the SEC or any other applicable entity having regulatory authority over Vivus' securities; provided that Vivus advises Sanofi of such intended disclosures and requests confidential treatment of certain commercial terms and technical terms hereof to the extent such confidential treatment is reasonably available to Vivus. In the event of any such filing, Vivus will provide Sanofi, a reasonable time prior to filing, with a copy of the Agreement marked to show provisions for which Vivus intends to seek confidential treatment and shall reasonably consider and incorporate Sanofi's comments thereon to the extent consistent with the legal requirements applicable to Vivus and that govern redaction of information from material agreements that must be publicly filed. Sanofi shall provide any such comments as promptly as practicable.

### **ARTICLE 13 TERM AND TERMINATION**

13.1 **Term.** This Agreement shall commence as of the Effective Date and, unless sooner terminated as provided hereunder, shall expire as follows:

(a) As to the Product in each country in the Sanofi Territory, this Agreement shall expire upon the expiration of the Royalty Payment Term with respect to such Product in such country; provided, however, that Sanofi's obligation under Section 7.5 to reimburse Vivus for Sanofi's pro-rata share of any sales milestone paid by Vivus to MTPC shall survive if such sales milestone has not yet come due (with such pro-rata share being based on Sanofi's pre-termination Net Sales); and

(b) This Agreement shall expire in its entirety upon the expiration of all royalty payment obligations arising under Section 7.4 of this Agreement with respect to the Product in all countries in the Sanofi Territory.

13.2 **Effect of Expiration** . Following the expiration of this Agreement pursuant to Section 13.1, Sanofi shall have the royalty-free, fully paid-up, perpetual right, under the Vivus Technology and the Vivus Trademarks to: (i) Manufacture or have Manufactured the Product inside and outside of the Sanofi Territory and (ii) Commercialize the Product in the Sanofi Territory.

13.3 **Termination by Either Party for Cause.**

(a) **Breach.** Either Party shall have the right to terminate this Agreement upon written notice to the other Party if such other Party, after receiving written notice from the terminating Party identifying a material breach by such other Party of its obligations under this Agreement, fails to cure such material breach within \*\*\* from the date of such notice (or, if such

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material breach cannot be cured within such \*\*\* period, if the non-terminating party does not commence and diligently continue actions to cure same during such \*\*\* period), or, in the case of payment obligations, \*\*\* from the date of such notice. For the avoidance of doubt (and without limiting Vivus' remedies for any other breaches by Sanofi), Sanofi's uncured failure to pay the amounts set forth in Section 7.1 or Section 7.2 shall be deemed to be a material breach of this Agreement.

(b) **Government Action.** Vivus shall have the right to terminate this Agreement immediately upon written notice to Sanofi on a country by country basis if either of the following occurs: (i) Sanofi is subject to investigation or any enforcement actions by the competent authorities in any country in the Sanofi Territory for violation of the Applicable Laws governing the promotion of drug products in Sanofi Territory; or (ii) Sanofi is excluded from participation in a healthcare program in any country in the Sanofi Territory.

13.4 **Termination for Patent Challenge.** Vivus may terminate this Agreement in its entirety upon written notice to Sanofi if Sanofi or any Affiliate, directly or indirectly, individually or in association with any other person or entity, commences any action or proceeding that challenges the validity, enforceability or scope of any Vivus Patent in the Sanofi Territory or the Vivus Territory. In the event Sanofi is aware that a sublicensee of its license rights hereunder, directly or indirectly, individually or in association with any other person or entity, commences any action or proceeding that challenges the validity, enforceability or scope of any Vivus Patent in the Sanofi Territory or the Vivus Territory, Sanofi shall promptly terminate the applicable sublicense. If Sanofi does not terminate such sublicense within \*\*\* of Sanofi becoming aware of such challenge, Vivus may terminate this Agreement in its entirety upon written notice to Sanofi.

13.5 **Termination by Sanofi for Convenience** . Sanofi shall have the right to terminate this Agreement in whole or on a country-by-country basis, for convenience, at any time during its term upon \*\*\* prior written notice to Vivus.

13.6 **Alternative to Termination by Sanofi for Vivus' Breach.** In the event that Vivus defaults with respect to any of its material obligations under this Agreement and does not cure such default within \*\*\* after the receipt of a notice from Sanofi specifying the nature of, and requiring the remedy of, such default (or, if such default cannot be cured within such \*\*\* period, if Vivus does not commence and diligently continue actions to cure same during such \*\*\* period), then Sanofi may, in lieu of terminating this Agreement in its entirety as provided in Section 13.3(a), elect to continue this Agreement in full force and effect except, upon written notice to Vivus of Sanofi's election under this Section 13.6, as follows:

(a) Vivus shall have no further rights to receive reports pursuant to Section 4.8; and

(b) Sanofi shall have the right to set off, against any payments or other amounts due by Sanofi but not paid to Vivus, all direct damages that have been suffered by

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Sanofi in whole or in part due to the default that gave rise to Sanofi's election under this Section; *provided however*, that any set off shall only apply with respect to any undisputed amount of such damages.

13.7 **Termination Upon Bankruptcy** . Either Party shall have the right to terminate this Agreement immediately by providing written notice, if: (a) the other Party applies for or consents to the appointment of a receiver, trustee, liquidator or custodian of itself or of all or a substantial part of its assets, (b) the other Party makes a general assignment for the benefit of its creditors, (c) the other Party is dissolved or liquidated in full or in substantial part, (d) the other Party is the subject of voluntary or involuntary bankruptcy proceedings instituted on behalf of or against such other Party (except for involuntary bankruptcy proceedings which are dismissed within \*\*\*), or (e) the other Party takes any corporate action for the purpose of effecting any of the foregoing.

13.8 **Effect of Early Termination of the Agreement**. Upon early termination of this Agreement pursuant to Section 13.7 or early termination by Vivus pursuant to Sections 13.3 or 13.4 or by Sanofi pursuant to Sections 13.3 or 13.5, the following shall apply (in addition to any other rights and obligations under Sections 13.9-13.13 or otherwise under this Agreement with respect to such termination) :

(a) The licenses granted to Sanofi under Section 2.1 and the license granted to Vivus under Section 2.2(a)(i) shall terminate, subject to Section 13.9 (and, as between the Parties, all rights in the Vivus Technology and the Vivus Trademark shall revert to Vivus, and all rights in the Sanofi Technology shall revert to Sanofi, subject to the licenses granted to Vivus under Section 2.2(a)(ii) and, if applicable, Section 13.8(c));

(b) Except in the cases of termination by Sanofi pursuant to Sections 13.3 or 13.7, to the extent permitted by Applicable Law, Sanofi shall transfer and assign to Vivus all Regulatory Materials and Regulatory Approvals with respect to Product that are Controlled by Sanofi or its Affiliates, if any;

(c) Except in the cases of termination by Sanofi pursuant to Sections 13.3 or 13.7, Sanofi shall grant to Vivus a non-exclusive, royalty-free license under the Sanofi Technology solely as may be necessary for the Development and Commercialization of the Product by Vivus in the Sanofi Territory;

(d) Except in the cases of termination by Sanofi pursuant to Sections 13.3 or 13.7, Sanofi shall grant to Vivus an exclusive, royalty-free license under any Sanofi Trademark, to Commercialize the Product in any country of the Sanofi Territory where such Sanofi Trademark is used;

(e) Except in the cases of termination by Sanofi pursuant to Sections 13.3 or 13.7, Sanofi shall provide reasonable assistance, at no cost to Vivus, as may be reasonably necessary for Vivus to commence or continue Developing and Commercializing the Product in

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the Sanofi Territory, including without limitation, upon request of Vivus, using reasonable efforts to (A) transfer any agreements or arrangements with distributors that apply solely to the sale or supply of Product in the Sanofi Territory; and (B) amend any agreement or arrangements with distributors that apply both to the sale or supply of the Product in the Sanofi Territory and to the sale or supply of other products, so as to transfer to Vivus the rights solely with respect to Product in the Sanofi Territory; and

(f) all sublicenses granted by Sanofi to Affiliates or Third Parties under the Vivus Technology shall immediately terminate.

13.9 **Right to Sell Stock on Hand** . Provided that Sanofi is not in material breach of any obligation under this Agreement at the time of any termination of this Agreement, Sanofi shall have the right for \*\*\* thereafter to dispose of all quantities of Product then in its inventory and to complete Manufacture of and dispose of any work-in-progress then being Manufactured, as though this Agreement had not terminated. Sanofi shall pay royalties thereon, in accordance with the provisions of this Agreement, as though this Agreement had not terminated. Notwithstanding the foregoing, Vivus shall have the right, at any time following termination, to purchase from Sanofi any or all of such Product and work-in-progress at the manufacturing cost therefor.

13.10 **Certain Pre-Termination Liabilities** . Following termination of this Agreement, Sanofi shall retain liability for payment of all gross to net sales deductions (including returns, rebates and chargeback) of Products that were sold prior to the effective date of termination (or during the post-termination sales period contemplated under Section 13.9). To the extent that that any such deductions are charged to or otherwise borne by Vivus, Sanofi shall reimburse Vivus promptly (but in any event no later than \*\*\* days) following Sanofi's receipt of an invoice therefor.

13.11 **Sales Volume** . Sanofi shall use commercially reasonable efforts to ensure that the average monthly sales volume of each Product leading up to the effective date of termination (or if applicable, the end of \*\*\* period pursuant to Section 13.9) does not substantially exceed the average monthly sales volume of such Product for the \*\*\* period prior to date of the notice of termination, and in any event Sanofi shall not take any affirmative action to cause such outcome.

13.12 **Accrued Liabilities; Other Remedies**. Termination or expiration of this Agreement for any reason shall not release either Party from any liability or obligation that already has accrued prior to such expiration or termination (including any milestone or other payment that has been triggered by an event occurring prior to the effective date of termination or expiration), nor affect the survival of any provision hereof to the extent it is expressly stated to survive such termination. Termination or expiration of this Agreement for any reason shall not constitute a waiver or release of, or otherwise be deemed to prejudice or adversely affect, any rights, remedies or claims, whether for damages or otherwise, that a Party may have hereunder or that may arise out of or in connection with such termination or expiration.

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13.13 **Survival**. The following provisions shall survive any expiration or termination of this Agreement for the period of time specified: Section 2.2(a) (ii), 2.2(b), 4.9, 7.9, 7.10, 8.1, 13.2, 13.8, 13.9, 13.10, 13.12, and 13.13; Articles 11, 12, 14, and 15; and any necessary definitions in Article 1.

## **ARTICLE 14 DISPUTE RESOLUTION**

14.1 **Governing Law**. Resolution of all disputes arising out of or related to this Agreement or the validity, construction, interpretation, enforcement, breach, performance, application or termination of this Agreement and any remedies relating thereto, shall be governed by and construed under the substantive laws of the State of New York, United States of America, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

14.2 **Disputes** . The Parties recognize that disputes as to certain matters may from time to time arise during the Term which relate to either Party's rights and/or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to meet and discuss in good faith any disputes, controversies or differences which may arise between the Parties out of or in relation to or in connection with this Agreement, including any alleged failure to perform, or breach, of this Agreement, or any issue relating to the interpretation or application of this Agreement. Such good faith efforts shall include at least one in-person meeting between the chief executive officers of each Party. If the matter is not resolved within \*\*\* following the request for discussions, either Party may then invoke the provisions of Section 14.3.

### **14.3 Arbitration.**

(a) **Claims**. Subject to Section 14.4 below, any claim, dispute, or controversy of whatever nature arising out of or relating to this Agreement that is not resolved under Section 14.1 within the required \*\*\* period, including, without limitation, any Claim concerning the interpretation, effect, termination, validity, performance and/or breach of this Agreement shall be resolved by final and binding arbitration administered by the International Chamber of Commerce ("ICC"). The arbitration and all associated discovery proceedings and



communications shall be conducted in English, and the arbitration shall be held in New York, New York, USA.

(b) **English Language** . All proceedings shall be held in English and a transcribed record prepared in English. Documents submitted in the arbitration (the originals of which are not in English) shall be submitted together with a reasonably complete and accurate English translation.

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(c) **Selection of Arbitrators** . The Parties shall each choose one arbitrator within \*\*\* days of receipt of notice of the intent to arbitrate and the said two arbitrators shall select by mutual agreement a third arbitrator within \*\*\* days after they have been selected as arbitrators. If no arbitrator is appointed within the times herein provided or any extension of time that is mutually agreed on, the ICC shall make such appointment (i.e. shall appoint three arbitrators) within \*\*\* days of such failure.

(d) **Arbitrators' Award**. The arbitrators' award shall include a written statement describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The arbitrator shall, in rendering his or her decision, apply the substantive laws of the State of New York, without giving effect to its conflicts of laws principles. The arbitrators' authority to award special, incidental, consequential or punitive damages shall be subject to the limitation set forth in Section 11.4. The award rendered by the arbitrators shall be final, binding and non-appealable, and judgment may be entered upon it in any court of competent jurisdiction.

(e) **Costs**. Each Party shall bear its own attorney's fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the arbitrators; *provided, however*, the arbitrators shall be authorized to determine whether a Party is the prevailing party, and if so, to award to that prevailing party reimbursement for any or all of its reasonable attorneys' fees, costs and disbursements (including, for example, expert witness fees and expenses, photocopy charges, travel expenses, *etc.* ), and/or the fees and costs of the ICC and the arbitrators.

14.4 **Court Actions**. Nothing contained in this Agreement shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a *bona fide* emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing discussions between the Parties or any ongoing arbitration proceeding. In addition, either Party may bring an action in any court of competent jurisdiction to resolve disputes pertaining to the validity, construction, scope, enforceability, infringement or other violations of Patents or other intellectual property rights, and no such claim shall be subject to arbitration pursuant to Section 14.2.

## ARTICLE 15 MISCELLANEOUS

15.1 **Entire Agreement; Amendment** . This Agreement, including the Exhibits hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior agreements and understandings between the Parties with respect to the subject matter hereof, including the Existing Confidentiality Agreement. The foregoing shall not be interpreted as a waiver of any remedies available to either Party as a result of any breach, prior to the Effective

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Date, by the other Party of its obligations pursuant the Existing Confidentiality Agreement. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

15.2 **Force Majeure** . Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall mean conditions beyond the control of the Parties, including an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, and failure of plant or machinery (provided that such failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances). Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a force majeure affecting such Party.

15.3 **Notices**. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 15.3, and shall be deemed to have been given for all purposes when received, if hand-delivered or by means of facsimile or other electronic transmission, or one Business Day after being sent by a reputable overnight delivery service.

If to Vivus:                   Vivus, Inc.  
351 E. Evelyn Avenue  
Mountain View, CA 94041  
Attention: General Counsel  
Fax: +1 (650) 934-5389

With a copy to:               Hogan Lovells US LLP  
4085 Campbell Ave.  
Suite 100  
Menlo Park, CA 94025  
Attention: Shane Albright  
Fax: +1 (650) 463-4199

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If to Sanofi: Sanofi  
54 rue La Boétie  
75008 Paris, France  
Attention: Vice-President Corporate Licensing  
Fax: +33 (1) 53 77 46 76

With a copy to: Sanofi  
54 rue La Boétie  
75008 Paris, France  
Attention: General Counsel  
Fax: +33 (1) 53 77 43 03

15.4 **No Strict Construction; Headings; Interpretation.** This Agreement has been prepared jointly and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section. The definitions of the terms herein apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun will include the corresponding masculine, feminine and neuter forms. The words “include”, “includes” and “including” will be deemed to be followed by the phrase “without limitation.” Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (b) any reference to any laws herein will be construed as referring to such laws and any rules or regulations promulgated thereunder as from time to time enacted, repealed or amended, (c) any reference herein to any person will be construed to include the person’s successors and assigns, (d) the words “herein”, “hereof” and “hereunder”, and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (e) any reference herein to the words “mutually agree” or “mutual written agreement” will not impose any obligation on either Party to agree to any terms relating thereto or to engage in discussions relating to such terms except as such Party may determine in such Party’s sole discretion, except as expressly provided in this Agreement, (f) as applied to a Party, the word “will” shall be construed to have the same meaning and effect as the word “shall,” and (g) all references herein without a reference to any other agreement to Articles, Sections, or Exhibits will be construed to refer to Articles, Sections, and Exhibits of or to this Agreement.

15.5 **Assignment** . Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that a Party may make such an assignment without the other Party’s consent to such Party’s Affiliate or to a

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successor to all or substantially all of the assets or business of such Party to which this Agreement pertains. Any permitted successor or assignee of rights and/or obligations hereunder shall, in a writing to the other Party, expressly assume performance of such rights and/or obligations. Notwithstanding any assignment of this Agreement, the assigning Party shall remain liable for performance of its obligations hereunder, unless the non-assigning Party agrees otherwise in writing. The Vivus Technology shall exclude any intellectual property held or developed by a permitted successor of Vivus prior to the transaction in which it became a successor of such Party, and the Sanofi Technology shall exclude any intellectual property held or developed by a permitted successor of Sanofi prior to the transaction in which it became a successor of such Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 15.5 shall be null, void and of no legal effect.

**15.6 Records Retention .** Each of Vivus and Sanofi will maintain complete and accurate records pertaining to its activities under this Agreement, including records pertaining to Development or Commercialization of any Products and reports and information provided to any Regulatory Authority or other governmental authority, in accordance with Applicable Law. Each of Vivus and Sanofi will retain such records for a duration prescribed by Applicable Law, but not in any event for less than \*\*\* years after the Effective Date (or longer if a Party is notified, ordered or otherwise required to maintain such records for a longer period in connection with a legal proceeding or government investigation).

**15.7 No Solicitation .** During \*\*\* years following the Effective Date, neither Sanofi nor any of its Affiliates will solicit or endeavor to entice away from Vivus or its Affiliates, hire, or offer employment to, any person or entity who is, or was within the \*\*\* period immediately prior thereto, employed by Vivus or its Affiliates, or otherwise interfere with any such person's relationship with Vivus or its Affiliates; provided, however, that this restrictive covenant shall not prohibit Sanofi or its Affiliates from making any general solicitation for employees or engaging in public advertising of employment opportunities (including through the use of employment agencies) not specifically directed to any of Vivus' or its Affiliates' respective directors, officers or employees.

**15.8 Successors and Assigns; No Third Party Beneficiaries .** This Agreement will be binding upon and inure to the benefit of the Parties and their successors and permitted assigns. No provision of this Agreement, express or implied, is intended to or will be deemed to confer upon Third Parties any right, benefit, remedy, claim, liability, reimbursement, claim of action or other right of any nature whatsoever under or by reason of this Agreement other than the Parties and, to the extent provided in Sections 11.1 and 11.2, the Indemnified Parties. Without limitation, this Agreement will not be construed so as to grant employees of either party in any country any rights against the other Party pursuant to the laws of such country.

**15.9 Performance by Affiliates .** Any obligation of Vivus under or pursuant to this Agreement may be satisfied, met or fulfilled, in whole or in part, at Vivus' sole and exclusive option, either by Vivus directly or by any Affiliate of Vivus that Vivus causes to satisfy, meet or

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fulfill such obligation, in whole or in part. Any obligation of Sanofi under or pursuant to this Agreement may be satisfied, met or fulfilled, in whole or in part, at Sanofi's sole and exclusive option, either by Sanofi directly or by any Affiliate of Sanofi that Sanofi causes to satisfy, meet or fulfill such obligation, in whole or in part. Each of the Parties guarantees the performance of all actions, agreements and obligations to be performed by any Affiliates of such Party under the terms and conditions of this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

15.10 **Further Assurances and Actions** . Each Party, upon the request of the other Party, without further consideration, will do, execute, acknowledge, and deliver or cause to be done, executed, acknowledged or delivered all such further acts, deeds, documents, assignments, transfers, conveyances, powers of attorney, instruments and assurances as may be reasonably necessary to effect complete consummation of the transactions contemplated by this Agreement, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement. The Parties agree to execute and deliver such other documents, certificates, agreements and other writings and to take such other actions as may be reasonably necessary in order to consummate or implement expeditiously the transactions contemplated by this Agreement.

15.11 **Compliance with Applicable Law**. Each Party shall comply with all Applicable Laws in the course of performing its obligations or exercising its rights pursuant to this Agreement.

15.12 **Severability** . If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

15.13 **No Waiver** . Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

15.14 **Independent Contractors**. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give either Party the power or authority to act for, bind, or commit the other Party in any way. Nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

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15.15 **Counterparts** . This Agreement may be executed in one (1) or more counterparts, including by facsimile or other electronic transmission, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

*Signature Page to Follow*

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**IN WITNESS WHEREOF**, the Parties have executed this Agreement in duplicate originals by their duly authorized officers as of the Effective Date.

**VIVUS, INC.**

**SANOFI**

By: /s/ John L. Slebir

By: /s/ Philippe Goupit

Name: John L. SLEBIR

Name: Philippe GOUPIT

Title: Vice President, Business Development

Title: Vice-President, Corporate Licenses,  
Strategy and Business Development

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**EXHIBITS**

- Exhibit A** Existing PDE-5 Inhibitors
- Exhibit B** Sanofi Territory
- Exhibit C** Vivus Patents
- Exhibit D** Vivus Trademarks / Trademarks' Guidelines and Quality Control
- Exhibit E** Terms and Conditions of Vivus Supply Agreement
- Exhibit F** Letter Agreement between \*\*\*

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**EXHIBIT A  
EXISTING PDE-5 INHIBITORS**

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**EXHIBIT B  
SANOFI TERRITORY**

**Africa :**

Egypt  
Sudan  
Algeria  
Morocco  
South Africa  
Tunisia  
Libya  
Burkina Faso  
Gambia  
Guinea  
Mali  
Mauritania  
Sao Tome  
Senegal  
Benin  
Ivory Coast  
Togo  
Niger  
Chad  
Kenya  
Mauritius  
Ethiopia  
Uganda  
Tanzania  
Eritrea  
Somalia  
Seychelles Island  
Burundi  
Rwanda  
Cameroon  
Gabon  
Congo  
Madagascar  
Democratic Republic of Congo  
Djibouti  
Central African Republic  
Islamic Republic of Comoros  
Republic of Equatorial Guinea  
Nigeria  
Ghana  
Liberia  
Sierra Leone

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Angola  
Mozambique  
Zambia  
Zimbabwe  
Malawi  
Botswana  
Namibia

**Middle East — Turkey :**

Turkey  
Saudi Arabia  
Yemen  
Qatar  
Bahrain  
United Arab Emirates  
Oman  
Kuwait  
Lebanon  
Syria  
Jordan  
Palestine  
Iraq  
Iran  
Israel

**Eurasia :**

Azerbaijan  
Kazakhstan  
Kirghizstan  
Uzbekistan  
Georgia  
Armenia  
Russia  
Ukraine  
Byelorussia

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**EXHIBIT C  
VIVUS PATENTS**

\*\*\*

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**EXHIBIT D**  
**VIVUS TRADEMARKS / TRADEMARKS GUIDELINES AND QUALITY CONTROL**  
**STENDRA**

Country in SANOFI Territory	Application Number	Filing date	Status
Egypt	A0031657	7-Sep-2012	pending
Sudan	A0031657	7-Sep-2012	pending
Algeria	130571	14-Feb-2013	pending
Morocco	A0031657	7-Sep-2012	pending
South Africa	2012/24040	7-Sep-2012	pending
Tunisia	TN/E/2013/00295	2/13/2013	pending
Libya	In process		
Sao Torne	A0031657	7-Sep-2012	pending
Kenya	A0031657	7-Sep-2012	pending
Madagascar	A0031657	7-Sep-2012	pending
Ghana	A0031657	7-Sep-2012	pending
Liberia	A0031657	7-Sep-2012	pending
Sierra Leone	A0031657	7-Sep-2012	pending
Mozambique	A0031657	7-Sep-2012	pending
Zambia	A0031657	7-Sep-2012	pending
Botswana	A0031657	7-Sep-2012	pending
Namibia	A0031657	7-Sep-2012	pending
Turkey	A0031657	7-Sep-2012	pending
Saudi Arabia	192302	16-Feb-2013	pending
Yemen	61718	17-Feb-2013	pending
Qatar	In process		
Bahrain	A0031657	7-Sep-2012	pending
United Arab Emirates	190455	21-Apr-2013	pending
Oman	A0031657	7-Sep-2012	pending
Kuwait	137985	10-Mar-2013	pending
Lebanon	149990	29-Apr-2013	pending
Syria	A0031657	7-Sep-2012	pending
Jordan	filed	25-Feb-2013	pending
Iraq	64002	21-Feb-2013	pending
Iran	A0031657	7-Sep-2012	pending
Israel	A0031657	7-Sep-2012	pending
Azerbaijan	A0031657	7-Sep-2012	pending
Kazakhstan	A0031657	7-Sep-2012	pending
Kirghizstan	A0031657	7-Sep-2012	pending
Uzbekistan	A0031657	7-Sep-2012	pending
Georgia	A0031657	7-Sep-2012	pending

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Armenia	A0031657	7-Sep-2012	pending
Russia	A0031657	7-Sep-2012	pending
Ukraine	A0031657	7-Sep-2012	pending
Byelorussia (Belarus)	A0031657	7-Sep-2012	pending

### SPEDRA

Country in SANOFI Territory	Application No./Registration No.	Filing date	Status
Egypt	A0029395	19-Apr-2012	pending
Sudan	A0029395	19-Apr-2012	pending
Algeria	In process		
Morocco	A0029395	19-Apr-2012	pending
South Africa	2012/10394	23-Apr-2012	pending
Tunisia	In process		
Libya	In process		
Sao Tome	A0029395	19-Apr-2012	pending
Kenya	A0029395	19-Apr-2012	pending
Madagascar	A0029395	19-Apr-2012	pending
Ghana	A0029395	19-Apr-2012	pending
Liberia	A0029395	19-Apr-2012	pending
Sierra Leone	A0029395	19-Apr-2012	pending
Mozambique	A0029395	19-Apr-2012	pending
Zambia	A0029395	19-Apr-2012	pending
Botswana	A0029395	19-Apr-2012	pending
Namibia	A0029395	19-Apr-2012	pending
Turkey	A0029395	19-Apr-2012	pending
Saudi Arabia	In process		
Yemen	In process		
Qatar	In process		
Bahrain	A0029395	19-Apr-2012	pending
United Arab Emirates	In process		
Oman	A0029395	19-Apr-2012	pending
Kuwait	In process		
Lebanon	In process		
Syria	A0029395	19-Apr-2012	pending
Jordan	In process		
Iraq	In process		
Iran	A0029395	19-Apr-2012	pending
Israel	A0029395	19-Apr-2012	pending
Azerbaijan	A0029395	19-Apr-2012	pending
Kazakhstan	A0029395	19-Apr-2012	pending
Kyrgyzstan	A0029395	19-Apr-2012	pending
Uzbekistan	A0029395	19-Apr-2012	pending

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Georgia	A0029395	19-Apr-2012	pending
Armenia	A0029395	19-Apr-2012	pending
Russia	A0029395/1118676	19-Apr-2012	registered
Ukraine	A0029395/1118676	19-Apr-2012	registered
Byelorussia (Belarus)	A0029395	19-Apr-2012	registered

**Trademark Quality Control Provisions:**

\*\*\* Sanofi agrees that at all times during the term of this Agreement and any extensions thereof, its services and goods shall be of such standard and quality as to be adequate and suited to the protection of the Vivus Trademarks and the goodwill associated therewith (the “Goodwill”). Any use of the Vivus Trademarks in substantially the same form as they are currently used by Vivus or in connection with the goods manufactured to substantially the same standards and quality as are currently in force by Vivus is hereby deemed approved without further submission being required. If Sanofi intends to make any changes that would reasonably be expected to adversely affect the Goodwill, Sanofi shall, before using the Vivus Trademarks or providing the goods and services, obtain the prior approval of Vivus by submitting representative samples of such modified trademarks or goods, or materials associated with such services, to Vivus. Any such proposed use submitted to Vivus shall be deemed approved upon the passage, without written objection, of \*\*\* after submission. Vivus shall have, at reasonable times and on reasonable notice, the right to inquire regarding the services provided by Sanofi and the right to inspect Sanofi’s use of the Vivus Trademarks and the manufacture of the goods on which the Vivus Trademarks are used or proposed to be used in order to carry out appropriate quality control. Sanofi agrees (i) to use the Vivus Trademarks only in a manner that will not (a) damage the reputation of or integrity of the Vivus Trademarks, (b) damage in any way the goodwill associated with the Vivus Trademarks, (c) cause a negative impact upon the good name of such other Party, and (ii) that it will conduct its business in compliance with all applicable trademark Laws and use the Vivus Trademarks only in accordance with this Agreement.

The goods or packaging on which the Vivus Trademarks are used shall, where reasonable, be marked to indicate that the Vivus Trademarks are trademarks of Vivus and are being used by Sanofi pursuant to a license granted by Vivus.

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**EXHIBIT E  
VIVUS SUPPLY AGREEMENT**

**[A COPY OF THE VIVUS SUPPLY AGREEMENT HAS BEEN SEPARATELY FILED WITH THE SECURITIES AND EXCHANGE COMMISSION]**

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**EXHIBIT F  
LETTER AGREEMENT**

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CONFIDENTIAL

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## SUPPLY AGREEMENT

**THIS SUPPLY AGREEMENT** (this “**Agreement**”) is entered into and effective as of December 11<sup>th</sup>, 2013 (the “**Effective Date**”) by and between VIVUS, Inc., a Delaware corporation with its principal place of business at 1172 Castro Street, Mountain View, CA 94040 (“**Vivus**”) and Sanofi Winthrop Industrie, a French corporation having its principal offices at 20, avenue Raymond Aron, 92160 Antony, France, acting on its own behalf and on behalf of its Affiliates (“**Purchaser**”). Vivus and Purchaser are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**”.

**WHEREAS**, Vivus and Sanofi, an Affiliate of Purchaser, have entered into a separate License and Commercialization Agreement effective as of December 11th, 2013 (the “**License Agreement**”) pursuant to which Vivus granted to Sanofi a license in the Sanofi Territory (as defined below) for the commercialization of the therapeutic drug avanafil (marketed as Stendra® in the United States and likely marketed as either Stendra™ or Spedra™ in the Sanofi Territory).

**WHEREAS**, Purchaser desires to purchase the Product from Vivus, and Vivus desires to supply the Product to Purchaser, on the terms and subject to the conditions of this Agreement.

**NOW, THEREFORE**, in consideration of the mutual covenants and promises set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

### 1. DEFINITIONS

“**Act**” shall mean the United States Federal Food, Drug, and Cosmetic Act, as it may be amended from time to time.

“**Affiliate(s)**” means, with respect to a particular Party, any person, firm, trust, corporation, company, partnership, or other entity or combination thereof that directly or indirectly controls, is controlled by or is under common control with such Party. For the purposes of this definition, the word “control” (including, with correlative meaning, the terms “controlled by” or “under the common control with”) means (a) ownership of fifty percent (50%) or more of the voting and equity rights of such person, firm, trust, corporation, company, partnership or other entity or combination thereof, or (b) the power to direct the management of such person, firm, trust, corporation, company, partnership, or other entity or combination thereof.

“**API**” means the Product’s active pharmaceutical ingredient

“**Applicable Law**” means any and all laws, statutes, ordinances, regulations, permits, orders, decrees, judgments, directives, or rules of any kind whatsoever pertaining to any of the activities contemplated in this Agreement that are promulgated by a federal, state, or other governmental authority, including, but not limited to, any regulations promulgated by any Regulatory Authority, all as amended from time to time.

“**Anti-Bribery Laws**” means any applicable anti-bribery and good business ethics legislation, regulations and/or codes, both national and foreign, including but not limited to, the United States Foreign Corrupt Practices Act of 1977, the United Kingdom Bribery Act, and national laws adopted and

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implemented pursuant to the Convention on Combating Bribery of Foreign Public Officials in International Business Transactions .

“ **cGMP** ” means current Good Manufacturing Practices, that is, the current standards for the manufacture, processing, packing, testing, shipping, and holding of drug active ingredients in the United States, as set forth in the Act and applicable regulations promulgated thereunder (including without limitation 21 C.F.R. Parts 210 and 211), as amended from time to time; and (b) comparable laws or regulations applicable to the manufacture, processing, packing, testing, shipping, and holding of drug active ingredients in the European Union, as they may be updated from time to time, including applicable guidelines promulgated under the International Conference on Harmonization.

“**Commercialization**” means the marketing, promotion, sale, offering for sale, importation and/or distribution of Product.  
“**Commercialize**” has a correlative meaning.

“ **Commercially Reasonable Efforts** ” means , with respect to a Party’s obligations under this Agreement, the reasonable and good faith efforts normally used by a similarly situated company in the pharmaceutical industry for a product that is of similar market potential and at a similar stage in its development or product life as the Product, which level of effort is at least commensurate with the level of effort that such Party would devote to its own internally discovered compounds or products that are of similar market potential and at a similar stage of development or product life as the Product.

“ **Compound** ” means the compound identified by the International Non-Proprietary Name avanafil and chemically known as (S)-4-(3-Chloro-4-methoxybenzylamino)-2-(2-hydroxymethylpyrrolidin-1-yl)-N-pyrimidin-2-ylmethyl-5-pyrimidinecarboxamide, including any metabolites, polymorphs, salts, esters, free acid forms, free base forms, pro-drug forms, racemates and all optically active forms thereof (each, a “Compound” and collectively, the “Compounds”).

“**Confidential Information**” means, with respect to a Party, all proprietary Information of such Party that is disclosed to or accessed by the other Party under this Agreement.

“**Control**” means, with respect to any material, Information, or intellectual property right, that a Party and/or its Affiliates owns or has a license or right to such material, Information, or intellectual property right and has the ability to grant to the other Party access, a license, or a sublicense (as applicable) to such material, Information, or intellectual property right on the terms and conditions set forth herein without violating the terms of any then-existing agreement or other arrangement with any Third Party.

“ **EMA** ” means the European Medicines Agency or its successor.

“ **European Union** ” means any and all member countries of the European Union, as updated from time to time.

“ **FDA** ” means the United States Food and Drug Administration or its successor.

“ **Forecast** ” shall have the meaning set forth in Section 2.2.

“**Information**” means any data, results, and information of any type whatsoever, in any tangible or intangible form, including know-how, trade secrets, practices, techniques, methods, processes,

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procedures, inventions, developments, specifications, formulations, formulae, software, algorithms, marketing reports, expertise, stability, technology, pharmacological, biological, chemical, biochemical, toxicological, and clinical test data, analytical and quality control data, and stability data.

“ **License Agreement** ” shall have the meaning set forth in the recitals above.

“ **MAA** ” means an application for Regulatory Approval filed with the EMA.

“ **Manufacturing Cost** ” has the meaning set forth in Appendix B .

“ **Menarini** ” shall mean A. Menarini Industrie Farmaceutiche Riunite Srl and/or any other company in the Menarini Group.

“**MTPC**” means Mitsubishi Tanabe Pharma Corporation.

“ **MTPC Agreement** ” means that certain Agreement between Vivus and MTPC (as successor in interest to Tanabe Seiyaku Co., Ltd.), effective as of December 28, 2000, as amended pursuant to the Amendment No. 1 to Agreement dated as of January 9, 2004 and the Second Amendment to Agreement dated as of August 1, 2012, the Third Amendment to Agreement dated as of February 21, 2013.

“**NDA**” means a New Drug Application, as defined in the Act.

“ **Person** ” means an individual, corporation, partnership, limited liability company, trust, association, joint venture, sole proprietorship, unincorporated organization, governmental authority, or any other form of entity not specifically listed herein.

“ **Price** ” means \*\*\*; provided, however, that such \*\*\* shall not apply to \*\*\* (as defined in Appendix B ). Notwithstanding the foregoing, the Price for the \*\*\* shall be as set forth in Appendix B , and the Price for Product manufactured by Sanofi Winthrop Industrie using API supplied by Vivus pursuant to Section 6.5 of the License Agreement shall be as set forth in Section 3.1.

“ **Product** ” means formulated tablets containing Compound which, if appropriately formulated, blistered and packaged would constitute the pharmaceutical product known as (a) Spedra™, as described in the EMA-approved MAA for such product (as such MAA may be modified in the future in accordance with this Agreement and/or the License Agreement) or (b) Stendra®, as described in the FDA-approved NDA for such product (as such NDA may be modified in the future in accordance with this Agreement and/or the License Agreement). Product will be ordered and supplied at three different dosage strengths: 50 mg, 100 mg, and 200 mg; and in two different forms: bulk tablets manufactured by MTPC or, as the case may be, by Sanofi Winthrop Industrie and, solely in the case of the \*\*\*.

“ **Product Shortage** ” means a circumstance that is not the result of a force majeure in which Vivus is unable to supply Product to Purchaser in compliance with the terms and conditions of this Agreement in the quantities sufficient to meet Purchaser’s requirements of Product as set forth in outstanding Purchase Orders and/or the Forecast.

“**Purchaser**” means Sanofi Winthrop Industrie and/or its Affiliates.

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“**Purchase Order**” shall have the meaning set forth in Section 2.3.

“**Quality Agreement**” shall have the meaning set forth in Section 5.4.

“**Regulatory Approval**” means all approvals necessary for the manufacture, marketing, importation and sale of the Product for one or more indications in a country or regulatory jurisdiction of the Sanofi Territory, which may include satisfaction of all applicable regulatory and notification requirements. For the avoidance of doubt, Regulatory Approval includes any pricing approval that may be required by Applicable Law.

“**Regulatory Authority**” means, in a particular country or regulatory jurisdiction of the Sanofi Territory, any applicable governmental authority involved in granting Regulatory Approval.

“**Specifications**” means the specifications, standards, limits, criteria and other requirements for or related to the Product provided hereunder, as set forth in Appendix A or otherwise agreed to by the Parties in writing.

“**Term**” shall have the meaning set forth in Section 9.1.

“**Third Party**” means any person, entity, or organization other than Vivus, Purchaser or an Affiliate of either Party.

“**Trademarks**” means trademarks and all registrations or applications for registration thereof.

“**Sanofi Territory**” shall have the meaning assigned to such term in the License Agreement, i.e. all the countries of Africa, the Middle East-Turkey, and Eurasia, as detailed in Appendix C, which list of territories shall be deemed automatically amended from time to time upon any amendment to the definition of “Sanofi Territory” in the License Agreement.

“**Sanofi Trademarks**” means any Trademark owned by or licensed to Purchaser by a Third Party.

“**Vivus Trademarks**” means the Trademarks “Stendra” and “Spedra”, all designs and styles used by Vivus in the depiction of the foregoing Trademark, and any copyrights therein, and all goodwill appurtenant to any of the foregoing, in each case Controlled by Vivus as of the Effective Date or during the term of the License Agreement, provided however that if the registration of any of the Vivus Trademarks is refused by any Regulatory Authority or trademark office in the Sanofi Territory and by mutual agreement of the Parties another Trademark owned by or licensed to Vivus or its Affiliates is selected to be used by Sanofi with respect to Commercialization of the Product in the Sanofi Territory, such other Trademark shall also be included in Vivus Trademarks.

“**\*\*\***” has the meaning set forth in Section 2.4.

## **2. SUPPLY OF PRODUCTS**

**2.1 Supply of Product.** During the Term, and subject to the provisions herein, for the purpose of Commercialization of the Product in the Sanofi Territory under the Vivus Trademarks or the Sanofi Trademarks by Purchaser, its sublicensees or their distributors in accordance with the provisions of

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the License Agreement, Vivus agrees to manufacture, test, and supply the Product to Purchaser or any of its Affiliates or designees, directly or through one or more Third Party subcontractors, and Purchaser agrees to purchase the Product from Vivus, pursuant to Purchase Orders that may be submitted to Vivus by Purchaser from time to time in accordance with Section 2.3 . .

**2.2 Forecasts.** Purchaser will submit to Vivus, no later than the \*\*\* preceding the start of every \*\*\* (i.e., \*\*\*) during the Term, a non-binding rolling forecast (“ **Forecast** ”) setting forth an estimate of the total quantity of Product that Purchaser reasonably believe it may purchase during the \*\*\* commencing with the beginning of the subsequent \*\*\*, along with estimated shipment dates.

**2.3 Purchase Orders.** Purchaser shall issue written purchase orders (“ **Purchase Orders** ”) from time to time to purchase the Product from Vivus. Purchase Orders shall be submitted to Vivus at least \*\*\* in advance of the desired shipment date specified therein. For each calendar quarter, Purchaser shall be required to submit Purchase Orders for at least \*\*\* percent (\*\*\*) of the quantities in the Forecast for such \*\*\* submitted by Purchaser to Vivus \*\*\* prior to the start of such \*\*\* (the “ **Binding Forecast** ”), and Vivus will have no obligation to supply Product in excess of \*\*\* percent (\*\*\*) of the quantity specified in such Binding Forecast. Each Purchase Order shall specify, at a minimum, the applicable volume of each dosage strength of Product ordered, and the requested delivery date. Upon receipt of a Purchase Order, subject to the provisions of Section 2.1, Vivus shall supply the Product in such quantities and deliver the Product to Purchaser (or Purchaser’s designee) on such delivery dates with a minimum shelf life of the Product of at least \*\*\* percent (\*\*\*). Vivus is not obligated to accept verbal orders of any kind for the supply of Product hereunder. To the extent there is any conflict or inconsistency between this Agreement and any Purchase Order, this Agreement shall govern.

**2.4** \*\*\*. At any time prior to \*\*\*, Purchaser may submit a \*\*\* for, and Vivus agrees to supply, up to \*\*\* consisting of \*\*\* of Product each, with \*\*\* (the “\*\*\*\*\*”). Specifications of the \*\*\* shall be in accordance with the EMA specifications for the Product as reported in the regulatory dossier filed in connection with the MAA. The \*\*\* is a \*\*\*, and Vivus shall not be obligated to supply any additional quantities of \*\*\* Product hereunder. The rest of this Article 2 shall apply to the \*\*\*, except that (a) the \*\*\* shall be submitted to Vivus at least \*\*\* in advance of the desired shipment date specified therein, and (b) Purchaser shall not be required to include the \*\*\* quantities in any of its Forecasts. Upon Purchaser’s request, Vivus shall use Commercially Reasonable Efforts to work with Purchaser and the Third Party Manufacturers involved in the manufacture of the Product comprising the \*\*\* toward delivering to Purchaser Product with an improved minimum shelf life of \*\*\* percent (\*\*%).

**2.5 Delivery and Shipping Terms.** Product shall be shipped EXW (Incoterms 2010) directly from MTPC’s manufacturing facility (or, if applicable, the manufacturing facility of any other manufacturer being utilized by Vivus for manufacturing Product). Title to the Product and risk of loss shall pass to Purchaser at the time of delivery of the Product to the applicable Third Party shipper at the loading dock of the manufacturing facility, and Purchaser shall be responsible for obtaining such insurance as Purchaser deems necessary with respect to the shipment at Purchaser’s expense. Purchaser shall arrange for, and pay, all shipping, freight, custom duties, and other charges associated with the shipment of the Product to Purchaser’s designated destination. Purchaser shall be responsible for obtaining any necessary export and/or import licenses, or other similar official authorizations, and for carrying out all customs formalities for the exportation and importation of the Product. Vivus shall issue (or shall have its manufacturer issue) a certificate of analysis (“ **COA** ”) for shipment of Product sent to Purchaser.

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**2.6 Packaging and Labeling.** Vivus will supply Product to the Purchaser in the form of bulk tablets, except for the \*\*\*, which shall be supplied in the form described in Section 2.4. Purchaser shall be responsible, at its sole expense, for packaging and labeling the Product for commercial sale (other than the white boxes provided with the \*\*\*). Any labels, product inserts, and other packaging for the Product shall be consistent with then-current Regulatory Approval(s) applicable to the sale and marketing of the Product in the Sanofi Territory and with Applicable Laws of the Sanofi Territory. Vivus' name will not appear on the label or anywhere else on the commercial packaging of the Product unless: (i) required by any Applicable Laws; or (ii) Vivus consents in writing to the use of its name.

**2.7 Product Shortage.** If Vivus becomes aware of any circumstances that may give rise to a Product Shortage for any calendar quarter, Vivus shall provide Purchaser with prompt written notice thereof. In the event of a Product Shortage, without prejudice to any other remedy Purchaser may have under this Agreement, Vivus shall be permitted to allocate the available Product among Purchaser and any other licensees and/or authorized distributors of Product worldwide, \*\*\* based on the volume of Product orders of Purchaser and such other licensees and distributors. The "volume of Product orders" will be calculated based on (a) orders for Product that were delivered during the preceding \*\*\* or that are then in transit (excluding in each case any orders where payment therefor is delinquent), and (b) the binding portion of any outstanding purchase orders or forecasts.

### **3. PRICE; PAYMENT**

**3.1 Prices for Product .** Purchaser shall pay to Vivus the Price for the units of Product supplied to Purchaser pursuant to this Agreement. For any Product supplied to Purchaser hereunder that has been manufactured by Sanofi Winthrop Industrie using API supplied by Vivus pursuant to Section 6.5 of the License Agreement , the Price shall be equal to \*\*\* of \*\*\* such Product and in having the Product \*\*\*. Purchaser shall be solely responsible for determining the price at which it will sell the Product.

**3.2 Payment.** Vivus shall provide to Purchaser written invoices setting forth the amount payable by Purchaser with respect to quantities of Product sold hereunder, including the Price applied by Vivus to each dosage strength of Product. To the extent that, for a given quantity of Product, Vivus is billed by MTPC or another Third Party manufacturer of Product in multiple invoices, Vivus may send multiple invoices to Purchaser for such quantity of Product. Purchaser shall pay Vivus for Product in the amount invoiced by Vivus, without deduction, deferment, set-off, lien, or counterclaim of any nature, within \*\*\* days from the date of the invoice. All payments to be made by Purchaser to Vivus under this Agreement represent net amounts Vivus is entitled to receive.

**3.3 Audit.** During the term of this Agreement, on an annual basis, Purchaser shall have the right to have Vivus' books and records reviewed (during normal business hours on a date mutually agreed with reasonable advance notice) by an independent auditor bound by confidentiality and restricted-use obligations no less stringent than those set forth in Article 13, for the sole purpose of verifying the calculation by Vivus of the Price of Product supplied to Purchaser that is manufactured by Sanofi Winthrop Industrie, as set forth in 3.1 above . The cost of such audit shall be borne by Purchaser unless the audit report reveals that the Price invoiced to Purchaser for any quantity of such Product is higher by at least \*\*\*% than the Price calculated in accordance with Section 3.1 using Vivus' out-of-pocket expenses as reported in Vivus books and records, in which case, Vivus shall reimburse Purchaser the cost of such audit. Any amount unduly paid by Purchaser for the supply of any such quantity of Product shall be credited by Vivus against future payments owed by Purchaser under this Agreement, or if such future

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payments are not reasonably expected to occur, shall be reimbursed by Vivus.

#### 4. REPRESENTATIONS AND WARRANTIES

**4.1 Mutual Representations.** Each Party hereby represents, warrants, and covenants (as applicable) to the other Party as follows, as of the Effective Date:

(a) Corporate Existence and Power. It is a corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has all requisite power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement.

(b) Authority and Binding Agreement. It has the requisite power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; it has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and this Agreement has been duly executed and delivered on its behalf, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms, subject as to enforcement of remedies to applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting generally the enforcement of creditors' rights and subject to a court's discretionary authority with respect to the granting of a decree ordering specific performance or other equitable remedies.

(c) Consents. All necessary consents, approvals and authorizations of all governmental authorities and other Third Parties required to be obtained by it in connection with the execution, delivery and performance of this Agreement have been obtained by it. For the avoidance of doubt, Purchaser shall be solely responsible for obtaining any product and/or distribution license so as to be able to sell and market the Product in a particular territory.

(d) Representations regarding Debarment and Compliance.

(i) Each Party represents, warrants and covenants that as of the Effective Date and during the Term, neither it nor its Affiliates nor, to its knowledge based upon reasonable inquiry, any of their respective directors, officers, or employees:

(A) are debarred under Section 306(a) or 306(b) of the Act;

(B) have been charged with, or convicted of, any felony or misdemeanor under Applicable Laws related to any of the following: (1) the development or approval of any drug product or the regulation of any drug product under the Act; Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, the national laws of individual EU Member States implementing the provisions of these Directives into their national law, Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, or any similar Applicable Laws; (2) a conspiracy to commit, aid or abet the development or

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approval of any drug product or regulation of any drug product; (3) health care program-related crimes (involving Medicare or any state health care program); (4) patient abuse, controlled substances, bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records; (5) interference with, obstruction of an investigation into, or prosecution of, any criminal offense; or (6) a conspiracy to commit, aid or abet any of these listed felonies or misdemeanors; or

(C) are excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any United States federal or state health care programs (including convicted of a criminal offense that falls within the scope of 42 U.S.C. §1320a-7 but not yet excluded, debarred, suspended, or otherwise declared ineligible), or excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any United States federal procurement or non-procurement programs.

(ii) Each Party will notify the other Party promptly, but in no event later than \*\*\*, after knowledge of any exclusion, debarment, suspension or other ineligibility set forth in Section 4.1(d)(i) occurring during the Term, or if such Party concludes based on its good faith business judgment that a pending action or investigation is likely to lead to the exclusion, debarment, suspension or other ineligibility of such Party.

(e) Representations regarding Anti-Bribery Laws.

Each Party represents and warrants that, on or before the Effective Date, to its knowledge based upon reasonable inquiry, neither it, its Affiliates nor any of their respective directors, officers, employees: (a) has made or agreed any payment or any offer or promise for payment, either directly or indirectly, of money or other assets, or transfer anything of value (a "Payment"), to government or political party officials (where "government official" shall, for purposes of this Section 10.6, include without limitation health care providers in state-run hospitals and health care systems and decision-makers in state-owned or -controlled enterprises), officials of international organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing for the purpose of influencing decisions or actions or where such Payment would constitute violation of any applicable Anti-Bribery Laws; and (b) has accepted any Payment for the purpose of influencing any decisions or actions to help anyone (including but not limited to any of the Parties) obtain or maintain business where such Payment would constitute violation of any Anti-Bribery Laws. Each Party covenants that during the Term, it will ensure that neither it, its Affiliates, nor any of their respective directors, officers and employees will make, agree to, offer or accept any of the Payment described in (a) and (b).

**4.2 Product Warranties of Vivus.**

(a) Vivus warrants that the Product shall: (i) comply with the Specifications, and (ii) be manufactured in compliance with cGMP.

(b) The foregoing warranty shall not apply to damaged Product to the extent such damage is directly caused in whole or in part by Purchaser's breach of this Agreement or, upon delivery in accordance with the terms of Section 2.5, use, handling, or storage that is not in accordance with the provisions of the Quality Agreement.

(c) Vivus' obligations as provided in Section 10.1 and Section 6.2 shall be the sole and

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exclusive remedies available to Purchaser with respect to Product that fails to meet the product warranties set forth in Section 4.2(a).

**4.3 No Other Representations or Warranties. EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 4, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF Vivus. EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 4, ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.**

## **5. QUALITY**

**5.1 General.** Vivus shall be responsible for establishing and maintaining such procedures for implementing corrective and preventive actions with respect to the manufacturing of the Product as it deems necessary in compliance with Applicable Law. Vivus shall cooperate with Purchaser at Vivus' expense in determining the cause of any quality problems involving the Product, identifying corrective actions, and ensuring the implementation and effectiveness thereof. Upon Purchaser's request, Vivus shall use Commercially Reasonable Efforts to implement at its own costs such corrective actions with respect to the Product, and shall provide Purchaser with written confirmation upon the completion thereof.

**5.2 Notice of Failure to Meet Specifications.** Vivus shall notify Purchaser promptly after the discovery that any lot of Product shipped to Purchaser, which had previously been approved in accordance with procedures set forth herein, fails to comply with its applicable Specifications. Vivus will make, at its expense, such further internal investigation of any failure to meet the Specifications Vivus deems appropriate under the circumstances and otherwise consistent with its obligations hereunder.

### **5.3 Changes to Specifications.**

(a) Changes Requested by Purchaser. Vivus shall discuss in good faith any reasonable requests by Purchaser to change the manufacturing process, Specifications, or any testing method with respect to the Product; provided, however that Vivus shall in no event be obligated to implement any such change unless Purchaser bears the costs of such implementation.

(b) Changes Requested by Vivus. Vivus shall have the right, in its sole discretion, to change any procedures, Specifications, methods (including testing methods) or standard operating procedures relating to the manufacture or supply of the Product. Notwithstanding the foregoing, Vivus shall not implement any such change that is (i) inconsistent with the then-current MAA or NDA for the Product or (ii) reasonably likely to have a material adverse effect on Vivus' ability to comply with the terms of this Agreement, including any Product delivery timelines hereunder.

**5.4 Quality Agreement.** Within \*\*\* following the Effective Date, the Parties shall enter into a quality agreement governing the agreed-upon Specifications and other technical aspects of supply of Products to Purchaser hereunder (the "**Quality Agreement**"). In the event of any inconsistency between this Agreement and the Quality Agreement, this Agreement shall control.

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## 6. ACCEPTANCE AND REJECTION PROCEDURES

**6.1 Inspection.** Purchaser or its designee shall promptly, upon arrival on its site, carefully inspect each shipment of Product for transport damages, losses and shortfalls. Apparent defects, such as, for instance, damaged containers or missing packages of Product, must be notified to the carrier promptly upon arrival of the shipment and the freight documents at Purchaser or its designee and, where possible, countersigned by the carrier's representative. Failure of Purchaser or its designee to notify such visually detectable defects to the carrier promptly upon arrival of the concerned shipment and freight documents shall exclude any liability of Vivus for such defects. Purchaser shall have \*\*\* after receipt of a shipment of Product to determine if such Product complies with the warranties set forth in Section 4.2(a) (the "**Inspection Period**"). Purchaser shall notify Vivus of any such non-compliance prior to the end of the Inspection Period, describing in detail the non-compliance. Notwithstanding the preceding provisions of this Section 6.1, if with respect to any unexpired Product, the non-compliance could not reasonably be expected to have been found by diligent and customary inspection during the Inspection Period and Purchaser notifies Vivus of such non-compliance, describing the Latent Defect in detail, within \*\*\* of the discovery of the Latent Defect and within the shelf life of the Product, such non-compliance shall be deemed to be a "Latent Defect" hereunder. Purchaser's notification of Vivus of a non-compliance during the Inspection Period or of a Latent Defect in the period permitted above shall be referred to herein as a "Claim". Purchaser shall be deemed to have accepted any Product if it fails to give a Claim in the periods permitted above. At Vivus' reasonable request, Purchaser shall provide Vivus with any documentation or analysis that is reasonably necessary for Vivus to exercise its rejection rights under its supply agreement with MTPC and/or any other relevant Third Party manufacturer.

**6.2 Remedies .** Except for Claims disputed pursuant to Section 6.2(b) hereof, if Purchaser submits a Claim, then as promptly as practicable after the submission of the Claim to Vivus (taking into account, without limitation, the time necessary for Vivus to receive a response from MTPC and/or any other relevant Third Party manufacturer with respect to such Claim), Vivus shall instruct Purchaser whether to return or destroy the Product in question and provide Purchaser with replacement Product. In the event that:

(a) Vivus agrees with the Claim, then Vivus shall pay for all out-of-pocket costs of returning or destroying Product that is the subject of any accepted Claim. Vivus shall bear the risk of loss for such Product, beginning at such time as they are taken at Purchaser's premises for return delivery.

(b) Vivus does not agree with the Claim, then the Parties agree to submit the Product in question to a mutually agreed independent Third Party that has the capability of testing the Product to determine whether or not it complies with the Specifications. The losing Party shall bear all costs and expenses related to such testing and pay for all shipping costs of returning the Product and/or sending the replacement Product, as the case may be.

## 7. REGULATORY MATTERS FOR COMMERCIALIZATION PURPOSES.

The Parties' or their respective Affiliates' rights and obligations with respect to Regulatory Approvals for the purpose of Commercialization of the Product in the Sanofi Territory are set forth in the License Agreement.

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## 8. RECORD-KEEPING; INSPECTION; AUDIT

**8.1 Recordkeeping.** Vivus will keep records of the manufacture and testing of the Product, and retain samples of Product sold hereunder as are necessary to comply with Applicable Laws, as well as to assist with resolving Product complaints and other similar investigations. Copies of the records and samples will be retained for a period of \*\*\* following the date of Product expiry, or longer if required by Applicable Laws. Purchaser is responsible for retaining samples of the Product necessary to comply with the legal/regulatory requirements applicable to Purchaser.

**8.2 Audits.** From and after the commencement of supply hereunder and through an independent auditor reasonably acceptable to Vivus, Purchaser shall have the right, upon reasonable advance notice and during regular business hours, to cause an inspection and audit of the facilities being used by Vivus or a Vivus Affiliate for the production of Product to assure compliance by Vivus with cGMPs. At Purchaser's reasonable request, Vivus agrees to facilitate a similar inspection and audit of the facilities being used by MTPC and/or any other Third Party manufacturer; provided, however, that Purchaser acknowledges and agrees that such inspection and audit will require approval of MTPC and/or such other Third Party manufacturer, and Vivus shall not be liable for any failure to obtain such approval.

**8.3 Procedure.** The inspection and audit provided for under Section 8.2 shall not be carried out by Purchaser more than once per calendar year. Each inspection and audit shall be conducted in a manner so as to minimize disruption of the business operations of Vivus. Vivus representatives will be permitted to participate as observers during any such inspection and audit. To the extent that Purchaser's requests an inspection or audit of the facilities of MTPC and/or any other Third Party manufacturer, Purchaser acknowledges that Vivus must coordinate the dates and schedule of such inspection and audit with MTPC and/or such other Third Party manufacturer.

**8.4 Results.** If an inspection or audit reveals a failure to comply with cGMP in all material respects, then Purchaser shall promptly provide to Vivus written notice of such fact, which notice shall contain in reasonable detail the deficiencies found in the applicable

facilities and, if practicable, those steps Purchaser believes should be undertaken in order to remedy such deficiencies. The Parties shall discuss in good faith the proposed deficiencies and, to the extent there is agreement on the proposed deficiencies, Vivus shall use reasonable efforts to remedy such deficiencies, or implement a plan to remedy such deficiencies, as soon as reasonably practical following receipt of the notification thereof.

## **9. TERM; TERMINATION**

**9.1 Term.** The term of this Agreement (the “**Term**”) will commence on the Effective Date and, unless earlier terminated pursuant to this Article 9, will continue until June 30<sup>th</sup>, 2015 or, in the event that MTPC’s obligations to supply Product to Vivus (the “MTPC Supply Obligations”) are amended such that the term thereof is extended beyond June 30, 2015, until the expiration of the MTPC Supply Obligations as amended.

**9.2 Termination for Default or Bankruptcy.** Either Party may terminate this Agreement (a) for material breach by the other Party if such breach continues uncured for a period of \*\*\* after receipt of notice thereof; or (b) if (i) the other Party shall institute bankruptcy, insolvency, liquidation or receivership proceedings or proceedings for reorganization under bankruptcy or comparable laws; or (ii) a petition shall be filed against the other Party for any proceedings described in clause (i) above, the effectiveness of which is not stayed or dismissed within \*\*\* after the filing thereof; or (iii) the other Party

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shall make a general assignment of all or substantially all of its assets for the benefit of creditors. Termination of this Agreement pursuant to this Section 9.2 shall not affect any other rights or remedies which may be available to the non-defaulting Party.

**9.3 Termination Upon Termination of License Agreement.** In addition to the termination rights expressly provided for elsewhere in this Agreement, the early termination of the License Agreement shall trigger automatically the termination of this Agreement with immediate effect with no notice being required from either Party.

**9.4 Effects of Termination.** Upon expiration or termination of this Agreement, Vivus shall manufacture and supply, and Purchaser shall purchase from Vivus any and all quantities of Product ordered by Purchaser pursuant to this Agreement prior to the date on which such notice is given, for the applicable Price. In addition, either Purchaser or one of its Affiliates shall purchase any and all materials held by Vivus or MTPC (or any other Third Party manufacturer of Product) for use in the manufacture of Product based on Forecasts provided by Purchaser, for an amount equal to \*\*\* of such materials. Termination or expiration of this Agreement will not affect any outstanding obligations due hereunder prior to the termination or expiration.

**9.5 Survival.** Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to the effective date of such expiration or termination. The following sections shall survive termination or expiration of this Agreement for any reason: Sections 9.4 and 9.5; and Articles 3 (solely with respect to Product ordered prior to termination or expiration), 4, 5, 6 (solely with respect to Product ordered prior to termination or expiration), 7, 8, 10, 11, 13, 14, and 16.

## 10. INDEMNIFICATION

**10.1 Indemnification by Vivus.** Vivus agrees to defend and indemnify and hold Purchaser, its sublicensees and their respective directors, officers and employees (the “**Purchaser Indemnified Parties**”) harmless against any and all Third Party claims, suits or proceedings, and all associated expenses, recoveries and damages, including court costs and reasonable attorneys’ fees and expenses, arising out of, based on, or caused by the breach by Vivus of any representation, warranty, or covenant contained in this Agreement, except in each case to the extent that such claims, suits, proceedings, expenses, recoveries or damages arise from the breach by Purchaser of any representation, warranty, or covenant contained in this Agreement or any negligence or willful misconduct by a Purchaser Indemnified Party.

**10.2 Indemnification by Purchaser.** Purchaser agrees to defend and indemnify and hold Vivus, its Affiliates, and their respective directors, officers and employees (the “**Vivus Indemnified Parties**”) harmless against any and all Third Party claims, suits, proceedings, and all associated expenses, recoveries, and damages including court costs and reasonable attorneys’ fees and expenses, arising out of, based on, or caused by the breach by Purchaser of any representation or warranty or covenant contained in this Agreement, except in each case to the extent that such claims, suits, proceedings, expenses, recoveries or damages arise from the breach by Vivus of any representation or warranty or covenant contained in this Agreement or any negligence or willful misconduct by a Vivus Indemnified Party.

**10.3 Indemnification Procedures.** The Party claiming indemnity under this Article 10 (the “**Indemnified Party**”) shall give written notice to the Party from whom indemnity is being sought (the “**Indemnifying Party**”) \*\*\* after learning of a written claim (“**Indemnified Claim**”). Failure by an

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Indemnified Party to give notice of an Indemnified Claim \*\*\* after receiving a writing reflecting such Claim shall not relieve the Indemnifying Party of its indemnification obligations hereunder except and solely to the extent that such Indemnifying Party is actually prejudiced as a result of such failure to give such notice. The Indemnifying Party shall have the right to assume the conduct and defense of the Indemnified Claim with counsel of its choice; provided that, the Indemnifying Party shall not have the right to assume any Indemnified Claim if (x) the Indemnifying Party fails to provide reasonable evidence of its ability and willingness to satisfy such claim, or (y) such claim involves a criminal or regulatory enforcement action. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance in connection with the defense of the Indemnified Claim. The Indemnified Party may monitor such defense with counsel of its own choosing at its sole expense. The Indemnifying Party may not settle the Indemnified Claim without the prior written consent of the Indemnified Party, such consent shall not be unreasonably withheld, delayed or conditioned. In no event shall the Indemnifying Party settle the Indemnified Claim unless such settlement provides an unconditional and full release of the Indemnified Party. If the Indemnifying Party does not assume and conduct the defense of the Indemnified Claim as provided above: (a) the Indemnified Party may assume and conduct the defense of the Indemnified claim at the Indemnifying Party's expense; (b) the Indemnified Party may consent to the entry of any judgment or enter into any settlement with respect to the Indemnified Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith); and (c) the Indemnifying Party will remain responsible to indemnify the Indemnified Party for Indemnified Claims as provided in this Article 10.

#### **11. LIMITATION OF LIABILITY.**

(a) NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY EXEMPLARY, SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES, COSTS OR EXPENSES (INCLUDING LOST PROFITS, LOST REVENUES AND/OR LOST SAVINGS) ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTHING IN THE PRECEDING SENTENCE IS INTENDED TO OR SHALL LIMIT OR RESTRICT (A) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY IN CONNECTION WITH THIRD PARTY CLAIMS UNDER ARTICLE 10, (B) DAMAGES OR INJUNCTIVE RELIEF AVAILABLE FOR A PARTY'S BREACH OF ARTICLE 13, (C) DAMAGES TO THE EXTENT ARISING FROM OR RELATING TO WILLFUL MISCONDUCT OR FRAUDULENT ACTS OR OMISSIONS OF A PARTY. IN NO EVENT SHALL VIVUS' AGGREGATE LIABILITY ARISING OUT OF OR RELATING TO THIS AGREEMENT UNDER ANY THEORY OF LIABILITY (WHETHER IN CONTRACT, TORT, STATUTORY OR OTHERWISE) EXCEED \*\*\* DOLLARS (US\$\*\*\*), EXCEPT IN CASES OF GROSS NEGLIGENCE OR WILLFUL MISCONDUCT.

(b) Allocation of Risks. The limitation of liability set forth in this Article 11 reflects a deliberate and bargained for allocation of risks between Purchaser and Vivus and is intended to be independent of any exclusive remedies available under this Agreement, including any failure of such remedies to achieve their essential purpose.

(c) Essential Part of the Bargain. The Parties acknowledge that the limitations of liability set forth in this Article 11 are an essential element of this Agreement between the Parties and that the Parties would not have entered into this Agreement without such limitations of liability.

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(d) Duty to Mitigate. Each Party shall use reasonable efforts to mitigate any damages incurred by such Party hereunder.

## 12. INSURANCE.

Each Party shall procure and maintain insurance or self-insure during the Term of this Agreement of this Agreement, adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situated. Such insurance shall be written by insurance companies of good international reputation..

It is understood that the insurance requirements above shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under Article 10. Each Party shall provide the other Party with written evidence of such insurance upon request.

## 13. CONFIDENTIALITY; PUBLICITY; PROPRIETARY RIGHTS

**13.1 Confidentiality.** Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each Party agrees that, for the Term and for \*\*\* years thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement any Confidential Information of the other Party except for that portion of such information or materials that the receiving Party can demonstrate by competent proof:

(a) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure by the other Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) is subsequently disclosed to the receiving Party or its Affiliate by a Third Party without obligations of confidentiality with respect thereto; or

(e) is subsequently independently discovered or developed by the receiving Party or its Affiliate without the aid, application, or use of Confidential Information.

Notwithstanding the foregoing, the receiving Party may disclose without violation of this Agreement such portion of the Confidential Information as is required or permitted to be disclosed if, on the advice of counsel, it is required under Applicable Law or pursuant to legal process to disclose such Confidential Information of the other Party; provided that unless otherwise prohibited by Applicable Law, the receiving Party first advises the disclosing Party of such intended disclosure and provides the disclosing Party with the opportunity to seek appropriate judicial or administrative relief to avoid, or obtain confidential treatment of, such disclosure at the disclosing Party's sole cost and expense.

**13.2 Authorized Disclosure.** Each Party may disclose Confidential Information belonging to the other Party to the extent such Party determines such disclosure is reasonably necessary in the

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following situations:

(a) prosecuting or defending litigation relating to this Agreement;

(b) in the case of Vivus, disclosure to MTPC as required pursuant to the MTPC Agreement;

(c) in the case of Vivus as the receiving Party, disclosure to its licensees, sublicensees, and collaborators with respect to the Product outside the Sanofi Territory or outside the Field, but solely to the extent that such Confidential Information (i) raises any material concerns regarding the safety of any Product; (ii) indicates or suggests a potential material liability of either Vivus or the applicable licensee, sublicensee, or collaborator to Third Parties in connection with any Product; (iii) is reasonably likely to lead to a recall or market withdrawal of any Product; or (iv) relates to any Product and is reasonably likely to have a material impact on a Regulatory Approval of any Product in such licensee's, sublicensee's, or collaborator's territory; provided that each such disclosee must be bound by obligations of confidentiality and non-use no less stringent than those set forth in Sections 13.1 and 13.2 prior to any such disclosure and further provided that Vivus shall cause any of its licensees to commit to the same obligations and shall disclose to Sanofi any confidential information received from any licensee of the Vivus Technology in order to enable Sanofi, its Affiliates and licensees to address adequately the situations set forth in the sub-sections (i) to (iv) of this Section 13.2(c);

(d) disclosure to its and its Affiliates' respective directors, officers, employees, consultants, attorneys, professional advisors, lenders, insurers, and sublicensees only on a need-to-know basis and solely as necessary in connection with this Agreement, provided that each disclosee must be bound by obligations of confidentiality and non-use no less stringent than those set forth in Sections 13.1 and 13.2 prior to any such disclosure; and

(e) disclosure to any bona fide potential or actual investor, acquirer, merger partner, or other potential or actual financial partner (and/or their respective consultants, attorneys, professional advisors) on a need-to-know basis and solely for the purpose of evaluating a potential investment, acquisition, merger, or similar transaction; provided that each disclosee must be bound by obligations of confidentiality and non-use no less stringent than those set forth in Sections 13.1 and 13.2 prior to any such disclosure. The receiving Party shall be liable for any breach of such confidentiality and non-use obligations by any such Third Party.

### **13.3 Publicity; Terms of Agreement.**

(a) The Parties agree that the material terms of this Agreement are the Confidential Information of both Parties, subject to the authorized disclosure provisions set forth in Section 13.2 and this Section 13.3.

(b) Each Party shall have the right to make an individual public announcement of the execution of this Agreement, the content and timing of which shall be mutually agreed upon by the Parties. After release of the press release announcing this Agreement, if either Party desires to make a public announcement concerning the material terms of this Agreement, such Party shall give reasonable prior advance notice of the proposed text of such announcement to the other Party for its prior review and approval, such approval not to be unreasonably withheld, conditioned or delayed. A Party commenting on such a proposed press release shall provide its comments, if any, within \*\*\* after receiving the press release for review. Neither Party shall be required to seek the permission of the other Party to disclose

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any information already disclosed or otherwise in the public domain, provided such information remains accurate.

(c) Vivus may publicly disclose without violation of this Agreement, such terms of this Agreement as are, on the advice of Vivus' counsel, required by the rules and regulations of the SEC or any other applicable entity having regulatory authority over Vivus' securities; provided that Vivus advises Purchaser of such intended disclosures and requests confidential treatment of certain commercial terms and technical terms hereof to the extent such confidential treatment is reasonably available to Vivus. In the event of any such filing, Vivus will provide Purchaser, a reasonable time prior to filing, with a copy of the Agreement marked to show provisions for which Vivus intends to seek confidential treatment and shall reasonably consider and incorporate Purchaser's comments thereon to the extent consistent with the legal requirements applicable to Purchaser and that govern redaction of information from material agreements that must be publicly filed. Purchaser shall provide any such comments as promptly as practicable.

**13.4 Proprietary Rights.** This Agreement shall not affect the ownership of any intellectual property owned by or licensed to either Party ("**Intellectual Property**") or any rights granted in the License Agreement with respect to such Intellectual Property.

#### **14. GOVERNING LAW; DISPUTE RESOLUTION**

**14.1 Governing Law.** Resolution of all disputes arising out of or related to this Agreement or the validity, construction, interpretation, enforcement, breach, performance, application or termination of this Agreement and any remedies relating thereto, shall be governed by and construed under the substantive laws of the State of New York, United States of America, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. Without limiting the foregoing, the United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement or transactions hereunder.

**14.2 Disputes.** The Parties recognize that disputes as to certain matters may from time to time arise during the Term which relate to either Party's rights and/or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to meet and discuss in good faith any disputes, controversies or differences which may arise between the Parties out of or in relation to or in connection with this Agreement, including any alleged failure to perform, or breach, of this Agreement, or any issue relating to the interpretation or application of this Agreement. Such good faith efforts shall include at least one in-person meeting between the chief executive officers of each Party. If the matter is not resolved within \*\*\* following the request for discussions, either Party may then invoke the provisions of Section 14.3.

#### **14.3 Arbitration.**

(a) **Claims.** Subject to Section 14.4 below, any claim, dispute, or controversy of whatever nature arising out of or relating to this Agreement that is not resolved under Section 14.2 within the required \*\*\* period, including, without limitation, any Claim concerning the interpretation, effect, termination, validity, performance and/or breach of this Agreement shall be resolved by final and binding arbitration administered by the International Chamber of Commerce ("**ICC**"). The arbitration and all associated discovery proceedings and communications shall be conducted in English, and the arbitration

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shall be held in New York, New York, USA.

(b) **English Language** . All proceedings shall be held in English and a transcribed record prepared in English. Documents submitted in the arbitration (the originals of which are not in English) shall be submitted together with a reasonably complete and accurate English translation.

(c) **Selection of Arbitrators** . The Parties shall each choose one arbitrator within \*\*\* of receipt of notice of the intent to arbitrate and the said two arbitrators shall select by mutual agreement a third arbitrator within \*\*\* after they have been selected as arbitrators. If no arbitrator is appointed within the times herein provided or any extension of time that is mutually agreed on, the ICC shall make such appointment (i.e. shall appoint three arbitrators) within \*\*\* of such failure.

(d) **Arbitrators' Award**. The arbitrators' award shall include a written statement describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The arbitrators shall, in rendering their decision, apply the substantive laws of the State of New York, without giving effect to its conflicts of laws principles. The arbitrators' authority to award special, incidental, consequential or punitive damages shall be subject to the limitation set forth in Section 11. The award rendered by the arbitrators shall be final, binding and non-appealable, and judgment may be entered upon it in any court of competent jurisdiction.

(e) **Costs**. Each Party shall bear its own attorney's fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the arbitrators; *provided, however*, the arbitrators shall be authorized to determine whether a Party is the prevailing party, and if so, to award to that prevailing party reimbursement for any or all of its reasonable attorneys' fees, costs and disbursements (including, for example, expert witness fees and expenses, photocopy charges, travel expenses, *etc.* ), and/or the fees and costs of the ICC and the arbitrators.

**14.4 Court Actions**. Nothing contained in this Agreement shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a *bona fide* emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing discussions between the Parties or any ongoing arbitration proceeding. In addition, either Party may bring an action in any court of competent jurisdiction to resolve disputes pertaining to the validity, construction, scope, enforceability, infringement or other violations of Patents or other intellectual property rights, and no such claim shall be subject to arbitration pursuant to Section 14.2.

## **15. USE OF NAMES**

Except as otherwise required by law or by the terms of this Agreement or as mutually agreed upon by the Parties, neither Party shall make any use of the name of the other Party in any advertising or promotional material, or otherwise, without the prior written consent of the other Party, which consent shall not be unreasonably withheld.

## **16. MISCELLANEOUS**

**16.1 Entire Agreement; Amendment** . This Agreement, including the Appendices hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior agreements and understandings

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between the Parties with respect to the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

**16.2 Force Majeure .** Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall mean conditions beyond the control of the Parties, including an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, and failure of plant or machinery (provided that such failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances). Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a force majeure affecting such Party.

**16.3 Notices.** Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 16.3, and shall be deemed to have been given for all purposes when received, if hand-delivered or by means of facsimile or other electronic transmission, or \*\*\* after being sent by a reputable overnight delivery service.

If to Vivus:                    Vivus, Inc.  
351 E. Evelyn Avenue  
Mountain View, CA 94041  
Attention: General Counsel  
Fax: (650) 934-5320

With a copy to:            Hogan Lovells US LLP  
4085 Campbell Ave.  
Suite 100  
Menlo Park, CA 94025  
Attention: Shane Albright, Partner  
Fax: (650) 463-4199

If to Purchaser:            Sanofi Winthrop Industrie  
20, avenue Raymond Aron  
92160 Antony, France  
Attention: AVP External Manufacturing, Europe & North America

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With a copy to: Sanofi  
54 rue La Boétie  
75008 Paris, France  
Attention: General Counsel  
Fax: +33.1.53.77.43.03

**16.4 No Strict Construction; Headings; Interpretation.** This Agreement has been prepared jointly and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section. The definitions of the terms herein apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun will include the corresponding masculine, feminine and neuter forms. The words “include”, “includes” and “including” will be deemed to be followed by the phrase “without limitation.” Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (b) any reference to any laws herein will be construed as referring to such laws and any rules or regulations promulgated thereunder as from time to time enacted, repealed or amended, (c) any reference herein to any person will be construed to include the person’s successors and assigns, (d) the words “herein”, “hereof” and “hereunder”, and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (e) any reference herein to the words “mutually agree” or “mutual written agreement” will not impose any obligation on either Party to agree to any terms relating thereto or to engage in discussions relating to such terms except as such Party may determine in such Party’s sole discretion, except as expressly provided in this Agreement, (f) as applied to a Party, the word “will” shall be construed to have the same meaning and effect as the word “shall,” and (g) all references herein without a reference to any other agreement to Articles, Sections, or Appendices will be construed to refer to Articles, Sections, and Appendices of or to this Agreement.

**16.5 Assignment .** Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that a Party may make such an assignment without the other Party’s consent to such Party’s Affiliate or to a successor to all or substantially all of the assets or business of such Party to which this Agreement pertains. Any permitted successor or assignee of rights and/or obligations hereunder shall, in a writing to the other Party, expressly assume performance of such rights and/or obligations. Notwithstanding any assignment of this Agreement, the assigning Party shall remain liable for performance of its obligations hereunder, unless the non-assigning Party agrees otherwise in writing. Any assignment or attempted assignment by either Party in violation of the terms of this Section 16.5 shall be null, void and of no legal effect.

**16.6 Records Retention .** Each of Vivus and Purchaser will maintain complete and accurate records pertaining to its activities under this Agreement, including records pertaining to Development or Commercialization of any Products and reports and information provided to any Regulatory Authority or other governmental authority, in accordance with Applicable Law. Each of Vivus and Purchaser will retain such records for a duration prescribed by Applicable Law, but not in any event for less than \*\*\* years after the Effective Date (or longer if a Party is notified, ordered or otherwise

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required to maintain such records for a longer period in connection with a legal proceeding or government investigation).

**16.7 No Solicitation** . During \*\*\* following the Effective Date, neither Purchaser nor any of its Affiliates will solicit or endeavor to entice away from Vivus or its Affiliates, hire, or offer employment to, any person or entity who is, or was within the \*\*\* period immediately prior thereto, employed by Vivus or its Affiliates, or otherwise interfere with any such person's relationship with Vivus or its Affiliates; provided, however, that this restrictive covenant shall not prohibit Purchaser from making any general solicitation for employees or engaging in public advertising of employment opportunities (including through the use of employment agencies) not specifically directed to any of Vivus' or its Affiliates' respective directors, officers or employees.

**16.8 Successors and Assigns; No Third Party Beneficiaries** . This Agreement will be binding upon and inure to the benefit of the Parties and their successors and permitted assigns. No provision of this Agreement, express or implied, is intended to or will be deemed to confer upon Third Parties any right, benefit, remedy, claim, liability, reimbursement, claim of action or other right of any nature whatsoever under or by reason of this Agreement other than the Parties and, to the extent provided in Sections 10.1 and 10.2, the Indemnified Parties. Without limitation, this Agreement will not be construed so as to grant employees of either party in any country any rights against the other Party pursuant to the laws of such country.

**16.9 Performance by Affiliates** . Any obligation of Vivus under or pursuant to this Agreement may be satisfied, met or fulfilled, in whole or in part, at Vivus' sole and exclusive option, either by Vivus directly or by any Affiliate of Vivus that Vivus causes to satisfy, meet or fulfill such obligation, in whole or in part. Any obligation of Purchaser under or pursuant to this Agreement may be satisfied, met or fulfilled, in whole or in part, at Purchaser's sole and exclusive option, either by Purchaser directly or by any Affiliate of Purchaser that Purchaser causes to satisfy, meet or fulfill such obligation, in whole or in part. Each of the Parties guarantees the performance of all actions, agreements and obligations to be performed by any Affiliates of such Party under the terms and conditions of this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

**16.10 Further Assurances and Actions** . Each Party, upon the request of the other Party, without further consideration, will do, execute, acknowledge, and deliver or cause to be done, executed, acknowledged or delivered all such further acts, deeds, documents, assignments, transfers, conveyances, powers of attorney, instruments and assurances as may be reasonably necessary to effect complete consummation of the transactions contemplated by this Agreement, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement. The Parties agree to execute and deliver such other documents, certificates, agreements and other writings and to take such other actions as may be reasonably necessary in order to consummate or implement expeditiously the transactions contemplated by this Agreement.

**16.11 Compliance with Applicable Law** . Each Party shall comply with all Applicable Laws in the course of performing its obligations or exercising its rights pursuant to this Agreement.

**16.12 Severability** . If any one or more of the provisions of this Agreement is held to be invalid

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or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

**16.13 No Waiver** . Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

**16.14 Independent Contractors** . Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give either Party the power or authority to act for, bind, or commit the other Party in any way. Nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

**16.15 Counterparts** . This Agreement may be executed in one (1) or more counterparts, including by facsimile or other electronic transmission, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

*[Signature page follows]*

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IN WITNESS WHEREOF, the Parties have caused this Agreement to be duly executed as of the date first above written.

**Sanofi Winthrop Industrie**

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

**VIVUS, Inc.**

By: /s/ John L. Slebir  
Name: John L. Slebir  
Title: SVP, General Counsel  
Date: 26 February 2014

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Appendix A

Specifications

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Appendix B**Manufacturing Cost for Product Manufactured by MTPC**

For Product manufactured by MTPC, the Manufacturing Cost shall be equal to \*\*\*:

\*\*\*

\*\*\* calculated based on a \*\*\* according to the following (the \*\*\*):

\*\*\*

The Manufacturing Cost for Product manufactured by MTPC shall initially be set at \*\*\* and the Price for Product hereunder will be calculated and invoiced to Purchaser based on \*\*\*. In the event the \*\*\*Purchaser, its Affiliates, or its sublicensees \*\*\*. The formula for calculation of such Manufacturing Cost Adjustment is as follows:

“Manufacturing Cost Adjustment” = \*\*\*.

No later than \*\*\* after the end of each \*\*\*, VIVUS shall notify Purchaser whether there is a Manufacturing Cost Adjustment with respect to such \*\*\* and if there is such a Manufacturing Cost Adjustment, shall invoice Purchaser for Product sold during such \*\*\* at a new Price calculated based on the Manufacturing Cost Adjustment, net of payments already made by Purchaser for such Product.

After the end of the Supply Period (as defined in the MTPC Agreement), it is anticipated that there will be a final reconciliation between MTPC and VIVUS to ensure the accuracy of all amounts paid by VIVUS to MTPC for manufacture of Product. To the extent that this final reconciliation results in any payments by or refunds to VIVUS in respect of Product manufactured by MTPC and ultimately sold to Purchaser hereunder, the Manufacturing Cost and Price for such Product shall be appropriately re-calculated hereunder, and appropriate payments to VIVUS shall be made (or appropriate credits to Purchaser shall be issued, as the case may be).

Purchaser acknowledges that the Manufacturing Cost specified above may need to be modified in order to maintain consistency between this Agreement and the MTPC Agreement if the price charged by MTPC to VIVUS for Product changes, it being understood that (a) such price will not \*\*\* prior to \*\*\* and (b) after such date such price can only \*\*\* if MTPC’s actual manufacturing cost for the Product exceeds \*\*\* percent (\*\*\*) of the Fixed Manufacturing Cost above.

\*\*\*.

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## Appendix C

### SANOFI TERRITORY

#### Africa :

Egypt  
Sudan  
Algeria  
Morocco  
South Africa  
Tunisia  
Libya  
Burkina Faso  
Gambia  
Guinea  
Mali  
Mauritania  
Sao Tome  
Senegal  
Benin  
Ivory Coast  
Togo  
Niger  
Chad  
Kenya  
Mauritius  
Ethiopia  
Uganda  
Tanzania  
Eritrea  
Somalia  
Seychelles Island  
Burundi  
Rwanda  
Cameroon  
Gabon  
Congo  
Madagascar  
Democratic Republic of Congo  
Djibouti  
Central African Republic  
Islamic Republic of Comoros  
Republic of Equatorial Guinea  
Nigeria  
Ghana  
Liberia  
Sierra Leone  
Angola  
Mozambique

#### Middle East — Turkey :

Turkey  
Saudi Arabia  
Yemen  
Qatar  
Bahrain  
United Arab Emirates  
Oman  
Kuwait  
Lebanon  
Syria  
Jordan  
Palestine  
Iraq  
Iran  
Israel

#### Eurasia :

Azerbaijan  
Kazakhstan  
Kirghizstan  
Uzbekistan  
Georgia  
Armenia  
Russia  
Ukraine  
Byelorussia

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Zambia  
Zimbabwe  
Malawi  
Botswana  
Namibia

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**LIST OF SUBSIDIARIES**

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

1. VIVUS UK Limited (United Kingdom), a wholly owned subsidiary of VIVUS, Inc.
  2. VIVUS BV (Netherlands), a wholly owned subsidiary of VIVUS, Inc.
  3. Vivus Limited (Bermuda), a wholly owned subsidiary of VIVUS, Inc.
  4. Vivus International, L.P. (Bermuda), General Partner Vivus Limited
-

QuickLinks

Exhibit 21.1

LIST OF SUBSIDIARIES

[QuickLinks](#) -- Click here to rapidly navigate through this document

**Exhibit 23.1**

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the Registration Statements on Forms S-8 (No. 333-142354, No. 333-150647, No. 333-157787, No. 333-164921, No. 333-168106 and No. 333-175926) and Forms S-3 (No. 333-150649 and No. 333-161948) of our reports dated February 27, 2014, relating to the consolidated financial statements, and the effectiveness of VIVUS, Inc.'s internal control over financial reporting, which appear in this Annual Report on Form 10-K. We also consent to the incorporation by reference of our report dated February 27, 2014 relating to the financial statement schedule which appears in this Annual Report on Form 10-K.

/s/ OUM & CO. LLP

San Francisco, California  
February 27, 2014

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QuickLinks

[Exhibit 23.1](#)

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

I, Seth H. Z. Fischer, Chief Executive Officer, certify that:

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

Date: February 27, 2014

By:           /s/ SETH H. Z. FISCHER          

Name: Seth H. Z. Fischer  
Title: *Chief Executive Officer*

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QuickLinks

Exhibit 31.1

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

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

I, Svai S. Sanford, Chief Financial Officer, certify that:

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

Date: February 27, 2014

By:           /s/ SVAI S. SANFORD          

Name: Svai S. Sanford  
Title: *Chief Financial Officer*

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QuickLinks

Exhibit 31.2

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



QuickLinks

Exhibit 32.1

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