VIVUS INC

FORM 10-K
(Annual Report)

Filed 03/08/17 for the Period Ending 12/31/16

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Telephone	6509345200
CIK	0000881524
Symbol	VVUS
SIC Code	2834 - Pharmaceutical Preparations
Industry	Pharmaceuticals
Sector	Healthcare
Fiscal Year	12/31

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

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2016
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	**94-3136179**
(State or other jurisdiction of incorporation or organization)	(IRS employer identification number)
900 E. Hamilton Avenue, Suite 550 Campbell, California	**95008**
(Address of principal executive office)	(Zip Code)

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

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

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

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, 2016, totaled approximately $116,562,897 based on the closing stock price as reported by the NASDAQ Global Select Market.

As of February 28, 2017, there were 105,583,530 shares of the Registrant's common stock, $0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Document Description	**10-K**
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, 2016, are incorporated by reference into Part III of this report.	Part III - ITEMS 10, 11, 12, 13, 14

VIVUS, INC.
FISCAL 2016 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

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:

- the timing of initiation and completion of the post-approval clinical studies required as part of the approval of Qsymia ® by the U.S. Food and Drug Administration, or FDA;
- the response from FDA to the data that we will submit relating to post-approval clinical studies required for Qsymia;
- the impact of the indicated uses and contraindications contained in the Qsymia label and the Risk Evaluation and Mitigation Strategy requirements;
- our ability to continue to certify and add to the Qsymia retail pharmacy network and sell Qsymia through this network;
- 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;
- that we may be required to provide further analysis of previously submitted clinical trial data;
- our ability to work with leading cardiovascular outcome trial experts in planning substantial revisions to the original design and execution of the clinical post-approval cardiovascular outcomes trial, or CVOT, with the goal of reducing trial costs and obtaining FDA agreement that a revised study would fulfill the requirement of demonstrating the long-term cardiovascular safety of Qsymia;
- our ongoing dialog with the European Medicines Agency, or EMA, relating to our CVOT for Qsymia, and the resubmission of an application for the grant of a marketing authorization to the 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;
- our ability to successfully seek approval for Qsymia in other territories outside the U.S. and EU;
- 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;
- 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;
- 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;
- our ability to minimize expenses that are not essential to expanding the use of STENDRA and Qsymia or that are not related to product development;
- our ability to ensure that the entire supply chain for Qsymia efficiently and consistently delivers Qsymia to our customers and to manage the supply chain for STENDRA/SPEDRA for our collaborators;
- 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;

- our ability to successfully complete on acceptable terms, and on a timely basis, avanafil partnering discussions for territories under our license with Mitsubishi Tanabe Pharma Corporation in which we do not have a commercial collaboration;
- Sanofi Chimie's ability to undertake manufacturing of the avanafil active pharmaceutical ingredient and Sanofi Winthrop Industrie's ability to undertake manufacturing of the tablets for avanafil;
- the ability of our partners to maintain regulatory approvals to manufacture and adequately supply our products to meet demand;
- our ability to accurately forecast Qsymia demand;
- our ability to commercialize Qsymia efficiently;
- the number of Qsymia prescriptions dispensed through the mail order system and through certified retail pharmacies;
- the impact of promotional programs for Qsymia on our net product revenue and net income (loss) in future periods;
- our history of losses and variable quarterly results;
- substantial competition;
- risks related to our ability to protect our intellectual property and litigation in which we are involved or may become involved;
- uncertainties of government or third-party payor reimbursement;
- our reliance on sole-source suppliers, third parties and our collaborative partners;
- our ability to continue to identify, acquire and develop innovative investigational drug candidates and drugs;
- risks related to the failure to obtain FDA or foreign authority clearances or approvals and noncompliance with FDA or foreign authority regulations;
- our ability to demonstrate through clinical testing the quality, safety, and efficacy of our investigational drug candidates;
- the timing of initiation and completion of clinical trials and submissions to foreign authorities;
- the results of post-marketing studies are not favorable;
- compliance with post-marketing regulatory standards, post-marketing obligations or pharmacovigilance rules is not maintained;
- the volatility and liquidity of the financial markets;
- our liquidity and capital resources;
- our expected future revenues, operations and expenditures;
- potential change in our business strategy to enhance long-term stockholder value;
- our ability to address or potentially reduce our outstanding debt balances:
- the impact, if any, of changes to our Board of Directors or management team; and
- other factors that are described from time to time in our periodic filings with the Securities and Exchange Commission, or the SEC, including those set forth in this filing as "Item 1A. Risk Factors."

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.

PART I

Item 1. *Busines s*

Overview

VIVUS is a biopharmaceutical company developing and commercializing innovative, next-generation therapies to address unmet medical needs in human health, with two approved therapies and one product candidate in active clinical development. Qsymia® (phentermine and topiramate extended release) is approved by FDA for chronic weight management and STENDRA® (avanafil) is approved by FDA for erectile dysfunction, or ED, and by the European Commission, or EC, under the trade name, SPEDRA, for the treatment of ED in the EU. Tacrolimus is in active clinical development for the treatment of Pulmonary Arterial Hypertension, or PAH.

Commercial Products

Qsymia

Qsymia was approved by FDA in July 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, or BMI, of 30 or greater, or obese patients, or who have a BMI of 27 or greater, or overweight patients, in the presence of at least one weight related comorbidity, such as hypertension, type 2 diabetes mellitus or high cholesterol, or 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.

We commercialize Qsymia in the U.S. primarily through a sales force supported by an internal commercial team, who promote Qsymia to physicians. We are focused on maintaining a commercial presence with important Qsymia prescribers, and we have capacity to cover physicians that begin prescribing branded anti-obesity products. We are constantly monitoring prescribing activity in the market, and we have seen new prescriptions being written by health care professionals, or HCPs, with respect to whom we have not previously dedicated field sales resources. The current alignment addresses this new prescriber group, and we believe we have been successful in initiating and maintaining dialog with these HCPs.

Our marketing efforts have focused on rolling out unique programs to encourage targeted prescribers to gain more experience with Qsymia with their obese patient population. We continue to invest in digital media in order to amplify our messaging to information-seeking consumers. The digital messaging encourages those consumers most likely to take action to speak with their physicians about obesity treatment options. We believe our enhanced web-based strategies deliver clear and compelling communications to potential patients. In June 2016, we announced an upgraded simplified patient savings plan to further drive Qsymia brand preference at the point of prescription and encourage long-term use of the brand.

STENDRA/SPEDRA

STENDRA is an oral phosphodiesterase type 5, or PDE5, inhibitor that we have licensed from Mitsubishi Tanabe Pharma Corporation, or MTPC. STENDRA was approved by FDA in April 2012 for the treatment of ED in the United States. In June 2013, the EC adopted a decision granting marketing authorization for SPEDRA, the approved trade name for avanafil in the EU, for the treatment of ED in the EU. In July 2013, we entered into an agreement with the 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, Australia and New Zealand. Menarini commenced its commercialization launch of the product in the EU in early 2014. As of the date of this filing, SPEDRA is commercially available in 30 countries within the territory granted to Menarini pursuant to its license and commercialization agreement, in addition to certain territories in Asia licensed directly from MTPC.

On September 30, 2016, we entered into a license and commercialization agreement, or the Metuchen License Agreement, and a commercial supply agreement, or the Metuchen Supply Agreement, with Metuchen Pharmaceuticals LLC, or Metuchen. Under the terms of the Metuchen License Agreement, Metuchen received an exclusive license to develop, commercialize and promote STENDRA in the United States, Canada, South America and India, or the Metuchen Territory, effective October 1, 2016. These agreements with Metuchen replaced the license and supply agreements that we entered into with Auxilium Pharmaceuticals, Inc., or Auxilium, in October 2013, whereby Auxilium received an exclusive license to commercialize and promote STENDRA in the United States and Canada and we would supply Auxilium with STENDRA for commercialization. Auxilium terminated the supply agreement effective June 30, 2016 and the license agreement effective September 30, 2016.

In December 2013, we entered into a license and commercialization agreement with Sanofi, or the Sanofi License Agreement, 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 CIS, including Russia, or the Sanofi Territory. Sanofi was responsible for obtaining regulatory approval in its territories. Effective as of December 11, 2013, we also entered into a supply agreement, or the Sanofi Supply Agreement, with Sanofi Winthrop Industrie, a wholly owned subsidiary of Sanofi, which terminated according to its terms on June 30, 2015.

We are currently in discussions with potential collaboration partners to develop, market and sell STENDRA for territories in which we do not currently have a commercial collaboration, including Mexico and Central America.

Development Programs

Pulmonary Arterial Hypertension - Tacrolimus

Pulmonary Arterial Hypertension, or PAH, is a chronic, life-threatening disease characterized by elevated blood pressure in the pulmonary arteries, which are the arteries between the heart and lungs, due to severe constriction of these blood vessels. Pulmonary blood pressure is normally between 8 and 20 mmHg at rest as measured by right heart catheterization; however, in patients with PAH, the pressure in the pulmonary artery is greater than 25 mmHg at rest or 30 mmHg during physical activity. These high pressures make it difficult for the heart to pump blood through the lungs to be oxygenated.

The prevalence of PAH varies among specific populations, but it is estimated at between 15 and 50 cases per million adults. PAH usually develops between the ages of 20 and 60 but can occur at any age, with a mean age of diagnosis around 45 years. Idiopathic PAH is the most common type, constituting approximately 40% of the total diagnosed PAH cases, and it occurs 2 to 4 times more frequently in females.

The current medical therapies for PAH involve endothelin receptor antagonists, or ERA, phosphodiesterase-5, or PDE5, inhibitors, prostacyclin analogues, selective IP receptor agonists, and soluble guanylate cyclase, or sGC stimulators, which aim to reduce symptoms and improve quality of life. All currently approved products treat the symptoms of PAH, but do not address the underlying disease. According to LifeSci Capital (Feb 2016 Analysis), the U.S. and worldwide markets for PAH pharmaceutical treatments in 2015 exceeded $2.7 billion and $4.5 billion, respectively.

On January 6, 2017, we entered into a Patent Assignment Agreement with Selten Pharma, Inc., or Selten, whereby we received exclusive, worldwide rights for the development and commercialization of BMPR2 activators for the treatment of PAH and related vascular diseases. As part of the agreement, Selten assigned to us its license to a group of patents owned by the Board of Trustees of the Leland Stanford Junior University, or Stanford, which cover uses of tacrolimus and ascomycin to treat PAH. Tacrolimus received an Orphan Drug Designation for the treatment of PAH on March 16, 2015. In 2017, we intend to focus on developing a proprietary formulation of tacrolimus to be used in a clinical development program and for commercial use.

Qsymia for Additional Indications

We are currently considering further development of Qsymia for the treatment of various diseases, including (i) obstructive sleep apnea, (ii) diabetes, (iii) nonalcoholic steatohepatitis, or NASH, (iv) nonalcoholic fatty liver disease, or NAFLD, also known as fatty liver disease, (v) hyperlipidemia, or an elevation of lipids, or fats, in the bloodstream, and

(vi) hypertension who do not respond well to antihypertensive medication. We expect no future development until we have concluded our discussions with FDA regarding a cardiovascular outcome trial, or CVOT, for Qsymia.

Additional Opportunities

We will continue to evaluate potential in-licensing opportunities to build our portfolio of product and product candidates.

VIVUS was incorporated in California in 1991 and reincorporated in Delaware in 1996. Our corporate headquarters is located at 900 E. Hamilton Avenue, Suite 550, Campbell, California 95008, and our telephone number is (650) 934-5200.

Products and Development Programs

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

Drug	Indication	Status	Commercial rights
Qsymia (phentermine and topiramate extended-release)	Obesity	*United States* Commercially available	Worldwide
		EU Marketing Authorization Application, or MAA, denied in 2014.	
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/SPEDRA (avanafil)	Erectile dysfunction	*United States* Commercially available sNDA: Label expansion for 15 minute onset claim approved Sep 2014.	Worldwide license from MTPC (excluding certain Asian markets). U.S., Canada, South America and India commercial rights licensed to Metuchen. EU, Australia and New Zealand commercial rights licensed to Menarini Group. Middle East, Africa, Turkey and Commonwealth of Independent States commercial rights licensed to Sanofi.
		EU Commercially available	
Tacrolimus	Pulmonary arterial hypertension	Phase 2a study completed	Worldwide

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, or obese patients, or with a BMI of 27 or greater, or overweight patients, in the presence of at least one weight-related comorbidity, such as hypertension, type 2 diabetes mellitus or high cholesterol, or 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.

On July 20, 2016, the U.S. District Court for the District of New Jersey issued a claim construction, or Markman, ruling governing the Qsymia Abbreviated New Drug Application, or ANDA, lawsuits. The Court adopted our proposed constructions for all but one of the disputed claim terms and adopted a compromise construction that was acceptable to us for the final claim term. Expert discovery is ongoing and no trial date has been scheduled.

Upon receiving approval to market Qsymia, FDA required that we perform additional studies of Qsymia including a cardiovascular outcome trial, or CVOT. To date, there have been no indications throughout the Qsymia clinical development program nor post-marketing experience of any increase in adverse cardiovascular events. Given this historical information, along with the established safety profiles of phentermine and topiramate, we continue to believe that Qsymia poses no true cardiovascular safety risk. We met with FDA in May 2015 to discuss alternative strategies for obtaining cardiovascular, or CV, outcomes data that would be substantially more feasible and that ensure timely collection of data to better inform on the CV safety of Qsymia. We worked with cardiovascular and epidemiology experts in exploring alternate solutions to demonstrate the long-term cardiovascular safety of Qsymia. After reviewing a summary of Phase 3 data relevant to CV risk and post-marketing safety data, the cardiology experts noted that they believe there was an absence of an overt CV risk signal and indicated that they did not believe a randomized placebo-controlled CVOT would provide additional information regarding the CV risk of Qsymia. The epidemiology experts maintained that a well-conducted retrospective observational study could provide data to further inform on potential CV risk. We worked with the expert group to develop a protocol and conduct a retrospective observational study. We are in the process of analyzing the collected information for discussion with FDA. Although we and consulted experts believe there is no overt signal for CV risk to justify the CVOT, we are committed to working with FDA to reach a resolution. There is no assurance, however, that FDA will accept any measures short of those specified in the CVOT to satisfy this requirement.

In May 2013, the EC issued a decision refusing the grant of marketing authorization in the EU for Qsiva™, the approved trade name for Qsymia in the EU. In September 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 CVOT to assess the long-term treatment effect of Qsymia on the incidence of major adverse CV events in overweight and obese subjects with confirmed CV disease. Our request was to allow this interim analysis to support the resubmission of an application for a marketing authorization for Qsiva for the treatment of obesity in accordance with the EU centralized marketing authorization procedure. We received feedback in 2014 from the EMA and the various competent authorities of the EU Member States associated with review of the CVOT protocol. As for the EU, even if FDA were to accept a retrospective observational study in lieu of a CVOT, there would be no assurance that the EMA would accept the same.

Foreign regulatory approvals, including EC 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 that have failed to receive such approval in that market, which could have a material adverse effect on our business, financial condition and results of operations.

STENDRA for the Treatment of Erectile Dysfunction

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.

STENDRA is an oral PDE5 inhibitor we have licensed from MTPC. STENDRA was approved in the U.S. by FDA on April 27, 2012, for the treatment of ED. As part of the approval of STENDRA, we were committed to conduct two post-approval clinical studies. The first was 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 was 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 completed.

On September 18, 2014, FDA approved a supplemental New Drug Application, or sNDA, for STENDRA. STENDRA is now indicated to be taken as early as approximately 15 minutes before sexual activity. On January 23, 2015, the EC adopted the commission implementing decision amending the marketing authorization for SPEDRA. SPEDRA is now approved in the EU to be taken as needed approximately 15 to 30 minutes before sexual activity.

We have granted an exclusive license to Menarini to commercialize and promote SPEDRA for the treatment of ED in over 40 European countries, including the EU, plus Australia and New Zealand. We have granted an exclusive license to Metuchen to market STENDRA in the United States, Canada, South America and India. 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 where we do not currently have a commercial collaboration under our license with MTPC, including Mexico and Central America.

On July 27, 2016, we filed a lawsuit in the U.S. District Court for the District of New Jersey against Hetero USA, Inc. and Hetero Labs Limited, collectively referred to as Hetero, in response to Hetero's ANDA filing with FDA, requesting approval to market and sell generic versions of the currently approved doses of STENDRA tablets prior to the expiration of U.S. Patents 6,656,935 and 7,501,409, collectively referred to as the Asserted Patents. On January 3, 2017, we entered into a settlement agreement with Hetero, or the Settlement Agreement. Under the Settlement Agreement, Hetero was granted a license to manufacture and commercialize the generic version of STENDRA described in its ANDA filing in the United States as of the date that is the later of (a) October 29, 2024, which is 180 days prior to the expiration of the last to expire of the Asserted Patents, or (b) the date that Hetero obtains final approval from FDA of the Hetero ANDA. The Settlement Agreement provides for a full settlement of all claims that were asserted in the suit. As required by law, the Settlement Agreement was submitted to the U.S. Federal Trade Commission and U.S. Department of Justice.

Tacrolimus for the Treatment of Pulmonary Arterial Hypertension

PAH is a chronic life-threatening disease characterized by elevated blood pressure in the pulmonary arteries (arteries between the heart and lungs) due to severe constriction of these blood vessels. Pulmonary blood pressure is normally between 8 and 20 mmHg at rest as measured by right heart catheterization; however, in patients with PAH, the pressure in the pulmonary artery is greater than 25 mmHg at rest or 30 mmHg during physical activity. These high pressures make it difficult for the heart to pump blood through the lungs to be oxygenated.

The prevalence of PAH varies among specific populations, but it is estimated at between 15 and 50 cases per million adults. PAH usually develops between the ages of 20 and 60, but can occur at any age with a mean age of diagnosis around 45 years. Idiopathic PAH is the most common type constituting approximately 40% of the total PAH cases, and it occurs 2 to 4 times more frequently in females. Risk factors for PAH include a family history of PAH, congenital heart disease, connective tissue disease, portal hypertension, sickle cell disease, thyroid disease, HIV infection, and use of certain drugs and toxins. PAH patients are classified by the World Health Organization (WHO) as class 1, 2, 3, or 4, with the most impaired patients being class 4.

The symptoms of PAH are non-specific and thus are unfortunately most frequently diagnosed when patients have reached an advanced stage of the disease. Early symptoms may include shortness of breath during routine activity, fatigue, chest pain, racing heartbeat, pain in upper right side of abdomen, and decreased appetite. As PAH progresses and worsens, symptoms may include feeling light-headed (especially during physical activity), fainting, swelling in the ankles or legs, and bluish lips or skin. At its worse point, the patient develops right heart failure and is routinely

hospitalized to manage their progressing disease which may ultimately lead to death. Currently, lung transplantation is the only option for patients who are not responsive to medical therapy.

The current medical therapies for PAH involve endothelin receptor antagonists, or ERA, phosphodiesterase-5, or PDE5, inhibitors, prostacyclin analogues, selective IP receptor agonists, and soluble guanylate cyclase, or sGC stimulators, which aim to reduce symptoms and improve quality of life. All currently approved products treat the symptoms of PAH, but do not address the underlying disease. According to LifeSci Capital (Feb 2016 Analysis), the U.S. and worldwide markets for PAH pharmaceutical treatments in 2015 exceeded $2.7 billion and $4.5 billion, respectively.

We believe that bone morphogenic protein receptor 2, or BMPR2, signaling could inhibit vascular smooth muscle proliferation. Reduced BMPR2 expression, including loss-of-function mutations in BMPR2, is prevalent in PAH patients and may contribute to smooth muscle proliferation. Studies have shown that low doses of tacrolimus have restored BMPR2 signaling and reversed proliferative effects in animal models. We believe that enhancement of BMPR2 signaling with tacrolimus may address a fundamental cause of PAH.

On March 16, 2015, tacrolimus for the treatment of PAH received an Orphan Drug Designation. An Orphan Drug Designation can provide benefits to us, such as: tax credits on clinical research, simplification of administrative procedures (reduction of the waiting period and reduction of the amount of registration fees), and marketing exclusivity of seven years after the marketing approval is granted for the approved orphan indication.

Stanford completed a randomized, double-blind Phase 2a with 23 class 1 and 2 PAH patients titrated to target blood levels. All target blood levels were well tolerated with no drug related serious adverse events, nephrotoxicity or incident diabetes. In addition, Stanford provided tacrolimus for compassionate use in three class 3 or 4 PAH patients. The compassionate use demonstrated dramatically reduced rates of hospitalizations and functional class improvements were observed.

On January 6, 2017, we entered into a Patent Assignment Agreement with Selten, whereby we received exclusive, worldwide rights for the development and commercialization of BMPR2 activators for the treatment of PAH and related vascular diseases. As part of the agreement, Selten assigned to us its license to a group of patents owned by Stanford which cover uses of tacrolimus and ascomycin to treat PAH. We are responsible for future financial obligations to Stanford under that license.

We have also assumed full responsibility for the development and commercialization of the licensed compounds for the treatment of PAH and related vascular diseases. Selten received an upfront payment of $1.0 million and is entitled to receive milestone payments based on global development status and future sales milestones, as well as tiered royalty payments on future sales of these compounds. The total potential milestone payments are $39.0 million to Selten and $550,000 to Stanford. The majority of the milestone payments to Selten may be paid, at our sole option, either in cash or our common stock, provided that in no event shall the payment of common stock exceed fifty percent of the aggregate amount of such milestone payments.

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 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 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 FDA as part of an investigational new drug application, or IND, which must be reviewed by 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 establishes 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 FDA as part of the IND. Further, each clinical study must be conducted under the auspices of an independent institutional review board, or IRB. The IRB 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, FDA, or the 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 FDA and others.

The results of the pre-clinical and clinical testing, together with chemistry and manufacturing information, are submitted to 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, 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 FDA under the Prescription Drug User Fee Act, or PDUFA, 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. 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 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, FDA may require the development and implementation of a REMS to address specific safety issues at the time of approval or after marketing of the product. A REMS 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 FDA. 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, FDA may require companies to conduct post-marketing studies or trials, referred to as PMRs, to evaluate safety issues related to the approved product, and may withdraw approval or impose marketing restrictions based on the results of PMR studies or trials or other relevant data. FDA has required us to perform PMR studies and trials for both of our approved products, Qsymia and STENDRA. FDA has broad post-market regulatory and enforcement powers, including the ability to levy civil monetary penalties, suspend or delay issuance of approvals, seize

or recall products, or withdraw approvals. Additionally, the Food and Drug Administration Amendments Act of 2007 requires all applicable clinical trials we conduct for our investigational drug candidates, both before and after approval, and the results of those applicable clinical 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 may subject us to significant civil penalties.

Facilities used to manufacture drugs are subject to periodic inspection by FDA, and other authorities where applicable, and must comply with 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.

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 FDA. 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 manufacture and 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 FDA, we are also subject to regulation under NIH 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. For example, in the EU, the conduct of clinical trials is governed by Directive 2001/20/EC which imposes obligations and procedures that are similar to those provided in applicable U.S. laws. The European Union Good Clinical Practice rules, or GCP, and EU Good Laboratory Practice, or GLP, obligations must also be respected during conduct of the trials. Clinical trials must be approved by the competent authorities and the competent Ethics Committees in the EU Member States in which the clinical trials take place. A clinical trial application, or CTA, must be submitted to each EU Member State's national health authority. Moreover, an application for a positive opinion must be submitted to the competent Ethics Committee prior to commencement of clinical trials of a medicinal product. The competent authorities of the EU Member States in which the clinical trial is conducted must authorize the conduct of the trial and the competent Ethics Committees must grant their positive opinion prior to commencement of a clinical trial in an EU Member State. 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.

To obtain marketing approval of a medicinal product in the EU, we would be required to submit marketing authorization applications based on the ICH Common Technical Document to the competent authorities, and must demonstrate the quality, safety and efficacy of our medicinal products. This would require us to conduct human clinical trials to generate the necessary clinical data. Moreover, we would be required to demonstrate in our application that studies have been conducted with the medicinal product in the pediatric population as provided by a Pediatric Investigation Plan, or PIP, approved by the Pediatric Committee of the EMA. Alternatively, confirmation that we have been granted a waiver or deferral from the conduct of these studies must be provided.

Medicinal products are authorized in the EU in one of two ways, either by the competent authorities of the EU Member States through the decentralized procedure or mutual recognition procedure, or through the centralized procedure by the European Commission following a positive opinion by the EMA. The authorization process is essentially the same irrespective of which route is used.

The centralized procedure provides for the grant of a single marketing authorization that is valid for all EU Member States. The centralized procedure is compulsory for medicinal products produced by certain biotechnological processes, products designated as orphan medicinal products, and products with a new active substance indicated for the treatment of certain diseases. It is optional for those products that are highly innovative or for which a centralized process is in the interest of patients. Under the centralized procedure in the EU, the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP). Accelerated evaluation may be granted by the CHMP in exceptional cases. These are defined as circumstances in which a medicinal product is expected to be of a "major public health interest." Three cumulative criteria must be fulfilled in such circumstances: the seriousness of the disease, such as heavy disabling or life-threatening diseases, to be treated; the absence or insufficiency of an appropriate alternative therapeutic approach; and anticipation of high therapeutic benefit. In these circumstances, the EMA ensures that the opinion of the CHMP is given within 150 days.

The decentralized procedure provides for approval by one or more other ("concerned") EU Member States of an assessment of an application for marketing authorization conducted by one EU Member State, known as the reference EU Member State. In accordance with this procedure, an applicant submits an application for marketing authorization to the reference EU Member State and the concerned EU Member States. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the European Commission, whose decision is binding on all EU Member States. In accordance with the mutual recognition procedure, the sponsor applies for national marketing authorization in one EU Member State. Upon receipt of this authorization the sponsor can then seek the recognition of this authorization by other EU Member States. Authorization in accordance with either of these procedures will result in authorization of the medicinal product only in the reference EU Member State and in the other concerned EU Member States.

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 available in the marketing authorization dossier for another, previously approved, medicinal product) are entitled to eight years' data exclusivity. During this period, applicants for authorization of generics or biosimilars 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 ten years' market exclusivity. During this ten year period no generic or biosimilar of this medicinal product can be placed on the EU market. The ten-year period of market exclusivity can be extended to a maximum of 11 years if, during the first eight years of those ten 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.

Similarly to the U.S., marketing authorization holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA and/or the competent authorities of the EU Member States. This oversight applies both before and after grant of manufacturing and marketing authorizations. It includes control of compliance with EU GMP rules and pharmacovigilance rules. We cannot guarantee that we would be able to comply with the post-marketing obligations imposed as part of the marketing authorization for SPEDRA. Failure to comply with

these requirements may lead to the suspension, variation or withdrawal of the marketing authorization for SPEDRA in the EU.

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 that may apply to the advertising and promotion of medicinal products. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, as approved by the competent authorities. The SmPC is the document that provides information to physicians concerning the safe and effective use of the medicinal product. It forms an intrinsic and integral part of the marketing authorization granted for the medicinal product. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion. The off-label promotion of medicinal products is prohibited in the EU. The applicable laws at the EU level and in the individual EU Member States also prohibit the direct-to-consumer advertising of prescription-only medicinal products. Violations of the rules governing the promotion of medicinal products in the EU could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict communications concerning the advertising and promotion of our products to the general public and may also impose limitations on our promotional activities with healthcare professionals.

Failure to comply with the EU Member State laws implementing the Community Code on medicinal products, and EU rules governing the promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices, with the EU Member State laws that apply to the promotion of medicinal products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements 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.

Interactions between pharmaceutical companies and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct in the individual EU Member States. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the EU. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of the EU Member States. One example is the UK Bribery Act 2010. This Act applies to any company incorporated in or "carrying on business" in the UK, irrespective of where in the world the alleged bribery activity occurs. This Act could have implications for our interactions with physicians in and outside the UK. Violation of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU Member States must be publically disclosed. Moreover, agreements with physicians must often be the subject of prior notification and approval by the physician's employer, his/her competent professional organization, and/or the competent authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

United States Healthcare Reform

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively referred to in this report as the Affordable Care Act was adopted in the United States. This law substantially changed the way healthcare is financed by both governmental and private insurers and significantly impacted the pharmaceutical industry. The Affordable Care Act contains a number of provisions that are expected to impact our business and operations. 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 February 2016, the Centers for Medicare and Medicaid Services, or CMS, the federal agency that administers Medicare and the Medicaid Drug Rebate program, issued final regulations to implement the changes to the Medicaid Drug Rebate program under the Affordable Care Act. These regulations become effective on April 1, 2016. In addition, 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 2016, 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 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. We currently do not have coverage under Medicare Part D for our drugs, but this could change in the future.

Moreover, legislative changes to the Affordable Care Act remain possible and appear likely in the 115th United States Congress and under the Trump Administration. We expect that the Affordable Care Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products or to successfully commercialize our product candidates, if approved.

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, but exempts "orphan drugs" from the ceiling price requirements for these covered entities. The Affordable Care Act also obligates the Secretary of the Department of Health and Human Services 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, the agency that administers the 340B program, recently initiated the process of updating the agreement with participating manufacturers. The Healthcare Reform 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. In 2015, HRSA issued proposed omnibus guidance that addresses many aspects of the 340B program, and in August 2016, HRSA issued a proposed regulation regarding an administrative dispute resolution process for the 340B program. It is unclear when or whether the guidance or regulation will be released in final form under the Trump Administration. On January 5, 2017, HRSA issued a final regulation regarding the calculation of 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities. The March 6, 2017 effective date of this regulation is subject to a temporary delay directed by the Trump Administration, and the regulation could be subject to further delay or other modification by the Trump Administration. Implementation of this final rule and the issuance of any other final regulations and guidance 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 an 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.

Coverage 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 Medicare and Medicaid, as well as managed care organizations, private health insurers and other organizations. 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. Further, federal budgetary concerns could result in the implementation of significant federal spending cuts, including cuts in Medicare and other health related spending in the near-term. For example, beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologics, were reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. Subsequent legislation extended the 2% reduction, on average, to 2025. These cuts reduce reimbursement payments related to our products, which could potentially negatively impact our revenue.

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 surveys and publishes retail community pharmacy acquisition cost information in the form of National Average Drug Acquisition Cost, or NADAC, files to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates. 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 Health Technology Assessments, or HTAs, 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.

In the EU, the sole legal instrument at the EU level governing the pricing and reimbursement of medicinal products is Council Directive 89/105/EEC, or the Price Transparency Directive. The aim of this Directive is to ensure that pricing and reimbursement mechanisms established in the EU Member States are transparent and objective, do not hinder the free movement and trade of medicinal products in the EU and do not hinder, prevent or distort competition on the market. The Price Transparency Directive does not provide any guidance concerning the specific criteria on the basis of which pricing and reimbursement decisions are to be made in individual EU Member States. Neither does it have any direct consequence for pricing nor reimbursement levels in individual EU Member States. The EU Member States are free to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices and/or reimbursement levels of medicinal products for human use. An EU Member State may approve a specific price or level of reimbursement for the medicinal product, or alternatively adopt a system of direct or indirect controls on the profitability of the company responsible for placing the medicinal product on the market, including volume-based arrangements and reference pricing mechanisms.

Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States. These EU Member States include the United Kingdom, France, Germany and Sweden. The HTA process in the EEA Member States is governed by the national laws of these countries. HTA is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. HTA generally focuses on the clinical efficacy and effectiveness, safety, cost, and cost-effectiveness of individual medicinal products as well as their potential implications for the healthcare system. Those elements of medicinal products are compared with other treatment options available on the market.

The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product vary between EU Member States.

In 2011, Directive 2011/24/EU was adopted at the EU level. This Directive concerns the application of patients' rights in cross-border healthcare. The Directive is intended to establish rules for facilitating access to safe and high-quality cross-border healthcare in the EU. It also provides for the establishment of a voluntary network of national authorities or bodies responsible for HTA in the individual EU Member States. The purpose of the network is to facilitate and support the exchange of scientific information concerning HTAs. This could lead to harmonization between EU Member States of the criteria taken into account in the conduct of HTA and their impact on pricing and reimbursement decisions.

Fraud and Abuse and Privacy and Data Security Laws and Regulations

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 and privacy and data security 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 liability may be established under the federal Anti-Kickback Law without proving 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 U.S. federal and state laws and regulations, including state data breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of personal information. In addition, most healthcare providers who prescribe our products 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 and the Health Information Technology for Economic and Clinical Health Act, or HITECH, which are collectively referred to as HIPAA. We are not a HIPAA-covered entity and we do not operate as a business associate to any covered entities. Therefore, the HIPAA privacy and security requirements do not apply to us (other than potentially with respect to providing certain employee benefits). 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 and/or conspiring to commit a 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. Other countries also have, or are developing, laws governing the collection, use, disclosure and protection of personal information. The collection and use of personal health data and other personal data in the EU is governed by the provisions of the Data Protection Directive as implemented into national laws by the EU Member States. This Directive imposes restrictions on the processing (e.g., collection, use, disclosure) of personal data, including a number of requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals prior to processing their personal data, 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 restrictions 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 General Data Protection Regulation (GDPR), an EU-wide regulation that will be fully enforceable by May 25, 2018, will introduce new data protection requirements in the EU and substantial fines for violations of the data protection rules. The GDPR will increase our responsibility and liability in relation to EU 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. The legislative and regulatory landscape for privacy and data security continues to evolve, and there has been an increasing amount of focus on privacy and data security issues with the potential to affect our business. These privacy and data security laws and regulations could increase our cost of doing business, and failure to comply with these laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may have contractual rights that limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our 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 certain health care providers 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. 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 and other transfers of value to physicians and teaching hospitals, and to submit such data to CMS, which will then make all of this data publicly available on the CMS website. Pharmaceutical manufacturers with products for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program are required to have started tracking reportable payments on August 1, 2013, and must submit a report to CMS on or before the 90th day of each calendar year disclosing reportable payments made in the previous calendar year. Failure to comply with the reporting obligations may result in civil monetary penalties; and
- the federal Foreign Corrupt Practices Act of 1977 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 or regulations 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 and regulations, 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, data security and fraud laws and regulations 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 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.

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 10 years after the date of the first sale for a particular product or 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 insufficiently effective or insufficiently safe relative to other PDE5 inhibitor compounds based on published information or 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. In 2015, we transferred the manufacturing of the API and tablets for STENDRA to Sanofi.

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 former 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 for the treatment of ED in over 40 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 ED, which was granted by the EC 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 ED for a limited time period, subject to certain exceptions.

Under the Menarini License Agreement, we have received payments of $63.0 million relating to license and milestone payments and royalty prepayments through December 31, 2016. Additionally, we are entitled to receive potential milestone payments based on certain net sales targets, 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) 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. 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. On January 29,

2015, Auxilium was purchased by Endo International, plc. 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.

We received an upfront license fee of $30.0 million in October 2013 and a regulatory milestone payment of $15.0 million in 2014 upon approval by FDA of a specific time of onset claim for STENDRA in the Auxilium Territory. Additionally, we have received royalty payments based on tiered percentages of the aggregate annual net sales of STENDRA in the Auxilium Territory on a quarterly basis.

Auxilium obtained 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.

Auxilium terminated the Auxilium Supply Agreement effective June 30, 2016 and the Auxilium License Agreement effective September 30, 2016.

Sanofi

On December 11, 2013, we entered into the Sanofi License Agreement with Sanofi. Effective as of December 11, 2013, we entered into the Sanofi Supply Agreement with Sanofi Winthrop Industrie, a wholly owned subsidiary of Sanofi, which terminated according to its terms on June 30, 2015. Under the terms of the Sanofi License Agreement, Sanofi received an exclusive license to commercialize and promote avanafil for therapeutic use in humans in the Sanofi Territory.

In December 2013, we received an upfront license fee of $5.0 million and a $1.5 million manufacturing milestone payment, and in February 2014, we received an additional $3.5 million in manufacturing milestone payments. We were also eligible to receive 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.

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 have obtained approval from FDA and the EMA for Sanofi Chimie to be a qualified supplier of avanafil API and of 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.

Metuchen Pharmaceuticals, LLC

On September 30, 2016, we entered into the Metuchen License Agreement and the Metuchen Supply Agreement with Metuchen. Under the terms of the Metuchen License Agreement, Metuchen received an exclusive, license to develop, commercialize and promote STENDRA in the Metuchen Territory, effective October 1, 2016. We and Metuchen have agreed not to develop, commercialize, or in-license any other product that operates as a PDE-5 inhibitor in the Metuchen Territory for a limited time period, subject to certain exceptions. The license agreement will terminate upon the expiration of the last-to-expire payment obligations under the license agreement; upon expiration of the term of the license agreement, the exclusive license granted under the license agreement shall become fully paid-up, royalty-free, perpetual and irrevocable as to us but not certain trademark royalties due to MTPC.

Metuchen will obtain STENDRA exclusively from us for a mutually agreed term pursuant to the supply agreement. Metuchen may elect to transfer the control of the supply chain for STENDRA for the Metuchen Territory to itself or its designee by assigning to Metuchen our agreements with the contract manufacturer. For 2016 and each subsequent calendar year during the term of the supply agreement, if Metuchen 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. Upon the termination of the supply agreement (other

than by Metuchen for our uncured material breach or upon completion of the transfer of the control of the supply chain), Metuchen's agreed minimum purchase amount of STENDRA from us shall accelerate for the entire then current initial term or renewal term, as applicable. The initial term under the Supply Agreement will be for a period of five years, with automatic renewal for successive two year periods unless either party provides a termination notice to the other party at least two years in advance of the expiration of the then current term. On September 30, 2016, we received $70 million from Metuchen under the license agreement. Metuchen will also reimburse us for payments made to cover royalty and milestone obligations to MTPC during the term of the license agreement, but will otherwise owe us no future royalties.

Selten Pharma, Inc.

On January 6, 2017, we entered into a Patent Assignment Agreement with Selten, whereby we received exclusive, worldwide rights for the development and commercialization of BMPR2 activators for the treatment of PAH and related vascular diseases. As part of the agreement, Selten assigned to us its license to a group of patents owned by Stanford, which cover uses of tacrolimus and ascomycin to treat PAH. We are responsible for future financial obligations to Stanford under that license.

We have also assumed full responsibility for the development and commercialization of the licensed compounds for the treatment of PAH and related vascular diseases. Selten received an upfront payment of $1.0 million and is entitled to receive milestone payments based on global development status and future sales milestones, as well as tiered royalty payments on future sales of these compounds. The total potential milestone payments are $39.0 million to Selten and $550,000 to Stanford. The majority of the milestone payments to Selten may be paid, at our sole option, either in cash or our common stock, provided that in no event shall the payment of common stock exceed fifty percent of the aggregate amount of such milestone payments.

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 became the focus of our development program for Qsymia. 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. 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, and he continues to be available as a consultant.

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, which primarily relates to Qsymia, our FDA-approved drug for the treatment of obesity, STENDRA, our FDA-approved drug for the treatment of ED, and tacrolimus is summarized as follows:

QSYMIA	
U.S. Patent No. 7,056,890	Expiring 06/14/2020
U.S. Patent No. 7,553,818	Expiring 06/14/2020
U.S. Patent No. 7,659,256	Expiring 06/14/2020
U.S. Patent No. 7,674,776	Expiring 06/14/2020
U.S. Patent No. 8,802,636	Expiring 06/14/2020
U.S. Patent No. 8,580,299	Expiring 06/14/2029*
U.S. Patent No. 8,895,058	Expiring 06/09/2028
U.S. Patent No. 9,011,905	Expiring 06/09/2028
U.S. Patent Application No. 15/172,448	Pending

U.S. Patent Application No. 15/333,059	Pending
U.S. Patent No. 8,580,298	Expiring 05/15/2029*
U.S. Patent No. 8,895,057	Expiring 06/09/2028
U.S. Patent No. 9,011,906	Expiring 06/09/2028
U.S. Patent No. 6,071,537	Expiring 06/23/2017
U.S. Patent Publication No. 2016/0310446 A1	Pending
U.S. Patent Publication No. 2016/0250180 A1	Pending
Canadian Patent No. 2,377,330	Expiring 06/14/2020
Canadian Patent No. 2,727,313	Expiring 06/09/2029
Canadian Patent No. 2,727,319	Pending
STENDRA	
U.S. Patent No. 6,656,935	Expiring 04/26/2025
U.S. Patent No. 7,501,409	Expiring 05/05/2023
Canadian Patent No. 2,383,466	Expiring 09/13/2020
ERECTILE DYSFUNCTION	
U.S. Patent No. 5,922,341	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
TACROLIMUS	
U.S. Patent No. 9,474,745	Expiring 04/30/2032
U.S. Patent Publication No. 2017/0007585 A1	Pending
PCT/US16/12694	Pending
PCT/US16/30737	Pending
PCT/US16/47148	Pending

* 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 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 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. 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. However, 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.

Catalent 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.

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 manufactures and supplies the API for STENDRA. 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 manufactures and supplies the tablets for 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.

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 commercialize Qsymia in the U.S. primarily through a dedicated contract sales force, supported by an internal commercial team. 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. We have rolled out marketing programs to encourage targeted prescribers to gain more experience with Qsymia. We have increased our investment in digital media in order to amplify our messaging to information-seeking consumers. The digital messaging encourages those consumers most likely to take action to speak with their physicians about obesity treatment options. We believe our enhanced web-based strategies will deliver clear and compelling communications to potential patients. We launched the "Smart Changes Program" in which we partner Qsymia with the Mayo Clinic diet to help on-line patients make the behavioral changes needed for sustained weight-loss.

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 broader network of certified retail pharmacies and through a small number of certified home delivery pharmacies and wholesalers. 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 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), an anti-obesity compound being marketed by Eisai Inc., Eisai Co., Ltd.'s U.S. subsidiary; Contrave ® (naltrexone/bupropion), Orexigen Therapeutics' anti-obesity product; Xenical ® (orlistat), marketed by Roche; alli ®, the over-the-counter version of orlistat, marketed by GlaxoSmithKline; and Novo Nordisk A/S' Saxenda ® (liraglutide) 3.0 mg.

Agents approved for type 2 diabetes that have demonstrated weight loss in clinical studies may also compete with Qsymia. These agents include Victoza ® (liraglutide; approved for diabetes at 1.2mg and 1.8mg dosage strengths) from Novo Nordisk A/S, a GLP-1 receptor agonist approved January 25, 2010, Invokana ® (canaglifozin) from Johnson & Johnson's Janssen Pharmaceuticals, an SGLT2 inhibitor, approved March 29, 2013; Farxiga™ (dapagliflozin) from AstraZeneca and Bristol-Myers Squibb, an SGLT2 inhibitor, approved January 8, 2014; Jardiance ® (empagliflozin) from Boehringer Ingelheim, an SGLT2 inhibitor, approved August 1, 2014; and Glyxambi ® (empagliflozin/linagliptin) from Boehringer Ingelheim and Eli Lilly, an SGLT2 inhibitor and DPP-4 inhibitor combination product, approved January 30, 2015. On January 14, 2015, FDA approved the Maestro Rechargeable System for certain obese adults, the first weight loss treatment device that targets the nerve pathway between the brain and the stomach that controls feelings of hunger and fullness. The Maestro Rechargeable System is approved to treat patients aged 18 and older who have not been able to lose weight with a weight loss program, and who have a body mass index of 35 to 45 with at least one other obesity-related condition, such as type 2 diabetes.

In addition, there are several other investigational drug candidates in Phase 2 clinical trials. Zafgen's beloranib, currently in Phase 2 for severe obesity, is a methionine aminopeptidase 2 (MetAP2) inhibitor, which is believed to work by re-establishing balance to the ways the body packages and metabolizes fat. 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. Although these products have not been approved by FDA for use in the treatment of chronic 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 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. We have received notifications under paragraph IV of the Hatch-Waxman Act challenging certain of our Qsymia patents. 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 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, 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 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.

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 $5.6 million, $10.1 million and $13.8 million in 2016, 2015 and 2014, respectively, in research and development expenses, primarily to support the approval efforts, post-marketing requirements, and clinical programs for Qsymia and STENDRA/SPEDRA.

Employees

As of February 28, 2017, we had 65 employees located at our corporate headquarters in Campbell, 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, we may be unable to maintain this product liability coverage for 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 18: "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* , 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.

Item 1A. ***Risk Factor s***

Set forth below and elsewhere in this Annual Report on Form 10-K and in other documents we file with the Securities and Exchange Commission, or the SEC, are risks and uncertainties that could cause actual results to differ

materially from the results contemplated by the forward-looking statements contained in this Annual Report on Form 10-K. These are not the only risks and uncertainties facing VIVUS. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

Risks Relating to our Business

Our success will depend on our ability and that of our collaborators to effectively and profitably commercialize Qsymia® and STENDRA.

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

- expand the use of Qsymia through targeted patient and physician education;
- obtain marketing authorization by the EC for Qsiva™ in the EU through the centralized marketing authorization procedure;
- manage our alliances with MTPC, Menarini, Metuchen 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 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 FDA, including Qsymia's Risk Evaluation and Mitigation Strategy, or REMS, any future changes to the REMS, and any other requirements established by FDA in the future;
- efficiently conduct the post-marketing studies required by 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 STENDRA and the finished products are manufactured in sufficient quantities and in compliance with requirements of FDA and similar foreign regulatory agencies and with an acceptable quality and pricing level in order to meet commercial demand;
- ensure that the entire supply chain for Qsymia and STENDRA, from APIs to finished products, efficiently and consistently delivers Qsymia and STENDRA to customers; and
- effectively and efficiently manage our sales force and commercial team for the promotion of Qsymia.

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.

We may not be able to successfully develop, launch and commercialize tacrolimus or any other potential future development programs.

We may not be able to effectively develop and profitably launch and commercialize tacrolimus or any other potential future development programs which we may undertake, which will include our ability to:

- effectively conduct phase 2 and phase 3 clinical testing on tacrolimus, which could be delayed by slow patient enrollment, long treatment time required to demonstrate effectiveness, disruption of operations at clinical trial sites, adverse medical events or side effects in treated patients, failure of patients taking the placebo to continue to participate in the clinical trials, and insufficient clinical trial data to support effectiveness of tacrolimus;
- obtain regulatory approval and market authorization for tacrolimus in the U.S., EU and other territories;
- develop, validate and maintain a commercially viable manufacturing process that is compliant with cGMP;
- establish and effectively manage a supply chain for tacrolimus to ensure that the API and the finished products are manufactured in sufficient quantities and in compliance with regulatory requirements and with acceptable quality and pricing in order to meet commercial demand;
- effectively determine and manage the appropriate commercialization strategy;
- manage costs;
- achieve market acceptance by patients, the medical community and third-party payors and generate product sales;
- effectively compete with other therapies;
- maintain a continued acceptable safety profile for tacrolimus following approval;
- comply with healthcare regulatory requirements; and
- maintain and defend our patents, if challenged.

If we are unable to successfully develop, launch and commercialize tacrolimus, 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.

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.

We commenced corporate restructuring plans in November 2013 and July 2015 that resulted in significant reductions in our workforce. These changes, 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.

We depend on our collaboration partners to gain or maintain approval, market, and sell STENDRA/SPEDRA in their respective licensed territories.

In July 2013, we entered into the Menarini License Agreement under which Menarini received an exclusive license to commercialize and promote SPEDRA for the treatment of ED in over 40 countries, including the EU, plus Australia and New Zealand. In October 2013, we entered into the Auxilium License Agreement and the Auxilium Supply Agreement under which Auxilium received an exclusive license to commercialize and promote STENDRA for the treatment of erectile dysfunction, or ED, in the United States and Canada. Auxilium terminated the Auxilium Supply Agreement effective June 30, 2016 and the Auxilium License Agreement effective September 30, 2016. On September 30, 2016, we entered into the Metuchen License Agreement whereby Metuchen received an exclusive license to develop, commercialize and promote STENDRA in the Metuchen Territory, effective October 1, 2016. In December 2013, we entered into the Sanofi License Agreement under which Sanofi received an exclusive license to commercialize and promote avanafil for therapeutic use in humans in the Sanofi Territory.

We are relying on our collaboration partners 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 our collaboration partners do not successfully commercialize STENDRA or SPEDRA, we may receive limited or no revenues under our agreements with them.

Under our license agreement with MTPC, we are obligated to ensure that Menarini, Metuchen, Sanofi, and any future 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 Menarini, Metuchen, Sanofi, or any future sublicensees 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.

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 MTPC, Menarini, Metuchen and Sanofi, 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. For example, in December 2015, Auxilium notified us of its intention to return the U.S. and Canadian commercial rights for STENDRA, and such commercial rights returned to us on September 30, 2016.

We currently rely on reports from our commercialization partners in determining our royalty revenues, and these reports may be subject to adjustment or restatement, which may materially affect our financial results.

We have royalty and milestone-bearing license and commercialization agreements for STENDRA or SPEDRA with Menarini and Sanofi and, prior to October 1, 2016, with Auxilium. In determining our royalty revenue from such agreements, we rely on our collaboration partners to provide accounting estimates and reports for various discounts and allowances, including product returns. As a result of fluctuations in inventory, allowances and buying patterns, actual sales and product returns of STENDRA or SPEDRA in particular reporting periods may be affected, resulting in the need for our commercialization partners to adjust or restate their accounting estimates set forth in the reports provided to us. For example, in April 2015, we were informed by Endo, upon their purchase of Auxilium, that Endo had revised its accounting estimate for STENDRA return reserve related to sales made in 2014. Under the terms of our license and commercialization agreement, adjustments to the return reserve can be deducted from reported net revenue. As a result, in the year ended December 31, 2015, we recorded an adjustment of $1.2 million to reduce our royalty revenue on net sales of STENDRA. The reduction in royalty revenue resulted in an increase to net loss of $1.2 million, or $0.01 per share, for the year ended December 31, 2015. Such adjustments or restatements may materially and negatively affect our financial position and results of operations. Beginning October 1, 2016, we ceased earning royalty revenue from U.S. sales as a result of the termination of our license and commercialization agreement with Auxilium. Our new license agreement with Metuchen is royalty-free as to us.

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 territories that are not covered by our current commercial collaboration agreements, such as Mexico and Central America. 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.

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 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 STENDRA has been approved in both the U.S. and the EU, our drug Qsymia has been approved in the U.S. but Qsiva (the intended trade name for Qsymia in the EU) was denied a marketing authorization by the EC 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 U.S. and the 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 Menarini, Sanofi and any potential future collaborators 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 Menarini, Sanofi and any potential future collaborators 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 have significant inventories on hand and, for the years ended December 31, 2015 and 2014, we recorded inventory impairment and commitment fees totaling $29.5 million and $2.2 million, respectively, 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 years ended December 31, 2015 and 2014, we recognized total charges of $29.5 million and $2.2 million, respectively, primarily for Qsymia inventories on hand in excess of projected demand. 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 is approved in the EU for 48 months of commercial product shelf life.

Our write-down for excess and obsolete inventory is subjective and requires 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 a crowded and competitive market and has limited sales history, is also 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, imposition of additional burdensome REMS requirements, suspension or revocation of regulatory approval 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 finished 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 topiramate or phentermine, which are the APIs used in Qsymia. We cannot guarantee that we will be successful in entering into supply agreements on reasonable terms or at all or that we will be able to obtain or maintain the necessary regulatory approvals for potential future suppliers in a timely manner or at all.

We anticipate that we will continue to rely on single-source suppliers for phentermine and topiramate for the foreseeable future. Any production shortfall on the part of our suppliers that impairs the supply of phentermine or 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.

We currently do not have any manufacturing facilities and intend to continue to rely on third parties for the supply of the API and tablets, as well as for the supply of starting materials. However, we cannot be certain that we will be able to obtain or maintain the necessary regulatory approvals for these suppliers in a timely manner or at all. 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-parties. In 2015, we transferred the manufacturing of the API and tables for STENDRA to Sanofi.

In July 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. In November 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 have obtained approval from FDA and the European Medicines Agency, or EMA, of Sanofi Chimie as a qualified supplier of avanafil API and of Sanofi Winthrop Industrie as a qualified supplier of the avanafil tablets. We have entered into supply agreements with Menarini and Metuchen under which we are obligated to supply them with avanafil tablets. If we are unable to maintain 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/SPEDRA 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 EC for Qsiva in the EU through the centralized procedure;
- our ability to maintain the certified retail pharmacy distribution channel in the United States for Qsymia;
- contraindications for Qsymia and STENDRA/SPEDRA;
- 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 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 our current 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 FDA or other regulatory authorities.

Our drugs may fail to achieve market acceptance or generate significant revenue to achieve sustainable 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 and trials mandated by FDA for Qsymia, and such studies and trials are expected to be costly and time consuming. If the results of these studies and trials reveal unacceptable safety risks, Qsymia may be required to be withdrawn from the market.

As part of the approval of Qsymia, we are required to conduct several post-marketing studies and trials, including a clinical trial 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 trial as currently designed will cost between $180 million and $220 million and the trial could take as long as five to six years to complete. In September 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 CVOT, known as AQCLAIM, 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. Our request was to allow this interim analysis to support the resubmission of an application for a marketing authorization for Qsiva for treatment of obesity in accordance with the EU centralized marketing authorization procedure. We received feedback in 2014 from the EMA and the various competent authorities of the EU Member States associated with review of the AQCLAIM CVOT protocol, and we received feedback from FDA in late 2014 regarding the amended protocol. As a part of addressing FDA comments from a May 2015 meeting to discuss alternatives to completion of a CVOT, we worked with cardiovascular and epidemiology experts in exploring alternate solutions to demonstrate the long-term cardiovascular safety of Qsymia. After reviewing a summary of Phase 3 data relevant to CV risk and post-marketing safety data, the cardiology experts noted that they believe there was an absence of an overt CV risk. The epidemiology experts maintained that a well-conducted retrospective observational study could provide data to further inform on potential CV risk. We worked with the expert group to develop a protocol and conduct a retrospective observational study. We are in the process of analyzing the collected information for discussion with FDA. Although we and the consulted experts believe there is no overt signal for CV risk to justify the AQCLAIM CVOT, VIVUS is committed to working with FDA to reach a resolution. As for the EU, even if FDA were to accept a retrospective observational study in lieu of a CVOT, there would be no assurance that the EMA would accept the same. There can be no assurance that we will be successful in developing a further revised protocol or that any such revised protocol will reduce the costs of the study or obtain FDA or EMA agreement that it will fulfill the requirement of demonstrating the long-term cardiovascular safety of Qsymia. Furthermore, there can be no assurance that FDA or EMA will not request or require us to provide additional information or undertake additional preclinical studies and clinical trials or retrospective observational studies.

In addition to these studies, FDA may also require us to perform other lengthy post-approval studies or trials, 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, including the completion of post-marketing studies and trials, can result in, among other things, civil monetary 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 have not complied with all the regulatory timelines for the required post-marketing trials and studies, and this may be considered a violation of the statute if FDA does not find good cause.

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 FDA that are commercially available and marketed by other companies, although the specific dose strengths 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) 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. 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™ and in the second quarter of 2014, Upsher-Smith Laboratories, Inc. launched Qudexy™. Both products provide an extended-release formulation of the generic drug topiramate that is indicated for certain types of seizures and migraines. 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, which could limit our pricing of Qsymia and negatively impact our revenues.

Once an applicant receives authorization to market a medicinal product in an EU Member State, through any application route, the applicant is 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 the price 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.

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

Qsymia and STENDRA/SPEDRA, 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 even with large self-insured retentions or deductibles, 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/SPEDRA or a future investigational drug candidate or product, 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; Contrave ® (naltrexone/bupropion), Orexigen Therapeutics, Inc.'s anti-obesity compound; and Saxenda ® (liraglutide), an anti-obesity compound marketed by Novo Nordisk A/S. Agents that have been approved for type 2 diabetes that have demonstrated weight loss in clinical studies may also compete with Qsymia. These include Farxiga™ (dapagliflozin) from AstraZeneca and Bristol-Myers Squibb, an SGLT2 inhibitor; Jardiance ® (empagliflozin) from Boehringer Ingelheim, an SGLT2 inhibitor; Victoza ® (liraglutide) from Novo Nordisk A/S, a GLP-1 receptor agonist; Invokana ® (canaglifozin) from Johnson & Johnson's Janssen Pharmaceuticals, an SGLT2 inhibitor and Glyxambi ® (empagliflozin/linagliptin) from Boehringer Ingelheim and Eli Lilly, an SGLT2 inhibitor and DPP-4 inhibitor combination product. Also, EnteroMedics® Inc. markets the Maestro Rechargeable System for certain obese adults, the first weight loss treatment device that targets the nerve pathway between the brain and the stomach that controls feelings of hunger and fullness.

There are also 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. 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 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, 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.

Qsymia 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 may be launched, which would harm our business. Generic manufacturers pursuing ANDA approval are not required to conduct costly and time-consuming clinical trials to establish the safety and efficacy of their products; rather, they are permitted to rely on FDA's finding that the innovator's product is safe and effective. Additionally, generic drug companies generally do not expend significant sums on sales and marketing activities, instead relying on physicians or payors to substitute the generic form of a drug for the branded form. Thus, generic manufacturers can sell their products at prices much lower than those charged by the innovative pharmaceutical or biotechnology companies who have incurred substantial expenses associated with the research and development of the drug product and who must spend significant sums marketing a new drug.

The FDCA provides that an ANDA holder and an innovator drug with a REMS with Elements to Assure Safe use, like Qsymia, must use a single shared REMS system to assure safe use unless FDA waives this requirement and permits the ANDA holder to implement a separate but comparable REMS. We cannot predict the outcome or impact on our business of any future action that we may take with regard to sharing our REMS program or if FDA grants a waiver allowing the generic competitor to market a generic drug with a separate but comparable REMS.

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. Most recently, on September 30, 2016, we entered into a license and commercialization agreement and a commercial supply agreement with Metuchen. Under the terms of the agreements, Metuchen received an exclusive license to develop, commercialize and promote STENDRA in the United States, Canada, South America and India, or the Territory, effective October 1, 2016. Additionally, on January 6, 2017, we entered into a Patent Assignment Agreement with Selten, whereby we received exclusive, worldwide rights for the development and commercialization of tacrolimus for the treatment of PAH and related vascular diseases. Further 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 identify, 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. Most recently, on January 6, 2017, we entered into a Patent Assignment Agreement with Selten, whereby we received exclusive, worldwide rights for the development and commercialization of tacrolimus for the treatment of PAH and related vascular diseases. 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 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 retain or hire 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, is our sole source of clinical and commercial supplies for Qsymia. While Catalent has significant experience in commercial scale manufacturing, there is no assurance that Catalent will be successful in continuing to supply Qsymia at current levels or increasing the scale of the 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 meet current demand or 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.

For avanafil, in July 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 for STENDRA and SPEDRA 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. Sanofi is responsible for all aspects of manufacture, including obtaining the starting materials for the production of API. If Sanofi is unable to manufacture the 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.

Any failure of current or future manufacturing sites, including those of Sanofi Chimie and Sanofi Winthrop Industrie, to receive or maintain 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 Menarini, Metuchen and Sanofi and our ability to enter into a collaboration agreement for the commercialization of STENDRA in our other territories not covered by our agreements with Menarini, Metuchen and Sanofi.

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 or breach affecting that information 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 and other personal data in the EU is governed by the provisions of the Data Protection Directive as implemented into national laws by the EU Member States. This Directive imposes restrictions on the processing (e.g., collection, use, disclosure) of personal data, including a number of requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals prior to processing their personal data, 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 restrictions 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 General Data Protection Regulation, or GDPR, an EU-wide regulation that will be fully enforceable by May 25, 2018, will introduce new data protection requirements in the EU and substantial fines for violations of the data protection rules. The GDPR will increase our responsibility and liability in relation to EU 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 and privacy and data security laws and regulations, we could face substantial penalties, liability and adverse publicity 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. In addition, our operations expose us to privacy and data security laws and regulations. The restrictions under applicable federal and state healthcare laws and regulations, and privacy and data security 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 liability may be established under the federal Anti-Kickback Law without proving 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 U.S. federal and state laws and regulations, including state data breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, disclosure and protection of personal information. Other countries also have, or are developing, laws governing the collection, use, disclosure and protection of personal information. In addition, most healthcare providers who prescribe our products 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 and by the Health Information Technology for Economic and Clinical Health Act, or HITECH, which are collectively referred to as HIPAA. We are not a HIPAA-covered entity and we do not operate as a business associate to any covered entities. Therefore, the HIPAA privacy and security requirements do not apply to us (other than potentially with respect to providing certain employee benefits). 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 and/or conspiring to commit a 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 security continues to evolve, and there has been an increasing amount of focus on privacy and data security issues with the potential to affect our business. These privacy and data security laws and regulations could increase our cost of doing business, and failure to comply with these laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and 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 certain health care providers 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. 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 and other transfers of value to physicians and teaching hospitals, and to submit such data to CMS, which will then make all of this data publicly available on the CMS website. Pharmaceutical manufacturers with products for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program were required to have started tracking reportable payments on August 1, 2013, and must submit a report to CMS on or before the 90th day of each calendar year disclosing reportable payments made in the previous calendar year. Failure to comply with the reporting obligations may result in civil monetary penalties; and
- the federal Foreign Corrupt Practices Act of 1977 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 SEC. 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 and regulations 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, or associated adverse publicity, 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 and regulations, 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 data, security and fraud laws and regulations 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.

Significant disruptions of information technology systems or security breaches could adversely affect our business.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including but not limited to trade secrets or other intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third party vendors who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of third party vendors with whom we contract, and the large amounts of confidential information stored on those systems, make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third party vendors, and/or business partners, or from cyber-attacks by malicious third parties. Cyber-attacks are increasing in their frequency, sophistication, and intensity, and have become increasingly difficult to detect. Cyber-attacks could include the deployment of harmful malware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information.

Significant disruptions of our information technology systems or security breaches could adversely affect our business operations and/or result in the loss, misappropriation and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information (including but not limited to trade secrets or other intellectual property, proprietary business information and personal information), and could result in financial, legal, business and reputational harm to us. For example, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding patients or employees, could harm our reputation, require us to comply with federal and/or state breach notification laws and foreign law equivalents, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. Security breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. While we have implemented security measures to protect our information technology systems and infrastructure, there can be no assurance that such measures will prevent service interruptions or security breaches that could adversely affect our business.

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

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, 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. 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, FDA may still impose significant restrictions on a drug's indicated uses or marketing or impose ongoing requirements for REMS or 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. 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, FDA has required a REMS that may act to limit access to the drug, reduce our revenues and/or increase our costs. 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 EC, 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 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. 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 rely on Sanofi Chimie and Sanofi Winthrop to supply avanafil API and tablets. We and these suppliers and service providers are required to follow cGMP requirements and are subject to routine and unannounced inspections by FDA and by state and foreign regulatory agencies for compliance with cGMP requirements and other applicable regulations. Upon inspection of these facilities, 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 in March 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 2015, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law.

In February 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate program under the Affordable Care Act These regulations become effective on April 1, 2016. Moreover, legislative changes to the Affordable Care Act remain possible and appear likely in the 115th United States Congress and under the Trump Administration. We expect that the Affordable Care Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products or to successfully commercialize our product candidates, if approved. 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, but exempts "orphan drugs" from the ceiling price requirements for these covered entities. The Affordable Care Act also obligates the Secretary of the U.S. Department of Health and Human Services, or HHS, 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, the agency that administers the 340B program, recently initiated the process of updating the agreement with participating manufacturers. The Healthcare Reform Act also obligates the Secretary of HHS to create regulations and processes to improve the integrity of the 340B program. In 2015, HRSA issued proposed omnibus guidance that addresses many aspects of the 340B program, and in August 2016, HRSA issued a proposed regulation regarding an administrative dispute resolution process for the 340B program. It is unclear when or whether the guidance or regulation will be released in final form under the Trump Administration. On January 5, 2017, HRSA issued a final regulation regarding the calculation of 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities. The March 6, 2017 effective date of this regulation is subject to a temporary delay directed by the Trump Administration, and the regulation could be subject to further delay or other modification by the Trump Administration. Implementation of this final rule and the issuance of any other final regulations and guidance 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 an 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 $178,156 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 $12,856 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.

If we misstate Non-FAMPs or FCPs, we must restate these figures. Additionally, pursuant to the VHCA, knowing provision of false information in connection with a Non-FAMP filing can subject us to penalties of $178,156 for each item of false information. If we overcharge the government in connection with our FSS contract or the Tricare Retail Pharmacy Program, 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 Medicare and the Medicaid Drug Rebate program, surveys and publishes retail community pharmacy acquisition cost information in the form of National Average Drug Acquisition Cost, or NADAC, files to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates. 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. Further, federal budgetary concerns could result in the implementation of significant federal spending cuts, including cuts in Medicare and other health related spending in the near-term. For example, beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologics, were reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. Subsequent legislation extended the 2% reduction, on average, to 2025. These cuts reduce reimbursement payments related to our products, which could potentially negatively impact our revenue.

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, collectively referred to in this report as 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 in March 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 in January 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 have coverage under Medicare Part D for our drugs, but this could change in the future.
- Effective in January 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 2017, 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.

In February 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate Program under the Affordable Care Act. These regulations become effective on April 1, 2016.

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, but exempts "orphan drugs" from the ceiling price requirements for these covered entities. The Affordable Care Act also obligates the Secretary of the Department of Health and Human Services 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, the agency that administers the 340B program, recently initiated the process of updating the agreement with participating manufacturers. The Healthcare Reform 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. In 2015, HRSA issued proposed omnibus guidance that addresses many aspects of the 340B program, and in August 2016, HRSA issued a proposed regulation regarding an administrative dispute resolution process for the 340B program. It is unclear when or whether the guidance or regulation will be released in final form under the Trump Administration. On January 5, 2017, HRSA issued a final regulation regarding the calculation of 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities. The March 6, 2017 effective date of this regulation is subject to a temporary delay directed by the Trump Administration, and the regulation could be subject to further delay or other modification by the Trump Administration. Implementation of this final rule and the issuance of any other final regulations and guidance 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 an 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. Moreover, legislative changes to the Affordable Care Act remain possible and appear likely in the 115th United States Congress and under the Trump Administration. We expect that the Affordable Care Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products or to successfully commercialize our product candidates, if approved.

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 single ingredient generic products 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 FDA, the EC, 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. 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 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, 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. 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.

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, 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 have received notices of ANDA filings for Qsymia submitted by generic drug companies. These ANDA filings assert that generic forms of Qsymia would not infringe on our issued patents. As a result of these filings, we have commenced litigation to defend our patent rights, which is expected to be costly and time-consuming and, depending on the outcome of the litigation, we may face competition from lower cost generic or follow-on products in the near term.

Qsymia is approved under the provisions of the Federal Food, Drug and Cosmetic Act, or FDCA, which renders it susceptible to potential competition from generic manufacturers via the Hatch-Waxman Act and ANDA process. The ANDA procedure includes provisions allowing generic manufacturers to challenge the innovator's patent protection by submitting "Paragraph IV" certifications to FDA in which the generic manufacturer claims that the innovator's patent is invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of the generic product. A patent owner who receives a Paragraph IV certification may choose to sue the generic applicant for patent infringement.

We have received a Paragraph IV certification notice from Actavis Laboratories FL, Inc., or Actavis, contending that our patents listed in the Orange Book for Qsymia (U.S. Patents 7,056,890, 7,553,818, 7,659,256, 7,674,776, 8,580,298, and 8,580,299) are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of a generic form of Qsymia. In response to this notice, we have filed suit to defend our patent rights. We have received a second Paragraph IV certification notice from Actavis contending that two additional patents listed in the Orange Book for Qsymia (U.S. Patents 8,895,057 and 8,895,058) are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of a generic form of Qsymia. In response to this second notice, we have filed a second lawsuit against Actavis. We have received a third Paragraph IV certification notice from Actavis contending that two additional patents listed in the Orange Book for Qsymia (U.S. Patents 9,011,905 and 9,011,906) are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of a generic form of Qsymia. In response to this third notice, we have filed a third lawsuit against Actavis. The lawsuits have been consolidated into a single suit. On July 20, 2016, the U.S. District Court for the District of New Jersey issued a claim construction (Markman) ruling governing the suit.

In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Actavis, FDA approval of Actavis' ANDA will be stayed until the earlier of (i) up to 30 months from our May 7, 2014 receipt of Actavis' Paragraph IV certification notice (i.e. November 7, 2016) or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed.

We have received a Paragraph IV certification notice from Teva Pharmaceutical USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively, Teva) contending that eight of our patents listed in the Orange Book for Qsymia (U.S. Patents 7,056,890, 7,533,818, 7,659,256, 7,674,776, 8,580,298, 8,580,299, 8,895,057, and 8,895,058) are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of a generic form of Qsymia. In response to this notice, we have filed suit against Teva to defend our patent rights. We have received a second Paragraph IV certification notice from Teva contending that two additional patents listed in the Orange Book for Qsymia (U.S. Patents 9,011,905 and 9,011,906) are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of a generic form of Qsymia. In response to this second notice, we have filed a second lawsuit against Teva. The lawsuits have been consolidated into a single suit. On July 20, 2016, the U.S. District Court for the District of New Jersey issued a claim construction (Markman) ruling governing the suit. On September 27, 2016, Dr. Reddy's Laboratories, S.A. and Dr. Reddy's Laboratories, Inc., collectively referred to as DRL, were substituted for Teva as defendants in the lawsuit.

In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Teva, FDA approval of Teva's ANDA will be stayed until the earlier of (i) up to 30 months from our March 5, 2015 receipt of Teva's Paragraph IV certification notice (i.e. September 5, 2017) or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed.

The schedule for both suits has now been consolidated for expert discovery and trial. Expert discovery is scheduled to close on April 21, 2017. A final pretrial conference is scheduled for May 31, 2017 and a second pretrial conference, if necessary, is scheduled for June 28, 2017. No trial date has been scheduled.

On June 20, 2016, we have received a Paragraph IV certification notice from Hetero USA Inc. and Hetero Labs Limited, collectively referred to as Hetero, contending that our patents listed in the Orange Book for STENDRA (U.S. Patents 6,656,935 and 7,501,409) are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of a generic form of STENDRA. On July 27, 2016, we filed a lawsuit in the U.S. District Court for the District of New

Jersey against Hetero. On January 3, 2017, we entered into a settlement agreement with Hetero. Under the settlement agreement, Hetero was granted a license to manufacture and commercialize the generic version of STENDRA described in its ANDA filing in the United States as of the date that is the later of (a) October 29, 2024, which is 180 days prior to the expiration of the last to expire of the Asserted Patents, or (b) the date that Hetero obtains final approval from FDA of the Hetero ANDA. The Settlement Agreement provides for a full settlement of all claims that were asserted in the suit.

Although we intend to vigorously enforce our intellectual property rights relating to Qsymia, there can be no assurance that we will prevail in our defense of our patent rights. Our existing patents could be invalidated, found unenforceable or found not to cover a generic form of Qsymia. If an ANDA filer were to receive approval to sell a generic version of Qsymia and/or prevail in any patent litigation, Qsymia would become subject to increased competition and our revenue would be adversely affected.

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 debt servicing requirements, 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 or development 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 the next twelve months. However, we anticipate that we will be required to obtain additional financing to fund our commercialization efforts, additional clinical studies for approved products, the development of our research and development pipeline and the servicing requirements of our debt. 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 EC for Qsiva in the EU through the centralized marketing authorization 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 FDA has required us to perform as part of the approval for Qsymia;
- our ability, along with our collaboration partners, to successfully commercialize STENDRA/SPEDRA;
- our ability to successfully commercialize STENDRA through a third party in other territories in which we do not currently 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 businesses, products and technologies. On January 6, 2017, we entered into a Patent Assignment Agreement with Selten whereby we received exclusive, worldwide rights for the development and commercialization of BMPR2 activators for the treatment of PAH and related vascular diseases. Selten received an upfront payment of $1.0 million and is entitled to milestone payments based on global development status and future sales milestones, as well as tiered royalty payments on future sales of these compounds. The total potential milestone payments are $39.6 million.

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.

As of December 31, 2016, we have $250.0 million in 4.5% Convertible Senior Notes due May 1, 2020, which we refer to as the Convertible Notes. 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. On October 8, 2015, IEH Biopharma LLC, a subsidiary of Icahn Enterprises L.P., announced that it had received tenders for $170,165,000 of the aggregate principal amount of our Convertible Notes in

its previously announced cash tender offer for any and all of the outstanding Convertible Notes. The Convertible Notes are convertible at the option of the holders under certain conditions at any time prior to the close of business on the business day immediately preceding November 1, 2019. 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 Secured Investments III Holdings Cayman LP, or 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, 2016, we had $269.5 million in cash, cash equivalents and available-for-sale securities. While at December 31, 2016, our excess cash balances were invested in money market, U.S. Treasury securities and corporate debt 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. These factors could impact the liquidity or valuation of our available-for-sale securities, all of which were invested in U.S. Treasury securities or corporate debt securities as of December 31, 2016. 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 were a defendant in federal and consolidated state shareholder derivative lawsuits. These securities-related class action lawsuits generally alleged that we and our officers misled the investing public regarding the safety and efficacy of Qsymia and the prospects for 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, on March 27, 2014, Mary Jane and Thomas Jasin, who purport to be purchasers of VIVUS common stock, filed an Amended Complaint in Santa Clara County Superior Court alleging securities fraud against us and three of our former officers and directors. In that complaint, captioned Jasin v. VIVUS, Inc., Case No. 114 cv 261427, plaintiffs asserted claims under California's securities and consumer protection securities statutes. Plaintiffs alleged generally that defendants misrepresented the prospects for our success, including with respect to the launch of Qsymia, while purportedly selling VIVUS stock for personal profit. Plaintiffs alleged losses of "at least" $2.8 million, and sought damages and other relief. On July 18, 2014, the same plaintiffs filed a complaint in the United States District Court for the Northern District of California, captioned Jasin v. VIVUS, Inc., Case No. 5:14 cv 03263. The Jasins' federal complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, based on facts substantially similar to those alleged in their state court action. On September 15, 2014, pursuant to an agreement between the parties, plaintiffs voluntarily dismissed their state court action with prejudice. Defendants moved to dismiss the federal action and moved to dismiss again after plaintiffs amended their complaint to include additional factual allegations and to add seven new claims under California law. The court granted the latter motion on June 18, 2015, dismissing the seven California claims with prejudice and dismissing the two federal claims with leave to amend. Plaintiffs filed a Second Amended Complaint on August 17, 2015. Defendants moved to dismiss that complaint as well. On April 19, 2016, the court granted defendants' motion to dismiss with prejudice and entered judgment in favor of defendants. Plaintiffs filed a notice of appeal to the Ninth Circuit Court of Appeals on May 18, 2016. Briefing on the appeal has now been completed. The Ninth Circuit has not yet scheduled the matter for oral argument or consideration.

We maintain directors' and officers' liability insurance that we believe affords coverage for much of the anticipated cost of the remaining *Jasin* action, subject to the use of our financial resources to pay for our self-insured retention and the policies' terms and conditions.

We have an accumulated deficit of $813.1 million as of December 31, 2016, and we may continue to incur substantial operating losses for the future.

We have generated a cumulative net loss of $813.1 million for the period from our inception through December 31, 2016, 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, 2016, we had approximately $635.7 million and $265.0 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. 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 through June 30, 2016 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 for our products in foreign jurisdictions, including authorization from the EC for Qsiva in the EU through the centralized marketing authorization procedure;
- the costs, timing and outcome of post-approval clinical studies which 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;
- the status of the CVOT and our related discussions with FDA;
- 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 or 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 equity awards 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 Menarini to commercialize and promote SPEDRA for the treatment of ED in over 40 countries, including the EU, plus Australia and New Zealand, with Metuchen to commercialize STENDRA in the U.S., Canada, South America and India, and with Sanofi to commercialize avanafil in Africa, the Middle East, Turkey and the CIS, including Russia, we and they may not be successful in commercializing avanafil 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 or 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. Any of our executive officers or directors may adopt trading plans under SEC Rule 10b5-1 to dispose of a portion of their stock. 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.

On November 8, 2016, our Board of Directors adopted an amendment and restatement of our Preferred Stock Rights Plan, which was originally adopted on March 26, 2007. As amended and restated, the Preferred Stock Rights Plan is designed to protect stockholder value by mitigating the likelihood of an "ownership change" that would result in significant limitations to our ability to use our net operating losses or other tax attributes to offset future income. As amended and restated, the Preferred Stock Rights Plan will continue in effect until November 9, 2019, unless earlier terminated or the rights are earlier exchanged or redeemed by our Board of Directors. We expect to submit the plan to a vote at the 2017 annual meeting of stockholders. If stockholders do not approve the plan at the 2017 annual meeting, it will expire at the close of business of the following day. The Preferred Stock Rights Plan has the effect of causing substantial dilution to a person or group that acquires more than 4.9% of our shares without the approval of our Board of Directors. The existence of the Preferred Stock 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 Comment s***

None.

Item 2. ***Propertie s***

In August 2016, we entered into a lease for new principal executive offices, consisting of approximately 13,981 square feet of office space at 900 East Hamilton Avenue, Campbell, California, or the Campbell Lease. The Campbell Lease has an initial term of approximately 58 months, commencing on December 27, 2016, with a beginning annual rental rate of $3.10 per rentable square foot, subject to agreed-upon increases. We are entitled to an abatement of the monthly rent for the first four months on the lease term, subject to conditions detailed in the Campbell Lease. We have one option to extend the lease term for two years at the fair market rental rate then prevailing as detailed in the Campbell Lease.

We have a lease on 4,914 square feet of office space located at 1174 Castro Street, Mountain View, California, or the Castro Facility. The lease for the Castro Facility 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 Castro Facility has been subleased commencing on September 1, 2014 for a period of 31 months.

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 16: "Commitments" to our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

Item 3. ***Legal Proceedings***

Shareholder Lawsuit

On March 27, 2014, Mary Jane and Thomas Jasin, who purport to be purchasers of VIVUS common stock, filed an Amended Complaint in Santa Clara County Superior Court alleging securities fraud against the Company and three of its former officers and directors. In that complaint, captioned *Jasin v. VIVUS, Inc.,* Case No. 114-cv-261427, plaintiffs asserted claims under California's securities and consumer protection securities statutes. Plaintiffs alleged generally that defendants misrepresented the prospects for the Company's success, including with respect to the launch of Qsymia, while purportedly selling VIVUS stock for personal profit. Plaintiffs alleged losses of "at least" $2.8 million, and sought damages and other relief. On July 18, 2014, the same plaintiffs filed a complaint in the United States District Court for the Northern District of California, captioned *Jasin v. VIVUS, Inc.,* Case No. 5:14-cv-03263. The Jasins' federal complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, based on facts substantially similar to those alleged in their state court action. On September 15, 2014, pursuant to an agreement between the parties, plaintiffs voluntarily dismissed their state court action with prejudice. Defendants moved to dismiss the federal action and moved to dismiss again after plaintiffs amended their complaint to include additional factual allegations and to add seven new claims under California law. The court granted the latter motion on June 18, 2015, dismissing the seven California claims with prejudice and dismissing the two federal claims with leave to amend. Plaintiffs filed a Second Amended Complaint on August 17, 2015. Defendants moved to dismiss that complaint as well. On April 19, 2016, the court granted defendants' motion to dismiss with prejudice and entered judgment in favor of defendants. Plaintiffs filed a notice of appeal to the Ninth Circuit Court of Appeals on May 18, 2016. Briefing on the appeal has now been completed. The Ninth Circuit has not yet scheduled the matter for oral argument or consideration. The Company maintains directors' and officers' liability insurance that it believes affords coverage for much of the anticipated cost of the remaining *Jasin* action, subject to the use of our financial resources to pay for our self-insured retention and the policies' terms and conditions.

The Company and the defendant former officers and directors cannot predict the outcome of the lawsuit, but they believe the lawsuit is without merit and intend to continue vigorously defending against the claims.

Qsymia ANDA Litigation

On May 7, 2014, the Company received a Paragraph IV certification notice from Actavis Laboratories FL indicating that it filed an abbreviated new drug application, or ANDA, with the U.S. Food and Drug Administration, or FDA, requesting approval to market a generic version of Qsymia and contending that the patents listed for Qsymia in FDA Orange Book at the time the notice was received (U.S. Patents 7,056,890, 7,553,818, 7,659,256, 7,674,776, 8,580,298, and 8,580,299 (collectively "patents-in-suit")) are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale or offer for sale of a generic form of Qsymia as described in their ANDA. On June 12, 2014, the Company filed a lawsuit in the U.S. District Court for the District of New Jersey against Actavis Laboratories FL, Inc., Actavis, Inc., and Actavis PLC, collectively referred to as Actavis. The lawsuit (Case No. 14-3786 (SRC)(CLW)) was filed on the basis that Actavis' submission of their ANDA to obtain approval to manufacture, use, sell or offer for sale generic versions of Qsymia prior to the expiration of the patents-in-suit constitutes infringement of one or more claims of those patents.

In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Actavis, FDA approval of Actavis' ANDA will be stayed until the earlier of (i) up to 30 months from the Company's May 7, 2014 receipt of Actavis' Paragraph IV certification notice (i.e. November 7, 2016) or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed.

On January 21, 2015, the Company received a second Paragraph IV certification notice from Actavis contending that two additional patents listed in the Orange Book for Qsymia (U.S. Patents 8,895,057 and 8,895,058) are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale, or offer for sale of a generic form of Qsymia. On March 4, 2015, the Company filed a second lawsuit in the U.S. District Court for the District of New Jersey

against Actavis (Case No. 15-1636 (SRC)(CLW)) in response to the second Paragraph IV certification notice on the basis that Actavis' submission of their ANDA constitutes infringement of one or more claims of the patents-in-suit.

On July 7, 2015, the Company received a third Paragraph IV certification notice from Actavis contending that two additional patents listed in the Orange Book for Qsymia (U.S. Patents 9,011,905 and 9,011,906) are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale, or offer for sale of a generic form of Qsymia. On August 17, 2015, the Company filed a third lawsuit in the U.S. District Court for the District of New Jersey against Actavis (Case No. 15-6256 (SRC) (CLW)) in response to the third Paragraph IV certification notice on the basis that Actavis' submission of their ANDA constitutes infringement of one or more claims of the patents-in-suit. The three lawsuits against Actavis have been consolidated into a single suit (Case No. 14-3786 (SRC)(CLW)). On July 20, 2016, the U.S. District Court for the District of New Jersey issued a claim construction (Markman) ruling governing the suit. The Court adopted the Company's proposed constructions for all but one of the disputed claim terms and adopted a compromise construction that was acceptable to the Company for the final claim term.

On March 5, 2015, the Company received a Paragraph IV certification notice from Teva Pharmaceuticals USA, Inc. indicating that it filed an ANDA with FDA, requesting approval to market a generic version of Qsymia and contending that eight patents listed for Qsymia in the Orange Book at the time of the notice (U.S. Patents 7,056,890, 7,553,818, 7,659,256, 7,674,776, 8,580,298, 8,580,299, 8,895,057 and 8,895,058) (collectively "patents-in-suit") are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of a generic form of Qsymia as described in their ANDA. On April 15, 2015, the Company filed a lawsuit in the U.S. District Court for the District of New Jersey against Teva Pharmaceutical USA, Inc. and Teva Pharmaceutical Industries, Ltd., collectively referred to as Teva. The lawsuit (Case No. 15-2693 (SRC)(CLW)) was filed on the basis that Teva's submission of their ANDA to obtain approval to manufacture, use, sell, or offer for sale generic versions of Qsymia prior to the expiration of the patents-in-suit constitutes infringement of one or more claims of those patents.

In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Teva, FDA approval of Teva's ANDA will be stayed until the earlier of (i) up to 30 months from our March 5, 2015 receipt of Teva's Paragraph IV certification notice (i.e. September 5, 2017) or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed.

On August 5, 2015, the Company received a second Paragraph IV certification notice from Teva contending that two additional patents listed in the Orange Book for Qsymia (U.S. Patents 9,011,905 and 9,011,906) are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale, or offer for sale of a generic form of Qsymia. On September 18, 2015, the Company filed a second lawsuit in the U.S. District Court for the District of New Jersey against Teva (Case No. 15-6957(SRC) (CLW)) in response to the second Paragraph IV certification notice on the basis that Teva's submission of their ANDA constitutes infringement of one or more claims of the patents-in-suit. The two lawsuits against Teva have been consolidated into a single suit (Case No. 15-2693 (SRC)(CLW)).

On July 20, 2016, the U.S. District Court for the District of New Jersey issued a claim construction (Markman) ruling governing the suit. The Court adopted the Company's proposed constructions for all but one of the disputed claim terms and adopted a compromise construction that was acceptable to the Company for the final claim term. On September 27, 2016, Dr. Reddy's Laboratories, S.A. and Dr. Reddy's Laboratories, Inc., collectively referred to as DRL, were substituted for Teva as defendants in the lawsuit as a result of Teva's transfer to DRL of ownership and all rights in the ANDA that is the subject of the lawsuit.

The schedule for both suits has now been consolidated for expert discovery and trial. Expert discovery is scheduled to close on April 21, 2017. A final pretrial conference is scheduled for May 31, 2017 and a second pretrial conference, if necessary, is scheduled for June 28, 2017. No trial date has been scheduled.

The Company intends to vigorously enforce its intellectual property rights relating to Qsymia, but the Company cannot predict the outcome of these matters.

STENDRA ANDA Litigation

On June 20, 2016, the Company received a Paragraph IV certification notice from Hetero USA, Inc. and Hetero Labs Limited, collectively referred to as Hetero, indicating that it filed an ANDA with FDA, requesting approval to market a generic version of STENDRA and contending that patents listed for STENDRA in the Orange Book at the time of the notice (U.S. Patents 6,656,935, and 7,501,409) (collectively "patents-in-suit") are invalid, unenforceable and/or

will not be infringed by the manufacture, use or sale of a generic form of STENDRA as described in their ANDA. On July 27, 2016, the Company filed a lawsuit in the U.S. District Court for the District of New Jersey against Hetero (Case No. 16-4560 (KSH)(CLW)). On January 3, 2017, we entered into a settlement agreement with Hetero. Under the settlement agreement, Hetero was granted a license to manufacture and commercialize the generic version of STENDRA described in its ANDA filing in the United States as of the date that is the later of (a) October 29, 2024, which is 180 days prior to the expiration of the last to expire of the patents-in-suit, or (b) the date that Hetero obtains final approval from FDA of the Hetero ANDA. The Settlement Agreement provides for a full settlement of all claims that were asserted in the suit.

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 Equit y, 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
2016				
High	$ 1.42	$ 1.85	$ 1.32	$ 1.47
Low	0.92	1.02	0.93	1.03
2015				
High	$ 3.40	$ 2.65	$ 2.39	$ 2.25
Low	2.41	2.22	0.94	0.95

Stockholders

As of February 28, 2017, there were 105,583,530 shares of outstanding common stock that were held by 2,833 stockholders of record and no outstanding shares of preferred stock. On February 28, 2017, the last reported sales price of our common stock on the NASDAQ Global Select Market was $1.12 per share.

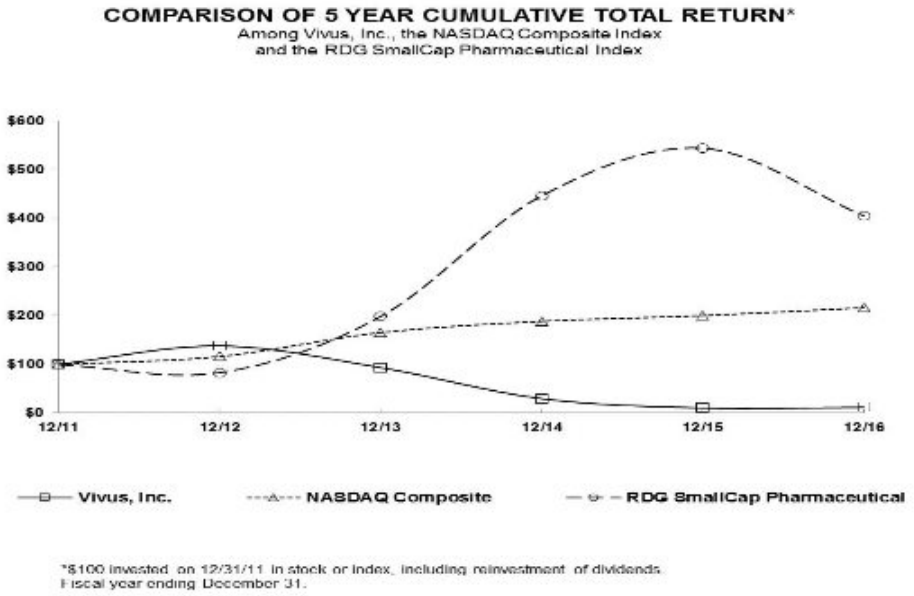
Dividends

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, 2011 through December 31, 2016 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 12/31/2011 in stock or index, including reinvestment of dividends. Fiscal year ending December 31.

Issuer Purchases of Equity Securities

Period	(a) Total number of shares (or units) purchased	(b) Average price paid per share (or unit)	(c) Total number of shares (or units) purchased as part of publicly announced plans or programs	(d) Maximum number (or approximate dollar value) of shares (or units) that may yet be purchased under the plans or programs
October 2016	4,248	$ 1.09	4,248	
November 2016	1,425	$ 1.10	1,425	
December 2016	1,425	$ 1.38	1,425	
Total	7,098	$ 1.15	7,098	29,890

(a) In the fourth quarter of 2016, restricted stock unit awards held by certain non-employee directors of the Company vested. These restricted stock units were settled by issuing to each non-employee director shares in the amount due to the director upon vesting, less the portion required to satisfy the estimated income tax

liability based on the published stock price at the close of market on the settlement date or the next trading day, which the Company issued to the non-employee director in cash.

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,				
	2016	**2015**	**2014**	**2013**	**2012**
Income Statement Data:					
Total revenue	$ 124,258	$ 95,430	$ 114,181	$ 81,082	$ 2,012
Total operating expenses	$ 68,573	$ 155,707	$ 164,892	$ 235,696	$ 141,917
Income (loss) from operations	$ 55,685	$ (60,277)	$ (50,711)	$ (154,614)	$ (139,905)
Income (loss) from continuing operations	$ 23,302	$ (93,107)	$ (82,647)	$ (174,946)	$ (139,733)
Net income (loss)	$ 23,302	$ (93,107)	$ (82,647)	$ (174,456)	$ (139,881)
Basic net income (loss) per share—Continuing operations	$ 0.22	$ (0.90)	$ (0.80)	$ (1.72)	$ (1.42)
Diluted net income (loss) per share—Continuing operations	$ 0.22	$ (0.90)	$ (0.80)	$ (1.72)	$ (1.42)
Balance Sheet Data:					
Working capital	$ 255,159	$ 214,143	$ 301,789	$ 371,934	$ 220,671
Total assets	$ 305,776	$ 277,202	$ 366,938	$ 431,796	$ 264,114
Long-term debt	$ 241,318	$ 231,390	$ 227,783	$ 213,106	$ —
Accumulated deficit	$ (813,054)	$ (836,356)	$ (743,249)	$ (660,602)	$ (486,146)
Stockholders' equity (deficit)	$ 18,185	$ (7,085)	$ 82,518	$ 153,369	$ 222,909

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

All percentage amounts and ratios were calculated using the underlying data in thousands. Operating results for the year ended December 31, 2016, 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 developing and commercializing innovative, next-generation therapies to address unmet medical needs in human health, with two approved therapies and one product candidate in active clinical development. Qsymia® (phentermine and topiramate extended release) is approved by FDA for chronic weight management and STENDRA® (avanafil) is approved by FDA for ED and by the EC under the trade name, SPEDRA, for the treatment of ED in the EU. Tacrolimus is in active clinical development for the treatment of PAH.

Commercial Products

Qsymia

Qsymia was approved by FDA in July 2012, as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adult obese or overweight patients in the presence of at least one weight

related comorbidity, such as hypertension, type 2 diabetes mellitus or high cholesterol, or 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.

We commercialize Qsymia in the U.S. primarily through a sales force supported by an internal commercial team, who promote Qsymia to physicians. We are focused on maintaining a commercial presence with important Qsymia prescribers, and we have capacity to cover prescriptions from physicians that begin prescribing branded anti-obesity products. We are constantly monitoring prescribing activity in the market, and we have seen new prescriptions being written by HCPs on whom we have not previously dedicated field sales resources. The current alignment addresses this new prescriber group, and we believe we have been successful in initiating and maintaining dialog with these HCPs.

Our marketing efforts have focused on rolling out unique programs to encourage targeted prescribers to gain more experience with Qsymia with their obese patient population. We continue to invest in digital media in order to amplify our messaging to information-seeking consumers. The digital messaging encourages those consumers most likely to take action to speak with their physicians about obesity treatment options. We believe our enhanced web-based strategies deliver clear and compelling communications to potential patients. In June 2016, we announced an upgraded simplified patient savings plan to further drive Qsymia brand preference at the point of prescription and to encourage long-term use of the brand.

We have recognized revenue for Qsymia based on prescription sell-through by certified retail pharmacies and home delivery pharmacy services networks to patients in the U.S.

STENDRA/SPEDRA

STENDRA is an oral PDE5 inhibitor that we have licensed from MTPC. STENDRA was approved by FDA in April 2012 for the treatment of ED in the United States. In June 2013, the EC adopted a decision granting marketing authorization for SPEDRA, the approved trade name for avanafil in the EU, for the treatment of ED in the EU.

In July 2013, we entered into the Menarini License Agreement 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, as well as Australia and New Zealand. Menarini commenced its commercialization launch of the product in the EU in early 2014. As of the date of this filing, SPEDRA is commercially available in 30 countries within the territory granted to Menarini pursuant to its license and commercialization agreement, in addition to certain territories in Asia licensed directly from MTPC.

Under the Menarini License Agreement, we have received payments of $63.0 million relating to license and milestone payments and royalty prepayments through December 31, 2016. Additionally, we are entitled to receive potential milestone payments based on certain net sales targets, 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.

In October 2013, we also entered into the Auxilium License Agreement and the Auxilium Supply Agreement under which Auxilium received an exclusive license to commercialize and promote STENDRA in the United States and Canada and we would supply Auxilium with STENDRA for commercialization. We received an upfront license fee of $30.0 million in October 2013 and a regulatory milestone payment of $15.0 million in 2014 upon approval by FDA of a specific time of onset claim for STENDRA in the Auxilium Territory. Additionally, we received royalty payments based on tiered percentages of the aggregate annual net sales of STENDRA in the Auxilium Territory on a quarterly basis. Auxilium terminated the Auxilium Supply Agreement effective June 30, 2016 and the Auxilium License Agreement effective September 30, 2016.

On September 30, 2016, we entered into the Metuchen License Agreement and the Metuchen Supply Agreement with Metuchen. Under the terms of the Metuchen License Agreement, Metuchen received an exclusive license to develop, commercialize and promote STENDRA in the Metuchen Territory, effective October 1, 2016. We received an upfront license fee of $70 million under the Metuchen License Agreement. Metuchen will also reimburse us for payments made to cover royalty and milestone obligations to MTPC during the term of the license agreement, but will otherwise owe us no future royalties. Metuchen will obtain STENDRA exclusively from us for a mutually agreed

term pursuant to the supply agreement. Metuchen may elect to transfer the control of the supply chain for STENDRA for the Territory to itself or its designee by assigning to Metuchen our agreements with the contract manufacturer.

In December 2013, we entered into the Sanofi License Agreement under which Sanofi received an exclusive license to commercialize and promote avanafil for therapeutic use in humans in the Sanofi Territory. Effective as of December 11, 2013, we also entered into the Sanofi Supply Agreement with Sanofi Winthrop Industrie, a wholly owned subsidiary of Sanofi, which terminated according to its terms on June 30, 2015. We received an upfront license fee of $5.0 million and a $1.5 million manufacturing milestone payment in December 2013. In February 2014, we received an additional $3.5 million in manufacturing milestone payments. We were also eligible to receive 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.

Development Program

Pulmonary Arterial Hypertension - Tacrolimus

PAH is a chronic, life-threatening disease characterized by elevated blood pressure in the pulmonary arteries, which are the arteries between the heart and lungs, due to severe constriction of these blood vessels. The current medical therapies for PAH involve ERA, PDE5 inhibitors, prostacyclin analogues, selective IP receptor agonists, and sGC stimulators, which aim to reduce symptoms and improve quality of life. All currently approved products treat the symptoms of PAH, but do not address the underlying disease. We believe that tacrolimus can be used to enhance reduced BMPR2 signaling that is prevalent in PAH patients and may therefore address a fundamental cause of PAH.

On January 6, 2017, we entered into the Patent Assignment Agreement with Selten, whereby we received exclusive, worldwide rights for the development and commercialization of tacrolimus for the treatment of PAH and related vascular diseases. Under this agreement, Selten received an upfront payment of $1.0 million and is entitled to milestone payments based on global development status and future sales milestones, as well as tiered royalty payments on future sales of these compounds. The total potential milestone payments are $39.0 million to Selten. We have assumed full responsibility for the development and commercialization of the licensed compounds for the treatment of PAH and related vascular diseases.

On March 16, 2015, tacrolimus for the treatment of PAH received an Orphan Drug Designation. In 2017, we intend to focus on developing a proprietary formulation of tacrolimus to be used in a clinical development program and for commercial use.

Business Strategy Review

Earlier this year, we initiated a business strategy review with an outside advisor. The first announcement was the licensing of STENDRA to Metuchen for the U.S., Canada, South America, and India, as discussed above. We will continue this process to evaluate strategies for maximizing our current assets as well as potentially building our portfolio of development and commercial assets through in-licensing opportunities. We will also look for opportunities to restructure our existing debt, including repayment or restructuring the outstanding balances.

NOL Rights Plan

On November 8, 2016 our board of directors approved an amendment and restatement of our stockholder rights plan originally adopted on March 26, 2007. The amended plan is designed to protect stockholder value by mitigating the likelihood of an “ownership change” that would result in significant limitations to our ability to use our net operating losses or other tax attributes to offset future income. The amended plan is similar to rights plans adopted by other public companies with significant net operating loss carryforwards.

In connection with the original adoption of the rights plan, one right was distributed for each share of our common stock outstanding as of the close of business on April 13, 2007 and one right was distributed with each share of our common stock that was issued after such date. The amended rights plan provides, subject to certain exceptions, that if any person or group acquires 4.9% or more of our outstanding common stock, there would be a triggering event potentially resulting in significant dilution in the voting power and economic ownership of that person or group. Existing

stockholders who hold 4.9% or more of our outstanding common stock as of the date of the amended rights plan will trigger a dilutive event only if they acquire an additional 1% of the outstanding shares of our common stock.

As extended and amended, the rights plan will continue in effect until November 9, 2019, unless earlier terminated or the rights are earlier exchanged or redeemed by our Board of Directors. We expect to submit the rights plan to a vote at the 2017 annual meeting of stockholders. If stockholders do not approve the plan at the 2017 annual meeting, it will expire at the close of business of the following day.

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. Our significant accounting policies are more fully described in Note 1 to our Consolidated Financial Statements included elsewhere in this report.

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 product revenue 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 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 includes a fixed rate per prescription shipped and monthly program management and data fees. These services are not deemed sufficiently separable from the customers' purchase of the product; therefore, they are recorded as a reduction of revenue at the time of revenue recognition.

Other 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, 2014	$ (702)	$ (1,424)	$ (134)	$ (79)	$ (2,339)
Current provision related to sales made during current period*	(17,579)	(6,973)	(1,712)	(2,110)	(28,374)
Payments	17,418	7,393	1,696	1,752	28,259
Balance at December 31, 2014	(863)	(1,004)	(150)	(437)	(2,454)
Current provision related to sales made during current period*	(19,044)	(6,958)	(1,934)	(2,706)	(30,642)
Payments	18,935	6,802	1,920	2,663	30,320
Balance at December 31, 2015	(972)	(1,160)	(164)	(480)	(2,776)
Current provision related to sales made during current period*	(18,919)	(7,153)	(1,679)	(871)	(28,622)
Payments	18,884	7,033	1,630	1,250	28,797
Balance at December 31, 2016	$ (1,007)	$ (1,280)	$ (213)	$ (101)	$ (2,601)

* Current provision related to sales made during current period includes $27.2 million, $28.7 million and $24.6 million for product revenue allowances related to revenue recognized during the years ended December 31, 2016, 2015 and 2014, respectively. The remaining amounts for the respective years were recorded on the consolidated balance sheets as deferred revenue at the end of each period.

We ship units of Qsymia through a distribution network that includes certified retail pharmacies. Qsymia has a 36–month shelf life and we grant rights to our customers to return unsold product six 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 duration of the return period, we have not had sufficient information to reliably estimate expected returns of Qsymia at the time of shipment, and therefore revenue is recognized when units are dispensed to patients through prescriptions, at which point, the product is not subject to return. We obtain 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. Our deferred revenue 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.

Supply Revenue

We recognize supply revenue from the sales of STENDRA or SPEDRA when the four basic revenue recognition criteria described above are met. We produce STENDRA or SPEDRA through a contract manufacturing partner and then sell it to our commercialization partners. We are the primary responsible party in the commercial supply arrangements and bear significant risk in the fulfillment of the obligations, including risks associated with manufacturing, regulatory compliance and quality assurance, as well as inventory, financial and credit loss. As such, we recognize supply revenue on a gross basis as the principal party in the arrangements. Under our product supply agreements, as long as the 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. As such, we recognize revenue for products that meet the dating criteria at the time of shipment.

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, 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 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 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 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 reported in a particular period.

ASC Topic 605 28, *Revenue Recognition — Milestone Method* or (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, 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 when the four basic revenue recognition criteria described above are met.

Inventories

Inventories are valued at the lower of cost or market. Cost is determined using the first in, first out method using a weighted average cost method calculated for each production batch. Inventory includes the cost of the active pharmaceutical ingredients, or API, 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.

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 lower actual sales, we may increase the write down for excess inventory for that product and record a charge to inventory impairment. We periodically evaluate the carrying value of inventory on hand for potential excess amount over demand.

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. We also record 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 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 uses are expensed to research and development as incurred.

Share-Based Payments

Compensation expense is recognized for share-based payments, including stock options, restricted stock units and shares issued under the employee stock purchase plan, using a fair value based method. We estimate the fair value of share based payment awards on the date of the grant using the Black Scholes option pricing model, which requires us to estimate the expected term of the award, the expected volatility, the risk-free interest rate and the expected dividends. 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, which are adjusted as necessary for any other factors which may reasonably affect the volatility of VIVUS's stock in the future. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for the expected term of the award. We do not anticipate paying any dividends in the near future. We develop pre-vesting forfeiture assumptions based on an analysis of historical data.

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.

Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Three levels of inputs are used to measure fair value. The three levels 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 in which little or no market data exists.

Our financial instruments include cash equivalents, available for sale securities, accounts receivable, accounts payable, accrued liabilities and debt. Available-for-sale securities are carried at fair value. The carrying value of cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate their fair value due to the relatively short term nature of these instruments. Debt instruments are initially recorded at face value, with stated interest and amortization of debt issuance discounts and costs recognized as interest expense.

Our convertible notes contain a conversion option that is classified as equity. We determined the fair value of the liability component of the debt instrument and allocated the excess amount of $95.3 million from the initial proceeds to the conversion option in additional paid-in capital. 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. This excess is reported as a debt discount and is amortized as non-cash interest expense, using the effective-interest method, over the expected life of the convertible notes. The convertible notes are recorded in the balance sheet as a component of long-term debt.

Issuance costs related to the conversion feature of the convertible notes were charged to additional paid in capital. The portion of the issuance costs 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 of $34.7 million was recorded to additional paid-in capital.

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 its exposure to credit risk by placing investments in high credit quality money market funds, U.S. Treasury securities or corporate debt securities and by placing investments with maturities that maintain safety and liquidity within our liquidity needs. We have also established guidelines for the issuance of credit to existing and potential customers.

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. Amounts that are 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. Historically, we have not had any significant uncollected accounts. We offer cash discounts to its customers, generally 2% of the sales price, as an incentive for prompt payment. The estimate of cash discounts is recorded at the time of sale. We account 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, 2016 or 2015.

Inventory Impairment and Other Non-Recurring Charges

Our inventory impairment and other non-recurring charges consist of inventory impairment charges, proxy contest expenses and charges from cost reduction plans, including employee severance, one time termination benefits and ongoing benefits related to the reduction of our workforce, facilities and other facility exit costs. Liabilities for costs associated with the cost reduction plan are recognized when the liability is incurred. In addition, liabilities associated with cost reduction 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 cost reduction 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 various agreements with certain of our employees.

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 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 its 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, 2016, 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 its 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 its deferred tax assets.

We recognize interest and penalties accrued on any unrecognized tax benefits as a component of our provision for income taxes.

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

Revenues

	Year Ended December 31,		
	2016	**2015**	**2014**
Net product revenue	$ 48,501	$ 54,622	$ 45,277
License and milestone revenue	69,400	11,574	38,614
Supply revenue	2,291	26,674	26,519
Royalty revenue	4,066	2,560	3,771
Total revenue	$ 124,258	$ 95,430	$ 114,181

Net Qsymia product revenue

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. Currently, 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 (in thousands):

	Year Ended December 31,		
	2016	2015	2014
Gross Qsymia product revenue	$ 73,689	$ 83,338	$ 69,870
Discount programs	(15,994)	(18,441)	(16,140)
Wholesaler/Pharmacy fees	(6,849)	(5,913)	(4,970)
Cash discounts	(1,474)	(1,656)	(1,373)
Rebates/Chargebacks	(871)	(2,706)	(2,110)
Net product revenue	$ 48,501	$ 54,622	$ 45,277

Prescriptions are as follows:

	Year Ended December 31,		
	2016	2015	2014
Prescriptions dispensed (in thousands)	442	566	534
Prescriptions dispensed as free goods (in thousands)	51	99	109
Percent of prescriptions including either a free good or discount offer	64 %	63 %	60 %

At December 31, 2016, we had Qsymia deferred gross revenue of $17.6 million, which represents Qsymia product shipped to wholesalers and certified retail pharmacies, but not yet dispensed to patients through prescriptions, net of prompt-payment discounts. We expect Qsymia net product revenue in 2017 to remain flat or decrease from 2016 levels due to market conditions.

License and milestone revenue

On September 30, 2016, we entered into the Metuchen License Agreement and the Metuchen Supply Agreement to commercialize and promote STENDRA for the treatment of ED in the Metuchen Territory. On September 30, 2016, we received $70 million from Metuchen under the Metuchen License Agreement. For the year ended December 31, 2016, we recognized this amount as license revenue, less an estimate of our future financial obligations under the license agreement.

For the year ended December 31, 2015, we recognized $11.6 million in license and milestone revenue with respect to STENDRA/SPEDRA, primarily attributable to milestone payments related to the approval of the Time-to-Onset Claim in the EU. For the year ended December 31, 2014, we recognized $38.6 million in license and milestone revenue primarily attributable to milestone payments related to product launches in certain EU countries, the approval of the Time-to-Onset Claim in the U.S. and the delivery of the license rights and know-how under the Sanofi License Agreement. License and milestone revenue is dependent upon the timing of the achievement of certain milestones and the timing of entering into collaborative agreements.

License and milestone revenues are dependent on the timing of entering into new collaborations and the timing of our collaborators meeting certain milestone events. As a result, our license and milestone revenue will fluctuate materially between periods.

Net STENDRA/SPEDRA supply revenue

We supply STENDRA/SPEDRA to our collaborations partners on a cost-plus basis. The variations in supply revenue are a result of the timing of orders placed by our partners and may or may not reflect end user demand for STENDRA/SPEDRA. The timing of purchases by our commercialization partners will be affected by, among other items, their minimum purchase commitments, end user demand, and distributor inventory levels. As a result, supply revenue has and will continue to fluctuate materially between reporting periods.

Royalty revenue

Royalty revenue was attributable to commercialization agreements with Menarini and Auxilium for which we earn royalties based on a certain percentage of net sales reported by commercialization partners. We record royalty revenue related to STENDRA based on reports provided by our partners. One of our partners, Auxilium, was acquired by Endo in January 2015. In April 2015, Endo revised its accounting estimate for its return reserve for STENDRA sold in 2014. As a result, in the first quarter of 2015, we recorded an adjustment of $1.2 million to reduce our royalty revenue. On September 30, 2016, Auxilium returned the U.S. and Canadian commercial rights for STENDRA to us. Also, on September 30, 2016, we entered into a license agreement and a supply agreement with Metuchen, providing them with, among other rights, commercial rights to sell STENDRA/SPEDRA in the U.S., Canada, South America, and India. The license agreement with Metuchen does not include future royalties to us on the sales of STENDRA/SPENDRA in their territories. We expect royalty revenue to decrease in 2017 from 2016 levels as beginning in the fourth quarter of 2016, we no longer receive royalty revenue from net sales in the U.S.

Cost of goods sold

	Year Ended December 31,		
	2016	2015	2014
Qsymia cost of goods sold	$ 7,523	$ 8,720	$ 7,155
STENDRA/SPEDRA cost of goods sold	3,079	25,437	26,232
Cost of goods sold	$ 10,602	$ 34,157	$ 33,387

Cost of goods sold for Qsymia dispensed to patients includes the inventory costs of API, 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 or SPEDRA shipped to our commercialization partners includes the inventory costs of API, tableting, bottling, freight, shipping and handling costs. The cost of goods sold associated with deferred revenue on Qsymia and STENDRA or SPEDRA 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. Cost of goods sold decreased overall in 2016 as compared to 2015 due to the reduction in net product and supply revenue. The change in the cost of goods sold as a percentage of net product and supply revenue was due to the full year effect of price increases in 2015 and the sales mix between Qsymia and STENDRA/SPEDRA during the periods. The increase in cost of goods sold in 2015 as compared to 2014 was due to increases in Qsymia product revenue.

Selling, general and administrative

	Years Ended December 31,			% Change Increase/(Decrease)	
	2016	2015	2014	2016 vs 2015	2015 vs 2014
	(In thousands, except percentages)				
Selling and marketing	$ 21,775	$ 52,988	$ 72,330	(59)%	(27)%
General and administrative	30,604	26,399	39,209	16 %	(33)%
Total selling, general and administrative expenses	$ 52,379	$ 79,387	$ 111,539	(34)%	(29)%

The decrease in selling and marketing expenses in 2016 as compared to 2015 was primarily due to the full year impact of cost saving efforts to reduce marketing programs and the reduction in the number of territories from 150 to approximately 50 effective in 2015. The decrease in selling and marketing expenses in 2015 as compared to 2014 was primarily due to lower promotional activities for Qsymia, driven by a lower workforce and more targeted spending.

The increase in general and administrative expenses in 2016 as compared to 2015 was primarily due to higher consultant and legal fees related to our business strategy review, partially offset by the full year impact of corporate restructuring plan begun in July 2015 as well as our continuing efforts to cut costs and lower spending for corporate activities. The decrease in general and administrative expenses in 2015 as compared to 2014 was primarily due to our cost control initiatives, including a reduction in headcount and other employee costs.

We expect selling and marketing expenses in general to remain flat or decrease in 2017 from 2016 as we continue our efforts to commercialize Qsymia in an efficient manner. However, our general and administrative expenses will be impacted by our Qsymia patent litigation, expenses from our continuing business strategy review and expenses from strategic transactions, if any.

Research and development

Drug Indication/Description	Years Ended December 31,			% Change Increase/(Decrease)	
	2016	2015	2014	2016 vs 2015	2015 vs 2014
	(In thousands, except percentages)				
Qsymia for obesity	$ 1,335	$ 3,328	$ 4,457	(60)%	(25)%
STENDRA for ED	147	840	2,356	(83)%	(64)%
Share-based compensation	493	398	1,177	24 %	(66)%
Overhead costs*	3,617	5,536	5,773	(35)%	(4)%
Total research and development expenses	$ 5,592	$ 10,102	$ 13,793	(45)%	(27)%

* 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 2016 as compared to 2015 was due primarily to lower headcount resulting from our corporate restructuring plan begun in July 2015 as well as the timing of studies associated with our post-marketing requirements for STENDRA and Qsymia. The decrease in total research and development expenses in 2015 as compared to 2014 was due primarily to the timing of clinical activity, the impact of our cost reduction efforts implemented during 2015 and lower share-based compensation expense, as a result of our lower share price and decrease in headcount.

We expect that our research and development expenses will increase in 2017 as we continue to complete our post-marketing requirements for Qsymia, specifically an adolescent efficacy trial, and begin development of tacrolimus for the treatment of PAH. In addition, our research and development expenses will increase if we begin development of any additional product candidates.

Inventory impairment and other non-recurring charges

Inventory impairment and other non-recurring charges consist of (in thousands):

	Years Ended December 31,		
	2016	2015	2014
Inventory impairment	$ —	$ 29,522	$ 2,170
Employee severance and related costs	—	2,503	1,711
Patent settlement	—	—	1,949
Share-based compensation	—	36	343
Total inventory impairment and other non-recurring expense	$ —	$ 32,061	$ 6,173

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. In 2015, we recorded inventory impairment charges primarily for Qsymia API inventory in excess of expected demand. In 2014, we recorded inventory impairment charges for finished goods and certain non-API raw materials on hand in excess of demand.

In 2015, we recorded employee severance and related costs and share-based compensation related to the July 2015 corporate restructuring plan, which reduced our workforce by approximately 60 full time equivalents. In 2014, we recorded employee severance and related costs, share-based compensation and operating lease termination costs related to the 2013 cost reduction plan that reduced our workforce by approximately 20 employees.

In 2014, we paid $5.0 million in connection with the transfer and assignment of certain patents from Janssen Pharmaceuticals, Inc. Of the $5.0 million, approximately $1.9 million was recognized as a non-recurring expense for the year ended December 31, 2014 as it related to a legal settlement. The remaining balance of approximately $3.1 million was recorded as an intangible asset and is being amortized as cost of goods sold through their expiration dates.

Interest and other expense (income)

Interest and other expense (income) consists primarily of interest expense and the amortization of issuance costs from our Convertible Notes and Senior Secured Notes and the amortization of the debt discount on the Convertible Notes. Interest expense (income) was $32.9 million, $33.3 million and $32.5 million for the years ended December 31, 2016, 2015 and 2014, respectively. The decrease in interest and other expense (income), net in 2016 as compared to 2015 was primarily due to the lowering of the debt balances due to the repayment of debt. Other expense and income were not significant. We expect interest and other expense (income) in 2017 to remain relatively consistent with 2016 levels.

Provision for (Benefit from) income taxes

We recorded a net provision for income taxes of $70,000 for the year ended December 31, 2016, as compared to $3,000 for the year ended December 31, 2015 and a net benefit from income taxes for the year ended December 31, 2014 of $629,000. The tax provisions for 2016 and 2015 are the result of certain state tax liabilities. The tax benefit in 2014 primarily relates to tax liabilities in certain states, offset by a tax refund received from the State of New Jersey as a result of a settlement of an audit and acceptance of a refund claim for the tax year ended December 31, 2007 amounting to $462,000 (including interest) and a reduction of the Company's unrecognized tax benefits as a result of the California Franchise Tax Board audit that was favorably settled amounting to approximately $208,000.

LIQUIDITY AND CAPITAL RESOURCES

Cash. Cash, cash equivalents and available-for-sale securities totaled $269.5 million at December 31, 2016, as compared to $241.6 million at December 31, 2015. The increase is primarily due to cash received from our license agreement with Metuchen, partially offset by cash used in the funding of our operations. We received payments for license and milestone revenue of $70.0 million, $11.6 million and $35.3 million in 2016, 2015 and 2014, respectively. Since inception, we have financed operations primarily from the issuance of equity, debt and debt-like securities.

We invest our excess cash balances in money market, U.S. government securities and corporate debt securities in accordance with our investment policy. 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. Historically, we have had no significant uncollectable accounts receivable. 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, 2016, was $9.5 million, as compared to $9.0 million at December 31, 2015. Currently, we do not have any significant concerns related to accounts receivable or collections. As of February 28, 2017, we had collected 93% of the accounts receivable outstanding at December 31, 2016.

Liabilities. Total liabilities were $287.6 million at December 31, 2016, compared to $284.3 million at December 31, 2015. The increase in total liabilities was primarily due to timing differences in our various liability accounts.

Summary Cash Flows

	Years Ended December 31,		
	2016	2015	2014
	(in thousands)		
Cash provided by (used for):			
Operating activities	$ 38,165	$ (46,332)	$ (38,105)
Investing activities	(40,078)	67,404	15,893
Financing activities	(8,699)	(8,851)	2,124

Operating Activities. The increase in cash from operating activities in 2016 as compared to cash used for operating activities in 2015 was primarily due to cash from the license agreements with Metuchen. Additional increases were due to decreased spending on inventory, partially offset by increases in accounts receivable. The increase in cash used from operating activities in 2015 as compared to 2014 was primarily due to the reduction in total revenue, due to a reduction in license and milestone receipts, and spending on inventory for contractually-mandated purchases, partially offset by lower operating expenses, primarily attributable to our cost reduction plan in 2015.

Investing Activities. Cash used or provided by investing activities primarily relates to the purchases and maturities of investment securities. The fluctuations from period to period are due primarily to the timing of purchases, sales and maturities of these investment securities and were impacted in 2016 due primarily to the investment of portions of the cash received from the Metuchen License Agreement.

Financing Activities. Cash used in financing activities for the years ended December 31, 2016 and 2015 consist primarily of our repayments of $8.7 million and $9.0 million, respectively, under our Senior Secured Notes. Cash provided by financing activities for the year ended December 31, 2014 consisted of cash received for the exercise of stock options and purchases of stock under the employee stock purchase plan.

We anticipate that our existing capital resources combined with anticipated future cash flows will be sufficient to support our operating needs at least for the next twelve months. 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, conduct post-approval clinical studies for Qsymia, conduct non-clinical and clinical research and development work to support regulatory submissions and applications for our current and 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 and supply agreements.

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, 2016, 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, 2016. 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:

Contractual obligations	Payments Due by Period				
	Total	2017	2018 - 2020	2021 - 2022	Thereafter
			(in thousands)		
Operating leases	$ 3,330	$ 529	$ 2,263	$ 538	$ —
Purchase obligations	27,010	16,485	10,525	—	—
Notes payable	282,264	9,866	272,398	—	—
Interest payable	30,150	13,521	16,629	—	—
Total contractual obligations	$ 342,754	$ 40,401	$ 301,815	$ 538	$ —

Operating Leases

We have a lease of 13,981 square feet of office space at 900 East Hamilton Avenue, Campbell, California, or the Campbell Lease. The Campbell Lease has an initial term of approximately 58 months, commencing on December 27, 2016, with a beginning annual rental rate of $3.10 per rentable square foot, subject to agreed-upon increases. The Company is entitled to an abatement of the monthly rent for the first four months on the lease term, subject to conditions detailed in the Campbell Lease. The Company has one option to extend the lease term for two years at the fair market rental rate then prevailing as detailed in the Campbell Lease.

We have a lease on 4,914 square feet of office space located at 1174 Castro Street, Mountain View, California, or the Castro Facility. The average base rent for the Castro Facility is approximately $2.87 per square foot or $14,124 per month. The lease for the Castro Facility 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. Commencing on September 1, 2014, we subleased the Castro Facility for a term of 31 months at a starting monthly rental rate of $4.42 per square feet (subject to agreed increases). The sublessee is entitled to abatement of the first monthly installment.

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.

The API and the tablets for STENDRA/SPEDRA (avanafil) are currently manufactured by Sanofi. We have minimum purchase commitments with Sanofi to purchase API materials and tablets through 2018. Our minimum purchase commitments with Sanofi totaled approximately $26.4 million as of December 31, 2016. We have purchase commitments for raw material supplies for Qsymia at December 31, 2016 of $624,000, and have open purchase orders totaling $774,000.

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, 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, 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 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 current conversion rate of the Convertible Notes is $14.86 per share.

Senior Secured Notes Due 2018

On March 25, 2013, we entered into a Purchase and Sale Agreement with BioPharma providing for the purchase of a debt-like instrument, or the Senior Secured Notes. Under the agreement, we received $50 million, less $500,000 in funding and facility payments, at the initial closing on April 9, 2013. We had the option, but elected not to exercise it, to receive an additional $60 million, less $600,000 in a funding payment, at a secondary closing no later than January 15, 2014. The scheduled quarterly payments on the Senior Secured Notes are subject to the net sales of (i) Qsymia 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. All unpaid balances are due in the second quarter of 2018. 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. We may elect to pay full scheduled quarterly payments if we choose.

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.

Selten Pharma, Inc.

On January 6, 2017, we entered into a Patent Assignment Agreement with Selten, whereby we received exclusive, worldwide rights for the development and commercialization of BMPR2 activators for the treatment of PAH and related vascular diseases. As part of the agreement, Selten assigned to us its license to a group of patents owned by Stanford, which cover uses of tacrolimus and ascomycin to treat PAH. We are responsible for future financial obligations to Stanford under that license.

We have also assumed full responsibility for the development and commercialization of the licensed compounds for the treatment of PAH and related vascular diseases. Selten received an upfront payment of $1.0 million and is entitled to receive milestone payments based on global development status and future sales milestones, as well as tiered royalty payments on future sales of these compounds. The total potential milestone payments are $39.0 million to Selten and $550,000 to Stanford. The majority of the milestone payments to Selten may be paid, at our sole option, either in cash or our common stock, provided that in no event shall the payment of common stock exceed fifty percent of the aggregate amount of such milestone payments.

Mitsubishi Tanabe Pharma Corporation

In January 2001, we entered into an exclusive development, license and clinical trial and commercial supply agreement with MTPC for the development and commercialization of avanafil. 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.

We have made and expect to make substantial milestone 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 10 years after the date of the first sale for a particular product or 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 insufficiently effective or insufficiently safe relative to other PDE5 inhibitor compounds based on published information or 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. 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, 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. Sanofi began producing API and tablets in 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.

Other

In October 2001, we entered into the Assignment Agreement with Thomas Najarian, M.D., for 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 the related Patents were transferred to us with worldwide rights to develop and commercialize the Combination Therapy and exploit the Patents. 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 the 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.

Off-Balance Sheet Arrangements

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

Indemnifications

In the normal course of business, we provide indemnifications of varying scope to 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 we are unable to estimate the maximum potential impact of these indemnification provisions on our future results of operations.

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

Recent Accounting Pronouncements

The information on recent account pronouncements in incorporated by reference to Note 1 to our Consolidated Financial Statements included elsewhere in this report.

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.

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, 2016, 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, 2016, by approximately $2.4 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 Dat a***

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	88
Consolidated Balance Sheets as of December 31, 2016 and 2015	90
Consolidated Statements of Operations for the years ended December 31, 2016, 2015 and 2014	91
Consolidated Statements of Comprehensive Loss for the years ended December 31, 2016, 2015 and 2014	91
Consolidated Statements of Stockholders' (Deficit) Equity for the years ended December 31, 2016, 2015 and 2014	92
Consolidated Statements of Cash Flows for the years ended December 31, 2016, 2015 and 2014	93
Notes to Consolidated Financial Statements	94
Financial Statement Schedule II	123

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, 2016 and 2015, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2016. In connection with our audits of the financial statements, we have also audited the financial statement schedule listed in the accompanying index. 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 financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of VIVUS, Inc. at December 31, 2016 and 2015, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2016, in conformity with accounting principles generally accepted in the United States of America. 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.

As discussed in Note 1 to the consolidated financial statements, in 2016 the Company changed the manner in which it accounts for the classification of debt issuance costs in the consolidated balance sheets due to the adoption of ASU 2015-03, *Interest – Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs* .

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, 2016, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 8, 2017 expressed an unqualified opinion thereon.

/s/ OUM & Co. LLP

San Francisco, California
March 8, 2017

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, 2016, based on criteria established in *Internal Control—Integrated Framework (2013)* 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 *Management's Annual Report on Internal Control Over Financial Reporting* included in Item 9A. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, 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, 2016, 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, 2016 and 2015, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2016 and our report dated March 8, 2017 expressed an unqualified opinion thereon.

/s/ OUM & Co. LLP

San Francisco, California
March 8, 2017

VIVUS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except par value)

	December 31,	
	2016	**2015**
ASSETS		Note 1
Current assets:		
Cash and cash equivalents	$ 84,783	$ 95,395
Available-for-sale securities	184,736	146,168
Accounts receivable, net	9,478	8,997
Inventories	16,186	13,602
Prepaid expenses and other current assets	8,251	9,430
Total current assets	303,434	273,592
Property and equipment, net	788	994
Non-current assets	1,554	2,616
Total assets	$ 305,776	$ 277,202
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 4,707	$ 7,060
Accrued and other liabilities	15,686	15,891
Deferred revenue	19,174	22,142
Current portion of long-term debt	8,708	14,356
Total current liabilities	48,275	59,449
Long-term debt, net of current portion	232,610	217,034
Deferred revenue, net of current portion	6,449	6,508
Non-current accrued and other liabilities	257	1,296
Total liabilities	287,591	284,287
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock; $1.00 par value; 5,000 shares authorized; no shares issued and outstanding at December 31, 2016 and 2015	—	—
Common stock; $.001 par value; 200,000 shares authorized; 104,874 and 104,055 shares issued and outstanding at December 31, 2016 and 2015, respectively	105	104
Additional paid-in capital	831,750	829,428
Accumulated other comprehensive loss	(616)	(261)
Accumulated deficit	(813,054)	(836,356)
Total stockholders' equity (deficit)	18,185	(7,085)
Total liabilities and stockholders' equity (deficit)	$ 305,776	$ 277,202

See accompanying notes to consolidated financial statements.

VIVUS, INC.
CONSOLIDATED STATEMENTS OF OPERATION S
(In thousands, except per share data)

	Year Ended December 31,		
	2016	2015	2014
Revenue:			
Net product revenue	$ 48,501	$ 54,622	$ 45,277
License and milestone revenue	69,400	11,574	38,614
Supply revenue	2,291	26,674	26,519
Royalty revenue	4,066	2,560	3,771
Total revenue	124,258	95,430	114,181
Operating expenses:			
Cost of goods sold	10,602	34,157	33,387
Selling, general and administrative	52,379	79,387	111,539
Research and development	5,592	10,102	13,793
Inventory impairment and other non-recurring charges	—	32,061	6,173
Total operating expenses	68,573	155,707	164,892
Income (loss) from operations	55,685	(60,277)	(50,711)
Interest and other expense:			
Interest expense	32,888	33,317	32,535
Other (income) expense, net	(575)	(490)	30
Interest expense and other expense, net	32,313	32,827	32,565
Income (loss) before income taxes	23,372	(93,104)	(83,276)
Provision for (Benefit from) income taxes	70	3	(629)
Net income (loss)	$ 23,302	$ (93,107)	$ (82,647)
Basic net income (loss) per share	$ 0.22	$ (0.90)	$ (0.80)
Diluted net income (loss) per share	$ 0.22	$ (0.90)	$ (0.80)
Shares used in per share computation:			
Basic	104,385	103,926	103,456
Diluted	104,969	103,926	103,456

VIVUS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(In thousands)

	Year Ended December 31,		
	2016	2015	2014
Net income (loss)	$ 23,302	$ (93,107)	$ (82,647)
Unrealized loss on securities, net of taxes	(355)	(233)	(94)
Comprehensive income (loss)	$ 22,947	$ (93,340)	$ (82,741)

See accompanying notes to consolidated financial statements.

VIVUS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

(In thousands)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Capital	Income (Loss)	Deficit	Total
Balances, December 31, 2013	103,161	$ 103	$ 813,802	$ 66	$ (660,602)	$ 153,369
Sale of common stock through employee stock purchase plan	113	—	405	—	—	405
Exercise of common stock options for cash	385	1	1,718	—	—	1,719
Vesting of restricted stock units	70	—	—	—	—	—
Share-based compensation expense	—	—	9,766	—	—	9,766
Net unrealized loss on securities	—	—	—	(94)	—	(94)
Net loss	—	—	—	—	(82,647)	(82,647)
Balances, December 31, 2014	103,729	104	825,691	(28)	(743,249)	82,518
Sale of common stock through employee stock purchase plan	77	—	147	—	—	147
Vesting of restricted stock units	249	—	—	—	—	—
Share-based compensation expense	—	—	3,590	—	—	3,590
Net unrealized loss on securities	—	—	—	(233)	—	(233)
Net loss	—	—	—	—	(93,107)	(93,107)
Balances, December 31, 2015	104,055	104	829,428	(261)	(836,356)	(7,085)
Sale of common stock through employee stock purchase plan	41	—	39	—	—	39
Vesting of restricted stock units	778	1	(1)	—	—	—
Share-based compensation expense	—	—	2,284	—	—	2,284
Net unrealized loss on securities	—	—	—	(355)	—	(355)
Net income	—	—	—	—	23,302	23,302
Balances, December 31, 2016	104,874	$ 105	$ 831,750	$ (616)	$ (813,054)	$ 18,185

See accompanying notes to consolidated financial statements.

VIVUS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,		
	2016	2015	2014
Cash flows from operating activities:			
Net income (loss)	$ 23,302	$ (93,107)	$ (82,647)
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization	1,080	1,387	1,112
Amortization of debt issuance costs and discounts	18,666	17,174	15,923
Amortization of discount or premium on available-for-sale securities	944	2,282	4,016
Share-based compensation expense	2,284	3,590	9,766
Loss on disposal of property and equipment	342	—	—
Inventory impairment charge	—	29,522	2,170
Changes in assets and liabilities:			
Accounts receivable	(481)	2,598	619
Inventories	(2,584)	(8,487)	11,886
Prepaid expenses and other assets	1,516	2,639	7,734
Accounts payable	(2,353)	(3,370)	(329)
Accrued and other liabilities	(1,524)	(889)	(9,061)
Deferred revenue	(3,027)	329	706
Net cash provided by (used for) operating activities	38,165	(46,332)	(38,105)
Cash flows from investing activities:			
Property and equipment purchases	(211)	(310)	(262)
Purchases of available-for-sale securities	(135,997)	(213,536)	(240,983)
Proceeds from maturity of available-for-sale securities	60,050	281,250	260,500
Proceeds from sales of available-for-sale securities	36,080	—	—
Non-current assets	—	—	(3,362)
Net cash (used for) provided by investing activities	(40,078)	67,404	15,893
Cash flows from financing activities:			
Repayments of notes payable	(8,738)	(8,998)	—
Net proceeds from exercise of common stock options	—	—	1,719
Sale of common stock through employee stock purchase plan	39	147	405
Net cash (used for) provided by financing activities	(8,699)	(8,851)	2,124
Net increase (decrease) in cash and cash equivalents	(10,612)	12,221	(20,088)
Cash and cash equivalents:			
Beginning of year	95,395	83,174	103,262
End of period	$ 84,783	$ 95,395	$ 83,174
Supplemental cash flow disclosure:			
Interest paid	$ 15,368	$ 18,756	$ 20,251
Income taxes paid	$ 59	$ 58	$ 94
Non-cash investing activities:			
Unrealized loss on securities	$ (355)	$ (233)	$ (94)

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 developing and commercializing innovative, next-generation therapies to address unmet medical needs in human health, with two approved therapies and one product candidate in active clinical development. Qsymia® (phentermine and topiramate extended release) is approved by FDA for chronic weight management and STENDRA® (avanafil) is approved by FDA for erectile dysfunction, or ED, and by the European Commission, or EC, under the trade name, SPEDRA, for the treatment of ED in the EU. Tacrolimus is in clinical development for the treatment of Pulmonary Arterial Hypertension, or PAH.

Qsymia incorporates a proprietary formulation combining low doses of active ingredients from two previously approved drugs, phentermine and topiramate, and is being commercialized by the Company in the U.S. primarily through a sales force supported by an internal commercial team, who promote Qsymia to physicians. Avanafil is an oral phosphodiesterase type 5 inhibitor that is being commercialized in the U.S., EU and other countries through commercialization collaborators.

At December 31, 2016, the Company's accumulated deficit was approximately $813.1 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 for the next twelve months. However, the Company anticipates that it 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, conduct post-approval clinical studies for Qsymia, conduct non-clinical and clinical research and development work to support regulatory submissions and applications for our current and 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 its drugs and investigational drug candidates and to make payments under its existing license agreements and supply agreements.

If the Company requires additional capital, it 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, the Company may be required to delay, reduce the scope of or eliminate one or more of its commercialization or development programs or obtain funds through collaborations with others that are on unfavorable terms or that may require the Company to relinquish rights to certain of its technologies, product candidates or products that it would otherwise seek to develop on its own.

Management has evaluated all events and transactions that occurred after December 31, 2016, 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. The Company operates in a single segment, the development and commercialization of novel therapeutic products.

Significant Accounting Policies

Reclassifications

In April 2015, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update No. 2015-03, *Interest - Imputation of Interest* (Subtopic 835-30): *Simplifying the Presentation of Debt Issuance Costs* . The standard requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The Company adopted

this standard as required beginning in the first quarter of 2016 and retrospectively applied this standard to the balance sheet as of December 31, 2015. The amounts impacted by the adoption of this standard are as follows:

	As Reported December 31, 2015	Adjustment to reflect ASU 2015-03	As Adjusted December 31, 2015
Prepaid expenses and other assets	$ 10,624	$ (1,194)	$ 9,430
Total current assets	$ 274,786	$ (1,194)	$ 273,592
Non-current assets	$ 4,801	$ (2,185)	$ 2,616
Total assets	$ 280,581	$ (3,379)	$ 277,202
Long-term debt, current portion	$ 15,550	$ (1,194)	$ 14,356
Total current liabilities	$ 60,643	$ (1,194)	$ 59,449
Long-term debt, net of current portion	$ 219,219	$ (2,185)	$ 217,034
Total liabilities	$ 287,666	$ (3,379)	$ 284,287
Total liabilities and stockholders' equity	$ 280,581	$ (3,379)	$ 277,202

Principles of Consolidation

The consolidated financial statements include the accounts of VIVUS, Inc., and its wholly owned subsidiaries. All significant intercompany transactions and balances have been eliminated in consolidation.

Use of Estimates

The Company's consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles as set forth in the FASB's Accounting Standards Codification, with consideration given to the various staff accounting bulletins and other applicable guidance issued by the U.S. Securities and Exchange Commission. These accounting principles require management to make certain estimates, judgments 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, contingencies, litigation, inventories, research and development expenses, income taxes, 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, 2016 and 2015, all cash equivalents were invested in money market funds and U.S. Treasury securities. These investments are recorded at fair value.

Available-for-Sale Securities

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 (deficit), unless the decline in value is deemed to be other than temporary, 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 periodically evaluates its investment securities for other-than-temporary declines based on quantitative and qualitative factors. Any losses that are deemed other-than-temporary are recognized as a non-operating loss. To date, the Company has not had any other-than-temporary declines in the value of any of the securities in its investment portfolio. 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 expense.

Fair Value Measurements

The Company's financial instruments include cash equivalents, available-for-sale securities, accounts receivable, accounts payable, accrued liabilities and debt. Available-for-sale securities are carried at fair value. The carrying value of cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate their fair value due to the relatively short-term nature of these instruments. Debt instruments are initially recorded at face value, with stated interest and amortization of debt issuance discounts and costs recognized as interest expense, which currently approximates fair value.

Issuance costs related to the conversion option of the Company's convertible notes were charged to additional paid-in capital. The portion of the issuance costs 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.

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 in high credit quality money market funds, U.S. Treasury securities or corporate debt securities and by placing investments with maturities that maintain safety and liquidity within the Company's liquidity needs. The Company has also established guidelines for the issuance of credit to existing and potential customers.

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. Amounts that are 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. Historically, the Company has not had any significant uncollected accounts. The Company offers cash discounts to its customers, generally 2% of the sales price, as an incentive for prompt payment. The estimate of cash discounts is recorded at the time 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, 2016 or 2015. The allowance for cash discounts is $213,000 and $164,000 at December 31, 2016 and 2015, respectively.

Inventories

Inventories are valued at the lower of cost or market. Cost is determined using the first-in, first-out method using a weighted average cost method calculated for each production batch. Inventory includes the cost of the active pharmaceutical ingredients, or API, 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 lower actual sales, the Company may increase the write down for excess inventory for that product and record a charge to inventory impairment. The Company periodically evaluates the carrying value of inventory on hand for potential excess amount over demand. As a result of this evaluation, for the year ended December 31, 2015, the Company recognized an impairment charge of $29.5 million for Qsymia API inventory in excess of projected demand. For the year ended December 31, 2014, the Company recognized a total charge of $2.2 million for Qsymia inventories on hand in excess of projected demand.

Property and Equipment

Property and equipment is stated at cost and includes computers and software, furniture and fixtures, leasehold improvements and manufacturing equipment. Depreciation is computed using the straight-line method over the estimated useful lives of two to seven years for computers and software, furniture and fixtures and manufacturing equipment. Leasehold improvements are amortized using the straight-line method over the shorter of the remaining 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. Gains and losses associated with dispositions are reflected as a non-operating gain or loss in the accompanying consolidated statements of operations.

Long-lived assets, including property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to an estimate of undiscounted future cash flows expected to be generated by the asset. If the carrying amount of the asset exceeds its estimated future cash flows, an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the asset. To date, the Company has had no significant write-offs of long-lived assets.

Debt Issuance Costs

Debt issuance costs, which are presented in the balance sheet as a direct deduction from the carrying amount of the debt liability, are amortized as interest expense using the effective-interest method over the expected term of the debt.

Revenue Recognition

Product Revenue:

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

Other 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.

The Company ships units of Qsymia through a distribution network that includes certified retail pharmacies. Qsymia has a 36–month shelf life and the Company grants rights to its customers to return unsold product six 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 duration of the return period, the Company has not had sufficient information to reliably estimate expected returns of Qsymia at the time of shipment, and therefore revenue is recognized when units are dispensed to patients through prescriptions, at which point, the product is not subject to return. The Company obtains 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, 2016, the Company had deferred gross revenue of $17.6 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.

Supply Revenue:

The Company recognizes supply revenue from the sales of STENDRA or SPEDRA when the four basic revenue recognition criteria described above are met. The Company produces STENDRA or SPEDRA through a contract manufacturing partner and then sells it to its commercialization partners. The Company is the primary responsible party in the commercial supply arrangements and bears significant risk in the fulfillment of the obligations, including risks associated with manufacturing, regulatory compliance and quality assurance, as well as inventory, financial and credit loss. As such, the Company recognizes supply revenue on a gross basis as the principal party in the arrangements. Under the Company's product supply agreements, as long as the 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. As such, the Company recognizes revenue for products that meet the dating criteria at the time of shipment.

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* or (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 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, 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 when the four basic revenue recognition criteria described above are met.

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 API, 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 API, 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, 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.

Advertising Expenses

Advertising expenses are expensed as incurred. The Company incurred advertising and sales promotion costs related to its marketing of Qsymia of $3.9 million, $12.6 million and $10.1 million in 2016, 2015 and 2014, respectively.

Share-Based Compensation

Compensation expense is recognized for share-based payments, including stock options, restricted stock units and shares issued under the employee stock purchase plan, using a fair-value based method. The Company estimates the fair value of share-based payment awards on the date of the grant using the Black-Scholes option-pricing model, which requires the Company to estimate the expected term of the award, the expected volatility, the risk-free interest rate and the expected dividends. 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, which are adjusted as necessary for any other factors which may reasonably affect the volatility of VIVUS's stock in the future. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for the expected term of the award. 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 and expected future activity.

Inventory Impairment and Other Non-Recurring Charges

The Company's inventory impairment and other non-recurring charges consist of inventory impairment charges, proxy contest expenses and charges from cost reduction plans, including employee severance, one time termination benefits and ongoing benefits related to the reduction of our workforce, facilities and other facility exit costs. Liabilities for costs associated with the cost reduction plan are recognized when the liability is incurred. In addition, liabilities associated with cost reduction 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 cost reduction 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 various agreements with certain of the Company's employees.

Income Taxes

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

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

The Company assesses the likelihood that it will be able to recover its deferred tax assets. The Company considers all available evidence, both positive and negative, including historical levels of income, expectations and risks associated with estimates of future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for a valuation allowance. If it is not more likely than not that the Company will recover its deferred tax assets, the Company will increase its provision for taxes by recording a valuation allowance against the deferred tax assets that the Company estimates will not ultimately be recoverable. As a result of the Company's analysis of all available evidence, both positive and negative, as of December 31, 2016, 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. The Company also recognizes interest and penalties accrued on any unrecognized tax benefits as a component of its provision for income taxes. As of December 31, 2016, the Company does not have any unrecognized tax positions.

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. 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.

Intangible Assets

The Company records acquired intangible assets at cost and amortizes them over the estimated useful life of the asset. When events or changes in circumstances indicate that the carrying value of intangible assets may not be recoverable, the Company evaluates such impairment if the net book value of such assets exceeds the future undiscounted cash flows attributable to such assets. Should an impairment exist, the impairment loss would be measured

based on the excess carrying value of the asset over the asset's fair value or discounted estimates of future cash flows attributable to the assets. To date, the Company has recorded no impairment losses on its intangible assets.

Net Income (Loss) Per Share

The Company computes basic net income (loss) per share applicable to common stockholders 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 (loss) per share and, accordingly, are excluded from the calculation. As discussed in Note 13, 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 pay 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 net income (loss) 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 no impact on diluted net income (loss) 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 following table presents the computation of basic and diluted net income (loss) per share (in thousands, except per share amounts):

	2016	2015	2014
Net income (loss)	$ 23,302	$ (93,107)	$ (82,647)
Basic:			
Weighted-average shares outstanding	104,385	103,926	103,456
Basic net income (loss) per share	$ 0.22	$ (0.90)	$ (0.80)
Diluted:			
Weighted-average shares outstanding used in basic calculation	104,385	103,926	103,456
Dilutive potential shares	584	—	—
Weighted-average shares outstanding used in diluted calculation	104,969	103,926	103,456
Diluted net income (loss) per share	$ 0.22	$ (0.90)	$ (0.80)

For the years ended December 31, 2016, 2015, and 2014, potentially dilutive outstanding stock options and RSUs of 10,122,000, 7,167,000 and 8,096,000, respectively, were not included in the computation of diluted net loss per share because the effect would have been anti-dilutive.

Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* . The standard is a comprehensive new revenue recognition model that requires revenue to be recognized in a manner to depict the transfer of goods or services to a customer at an amount that reflects the consideration expected to be received in exchange for those goods or services. This new standard will supersede most current revenue recognition guidance. In July 2015, the FASB voted to delay the effective date of the standard by one year to the first quarter of 2018. Early adoption is permitted, but not before the first quarter of 2017. This new revenue standard may be applied retrospectively to each prior period presented or retrospectively with the cumulative effect recognized in retained earnings as of the date of adoption, or the "modified retrospective basis." Preliminarily, the Company plans to adopt the standard in the first quarter of 2018 using the modified retrospective basis. The Company currently defers revenue on certain product shipments due to an inability to estimate returns at the level of confidence required by current accounting guidance. If the Company is unable to reasonably estimate returns prior to the adoption of this standard, the adoption of

this standard could have a material impact on the Company's net product revenues in the first quarter of adoption as well as on the timing of future recognition of net product revenues.

In July 2015, the FASB issued Accounting Standards Update 2015-11, *Simplifying the Measurement of Inventory - Inventory (Topic 330),* which changes the measurement principle for inventory from the lower of cost or market to lower of cost and net realizable value. Net realizable value is defined as the "estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation." The standard eliminates the guidance that entities consider replacement cost or net realizable value less an approximately normal profit margin in the subsequent measurement of inventory when cost is determined on a first-in, first-out or average cost basis. The standard is effective for public entities with fiscal years beginning after December 15, 2016. The Company is currently evaluating the impact of the adoption of this standard on the Company's consolidated financial statements.

In February 2016, the FASB issued Accounting Standards Update 2016-02, *Leases (Topic 842),* which modifies the accounting by lessees for all leases with a term greater than 12 months. The standard will require lessees to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases. For public companies, the standard is effective for annual and interim periods beginning on or after December 15, 2018. Early adoption is permitted. The Company's only significant lease is its operating lease for its corporate headquarters in Campbell, California, and, while the Company cannot yet estimate the amounts by which its financial statements will be affected by the adoption of this guidance, it expects that the recognition of expense will be similar to current guidance but that there will be a significant change in the balance sheet due to the recognition of right of use assets and the corresponding lease liabilities. The Company plans to adopt the new leases guidance effective January 1, 2019 using a modified retrospective transition method.

In March 2016, the FASB issued Accounting Standards Update 2016-09, *Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting* . The standard is intended to simplify several areas of accounting for share-based compensation arrangements, including the income tax impact, classification on the statement of cash flows and forfeitures. This standard is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016, and early adoption is permitted. The Company does not expect adoption of this standard to have a material impact on the Company's consolidated financial statements.

In August 2016, the FASB issued Accounting Standards Update 2016-15, *Statement of Cash Flows (Topic 230) Classification of Certain Cash Receipts and Cash Payments* . The standard clarifies how certain cash receipts and cash payments will be presented and classified in the statement of cash flows. The new standard is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017, and early adoption is permitted. The Company is currently evaluating the impact that the standard will have on its consolidated financial statements.

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 consist of the following (in thousands):

	As of December 31, 2016			
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	$ 84,783	$ —	$ —	$ 84,783
U.S. Treasury securities	24,780	7	(110)	24,677
Corporate debt securities	160,571	52	(564)	160,059
Total	270,134	59	(674)	269,519
Less amounts classified as cash and cash equivalents	(84,783)	—	—	(84,783)
Total available-for-sale securities	$ 185,351	$ 59	$ (674)	$ 184,736

Cash and cash equivalents and available-for-sale securities	As of December 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash and money market funds	$ 95,395	$ —	$ —	$ 95,395
U.S. Treasury securities	84,734	—	(107)	84,627
Corporate debt securities	61,696	20	(175)	61,541
Total	241,825	20	(282)	241,563
Less amounts classified as cash and cash equivalents	(95,395)	—	—	(95,395)
Total available-for-sale securities	$ 146,430	$ 20	$ (282)	$ 146,168

As of December 31, 2016, the Company's available-for-sale securities have original contractual maturities up to 57 months. In response to changes in the availability of and the yield on alternative investments as well as liquidity requirements, the Company may sell 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.

Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Three levels of inputs, of which the first two are considered observable and the last unobservable, may be used to measure fair value. The three levels are:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2 — Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The following table represents the fair value hierarchy for our cash equivalents and available-for-sale securities by major security type (in thousands):

	As of December 31, 2016			
	Level 1	Level 2	Level 3	Total
Cash and money market funds	$ 84,783	$ —	$ —	$ 84,783
U.S. Treasury securities	24,677	—	—	24,677
Corporate debt securities	—	160,059	—	160,059
Total	$ 109,460	$ 160,059	$ —	$ 269,519

	As of December 31, 2015			
	Level 1	Level 2	Level 3	Total
Cash and money market funds	$ 95,395	$ —	$ —	$ 95,395
U.S. Treasury securities	84,627			84,627
Corporate debt securities	—	61,541	—	61,541
Total	$ 180,022	$ 61,541	$ —	$ 241,563

Note 3. Accounts Receivable

Accounts receivable consist of the following (in thousands):

	Balance as of	
	December 31, 2016	December 31, 2015
Qsymia	$ 8,982	$ 8,508
STENDRA/SPEDRA	709	652
	9,691	9,160
Qsymia allowance for cash discounts	(213)	(163)
Net	$ 9,478	$ 8,997

There was no allowance for doubtful accounts at December 31, 2016 or 2015.

Note 4. Inventories

Inventories consist of the following (in thousands):

	Balance as of	
	December 31, 2016	December 31, 2015
Raw materials	$ 9,412	$ 8,645
Work-in-process	2,984	247
Finished goods	3,110	4,282
Deferred costs	680	428
Inventories	$ 16,186	$ 13,602

Raw materials inventories consist primarily of the active pharmaceutical ingredients, or API, for Qsymia and STENDRA/SPEDRA.

Note 5. Prepaid Expenses and Other Current Assets

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

	Balance as of	
	December 31, 2016	December 31, 2015
Prepaid sales and marketing expenses	$ 1,767	$ 3,434
Prepaid insurance	1,182	1,124
Other prepaid expenses and assets	5,302	4,872
Total	$ 8,251	$ 9,430

The amounts included in prepaid expenses and other assets consist primarily of prepayments for future services, miscellaneous non-trade receivables, prepaid interest and interest income receivable. These costs have been deferred as prepaid expenses and other current assets on the 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 receivable is collected by the Company.

Note 6. Property and Equipment

Property and equipment consist of the following (in thousands):

	Balance as of	
	December 31, 2016	December 31, 2015
Computers and software	$ 1,965	$ 2,300
Furniture and fixtures	516	943
Manufacturing equipment	213	213
Leasehold improvements	492	876
	3,186	4,332
Accumulated depreciation	(2,398)	(3,338)
Property and equipment, net	$ 788	$ 994

Note 7. Non-Current Assets

Non-current assets primarily consist of patent acquisition and assignment costs (see Note 10).

Note 8. Accrued and Other Liabilities

Accrued and other liabilities consist of the following (in thousands):

	Balance as of	
	December 31, 2016	December 31, 2015
Accrued employee compensation and benefits	$ 3,014	$ 3,621
Accrued non-recurring charges (see Note 10)	5	503
Accrued interest on debt (see Note 13)	1,509	1,293
Accrued manufacturing costs	6,835	5,408
Other accrued liabilities	4,323	5,066
Total	$ 15,686	$ 15,891

The amounts included in other accrued liabilities consist of obligations primarily related to sales, marketing, research, clinical development, corporate activities, the STENDRA license and royalties.

Note 9. Non-Current Accrued and Other Liabilities

Non-current accrued and other liabilities were $0.3 million and $1.3 million at December 31, 2016 and 2015, respectively, and were primarily comprised of deferred rent and costs associated with the exit of certain operating leases and security deposits relating to the sublease agreements (see Note 10).

Note 10. Inventory Impairment and Other Non-Recurring Charges

Inventory impairment and other non-recurring charges consist of the following (in thousands):

	Year Ended December 31,		
	2016	2015	2014
Inventory impairment (see Note 4)	$ —	$ 29,522	$ 2,170
Employee severance and related costs	—	2,503	1,711
Patent settlement	—	—	1,949
Share-based compensation (see Note 15)	—	36	343
Total inventory impairment and other non-recurring expense	$ —	$ 32,061	$ 6,173

As discussed in Note 4, in 2015 the Company recorded inventory impairment charges primarily for Qsymia API inventory in excess of expected demand. In 2014, the Company recorded inventory impairment charges for finished goods and certain non-API raw materials on hand in excess of demand.

In 2015, the Company recorded employee severance and related costs and share-based compensation related to the July 2015 corporate restructuring plan, which reduced the Company's workforce by approximately 60 job positions. In 2014, the Company recorded employee severance and related costs and share-based compensation costs related to the 2013 cost reduction plan that reduced the Company's workforce by approximately 20 employees.

In 2014, the Company paid $5.0 million in connection with the transfer and assignment of certain patents from Janssen Pharmaceuticals, Inc. Of the $5.0 million, approximately $1.9 million was recognized as a non-recurring expense for the year ended December 31, 2014 as it related to a legal settlement. The remaining balance of approximately $3.1 million was recorded as an intangible asset and is being amortized as cost of goods sold through the expiration dates.

The following table sets forth activity for the cost reduction plans (in thousands):

	Severance obligations	Facilities-related obligations	Total
Balance of accrued costs at December 31, 2013	$ 6,509	$ 1,022	$ 7,531
Charges	1,711	—	1,711
Payments	(4,940)	(450)	(5,390)
Balance of accrued costs at December 31, 2014	3,280	572	3,852
Charges	2,474	—	2,474
Payments	(5,344)	(101)	(5,445)
Balance of accrued costs at December 31, 2015	410	471	881
Charges	—	—	—
Reclassifications	(268)	(402)	(670)
Payments	(137)	(69)	(206)
Balance of accrued costs at December 31, 2016	$ 5	$ —	$ 5

Accrued employee severance costs as of December 31, 2016 are included under current liabilities in "Accrued and other liabilities ."

The balance of the accrued employee severance and facilities-related costs at December 31, 2016 is anticipated to be paid out in 2017.

Note 11. Deferred Revenue

Deferred revenue consists of the following (in thousands):

	Balance as of	
	December 31, 2016	December 31, 2015
Qsymia deferred revenue - current	$ 17,558	$ 19,275
STENDRA deferred revenue - current	1,616	2,867
Deferred revenue - current	$ 19,174	$ 22,142
STENDRA deferred revenue - non-current	$ 6,449	$ 6,508

Qsymia deferred revenue consists of product shipped to the Company's wholesalers, certified retail pharmacies and certified home delivery pharmacy services networks, but not yet dispensed to patients through prescriptions, net of prompt payment discounts. SPEDRA deferred revenue relates to a prepayment for future royalties on sales of SPEDRA.

Note 12. License, Commercialization and Supply Agreements

In January 2001, the Company 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. Under the terms of the agreement, MTPC agreed to grant an exclusive license to the Company 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 we develop containing avanafil. The MTPC agreement contains a number of milestone payments to be made by us based on various triggering events. The term of the MTPC agreement is based on a country by country and on a product by product basis. In August 2012, the Company entered into an amendment to the agreement with MTPC that permitted the Company to manufacture the active pharmaceutical ingredient, or API, and tablets for STENDRA by itself or through third parties. In 2015, the Company transferred the manufacturing of the API and tablets for STENDRA to Sanofi.

In July 2013, the Company 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 SPEDRA for the treatment of ED in over 40 countries, including the EU, plus Australia and New Zealand. Additionally, the Company transfered to Menarini ownership of the marketing authorization for SPEDRA in the EU for the treatment of ED, which was granted by the EC in June 2013. Under the Menarini License Agreement, the Company has and is entitled to receive potential milestone payments based on certain net sales targets, plus royalties on SPEDRA sales. Under the terms of the Menarini Supply Agreement, the Company will supply Menarini with STENDRA drug product until December 31, 2018. Menarini also has the right to manufacture STENDRA independently, provided that it continues to satisfy certain minimum purchase obligations to the Company. 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.

In October 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. Auxilium terminated the Auxilium Supply Agreement effective June 30, 2016 and the Auxilium License Agreement effective September 30, 2016.

In December 2013, the Company entered into a license and commercialization agreement, or the Sanofi License Agreement, with Sanofi. Under the terms of the Sanofi License Agreement, Sanofi received an exclusive license to commercialize and promote avanafil for therapeutic use in humans in Africa, the Middle East—Turkey and Commonwealth of Independent States, including Russia, or the Sanofi Territory. In July 2013, the Company 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. In November 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 has minimum annual purchase commitments under these agreements for at least the initial five year terms.

On September 30, 2016, the Company entered into a license and commercialization agreement, or the Metuchen License Agreement, and a commercial supply agreement, or the Metuchen Supply Agreement, with Metuchen. Under the terms of the license agreement, Metuchen received an exclusive license to develop, commercialize and promote STENDRA in the United States, Canada, South America and India, or the Metuchen Territory, effective October 1, 2016. The Company and Metuchen have agreed not to develop, commercialize, or in-license any other product that operates as a PDE-5 inhibitor in the Metuchen Territory for a limited time period, subject to certain exceptions. The license agreement will terminate upon the expiration of the last-to-expire payment obligations under the license agreement; upon expiration of the term of the license agreement, the exclusive license granted under the license agreement shall become fully paid-up, royalty-free, perpetual and irrevocable as to the Company but not certain trademark royalties due to MTPC.

Metuchen will obtain STENDRA exclusively from the Company for a mutually agreed term pursuant to the Metuchen Supply Agreement. Metuchen may elect to transfer the control of the supply chain for STENDRA for the Metuchen Territory to itself or its designee by assigning to Metuchen the Company's agreements with the contract manufacturer. For 2016 and each subsequent calendar year during the term of the Metuchen Supply Agreement, if Metuchen fails to purchase an agreed minimum purchase amount of STENDRA from the Company, it will reimburse the Company for the shortfall as it relates to the Company's out of pocket costs to acquire certain raw materials needed to manufacture STENDRA. Upon the termination of the Metuchen Supply Agreement (other than by Metuchen for the Company's uncured material breach or upon completion of the transfer of the control of the supply chain), Metuchen's agreed minimum purchase amount of STENDRA from the Company shall accelerate for the entire then current initial term or renewal term, as applicable. The initial term under the Metuchen Supply Agreement will be for a period of five years, with automatic renewal for successive two year periods unless either party provides a termination notice to the other party at least two years in advance of the expiration of the then current term. On September 30, 2016, the Company received $70 million from Metuchen under the Metuchen License Agreement. Metuchen will also reimburse the Company for payments made to cover royalty and milestone obligations to MTPC during the term of the license agreement. For the year ended December 31, 2016, the Company recognized this amount as license revenue, less an estimate of its financial obligations under the Metuchen License Agreement.

Note 13. Long-Term Debt

Convertible Senior Notes Due 2020

In May 2013, the Company closed an offering of $220.0 million in 4.5% Convertible Senior Notes due May 2020, or the Convertible Notes. The Convertible Notes are governed by an indenture, dated May 2013 between the Company and Deutsche Bank National Trust Company, as trustee. In May 2013, the Company closed on an additional $30.0 million of Convertible Notes upon exercise of an option by the initial purchasers of the Convertible Notes at a conversion rate of approximately $14.86 per share. Total net proceeds from the Convertible Notes were approximately $241.8 million. The Convertible Notes are convertible at the option of the holders under certain conditions at any time prior to the close of business on the business day immediately preceding November 1, 2019. 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 our common stock, at the Company's election. Interest payments are made quarterly.

For the year ended December 31, 2016, total interest expense related to the Convertible Notes was $29.8 million, including amortization of $17.5 million of the debt discount and $929,000 of deferred financing costs. For the year ended December 31, 2015, total interest expense related to the Convertible Notes was $27.2 million, including amortization of $16.0 million of the debt discount and $848,000 of deferred financing costs. For the year ended

December 31, 2014, total interest expense related to the Convertible Notes was $25.0 million, including amortization of $14.7 million of the debt discount and $784,000 of deferred financing costs.

Senior Secured Notes Due 2018

In March 2013, the Company entered into the Purchase and Sale Agreement between the Company and BioPharma Secured Investments III Holdings Cayman LP, a Cayman Islands exempted limited partnership, 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 in April 2013. The scheduled quarterly payments on the Senior Secured Notes are subject to the net sales of (i) Qsymia 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. The Company may elect to pay full scheduled quarterly payments if it chooses.

For the year ended December 31, 2016, the interest expense related to the Senior Secured Notes was $4.6 million, including amortization of deferred financing costs amounting to $235,000. For the year ended December 31, 2015, the interest expense related to the Senior Secured Notes was $6.3 million, including amortization of deferred financing costs amounting to $393,000. For the year ended December 31, 2014, the interest expense related to the Senior Secured Notes was $7.5 million, including amortization of deferred financing costs amounting to $468,000.

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

	December 31, 2016
Convertible Senior Notes due 2020	$ 250,000
Senior Secured Notes due 2018	32,264
	282,264
Less: Debt issuance costs	(2,216)
Less: Discount on convertible senior notes	(38,730)
	241,318
Less: Current portion	(8,708)
Long-term debt, net of current portion	$ 232,610

Future estimated payments on the Senior Secured Notes as of December 31, 2016 are as follows:	
2017	$ 23,386
2018	39,027
Total	62,413
Less: Interest portion	(30,149)
Senior Secured Notes	$ 32,264

Note 14. Stockholders' Equity

Common Stock

The Company is authorized to issue 200,000,000 shares of common stock. As of December 31, 2016 and 2015, there were 104,874,000 and 104,055,000 shares, respectively, issued and outstanding.

Preferred Stock

The Company is authorized to issue 5,000,000 shares of undesignated preferred stock with a par value of $1.00 per share. As of December 31, 2016 and 2015, 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.

On November 9, 2016, the Company adopted an Amended and Restated Preferred Stock Rights Agreement, or the A&R Rights Agreement, which amended and extended the Rights Plan. The A&R Rights Agreement was approved to mitigate the likelihood of an "ownership change" within the meaning of Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, and thereby preserve the current ability of the Company to utilize certain net operating loss carryovers and other tax benefits of the Company and its subsidiaries to offset future income. The A&R Rights Agreement is intended to act as a deterrent to any person or group acquiring beneficial ownership of 4.9% or more of the outstanding common stock of the Company without the approval of the Board.

The A&R Rights Agreement extends the expiration date of the rights from April 13, 2017 to November 9, 2019 (subject to earlier expiration under the circumstances described below). It also lowers the threshold at which a person or group becomes an "Acquiring Person" to 4.9% of the outstanding Common Stock, subject to certain exceptions (including that any person or group who, as of the time of the first public announcement of the approval of the A&R Rights Agreement, beneficially owns 4.9% or more of the then-outstanding shares of Common Stock, will not be deemed to be an "Acquiring Person" so long as such person or group does not thereafter acquire an additional 1% of the outstanding shares of Common Stock, subject to certain exceptions); and amends certain other provisions, including the definitions of "Beneficial Ownership" and "Exempt Person", to include terms appropriate for the purpose of preserving the tax benefits.

Each right would initially entitle the holder to purchase one one-thousandth of a share of the Company's Series A Participating Preferred Stock, par value $0.001 per share, or the Preferred Stock, for a purchase price of $5.30 (subject to adjustment). Under certain circumstances set forth in the A&R Rights Agreement, the Company may suspend the exercisability of the rights.

The rights and the A&R Rights Agreement will expire on the earliest of (i) November 9, 2019, (ii) the time at which the rights are redeemed or exchanged pursuant to the A&R Rights Agreement, (iii) the repeal of Section 382 of the Code or any successor statute if the Board determines that the A&R Rights Agreement is no longer necessary or desirable for the preservation of the tax benefits, (iv) the first business day following the date on which the A&R Rights Agreement fails to be ratified by the Company's stockholders at the Company's 2017 annual meeting and (v) the beginning of a taxable year to which the Board determines that no tax benefits may be carried forward.

Note 15. Stock Option and Purchase Plans

Stock Option Plan

On March 29, 2010, the Company's Board of Directors terminated the 2001 Stock Option Plan and adopted and approved a new 2010 Equity Incentive Plan, or the 2010 Plan, which was approved by the Company's stockholders at the 2010 Annual Meeting of Shareholders. The 2001 Plan continues to govern awards previously granted under it. 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.

The 2010 Plan's original share reserve was 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). In September 2014 and November 2016, the Company's stockholders approved increases to the total number of shares reserved under the 2010 Plan by 5,950,000 and 5,000,000 shares, respectively, for a total of 19,350,000 shares.

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:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value
Restricted stock units outstanding January 1, 2014	—	$ —
Granted	521,900	8.20
Vested	(70,500)	8.37
Forfeited	(117,900)	8.17
Restricted stock units outstanding, December 31, 2014	333,500	8.17
Granted	1,954,000	1.85
Vested	(248,688)	2.73
Forfeited	(628,937)	7.99
Restricted stock units outstanding December 31, 2015	1,409,875	1.87
Granted	562,500	1.43
Vested	(1,359,829)	1.68
Forfeited	(70,789)	1.95
Restricted stock units outstanding, December 31, 2016	541,757	$ 1.91

Stock Options

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

	Years Ended December 31,					
	2016		2015		2014	
	Number of Shares	Weighted-Average Exercise Price	Number of Shares	Weighted-Average Exercise Price	Number of Shares	Weighted-Average Exercise Price
Options outstanding at beginning of year	5,722,105	$ 7.97	5,956,459	$ 12.09	8,906,451	$ 12.06
Granted	4,980,835	$ 1.06	3,499,200	$ 2.46	935,800	$ 6.89
Exercised	—	$ —	—	$ —	(374,530)	$ 4.48
Cancelled	(1,134,797)	$ 5.89	(3,733,554)	$ 9.38	(3,511,262)	$ 11.45
Options outstanding at end of year	9,568,143	$ 4.62	5,722,105	$ 7.97	5,956,459	$ 12.09
Options exercisable at end of year	3,740,459	$ 9.62	3,042,888	$ 11.48	4,053,329	$ 12.34
Weighted average grant-date fair value of options granted during the year		$ 0.55		$ 1.44		$ 4.34

At December 31, 2016, stock options were outstanding and exercisable as follows:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding at December 31, 2016	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable December 31, 2016	Weighted-Average Exercise Price
$ 1.06 — $ 1.06	4,643,506	6.08 years	$ 1.06	29,739	$ 1.06
$ 1.26 — $ 6.05	2,451,717	4.88 years	$ 2.69	1,305,535	$ 2.94
$ 6.39 — $ 24.23	2,412,920	4.31 years	$ 12.90	2,345,185	$ 13.04
$ 25.74 — $ 25.74	60,000	5.45 years	$ 25.74	60,000	$ 25.74
$ 1.06 — $ 25.74	9,568,143	5.32 years	$ 4.62	3,740,459	$ 9.62

The aggregate intrinsic value of outstanding options as of December 31, 2016 was $418,000. At December 31, 2016, 8,895,532 options remained available for grant.

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:

	2016	2015	2014
Expected life (in years)	4.33	4.69	4.84
Volatility	65.8 %	70.8 %	79.1 %
Risk-free interest rate	1.36 %	1.28 %	1.74 %
Dividend yield	—	—	—

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. The reserved amount was increased to 1,400,000 in 2003 and 2,000,000 in 2011. Under the ESPP, 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 each six-month offering period.

As of December 31, 2016, 1,732,884 shares have been issued to employees and there are 267,116 shares available for issuance under the ESPP. The weighted average fair value of shares issued under the ESPP in 2016, 2015 and 2014 was $0.33, $0.69 and $1.05 per share, respectively.

Valuation Assumptions

The fair value of shares issued under the ESPP is estimated using the Black-Scholes option pricing model, assuming no expected dividends and the following weighted average assumptions:

	2016	2015	2014
Expected life (in years)	0.5	0.5	0.5
Volatility	50.0 %	63.4 %	44.9 %
Risk-free interest rate	0.5 %	0.2 %	0.1 %
Dividend yield	—	—	—

Share-Based Compensation Expense

Total estimated share-based compensation expense, related to all of the Company's share-based awards, was comprised as follows (in thousands):

	2016	2015	2014
Cost of goods sold	$ 147	$ 132	$ 118
Selling, general and administrative	1,644	2,862	1,177
Research and development	493	398	8,128
Non-recurring charges	—	198	343
Total share-based compensation expense	$ 2,284	$ 3,590	$ 9,766

Total share-based compensation cost capitalized as part of the cost of inventory was $33,000, $23,000 and $0 for the years ended December 31, 2016, 2015 and 2014, respectively.

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

	2016	2015	2014
Restricted stock units	$ 1,591	$ 1,409	$ 1,334
Stock options	675	2,143	8,305
Employee stock purchase plan	18	38	127
	$ 2,284	$ 3,590	$ 9,766

As of December 31, 2016, unrecognized estimated compensation expense totaled $5.0 million related to non-vested stock options and restricted stock units and $8,000 related to the ESPP. The weighted average remaining requisite service period for the non-vested stock options was 2.9 years and for the ESPP was less than 6 months.

Note 16. 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, which was expanded and extended through March 2017. Under the Castro Lease, the Company leased 4,914 square feet at an average base rent of $2.87 per square foot. Commencing on September 1, 2014, the Company subleased the Castro Lease for a term of 31 months at a starting monthly rental rate of $4.42 per square feet (subject to agreed increases). Minimum rents expected to be received under this sublease are $69,000 for the year ending December 31, 2017.

In August 2016, the Company entered into a lease for new principal executive offices, consisting of approximately 13,981 square feet of office space at 900 E. Hamilton Avenue, Campbell, California, or the Campbell Lease. The Campbell Lease has an initial term of approximately 58 months, commencing on December 27, 2016, with a beginning annual rental rate of $3.10 per rentable square foot, subject to agreed-upon increases. The Company is entitled to an abatement of the monthly rent for the first four months on the lease term, subject to conditions detailed in the Campbell Lease. The Company has one option to extend the lease term for two years at the fair market rental rate then prevailing as detailed in the Campbell Lease.

Future minimum lease payments under operating leases at December 31, 2016, were as follows (in thousands):

2017	$ 347
2018	531
2019	548
2020	564
2021	435
	$ 2,425

Cardiovascular Outcomes Trial

As a condition of FDA granting approval to commercialize Qsymia in the U.S., the Company agreed to complete certain post-marketing requirements. One requirement was to perform a cardiovascular outcomes trial, or CVOT, on Qsymia. The cost of a CVOT is estimated to be between $180 million and $220 million incurred over a period of approximately five years. The Company is working with FDA to determine a pathway to provide FDA with information to support the safety of Qsymia in a more cost effective manner. To date, the Company has not incurred expenses related to the CVOT.

Note 17. 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, 2016 and 2015, are as follows (in thousands):

	2016	2015
Deferred tax assets:		
Net operating loss carry forwards	$ 220,053	$ 235,714
Research and development credit carry forwards	16,550	16,562
Share-based compensation	7,579	7,939
Accruals and other	21,833	20,589
Depreciation	75	104
Deferred revenue	3,123	3,492
	269,213	284,400
Valuation allowance	(269,213)	(284,400)
Total	$ —	$ —

The net decrease in the valuation allowance in 2016 was $15.2 million. The net increase in the valuation allowance in 2015 was $24.1 million. As of December 31, 2016, the Company had no significant deferred tax liabilities.

As of December 31, 2016, the Company had approximately $635.7 million and $265.0 million of net operating loss, or NOL, carryforwards with which to offset its future taxable income for federal and state income tax reporting purposes, respectively. The federal and state NOL carryforwards will begin expiring in 2022 and 2028, respectively, unless previously utilized.

As of December 31, 2016, the Company has federal and state research credit carryforwards of approximately $13.2 million, and $5.2 million, respectively. The federal research credit carryforwards will begin expiring in 2018, unless previously utilized. The state research credit carryforwards do not expire.

Utilization of the Company's NOL 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, the Company will adjust the Tax Attributes accordingly. The Company faces the risk that its ability to use its Tax Attributes will be substantially restricted if it undergoes 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. The Company has completed studies through June 30, 2016 and concluded that no adjustments were required. If there is a future change of control, the Company's 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 financial statements.

The Company uses the with-and-without approach described in guidance which has been incorporated into ASC 740 *Income Taxes* to determine the recognition and measurement of excess tax benefits. Accordingly, the Company has elected to recognize excess income tax benefits from stock option exercises in additional paid-in capital only if an incremental income tax benefit would be realized after considering all other Tax Attributes presently available to the Company. As of December 31, 2016, the amount of excess tax benefits from stock options included in federal and state net operating losses is $48.4 million and $9.9 million, respectively. The impact of this excess tax benefit is recognized as additional paid-in capital when it reduces taxes payable. In addition, the Company has elected to account for the indirect effects of stock-based awards on other Tax Attributes, such as the research and alternative minimum tax credits, through the consolidated statement of operations.

The provision (benefit) for income taxes is based upon the loss from continuing operations before income taxes as follows (in thousands):

	2016	2015	2014
Income (loss) before income taxes:			
Domestic	$ 23,592	$ (92,967)	$ (83,151)
International	(220)	(137)	(125)
Income (loss) before taxes	$ 23,372	$ (93,104)	$ (83,276)

The provision (benefit) for income taxes consists of the following (in thousands):

	2016	2015	2014
Current:			
Federal	$ —	$ —	$ —
State	70	3	(629)
Foreign	—	—	—
Total current provision (benefit) for income taxes	$ 70	$ 3	$ (629)
Deferred:			
Federal	$ —	$ —	$ —
State	—	—	—
Foreign	—	—	—
Total deferred provision for income taxes	$ —	$ —	$ —
Total provision (benefit) for income taxes from continuing operations	$ 70	$ 3	$ (629)

The effective tax rate differs from the amount computed by applying the statutory federal income tax rates as follows:

	2016	2015	2014
Tax at U.S. federal statutory rate	35 %	(35)%	(35)%
State income taxes, net of federal tax effect	4	(2)	—
Change in valuation allowance	(67)	31	29
Permanent items	28	6	7
Other	—	—	(2)
Effective tax rate	— %	— %	(1)%

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

	2016	2015	2014
Unrecognized tax benefits as of January 1	$ 38	$ —	$ 1,662
Gross increase/(decrease) for tax positions of prior years	2	—	—
Gross increase/(decrease) for tax positions of current year	25	38	—
Settlements	—	—	(1,662)
Lapse of statute of limitations	—	—	—
Unrecognized tax benefits balance at December 31	$ 65	$ 38	$ —

The remaining balance recorded on the Company's consolidated balance sheets is as follows (in thousands):

	2016	2015
Total unrecognized tax benefits	$ 65	$ 38
Amounts netted against deferred tax assets	(65)	(38)
Unrecognized tax benefits recorded on consolidated balance sheets	$ —	$ —

As the Company is not currently under examination, it is reasonable to assume that the balance of gross unrecognized tax benefits will likely not change in the next twelve months. The Company currently has not recorded interest and penalties relating to uncertain tax positions.

Note 18. 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.

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.

Product revenue by geographic region is as follows (in thousands):

	Years Ended December 31,					
	2016			2015		
	U.S.	ROW	Total	U.S.	ROW	Total
Qsymia—Net product revenue	$ 48,501	$ —	$ 48,501	$ 54,622	$ —	$ 54,622
STENDRA/SPEDRA—License and milestone revenue	69,400	—	69,400	—	11,574	11,574
STENDRA/SPEDRA—Supply revenue	765	1,526	2,291	16,602	10,072	26,674
STENDRA/SPEDRA —Royalty revenue	1,649	2,417	4,066	418	2,142	2,560
Total revenue	$ 120,315	$ 3,943 (1)	$ 124,258	$ 71,642	$ 23,788 (2)	$ 95,430

	2014		
	U.S.	ROW	Total
Qsymia—Net product revenue	$ 45,277	$ —	$ 45,277
STENDRA/SPEDRA—License and milestone revenue	15,406	23,208	38,614
STENDRA/SPEDRA—Supply revenue	9,059	17,460	26,519
STENDRA/SPEDRA —Royalty revenue	2,176	1,595	3,771
Total revenue	$ 71,918	$ 42,263 (3)	$ 114,181

(1) $3.9 million of which is attributable to Germany.

(2) $23.7 million of which is attributable to Germany.

(3) $37.2 million of which is attributable to Germany.

Major customers

Revenues from significant customers as a percentage of net Qsymia product revenues is as follows:

	2016	2015	2014
Amerisource Bergen	35 %	31 %	35 %
McKesson	34 %	37 %	33 %
Cardinal Health, Inc.	29 %	30 %	28 %

Accounts receivable by significant customer as a percentage of the total gross accounts receivable balance are as follows:

	2016	2015
Amerisource Bergen	40 %	32 %
McKesson	30 %	33 %
Cardinal Health, Inc.	21 %	25 %

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 commercial supplies for Qsymia. Until 2015, MTPC was the Company's sole-source supplier for the API and the tablets for STENDRA (avanafil). In 2015, the Company transitioned to Sanofi as it sole-source supply for STENDRA API and tablets. 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. In July 2013, the Company 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. In November 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.

During the years ended December 31, 2016, 2015 and 2014, 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 27%, 11% and 27%, respectively, of total research and development expenses.

Note 19. 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, 2016, 2015 and 2014 were $272,000, $406,000 and $467,000, respectively.

Note 20. Legal Matters

Shareholder Lawsuit

On March 27, 2014, Mary Jane and Thomas Jasin, who purport to be purchasers of VIVUS common stock, filed an Amended Complaint in Santa Clara County Superior Court alleging securities fraud against the Company and three of its former officers and directors. In that complaint, captioned *Jasin v. VIVUS, Inc* ., Case No. 114-cv-261427, plaintiffs asserted claims under California's securities and consumer protection securities statutes. Plaintiffs alleged generally that defendants misrepresented the prospects for the Company's success, including with respect to the launch of Qsymia, while purportedly selling VIVUS stock for personal profit. Plaintiffs alleged losses of "at least" $2.8 million, and sought damages and other relief. On July 18, 2014, the same plaintiffs filed a complaint in the United States District Court for the Northern District of California, captioned *Jasin v. VIVUS, Inc* ., Case No. 5:14-cv-03263. The Jasins' federal complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, based on facts substantially similar to those alleged in their state court action. On September 15, 2014, pursuant to an agreement between the parties, plaintiffs voluntarily dismissed their state court action with prejudice. Defendants moved to dismiss the federal action and moved to dismiss again after plaintiffs amended their complaint to include additional factual allegations and to add seven new claims under California law. The court granted the latter motion on June 18, 2015, dismissing the seven California claims with prejudice and dismissing the two federal claims with leave to amend. Plaintiffs filed a Second Amended Complaint on August 17, 2015. Defendants moved to dismiss that complaint as well. On April 19, 2016, the court granted defendants' motion to dismiss with prejudice and entered judgment in favor of defendants. Plaintiffs filed a notice of appeal to the Ninth Circuit Court of Appeals on May 18, 2016. Briefing on the appeal has now been completed. The Ninth Circuit has not yet scheduled the matter for oral argument or consideration. The Company maintains directors' and officers' liability insurance that it believes affords coverage for much of the anticipated cost of the remaining *Jasin* action, subject to the use of the Company's financial resources to pay for its self-insured retention and the policies' terms and conditions.

The Company and the defendant former officers and directors cannot predict the outcome of the lawsuit, but they believe the lawsuit is without merit and intend to continue vigorously defending against the claims.

Qsymia ANDA Litigation

On May 7, 2014, the Company received a Paragraph IV certification notice from Actavis Laboratories FL indicating that it filed an abbreviated new drug application, or ANDA, with the U.S. Food and Drug Administration, or FDA, requesting approval to market a generic version of Qsymia and contending that the patents listed for Qsymia in FDA Orange Book at the time the notice was received (U.S. Patents 7,056,890, 7,553,818, 7,659,256, 7,674,776, 8,580,298, and 8,580,299 (collectively "patents-in-suit")) are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale or offer for sale of a generic form of Qsymia as described in their ANDA. On June 12, 2014, the Company filed a lawsuit in the U.S. District Court for the District of New Jersey against Actavis Laboratories FL, Inc., Actavis, Inc., and Actavis PLC, collectively referred to as Actavis. The lawsuit (Case No. 14-3786 (SRC)(CLW)) was filed on the basis that Actavis' submission of their ANDA to obtain approval to manufacture, use, sell or offer for sale generic versions of Qsymia prior to the expiration of the patents-in-suit constitutes infringement of one or more claims of those patents.

In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Actavis, FDA approval of Actavis' ANDA will be stayed until the earlier of (i) up to 30 months from the Company's May 7, 2014 receipt of Actavis' Paragraph IV certification notice (i.e. November 7, 2016) or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed.

On January 21, 2015, the Company received a second Paragraph IV certification notice from Actavis contending that two additional patents listed in the Orange Book for Qsymia (U.S. Patents 8,895,057 and 8,895,058) are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale, or offer for sale of a generic form of Qsymia. On March 4, 2015, the Company filed a second lawsuit in the U.S. District Court for the District of New Jersey against Actavis (Case No. 15-1636 (SRC)(CLW)) in response to the second Paragraph IV certification notice on the basis that Actavis' submission of their ANDA constitutes infringement of one or more claims of the patents-in-suit.

On July 7, 2015, the Company received a third Paragraph IV certification notice from Actavis contending that two additional patents listed in the Orange Book for Qsymia (U.S. Patents 9,011,905 and 9,011,906) are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale, or offer for sale of a generic form of Qsymia. On August 17, 2015, the Company filed a third lawsuit in the U.S. District Court for the District of New Jersey against Actavis (Case No. 15-6256 (SRC) (CLW)) in response to the third Paragraph IV certification notice on the basis that Actavis' submission of their ANDA constitutes infringement of one or more claims of the patents-in-suit. The three lawsuits against Actavis have been consolidated into a single suit (Case No. 14-3786 (SRC)(CLW)). On July 20, 2016, the U.S. District Court for the District of New Jersey issued a claim construction (Markman) ruling governing the suit. The Court adopted the Company's proposed constructions for all but one of the disputed claim terms and adopted a compromise construction that was acceptable to the Company for the final claim term.

On March 5, 2015, the Company received a Paragraph IV certification notice from Teva Pharmaceuticals USA, Inc. indicating that it filed an ANDA with FDA, requesting approval to market a generic version of Qsymia and contending that eight patents listed for Qsymia in the Orange Book at the time of the notice (U.S. Patents 7,056,890, 7,553,818, 7,659,256, 7,674,776, 8,580,298, 8,580,299, 8,895,057 and 8,895,058) (collectively "patents-in-suit") are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of a generic form of Qsymia as described in their ANDA. On April 15, 2015, the Company filed a lawsuit in the U.S. District Court for the District of New Jersey against Teva Pharmaceutical USA, Inc. and Teva Pharmaceutical Industries, Ltd., collectively referred to as Teva. The lawsuit (Case No. 15-2693 (SRC)(CLW)) was filed on the basis that Teva's submission of their ANDA to obtain approval to manufacture, use, sell, or offer for sale generic versions of Qsymia prior to the expiration of the patents-in-suit constitutes infringement of one or more claims of those patents.

In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Teva, FDA approval of Teva's ANDA will be stayed until the earlier of (i) up to 30 months from our March 5, 2015 receipt of Teva's Paragraph IV certification notice (i.e. September 5, 2017) or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed.

On August 5, 2015, the Company received a second Paragraph IV certification notice from Teva contending that two additional patents listed in the Orange Book for Qsymia (U.S. Patents 9,011,905 and 9,011,906) are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale, or offer for sale of a generic form of Qsymia. On September 18, 2015, the Company filed a second lawsuit in the U.S. District Court for the District of New Jersey against Teva (Case No. 15-6957(SRC) (CLW)) in response to the second Paragraph IV certification notice on the basis that Teva's submission of their ANDA constitutes infringement of one or more claims of the patents-in-suit. The two lawsuits against Teva have been consolidated into a single suit (Case No. 15-2693 (SRC)(CLW)).

On July 20, 2016, the U.S. District Court for the District of New Jersey issued a claim construction (Markman) ruling governing the suit. The Court adopted the Company's proposed constructions for all but one of the disputed claim terms and adopted a compromise construction that was acceptable to the Company for the final claim term. On September 27, 2016, Dr. Reddy's Laboratories, S.A. and Dr. Reddy's Laboratories, Inc., collectively referred to as DRL, were substituted for Teva as defendants in the lawsuit as a result of Teva's transfer to DRL of ownership and all rights in the ANDA that is the subject of the lawsuit.

The schedule for both suits has now been consolidated for expert discovery and trial. Expert discovery is scheduled to close on April 21, 2017. A final pretrial conference is scheduled for May 31, 2017 and a second pretrial conference, if necessary, is scheduled for June 28, 2017. No trial date has been scheduled.

The Company intends to vigorously enforce its intellectual property rights relating to Qsymia, but the Company cannot predict the outcome of these matters.

STENDRA ANDA Litigation

On June 20, 2016, the Company received a Paragraph IV certification notice from Hetero USA, Inc. and Hetero Labs Limited, collectively referred to as Hetero, indicating that it filed an ANDA with FDA, requesting approval to market a generic version of STENDRA and contending that patents listed for STENDRA in the Orange Book at the time of the notice (U.S. Patents 6,656,935, and 7,501,409) (collectively "patents-in-suit") are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of a generic form of STENDRA as described in their ANDA. On July 27, 2016, the Company filed a lawsuit in the U.S. District Court for the District of New Jersey against Hetero (Case No. 16-4560 (KSH)(CLW)). On January 3, 2017, we entered into a settlement agreement with Hetero. Under the settlement agreement, Hetero was granted a license to manufacture and commercialize the generic version of STENDRA described in its ANDA filing in the United States as of the date that is the later of (a) October 29, 2024, which is 180 days prior to the expiration of the last to expire of the patents-in-suit, or (b) the date that Hetero obtains final approval from FDA of the Hetero ANDA. The Settlement Agreement provides for a full settlement of all claims that were asserted in the suit.

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 .

Note 21. Selected Financial Data (Unaudited)

Selected Quarterly Financial Data (in thousands except per share data):

	Quarter Ended,			
	March 31	June 30	September 30	December 31
2016				
Total revenue	$ 15,324	$ 13,776	$ 13,353	$ 81,805
Total gross profit	11,620	11,129	11,288	79,619
Operating expenses	19,855	17,435	14,201	17,082
Net (loss) income	(12,708)	(11,401)	(9,152)	56,563
Basic net (loss) income per share	(0.12)	(0.11)	(0.09)	0.54
Diluted net (loss) income per share	$ (0.12)	$ (0.11)	$ (0.09)	$ 0.54
2015				
Total revenue	$ 32,166	$ 22,985	$ 24,936	$ 15,343
Total gross profit	22,270	13,115	13,171	12,717
Operating expenses	38,990	64,192	32,965	19,560
Net loss	(15,466)	(49,352)	(16,106)	(12,183)
Basic and diluted net loss per share	$ (0.15)	$ (0.48)	$ (0.15)	$ (0.12)

Note 22. Subsequent Events

On January 6, 2017, the Company entered into a Patent Assignment Agreement with Selten Pharma, Inc., or Selten, whereby the Company received exclusive, worldwide rights for the development and commercialization of BMPR2 activators for the treatment of Pulmonary Arterial Hypertension, or PAH. As part of the agreement, Selten assigned to the Company its license to a group of patents owned by the Board of Trustees of the Leland Stanford Junior University, or Stanford, which cover uses of tacrolimus and ascomycin to treat PAH. The Company is responsible for future financial obligations to Stanford under that license.

The Company has assumed full responsibility for the development and commercialization of the licensed compounds for the treatment of PAH and related vascular diseases. Selten will receive an upfront payment of $1.0 million and milestone payments based on global development status and future sales milestones, as well as tiered royalty

payments on future sales of these compounds. The total potential milestone payments are $39.0 million to Selten and $550,000 to Stanford. The majority of the milestone payments to Selten may be paid, at the Company's sole option, either in cash or in the Company's common stock, provided that in no event shall the payment of common stock exceed fifty percent of the aggregate amount of such milestone payments.

FINANCIAL STATEMENT SCHEDULE

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

VIVUS, Inc.
SCHEDULE II—VALUATION AND QUALIFYING ACCOUNTS
(in thousands)

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

	Balance at Beginning of Period	Charged to Operations*	Charges Utilized	Balance at End of Period
Allowance for Cash Discounts				
Fiscal year ended December 31, 2014	$ 134	$ 1,712	$ (1,696)	$ 150
Fiscal year ended December 31, 2015	$ 150	$ 1,933	$ (1,919)	$ 164
Fiscal year ended December 31, 2016	$ 164	$ 1,679	$ (1,630)	$ 213

* Amount charged to operations during fiscal years ended December 31, 2016, 2015 and 2014, includes 1,474,000, $1,656,000 and $1,373,000, respectively, for cash discount allowances related to revenue recognized during each fiscal year. The remaining amounts were recorded on the consolidated balance sheets as deferred revenue at the end of each period, respectively.

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

None.

Item 9A. ***Controls and Procedure s***

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 the design and operation of our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

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

(1) Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

(2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorization of our management and directors; and

(3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisitions, use or disposition of our assets that could have a material effect on the financial statements.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk. Our management is responsible for establishing and maintaining adequate internal control over financial reporting for the company, as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act.

Our 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 (2013), known as COSO Framework, 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, 2016.

Attestation Report of the Registered Public Accounting Firm

OUM & Co. LLP, the independent registered public accounting firm that audited our Consolidated Financial Statements included elsewhere in this 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, 2016. This report, which expresses an unqualified opinion on the effectiveness of our internal controls over financial reporting as of December 31, 2016, is included herein.

Changes in Internal Controls Over Financial Reporting

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 Informatio n***

None.

PART III

Item 10. ***Directors, Executive Officer s and Corporate Governance***

The information required by this item is hereby incorporated by reference from the information under the captions "Election of Directors," "Corporate Governance—Board Committees," "Executive Officers" and "Section 16(a) Beneficial Ownership Reporting Compliance" 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 2017 Annual Meeting of Stockholders.

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

Item 11. ***Executive Compensatio n***

The information required by this item is incorporated by reference from the information under the caption "Corporate Governance—Compensation Committee Interlocks and Insider Participation," "Executive Compensation" and "Executive and Director Compensation Tables" in the Company's Proxy Statement referred to in Item 10 above.

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

Equity Compensation Plan Information

Information about our equity compensation plans at December 31, 2016, that were approved by our stockholders was as follows:

Plan Category	Number of Shares to be issued Upon Exercise of Outstanding Options and Rights	Weighted Average Exercise Price of Outstanding Options	Number of Shares Remaining Available for Future Issuance(c)
Equity compensation plans approved by stockholders(a)	10,109,900	$ 4.62	9,162,648
Equity compensation plans not approved by stockholders(b)	—	$ —	—
Total	10,109,900	$ 4.62	9,162,648

(a) Consists of three plans: our 2001 Stock Option Plan, our 2010 Equity Incentive Plan and our 1994 Employee Stock Purchase Plan.

(b) The Company currently has no instruments outstanding or available for issuance under non-approved equity compensation plans.

(c) Includes 8,895,532 shares for the 2010 Equity Incentive Plan and 267,116 shares for the 1994 Employee Stock Purchase Plan.

The remaining 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 Relationship s 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 "Corporate Governance—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 Schedule s***

(a) Documents filed as part of this report

1. Financial Statements

Reference is made to the financial statements included under Item 8 of Part II hereof.

2. Financial Statement Schedules

Reference is made to the financial statement schedules included under Item 8 of Part II hereof. 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 attached hereto and are incorporated herein by reference.

SIGNATURE S

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

VIVUS, INC.,
a Delaware Corporation

By: /s/ Seth H. Z. Fischer
Seth H. Z. Fischer
Chief Executive Officer
(Principal Executive Officer)

Date: March 8, 2017

POWER OF ATTORNE Y

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

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

Signature	Title	Date
/s/ Seth H. Z. Fischer Seth H. Z. Fischer	Chief Executive Officer (Principal Executive Officer) and Director	March 8, 2017
/s/ David Y. Norton David Y. Norton	Chairman of the Board of Directors and Director	March 8, 2017
/s/ Mark K. Oki Mark K. Oki	Chief Financial Officer and Chief Accounting Officer (Principal Financial and Accounting Officer)	March 8, 2017
/s/ Jorge Plutzky, M.D. Jorge Plutzky, M.D.	Director	March 8, 2017
/s/ Eric W. Roberts Eric W. Roberts	Director	March 8, 2017
/s/ Herman Rosenman Herman Rosenman	Director	March 8, 2017
/s/ Allan L. Shaw Allan L. Shaw	Director	March 8, 2017

VIVUS, INC.
REPORT ON FORM 10-K FOR
THE YEAR ENDED DECEMBER 31, 2016
EXHIBIT INDE X

Exhibit Number	Description
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)	Amendment No. 5 to the Amended and Restated Bylaws of the Registrant
3.8(10)	Amended and Restated Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock of the Registrant
4.1(11)	Specimen Common Stock Certificate of the Registrant
4.2(12)	Amended and Restated Preferred Stock Rights Agreement, dated as of November 9, 2016, by and between the Registrant and Computershare Trust Company, N.A.
4.3(13)	Indenture dated as of May 21, 2013, by and between the Registrant and Deutsche Bank Trust Company Americas, as trustee
4.4(14)	Form of 4.50% Convertible Senior Note due May 1, 2020
10.1(15)*	Form of Indemnification Agreement by and among the Registrant and the Officers of the Registrant
10.2(16)*	Form of Indemnification Agreement by and among the Registrant and the Directors of the Registrant
10.3(17)*	1994 Employee Stock Purchase Plan, as amended, Form of Subscription Agreement and Form of Notice of Withdrawal
10.4(18)*	2001 Stock Option Plan and Form of Agreement thereunder
10.5(19)*	2001 Stock Option Plan, as amended on July 12, 2006
10.6(20)*	Form of Notice of Grant and Restricted Stock Unit Agreement under the VIVUS, Inc. 2001 Stock Option Plan
10.7(21)*	2010 Equity Incentive Plan and Form of Agreement thereunder
10.8(22)*	2010 Equity Incentive Plan, as amended on September 12, 2014
10.9(23)*	2010 Equity Incentive Plan (as amended and restated)
10.10(24)*	Stand-Alone Stock Option Agreement with Michael P. Miller dated as of April 30, 2010
10.11(25)†	Agreement effective as of December 28, 2000, between the Registrant and Tanabe Seiyaku Co., Ltd.
10.12(26)	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.
10.13(27)	Termination and Release executed by Tanabe Holding America, Inc. dated May 1, 2007
10.14(28)†	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.)
10.15(29)†	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.)
10.16(30)†	Settlement and Modification Agreement dated July 12, 2001, between ASIVI, LLC, AndroSolutions, Inc., Gary W. Neal and the Registrant
10.17(31)†	Assignment Agreement between Thomas Najarian, M.D. and the Registrant dated October 16, 2001
10.18(32)†	Master Services Agreement dated as of September 12, 2007, between the Registrant and Medpace, Inc.

Exhibit Number	Description
10.19(33)†	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
10.20(34)†	Commercial Manufacturing and Packaging Agreement by and between the Registrant and Catalent Pharma Solutions, LLC dated as of July 17, 2012
10.21(35)	Lease Agreement effective November 1, 2006, by and between the Registrant and Castro Mountain View, LLC, Thomas A. Lynch, Trudy Molina Flores, Trustee of the Jolen Flores and Trudy Molina Flores Joint Living Trust dated April 3, 2001, E William and Charlotte Duerkson, The Duerkson Family Trust dated February 16, 1999, The Dutton Family Trust dated September 16, 1993, The Noel S. Schuurman Trust, The Duarte Family Partners, L.P., The Marie Antoinette Clough Revocable Living Trust dated January 11, 1989, Blue Oak Properties, Inc., and CP6CC, LLC
10.22(36)	First Amendment to Lease dated November 18, 2008, between Castro Mountain View, LLC, CP6CC, LLC and the Registrant
10.23(37)	Second Amendment to Lease effective November 12, 2009, between Castro Mountain View, LLC, CP6CC, LLC and the Registrant
10.24(38)	Third Amendment to Lease effective December 3, 2010, between Castro Mountain View, LLC, CP6CC, LLC and the Registrant
10.25(39)	Fourth Amendment to Lease effective February 14, 2012, between Castro Mountain View, LLC, CP6CC, LLC and the Registrant
10.26(40)	Lease Agreement effective December 11, 2012, by and between the Registrant and SFERS Real Estate Corp. U.
10.27(41)†	Purchase and Sale Agreement effective as of March 25, 2013, between the Registrant and BioPharma Secured Investments III Holdings Cayman LP
10.28(42)	Capped Call Confirmation dated May 15, 2013, by and between the Registrant and Deutsche Bank AG, London Branch
10.29(43)*	Form of Amended and Restated Change of Control and Severance Agreement
10.30(44)†	License and Commercialization Agreement dated July 5, 2013, between the Registrant and Berlin-Chemie AG
10.31(45)†	Commercial Supply Agreement dated as of July 5, 2013, between the Registrant and Berlin-Chemie AG
10.32(46)	Agreement dated July 18, 2013, by and between the Registrant and First Manhattan Co.
10.33(47)*	Letter Agreement dated July 18, 2013, by and among the Registrant, First Manhattan Co. and Peter Y. Tam
10.34(48)	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
10.35(49)†	Commercial Supply Agreement dated July 31, 2013, by and between the Registrant and Sanofi Chimie
10.36(50)*	Employment Agreement dated September 3, 2013, by and between the Registrant and Seth H. Z. Fischer
10.37(51)†	License and Commercialization Agreement dated as of October 10, 2013, by and between the Registrant and Auxilium Pharmaceuticals, Inc.
10.38(52)†	Commercial Supply Agreement dated as of October 10, 2013, by and between the Registrant and Auxilium Pharmaceuticals, Inc.
10.39(53)*	Letter Agreement dated November 4, 2013, by and between the Registrant and Timothy E. Morris
10.40(54)†	Manufacturing and Supply Agreement dated November 18, 2013, by and between the Registrant and Sanofi Winthrop Industrie
10.41(55)†	License and Commercialization Agreement dated December 11, 2013, by and between the Registrant and Sanofi
10.42(56)†	Supply Agreement effective as of December 11, 2013, by and between the Registrant and Sanofi Winthrop Industrie
10.43(57)†	Patent Assignment Agreement, dated August 24, 2014, by and between the Registrant and Janssen Pharmaceuticals, Inc.

Exhibit Number	Description
10.44(58)*	Letter Agreement dated April 13, 2015, by and between the Registrant and Guy P. Marsh
10.45(59)*	Form of Second Amended and Restated Change of Control and Severance Agreement
10.46(60)*	Letter Agreement dated July 20, 2015, by and between the Registrant and Wesley W. Day, Ph.D.
10.47(61)*	Letter Agreement dated August 17, 2015, by and between the Registrant and Svai S. Sanford
10.48(62)	Letter Regarding Termination Notice dated December 30, 2015, from Auxilium Pharmaceuticals, Inc. and Endo Ventures Limited to the Registrant
10.49(63)	Letter Regarding Termination Notice dated as of June 30, 2016, from Auxilium Pharmaceuticals, Inc. and Endo Ventures Limited to the Registrant
10.50(64)	Letter Regarding Termination Notice dated as of August 29, 2016, from Auxilium Pharmaceuticals, LLC and Endo Ventures Limited to the Registrant
10.51(65)	First Amendment to Lease effective August 30, 2016, between the Registrant and MV Campus Owner, LLC, the successor in interest to SFERS Real Estate Corp. U.
10.52(66)	Office Lease effective September 2, 2016, between the Registrant and AG-SW Hamilton Plaza Owner, L.P.
10.53(67)††	License and Commercialization Agreement dated as of September 30, 2016, by and between the Registrant and Metuchen Pharmaceuticals LLC
10.54(68)††	Commercial Supply Agreement dated as of September 30, 2016, by and between the Registrant and Metuchen Pharmaceuticals LLC
10.55††	Patent Assignment Agreement dated as of January 6, 2017, by and between the Registrant and Selten Pharma, Inc.
10.56††	License Assignment Agreement dated as of January 6, 2017, by and between the Registrant and Selten Pharma, Inc.
21.1	List of Subsidiaries
23.1	Consent of 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 Annual Report on Form 10-K for the year ended December 31, 2016, 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 SEC 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 SEC 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 SEC 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 SEC 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 SEC 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 SEC 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 SEC 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 SEC 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 SEC on July 24, 2013.

(9) Incorporated by reference to Exhibit 3.1 filed with the Registrant's Current Report on Form 8-K filed with the SEC on September 18, 2015.

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

(11) 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 SEC on April 16, 1997.

(12) Incorporated by reference to Exhibit 4.1 filed with the Registrant's Current Report on Form 8-K filed with the SEC on November 9, 2016.

(13) Incorporated by reference to Exhibit 4.1 filed with the Registrant's Current Report on Form 8-K filed with the SEC on May 21, 2013.

(14) Incorporated by reference to Exhibit 4.2 filed with the Registrant's Current Report on Form 8-K filed with the SEC on May 21, 2013.

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

(16) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the SEC on August 12, 2014.

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

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

(19) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the SEC on July 13, 2006.

(20) Incorporated by reference to Exhibit 10.2 filed with the Registrant's Current Report on Form 8-K filed with the SEC on July 13, 2006.

(21) 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 SEC on March 1, 2011.

(22) Incorporated by reference to Exhibit 4.1 filed with the Registrant's Registration Statement on Form S-8 filed with the SEC on November 5, 2014.

(23) Incorporated by reference to Exhibit 4.1 filed with the Registrant's Registration Statement on Form S-8 filed with the SEC on December 14, 2016.

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

(25) 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 SEC on February 26, 2013.

(26) 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 SEC on May 7, 2004.

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

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

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

(30) 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 SEC on February 26, 2013.

(31) 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 SEC on March 10, 2010.

(32) 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 SEC on May 8, 2013.

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

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

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

(36) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the SEC on December 18, 2008.

(37) 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 SEC on March 10, 2010.

(38) 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 SEC on March 1, 2011.

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

(40) 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 SEC on February 26, 2013.

(41) 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 SEC on May 8, 2013.

(42) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the SEC on May 16, 2013.

(43) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the SEC on July 5, 2013.

(44) 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 SEC on August 8, 2013.

(45) 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 SEC on August 8, 2013.

(46) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the SEC on July 19, 2013.

(47) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the SEC on July 24, 2013.

(48) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the SEC on July 29, 2013.

(49) 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 SEC 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 SEC on September 4, 2013.

(51) 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 SEC on November 7, 2013.

(52) 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 SEC on November 7, 2013.

(53) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the SEC on November 5, 2013.

(54) Incorporated by reference to Exhibit 10.45 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2013, filed with the SEC on February 28, 2014.

(55) Incorporated by reference to Exhibit 10.46 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2013, filed with the SEC on February 28, 2014.

(56) Incorporated by reference to Exhibit 10.47 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2013, filed with the SEC on February 28, 2014.

(57) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2014, filed with the SEC on November 5, 2014.

(58) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2015, filed with the SEC on August 3, 2015.

(59) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the SEC on June 24, 2015.

(60) 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, 2015, filed with the SEC on August 3, 2015.

(61) Incorporated by reference to Exhibit 10.3 filed with the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2015, filed with the SEC on November 4, 2015.

(62) Incorporated by reference to Exhibit 10.53 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2015, filed with the SEC on March 9, 2016.

(63) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2016, filed with the SEC on August 4, 2016.

(64) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2016, filed with the SEC on November 9, 2016.

(65) Incorporated by reference to Exhibit 10.2 filed with the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2016, filed with the SEC on November 9, 2016.

(66) Incorporated by reference to Exhibit 10.3 filed with the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2016, filed with the SEC on November 9, 2016.

(67) Incorporated by reference to Exhibit 10.4 filed with the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2016, filed with the SEC on November 9, 2016.

(68) Incorporated by reference to Exhibit 10.5 filed with the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2016, filed with the SEC on November 9, 2016.

Exhibit 10.55

CONFIDENTIAL

*****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.**

PATENT ASSIGNMENT AGREEMENT

This Patent Assignment Agreement is entered into as of the Effective Date (as defined below), by and between Selten Pharma, Inc., a Cayman Islands company, having a principal place of business at 751 Laurel St, #520, San Carlos, CA 94070, (" SELTEN ") and VIVUS, Inc., a Delaware company having a principal place of business at 900 E. Hamilton Ave., Suite 550, Campbell, California 95008 (" VIVUS ").

BACKGROUND

WHEREAS:

SELTEN and its Affiliates own the Patent Rights as defined below, which include one or more claims relating to certain drug products containing Tacrolimus and Ascomycin (as defined below); and

VIVUS desires to obtain and SELTEN desires to assign to VIVUS the Patent Rights on the financial terms and other conditions set forth below.

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

Article 1
Definitions

The terms in this Agreement with initial letters capitalized, whether used in the singular or the plural, will have the meaning set forth below or, if not listed below, the meaning designated where first used in this Agreement, and correlative capitalized terms will have corresponding meanings.

1.1. " Affiliate " means, with respect to a specified Party, any corporation or other entity that directly or indirectly controls, is controlled by, or is under common control with such Party. For the purposes of this definition, the term "control" (including, with correlative meanings, the terms "controlled by" and "under common control with") means possession of at least fifty percent (50%) of the voting stock or other ownership interest of the entity, or the power to direct or cause the direction of the management and policies of the entity, or the power to elect or appoint at least fifty percent (50%) of the members of the governing body of the entity through the ownership of the outstanding voting securities or by contract or otherwise.

1.2. " Agreement " means this Patent Assignment Agreement, including its Attachments, as the

same may be amended from time to time.

1.3. " Ascomycin " means the compound having the systematic (IUPAC) name (3 *S* ,4 *R* ,5 *S* ,8 *R* ,9 *Z* ,12 *S* ,14 *S* ,15 *R* ,16 *S* ,18 *R* ,19 *R* ,26a *S*)-8-ethyl-5,19-dihydroxy-3-{(*E*)-2-[(1 *R* ,3 *R* ,4 *R*)-4-hydroxy-3- methoxycyclohexyl]-1-methylvinyl}-14,16-dimethoxy-4,10,12,18-tetramethyl-4,5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26a-heptadecahydro-3 *H* -15,19-epoxypyrido[2,1- *c*][1,4] oxazacyclotriclosine-1,7,20,21(23 *H*)-tetrone and may also be referred to as FK520 or SPI-054.

1.4. " Bankruptcy " means, with respect to a Party, that: (a) the Party has been declared insolvent or bankrupt by a court of competent jurisdiction and such declaration is not appealable or is not appealed; or (b) a voluntary or involuntary petition in bankruptcy has been filed in any court of competent jurisdiction against the Party and such petition has not dismissed within *** days after filing; or (c) the Party has made or executed an assignment of substantially all of its assets for the benefit of creditors.

1.5. " Business Day " means any day other than a Saturday, Sunday, or a day that is a national or bank holiday in the United States.

1.6. **"** Commercialization **"** means any and all activities directed to the manufacture, distribution, marketing, detailing, promotion, selling and, outside of the United States, securing of reimbursement of Product. When used as a verb, "Commercialize" shall mean to engage in Commercialization.

1.7. " Commercially Reasonable Efforts " means those commercially reasonable efforts and resources consistent with the usual practices of a company similar in size and resources to VIVUS in pursuing the development, manufacturing or Commercialization of a biologic or pharmaceutical product or therapy owned or licensed by it, with similar product characteristics, which is at a similar stage of research, development or Commercialization, taking into account efficacy, safety, proprietary position of the product or therapy, including patent and regulatory exclusivity, regulatory structure involved including anticipated or approved labeling and anticipated or approved post-approval requirements, present and future market and commercial potential including competitive market conditions and probability of the profitability of the product or therapy in light of pricing and reimbursement issues, and all other relevant factors including technical, legal, scientific and/or medical factors and the unique nature of Product to be developed, manufactured or Commercialized under this Agreement.

1.8. " Competing Product " means a product with application in the Field (as defined below) or a product comprising the Licensed Compound.

1.9. " Confidential Information " has the meaning ascribed to such term in Section 5.2.

1.10. " Diligent Efforts " means, with respect to a Party in reference to commercialization, expending commercially reasonable efforts that are consistent with the efforts typically expended in the pharmaceutical industry, by companies similarly capitalized and situated as the Party, considering relevant factors, for example, technical challenges, market potential, regulatory

requirements, patient population, profitability and competitive position, as may be applicable.

1.11. " Dollars " means the legal currency of the United States.

1.12. " Effective Date " means the date of execution by the last Party to sign below.

1.13. " Exchange Rates " means the exchange rates the Parties agree to use to convert royalty payments in local currency into US dollars. Exchange rates will be set quarterly based on the close price exchange rates published in the *Wall Street Journal* on the last Business Day of each calendar quarter. The reset exchange rates shall apply to all royalty payment based on Net Sales recognized in the same calendar quarter. The exchange rates shall apply to all royalty payments related to the Net Sales recognized during the period for which fixed exchange rate applies independent of the actual invoice date.

1.14. " FDA " means the United States Food and Drug Administration or any successor agency in the United States with responsibilities comparable to those of the United States Food and Drug Administration.

1.15. " Field " means the treatment, diagnosis, and/or prevention of pulmonary arterial hypertension (" PAH ") and related vascular diseases.

1.16. " First Commercial Sale " means the first sale in an arm's-length transaction of a VIVUS Product to a Third Party by VIVUS (or any of its Affiliates, assignees or licensees) in a country, following receipt of any necessary Regulatory Approval of the VIVUS Product to permit its marketing in such country.

1.17. " Indication " means any disease or condition listed under the header "INDICATIONS AND USAGE" of a Product's approved label upon marketing approval for the Product by a Regulatory Authority.

1.18. " Licensed Compound " means each of the compounds Tacrolimus and Ascomycin, (each, a " Licensed Compound " and collectively, the " Licensed Compounds ").

1.19. " Net Sales " for purposes of this Agreement means the amount invoiced or otherwise billed by VIVUS or its Affiliates or sublicensees (" Selling Party ") for sales of a VIVUS Product to a Third Party purchaser, less the following (collectively, " Net Sales Deductions "):

(a) discounts actually given on a VIVUS Product, including cash, trade and quantity discounts, price reduction or incentive programs (including sales coupons and co-payment programs), retroactive price adjustments with respect to sales of such VIVUS Product, and charge-back payments;

(b) credits, refunds, returns or allowances actually allowed, paid, received or given, including credits, allowances, discounts and rebates to, and chargebacks from the account of customers for nonconforming, damaged, rejected, outdated and returned, withdrawn or

recalled VIVUS Product or on account of retroactive price reductions affecting such VIVUS Product;

(c) rebates, reimbursements, administrative fees or similar allowances actually granted to managed health care organizations or to federal, state and local governments in the VIVUS Territory or any other organization that utilizes any governmental discount program with respect to a VIVUS Product;

(d) inventory management agreement (IMA) fees, wholesaler fees, and specialty pharmacy charges, in each case, to the extent specifically attributable to the applicable VIVUS Product;

(e) freight, postage, shipping and insurance charges actually allowed or paid for delivery of a VIVUS Product, to the extent billed as a separate line item by the Selling Party to the Third Party purchaser;

(f) taxes, duties or other governmental charges imposed on the sale of a VIVUS Product and actually paid by the Selling Party (as adjusted for rebates and refunds, but specifically excluding taxes based on net income of the Selling Party), to the extent billed as a separate line item by the Selling Party to the Third Party purchaser;

provided that all of the foregoing deductions shall be calculated in accordance with then-current generally accepted accounting principles in the Unites States, consistently applied during the applicable calculation period throughout the Selling Party's organization (" GAAP "). To the extent that Net Sales Deductions are based on estimates, such estimates will be adjusted to actual on a periodic basis.

A sale of a VIVUS Product is deemed to occur in accordance with GAAP.

For sake of clarity and avoidance of doubt, the transfer of a VIVUS Product by a Selling Party or one of its Affiliates to another Affiliate of such Selling Party or to a sublicensee of such Selling Party for resale shall not be considered a sale; in such cases, Net Sales shall be determined based on the amount invoiced or otherwise billed by such Affiliate or sublicensee to an independent Third Party, less the Net Sales Deductions allowed under this Section.

1.20. " NDA " means a New Drug Application, as defined in the United States Federal Food, Drug and Cosmetic Act.

1.21. " Net Sales Deductions " has the meaning set forth in the definition of "Net Sales" in this Article 1.

1.22. " Party " means SELTEN or VIVUS, as referred to individually. " Parties " means SELTEN and VIVUS, as referred to collectively.

1.23. " Patent Office " means the United States Patent and Trademark Office, European Patent

Office, or other government agency or office responsible for the examination of patent applications or granting of patents in a country, region, or supra-national territory.

1.24. " Patent Rights " means those patents and patent applications owned by SELTEN or its Affiliates set forth in Attachment 1 , including, without limitation, any and all: (a) continuations, continuations-in-part, requests for continued examination, divisions, renewals, substitute applications, and all patents granted thereon, and (b) reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms; and (c) any foreign counterparts of the foregoing.

1.25. " Prosecute " means, in reference to any Patent Rights, to prosecute, maintain, defend, and take any other action with respect to the Patent Rights in any Patent Office.

1.26. " Product " means pharmaceutical compositions containing a Licensed Compound, in the form, formulation, and dosage strength(s) as defined in the NDA approved by the FDA or in the approval of any other Regulatory Authority and any other improvements, line extensions, delivery mechanisms, dosage strengths, formulations, or forms as may be approved in the future by the FDA or other Regulatory Authority, in each case, that contain a Licensed Compound alone or in combination with one or more other active ingredients.

1.27. " Regulatory Approval " means receipt of all official approvals from the applicable Regulatory Authority or other government, pricing, and/or health authorities in a jurisdiction (country or supra-national organization), such as the FDA or EMA, required for the use or sale of a VIVUS Product for a particular Indication in such jurisdiction, including any approvals for importation, manufacture, pricing, and/or reimbursement where necessary. For the avoidance of doubt, a notice of approvability or an approvable letter from such a Regulatory Authority shall not be deemed an approval .

1.28. " Regulatory Drug Application " means a new drug application or product license application or its equivalent filed with and accepted by the FDA after completion of human clinical trials to obtain marketing approval for a Product, or any comparable application filed with and accepted by the Regulatory Authority of a country or jurisdiction other than the United States.

1.29. " Regulatory Authority " means any applicable supranational, European Union, federal, national, regional, state or local regulatory agency, department, bureau, commission, council or other government entity with authority over the development, manufacture, use, marketing and/or sale (including approval of NDAs and other Regulatory Applications) of a pharmaceutical Product in any regulatory jurisdiction throughout the world, including without limitation, the FDA in the United States.

1.30. " SELTEN Know-How " means all Information that is Controlled as of the Effective Date or during the Term by SELTEN or its Affiliates that relates to any Product in the Field or the research, development, manufacture, use or sale of a Product in the Field in the VIVUS Territory, including but not limited to any notes, records, data, reports, formulations, study

designs, and protocols, in each case related to a Licensed Compound.

1.31. " Stanford Agreement " shall mean the Exclusive Agreement between The Board of Trustees of the Leland Stanford Junior University and Selten Pharma, Inc. having effective date October 25, 2015 as amended from time to time.

1.32. " Term " has the meaning ascribed to such term in Section 8.1.

1.33. " Third Party " means any Person other than a Party or any of its Affiliates.

1.34. " Tacrolimus " means the compound having the systematic (IUPAC) name [3S- [3R* [E(1S*,3S*,4S*)],4S*,5R*,8S*,9E,12R*,14R*,15S*,16R*,18S*,19S*,26aR*]]-5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26a-hexadecahydro-5,19-dihydroxy- 3-[2-(4-hydroxy-3-methoxycyclohexyl)-1-methylethenyl]-14,16-dimethoxy-4,10, 12,18-tetramethyl-8-(2-propenyl)-15,19-epoxy-3H-pyrido[2,1-c][1,4] oxaazacyclotricosine-1,7,20,21(4H,23H)-tetrone, monohydrate and also may be referred to as FK506 or SPI-026.

1.35. " VIVUS Product " means a Product sold by or on behalf of VIVUS.

1.36. " VIVUS Territory " means worldwide.

Article 2
Assignment of Patents and License to Know-How

2.1. **Assignment of Patent Rights.** As of the Effective Date and subject to the terms and conditions of this Agreement, SELTEN shall and hereby does agree to transfer and assign, and shall cause its applicable Affiliates to transfer and assign, to VIVUS all of SELTEN's and its Affiliates' rights, title and interest in and to the Patent Rights, including (i) the right to exclusively or non-exclusively license, sublicense, claim priority to, prosecute, assign and/or otherwise exploit the Patent Rights, without accounting to SELTEN and without payment of consideration to SELTEN other than as set forth herein; and (ii) all causes of action and enforcement rights for the Patent Rights, including all rights to pursue damages, injunctive relief and other remedies for past and future infringement of the Patents Rights .

2.2. **Assignment of Orphan-Drug Designation** . As of the Effective Date and subject to the terms and conditions of this Agreement, SELTEN shall and hereby does agree to transfer and assign, and shall cause its applicable Affiliates to transfer and assign, to VIVUS all of SELTEN's and its Affiliates' rights, title and interest in and to any orphan-drug designation it holds in any Licensed Compound , including but not limited to the orphan drug designation for tacrolimus designated on March 16, 2015.

2.3. **Confirmatory Documentation.** Promptly after the Effective Date, SELTEN shall execute, and cause its applicable Affiliates to execute, a confirmatory assignment of the Patent Rights substantially in the form attached as Attachment 2 hereto for VIVUS's recordation with Patent Offices and agrees to execute all other documents reasonably requested by VIVUS and

reasonably necessary to evidence with any Patent Office the transfer of said Patent Rights to VIVUS . VIVUS shall be solely responsible at its own expense for notifying any Patent Offices or other appropriate government agencies of the transfer of ownership of the Patent Rights, and for formally recording documentation of the assignment of the Patent Rights in any Patent Offices, and VIVUS assumes all risk associated with any failure to timely do so with respect to any Patent Rights. Without limiting the foregoing, SELTEN agrees to use Diligent Efforts to assist VIVUS, at VIVUS's expense, to secure VIVUS's rights in the Patent Rights in any and all countries where they are now issued or pending, including the execution of all assignments and all other instruments which VIVUS considers reasonably necessary or appropriate in order to perfect the assignment and conveyance to VIVUS, its successors and assigns of the sole and exclusive right, title and interest in and to such Patent Rights. SELTEN also agrees to use Diligent Efforts to transfer to VIVUS any ownership or beneficial interest it holds in any orphan-drug designation for Tacrolimus, including but not limited to submitting any information or statement required by 21 CFR §316.27.

2.4. **License to SELTEN Know How.** As of the Effective Date and subject to the terms and conditions of this Agreement, SELTEN hereby grants to VIVUS an exclusive (even as to SELTEN) license under the SELTEN Know-How (i) to use, distribute, import, promote, market, sell, offer for sale, and otherwise commercialize Products in the Field in the VIVUS Territory; (ii) to conduct development activities in support of Regulatory Approval of a Product in the VIVUS Territory; and (iii) to otherwise exploit the Patent Rights.

2.5. **No Implied Licenses.** Except as expressly granted herein, no license or any other right is granted by a Party under any of its patents or any other intellectual property rights to the other Party.

2.6. **Exclusivity.**

(a) SELTEN hereby covenants that neither it nor its Affiliates will, directly or indirectly (including via a license with a Third Party), begin a phase II study on a Competing Product earlier than *** years from the Effective Date.

(b) The Parties acknowledge that a failure to comply with the provisions of this Section 2.6 shall constitute a material breach of this Agreement.

2.7 **Right of First Refusal** . During the term of this Agreement, VIVUS will have a right of first refusal (the "ROFR") with respect to any license, sale, assignment, transfer or other disposition by SELTEN of any material portion of intellectual property related to any Competing Product(s) conceived or developed by SELTEN either alone or in collaboration with a Third Party. SELTEN will first provide VIVUS with written notice of such Competing Product in sufficient detail to allow VIVUS to evaluate the Competing Product. VIVUS shall have *** days from receipt of such notice to provide SELTEN written notice of VIVUS's intent to pursue a license and if so, the parties shall negotiate, in good faith, a mutually agreeable license for the Competing Product. If the Parties, acting in good faith, are unable to negotiate a license to the Competing Product within *** days from SELTEN's receipt of VIVUS's written notice (the

"Negotiation Period"), SELTEN agrees that it will not license the Competing Product to a Third Party on terms more favorable than those last offered to VIVUS for *** from the end of the Negotiation Period, and without first offering the more favorable terms to VIVUS and allowing VIVUS to consider such terms for *** days.

Article 3
Financials and Reporting

3.1. **Upfront Payment.** VIVUS shall pay to SELTEN a one-time, non-refundable, non-creditable, upfront payment of *** Dollars ($ ***), which amount will be due upon execution of this Agreement and payable within *** days thereafter.

3.2. **Early Termination for Formulation Failure.** In the event VIVUS has been unable to develop a formulation for Tacrolimus that is suitable for phase II studies, as determined by VIVUS and at VIVUS's sole discretion, by *** , *** , VIVUS will terminate this Agreement subject to Sections 8.2 and 8.3.

3.3. **Milestone Payments.** VIVUS shall make each of the one-time milestone payments indicated below to SELTEN upon the achievement by VIVUS of the corresponding milestone event:

SELTEN Regulatory/Development Milestone Event*	***Payment***
***	$ *** **
***	$ *** **
***	$ ***
***	$ *** **
SELTEN Sales Milestone Event	
***	$ *** **
***	$ *** **
***	$ *** **

* These milestone payments by VIVUS to SELTEN will be applicable to either Licensed Compound; provided that such milestone payments shall not exceed *** dollars ($ ***) in the aggregate.

** These milestone payments by VIVUS to SELTEN are payable, at VIVUS's sole option, in all cash or a combination of cash and freely tradeable common stock of VIVUS (the " Payment Option "); provided that in no event shall the payment of common stock exceed *** percent (*** %) of the aggregate amount of such milestone payments. For the sake of clarity, VIVUS may exercise the Payment Option for each of the milestone payments.

Each milestone payment in this Section 3.3 shall be paid only once. The maximum total amount of payment to SELTEN pursuant to this Section 3.3 shall be *** dollars ($ ***). VIVUS shall notify and pay to SELTEN the applicable milestone payment together with the delivery of the quarterly report pursuant to Section 3.6 for the calendar quarter in which the applicable milestone event was achieved. For clarity, in the event that more than one (1) of the *** thresholds is achieved in a calendar year, VIVUS shall owe each of the corresponding payments. Each milestone payment hereunder shall be made by wire transfer of immediately available funds into an account designated in writing by SELTEN. Each such milestone payment is non-refundable and non-creditable against any other payments due hereunder. VIVUS shall use Diligent Efforts to deliver to SELTEN a courtesy copy of the same report that VIVUS provides to STANFORD under Clause 8.1 of the Stanford Agreement.

3.4. **Royalty Payments to SELTEN**

3.4.1. VIVUS shall pay to SELTEN, on a quarterly basis beginning with the *** ending after the Execution Date, royalties calculated as a percentage of Net Sales of a VIVUS Product in the Field in the VIVUS Territory as follows (" Royalty Payments "):

Aggregate Net Sales of a Product in a calendar year in the Field in the VIVUS Territory	***Royalty Rate***
***	*** %
***	*** %
***	*** %

3.4.2. Such royalties shall be payable, on a country-by-country and Product-by-Product basis, beginning on the First Commercial Sale of a VIVUS Product in a particular country and ending on the later of (i) *** years after the First-Commercial Sale in such country, or (ii) the date of expiration of the last-to-expire Patent Right having an issued claim covering the VIVUS Product in such country.

3.4.3. VIVUS shall have the option to terminate VIVUS's milestone and royalty payment obligations under Sections 3.3 and 3.4, and to fully pay up the remaining consideration for the assignment of the Patent Rights hereunder, upon making a lump-sum payment to SELTEN in an amount equal to: (i) *** Dollars ($ ***) if paid on or before the *** day anniversary of Regulatory Approval in the U.S. or (ii) *** Dollars ($ ***) if paid on or before the *** month anniversary of the first commercial sale of a VIVUS Product to a Third Party (the " Buyout Amount ").

3.4.4. During the Term, from the Effective Date until such time as VIVUS pays the Buyout Amount to SELTEN, VIVUS shall use Commercially Reasonable Efforts to commercialize each VIVUS Product in each country where VIVUS receives Regulatory Approval for such VIVUS Product. Upon payment of the Buyout Amount, VIVUS's milestone and royalty payment obligations shall terminate.

3.4.5. In the event of an uncured material breach of Section 2.6 VIVUS shall owe no royalties or milestones to SELTEN for any VIVUS Product sold during a calendar quarter in which a Competing Product is sold by SELTEN or its Affiliates in the VIVUS Territory.

3.5. **Royalty Reduction.** In the event the manufacture or Commercialization of a VIVUS Product, disclosed and claimed in Patent Rights set forth in Attachment 1 or included in the Licensed Patent as defined in the Stanford Agreement, in the VIVUS Territory would necessarily infringe the issued patents of any Third Party absent a license thereunder and VIVUS must obtain a royalty-bearing license under such patents, then VIVUS may deduct such Third Party royalty payments from the Royalty Payments due to SELTEN pursuant to Section 3.4 with respect to a particular VIVUS Product in a particular country in the VIVUS Territory, provided that in no event shall the amount paid to SELTEN during any calendar year be reduced to a royalty rate that is less than *** % of the Royalty Rate due under 3.4.1. For clarity, such royalty reduction shall not be applicable to the royalty due to Stanford pursuant to the Exclusive Agreement.

3.6. **Royalty Payments and Report.** Royalty payments are due and payable in Dollars *** days after the end of each calendar quarter. Each payment of royalties due under this Agreement will be accompanied with a report setting forth, on a Product-by-Product and country-by-country basis, the number of units of VIVUS Product sold by VIVUS, its Affiliates and licensees during the applicable calendar quarter, gross sales of VIVUS Product in the applicable country during such calendar quarter, a calculation of Net Sales in the applicable country showing the itemized deductions to the extent practicable provided for in the definition of "Net Sales" during such calendar quarter. This report shall also include the Exchange Rates set for in Section 1.13 and other methodology used in converting Net Sales into Dollars, from the currencies in which sales were made in order to determine the appropriate royalties owed to SELTEN for Net Sales of VIVUS Products during such calendar quarter, with all such amounts reflected in United States Dollars. VIVUS and its Affiliates and licensees shall keep complete and accurate records in sufficient detail to enable the royalties payable hereunder to be determined.

3.7. **Records; Inspection.** VIVUS shall keep, and shall cause its Affiliates and licensees to keep, for a period of not less than *** years, true and complete records relating to the determination of Net Sales of VIVUS Products and the royalties due to SELTEN pursuant to Section 3.4. SELTEN shall have the right, at its sole expense, during the Term following the First Commercial Sale of any VIVUS Product and following reasonable notice, to inspect through an independent accountant reasonably acceptable to VIVUS during regular business hours, the records of VIVUS (or its Affiliates or licensees) relating to the sales of any VIVUS Products; provided, however, that such inspection shall not (i) take place more often than once each calendar year and (ii) audit any records that date prior to the date of the last inspection under this Section, and further provided that, such accountants shall in strict confidence and report to SELTEN only as to the accuracy of the royalty statements and payments and the amount of any underpayment. Copies of such reports shall be supplied to VIVUS. If any audit or inspection of VIVUS's records reveals an underpayment by VIVUS, VIVUS shall make payment to SELTEN of an amount equal to such underpayment within *** days following

notification by SELTEN to VIVUS of the amount underpaid. In the event that there has been an underpayment greater than or equal to *** percent (*** %), VIVUS shall reimburse SELTEN for the reasonable costs of the relevant audit or inspection.

3.8. **Methods of Payment.** All royalties, milestones and other payments to be made by VIVUS to SELTEN in cash hereunder shall be made by wire transfer from a banking institution in the United States in Dollars in accordance with instructions given in writing by SELTEN. All cash payments shall be made in immediately available funds by electronic transfer by VIVUS, to the bank account identified below or such other bank account as SELTEN may designate in writing to VIVUS. Any payments due and payable under this Agreement on a date that is not a Business Day may be made on the next Business Day.

Payment instructions are as follows:

***	***
***	***
***	***
***	***
***	***
***	***

3.9. **Delay in Payment.** In case of any delay in payment by VIVUS to SELTEN, interest on the overdue payment will accrue at *** as reported in *The Wall Street Journal* , as determined for each month on the last Business Day of that month, plus *** percent (*** %), assessed from the day payment was initially due. The foregoing interest will be due from VIVUS without any notice of delinquency from SELTEN.

3.10. **Taxes.**

3.10.1. VIVUS will make all payments to SELTEN under this Agreement without deduction or withholding for taxes except to the extent that any such deduction or withholding is required by law in effect at the time of payment.

3.10.2. Any tax required to be withheld on amounts payable under this Agreement will promptly be paid by VIVUS on behalf of SELTEN to the appropriate governmental authority, and VIVUS will furnish SELTEN with proof of payment of such tax. Any such tax required to be withheld will be an expense of and borne by SELTEN .

3.10.3. VIVUS and SELTEN will cooperate with respect to all documentation required by any taxing authority or reasonably requested by VIVUS to secure a reduction in the rate of applicable withholding taxes.

Article 4
Prosecution and Enforcement of Assigned Patents

4.1. **Prosecution and Enforcement.** As of the Effective Date of this Agreement, VIVUS will become responsible for Prosecuting and enforcing the Patents Rights at VIVUS's sole cost and expense.

4.2. **Cooperation.** As of the Effective Date, SELTEN shall use best efforts to cooperate with VIVUS to effect the transfer of the right to Prosecute the Patent Rights before Patent Offices and initiate any enforcement actions, including by executing all lawful documents required to vest title to the Patent Rights in VIVUS. SELTEN will use best efforts to assist VIVUS in every reasonable way in the procurement, maintenance, enforcement and defense of the Patent Rights, including the disclosure to VIVUS of all pertinent information and data with respect thereto, the execution of all lawful oaths, assignments, declarations and all other instruments which VIVUS shall deem necessary in order to apply for and obtain such rights and in order to assign and convey to VIVUS, its successors and assigns the sole and exclusive rights, title and interest in and to such Patent Rights.

4.3. **Reimbursement of Transitional Prosecution Costs.** From the Effective Date of this Agreement until such time during the Term that any Patent Office having jurisdiction over any Patent Rights officially recognizes VIVUS as the owner of such Patent Rights, SELTEN shall follow VIVUS's reasonable directions with respect to the Prosecution of the Patent Rights, and VIVUS shall reimburse SELTEN for all reasonable, documented out-of-pocket costs expended in connection therewith.

Article 5
Confidential Information

5.1. **Public Announcements.** The existence and the terms of this Agreement shall be treated by each Party as the other Party's Confidential Information. The Parties hereby consent to issuing the joint press release appended to this Agreement as Attachment 3 , following execution of the Agreement. Otherwise, neither Party shall originate any publicity, news release, public announcements, or public disclosures, written or oral, whether to the public or press, stockholders or otherwise, relating to this Agreement, including its existence, the subject matter to which it relates, performance under it or any of its terms, save only such announcements that are required to be made by law, regulations, the rules of a securities exchange, or the order of a court or other governmental body of competent jurisdiction or that are otherwise agreed to by the Parties. The Parties shall use Diligent Efforts to keep such announcements brief and factual. If a Party decides to make such an announcement, required by law regulations, court order, or the rules of a securities exchange, or desires to make any other public disclosure relating to this Agreement, it shall give each other Party at least *** Business Days advance notice, where practicable, of the proposed text of the announcement or disclosure so that each other Party shall have an opportunity to comment. To the extent that a reviewing Party reasonably requests the deletion of any information in the proposed text, the disclosing Party shall delete such information unless, in the reasonable opinion of the disclosing Party's legal counsel, such confidential information is legally required to be fully disclosed. Nothing herein shall prevent a Party from re-disclosing any factual information that has previously been disclosed to the public,

provided that such information remains accurate.

5.2. **Confidentiality.** The Parties acknowledge that it may be necessary or desirable for them to share certain proprietary or confidential information or material (" Confidential Information ") to facilitate their performance hereunder. Each Party agrees to keep the other party's Confidential Information received during the Term of this Agreement in confidence and not to disclose it to any Third Party or use the other Party's Confidential Information for any purpose other than for purposes hereunder, without the prior written consent of the other Party. The obligation of confidentiality shall continue for a period of *** years from the date of execution of this Agreement. Each Party may disclose the other Party's Confidential Information to its employees and consultants, and employees and consultants of its Affiliates, who have a need to know such information and are bound by obligations of confidentiality and non-use similar to those herein. Without limitation, each Party agrees to take commercially reasonable precautions to prevent the unauthorized disclosure to any Third Party of the Confidential Information received from another Party hereunder. In order to be deemed confidential, the Confidential Information shall be supplied to the receiving Party in written form and identified as being confidential or, if disclosed orally, shall be confirmed in writing as being confidential within *** days of its oral disclosure. Upon termination of this Agreement or at the disclosing Party's reasonable request, a receiving Party shall promptly return or destroy all copies of the disclosing Party's Confidential Information, except that one (1) copy may be retained in archival legal files for the receiving Party to ensure compliance hereunder. The receiving Party's obligation of confidentiality hereunder, however, shall not apply to Confidential Information that: (a) at the time of disclosure to the receiving Party is published, known publicly or is otherwise in the public domain; (b) after disclosure to the receiving Party is published or becomes known publicly or otherwise becomes part of the public domain through no fault of the receiving Party; (c) prior to the time of disclosure to the receiving Party, was known to the receiving Party as evidenced by its written records; (d) has been or is disclosed to the receiving Party in good faith by a Third Party who was not, or is not, under any obligation of confidentiality to the other Party at the time the Third Party discloses to the receiving Party; or (e) is independently developed by or on behalf of the receiving Party without reliance on the Information received hereunder as evidenced by its written records. Nothing herein, however, shall prohibit a receiving Party from disclosing a disclosing Party's Confidential Information to the extent it is required to be disclosed by law, regulation, rules of a securities exchange, or order of a court or other governmental body of competent jurisdiction, provided that the receiving Party gives the disclosing Party, prior to making any legally required disclosure, prompt notice of such requirement and an opportunity to intervene to protect or limit the disclosure.

5.3. **SEC Filings and Other Disclosures.** In addition to the disclosures that are permitted under Section 5.1 and that are permitted generally for Confidential Information pursuant to Section 5.2, a Party may disclose the terms of this Agreement and any information resulting from the activities contemplated by this Agreement (a) to the extent required to comply with the applicable rules and regulations promulgated by the United States Securities and Exchange Commission or similar security regulatory authorities in other countries, (b) to comply with the applicable rules of a securities exchange, or (c) in connection with a prospective acquisition,

merger, financing or license for such Party, to prospective acquirers or merger candidates or to existing or potential investors or licensees who are under an obligation of confidentiality substantially consistent with the terms hereof.

Article 6
Representations and Warranties

6.1. **Representations, Warranties of Each Party.** Each Party hereby makes the following representations, warranties and covenants:

6.1.1. **Authority.** As of the Effective Date, it has the full right, power and authority to enter into this Agreement; this Agreement has been duly executed by such Party and constitutes a legal, valid and binding obligation of such Party, enforceable in accordance with its terms; and

6.1.2. **No Conflicts.** The execution, delivery and performance of this Agreement by such Party does not conflict with any material agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

6.2. **Additional Representations and Warranties of SELTEN.** In addition to the representations and warranties made by SELTEN under Section 6.1, SELTEN further represents and warrants that:

6.2.1. SELTEN has the right to assign the Patent Rights on behalf of it and its applicable Affiliates, and neither SELTEN nor any of its Affiliates has previously assigned, transferred, conveyed or otherwise encumbered the rights, title and interest in the Patent Rights, and there are currently no existing license agreements to which SELTEN or any of its Affiliates is a party for such Patent Rights;

6.2.2. SELTEN has not received written notice of any claim or threatened claim by any Third Party that (i) such Third Party has any rights to the Patent Rights or (ii) any issued patents within the Patent Rights are invalid or unenforceable;

6.2.3. To SELTEN's knowledge as of the Effective Date, there is no litigation threatened, impending or existing against SELTEN or to which SELTEN is a party relating to the Patent Rights;

6.2.4. To SELTEN's knowledge as of the Effective Date, SELTEN is not aware of any claim of infringement of any patents owned or controlled by SELTEN existing as of the Effective Date of this Agreement, that are not included in the Patent Rights and which SELTEN could assert against VIVUS regarding its sales of any product;

6.2.5. Contingent upon SELTEN's receipt of the Upfront Payment set forth in Section

3.1, SELTEN hereby covenants not to assert against VIVUS in any court or other body of competent jurisdiction an infringement claim alleging that any claim of any patent or patent application, that is owned by SELTEN as of the Effective Date or in the future, whether such patent claim has issued as of the Effective Date of this Agreement or issues thereafter from an application owned by SELTEN pending as of the Effective Date or in the future, covers the Product or its use in the Field. For the avoidance of doubt, the foregoing covenant extends to any process for manufacturing any Product, any composition of a Licensed Compound, and any use of a Product in the Field. Further for the avoidance of doubt, the foregoing covenant extends to any patents owned by any Affiliates of SELTEN;

6.2.6. During the Term of this Agreement, SELTEN will comply in all material respects with all applicable laws and regulations concerning SELTEN's obligations under this Agreement: and

6.2.7. SELTEN has not received any communication from the FDA indicating that the orphan designation for Tacrolimus for the treatment of pulmonary arterial hypertension will be withdrawn, challenged or otherwise revoked and SELTEN has no knowledge of any Third Party that has filed an IND for Tacrolimus for the treatment of pulmonary arterial hypertension.

6.3. **Additional Representations and Warranties of VIVUS.** In addition to the representations and warranties made by VIVUS under Section 6.1, VIVUS further represents and warrants that :

6.3.1. During the Term of this Agreement, VIVUS will comply in all material respects with all applicable laws and regulations concerning the development, commercialization, manufacture, use, distribution, and sale of Products ; and

6.3.2. During the Term of this Agreement, VIVUS will comply in all material respects with all applicable laws and regulations concerning VIVUS's obligations under this Agreement.

6.3.3. VIVUS will use Commercially Reasonable Efforts in completing development and regulatory activities for a Licensed Compound in the VIVUS Territory.

6.4. **No Implication by SELTEN.** Except as expressly stated herein, nothing in the Agreement will be construed as:

(a) a warranty or representation by SELTEN as to the enforceability, validity or patentability or scope of any of the Patent Rights;

(b) a warranty or representation by SELTEN that any Product or any other thing that has been or will be made, used, sold, offered for sale, or imported under any Patent Rights is or will be free from infringement of any patents or other intellectual property rights of any Third Parties or Affiliates of SELTEN; or

(c) a warranty or representation by SELTEN that any Patent Rights cover any Products.

6.5. **Disclaimer of Warranties.** EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT , NEITHER OF THE PARTIES MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OR CONDITIONS OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO ANY PATENT RIGHTS TRANSFERRED HEREUNDER, INCLUDING, BUT NOT LIMITED TO, ANY WARRANTY OF ENFORCEABILITY, VALIDITY, PATENTABILITY, NONINFRINGEMENT, OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

Article 7
Indemnification and Insurance

7.1. **Indemnification.**

7.1.1 **Indemnification by VIVUS.** Subject to Section 7.2, VIVUS shall indemnify, defend and hold harmless SELTEN and its Affiliates, and their respective directors, officers, employees and agents (each, a " SELTEN Indemnified Party ") from and against any and all liability, loss, damage, expense (including reasonable and necessary attorneys' fees and expenses) and cost (collectively, " Liability ") arising out of or relating to claims of any nature by any Third Parties: (a) arising out of or relating to any breach by VIVUS of any of its representations, warranties or covenants set forth herein; or (b) relating to the development, commercialization, administration, use or manufacture of, or any other activity involving, any Product by or on behalf of VIVUS before, on, or after the Effective Date, except, in each case (a) and (b), to the extent caused in whole or in part by the gross negligence or willful misconduct of a SELTEN Indemnified Party.

7.1.2 **Indemnification by SELTEN.** Subject to Section 7.2, SELTEN will indemnify, defend and hold harmless VIVUS and its Affiliates, and their respective directors, officers, employees and agents (each, a " VIVUS Indemnified Party ") from and against any and all Liability arising out of or relating to claims of any nature by any Third Parties arising out of or relating to any breach by SELTEN of any of its representations, warranties or covenants set forth herein, except, in each case, to the extent caused by the gross negligence or willful misconduct of a VIVUS Indemnified Party.

7.2 **Conditions to Indemnification.** If either a SELTEN Indemnified Party or a VIVUS Indemnified Party (each, an " Indemnified Party ") intends to claim indemnification under Article 7, the Indemnified Party shall (a) give the other Party (the " Indemnifying Party ") reasonably prompt written notice of any Liability in respect of which the Indemnified Party intends to claim such indemnification, (b) reasonably cooperate with the Indemnifying Party at the Indemnifying Party's request and expense, in the defense or settlement of the claim, and (c) give the Indemnifying Party the right to control the defense or settlement of the claim, except that the Indemnifying Party shall not enter into any settlement that adversely affects the Indemnified Party's rights or obligations under this Agreement without the Indemnified Party's prior express written consent, which will not be unreasonably withheld or delayed. The

Indemnified Party may participate in the defense or settlement of any such claim at its own expense with counsel of its choosing. Notwithstanding the foregoing, any failure of the Indemnified Party to comply with the provisions of this Section 7.2 will not relieve the Indemnifying Party of any defense or indemnity obligations hereunder except to the extent that the Indemnifying Party is prejudiced by such failure.

7.3 **Limitations of Indemnification.** SUBJECT TO AND WITHOUT LIMITING THE INDEMNIFICATION OBLIGATIONS OF EACH PARTY WITH RESPECT TO THIRD PARTY CLAIMS UNDER SECTION 7.1, NEITHER PARTY NOR ANY OF ITS AFFILIATES WILL BE LIABLE TO THE OTHER UNDER ANY CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY FOR ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES OR FOR LOST PROFITS, MILESTONES OR ROYALTIES, ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT OR ITS SUBJECT MATTER .

Article 8
Term and Termination

8.1 **Term.** The term of this Agreement will commence on the Effective Date and will extend, unless this Agreement is terminated earlier in accordance with this Article 8, until the later of (i) the expiration of all Patent Rights or (ii) the expiration of the Stanford Agreement (the " Term ").

8.2 **Early Termination** . Subject to Section 3.2, VIVUS may terminate this Agreement at any time by providing thirty (30) days written notice to SELTEN. Termination shall be effective upon assignment of the Patent Rights to SELTEN pursuant to Section 8.3 below.

8.3 **Reassignment of Patent Rights with Termination.** If VIVUS elects to terminate this Agreement under Section 8.2, VIVUS shall assign and transfer to SELTEN VIVUS's entire right, title and interest in and to the Patent Rights remaining at the date of such termination by executing an instrument to such effect in form and substance reasonably satisfactory to SELTEN and will perform all other actions reasonably requested by SELTEN to effect and confirm such transfer.

8.4 **Exclusivity.** In the event this Agreement is terminated pursuant to Sections 3.2 or 8.2, VIVUS hereby covenants that neither it nor its Affiliates will, directly or indirectly (including via a license with a Third Party), begin a phase II study on a Competing Product earlier than *** years from the date at which such termination becomes effective. The Parties acknowledge that a failure to comply with the provisions of this Section 8.4 shall constitute a material breach of this Agreement.

8.5 **Survival of Obligations.** The expiration or termination of this Agreement will

not relieve the Parties of any rights or obligations accruing prior to such termination, and any such termination will be without prejudice to the rights of either Party against the other. The provisions of Articles 4, 5, 6, 7, 9, and 10 and Sections 8.3 and 8.4, will survive any expiration or termination of this Agreement. Additionally, VIVUS's ownership of the Patent Rights as of the Effective Date shall in no event be affected by the expiration or termination of this Agreement, except upon early termination as provided in Section 3.2 and this Article 8.

Article 9
Dispute Resolution; Governing Law

9.1 **Mediation .** In the event of any controversy or claim arising out of or relating to this Agreement, including any involving any Affiliates of any Party, (a " Dispute "), a Party seeking to resolve such Dispute shall provide notice thereof to the other Party. Any Dispute shall first be submitted to mediation according to the *Commercial Mediation Procedures* of the American Arbitration Association (" AAA ") (*see* www.adr.org). Such mediation shall be attended on behalf of each Party for at least one (1) session by a senior business person with authority to resolve the Dispute. Any period of limitations that would otherwise expire between the initiation of a mediation and its conclusion shall be extended until *** days after the conclusion of the mediation.

9.2 **Arbitration.** Any Dispute that cannot be resolved by mediation within *** days of notice by one (1) Party to the other of the existence of a Dispute (unless the Parties agree to extend that period) shall be resolved by arbitration in accordance with the *Commercial Arbitration Rules* of the AAA (" AAA Rules "; *see* www.adr.org) and the Federal Arbitration Act, 9 U.S.C. §1 et seq. The arbitration shall be conducted in San Francisco, California, by *** appointed in accordance with the AAA Rules. The *** shall follow the *ICDR Guidelines for Arbitrators Concerning Exchanges of Information* in managing and ruling on requests for discovery. The *** , by accepting appointment, undertakes to exert *** best efforts to conduct the process so as to issue an award within *** months of *** appointment, but failure to meet that timetable shall not affect the validity of the award. The *** shall decide the Dispute in accordance with the substantive law as provided in Section 9.3 below. The *** may award reasonable attorneys fees and costs to the prevailing party to the arbitration. The award of the *** may be entered in any court of competent jurisdiction.

9.3 **Governing Law.** This Agreement will be governed by and interpreted in accordance with the laws of the State of California without reference to its choice of laws or conflicts of laws provisions.

Article 10
Miscellaneous

10.1 **Entire Agreement.** This Agreement, including each attachment and any other exhibit or schedule hereto, constitutes and contains the entire understanding and agreement of the Parties respecting the subject matter of this Agreement and cancels and supersedes any and all prior or contemporaneous negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter.

10.2 **Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments 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.

10.3 **Binding Effect.** This Agreement and the rights granted herein will be binding upon, and will inure to the benefit of SELTEN, VIVUS and their respective lawful successors and permitted assigns.

10.4 **Assignment.** Neither Party may assign its rights or delegate its duties under this Agreement without the prior written consent of the other relevant Party, which will not be unreasonably withheld, provided that any Party may transfer this Agreement to an Affiliate without any requirement that it obtain the consent of the other Party and further provided that any Party may transfer this Agreement to a successor in connection with the transfer of all or substantially all of its assets or that portion of its business pertaining to the subject matter of this Agreement, whether by merger, consolidation, sale of assets, or otherwise, without any requirement that it obtain the consent of the other Party.

10.5 **Use of Names.** Except as expressly provided, no right, expressed or implied, is granted by this Agreement to a Party to use in any manner the name or any other trade name of the other Party or its Affiliates in connection with this Agreement.

10.6 **No Waiver.** No waiver, modification or amendment of any provision of this Agreement will be valid or effective unless made in writing and signed by a duly authorized officer of each Party. The failure of either Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition.

10.7 **Independent Contractors.** The Parties are independent contractors and not agents or employees of the other Party under this Agreement. Nothing contained in this Agreement is intended nor is to be construed so as to constitute SELTEN or VIVUS as partners or joint venturers with respect to this Agreement. No Party will 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 other contract, agreement or undertaking with any Third Party except as may be explicitly provided for herein or authorized in writing.

10.8 **Notices and Deliveries.** Any notices, request, delivery, approval or consent required or permitted to be given under this Agreement will be in writing and will be deemed to have been sufficiently given when it is received, whether delivered in person, transmitted by facsimile with contemporaneous confirmation, delivered by registered letter (or its equivalent) or delivered by certified overnight courier service, to the Party to which it is directed at its address shown below or such other address as such Party will have last given by notice to the other Parties.

If to VIVUS:

VIVUS, Inc.
900 E. Hamilton Ave.
Suite 550
Campbell, California 95008
Attention: Chief Executive Officer

with a copy to:

VIVUS, Inc.
900 E. Hamilton Ave.
Suite 550
Campbell, California 95008
Attention: General Counsel

If to SELTEN:

Selten Pharma, Inc.
751 Laurel St., #520
San Carlos, CA 94070
Attention: Chief Executive Officer

10.9 **Severability.** In the event that any provision of this Agreement will, for any reason, be held to be invalid or unenforceable in any respect, such invalidity or unenforceability will not affect any other provision hereof, and this Agreement will be construed as if such invalid or unenforceable provision had not been included herein.

10.10 **Advice of Counsel.** Each Party acknowledges and agrees it has participated in the drafting of this Agreement. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will exist or be implied against the Party which drafted such terms and provisions.

10.11 **Counterparts.** This Agreement may be executed in any number of counterparts (including by facsimile or electronic transmission), each of which need not contain the signature of more than one Party, but all such counterparts taken together will constitute one and the same agreement. Signatures provided by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail shall be deemed to be original signatures.

10.12 **Waiver.** Except as specifically provided for herein, the waiver from time to time by either of the Parties of any of their rights or their failure to exercise any remedy will not operate or be construed as a continuing waiver of same or of any other of such Party's rights or remedies provided in this Agreement.

10.13 **Compliance with Laws.** Each Party will comply with all applicable laws, rules, regulations and orders of the United States and applicable foreign countries and supra-governmental organizations and all jurisdictions and any agency or court thereof in connection with this Agreement and the transactions contemplated thereby.

10.14 **Construction.** Except where the context requires otherwise, whenever used the singular includes the plural, the plural includes the singular, the use of any gender is applicable to all genders and the word "or" has the inclusive meaning represented by the phrase "and/or". Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The headings of this Agreement and any descriptions of Attachments and Exhibits or descriptions of cross-references are for convenience of reference only and do not define, describe, extend or limit the scope or intent of this Agreement or the scope or intent of any provision contained in this Agreement. The terms "including," "include(s)," "such as," and "for example" as used in this Agreement mean including the generality of any description preceding such term and will be deemed to be followed by "without limitation".

[*Remainder of page intentionally left blank.*]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective duly authorized officers as of the date specified below.

SELTEN PHARMA, INC.

By: /s/ Narinder Banait

Name: Narinder S. Banait

Title: Co-CEO, General Counsel

Date: January 6, 2017

VIVUS, INC.

By: /s/ John L. Slebir

Name: John L. Slebir

Title: SVP, General Counsel

Date: January 6, 2017

Attachment 1

Patent Rights

***

TITLE: COMBINATION THERAPY FOR PULMONARY HYPERTENSION

Country	Patent Application Number
***	***
***	***

***

TITLE : COMPOSITIONS AND METHODS FOR THE TREATMENT OR PREVENTION OF PULMONARY HYPERTENSION

Country	Patent Application Number
***	***
***	***

***

TITLE: PHARMACEUTICAL COMPOSITION

Country	Patent Application Number
***	***
***	***

***** 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.**

Attachment 2
Form of Patent Assignment

GENERAL PATENT ASSIGNMENT

WHEREAS, **SELTEN PHARMA, INC.** a Cayman Islands corporation, having its place of business at 751 Laurel St., San Carlos, CA 94070 (hereinafter called " Assignor "), has established ownership rights in and to the patents and patent applications identified in the attached Exhibit (the " Patents "); and

WHEREAS, **VIVUS, INC.** , a corporation of the State of Delaware, having its principle place of business at 900 E. Hamilton Ave. Suite 550, Campbell, California 95008 (hereinafter called " Assignee "), desires to acquire all of Assignor's right, title and interest in and to the Patents and any provisional or other right to recover damages, including royalties, for prior infringements of the Patents; and

NOW, THEREFORE , for good and sufficient consideration, the receipt of which is hereby acknowledged, and to the extent that the Assignor has not done so already via a prior agreement with the Assignee, or if the Assignor has already done so via a prior agreement with the Assignee then in confirmation of any obligation to do so in said prior agreement, the Assignor has sold, assigned, transferred, and set over, and by these presents does sell, assign, transfer, and set over, unto the Assignee, its successors, legal representatives, and assigns, the Assignor's entire right, title, and interest in:

(a) the Patents, including any and all: (1) continuations, continuations-in-part, requests for continued examination, divisions, renewals, substitute applications, and all patents granted thereon, and (2) reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms; and (3) any foreign counterparts of the foregoing; and

(b) any provisional or other right to recover damages, including royalties, for prior infringements of the Patents.

The above-granted rights, titles, and interests are to be held and enjoyed by the Assignee, for its own use and behalf and the use and behalf of its successors, legal representatives, and assigns, as fully and entirely as the same would have been held and enjoyed by the Assignor had this sale and assignment not been made.

The Assignor hereby covenants and agrees to and with the Assignee, its successors, legal representatives, and assigns, that the Assignor will sign all papers and documents, take all lawful oaths, and do all acts necessary or required to be done in connection with any and all proceedings for the procurement, maintenance, enforcement and defense of said patents, and said patent applications, including interference proceedings, without charge to the Assignor, its successors, legal representatives, and assigns, but at the cost and expense of the Assignee, its successors, legal representatives, and assigns.

IN WITNESS WHEREOF, Assignor and Assignee have caused this General Patent Assignment to be executed by their duly authorized officers or agents on this __ day of ___, 2017.

ASSIGNOR: **SELTEN PHARMA, INC.**

BY: _____ DATE: _____

TITLE: _____

WITNESS: _____ DATE: _____

WITNESS: _____ DATE: _____

ASSIGNEE: **VIVUS, INC.**

BY: _____ DATE: _____

TITLE: _____

WITNESS: _____ DATE: _____

WITNESS: _____ DATE: _____

***** 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.**

Attachment 3
JOINT Press Release

VIVUS AND SELTEN PHARMA ANNOUNCE AGREEMENT FOR THE DEVELOPMENT AND COMMERCIALIZATION RIGHTS TO TREATMENTS FOR PULMONARY ARTERIAL HYPERTENSION (PAH)

MOUNTAIN VIEW, Calif., and SAN CARLOS, Calif., January __, 2017 - VIVUS, Inc. (Nasdaq: VVUS) and Selten Pharma, Inc., announced VIVUS' acquisition from Selten of exclusive, worldwide rights for the development and commercialization of tacrolimus and ascomycin for the treatment of Pulmonary Arterial Hypertension (PAH) and related vascular diseases. VIVUS assumes all development and commercialization responsibilities.

Selten has assigned VIVUS its license to a family of patents owned by the Board of Trustees of the Leland Stanford Junior University (Stanford) and all rights under a collection of patent applications owned by Selten . The licensed patent family includes U.S. Patent No. 9,474,745 and is directed to methods of using tacrolimus to treat PAH. The assigned patent applications are directed to additional compounds and methods for the treatment of PAH and formulations for tacrolimus. In March 2015, Selten received orphan drug designation for tacrolimus for the treatment of PAH.

VIVUS is responsible for all future financial obligations to Stanford under the Stanford license . Selten will receive an upfront payment, and development and sales milestone payments, as well as tiered royalties on future sales of these compounds.

"Pulmonary Arterial Hypertension is a degenerative disease with current treatment options that only address the symptoms to slow the progression of the disease. We are excited about the potential of tacrolimus and ascomycin to significantly improve the quality of life and life expectancy of PAH patients," said Seth H.Z. Fischer, VIVUS' Chief Executive Officer. "The move into PAH is the latest announcement in our effort to reshape VIVUS to build long-term stockholder value, and we look forward to additional announcements in the future."

"We are excited to partner with VIVUS to strive to bring new therapies to PAH patients who have limited treatment options," said Leo Gu, Ph.D., President and Co-CEO of Selten. "Early compassionate use of the licensed compounds demonstrate potential to go beyond symptom management and impact the progression of disease," he added.

"It has been a pleasure to collaborate with VIVUS on this strategic deal, and we are looking forward to these important therapies being developed and making a difference in patients' lives," said Narinder S. Banait, Ph.D., J.D. General Counsel, and Co-CEO of Selten. "Selten will continue to focus on rare diseases," he added.

About Pulmonary Arterial Hypertension (PAH)

PAH is a chronic life-threatening disease characterized by elevated blood pressure in the pulmonary arteries (arteries between the heart and lungs) due to severe constriction of these blood vessels. These high pressures make it difficult for the heart to pump blood through the lungs to be oxygenated. The symptoms of PAH are non-specific and can range from mild shortness of breath and fatigue during normal daily activity to symptoms of right heart failure and severe restrictions on exercise capacity and ultimately reduced life expectancy. PAH includes patients with idiopathic PAH, familial PAH, and associated PAH, which is related to certain conditions including connective tissue diseases, congenital systemic-to-pulmonary-shunts, portal hypertension, HIV infection, drugs and toxins. The current treatments for PAH involve calcium channel antagonists, prostacyclins, prostacyclin receptor (IP receptor) agonist, endothelin receptor antagonists, phosphodiesterase-5 (PDE5) inhibitors, and long-term anticoagulant therapy, with the aim to reduce symptoms and improve quality of life.

About VIVUS

VIVUS is a biopharmaceutical company commercializing Qsymia ® (phentermine and topiramate extended-release) capsules CIV for the treatment of obesity . For more information about the company, please visit www.vivus.com.

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995 and are subject to risks, uncertainties and other factors, including risks and uncertainties related to potential change in our business strategy to enhance long-term stockholder value ; risks and uncertainties related to the timing, strategy and success of the development and commercialization of tacrolimus and ascomycin for the treatment of Pulmonary Arterial Hypertension and related vascular diseases; and risks and uncertainties related to our ability to continue to identify, acquire and develop innovative investigational drug candidates and drugs. These risks and uncertainties could cause actual results to differ materially from those referred to in these forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. Investors should read the risk factors set forth in VIVUS' Form 10-K for the year ended December 31, 2015 as filed on March 9, 2016 and as amended by the Form 10-K/A filed on April 22, 2016, and periodic reports filed with the Securities and Exchange Commission. VIVUS does not undertake an obligation to update or revise any forward-looking statements.

About Selten Pharma, Inc.

Selten Pharma, Inc. is a privately held clinical-stage biopharmaceutical company focused on the development and commercialization of therapies for the treatment of rare diseases. The

company has drug candidates in various stages of clinical and preclinical development. Selten's pipeline and product development strategy offers the possibility of rapid commercialization with lower risks than typical new chemical entities.

Contacts:

VIVUS, Inc.
Mark Oki
Chief Financial Officer
oki@vivus.com
650-934-5200

VIVUS Investor Relations:
The Trout Group
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Managing Director
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Selten Pharma, Inc.
Tiberend Strategic Advisors, Inc.
Andrew Mielach
212-375-2694
amielach@tiberend.com

Exhibit 10.56

CONFIDENTIAL

***** 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.**

LICENSE ASSIGNMENT AGREEMENT

This License Assignment Agreement is made and effective as of the Effective Date (as defined below), by and among Selten Pharma, Inc., a Cayman Islands company, having a principal place of business at 751 Laurel St. # 520, San Carlos, CA 94070 (" SELTEN ") and VIVUS, Inc., a Delaware company, having a principal place of business at 900 E. Hamilton Ave., Suite 550, Campbell, California 95008 (" VIVUS ").

BACKGROUND

WHEREAS:

1. SELTEN, by virtue of the Exclusive Agreement (as defined below), is the exclusive licensee of the Licensed Patents (as defined below) of The Board of Trustees of the Leland Stanford Junior University (the " UNIVERSITY "); and

2. VIVUS desires to obtain from SELTEN, and SELTEN desires to assign to VIVUS, all of SELTEN's rights, interest, and obligations under such Exclusive Agreement.

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

Article 1
Definitions

The terms in this Agreement with initial letters capitalized, whether used in the singular or the plural, will have the meaning set forth below or, if not listed below, the meaning designated where first used in this Agreement.

1.1. " Affiliate " means, with respect to a specified Party, any corporation or other entity that directly or indirectly controls, is controlled by, or is under common control with such Party. For the purposes of this definition, the term "control" (including, with correlative meanings, the terms "controlled by" and "under common control with") means possession of at least fifty percent (50%) of the voting stock or other ownership interest of the entity, or the power to direct or cause the direction of the management and policies of the entity, or the power to elect or appoint at least fifty percent (50%) of the members of the governing body of the entity through the ownership of the outstanding voting securities or by contract or otherwise.

1.2. " Agreement " means this License Assignment Agreement, including its Attachments, as the same may be amended from time to time.

1.3. " Dollars " means the legal currency of the United States.

1.4. " Effective Date " means the date of execution by the last Party to sign below.

1.5. " Exclusive Agreement " means the Exclusive Agreement between SELTEN and the UNIVERSITY entered into on October 25, 2015, as amended by the first amendment dated October 24, 2016, a copy of which is attached hereto as Attachment 1 .

1.6. " Licensed Patents " means United States Patent Application, Serial Number ***; PCT Application Serial Number ***, US Provisional Application No. ***, any foreign patent application corresponding thereto, and any divisional, continuation, or reexamination application, extension, and each patent that issues or reissues from any of these patent applications.

1.7. " Licensed Product " means a product or part of a product for human therapeutics, where the making, using, importing or selling of which, absent the license granted in the Exclusive Agreement, infringes, induces infringement, or contributes to infringement of a Licensed Patent.

1.8. " Party " means SELTEN or VIVUS, as referred to individually. " Parties " means SELTEN and VIVUS, as referred to collectively.

1.9. "Patent Assignment Agreement" means the agreement between SELTEN and VIVUS entered into on January __, 2017, whereby SELTEN assigned certain patent rights owned by SELTEN to VIVUS.

1.10. " Tacrolimus " means the compound having the systematic (IUPAC) name [3S- [3R* [E(1S*,3S*,4S*)],4S*,5R*,8S*,9E,12R*,14R*,15S*,16R*,18S*,19S*,26aR*]]- 5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26a-hexadecahydro-5,19-dihydroxy- 3-[2-(4-hydroxy-3-methoxycyclohexyl)-1-methylethenyl]-14,16-dimethoxy-4,10, 12,18-tetramethyl-8-(2-propenyl)-15,19-epoxy-3H-pyrido[2,1-c][1,4] oxaazacyclotricosine-1,7,20,21(4H,23H)-tetrone, monohydrate and also may be referred to as FK506 or SPI-026.

1.11. " Third Party " means any person or entity other than a Party or any of its Affiliates.

Article 2
Assignment

2.1. **Assignment of Exclusive Agreement.** Upon SELTEN's receipt of the payment specified in Section 3.1, SELTEN shall and hereby does transfer, assign, and novate the Exclusive Agreement in favor of VIVUS, with retroactive effect to the Effective Date. VIVUS hereby agrees to accept the rights and obligations of SELTEN under the Exclusive Agreement in accordance with the terms and conditions therein, as such Exclusive Agreement may be amended in writing by VIVUS and the UNIVERSITY upon execution of this Agreement or thereafter.

2.2. **VIVUS's Assumption of the Exclusive Agreement.** The Exclusive Agreement is hereby amended by replacing all occurrences therein of "SELTEN" with "VIVUS". As of the

Effective Date, VIVUS hereby assumes and agrees to perform all of the obligations of SELTEN under the Exclusive Agreement.

Article 3
Financials

3.1. **Payment to SELTEN.** As consideration for SELTEN's assignment of the Exclusive Agreement pursuant to Section 2.1, VIVUS will pay to SELTEN *** Dollars ($***), which amount will be due upon execution of this Agreement and payable within *** days thereafter.

3.2. **Currency, Timing and Mode of Payment.** All payments to SELTEN hereunder will be paid in Dollars and made by wire transfer in the requisite amount to the account designated by SELTEN. In case of any delay in payment by VIVUS to SELTEN, interest on the overdue payment will accrue at *** as reported in *The Wall Street Journal* , as determined for each month on the last business day of that month, plus *** percent (***%), assessed from the day payment was initially due.

3.3. **Taxes.**

3.3.1. VIVUS will make all payments to SELTEN under this Agreement without deduction or withholding for taxes except to the extent that any such deduction or withholding is required by law in effect at the time of payment.

3.3.2. Any tax required to be withheld on amounts payable under this Agreement will promptly be paid by VIVUS on behalf of SELTEN to the appropriate governmental authority, and VIVUS will furnish SELTEN with proof of payment of such tax. Any such tax required to be withheld will be an expense of and borne solely by SELTEN .

3.3.3. VIVUS and SELTEN will cooperate with respect to all documentation required by any taxing authority or reasonably requested by VIVUS to secure a reduction in the rate of applicable withholding taxes.

Article 4
Representations and Warranties

4.1. **Representations, Warranties of Each Party.** Each of the Parties makes the following representations, warranties and covenants:

4.1.1. **Authority.** As of the Effective Date, it has the full right, power and authority to enter into this Agreement. This Agreement has been duly executed by such Party and constitutes a legal, valid and binding obligation of such Party, enforceable in accordance with its terms.

4.1.2. **No Conflicts.** The execution, delivery and performance of this Agreement by such Party does not conflict with any material agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, nor violate any material law

or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

4.2. **Additional Representations and Warranties of SELTEN.** In addition to the representations and warranties made by SELTEN under Section 4.1, SELTEN hereby represents and warrants that:

4.2.1. the Exclusive Agreement is in full force and effect;

4.2.2. SELTEN is not delinquent on any report or payment due under the Exclusive Agreement;

4.2.3. SELTEN is not in material breach of any provision of the Exclusive Agreement;

4.2.4. SELTEN has not missed a milestone described in Appendix A of the Exclusive Agreement;

4.2.5. SELTEN has not provided to the UNIVERSITY any false report required to be provided to the UNIVERSITY under the Exclusive Agreement;

4.2.6. UNIVERSITY has not provided to SELTEN any notice of any event that would provide the UNIVERSITY grounds to terminate the Exclusive Agreement pursuant to Section 15.2 of the Exclusive Agreement; and

4.2.7. SELTEN has full right and authority to transfer the Exclusive Agreement, the assignment granted herein is fully compliant with Article 16 of the Exclusive Agreement and the conditions of section 16.2 of the Exclusive Agreement have been performed completely, and the Exclusive Agreement herein transferred is free of lien, encumbrance or adverse claim.

4.3. **Additional Representations and Warranties of VIVUS.** In addition to the representations and warranties made by VIVUS under Section 4.1, VIVUS hereby represents and warrants that VIVUS will comply with all of its obligations, including any financial obligations to the UNIVERSITY, as set forth in the Exclusive Agreement (as may be amended from time to time).

4.4. **Disclaimer of Warranties.** EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT , NEITHER OF THE PARTIES OR THEIR AFFILIATES MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OR CONDITIONS OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO PRODUCTS, OR RIGHTS TRANSFERRED HEREUNDER, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR VALIDITY OR ENFORCEABILITY OF ANY PATENT RIGHTS.

Article 5
Term

5.1. **Term.** The term of this Agreement will commence on the Effective Date and will extend until expiration of the Exclusive Agreement (the " Term ").

5.2. **Early Termination.** In the event VIVUS terminates the Patent Assignment Agreement prior to the expiration of the Term, this Agreement will also terminate.

5.3. **Reassignment of the Exclusive Agreement upon Termination.** In the event of termination of this Agreement, VIVUS shall reassign the Exclusive Agreement to SELTEN by executing an instrument to such effect in form and substance reasonably satisfactory to SELTEN and will perform all other actions reasonably requested by SELTEN to effect and confirm such transfer.

5.4. **Survival of Obligations.** The expiration or termination of this Agreement will not relieve the Parties of any obligations accruing prior to such termination, and any such termination will be without prejudice to the rights of a Party against another. The provisions of this Agreement will survive any expiration or termination of this Agreement. Additionally, the assignment of the Exclusive Agreement to VIVUS and the Exclusive Agreement shall in no event be affected by the expiration or termination of this Agreement.

Article 6
Dispute Resolution; Governing Law

6.1. **Mediation and Arbitration.** Any dispute, controversy or claim arising out of or relating to this Agreement, including any such controversy or claim involving a Party or any of its Affiliates or successor, shall be resolved in accordance with the dispute resolution provisions set forth as of the Effective Date hereof at Article 17 of the Exclusive Agreement (as Attachment 1), which are hereby incorporated by reference herein, as applicable *mutatis mutandi* .

6.2 **Governing Law.** This Agreement shall be construed and interpreted under the laws of the State of California, USA, except that questions affecting the construction and effect of any patent within the Licensed Patents under the Exclusive Agreement shall be determined by the applicable law of the country or jurisdiction in which the patent has been granted.

Article 7
Publicity; Confidentiality

7.1 **Public Announcements.** The existence and the terms of this Agreement shall be treated by each Party as the other Party's Confidential Information. The Parties hereby consent to issuance of the joint press release appended to the Patent Assignment Agreement between SELTEN and VIVUS as Attachment 3 thereto, following execution of the Agreement. Otherwise, neither Party shall originate any publicity, news release, public announcements, or

public disclosures, written or oral, whether to the public or press, stockholders or otherwise, relating to this Agreement, including its existence, the subject matter to which it relates, performance under it or any of its terms, save only such announcements that are required to be made by law, regulations, the rules of a securities exchange, or the order of a court or other governmental body of competent jurisdiction or that are otherwise agreed to by the Parties. The Parties shall use commercially reasonable efforts to keep such announcements brief and factual. If a Party decides to make such an announcement required by law, regulations, court order, or the rules of a securities exchange, or desires to make any other public disclosure relating to this Agreement, it shall give each other Party at least *** business days advance notice, where practicable, of the proposed text of the announcement or disclosure so that each other Party shall have an opportunity to comment. To the extent that a reviewing Party reasonably requests the deletion of any information in the proposed text, the disclosing Party shall delete such information unless, in the reasonable opinion of the disclosing Party's legal counsel, such confidential information is legally required to be fully disclosed. Nothing herein shall prevent a Party from re-disclosing any factual information that has previously been disclosed to the public, provided that such information remains accurate.

7.2 **Confidentiality.** The Parties acknowledge that it may be necessary or desirable for them to share certain proprietary or confidential information or material (" Confidential Information ") to facilitate their performance hereunder. Each Party agrees to keep the other party's Confidential Information received during the term of this Agreement in confidence and not to disclose it to any Third Party or use the other Party's Confidential Information for any purpose other than for purposes hereunder, without the prior written consent of the other Party. The obligation of confidentiality shall continue for a period of *** years after disclosure. Each Party may disclose the other Party's Confidential Information to its employees and consultants, and employees and consultants of its Affiliates, who have a need to know such information and are bound by obligations of confidentiality and non-use similar to those herein. Without limitation, each Party agrees to take commercially reasonable precautions to prevent the unauthorized disclosure to any Third Party of the Confidential Information received from another Party hereunder. In order to be deemed confidential, the Confidential Information shall be supplied to the receiving Party in written form and identified as being confidential or, if disclosed orally, shall be confirmed in writing as being confidential within forty-five (45) days of its oral disclosure. Upon termination of this Agreement or at the disclosing Party's reasonable request, a receiving Party shall promptly return or destroy all copies of the disclosing Party's Confidential Information, except that one (1) copy may be retained in archival legal files for the receiving Party to ensure compliance hereunder. The receiving Party's obligation of confidentiality hereunder, however, shall not apply to Confidential Information that: (a) at the time of disclosure to the receiving Party is published, known publicly or is otherwise in the public domain; (b) after disclosure to the receiving Party is published or becomes known publicly or otherwise becomes part of the public domain through no fault of the receiving Party; (c) prior to the time of disclosure to the receiving Party, was known to the receiving Party as evidenced by its written records; (d) has been or is disclosed to the receiving Party in good faith by a Third Party who was not, or is not, under any obligation of confidentiality to the other Party at the time the Third Party discloses to the receiving Party; or (e) is independently developed by

or on behalf of the receiving Party without reliance on the Information received hereunder as evidenced by its written records. Nothing herein, however, shall prohibit a receiving Party from disclosing a disclosing Party's Confidential Information to the extent it is required to be disclosed by law, regulation, rules of a securities exchange, or order of a court or other governmental body of competent jurisdiction, provided that the receiving Party gives the disclosing Party, prior to making any legally required disclosure, prompt notice of such requirement and an opportunity to intervene to protect or limit the disclosure.

7.3 **SEC Filings and Other Disclosures.** In addition to the disclosures that are permitted under Section 7.1 and that are permitted generally for Confidential Information pursuant to Section 7.2, a Party may disclose the terms of this Agreement and any information resulting from the activities contemplated by this Agreement ((a) to the extent required to comply with the applicable rules and regulations promulgated by the United States Securities and Exchange Commission or similar security regulatory authorities in other countries, (b) to comply with the applicable rules of a securities exchange, or (c) in connection with a prospective acquisition, merger, financing or license for such Party, to prospective acquirers or merger candidates or to existing or potential investors or licensees who are under an obligation of confidentiality substantially consistent with the terms hereof.

Article 8
Indemnification

8.1 **VIVUS's Indemnification of SELTEN.**

8.1.1 With respect to any and all Licensed Products sold by VIVUS, its Affiliates, and assignees or sublicensees under the Exclusive Agreement, subject to the conditions of Section 8.1.2 below, VIVUS shall indemnify and hold harmless SELTEN from any and all costs, expenses, damages, judgments, and liabilities (including reasonable and necessary attorneys' fees) incurred by or rendered against SELTEN or its Affiliates arising from the use, testing, recall, labeling, promotion, or sale or other disposition of any Licensed Products, except in each case to the extent caused in whole or in part by the gross negligence or willful misconduct of SELTEN.

8.1.2 Upon the assertion of any claim or suit for which SELTEN seeks indemnification under this Article, it shall give VIVUS prompt written notice of any such claim or suit, and shall permit VIVUS to undertake the defense thereof, at VIVUS's expense. SELTEN shall cooperate in such defense to the extent reasonably requested by VIVUS, at VIVUS's expense and shall give VIVUS the right to control the defense or settlement of the claim, except that VIVUS shall not enter into any settlement that adversely affects SELTEN's rights or obligations under this Agreement without SELTEN's prior express written consent, which will not be unreasonably withheld or delayed. SELTEN may participate in the defense or settlement of any such claim at its own expense with counsel of its choosing.

8.1.3 IN NO EVENT SHALL A PARTY BE LIABLE TO ANOTHER PARTY FOR ANY SPECIAL, CONSEQUENTIAL, OR INCIDENTAL DAMAGES ARISING UNDER OR AS A RESULT OF THIS AGREEMENT, INCLUDING, BUT NOT LIMITED TO, THE LOSS OF PROSPECTIVE PROFITS OR ANTICIPATED SALES, OR ON ACCOUNT OF EXPENSES, INVESTMENTS, OR COMMITMENTS IN CONNECTION WITH THE BUSINESS OR GOODWILL OF THE OTHER PARTY OR OTHERWISE.

Article 9
Miscellaneous

9.1. **Entire Agreement.** This Agreement, including each attachment and any other exhibit or schedule hereto, constitutes and contains the entire understanding and agreement of the Parties respecting the Licensed Patents and other subject matter of the Exclusive Agreement and cancels and supersedes any and all prior or contemporaneous negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter.

9.2. **Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments 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.

9.3. **Binding Effect.** This Agreement and the rights granted herein will be binding upon, and will inure to the benefit of SELTEN and VIVUS, and their respective lawful successors and permitted assigns.

9.4. **Assignment.** No Party may assign its rights or delegate its duties under this Agreement without the prior written consent of the other relevant Party, which will not be unreasonably withheld or delayed, provided that any Party may transfer this Agreement to an Affiliate without any requirement that it obtain the consent of the other Parties and further provided that any Party may transfer this Agreement to a successor in connection with the transfer of all or substantially all of its assets or that portion of its business pertaining to the subject matter of this Agreement, whether by merger, consolidation, sale of assets, or otherwise, without any requirement that it obtain the consent of the other Party.

9.5. **Use of Names.** Except as expressly provided, no right, expressed or implied, is granted by this Agreement to a Party to use in any manner the name or any other trade name, trademark, or logo of the other Party or its Affiliates in connection with this Agreement.

9.6. **No Waiver.** No waiver, modification or amendment of any provision of this Agreement will be valid or effective unless made in writing and signed by a duly authorized officer of each Party. The failure of either Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition.

9.7. **Independent Contractors.** The Parties are independent contractors and not agents or employees of the other Parties under this Agreement. Nothing contained in this Agreement is intended nor is to be construed so as to constitute SELTEN or VIVUS as partners or joint venturers with respect to this Agreement. No Party will have any express or implied right or authority to assume or create any obligations on behalf of or in the name of another Party or to bind another Party to any other contract, agreement or undertaking with any Third Party except as may be explicitly provided for herein or authorized in writing.

9.8. **Notices and Deliveries.** Any notices, request, delivery, approval or consent required or permitted to be given under this Agreement will be in writing and will be deemed to have been sufficiently given when it is received, whether delivered in person, transmitted by facsimile with contemporaneous confirmation, delivered by registered letter (or its equivalent) or delivered by certified overnight courier service, to the Party to which it is directed at its address shown below or such other address as such Party will have last given by notice to the other Parties.

If to VIVUS:

VIVUS, Inc.
900 E. Hamilton Ave.
Suite 550
Campbell, California 95008
Attention: CEO

with a copy to:
General Counsel

If to SELTEN:

Selten Pharma, Inc.
751 Laurel St., #520
San Carlos, CA 94070
Attention: CEO

9.9. **Severability.** In the event that any provision of this Agreement will, for any reason, be held to be invalid or unenforceable in any respect, such invalidity or unenforceability will not affect any other provision hereof, and this Agreement will be construed as if such invalid or unenforceable provision had not been included herein.

9.10. **Advice of Counsel.** Each Party acknowledges and agrees it has participated in the drafting of this Agreement. In interpreting and applying the terms and provisions of this

Agreement, the Parties agree that no presumption will exist or be implied against the Party which drafted such terms and provisions.

9.11. **Counterparts.** This Agreement may be executed in any number of counterparts (including by facsimile or electronic transmission), each of which need not contain the signature of more than one Party, but all such counterparts taken together will constitute one and the same agreement. Signatures provided by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail shall be deemed to be original signatures.

9.12. **Waiver.** Except as specifically provided for herein, the waiver from time to time by either of the Parties of any of their rights or their failure to exercise any remedy will not operate or be construed as a continuing waiver of same or of any other of such Party's rights or remedies provided in this Agreement.

9.13. **Compliance with Laws.** Each Party will comply with all applicable laws, rules, regulations and orders of the United States and applicable foreign countries and supra-governmental organizations and all jurisdictions and any agency or court thereof in connection with this Agreement and the transactions contemplated hereunder.

9.14. **Construction.** Except where the context requires otherwise, whenever used the singular includes the plural, the plural includes the singular, the use of any gender is applicable to all genders and the word "or" has the inclusive meaning represented by the phrase "and/or". Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The headings of this Agreement and any descriptions of Attachments and Exhibits or descriptions of cross-references are for convenience of reference only and do not define, describe, extend or limit the scope or intent of this Agreement or the scope or intent of any provision contained in this Agreement. The terms "comprising", "comprise(s)", "including," "include(s)," "such as," and "for example" are used in this Agreement in their open sense, and therefore will be interpreted to include the generality of any description preceding such term and will be deemed to be followed by "without limitation" whether expressly stated or not.

[*Remainder of page intentionally left blank.*]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective duly authorized officers.

SELTEN PHARMA, INC.

By: /s/ Narinder Banait

Name: Narinder S. Banait

Title: Co-CEO, General Counsel

Date: January 6, 2017

VIVUS, INC.

By: /s/ John L. Slebir

Name: John L. Slebir

Title: SVP, General Counsel

Date: January 6, 2017

Attachment 1

Copy of Exclusive Agreement as Amended

***** 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.**

EXCLUSIVE AGREEMENT

This Agreement between THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY ("Stanford"), an institution of higher education having powers under the laws of the State of California, and SELTEN PHARMA, INC. ("Selten or Company"), a corporation having a principal place of business at 14435C Big Basin Way #246, Saratoga, CA 95070, is effective on the 25th day of October, 2015 ("Effective Date").

1. BACKGROUND

Stanford is the assignee of an invention related to a treatment for pulmonary hypertension also known as "FK-506 (Tacrolimus) for treatment of pulmonary hypertension," invented in the laboratory of Dr. Edda Spiekerkoetter, Dr. Marlene Rabinovitch, and Dr. Philip Beachy, an employee of the Howard Hughes Medical Institute ("EIHMI"). It is described in Stanford Docket S11-009 ("Invention"). The Invention was made in the course of research supported by the National Institutes of Health.

Selten and Stanford are parties to an Option Agreement effective October 17 th, 2013 covering the Invention, later amended on October 17 th, 2014, and which expired on November 10, 2014.

Stanford wants to have the invention perfected and marketed as soon as possible so that resulting products may be available for public use and benefit.

2. DEFINITIONS

2.1 **"Change of Control"** means the following, as applied only to the entirety of that part of Selten's business that exercises all of the rights granted under this Agreement:

(A) acquisition of ownership—directly or indirectly, beneficially or of record—by any person or group (within the meaning of the Exchange Act and the rules of the SEC or equivalent body under a different jurisdiction) of the capital stock of Selten representing more than 45% of the aggregate ordinary voting power represented by the issued and outstanding capital stock of Selten unless Selten's shareholders immediately prior to such transaction would hold 55% or more of the aggregate ordinary voting power represented by the issued and outstanding capital stock of such person or surviving entity; and/or

(B) the sale of all or substantially all Selten's assets and/or business in one transaction or in a series of related transactions.

2.2 **"Exclusive"** means that, subject to Articles 3 and 5, Stanford will not grant further licenses under the Licensed Patents in the Licensed Field of Use in the Licensed Territory.

2.3 **"Fully Diluted Basis"** means the total number of shares of Selten's issued and outstanding common stock, assuming:

(A) the conversion of all issued and outstanding securities convertible into common stock;

(B) the exercise of all issued and outstanding warrants or options, regardless of whether then exercisable; and

(C) the issuance, grant, and exercise of all securities reserved for issuance pursuant to any Selten stock or stock option plan then in effect.

2.4 **"HHMI Indemnitees"** means HHMI and its trustees, officers, employees, and agents.

2.5 **"Licensed Field of Use"** means human therapeutics.

2.6 **"Licensed Patent"** means Stanford's U.S. Patent Application, Serial Number ***, filed ***; PCT Application Serial Number ***, filed on ***; US Provisional Application No ***, filed on ***, any foreign patent application corresponding thereto, and any divisional, continuation, or reexamination application, extension, and each patent that issues or reissues from any of these patent applications. Any claim of an unexpired Licensed Patent is presumed to be valid unless it has been held to be invalid by a final judgment of a court of competent jurisdiction from which no appeal can be or is taken. "Licensed Patent" excludes any continuation-in-part (CIP) patent application or patent.

2.7 **"Licensed Product"** means a product or part of a product in the Licensed Field of Use the making, using, importing or selling of which, absent this license, infringes, induces infringement, or contributes to infringement of a Licensed Patent.

2.8 **"Licensed Territory"** means worldwide.

2.9 **"Net Sales"** means all gross revenue derived by Selten or Sublicensees, their distributors or designees, from the sale, transfer or other disposition of Licensed Product to an end user. Sales or transfers to distributors or Sublicensees shall not be included in Net Sales until the actual sale or transfer by distributors or Sublicensees to a non-affiliate third party except if such distributor or Sublicensee is an end user. In the event that such distributor or Sublicensee is an end user, then Net Sales will based on the average selling or transfer price of Licensed Products at the time that the Licensed Products were sold or transferred. Net Sales excludes the following items (but only as they pertain to the making, using, importing or selling of Licensed Products, are included in gross revenue, and are separately billed):

(A) import, export, excise and sales taxes, and custom duties;

(B) costs of insurance, packing, and transportation from the place of manufacture to the customer's premises or point of installation;

(C) costs of installation at the place of use; and

(D) credit for returns, allowances, or trades;

(E) cash, trade, or quantity discounts actually granted to third parties.

2.10 **"Nonroyalty Sublicensing Consideration"** means any consideration received by Selten from a Sublicensee hereunder but excluding any consideration for:

(A) royalties on products sales (royalties on product sales by Sublicensees will be treated as if Selten made the sale of such product);

(B) investments in Selten stock;

(C) research and development expenses calculated on a fully burdened basis;

(D) debt; and

(E) reimbursement of out-of pocket patent prosecution and maintenance expenses for Patent Matters.

2.11 **"Patent Matters"** means preparing, filing, and prosecuting broad and extensive patent claims (including any interference or reexamination actions) for Stanford's benefit in the Licensed Territory and for maintaining all Licensed Patents.

2.12 **"Stanford Indemnitees"** means Stanford and Stanford Hospitals and Clinics, and their respective trustees, officers, employees, students, agents, faculty, representatives, and volunteers.

2.13 **"Sublicense"** means any agreement between Selten and a third party ("Sublicensee") that contains a grant to Stanford's Licensed Patents regardless of the name given to the agreement by the parties; however, an agreement to make, have made, use or sell Licensed Products on behalf of Selten is not considered a Sublicense.

3. GRANT

3.1 **Grant.** Subject to the terms and conditions of this Agreement, Stanford grants Selten a license under the Licensed Patent in the Licensed Field of Use to make, have made, use, import, offer to sell and sell Licensed Product in the Licensed Territory.

3.2 **Exclusivity.** The license is Exclusive, including the right to sublicense under Article 4, in the Licensed Field of Use beginning on the Effective Date and ending when the last Licensed Patent expires.

3.3 **Nonexclusivity.** After the Exclusive term, the license will be nonexclusive.

3.4 **Retained Rights.** Stanford retains the right, on behalf of itself, Stanford Hospital and Clinics, and all other non-profit research institutions, to practice the Licensed Patent for

any non-profit purpose, including sponsored research and collaborations. Selten agrees that, notwithstanding any other provision of this Agreement, it has no right to enforce the Licensed Patent against any such institution. Stanford and any such other institution have the right to publish any information included in a Licensed Patent. Selten acknowledges that it has been informed that the Licensed Patent was developed, at least in part, by employees of HHMI and that HHMI has a paid-up, non-exclusive, irrevocable license to use the Licensed Patent for HHMI's research purposes, but with no right to assign or sublicense (the "HHMI License"). This Agreement is explicitly made subject to the HHMI License.

3.5 **Specific Exclusion.** Stanford does not:

(A) grant to Selten any other licenses, implied or otherwise, to any patents or other rights of Stanford other than those rights granted under Licensed Patent, regardless of whether the patents or other rights are dominant or subordinate to any Licensed Patent, or are required to exploit any Licensed Patent;

(B) commit to Selten to bring suit against third parties for infringement, except as described in Article 14; and

(C) agree to furnish to Selten any technology or technological information or to provide Selten with any assistance.

4. SUBLICENSING

4.1 **Permitted Sublicensing.** Selten may grant Sublicenses in the Licensed Field of Use only during the Exclusive term and only if Selten is developing or selling Licensed Products. Sublicenses with any exclusivity must include diligence requirements commensurate with the diligence requirements of Appendix A. Stanford agrees that Selten may apportion without discrimination between Selten and Stanford patents a commercially reasonable percentage of sublicensing payments made to Stanford pursuant to Section 4.6, provided however that Selten provides Stanford with the proposed apportionment and justification prior to Selten's payment pursuant to Section 8.1. Stanford and Selten agree to meet to discuss such proposed apportionment if in Stanford's opinion the apportionment does not reasonably reflect the value of the Licensed Patents.

4.2 **Required Sublicensing.** If Selten is unable or unwilling to serve or develop a potential market or market territory for which there is a company willing to be a Sublicensee, Selten will, at Stanford's request, negotiate in good faith a Sublicense with any such Sublicensee. Stanford would like licensees to address unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improved therapeutics, diagnostics and agricultural technologies for the developing world.

4.3 **Sublicense Requirements.** Any Sublicense:

(A) is subject to this Agreement;

(B) will reflect that any Sublicensee will not further sublicense;

(C) will prohibit Sublicensee from paying royalties to an escrow or other similar account;

(D) will expressly include the provisions of Articles 8, 9, 10 and 19.6 for the benefit of Stanford and HHMI; and

(E) will include the provisions of Section 4.4 and require the transfer of all the Sublicensee's obligations to Selten, including the payment of royalties specified in the Sublicense, to Stanford or its designee, if this Agreement is terminated. If the Sublicensee is a spin-out from Selten, Selten must guarantee the Sublicensee's performance with respect to the payment of Stanford's share of Sublicense royalties.

4.4 **Litigation by Sublicensee.** Any Sublicense must include the following clauses:

(A) In the event Sublicensee brings an action seeking to invalidate any Licensed Patent:

(1) Sublicensee will double the payment paid to Selten during the pendency of such action. Moreover, should the outcome of such action determine that any claim of a patent challenged by the Sublicensee is both valid and infringed by a Licensed Product, Sublicensee will pay triple times the payment paid under the original Sublicense;

(2) Sublicensee will have no right to recoup any royalties paid before or during the period challenge;

(3) any dispute regarding the validity of any Licensed Patent shall be litigated in the courts located in Santa Clara County, and the parties agree not to challenge personal jurisdiction in that forum; and

(4) Sublicensee shall not pay royalties into any escrow or other similar account.

(B) Sublicensee will provide written notice to Stanford at least three months prior to bringing an action seeking to invalidate a Licensed Patent. Sublicensee will include with such written notice an identification of all prior art it believes invalidates any claim of the Licensed Patent.

4.5 **Copy of Sublicenses and Sublicensee Royalty Reports.** Selten will submit to Stanford a copy of each Sublicense, any subsequent amendments and all copies of Sublicensees' royalty reports. Beginning with the first Sublicense, the Chief Financial Officer or equivalent will certify annually regarding the name and number of Sublicensees.

4.6 **Sharing of Sublicensing Income.** Selten will pay to Stanford a portion of Nonroyalty Sublicensing Consideration at a rate determined based on the timing of execution of the Sublicense, as provided below:

(A) ***% for Sublicenses executed prior to the ***;

(B) ***% for Sublicenses executed after the ***;

(C) ***% for Sublicenses executed after ***.

4.7 **Royalty-Free Sublicenses.** If Selten pays all royalties due Stanford from a Sublicensee's Net Sales, Selten may grant that Sublicensee a royalty-free or non-cash:

(A) Sublicense or

(B) cross-license.

5. GOVERNMENT RIGHTS

This Agreement is subject to Title 35 Sections 200-204 of the United States Code. Among other things, these provisions provide the United States Government with nonexclusive rights in the Licensed Patent. They also impose the obligation that Licensed Product sold or produced in the United States be "manufactured substantially in the United States." Selten will ensure all obligations of these provisions are met.

6. DILIGENCE

6.1 **Milestones.** Because the invention is not yet commercially viable as of the Effective Date, Selten will diligently develop, manufacture, and sell Licensed Product and will diligently develop markets for Licensed Product. In addition, Selten will meet the milestones shown in Appendix A, and notify Stanford in writing as each milestone is met. Notwithstanding the foregoing, in the event that Company believes that it will be unable to achieve a particular milestone, Company will have the right, which it must exercise no later than *** days prior to the date of such milestone, to extend such milestone by a period of *** months upon the payment of a $*** fee.

6.2 **Progress Report.** By *** of each year, Selten will submit a written annual report to Stanford covering the preceding calendar year. The report will include information sufficient to enable Stanford to satisfy reporting requirements of the U.S. Government and for Stanford to ascertain progress by Selten toward meeting this Agreement's diligence requirements. Each report will describe, where relevant: Selten's progress toward commercialization of Licensed Product, including work completed, key scientific discoveries, summary of work-in-progress, current schedule of anticipated events or milestones, market plans for introduction of Licensed Product, and significant corporate transactions involving Licensed Product. Selten will specifically describe how each Licensed Product is related to each Licensed Patent.

6.3 **Clinical Trial Notice.** Selten will notify the Stanford University Office of Technology Licensing prior to commencing any clinical trials at Stanford.

7. ROYALTIES

7.1 **Issue Royalty.** Selten will pay to Stanford a noncreditable, nonrefundable license issue royalty of $*** upon signing this Agreement.

7.2 Purchase Right.

(A) Stanford shall have the right, but not the obligation, to purchase for cash up to its Share of the securities issued in any Qualifying Offering on the terms, and subject to the conditions, set forth in this Section 7.2 (the "Purchase Right"). For purposes of this Agreement:

(1) "Adjustment Event" means the final closing of the first Threshold Qualifying Offering occurring after the date of this Agreement.

(2) "Qualifying Offering" means a private offering of Selten's equity securities (or securities convertible into or exercisable for Selten's equity securities) for cash (or in satisfaction of debt issued for cash) having its final closing on or after the date of this Agreement and which includes investment by one or more venture capital, professional angel, corporate or other similar institutional investors other than Stanford.

(3) “Share” means:

(a) ***% with respect to any Qualifying Offering having a closing on or before the date of an Adjustment Event; or

(b) with respect to any Qualifying Offering having a closing after an Adjustment Event, but before a Termination Event, the percentage necessary for Stanford to maintain its pro rata ownership interest in Selten on a Fully-Diluted Basis.

(4) "Threshold Qualifying Offering" means any Qualifying Offering which either (i) is at least $*** in size or (ii) involves the sale to outside investors of at least ***% of the securities outstanding after such round on a Fully-Diluted Basis.

(B) The Purchase Right shall terminate upon the earliest to occur of the following (each a "Termination Event"):

(1) Stanford's execution of an investor rights agreement or similar agreement (each a "Rights Agreement") in connection with a Threshold Qualifying Offering so long the Rights Agreement satisfies the terms of this Section 7.2 and Section 7.3 below;

(2) Stanford purchases less than its entire Share of a Qualifying Offering; and

(3) Stanford fails to give an election notice within the Notice Period for a Qualifying Offering which has its final closing within 90 days of the date such notice is received by Stanford and which is closed on terms that are the same or less favorable to the investors as the terms stated in Selten's notice to Stanford.

(C) The Purchase Right shall not apply to the issuance of securities: (i) to employees, current members of Selten's Board of Directors and other service providers pursuant to a plan approved by Selten's Board of Directors; or (ii) as additional consideration in lending or leasing transactions; or (iii) to an entity pursuant to an arrangement that Selten's Board of Directors determines in good faith is a strategic partnership or similar arrangement of Selten (i.e., an arrangement in which the entity's purchase of securities is not primarily for the purpose of financing Selten); or (iv) to shareholders of another corporation in connection with the acquisition of that corporation by Selten.

7.3 Rights Agreements; Information Rights; Notice; Elections.

(A) Selten shall ensure that each Rights Agreement executed by Stanford in connection with a Qualifying Offering will grant to Stanford the same rights as all other investors who are parties to that Rights Agreement. In particular, Selten shall ensure that each such Rights Agreement will grant to Stanford the same right to purchase additional securities in future offerings, the same information rights, and the same registration rights as are granted to other parties thereto, including all such rights granted to any investor designated as a "Major Investor" or other similar designation, even if Stanford is not so designated.

(B) Notwithstanding any terms to the contrary contained in any applicable Rights Agreement:

(1) Stanford shall not have any board representation or board meeting attendance rights;

(2) In connection with all Qualifying Offerings, Selten shall give Stanford notice of the terms of the offering, including: (i) the names of the investors, the allocation of shares among them and the total amounts to be invested by each of them in such offering; (ii) pre- and post- (projected) financing capitalization table; (iii) investor presentation (if available); (iv) an introduction to the lead investor in such offering for the purpose of discussing the lead investor's due diligence process; and (v) such other documents and information as Stanford may reasonably request for the purpose of making an investment decision or verifying the number of shares it is entitled to purchase in such offering; and

(3) Stanford may elect to exercise its Purchase Right, in whole or in part, by notice given to Selten within *** Stanford business days (i.e., days other than Saturdays, Sundays, and holidays or other days on which Stanford is officially closed) after receipt of Selten's notice ("Notice Period").

(C) If Stanford has no information rights under a Rights Agreement and to the extent that such information has been prepared by Selten for other purposes, so long as Stanford holds Selten securities, Selten shall furnish to Stanford, upon request and as promptly as reasonably practicable, Selten's annual consolidated financial statements and annual operating plan, including an annual report of the holders of Selten's units and other securities, and such other information as Stanford may reasonably request from time to time for the purpose of valuing its interest in Selten.

(D) Notwithstanding any notice provision in this Agreement to the contrary, any notice given under this Agreement that refers or relates to any of Section 7.2 above or this Section 7.3 shall be copied concurrently to pvfnotices@stanford.edu ; provided, however, that delivery of the copy will not by itself constitute notice for any purpose under this Agreement.

7.4 **License Maintenance Fee.** Beginning on *** and each *** thereafter, Selten will pay Stanford a *** license maintenance fee as follows. *** maintenance payments are nonrefundable, but they are creditable each year as described in Section 7.7.:

(A) $*** in *** and ***;

(B) $*** in *** and *** and

(C) On the first *** after ***:

(1) $*** if ***; or

(2) $*** if ***.

7.5 **Milestone Payments.** Selten will pay Stanford the following milestone payments:

(A) $*** upon the ***;

(B) $*** upon ***; and

(C) $*** upon ***.

7.6 **Earned Royalty.** Selten will pay Stanford earned royalties on Net Sales as follows:

(A) *** % of Net Sales if aggregate Net Sales in the preceding calendar year is less than $***;

(B) *** % of Net Sales if aggregate Net Sales in the preceding calendar year is more or equal to $*** but lower than $***;

(C) ***% of Net Sales if aggregate Net Sales in the preceding calendar year is more than $***.

(D) **Earned Royalty if Selten Challenges the Patent.** Notwithstanding the above, should Selten bring an action seeking to invalidate any Licensed Patent, Selten will pay royalties to Stanford at the rate of *** percent (***%) of the Net Sales of all Licensed Products sold during the pendency of such action. Moreover, should the outcome of such action determine that any claim of a patent challenged by Selten is both valid and infringed by a Licensed Product, Selten will pay royalties at the rate of *** percent (***%) of the Net Sales of all Licensed Products sold.

7.7 **Creditable Payments.** The license maintenance fee for a year may be offset against earned royalty payments due on Net Sales occurring in that year.

For example:

(A) if Selten pays Stanford a $*** maintenance payment for year Y, and according to Section 7.6 $*** in earned royalties are due Stanford for Net Sales in year Y, Selten will only need to pay Stanford an additional $*** for that year's earned royalties.

(B) if Selten pays Stanford a $*** maintenance payment for year Y, and according to Section 7.6 $*** in earned royalties are due Stanford for Net Sales in year Y, Selten will not need to pay Stanford any earned royalty payment for that year. Selten will not be able to offset the remaining $*** against a future year's earned royalties.

7.8 **Obligation to Pay Royalties.** A royalty is due Stanford under this Agreement for any activity conducted under the licenses granted. For convenience's sake, the amount of that royalty is calculated using Net Sales. Nonetheless, if certain Licensed Products are made, used, imported, or offered for sale before the date this Agreement terminates, and those Licensed Products are sold after the termination date, Selten will pay Stanford an earned royalty for its exercise of rights based on the Net Sales of those Licensed Products.

7.9 **No Escrow.** Selten shall not pay royalties into any escrow or other similar account.

7.10 **Currency.** Selten will calculate the royalty on sales in currencies other than U.S. Dollars using the appropriate foreign exchange rate for the currency quoted by the Wall Street Journal on the close of business on the last banking day of each calendar quarter. Selten will make royalty payments to Stanford in U.S. Dollars.

7.11 **Non-U.S. Taxes.** Selten will pay all non-U.S. taxes related to royalty payments. These payments are not deductible from any payments due to Stanford.

7.12 **Interest.** Any payments not made when due will bear interest at the lower of (a) the *** or (b) the maximum rate permitted by law.

8. ROYALTY REPORTS, PAYMENTS, AND ACCOUNTING

8.1 Quarterly Earned Royalty Payment and Report. Beginning with the first sale of a Licensed Product by Selten or a Sublicensee, Selten will submit to Stanford a written report (even if there are no sales) and an earned royalty payment within *** days after the end of each ***. This report will be in the form of Appendix B and will state the number, description, and aggregate Net Sales of Licensed Product during the completed calendar quarter. The report will include an overview of the process and documents relied upon to permit Stanford to understand how the earned royalties are calculated. With each report Selten will include any earned royalty payment due Stanford for the completed calendar quarter (as calculated under Section 7.6).

8.2 **No Refund.** In the event that a validity or non-infringement challenge of a Licensed Patent brought by Selten is successful, Selten will have no right to recoup any royalties paid before or during the period challenge.

8.3 **Termination Report.** Selten will pay to Stanford all applicable royalties and submit to Stanford a written report within *** days after the license terminates. Selten will continue to submit earned royalty payments and reports to Stanford after the license terminates, until all Licensed Products made or imported under the license have been sold.

8.4 **Accounting.** Selten will maintain records showing manufacture, importation, sale, and use of a Licensed Product for *** years from the date of sale of that Licensed Product. Records will include general-ledger records showing cash receipts and expenses, and records that include: production records, customers, invoices, serial numbers, and related information in sufficient detail to enable Stanford to determine the royalties payable under this Agreement.

8.5 **Audit by Stanford.** Selten will allow Stanford or its designee to examine Selten's records to verify payments made by Selten under this Agreement.

8.6 **Paying for Audit.** Stanford will pay for any audit done under Section 8.5. But if the audit reveals an underreporting of earned royalties due Stanford of ***% or more for the period being audited, Selten will pay the audit costs.

8.7 **Self-audit.** Selten will conduct an independent audit of sales and royalties at least every *** years if annual sales of Licensed Product are over $***. The audit will address, at a minimum, the amount of gross sales by or on behalf of Selten during the audit period, the **amount** of funds owed to Stanford under this Agreement, and whether the amount owed has been paid to Stanford and is reflected in the records of Selten. Selten will submit the auditor's report promptly to Stanford upon completion. Selten will pay for the entire cost of the audit.

8.8 **Confidential Information.** Stanford will maintain the reports and any information provided by Licensee to Stanford pursuant to Sections 4.5, 6.2, 8.1, 8.3 and 8.7 in confidence and not disclose such information or reports to any third party, except as required by law. Stanford's obligation of confidentiality hereunder will be fulfilled by

using at least the same degree of care with Selten's confidential information as it uses to protect its other confidential information.

9. EXCLUSIONS AND NEGATION OF WARRANTIES

9.1 Negation of Warranties. Stanford provides Selten the rights granted in this Agreement AS IS and WITH ALL FAULTS. Stanford makes no representations and extends no warranties of any kind, either express or implied. Among other things, Stanford disclaims any express or implied warranty:

(A) of merchantability, of fitness for a particular purpose;

(B) of non-infringement; or

(C) arising out of any course of dealing.

9.2 **No Representation of Licensed Patent.** Selten also acknowledges that Stanford does not represent or warrant:

(A) the validity or scope of any Licensed Patent; or

(B) that the exploitation of Licensed Patent will be successful.

10. INDEMNITY

10.1 **Indemnification.** Selten will indemnify, hold harmless, and defend all Stanford Indemnitees against any claim of any kind arising out of or related to the exercise of any rights granted Selten under this Agreement or the breach of this Agreement by Selten.

10.2 **HHMI Indemnification.** HHMI Indemnitees will be indemnified, defended by counsel acceptable to HHMI, and held harmless by SELTEN from and against any claim, liability, cost, expense, damage, deficiency, loss, or obligation, of any kind or nature (including, without limitation, reasonable attorneys' fees and other costs and expenses of defense) (collectively, "Claims"), based upon, arising out of, or otherwise relating to this Agreement, including without limitation any cause of action relating to product liability. The previous sentence will not apply to any Claim that is determined with finality by a court of competent jurisdiction to result solely from the gross negligence or willful misconduct of an IIHMI Indemnitee. Notwithstanding any other provisions of this Agreement, SELTEN's obligation to defend, indemnify and hold harmless the HHMI Indemnitees under this paragraph will not be subject to any limitation or exclusion of liability or damages or otherwise limited in any way.

10.3 **No Indirect Liability.** Neither party shall be liable to the other for any indirect, special, consequential or other damages whatsoever, whether grounded in tort (including negligence), strict liability, contract or otherwise arising out of or in connection with solely this Agreement under any theory of liability, provided, however, that the foregoing shall not apply to any right of action for infringement, contributory infringement or

inducement of infringement Stanford may have under any applicable law. Stanford shall not have any responsibilities or liabilities whatsoever with respect to Licensed Products(s).

10.4 **Workers' Compensation.** Selten will comply with all statutory workers' compensation and employers' liability requirements for activities performed under this Agreement.

10.5 **Insurance.** During the term of this Agreement, Selten will maintain Comprehensive General Liability Insurance, including Product Liability Insurance, with a reputable and financially secure insurance carrier to cover the activities of Selten and its Sublicensees. Within *** days of filing an IND or immediately prior to any testing of Licensed Products in humans, whichever is earlier, the insurance will provide minimum limits of liability of $*** and will include all Stanford Indemnitees and HHMI Indemnitees as additional insureds. Insurance must cover claims incurred, discovered, manifested, or made during or after the expiration of this Agreement and must be placed with carriers with ratings of at least A- as rated by A.M. Best. Within *** days of the Effective Date of this Agreement, Selten will furnish a Certificate of Insurance evidencing primary coverage and additional insured requirements. Selten will provide to Stanford *** days prior written notice of cancellation or material change to this insurance coverage. Selten will advise Stanford in writing that it maintains excess liability coverage (following form) over primary insurance for at least the minimum limits set forth above. All insurance of Selten will be primary coverage; insurance of Stanford Indemnitees, and HHMI Indemnitees will be excess and noncontributory.

11. EXPORT

Selten and its affiliates and Sublicensees shall comply with all United States laws and regulations controlling the export of licensed commodities and technical data. (For the purpose of this paragraph, "licensed commodities" means any article, material or supply but does not include information; and "technical data" means tangible or intangible technical information that is subject to U.S. export regulations, including blueprints, plans, diagrams, models, formulae, tables, engineering designs and specifications, manuals and instructions.) These laws and regulations may include, but are not limited to, the Export Administration Regulations (15 CFR 730-774), the International Traffic in Arms Regulations (22 CFR 120-130) and the various economic sanctions regulations administered by the U.S. Department of the Treasury (31 CFR 500-600).

Among other things, these laws and regulations prohibit or require a license for the export or retransfer of certain commodities and technical data to specified countries, entities and persons. Selten hereby gives written assurance that it will comply with, and will cause its Sublicensees to comply with all United States export control laws and regulations, that it bears sole responsibility for any violation of such laws and regulations by itself or Sublicensees, and that it will indemnify, defend and hold Stanford and the HHMI Indemnitees harmless for the consequences of any such violation.

12. MARKING

Before any Licensed Patent issues, Selten will mark Licensed Product with the words "Patent Pending." Otherwise, Selten will mark Licensed Product with the number of any issued Licensed Patent.

13. STANFORD NAMES AND MARKS

13.1 **Stanford Names.** Selten will not use (i) Stanford's name or other trademarks, (ii) the name or trademarks of any organization related to Stanford, or (iii) the name of any Stanford faculty member, employee, student or volunteer without the prior written consent of Stanford. Permission may be withheld at Stanford's sole discretion. This prohibition includes, but is not limited to, use in press releases, advertising, marketing materials, other promotional materials, presentations, case studies, reports, websites, application or software interfaces, and other electronic media.

13.2 **HHMI Names.** Selten will not use the name of HHMI or of any HHMI employee in a manner that reasonably could constitute an endorsement of a commercial product or service; but use for other purposes, even if commercially motivated, is permitted provided that (1) the use is limited to accurately reporting factual events or occurrences, and (2) any reference to the name of HHMI or any HHMI employees in press releases or similar materials intended for public release is approved by HHMI in advance.

14. PROSECUTION AND PROTECTION OF PATENTS

14.1 **Patent Prosecution.** Stanford will be solely responsible for preparing, filing, and prosecuting and maintaining the Licensed Patents. During the Exclusive Term, Stanford agrees to (i) keep Selten reasonably informed as to the filing, prosecution and maintenance of the Licensed Patents, (ii) furnish to Selten copies of material documents relevant to such filing, prosecution and maintenance, (iii) allow Selten a reasonable opportunity to comment on material documents filed with any patent office with respect to the Licensed Patents and consider in good faith Selten's comments and (iv) instruct Stanford's legal representative to include Selten in all communications. At Stanford's request, Selten will provide all information and assistance to Stanford to ensure that Licensed Patent is as extensive as possible. In the event Selten decides that it no longer intends to pay for prosecution or maintenance of one or more Licensed Patents, Selten shall give Stanford a 3-month notice. Stanford may in its discretion continue to prosecute and maintain such Licensed Patent(s) at its expense, in which case such Licensed Patent(s) shall no longer be covered by the licenses granted under this Agreement.

14.2 **Patent Costs.** Within *** days after receiving a statement from Stanford, Selten will reimburse Stanford:

(A) $*** to offset Licensed Patent's patenting expenses, including any interference or reexamination matters, incurred by Stanford before the Effective Date; and

(B) for all Licensed Patent's patenting expenses, including any interference or reexamination matters, incurred by Stanford after the Effective Date. In all instances, Stanford will pay the fees prescribed for large entities to the United States Patent and Trademark Office.

14.3 **Infringement Procedure.** Each party will promptly notify the other if it believes a third party infringes a Licensed Patent or if a third party files a declaratory judgment action with respect to any Licensed Patent. During the Exclusive term of this Agreement and if Selten is developing Licensed Product, Selten may have the right to institute a suit against any infringer or defend any declaratory judgment action initiated by this third party as provided in Section 14.4 through and including Section 14.8.

14.4 **Selten Suit.** Selten has the first right to institute suit, and prosecute a suit or defend any declaratory judgment action so long as it conforms with the requirements of this Section and Selten is diligently developing or selling Licensed Product. If Selten decides to institute suit or defend any action, it will notify Stanford in writing and give Stanford the opportunity to jointly initiate suit or defend the action as provided in Section 14.5. If Stanford declines to join, Selten will diligently pursue the suit and Selten will bear the entire cost of the litigation, including expenses and counsel fees incurred by Stanford. Selten will keep Stanford reasonably apprised of all developments in the suit, and will seek Stanford's input and approval on any substantive submissions or positions taken in the litigation regarding the scope, validity and enforceability of the Licensed Patent. Selten will not prosecute, settle or otherwise compromise any such suit in a manner that adversely affects Stanford's interests without Stanford's prior written consent. Stanford may be named as a party only if

(A) Selten's and Stanford's respective counsel recommend that such action is necessary in their reasonable opinion to achieve standing;

(B) Stanford is not the first named party in the action; and

(C) the pleadings and any public statements about the action state that Selten is pursuing the action and that Selten has the right to join Stanford as a party.

14.5 **Joint Suit.** If Stanford and Selten so agree, they may institute suit or defend the declaratory judgment action jointly. If so, they will:

(A) prosecute the suit in both their names;

(B) bear the out-of-pocket costs equally;

(C) share any recovery or settlement equally; and

(D) agree how they will exercise control over the action.

14.6 **Stanford Suit.** If neither Section 14.4 nor 14.5 apply, Stanford may institute and may name Selten as a party for standing purposes. If Stanford decides to institute suit, it will notify Selten in writing. If Selten does not notify Stanford in writing that it desires to

jointly prosecute the suit within *** days after the date of the notice, Selten will assign and hereby does assign to Stanford all rights, causes of action, and damages resulting from the alleged infringement. Stanford will bear the entire cost of the litigation and will retain the entire amount of any recovery or settlement.

14.7 **Recovery.** If Selten sues under Section 14.4, then any recovery in excess of any unrecovered litigation costs and fees will be shared with Stanford as follows:

(A) any payment for past sales will be deemed Net Sales, and Selten will pay Stanford royalties at the rates specified in Section 7.6;

(B) any payment for future sales will be deemed a payment under a Sublicense, and royalties will be shared as specified in Article 4.6.

(C) Selten and Stanford will negotiate in good faith appropriate compensation to Stanford for any non-cash settlement or non-cash cross-license.

14.8 **Abandonment of Suit.** If either Stanford or Selten commences a suit and then wants to abandon the suit, it will give timely notice to the other party. The other party may continue prosecution of the suit after Stanford and Selten agree on the sharing of expenses and any recovery in the suit.

15. TERMINATION

15.1 **Termination by Selten.** Selten may terminate this Agreement by giving Stanford written notice at least *** days in advance of the effective date of termination selected by Selten.

15.2 Termination by Stanford.

(A) Stanford may also terminate this Agreement if Selten:

(1) is delinquent on any report or payment;

(2) is not diligently developing and commercializing Licensed Product;

(3) misses a milestone described in Appendix A;

(4) is in material breach of any provision; or

(5) provides any false report.

(B) Termination under this Section 15.2 will take effect *** days after written notice by Stanford unless Selten remedies the problem in that ***-day period.

15.3 **Surviving Provisions.** Surviving any termination or expiration are: (A) Selten's obligation to pay royalties accrued or accruable;

(B) any claim of Selten or Stanford, accrued or to accrue, because of any breach or default by the other party; and

(C) the provisions of Articles 8, 9, 10, and 19.6 and any other provision that by its nature is intended to survive.

(D) Upon termination, any Sublicensee who is not then in material breach shall have its Sublicense converted to a direct license from Stanford under the terms and conditions of this Agreement, as further limited and restricted by the terms of the original Sublicense.

16. ASSIGNMENT/CHANGE OF CONTROL AND NON-ASSIGNABILITY

16.1 **Assignment/ Change of Control. Selten may assign this Agreement in connection with a Change of Control, merger, reorganization or sale of that part of Selten's business that exercises all rights granted under this Agreement if there is compliance with Section 16.2.**

16.2 Conditions of Assignment. Selten may assign this Agreement pursuant to Section 16.1 upon prior and complete performance of the following conditions:

(A) Selten must give Stanford *** days prior written notice of the assignment, including the new assignee's contact information; and

(B) the new assignee must agree in writing to Stanford to be bound by this Agreement; and

(C) Stanford must have received a $*** fee unless the transaction does not constitute a Change of Control.

16.3 **After the Assignment.** Upon a permitted assignment of this Agreement pursuant to Article 16, Selten will be released of liability under this Agreement and the term "Selten" in this Agreement will mean the assignee.

16.4 **Bankruptcy.** In the event of a bankruptcy or insolvency, assignment is permitted only to a party that can provide adequate assurance of future performance, including diligent development and sales of Licensed Product.

16.5 **Nonassignability of Agreement.** Except in conformity with Sections 16.1 and 16.4, this Agreement is not assignable by Selten under any other circumstances and any attempt to assign this Agreement by Selten is null and void.

17. DISPUTE RESOLUTION

17.1 **Dispute Resolution by Arbitration.** Any dispute between the parties regarding any payments made or due under this Agreement will be settled by arbitration in accordance with the JAMS Arbitration Rules and Procedures. The parties are not obligated to settle any other dispute that may arise under this Agreement by arbitration.

17.2 **Request for Arbitration.** Either party may request such arbitration. Stanford and Selten will mutually agree in writing on a third party arbitrator within *** days of the arbitration request. The arbitrator's decision will be final and nonappealable and may be entered in any court having jurisdiction.

17.3 **Discovery.** The parties will be entitled to discovery as if the arbitration were a civil suit in the California Superior Court. The arbitrator may limit the scope, time, and issues involved in discovery.

17.4 **Place of Arbitration.** The arbitration will be held in Stanford, California unless the parties mutually agree in writing to another place.

17.5 **Patent Validity.** Any dispute regarding the validity of any Licensed Patent shall be litigated in the courts located in Santa Clara County, California, and the parties agree not to challenge personal jurisdiction in that forum.

17.6 **HHMI Rights or Property Not Subject to Arbitration.** No dispute affecting the rights or property of IIHMI shall be subject to the arbitration provisions set forth above.

18. NOTICES

18.1 **Legal Action.** Selten will provide written notice to Stanford at least three months prior to bringing an action seeking to invalidate any Licensed Patent or a declaration of non-infringement. Selten will include with such written notice an identification of all prior art it believes invalidates any claim of the Licensed Patent.

18.2 **All Notices.** All notices under this Agreement are deemed fully given when written, addressed, and sent as follows:

All general notices to Selten are mailed or emailed to:

Selten Pharma, Inc. Attn.: CEO
14435C Big Basin Way #246,
Saratoga, CA 95070
nbanait@seltenpharma.com

All financial invoices to Selten (i.e., accounting contact) are e-mailed to:

Narinder S. Banait
nbanait@seltenpharma.com

All progress report invoices to Selten (i.e., technical contact) are e-mailed to:

Narinder S. Banait
nbanait@seltenpharma.com

All general notices to Stanford are e-mailed or mailed to:

Office of Technology Licensing RE: S11-009
3000 El Camino Real
Building 5, Suite 300
Palo Alto, CA 94306-2100
info@otlmail.stanford.edu

All payments to Stanford are mailed to:

Stanford University
Office of Technology Licensing RE: S11-009
Department #44439
P.O. Box 44000
San Francisco, CA 94144-4439

All progress reports to Stanford are e-mailed or mailed to:

Office of Technology Licensing
3000 El Camino Real
Building 5, Suite 300
Palo Alto, CA 94306-2100
info@otlmail.stanford.edu

Either party may change its address with written notice to the other party.

19. MISCELLANEOUS

19.1 **Waiver.** No term of this Agreement can be waived except by the written consent of the party waiving compliance.

19.2 **Choice of Law.** This Agreement and any dispute arising under it is governed by the laws of the State of California, United States of America, applicable to agreements negotiated, executed, and performed within California.

19.3 **Entire Agreement.** The parties have read this Agreement and agree to be bound by its terms, and further agree that it constitutes the complete and entire agreement of the parties and supersedes all previous communications, oral or written, and all other communications between them relating to the license and to the subject hereof. This Agreement may not be amended except by writing executed by authorized representatives of both parties. No representations or statements of any kind made by either party, which are not expressly stated herein, will be binding on such party.

19.4 **Exclusive Forum.** The state and federal courts having jurisdiction over Stanford, California, United States of America, provide the exclusive forum for any court action between the parties relating to this Agreement. Selten submits to the jurisdiction of such courts, and waives any claim that such a court lacks jurisdiction over Selten or constitutes an inconvenient or improper forum.

19.5 **Headings.** No headings in this Agreement affect its interpretation.

19.6 **Third Party Beneficiary.** HHMI is not a party to this Agreement and has no liability to any licensee, or user of anything covered by this Agreement, but HHMI is an intended third-party beneficiary of this Agreement and certain of its provisions are for the benefit of HHMI and are enforceable by HHMI in its own name.

19.7 **Force Majeure.** Neither party shall be liable for any failure to perform as required by this Agreement to the extent such failure to perform is due to circumstances reasonably beyond such party's control, including, without limitation, acts of God, labor disputes, accidents, failure of any governmental approval, civil disorders, terrorism, failure of utilities, mechanical breakdowns, material shortages, or other such occurrences. The affected party shall notify the other party of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake all reasonable efforts necessary to cure such force majeure circumstances.

THIS SPACE IS INTENTIONALLY LEFT BLANK

19.8 Electronic Copy. The parties to this document agree that a copy of the original signature (including an electronic copy) may be used for any and all purposes for which the original signature may have been used. The parties further waive any right to challenge the admissibility or authenticity of this document in a court of law based solely on the absence of an original signature.

The parties execute this Agreement in duplicate originals by their duly authorized officers or representatives.

THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY

Signature: /s/ Katharine Ku

Name: Katharine Ku

Title: Executive Director, Technology Licensing

Date: October 22, 2015

SELTEN PHARMA, INC.

Signature: /s/ Narinder S. Banait

Name: Narinder S. Banait

Title: General Counsel and Co-CEO

Date: October 22, 2015

Appendix A – Milestones

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***** 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.**

Appendix B — Sample Reporting Form

Stanford Docket No. S11-009

This report is provided pursuant to the license agreement between Stanford University and (Selten Name)

License Agreement Effective Date:

Name(s) of Licensed Products being reported:

Report Covering Period	
Yearly Maintenance Fee	$
Number of Sublicenses Executed	
Gross Revenue	
U.S. Gross Revenue	$
Non-U.S. Gross Revenue	$
Net Sales	
U.S. Net Sales	$
Non-U.S. Net Sales	$
Royalty Calculation	
Royalty Subtotal	$
Credit	$
Royalty Due	$

Comments:

THIS FIRST AMENDMENT (the **"Amendment")** to the Exclusive Agreement dated October 25, 2015 between SELTEN PHARMA, INC., a corporation having a principal place of business at 14435C Big Basin Way #246, Saratoga, CA 95070, **("Selten or Company")** and THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY **("Stanford"),** an institution of higher education having powers under the laws of the State of California, **("Agreement")** is entered into and made effective as of October 25, 2016. Capitalized terms not otherwise defined herein shall have the meaning given such terms in the Agreement.

WHEREAS, the parties wish to amend certain terms of the Agreement as set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants, agreements, representations and warranties herein contained and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. Exhibit A of the Agreement shall be deleted in its entirety and replaced with Exhibit Al attached hereto.

All other terms and provisions of the Agreement not amended hereby shall remain in full force and effect. In the event of any inconsistency between the terms of this Amendment and the Agreement, the terms of this Amendment shall govern.

The parties execute this Amendment in duplicate originals by their duly authorized officers or representatives.

THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY

Signature: /s/ Mona Wan

Name: Mona Wan

Title: Associate Director

Date: October 24, 2016

SELTEN PHARMA, INC.

Signature: /s/ Narinder S. Banait

Name: Narinder S. Banait

Title: Co-CEO and General Counsel

Date: October 24, 2016

Appendix Al — Milestones

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***** 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.**

Exhibit 21.1

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

5. Vivus International Limited (Ireland), a wholly owned subsidiary of VIVUS, Inc.

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, No. 333-175926, No. 333-199881 and No. 333-215089) and Form S-3 (No. 333-161948) of our reports dated March 8, 2017, relating to the consolidated financial statements, financial statement schedule, and the effectiveness of VIVUS, Inc.'s internal control over financial reporting, which appear in this Annual Report on Form 10-K.

/s/ OUM & CO. LLP
San Francisco, California
March 8, 2017

Exhibit 31.1

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: March 8, 2017

By: /s/ Seth H. Z. Fischer
Name: Seth H. Z. Fischer
Title: *Chief Executive Officer*

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT

TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mark K. Oki, Chief Financial Officer and Chief Accounting Officer, certify that:

1. I have reviewed this annual report on Form 10-K of VIVUS, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 8, 2017

By: /s/ Mark K. Oki
Name: Mark K. Oki
Title: *Chief Financial Officer and Chief Accounting Officer*

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

I, Seth H. Z. Fischer, Chief Executive Officer of VIVUS, Inc., certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of VIVUS, Inc. on Form 10-K for the period ending December 31, 2016 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report on Form 10-K fairly presents in all material respects the financial condition and results of operations of VIVUS, Inc. This written statement is being furnished to the Securities and Exchange Commission as an exhibit to such Annual Report on Form 10-K. A signed original of this statement has been provided to VIVUS, Inc. and will be retained by VIVUS, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Date: March 8, 2017

By: /s/ Seth H. Z. Fischer
Seth H. Z. Fischer
Chief Executive Officer

I, Mark K. Oki, Chief Financial Officer and Chief Accounting Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of VIVUS, Inc. on Form 10-K for the period ending December 31, 2016 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report on Form 10-K fairly presents in all material respects the financial condition and results of operations of VIVUS, Inc. This written statement is being furnished to the Securities and Exchange Commission as an exhibit to such Annual Report on Form 10-K. A signed original of this statement has been provided to VIVUS, Inc. and will be retained by VIVUS, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Date: March 8, 2017

By: /s/ Mark K. Oki
Mark K. Oki
Chief Financial Officer and Chief Accounting Officer